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Advances in technology-assisted rehabilitation

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Published in
Frontiers in Rehabilitation Sciences

ISSN 1664-8714
ISBN 978-2-8325-5333-6
DOI 10.3389/978-2-8325-5333-6

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Advances in technology-assisted rehabilitation

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Citation

Kannenberg, A., Wurdeman, S., Rupp, R., Frossard, L., eds. (2024). *Advances in technology-assisted rehabilitation*. Lausanne: Frontiers Media SA.
doi: 10.3389/978-2-8325-5333-6

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Editorial
PUBLISHED 06 August 2024
DOI 10.3389/fresc.2024.1465671

OPEN ACCESS

EDITED AND REVIEWED BY
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RECEIVED 16 July 2024
ACCEPTED 22 July 2024
PUBLISHED 06 August 2024

CITATION
Kannenberg A, Rupp R, Wurdeman SR and Frossard L (2024) Editorial: Advances in technology-assisted rehabilitation. Front. Rehabil. Sci. 5:1465671. doi: 10.3389/fresc.2024.1465671

Editorial: Advances in technology-assisted rehabilitation

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KEYWORDS

rehabilitation, technology-assisted care delivery, prosthetics, orthotics, robotics, wearable sensors

Editorial on the Research Topic
Advances in technology-assisted rehabilitation

1 Context

The 2011 World Report on Disability of the World Health Organization (WHO) estimated that more than a billion people worldwide—about 15% of the 2010 global population—experience some form of disability (1). In 2019, a study estimated that more than 2.4 billion people globally are affected by conditions that could benefit from rehabilitation (2). These numbers have only been growing due to population ageing and increase in the prevalence of non-communicable diseases (1, 3). Chronic diseases are estimated to account for 66.5% of all years lived with disability (4). Altogether, these projections are likely to increase the socio-economic burden of diseases requiring rehabilitation, including costs on healthcare systems already under tremendous financial pressure.

Individual disability results from the interaction between impairments of the overall physical and mental state and particular health condition of body parts or systems as well as personal and environmental factors (e.g., negative attitudes towards people with a disability, lack of motivation in self-care management, lack of access to transportation and public buildings, limited social support) (5). The environment of a person has a huge impact on the experience and extent of a disability. Inaccessible environments may create barriers to the full and effective participation of persons with disabilities in society on an equal basis with others (e.g., distance between home and closest point of care). Progress on improving social participation can be made by addressing these barriers and facilitating these persons with disabilities in their lives (e.g., role of carer, peer support) (1, 3).

Rehabilitation addresses the impact of an impaired health condition on a person's everyday life by optimizing their function and reducing the experience of disability.

Rehabilitation ensures people with an impairment of a body structure and function (or mental functioning) can remain as independent as possible and participate in meaningful life roles through education, work, and recreational activities. Global demographics and health trends, such as population ageing, medical workforce shortages, rising prevalence of non-communicable diseases, as well as continued consequences of conflict, injury and developmental conditions are placing increasing demands on the health care systems. The need for safer, more efficient and cost-effective rehabilitation interventions (e.g., devices, programs, therapies) is rapidly growing, yet in many parts of the world this need is largely unmet (1).

Altogether, improving effectiveness and efficiency of technology-assisted rehabilitation may contribute to address the challenges associated with the increasing needs for high-quality rehabilitation under conditions of limited human and financial resources (6–10). For that reason, substantial attention and resources have been directed at rehabilitative and assistive technologies recently. As an example, the WHO started the Global Cooperation on Assistive Technology in 2014 (8) and published the first-ever Global Guide on Assistive Technology in 2021 (10).

One type of technology for rehabilitation of motor functions can support professionals, such as physical and occupational therapists, in providing physically demanding trainings to patients allowing them to reach their maximum potential to live an independent life again. For example, such technologies can support patients to actively participate in restorative trainings with multiple repetitions of movement tasks, in documenting treatment progress, and potentially also in the ability to oversee and direct the treatment of more than just one patient at a time (11–15).

Another type of rehabilitation technologies, such as prostheses, orthoses, wearable sensors or functional electrical stimulation garments can directly assist and support people with motor impairments to achieve their daily lives activities goals. For example, these technologies can help restore motor functions such as grasping and walking by compensating for permanently lost anatomical structures, such as after an amputation, and/or diminished or lost function due to injury or central nervous or neuromuscular disorders (16).

Unfortunately, the successful translation of technological innovations into rehabilitation settings and patients' lives often remains limited (17). It is estimated that only about 10% of patients receive the assistive devices they need. This inequity is even worse in low- and middle-income countries (8, 17). Interestingly, though health care experiences growing staffing shortages, especially in the developed countries, there still appears to be resistance among healthcare providers to adopt assistive technologies (11, 18). This might be partially due to the combination of an abundance of informative technical publications (e.g., proof of concept, early outcomes with prototype) as well as the scarcity of high-quality research on clinical outcomes (e.g., randomized clinical trial to assess safety and efficacy) and the absence of realistic health economic evaluations [e.g., cost-utility analyses (19)]. Therefore, it appears prudent to research the effectiveness of assistive and rehabilitation technologies and to create a dedicated venue for the publication of such research.

2 Scope of the research topic

The research topic of technology-assisted rehabilitation was intentionally defined broadly to address a wide spectrum of topics starting from technology development including perspectives on determination of patient needs and demands, continuing with clinical studies with prototypes and commercially available devices, clinical research to address regulatory and/or reimbursement requirements, and ending with health-economic research with assistive technology to support in- and out-patient rehabilitation and/or temporary or long-term everyday home use.

3 Contributions

3.1 Outline of contributions

In total, 19 manuscripts were submitted for review and 16 papers from 89 authors (30% female) from 41 institutions across 6 countries were accepted for publication in this research topic. It presents 12 original research articles, 2 literature reviews, and one policy and practice review and perspective each.

3.2 Ethical perspectives of technology development

Gavette et al. provide a perspective on the ethical considerations surrounding the development and translation of prosthetic technologies into clinical practice that have received little attention to in the past. Based on current literature, they present perspectives from their multidisciplinary views as prosthetists, researchers in prosthetics on wearable technologies for rehabilitation, machine learning, artificial intelligence, and ethics of advanced technologies. The authors discuss ethical considerations for current advances in prosthetic technology, as well as topics for future research, that may inform product and policy decisions and positively influence the lives of patients.

3.3 Policy and practice review

Jones et al. present a summary of findings and recommendations of two multi-stakeholder workshops to address research gaps and requirements defined by the National Health Service (NHS) England to adopt coverage of multi-grip myoelectric prosthetic hands. The workshops involved people

from a broad range of stakeholder groups and discussed design requirements for policy-driven research studies and research questions identified in the policy review. The consented recommendations include the need for qualitative and quantitative research evidence, use of goal-based outcome measures, conduct of longitudinal studies, and addressing of the complexity of national and international policy-driven research, such as clinical resource capacity and participant involvement.

3.4 Original research articles—upper limb prosthetics

Simon et al. performed a study on the further advancement of pattern recognition systems for the control of upper limb prostheses. The study enrolled six individuals with no upper limb absence and four persons with transradial amputation who controlled a virtual prosthesis with the current standard 8-channel or 16-channel EMG pattern recognition. Participants had significant improvements in control when using 16 compared to 8 EMG channels including decreased classification error and decreased completion time. Scores of the Assessment for Capacity of Myoelectric Control (ACMC) increased by more than three times the minimal detectable change from the 8 to the 16-channel condition.

Maas et al. conducted a randomized controlled study on technology-assisted motor learning to optimize training of myoelectric control of upper limb prosthesis. Thirty-six participants with no motor impairments were randomly assigned to either a task-specific serious game training group, a non-task-specific serious game training group, or a control group using a computer mouse. Differences between groups over test sessions lacked a systematic structure and were not significant. The authors concluded that transfer effects from game training to actual prosthesis use did not take place in the non-disabled study participants. However, an important finding was that significant individual differences were found which not just means that motor learning is different for each person but that these individual differences should be considered in future studies and their translation to rehabilitation practice.

3.5 Original research articles—lower limb prosthetics

Monaghan et al. performed a retrospective review of health records of 174 individuals with unilateral transtibial limb loss who received care at Walter Reed National Military Medical Center (Bethesda, Maryland, USA) between 2001 and 2019 to analyze prescription patterns for the first prosthetic foot after amputation. They identified patient-specific characteristics, such as sex, time between injury and initial prescription, time from amputation to initial prescription, and amputation etiology that influenced initial ankle-foot prosthesis prescription. Using these factors as predictors, they were able to correctly classify 72% of all first prosthetic feet prescribed proving a systematic prescription pattern over almost two decades.

Tacca et al. pursued a new approach to evaluating the mechanical properties of prosthetic feet. They characterized stiffness values and hysteresis of 33 stiffness categories and sizes of a commercially available prosthetic foot with and without a shoe. They found that foot size had a significant impact on axial and torsional stiffness values and hysteresis within the same manufacturer-defined stiffness category, and that use of a shoe had also a significant impact on stiffness. Their results suggest manufacturers should adjust the design of prosthetic feet in each stiffness category to ensure mechanical properties are consistent across different sizes and highlight the need to consider the effects of shoes.

Klute et al. conducted a clinical study with a novel, torsionally active ankle-foot prototype prosthesis (TAP) that can generate transverse plane rotation trajectories proportional to sagittal plane ankle angles corresponding at varying coupling ratios. Eleven individuals with unilateral transtibial amputation walked in a straight line and in both directions around a circle with the TAP set at randomized coupling ratios. The general pattern of results suggested a quadratic relationship between the peak transverse plane moment and coupling ratio with a minimum at the 6:1 coupling ratio. The coupling ratio did not appear to adversely affect propulsion or body support. Subjects indicated they found all coupling ratios to be comfortable.

Herrin et al. report a new approach to optimize the individual tuning of a tethered, research-grade powered prosthetic foot using eight different metrics of gait quality in seven individuals with unilateral transtibial amputation. Differences between the tuned and untuned conditions were reflected in several parameters, with improvements seen in all of them during use of the tuned prosthesis. All these metrics relate to the timing of force generation during walking, which is information not directly accessible to a prosthetist in everyday clinic. This work indicates that real-time biomechanical data provided to the prosthetist may improve future clinical tuning procedures for powered prostheses.

Klenow et al. performed a study with an updated microprocessor-controlled prosthetic knee (MPK—Genium^{TM}, Otto Bock, Duderstadt, Germany) with newly developed parameter presets for individuals with bilateral transfemoral amputation. A convenience sample of 17 unilateral and 9 bilateral MPK users was recruited for the study that assessed a battery of performance-based and patient-reported outcome measures. Stumble frequency was significantly reduced by 85% with the updated Genium MPK. The bilateral group reported significant 50% and 57% greater relative improvements in patient-reported ease and safety, respectively, of completing activities of daily living (ADL) compared to the unilateral group.

Krout et al. report early research efforts to manage low-level weight bearing to help maintain perfusion and improve proprioception and residual limb tissue health in transtibial prosthesis users. The goal of the project was to develop a sensor to measure distal weight bearing and to evaluate socket design variables that affect weight bearing. Participants accepted weight-

bearing levels ranging from 1.1% to 6.4% of body weight. Two of the three participants preferred distal weight bearing over non-presence. The next steps will be to determine target weight bearing levels and ranges, and to simplify the sensor and socket adjustment mechanism for clinical use.

Dickinson et al. conducted a retrospective chart review of socket rectifications in 134 randomly selected prosthetic users using 163 CAD/CAM transtibial sockets to assist future socket design choices. Limb and socket scans were compared to determine individual rectification of patella tendon bearing (PTB) and total surface bearing (TSB) socket designs, and associations between different rectification sizes were assessed using a variety of methods. Differences in design features were apparent between sockets, notably for paratibial carves, gross volume reduction, and distal end elongation. Design patterns were consistent with expert clinician practice. This study demonstrates how we might learn from design records to support education and enhance evidence-based socket design.

Leister et al. performed a study comparing the daily step count measured in 79 participants with transtibial amputation with the affordable but unvalidated FitBit Inspire 3 and the research-grade, validated activPAL. The study results show that the FitBit Inspire 3 counted 1,094 ± 1,423 more steps per day than the activPAL. However, a high correlation between the results of both monitors was found. Because of the significant mean differences, the activPAL and FitBit Inspire 3 are not interchangeable for estimating physical activity in persons with transtibial amputation. However, due to the high correlation of results, the consistent application of each of the devices results in similar classification rankings based on step counts.

3.6 Original research article and systematic literature review—bone-anchored prosthetics

Gladish et al. report the characterization of mechanical loads distal to the percutaneous part of the osseointegrated implant for fitting bone-anchored prostheses in four male individuals, two with unilateral and two with bilateral transfemoral amputation. Tri-directional forces and moments were wirelessly recorded through a sensor during six functional tests. Peak mechanical loads were largest during non-steady state components of the functional tests (e.g., side-stepping, standing up from the ground). Relative to walking, peak forces during functional tests were 110% to 181%, and peak moments 108% to 211% larger. The results allow for a more comprehensive understanding of the mechanical loads applied to bone-anchored implants, which is critical to maximize implant survivability and long-term outcomes.

Rehani et al. presents a systematic review of the literature on outcomes, complications, patient experiences, and cost-effectiveness of transfemoral bone-anchored prostheses, in which thirty-eight studies were included. The most common study design was the single-arm pre-/post-intervention trial. The clinical efficacy of bone-anchored prostheses was evident in selected populations. Overall, patients reported increased health-related quality of life, mobility, and prosthesis usage. The most common complication was a superficial or soft-tissue infection, while more serious complications were rare. The evidence from literature indicates that bone-anchored prostheses are cost-effective for those individuals who face significant challenges in using socket-suspension systems.

3.7 Original research article and literature review—lower limb orthotics

Hovorka et al. performed a study that investigated the neuromuscular output during the early adaptation period to constraint of ankle joint motion. Electromyography (EMG) of calf muscles was used to monitor muscle activation output in non-disabled individuals between constrained and unconstrained ankle motion using an ankle-foot orthosis (AFO) combined with footwear. Results support an emergent theory that when ankle joint motion is constrained during walking, skeletal muscle activation of uniarticular muscles acting on the constrained ankle joint is altered. Thus, clinicians need to be aware of this adaptive response period particularly in users that do not have a neuromotor deficit.

LeCursi et al. report on a study that aimed at proposing an explicit methodology for the adjustment of multi-function articulated AFOs in the clinical setting. Multi-function articulated AFOs offer features that permit more comprehensive and reversible adjustments of AFO ankle alignment and resistance to ankle motion. However, no standard method exists for the application and optimization of these therapeutic devices. Published evidence supporting most decision points of the algorithm is presented, two hypothetical case examples are given to illustrate the application of the method to the optimization of articulated AFOs, and gaps in evidence in this respect were identified.

4 From product idea to clinical standard

The papers published in this research topic are intended to motivate researchers and clinicians to engage in product development, clinical research, and compilation of peer-reviewed publications that further advance innovations in technology-assisted rehabilitation. Generation of evidence, preferably through registered clinical trials of high methodological quality are a necessity and prerequisite for widespread clinical adoption and acceptance as standard of care by healthcare payers. Robust, independent evidence for long-term effects and benefits of innovations will also be necessary to overcome the so called “decline effect”. This describes the phenomenon of initially strong results of new treatment options in early studies conducted by the developers that are later contrasted with more realistic results of independent,

bigger studies with longer follow-ups (20). This will be critical to convince public and private healthcare funding bodies to support a particular innovation, particularly with the emergence of value-based reimbursement models (e.g., hospital, physicians, workmańs compensation, and insurance) (21–23).

Author contributions

AK: Conceptualization, Methodology, Supervision, Writing – original draft, Writing – review & editing. RR: Conceptualization, Project administration, Writing – review & editing. SW: Conceptualization, Project administration, Writing – review & editing. LF: Conceptualization, Funding acquisition, Methodology, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article.

The contribution from LF was partially supported by the US Department of Defense RESTORE Award W81XWH2110215-DM190659 and the NHMRC Idea 202963.

Acknowledgments

Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by the RESTORE program and NHMRC.

Conflict of interest

AK was a co-author for the paper of Klenow et al. that was edited independently by the editorial office of Frontiers. AK is a full-time employee of Otto Bock, a manufacturer of prosthetic and orthotic components. SW is employed by Hanger, Inc., and SW, RR and LF declare that the Editorial was developed in the absence of commercial or financial interests that could be construed as a conflict of interest.

Publisher's note

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 25 August 2023
DOI 10.3389/fresc.2023.1235693

OPEN ACCESS

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RECEIVED 06 June 2023
ACCEPTED 10 August 2023
PUBLISHED 25 August 2023

CITATION
Monaghan PG, Knight AD, Brinkerhoff SA, Harrison KD, Dearth CL, Hendershot BD, Sefton JM, Zabala M, Vazquez A, Shannon D, Crumbley D and Roper JA (2023) Characterization of initial ankle-foot prosthesis prescription patterns in U.S. Service members following unilateral transtibial amputation. Front. Rehabil. Sci. 4:1235693. doi: 10.3389/fresc.2023.1235693

Characterization of initial ankle-foot prosthesis prescription patterns in U.S. Service members following unilateral transtibial amputation

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Introduction: The purpose of this study was to explore relationships between patient-specific characteristics and initial ankle-foot prosthesis prescription patterns among U.S. Service members with unilateral transtibial limb loss.
Methods: A retrospective review of health records identified 174 individuals with unilateral transtibial limb loss who received care at Walter Reed National Military Medical Center between 2001 and 2019. We examined patient-specific factors such as demographics, participant duty status at injury and amputation, amputation etiology, and timing between injury, amputation, and initial prescription. The type of first prescribed ankle-foot prosthesis was categorized as energy storing and return - nonarticulating, energy storing and return - articulating, or computer controlled.
Results: Sex, amputation etiology, time from injury to initial prescription, and time from amputation to initial prescription differed by type of initial ankle-foot prosthesis prescription. Service members with shorter intervals between injury-initial prescription and amputation-initial prescription, and those injured by combat blast, were more likely to receive a non-articulating device. Incorporating sex, time from injury-initial prescription, time from amputation-initial prescription, and amputation etiology as predictors of prosthesis type, we were able to correctly classify 72% of all first prostheses prescribed.
Discussion: Patient-specific characteristics such as sex, the time between injury-initial prescription, time from amputation-initial prescription and amputation etiology are essential characteristics that influence initial ankle-foot prosthesis prescription patterns in U.S. Service members.

KEYWORDS

military, lower-limb, device, prosthetic, rehabilitation

1. Introduction

Projections estimate that by 2050, the number of persons with limb loss in the United States (U.S.) will more than double to 3.6 million (1), largely due to dysvascular disease. Between 2001 and 2017, 1705 U.S. Service members sustained 1914 total deployment-related (major) amputations (2). Lower limb amputations account for 86% of all amputations within the United States(3); specifically, transtibial amputations are the most common form of lower limb loss, and account for 52% of all amputations in U.S. Service members (2, 4). Use of a lower limb prosthesis improves the quality of life and mobility for individuals with lower limb loss (5). Yet, while prosthetic device prescription is critical in achieving optimal outcomes (6), there remains minimal evidence to guide optimal device selection. Ankle-foot prosthesis prescription is a challenging and complex process, compounded with the abundance of commercially available ankle-foot componentry (7). Previous studies have highlighted insufficient evidence from high-quality comparative studies to develop or establish criteria for the prescription of prosthetic ankle-foot devices (8). Consequently, prescription tends to be primarily governed by the professional judgment of the limb loss care team (4).Patient-specific factors likely play a role in prosthesis prescription. For example, recently the US Department of Veterans Affairs and the US Department of Defense developed clinical practice guidelines for rehabilitation of lower limb amputation to address key clinical questions. One of the key outcomes was the need to consider what factors (demographic, clinical, biologic, environment, socioeconomic) are associated with better outcomes (9). However, individuals with lower limb loss exhibit marked heterogeneity regarding specific demographics and possess distinct medical and injury histories. For example, 72% of transtibial amputations among civilians are attributable to dysvascular etiologies, while only 7% are trauma-related (3, 4). Whereas, trauma-related injuries are the most prevalent cause of limb loss among U.S. Service members (2, 10); 90% of the 1914 major limb amputations reported between 2001 and 2017 amongst U.S. Service members were attributed to traumatic blast injury (2). Moreover, the particular type of trauma experienced, such as a gunshot wound, motor vehicle accident/crash, or an explosive blast, can influence the surgical procedure and prosthetic prescription process (11). The mechanistic underpinnings of the injury are important to consider in device prescription and may improve outcomes. The interval between the occurrences of injury, the resultant amputation procedure, and the initial prosthetic fitting directly influences outcomes. Although many amputations in combat-related settings occur acutely (within 3 months of injury), Stinner and colleagues report that out of 348 major limb amputations, 15% of those procedures occurred three months post-injury (12). Delayed amputations (amputations occurring greater than 48 h after admission) can increase disability and lead to poorer psychological and functional outcomes (13, 14). For example, Melcer and colleagues highlighted that patients treated with late as opposed to early amputations following combat injuries demonstrated higher rates of adverse physical and psychological outcomes (15). Further, patients who receive an amputation three months post-injury experience reduced functional outcomes at two years compared to groups who receive the amputation closer to the time of injury (16). The time between amputation and initial prosthetic prescription may also influence patient satisfaction with their prosthetic device and the frequency of use. Previous reports have documented that 43% of Veterans with transtibial amputation were fit with a prosthesis within 10.3 months of amputation, with this prescription rate increasing to 52% within 17.5 months (17). Receipt of the first prosthetic device greater than 60-days post-amputation is strongly related to less frequent device use and less satisfaction regarding the prosthesis fit, comfort, appearance, and overall performance (18). Early prosthetic prescription has many physical and psychological benefits (19). Many commercial ankle-foot componentry devices are available for the limb loss care team to prescribe (7), including articulating and non-articulating energy-storage-and-return (ESR) devices. Despite the lack of clear clinical guidelines, ESR is among the most commonly prescribed ankle-foot devices within the Department of Defense (DoD) (20). Using ESR devices can offer several advantages, such as increasing walking speed, reducing the energetic cost of walking, improving elastic response, and aiding propulsion (21–23). Various non-articulating ESR ankle-foot devices can have different mechanical characteristics; however, studies have demonstrated no significant differences in functional outcomes between these non-articulating ESR ankle-foot devices (24). Furthermore, the use of a microprocessor-controlled ankle-foot device has demonstrated improved ambulation during stair ascent (25). While studies have compared articulating ankle-foot devices with other categories of ankle-foot devices, few have reported significant differences regarding functional outcomes. While individual goals and the functional status of the person are crucial to consider within the prescription process, there remains insufficient evidence to support the prescription of specific prosthetic ankle-foot devices within these overarching classifications (26). The purpose of this study was to retrospectively describe the types and sequence/timing of the initial prescribed ankle-foot prosthesis(es), and evaluate corresponding relationships with patient-specific demographics and injury characteristics in U.S. Service members receiving care within the Department of Defense at Walter Reed National Military Medical Center. Defining such relationships will provide a necessary first step toward developing patient-specific strategies and provide an evidence-based benchmark for selecting an ankle-foot prosthesis.. Failure to consider these factors may reduce treatment effectiveness, amplify disability, and decrease device satisfaction/use.

2. Materials and methods

2.1. Experimental design and procedures

This study consisted of a retrospective analysis of electronic health records of U.S. Service members with unilateral transtibial limb loss who received care at Walter Reed National Military Medical Center between January 1, 2001 and September 1, 2019.

Research personnel reviewed the electronic health records to identify and extract participant demographics and relevant medical history, as well as all prosthetic devices received. A total of 305 U.S. Service members and/or dependents with unilateral transtibial limb loss were identified; of these, 131 were removed due to missing data (e.g., injury/amputation timing, could not adequately characterize prosthetic devices received), resulting in a final sample of 174 participants (**Supplementary Table S5**). This study was approved by the Institutional Review Boards at Walter Reed National Military Medical Center and Auburn University.

2.2. Outcome measures

Participant demographics are provided in **Table 1** and include age at the injury that resulted in amputation, age at ankle-foot prosthesis prescription, and sex. Participants' duty status at the time of injury and amputation were also collected and classified as active, retired, or active reserve, as well as dependent. The amputation etiology was also recorded and classified as combat blast injury, non-combat blast injury, motor vehicle accident, dysvascular causes, cancer, or other. Details related to prosthetic devices were extracted, including the make, model, and corresponding delivery timeline/sequence (i.e., to define first and/or subsequent devices). Instructions for use and specification documents were derived from the manufacturers' manual (see supplemental material). Prosthetic devices were categorized into groups based on type, function, and features into three overarching groups; (1) energy-storage-and-return and non-articulating (ESR-NA; passive, flexible/dynamic elastic response), (2) energy-storage-and-return storing and articulating (ESR-AR; passive, mechanical articulation, hinged ankle), and (3) computer-controlled (COMP; active/adaptive articulation with use of software, sensors, batteries, etc.). Note, the COMP category includes ankle-foot devices with powered propulsion. Prosthetic ankle-foot devices included in this investigation were classified at the time of study initiation by a diverse panel of experts including prosthetists and limb loss researchers. The panel considered device structure, componentry, function, and biomechanical properties to create ankle-foot device categories. More specific characteristics and features of the initial ankle-foot devices, including the subtype make and model, can be observed in **Supplementary Table S4** (**Supplementary Material**). Ankle-foot device prescriptions were formalized by a physician, considering input from a variety of multidisciplinary team members. The number of days between i) injury and amputation, ii) injury to initial prosthesis prescription, and iii) amputation to initial prosthesis prescription were also calculated. For persons with amputations secondary to vascular disease and cancer, the time from injury to amputation was calculated as the number of days between the reported date of diagnosis of the condition and the reported date of amputation. It is also crucial to highlight that the date of diagnosis may not correspond to the actual onset of the disease process, as there may be a significant time between the condition onset and diagnosis date. However, due to the nature of our study design, the date of diagnosis was the most appropriate and accurate index to include to capture this outcome.

2.3. Statistical analyses

Age at injury, age at prescription, time from injury to amputation, time from injury to first prescription, and time from amputation to first prescription were assessed for normality using a Shapiro-Wilk test. The distributions of all five outcome measures were skewed right and departed from normality (Age at injury, $W = 0.729$, $p < 0.001$; age at prescription, $W = 0.777$, $p < 0.001$; time from injury to amputation, $W = 0.533$, $p < 0.001$; time from injury to first prescription, $W = 0673$, $p < 0.001$; time from amputation to first prescription, $W = 0.425$, $p < 0.001$). Therefore, age at injury, age at prescription, time from injury to amputation, time from injury to first prescription, and time from amputation to first prescription were categorized by the median based on their distributions and compared to the type of first device with the Pearson's Chi-square test. Sex, military status at injury, and amputation etiology were also compared to the type of first device with the Pearson's chi-square test. We then estimated the probability of the first prescribed ankle-foot prosthesis type using a multinomial logistic regression model, where ESR-NA was the reference category. Of the 174 participants, 138 were first prescribed an ESR-NA, 28 an ESR-AR, and 8 a COMP. The COMP category included 7 passive and 1 powered ankle-foot device. The sample size for those prescribed an ESR-NA was considerably larger than for the other two device types; therefore, we used choice-based sampling (27) to randomly sample 28 patients of the 138 prescribed an ESR-NA to represent the sample in the multinomial logistic regression model. Therefore, the multinomial logistic regression model included 64 patients: 28 prescribed an ESR-NA, 28 prescribed an ESR-AR, and 8 prescribed a COMP. No differences were observed between the choice-based sample of $n = 28$ for ESR-NA and the original sample of $n = 138$ (comparison of demographic information can be seen in **Supplementary Table S6**). Regression model predictors included any measures that significantly differed by type of first prescribed device according to the Pearson's Chi-square tests above. A p-value of less than 0.05 was considered to indicate statistical significance.

3. Results

In the full sample of 174 patients, 4 of the 8 measures differed by the first device prescribed. Time from injury to initial prescription [$X^2(2) = 8.998$, $p = 0.011$] and time from amputation to initial prescription [$X^2(2) = 8.619$, $p = 0.013$] differed such that those prescribed an ESR-AR or a COMP were more likely to be prescribed their device later than those prescribed an ESR-NA (**Figure 1**). Amputation etiology differed such that those prescribed a COMP were most likely to have been injured by a motor vehicle, while those prescribed an ESR-NA were most likely to have been injured by a combat blast and least likely to

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TABLE 1 Sample demographics, by device type of first prescribed ankle-foot prosthesis.

		All duty categories	Active duty	Not active duty
All foot categories	*N*	*174*	*155*	*19*
	Age at injury	29.1 (11.6)	26.1 (5.9)	53.5 (16.8)
	Age at prescription	31.3 (11.7)	28.3 (6.6)	55.1 (16.7)
	Days from amputation to prescription	311.7 (689.3)	330.5 (726.5)	158.3 (153.1)
	Days from injury to amputation	307.0 (661.7)	327.2 (693.8)	142.6 (240.0)
	Days from injury to prescription	631.3 (921.1)	657.7 (953.7)	416.3 (563.5)
	Sex	163 Male	151 Male	12 Male
		11 Female	4 Female	7 Female
	Duty status at injury	155 Active Duty	150 Active Duty	1 Active Reserve
		1 Active Reserve		6 Dependent
		6 Dependent		12 Retired
		12 Retired		
	Amputation etiology	6 Cancer	1 Cancer	5 Cancer
		109 Combat blast	109 Combat blast	10 Dys. disease
		10 Dys. disease	15 Gunshot	1 Gunshot
		16 Gunshot	16 Motor vehicle	1 Motor vehicle
		17 Motor vehicle	14 Other	2 Other
		16 Other		
ESR-NA	*N*	*138*	*127*	*11*
	Age at injury	28.0 (10.9)	25.7 (5.6)	54.3 (20.1)
	Age at prescription	30.1 (11.1)	27.8 (6.2)	55.8 (19.8)
	Days from amputation to prescription	271.4 (624.4)	280.5 (648.1)	166.6 (190.4)
	Days from injury to amputation	273.0 (585.2)	288.9 (605.8)	89.8 (164.4)
	Days from injury to prescription	560.3 (841.9)	569.4 (856.1)	455.7 (679.9)
	Sex	129 Male	124 Male	5 Male
		6 Female	3 Female	3 Female
	Duty status at injury	127 Active Duty	124 Active Duty	1 Active Reserve
		1 Active Reserve		3 Dependent
		3 Dependent		7 Retired
		7 Retired		
	Amputation etiology	2 Cancer	92 Combat blast	2 Cancer
		92 Combat blast	12 Gunshot	6 Dys. disease
		6 Dys. disease	13 Motor vehicle	1 Gunshot
		13 Gunshot	10 Other	2 Other
		13 Motor vehicle		
		12 Other		
ESR-AR	*N*	*28*	*21*	*7*
	Age at injury	33.5 (14.5)	26.7 (6.8)	53.9 (12.2)
	Age at prescription	36.8 (14.1)	30.7 (8.0)	55.2 (12.6)
	Days from amputation to prescription	464.9 (988.2	579.8 (1,123.4)	120.1 (54.3)
	Days from injury to amputation	533.2 (988.2)	666.4 (1,108.0)	133.7 (231.5)
	Days from injury to prescription	998.1 (1,269.7)	1,246.2 (1,377.6)	253.9 (257.1)
	Sex	25 Male	21 Male	4 Male
		3 Female		3 Female
	Duty status at injury	21 Active Duty	21 Active duty	3 Dependent
		3 Dependent		4 Retired
		4 Retired		
	Amputation etiology	3 Cancer	13 Combat blast	3 Cancer
		13 Combat blast	3 Gunshot	1 Dys. disease
		4 Dys. disease	1 Motor vehicle	
		3 Gunshot	4 Other	
		1 Motor vehicle		
		4 Other		
COMP	*N*	*8*	*7*	*1*
	Age at injury	31.5 (7.6)	30.0 (6.8)	42
	Age at prescription	33.4 (8.1)	31.7 (6.9)	45.7
	Days from amputation to prescription	469.6 (437.3)	489 (468.6)	334
	Days from injury to amputation	102.0 (276.5)	4.3 (7.4)	786
	Days from injury to prescription	571.6 (484.8)	493.3 (465.7)	1,120.00
	Sex	6 Male	6 Male	1 Female
		2 Female	1 Female	
	Duty status at injury	7 Active Duty	7 Active Duty	1 Retired
		1 Retired		
	Amputation etiology	1 Cancer	1 Cancer	1 Motor vehicle
		4 Combat blast	4 Combat blast	
		3 Motor vehicle	2 Motor vehicle	

Values for continuous outcomes are given in Mean (Standard Deviation) [minimum, maximum]. Values for categorical outcomes are given in frequency counts. ESR-NA, energy-storage-and-return and non-articulating; ESR-AR, energy-storage-and-return and articulating; COMP, computer-controlled.

have cancer as the cause of amputation [$X^2(12) = 24.294$, $p = 0.019$]. Finally, people prescribed COMP devices were more likely to be female than people prescribed an ESR-AR or an ESR-NA [$X^2(2) = 6.533$, $p = 0.038$]. The proportion of each device by these variables can be seen in Figure 2. Age at injury [$X^2(2) = 1.512$, $p = 0.469$], age at prescription [$X^2(2) = 3.537$, $p = 0.171$], time from injury to amputation [$X^2(2) = 3.420$, $p = 0.181$], and participant duty status at injury [$X^2(2) = 9.481$, $p = 0.148$] did not differ by type of first device prescribed. Therefore, the multinomial logistic regression model to predict the type of first device prescribed was stratified by time from injury to initial prescription, time from amputation to initial prescription, sex, and amputation etiology. The model correctly classified the first device prescribed for 46 out of 64 patients (72%) and misclassified 18 patients (28%). The model correctly classified 71% of patients prescribed an ESR-NA; 71% of patients prescribed an ESR-AR, and 38% of

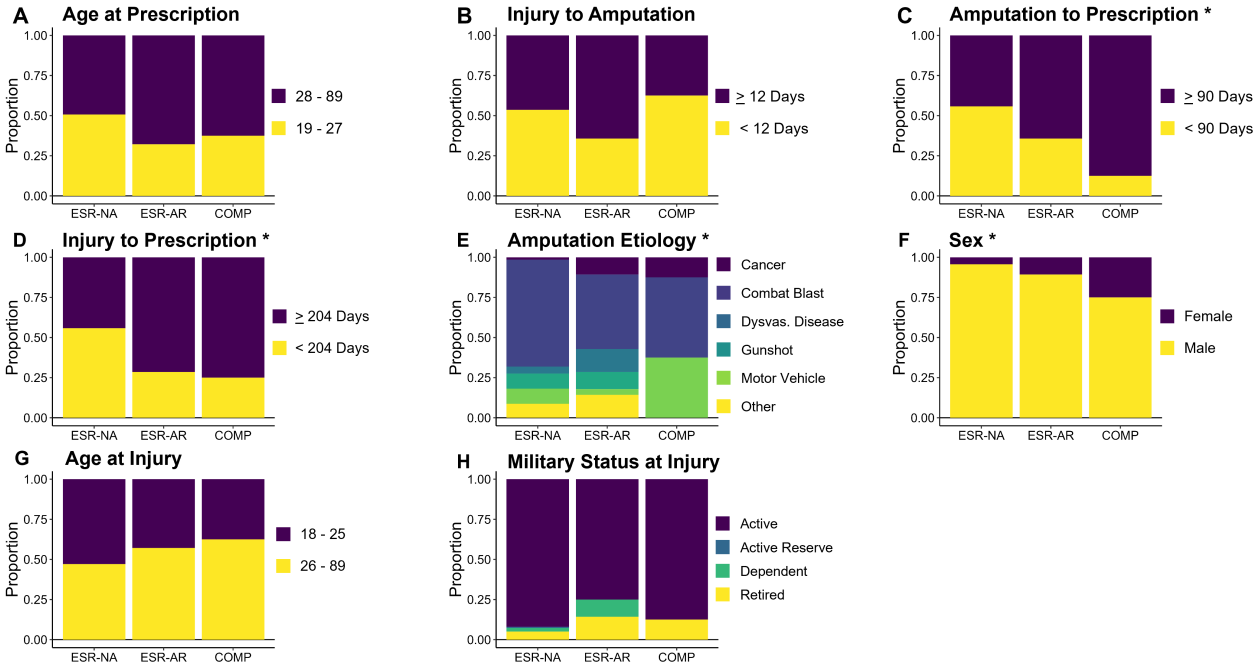

FIGURE 1
Proportion of patients prescribed an ESR-NA, ESR-AR, and COMP as their first device by (A) age at prescription, (B) time from injury to amputation, (C) time from injury to prescription, (D) time from amputation to prescription, (E) amputation etiology, (F) sex, (G) age at Injury and (H) military status at injury. $N = 174$; $n = 138$ ESR-NA; $n = 28$ ESR-AR; $n = 8$ COMP. ESR-NA, energy-storage-and-return and non-articulating; ESR-AR, energy-storage-and-return and articulating; COMP, computer-controlled. Asterisks indicate significant chi-squared tests; *$p < 0.05$, **$p < 0.01$.

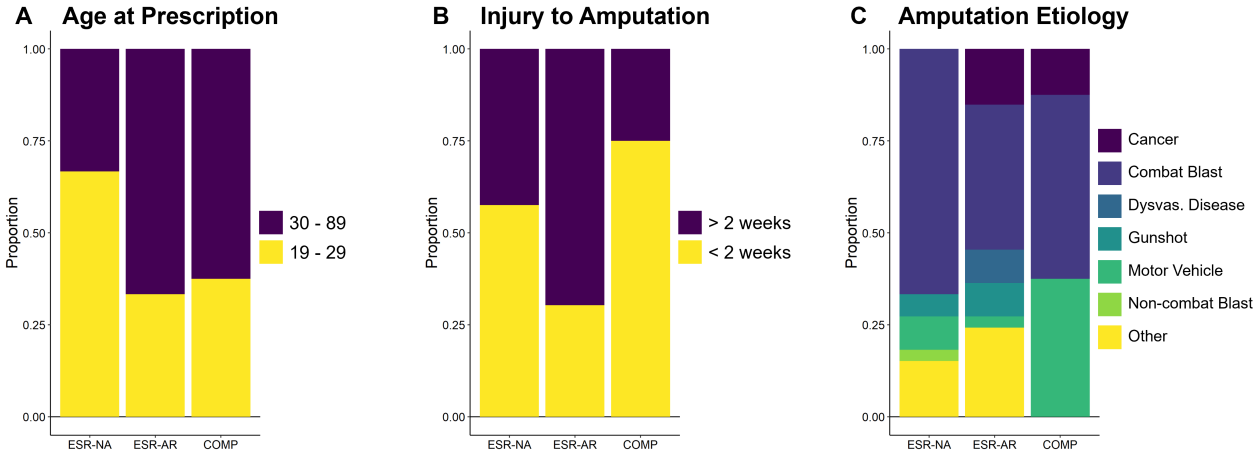

FIGURE 2
Proportion of patients prescribed an ESR-NA, ESR-AR, and COMP as their first device by (A) age at prescription, (B) time from injury to amputation, and (C) MOI. $N = 64$; $n = 28$ ESR-NA; $n = 28$ ESR-AR; $n = 8$ COMP. ESR-NA, energy-storage-and-return and non-articulating; ESR-AR, energy-storage-and-return and articulating; COMP, computer-controlled.

patients prescribed a COMP (Table 2). The odds that a patient would be prescribed an ESR-AR over an ESR-NA were affected by amputation etiology, such that those injured by a motor vehicle accident or a combat blast were less likely to be prescribed an ESR-AR than an ESR-NA, and those amputated as a result of dysvascular disease, cancer, gunshot, or other mechanism were more likely to be prescribed an ESR-AR than an ESR-NA. The probabilities and *p*-values that a patient would

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TABLE 2 Predicted versus actual classifications by device type of first prescribed ankle-foot prosthesis.

		Actual			
		ESR-NA	ESR-AR	COMP	
Predicted	ESR-NA	20 (71%)	8	3	31
	ESR-AR	8	20 (71%)	2	30
	COMP	0	0	3 (38%)	3
		28	28	8	

The shaded cells are those devices correctly predicted by the multinomial logistic regression model. ESR-NA, energy-storage-and-return and non-articulating; ESR-AR, energy-storage-and-return and articulating; COMP, computer-controlled.

TABLE 3 The probability that a patient would be prescribed an ESR-AR or a COMP versus an ESR-NA device.

Probability of being prescribed an ESR-AR over an ESR-NA		
Outcome	Probability	*p*-value
Days from injury to prescription = less than 204 days	0.26	0.151
Days from injury to prescription = at least 204 days	0.74	
Days from injury to amputation = less than 12 days	0.30	0.196
Days from injury to amputation = at least 12 days	0.70	
Amputation etiology = cancer	>0.99	**<0.001**
Amputation etiology = combat blast	<0.01	**<0.001**
Amputation etiology = dysvascular disease	0.85	**<0.001**
Amputation etiology = gunshot	0.58	**<0.001**
Amputation etiology = motor vehicle accident	0.31	**<0.001**
Amputation etiology = other	0.65	**<0.001**
Sex = Male	0.84	0.324
Sex = Female	0.16	
Probability of being prescribed a COMP over an ESR-NA		
Outcome	Probability	*p*-value
Days from injury to prescription = less than 204 days	0.25	0.286
Days from injury to amputation = at least 204 days	0.75	
Days from injury to amputation = less than 12 days	0.62	0.628
Days from injury to amputation = at least 12 days	0.38	
Amputation etiology = cancer	>0.99	**<0.001**
Amputation etiology = combat blast	>0.99	**<0.001**
Amputation etiology = dysvascular disease	<0.01	**<0.001**
Amputation etiology = gunshot	<0.01	**<0.001**
Amputation etiology = motor vehicle accident	0.74	**<0.001**
Amputation etiology = other	<0.01	**<0.001**
Sex = Male	<0.01	**<0.001**
Sex = Female	>0.99	

Values in bold indicate significant probabilities. ESR-NA, energy-storage-and-return and non-articulating; ESR-AR, energy-storage-and-return and articulating; COMP, computer-controlled.

be prescribed an ESR-AR over an ESR-NA are shown in Table 3. The odds that a patient would be prescribed a COMP over an ESR-NA were affected by amputation etiology and sex, such that those who were injured by dysvascular disease, gunshot, or other mechanism were less likely to be prescribed a COMP than an ESR-NA, and those injured by cancer, combat blast, or motor vehicle accident were more likely to be prescribed a COMP than an ESR-NA. Sex affected the odds such that females were more likely to be receive a COMP than an ESR-NA. The probabilities and *p*-values that a patient would be prescribed a COMP vs. an ESR-NA are shown in Table 3.

4. Discussion

This study aimed to characterize initial ankle-foot prosthesis prescription patterns within U.S. Service members and dependents with unilateral transtibial limb loss receiving care within the Department of Defense at Walter Reed National Military Medical Center. It is important to note that we analyzed initial device prescription, which may not be representative of the optimal outcome, yet still an important distinction within the prescription process. We first explored this relationship in the entire sample ($N = 174$) and then examined it with a more even distribution amongst ankle-foot prosthesis types in our final model ($N = 68$). We also assessed the ability of our final model to predict and correctly classify the initial ankle-foot prosthesis prescribed. We report three main findings from the final model: (1) initial ankle-foot prosthesis prescription differed by time from injury to initial prescription, time from amputation to initial prescription, sex, and amputation etiology; (2) incorporating time from injury to initial prescription, time from amputation to initial prescription, sex, and amputation etiology as predictors of initial ankle-foot prosthesis type, we were able to correctly classify 72% of all first prostheses prescribed; (3) females were more likely to have first prescriptions of COMP devices. The time between injury and initial prescription, and the time between amputation and initial prescription impacted the choice of the first ankle-foot prosthesis. The mean (SD) number of days between injury and initial ankle-foot prescription for those receiving an ESR-NA prosthesis was 560 (842) days, 998 (1,270) days for ESR-AR prosthesis, and 572 (485) days for a COMP prosthesis. We report that U.S. Service members who were prescribed an ESR-AR or a COMP were more likely to experience a longer time between injury and amputation (> 90 days), and amputation to prescription (> 204 days). Therefore, it is evident that timing within the prescription procedure can significantly influence initial prescription patterns, however there are many factors that may influence the timing of such events. For example, many combat-related amputations occur acutely. However, previous work has documented that out of 348 major limb amputations, 15% occurred three months post-injury (12). Our outcomes also align with those of Krueger and colleagues, who demonstrated that 10% of U.S Service members underwent an amputation greater than 90 days after the date of injury (10). Previous literature has also revealed that amputations three months post-injury were associated with poor functional outcomes two years post-amputation (16). Identifying an optimal ankle-foot prosthesis at initial prescription is crucial to the rehabilitation process post-amputation; it has been associated with increased physical functioning, vitality and satisfaction, and reduced bodily pain (18). Nevertheless, prosthetic prescription has been identified as one of the major issues individuals encounter during the rehabilitation process (28). Our findings demonstrate that the interval between injury and prescription and amputation and prescription may influence initial ankle-foot prescription patterns in U.S. Service members. Of note, although not a primary aim included within our analysis, it is plausible

that a Service member's specific rank/designation (e.g., special ops) may also influence the timing between prosthesis prescription (and other care) relative to injury and/or amputation. The decision-making process on whether to amputate or attempt limb salvage is multi-faceted and complex, considering numerous factors, such as the patient's pre-injury status, injury factors, and available resources (13, 29). The timing between initial prosthesis prescription and relative to injury/or amputation may be impacted by the physical and psychological status of the individual. Although not part of the aim of this investigation, secondary health conditions and complications following lower limb amputations are common (30). Therefore, it is plausible that these factors may reflect the wide range of timing variables in our sample. Considering individual factors such as the timing of injury and amputation relative to initial prosthesis prescription may enhance initial ankle-foot prosthesis prescription by attenuating potential prosthesis-related issues U.S. Service members may encounter during the rehabilitation process. The amputation etiology also significantly influenced the initial prosthesis prescription in U.S. Service members. Combat blast injury was the most reported injury resulting in amputation within the current sample. This aligns with previous literature reporting blast injury as the common cause of amputation within this population sector (2). For example, Farrokhi and colleagues report that during a 17-year surveillance period in a U.S. Service member population, 90.6% of amputations were caused by blast injury (2). Here, 84% of U.S. Service members experiencing a combat-blast injury were initially prescribed an ESR-NA prosthesis, 12% were prescribed an ESR-AR prosthesis, and 4% were prescribed a COMP prosthesis. There was a greater than 99% probability that those injured by a combat blast would be prescribed an ESR-NA over an ESR-AR or over a COMP. There was also an 85% and >99% probability that those amputated as a result of dysvascular disease and cancer, respectively, would be prescribed an ESR-AR over an ESR-NA. While individuals with lower limb loss exhibit marked heterogeneity concerning the etiology of amputation, even within a U.S. Service member population, the cause of amputation may vary. It is also crucial to consider the range of duty status (active, reserve, dependent, and retired) within this sample (**Table 1**) and how this may relate to amputation etiology. Dysvascular disease has been reported to be the leading cause of amputation in the civilian population, particularly with advancing age (1). The mechanistic underpinnings of the injury are crucial to understanding aspects of the prosthetic rehabilitation process, especially as they influence the particular type of prosthesis an individual may receive. Our model, incorporating the time from injury to initial prosthesis prescription, time from amputation to initial prosthesis prescription, sex, and amputation etiology as predictors, correctly predicted and classified 72% of all initial prosthesis types prescribed to U.S. Service members. Within each prosthesis type, our model correctly classified 71% of ESR-NA prostheses, 71% of ESR-AR prostheses, and 38% of the COMP prosthesis. The lower success rate in classifying the COMP prosthesis may result from the smaller number of U.S. Service members in our sample that were prescribed a COMP prosthesis ($N = 8$) compared to other prosthesis types. This is perhaps unsurprising, as ESR devices are the current gold standard for prescription within the Department of Defense (DoD) (20). ESR devices can offer several advantages, such as increasing walking speed, reducing the energetic cost of walking, improving elastic response, and aiding propulsion (21–23). Furthermore, it is also important to highlight that limited commercial options are available when considering powered propulsion COMP devices. However, it is encouraging that four patient-specific characteristics could correctly predict initial prosthesis type. These findings indicate that individual characteristics may relate to specific ankle-foot prosthesis prescription patterns among U.S. Service members. Our study also revealed that initial ankle-foot prosthesis prescription patterns may be impacted by sex. Females exhibited an increased probability and were more likely to be prescribed a COMP device than an ESR-NA device. Although generally consistent with the larger Service member and veteran populations, females comprised just 6.3% of our total sample ($N = 11/174$). Considering ankle foot-foot prosthesis category, 25% of COMP were females, 10.7% of ESR-AR were females, and 4.3% of ESR-NA were females. While the model does depict an increased likelihood of females receiving a COMP prosthesis, it is imperative to interpret these findings with caution due to both the small number of females and overall prescriptions of a COMP prosthesis ($N = 8$) compared to other prosthesis types. Nonetheless, females with limb loss present with unique considerations for prosthesis prescription and additional work is certainly needed to improve outcomes for this population. While the main focus was toward describing initial ankle-foot prosthesis prescription patterns in active-duty U.S. Service members, we ultimately identified several patients outside of this designation (e.g., dependent, retired) who received care during the study window. Duty status at injury or amputation was not different at initial device prescription (**Table 1** highlights how ankle-foot prosthesis prescription may be influenced by duty status). When examining the distribution across prosthetic foot type for the subset who were active-duty U.S. Service Members ($n = 155$), as in the full sample, time from injury to prescription, time from amputation to prescription, and amputation etiology predicted first device prescribed. However, in this subset of active-duty Service members, time from injury to amputation also predicted first device prescribed, and sex did not. Of note, the primary amputation etiology for non-active-duty personnel was dysvascular etiology compared to combat blast injury for active duty (**Table 1**). While the scope of this paper was to provide a necessary first step in characterizing ankle-foot prosthesis prescription patterns primarily in active duty U.S. Service members, future studies should expand to other patient groups and clinical settings, particularly for improving generalizability to the veteran and civilian sectors. Furthermore, while the focus of our study was solely on initial device prescription, most of the Service members within our study went on to receive additional prescriptions. While outside the scope of this particular study, future work should examine how ankle-foot device prescription altered for each individual over time as this could help guide studies using outcome measures or end user feedback. Several

other key considerations concerning ankle-foot component selection were not included in our study but are important to note. First, it is crucial to consider the functional status and mobility needs of individuals following limb loss. For example, many of the Service members in our study may be higher functioning and seeking to return to service as soon as possible. Therefore, it is plausible that they may require an ankle-foot device with particular features that allows them to negotiate different environments. Second, the prescription process is incredibly complex; individuals can often present with comorbid health conditions and experience secondary complications alongside prosthesis fitting. Therefore, it is critical to interpret our results cautiously as we did not report on such factors vital within the prescription procedure. It is plausible that a longer time between injury and prescription and amputation and prescription may reflect the physical and psychological state of the Service members. Third, we report only on the initial ankle-foot device prescribed to Service members, which may not reflect optimal (or only) device selection.

4.1. Study limitations

There are several limitations to consider with our study. First, without subsequent device use and clinical outcomes we are unable to deduce if specific prescriptions were optimal (improved satisfaction, quality of life, and physical function), nor if other clinical or institutional factors may have driven these initial prescription patterns. Future work should explore how such relationships may influence aspects of physical function, mobility, and quality of life. However, identifying shared characteristics in people prescribed specific ankle-foot devices may aid in better understanding of the role of these characteristics in clinical decision-making and in guiding future research initiatives. Further, due to the retrospective nature of the study design, incomplete or missing data was unable to be recovered, leading to the exclusion of many participants (118 participants were excluded due to missing initial prosthesis type, initial prosthesis prescription date, injury date, or amputation date). Additionally, collinearity between amputation etiology (combat blast) and age at device prescription likely confounded the odds ratios and confidence intervals for the combat blast in the logistic regression. Our analysis was restricted to individuals who received post-amputation care at Walter Reed National Military Medical Center; therefore, these relationships may not necessarily be generalized across the Department of Defense, Veterans Affairs, or to civilian practice. U.S. Service members also typically receive extensive therapies, training, and rehabilitation, both pre- and post-prosthesis, and including device- and activity-specific training. Although not the focus of this study, these are critical factors when considering optimal use/success of a prosthesis, and likely a major difference between population/care sectors. Prospective studies examining prothesis prescription patterns should utilize a more comprehensive approach, in particular obtaining both functional and patient-reported outcomes. While our study did not compare the association between the Medicare Functional Classification Levels (i.e., K-Level) and initial ankle-foot device prescription, such a functional index is not explicitly required within the DoD setting, contrary to the private sector. This study may also be limited, considering we included three categories of ankle-foot types. Future work should seek to explore the relationships between initial prescription patterns and a more specific/precise categorization of ankle-foot types.

5. Conclusions

This study identified patient-specific characteristics such as sex, time between injury and amputation, and amputation etiology influencing (first) ankle-foot prosthesis prescription in U.S. Service members and dependents receiving care within the Department of Defense at Walter Reed National Military Medical Center. Our findings suggest that younger Service members are more likely to receive an initial ESR-NA prosthesis, a shorter time between injury and amputation and a non-combat blast injury increases the odds of initially receiving an ESR-AR prosthesis. While more work is needed to track subsequent prosthesis use and outcomes, our study reinforces the importance of considering patient-specific factors during prosthesis prescription, to ensure an optimal first device prescription and post-amputation quality of life.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Walter Reed National Military Medical Center and Auburn University. The studies were conducted in accordance with the local legislation and institutional requirements. Informed consent and HIPAA waivers were approved given it would have been impracticable to retrospectively locate all individuals who received prosthetic services since January 2001.

Author contributions

JR, BH, AK, and CD contributed to conception and design of this study. SB and DS performed statistical analysis. PM wrote the first draft of the manuscript. All authors PM, AK, SB, KH, CD, BH, DC, DS, MZ, JS, AV, and JR revised the manuscript and approved the final version. All authors contributed to the article and approved the submitted version.

Funding

This work is supported by the Assistant Secretary of Defense for Health Affairs, through the Orthotics and Prosthetics Outcomes Research Program under Award No. W81XWH1810819.

Acknowledgments

The authors wish to acknowledge Meghan Tullos, Barbara Springer, Anastasia McUlsky, and Binni Khatri for assistance in electronic health record data extraction/aggregation. The authors also wish to acknowledge students from Auburn University's Locomotor and Movement Control Lab, Neuromechanics Lab and School of Nursing for their assistance with data input. The views expressed in this manuscript are those of the authors and do not necessarily reflect the official policy of the Uniformed Services University of the Health Sciences, Departments of the Army, Navy, Air Force, Department of Defense, Veterans Affairs, nor the US Government. The identification of specific products or scientific instrumentation does not constitute endorsement or implied endorsement on the part of the authors, Department of Defense, or any component agency.

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The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fresc.2023.1235693/full#supplementary-material

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 21 December 2023
DOI 10.3389/fresc.2023.1322202

OPEN ACCESS

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RECEIVED 16 October 2023
ACCEPTED 06 December 2023
PUBLISHED 21 December 2023

CITATION
Krout AJ, Weissinger MJ, Mertens JC, Allyn KJ, Larsen BG, McCarthy NK, Garbini JL and Sanders JE (2023) Distal weight bearing in transtibial prosthesis users wearing pin suspension.
Front. Rehabil. Sci. 4:1322202.
doi: 10.3389/fresc.2023.1322202

Distal weight bearing in transtibial prosthesis users wearing pin suspension

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Introduction: Low-level distal weight bearing in transtibial prosthesis users may help maintain perfusion and improve both proprioception and residual limb tissue health.
Methods: The primary objectives of this research were to develop a sensor to continuously measure distal weight bearing, evaluate how prosthesis design variables affected weight bearing levels, and assess fluctuations in distal weight bearing during at-home and community use.
Results: In-lab testing on a small group of participants wearing adjustable sockets demonstrated that if distal contact was present, when socket size was increased distal weight bearing increased and when socket size was reduced distal weight bearing decreased. During take-home use, participants accepted the distal weight bearing level set by the research team. It ranged between 1.1% and 6.4% BW for all days tested. The coefficient of variation (standard deviation/mean) ranged from 25% to 43% and was expected due in part to differences in walking style, speed, terrain, direction of ambulation, and bout duration. Two participants commented that they preferred presence of distal weight bearing to non-presence.
Discussion: Next steps in this research are to develop clinical practices to determine target distal weight bearing levels and ranges, and to simplify the design of the sensor and weight bearing adjustment mechanism for clinical use.

KEYWORDS

prosthetics, residual limb, distal weight bearing, transtibial amputee, socket fit, pin suspension, limb-socket interface, end bearing

1. Introduction

Distal weight bearing, force transferred from the bottom of the residual limb to the socket, is relevant to the well-being of a person with transtibial amputation. Some distal weight bearing may generate a pumping effect on the residual limb during walking that helps maintain perfusion and reduce edema (1). Research from the zoology and evolutionary biology literature suggest that soft tissue will adapt its collagen architecture to better tolerate mechanical stress if subject to low to moderate cyclic loads (2). Excessive distal weight bearing may put residual limb tissues at risk of injury. Prosthetists use primarily two techniques during office visits to assess distal weight bearing: (i) A putty ball is placed in the bottom of the socket and its thickness before and after weight bearing is compared. (ii) The color of distal soft tissue after walking is assessed—a bright red color may indicate excessive distal pressure and the need for an adjustment.

In previous studies, researchers measured distal weight bearing in participants with transtibial amputation (3–5). Katz et al. (3) assessed distal weight bearing by isolating the distal section of the socket and instrumenting it with a load cell. Different thickness spacers were placed underneath the distal section to shorten the socket and increase the force on the distal residual limb. Testing was conducted on a group of six participants 27–67 years old who regularly used a patellar tendon bearing socket with strap suspension and a Pelite™ liner. Participants' applied force to the distal end of their socket while weight bearing just under their pain threshold was a median of 30% (range 13%–48%) of their maximum vertical ground reaction force when they were walking and a median of 30% (range of 11%–55%) of their maximum vertical ground reaction force when they were standing. Persson and Liedberg (4) conducted testing on 85 participants with transtibial amputation (mean age 67 years). Participants' residual limb maximum weight bearing during standing was measured using a fitting stool equipped with a curved top surface to support the residual limb. No socket was worn. Participants' residual limb maximum weight bearing without pain during standing was a mean of 17.2% (SD 13.1) of their body weight (BW). Participants with diabetes tolerated a greater force (mean 21.5% BW) than participants without diabetes (mean 14.3% BW) to a significance level of 0.05. Participants with a residual limb that was rounded at the distal end demonstrated a lower residual limb weight bearing force (mean 16.2% BW) than participants with a pointed distal end (mean 18.5% BW) but the difference was not statistically significant. Rich et al. (5) inserted a pneumatic pressure sensor into the distal end of the socket in six participants with transtibial amputation using sleeve suspension. The sensor data were not quantified into units of force though a relative change in the data within an in-lab test session for different sock thicknesses was demonstrated.

This research is directed towards a novel instrument to clinically evaluate if low-level distal end bearing is beneficial to participants with transtibial amputation using sockets with locking pin suspension. The instrument sensed pin vertical position and residual limb distal weight bearing. We manually adjusted the system to achieve different weight bearing levels. A small group of participants with transtibial amputation wore the device during a structured in-lab protocol to determine if distal weight bearing increased when socket size was increased and decreased when socket size was decreased. Then the instrumentation was improved to simultaneously collect liner-to-socket distance data from sensors embedded in the socket so that relationships between limb-socket position and distal limb motion could be explored. Participants wore the test prosthesis in their free-living environment for approximately one week. The daily standard deviation in the data was calculated, and plots of sensed distance against pin height were generated. The instrument may be a clinically useful platform for measuring how prosthesis design variables and participant characteristics affect limb motion and distal weight bearing, and potentially allow for an automatically adjusting socket that controls distal weight bearing to clinically beneficial levels. The technology is intended to support patient education, clinical diagnostics, and treatment design to optimize prosthetic fit for individual patient care.

2. Materials and methods

2.1. Participant inclusion and exclusion criteria

Participants were included in this study if they were at least 18 years of age, had a transtibial amputation at least 18 months prior, were using a definitive prosthesis, were at a MFCL level (6) of K2 (had the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces) or higher, and had participated in a study wearing a three-panel motor-driven adjustable socket (7). The socket from that study needed to be of acceptable fit as deemed by the research prosthetist. This last criterion was necessary to ensure that a properly fitting adjustable socket was available for use in the present study. Additional inclusion criteria were that participants self-reported walking at least 7 h/wk and were capable of continuous walking on a treadmill for at least 8 min. Participants were not included if they used a walking aide (e.g., cane, walker) or were currently experiencing residual limb skin injury.

2.2. Sensors and sockets

Locking pin suspension is a means for maintaining proper position of the residual limb in the socket during the swing phase of gait. A rastered pin with about 7 notches that fastens to the bottom of the liner is inserted into a ratchet in the bottom of the socket. The ratchet holds the pin at the deepest pin notch reached during ambulation. The participant may release the ratchet via a simple mechanism accessible on the side of the socket.

A sensor that measured the depth of the locking pin within the shuttle lock, developed in our prior work (8), was re-designed to incorporate springs into a platform that supported the locking pin. This addition allowed the sensor's measurement of pin position to be converted to measurement of applied force by multiplying by the stiffness of the springs. The force applied through the locking pin was measured continuously during prosthesis use.

Four springs were placed on extensions of the four posts that connected the socket to the pyramid adapter of a transtibial prosthesis. The springs provided an elastic element that supported the locking pin via a spring plate and plunger as shown in **Figure 1A**. A vertical adjustment screw passing through a linear bearing was threaded into the spring plate such that adjustment of the screw extended the plunger, changing the distance between the springs and pin (termed the *plunger length* in **Figure 1D**), drawing it closer to contact with the bottom of the locking pin. A concept diagram of how adjustment of the plunger length affected the height of the locking pin and the

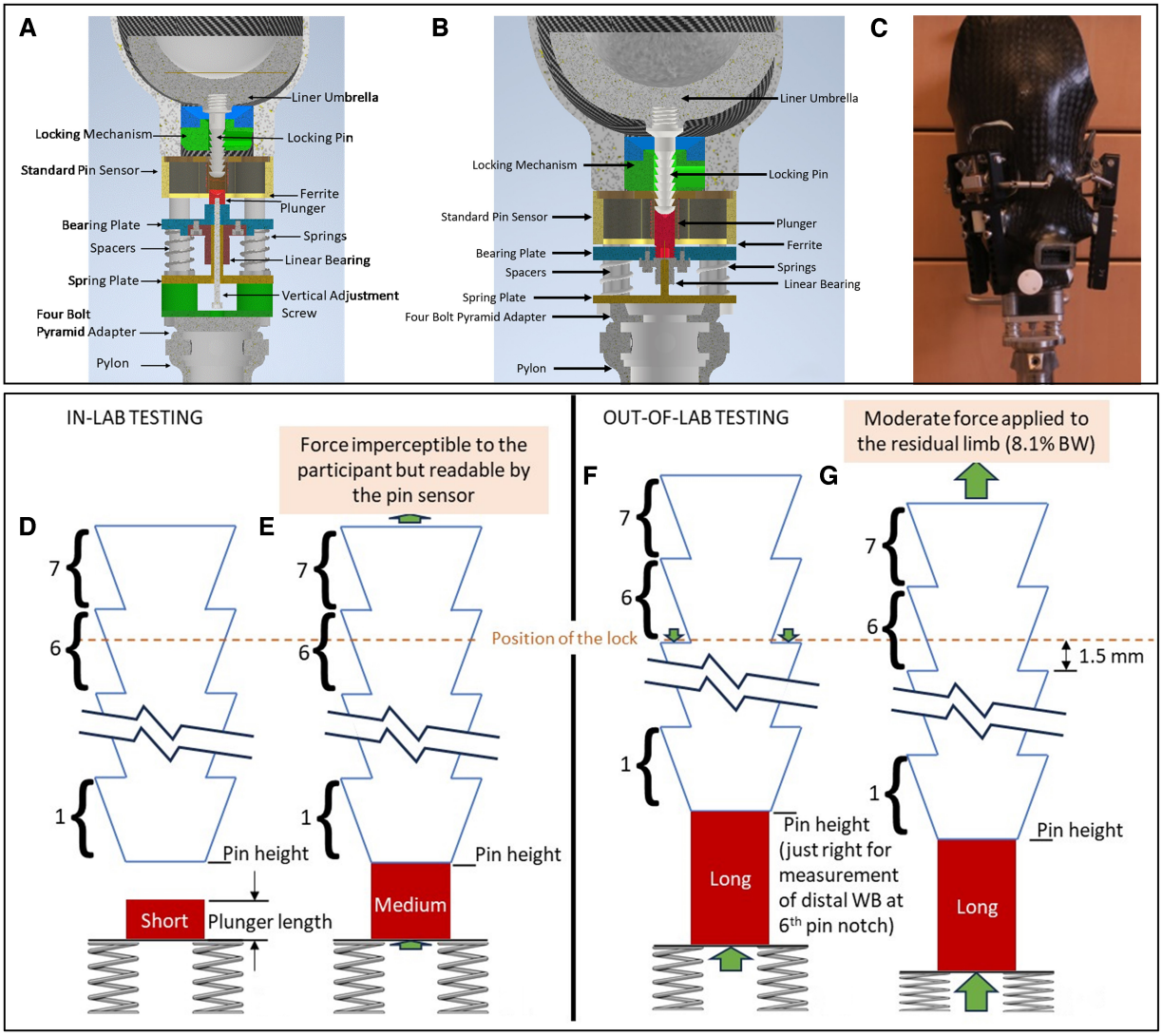

FIGURE 1
(A–G) instrumentation. (A) Design used for in-lab testing. The resting pin height was adjusted by turning the "Vertical adjustment screw" using an Allen key. The pylon had to be removed to access the Allen key. This version of the sensor weighed 326.4 g. (B) Design used for take-home testing. The pin height was adjusted by selecting a plunger length that caused the springs to engage at 0.1 mm before the pin entered the participant's normal pin notch. This version of the sensor weighed 241.0 g. (C) Instrumented socket ready for take-home use. An adjustable-size socket with motor-driven panels was used in this study. In D–G, the locking pin (solid blue line), plunger (red), and springs (gray) are shown. The dashed orange line indicates the position of the pin lock, and the green arrows show force applied to the locking pin and plunger in the four states (D–G). The *1*, *6*, and *7* indicate the pin notch. Images (D) and (E) reflect conditions during the in-lab test protocol, and (F) and (G) reflect conditions during the out-of-lab protocol. (D) Using a short plunger, the participant does not displace deep enough into the socket during stance phase to contact the top of the plunger and thus no distal weight bearing force is applied. (E) Using a medium plunger, the participant lightly contacts the plunger during stance phase. The resistance from the springs applies a very low distal weight bearing force imperceptible to the participant but readable by the pin sensor. (F) The long plunger length pushes up the locking pin such that resistance from the springs applies a force through the pin just as it transitions to the 6th pin notch, this participant's usual pin notch. The force is 0.1 mm × 38.4 N/mm = 3.8 N = 0.5% BW for a 73 kg (160 lb) person. Because the lock holds the pin at this position, no force is applied to the residual limb until weight bearing is ≥3.8 N. (G) The participant distal weight bearing during stance phase causes the pin to move down 1.50 mm from (F), applying an additional force of 1.50 mm×38.4 N/mm = 57.6 N, a total of 61.4 N (13.8 lb), corresponding to an 8.6% BW force for a 73 kg (160 lb) person.

compression of the springs is shown in Figures 1D–G. Plunger lengths ranging from 0.0 to 10.0 mm were tested in this study. The screw for adjustment was accessed through a hole in the bottom of the baseplate while the prosthesis was doffed. The initial design (Figure 1A) was used during an in-lab structured protocol described below.

A more compact design (Figure 1B) that eliminated the vertical adjustment screw and applied force directly to the plunger was used for out-of-lab tests. In this design, different plunger lengths were selected for each user so that the springs started to be compressed just above the transition to the lowest serration in the ratchet, i.e., the participant's deepest pin notch

(Figure 1F). Physically, during weight bearing at this plunger length, the plunger contacted the bottom of the pin, the springs further compressed (Figure 1G), and the pin displaced deeper into the pin sensor causing a change in the sensed pin height. Because the vertical adjustment screw was removed for the out-of-lab design, the height of the system was reduced from 77 mm to 42 mm. The out-of-lab pin sensor weighed 78.0 g, and the assembly underneath weighed 163 g, an overall reduction of 85.4 g from the initial design shown in Figure 1A. To calibrate the pin sensor, a bench test jig was used to position the pin at known heights above the sensor (Supplementary Presentation S1).

An in-lab study protocol was designed to collect data on transtibial prosthesis users at different plunger lengths and at different socket sizes. A motor-driven adjustable socket was used to set the socket size (Figure 1C). The test sockets were created for the study participants as part of a prior research investigation (7). The test sockets were equipped with three adjustable panels positioned at anterior medial, anterior lateral, and posterior mid-limb locations. Motors fastened to frames on the outside of the socket drove a screw-driven winch mechanism, moving the panels radially inward and outward. The winch was attached to a rod that passed through the back side of the panel, allowing the panel to rotate about an axis parallel to the socket surface in the transverse plane (Figure 1C). This design avoided panel protrusion into the residual limb at the top or bottom of the panel. No padding was necessary on the insides of the panels nor was a flexible inner socket needed. Panel radial motion was controlled via wireless commands sent from a phone app.

The test sockets were duplicate in shape to participants' regular sockets. To make the test sockets, we measured the shapes of participants' regular sockets using a high-resolution coordinate measurement machine (FARO Arm Platinum, Lake Mary, FL). Each socket was fabricated with six thin inductive sensor antennae placed within the socket wall. Sensors were positioned at anterior proximal, anterior mid-limb, anterior distal, posterior lateral mid-limb, posterior medial mid-limb, and posterior distal locations as shown in Supplementary Presentation S2, using methods detailed in prior work (9). The sensors measured the distance to a trace amount of iron powder placed in the elastomeric liner just under the fabric backing. The liners were purchased from a prosthetics manufacturer contracted to make the liners for research purposes (WillowWood, Mt. Sterling, OH). Participants wore the ferrous liner during both the in-lab and out-of-lab test sessions.

A standard 18.5-mm length locking pin with seven notches was used in all tests since this length ensured that the pin sensor data were within range. Notch 1 engaged the locking mechanism. At the highest pin notch during calibration, typically notch 7, the pin was at the minimum pin height, which was defined as the 0.00 mm pin height.

Bench tests were conducted to evaluate the spring constant of the four-spring support system. Three different sets of four springs were tested. Different spring stiffnesses were expected to be necessary to accommodate different participant weights to keep the pin within a proper displacement range during ambulation and maintain sufficient sensitivity. The pin sensor and four-spring support system was fastened to the base of a unidirectional testing machine (model 5944, Instron, Norwood, MA), and a controlled crosshead displacement was applied. The displacement rate was 3 mm/min, and both loading and unloading tests were conducted. The pin height was plotted against force, and the spring constant was determined using a least-squares fit to the data.

2.3. In-lab testing protocol

The purposes of the in-lab study were to evaluate if increasing socket size (using adjustable panels on the socket) introduced a measurable decrease in pin height and to identify the minimum plunger length at which distal weight bearing was introduced. Only pin sensor data and not limb-socket distance sensor data were collected.

Before the participant arrived, the liner to be worn was inserted and pushed into the bottom of the socket (no residual limb) to record the minimum possible pin height. The minimal possible pin height was at the deepest possible location of the pin at full insertion for the liner-socket combination being used. For all three participant sockets, at the minimum possible pin height the outer edge of the umbrella contacted a ledge on the side of the socket that prevented further downward displacement leaving an air gap (Figure 2A) between the bottom of the umbrella and the ledge made in the socket during fabrication to prevent excessive downward displacement of the liner. The diameter of the relatively stiff part of the umbrella on the bottom of the liner was measured using calipers so that later the distal weight bearing force measurement could be converted to distal tissue pressure. To determine the appropriate range of panel positions to test, each participant performed an initial walk where the panels were incrementally loosened in 0.20-mm radial increments using a phone app that controlled the motors (10, 11). The user's self-reported maximum acceptable socket size was identified. The panels were incrementally tightened, and the user's self-reported minimum acceptable socket size was identified. These two positions were designated as the loosest and tightest socket sizes, respectively. The midpoint between them was termed the midpoint size.

Participants performed four 8-min walks separated by approximately 4-min sits to change the plunger length (Figure 3). During each 8-min walk, the panels were initially positioned at their tightest setting. The panel position was changed at 2-min intervals to midpoint, loosest, and back to tightest. During each walk, participants were queried if the setting caused discomfort. This 8-min walk cycle was repeated four separate times with the plunger length at settings of 0.0 (lowest position), 3.5, 7.0, and 10.0 mm (highest position). The shortest plunger length at which the participant bore weight through the pin and engaged the springs (Figure 1F) was identified.

2.4. Out-of-lab take-home testing

During the out-of-lab take-home test, the more compact design of the spring pin system was used (Figure 1B), and both pin sensor

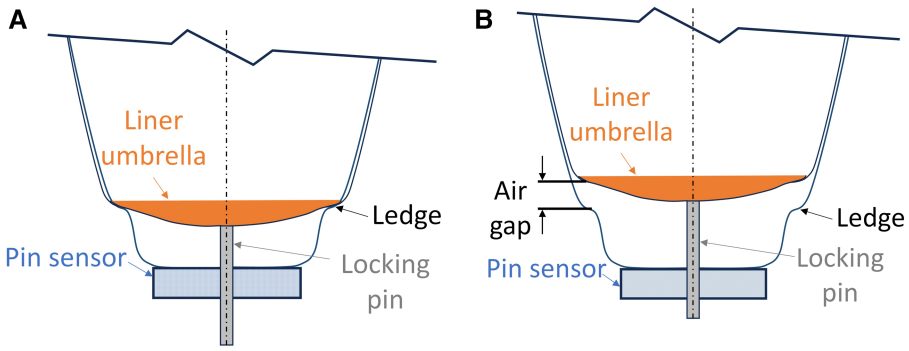

FIGURE 2
(A) Diagram showing the lowest possible pin height. The liner umbrella is at its lowest possible position. There is no air gap between the liner umbrella and the ledge. (B) Diagram showing an air gap between the liner umbrella and the ledge. The ledge is formed by the technician during socket fabrication to ensure that the liner does not move down excessively into the socket.

data and limb-socket distance sensor data were collected. Before the participant arrived, the liner to be worn was inserted and pushed deep into the socket (no residual limb) to determine the minimum possible pin height. The minimum possible pin height was used later in data presentation to provide a meaningful reference for clinical interpretation.

After arriving at the lab, the participant donned the test socket. The panels were kept at the neutral position, i.e., panels flush with the surrounding socket, for the duration of the protocol. The participant walked on the treadmill at a self-selected walking speed for 4 min to achieve a stable pin height during stance phase. This baseline pin height and knowledge of the participant's usual pin notch were used to calculate an appropriate plunger length. At the appropriate length, the plunger contacted the pin 0.1 mm before the pin entered the participant's usual pin notch. Once the pin was pushed into that notch and the ratchet locked into place, the slight pre-stress in the springs (38.4 N/mm × 0.1 mm = 3.84 N) ensured that at distal weight bearing forces greater than 3.84 N the pin provided a consistent rate of resistance (N/mm deflection) against the bottom of the residual limb.

The proper plunger length was installed in the spring pin system. The participant walked on the treadmill a second time to evaluate if the pin height data were within the sensor's measurement range (Corrections were not needed during any participant tests). The participant walked on streets and paved paths outside the lab for approximately 30 min to evaluate if further adjustment to the prosthesis was needed (not needed for any participant). Participants left the lab and wore the investigational prosthesis in their free-living environment for approximately one week (5–7 days). Data were collected to a portable data logger, similar to that described in prior work (12).

2.5. Data analysis

Pin sensor data collected from the in-lab and out-of-lab sessions were converted from raw signal counts to mm using the calibration data. To convert it to force (in N), the pin height data was zeroed to the pin height where the springs began to compress then multiplied by the spring constant to calculate force.

Trial	Walk 1				Walk 2				Walk 3				Walk 4			
Vert. Adj. Screw Setting	0.0 mm				3.5 mm				7.0 mm				10.0 mm			
Socket Size Setting	Tightest Socket Fit	Midpoint Socket Fit	Loosest Socket Fit	Tightest Socket Fit	Tightest Socket Fit	Midpoint Socket Fit	Loosest Socket Fit	Tightest Socket Fit	Tightest Socket Fit	Midpoint Socket Fit	Loosest Socket Fit	Tightest Socket Fit	Tightest Socket Fit	Midpoint Socket Fit	Loosest Socket Fit	Tightest Socket Fit

FIGURE 3
In-Lab testing protocol. Vertical adjustment (Vert. Adj.) screw setting changes were made in between the four 8-min walks while the socket was doffed. Socket size adjustments were made every 2 min while participants walked on the treadmill.

The out-of-lab data were segmented into prosthesis days using a strategy similar to that used in our prior work (12). A prosthesis day was defined as the first don longer than 30 min. If a don shorter than 30 min occurred less than 60 min before the start of the first don, then that don was considered the beginning of the prosthesis day. The end of the prosthesis day was defined as the start of a doff period longer than 60 min such that there were no donned periods longer than 30 min between this point and the start of the beginning of the next prosthesis day. Data within prosthesis days were classified as walks, shifts, stationary, partial doff, or full doff, using methods from prior work, summarized in **Supplementary Figure F1**. We calculated the time spent at each activity and expressed it as a percentage of the sum of all prosthesis day durations. Walks were further classified as bouts (≥5 steps) or low locomotion (<5 steps), and shifts were further classified as stand shifts or sit shifts. For both the in-lab and out-of-lab sessions, further analysis was carried out only on steps within walking bouts. The minimum pin height during stance phase and the maximum pin height during swing phase for each step were determined. They were termed the *stance phase minimum* and *swing phase maximum*, respectively. Means of the stance phase minima and swing phase maxima for each 2-min walk from the in-lab study and for all steps within bouts for the out-of-lab study were calculated. The surface area of the relatively stiff part of the umbrella on the bottom of the liner was calculated and used to approximate the pressure applied to the bottom of the residual limb. This calculation, termed the *tissue pressure* (in kPa), assumed that all force applied through the umbrella to the springs was evenly distributed over the bottom of the participant's residual limb.

For the out-of-lab sessions, data from the distance sensors embedded in the socket wall were converted from counts to mm using calibration data, and that data was thermally compensated to account for variations in socket temperature as described in prior work and summarized in **Supplementary Presentation S3**. For all steps within walking bouts, stance phase minima from the pin sensor were plotted against socket sensor stance phase minima to investigate relationships between the variables.

3. Results

3.1. Participants

Three participants executed the in-lab protocol (#1, #2, #3), and three executed the out-of-lab protocol (#1, #2, #4). All participants had their amputation as a result of trauma, were at a K-3 or K-4 level of activity, and traditionally wore a locking pin suspension system with a dynamic response foot. Participants were 36–76 years in age, and their amputee-adjusted body mass index (BMI) was between 24.7 and 34.7 kg/m^2. Participant and prosthesis characteristics are summarized in **Table 1**. The umbrella diameter for the investigational prosthesis was the same size as the participant's traditional liner for participant #1 (93.4 mm), larger for participant #2 (74.7 mm vs. 72.4 mm), and smaller for participant #3 (68.4 mm vs. 71.8 mm) and participant #4 (74.7 mm vs. 86.3 mm). The relatively stiff part of the umbrella was of diameter 70.0 mm for participant #1, 60.0 mm for participants #2 and #4, and 68.4 mm for participant #3.

3.2. Bench tests

The force-displacement data from mechanical testing of the spring assembly showed a linear response with minimal hysteresis (**Figure 4**). The spring constants for the in-lab system (**Figure 1A**) were 34.3, 62.7, and 121.4 N/mm for the three sets of springs tested. During the in-lab evaluations, the lowest stiffness springs were deemed the most appropriate for all three participants, achieving sufficient sensitivity to detect a meaningful signal while at the same time not bottoming out or causing participant discomfort. In the out-of-lab tests where the more compact system configuration was implemented (**Figure 1B**), the spring constant for all participants was 38.7 N/mm.

3.3. In-lab tests

While wearing the test prosthesis at the 0.0 mm plunger length, no participant reached the deepest possible pin height (indicated with a dashed orange line in **Figures 5A–C**). There was an air gap of between 0.3 mm and 3.2 mm between the umbrella and the bottom ledge of the socket (**Figure 2B**) at the 0.0 mm plunger length during stance phase for the in-lab tests.

For all three participants, at least one plunger length produced distal weight bearing (7.5 and 10.0 mm for participants #1 and #3; 10.0 mm for participant #2) (**Figures 5A–C**). The highest mean distal weight bearing during stance phase of a 2-min walk at the highest plunger length was 8.8% BW for participant #1, 5.8% BW for participant #2, and 9.3% BW for participant #3.

At plunger lengths that produced distal weight bearing, all three participants showed a decrease in pin height and an increase in percent weight bearing when the panels were loosened from the tightest to both the midpoint and loosest positions (**Figures 5A–C**). Participants showed an increase in pin height and a decrease in percent weight bearing when the panels

TABLE 1 Participant characteristics.

Partic	Gender	Age (year)	BMI (kg/m^2)	Time since Amp (year)	Smoker	*K*-Level	Limb shape
1	M	59	33.0	32	Never	4	Cylindrical, short, fleshy
2	M	62	24.7	38	Never	4	Conical, medium, bony
3	M	36	34.7	16	Yes	4	Cylindrical, medium, muscular
4	M	76	27.3	48	Yes, 46 years ago	3	Conical, short, bony

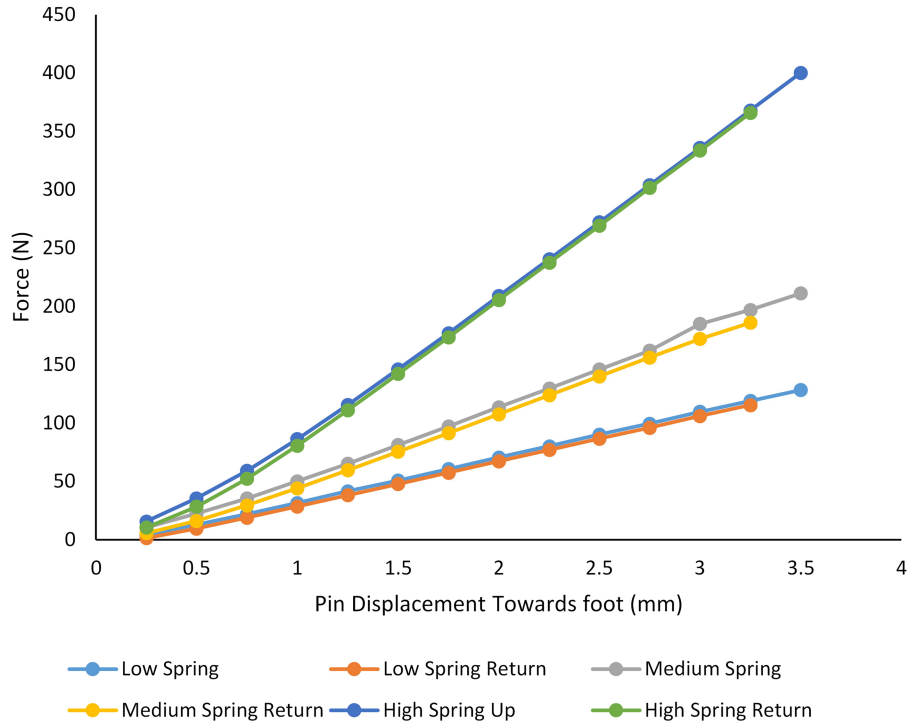

FIGURE 4
Bench test results. A testing machine was used to compression test the three different sets of springs. Stiffnesses of 34.3, 62.7, and 121.4 N/mm were measured. The lowest stiffness set of springs (red and blue lines) was used for all participants.

were tightened from the loosest to the tightest position. Participant #1 made an unsolicited comment during the in-lab tests that his socket was more comfortable when he was distal weight bearing.

At plunger lengths that produced distal weight bearing (7.0 and/or 10.0 mm depending on the participant), the coefficient of variation in pin height (standard deviation divided by the mean) during walking was higher for the stance phase minima than the swing phase maxima for each participant. The maximum coefficient of variation in the stance phase minima at a socket panel position was 2.8%, 2.4%, and 1.0% for participants #1, #2, and #3, respectively, and those for the swing phase maxima were <0.2% for all three participants.

For the trials where the springs were compressed, the calculated tissue pressures on the bottom of the residual limb during stance phase ranged up to 22.4 kPa for participant #1, 16.3 kPa for participant #2, and 27.4 kPa for participant #3 (**Figure 6**). Distal pressure increased as the panels were loosened for participant #1 and #2, while participant #3 had relatively consistent distal pressure across different panel positions.

Participants #1 and #2 did not reach their deepest pin notch in some of the 2-min walks. Participant #1 reached only the second deepest pin notch (notch 5) during the first two walks at the 0.0 mm plunger length but not the other two walks, and during all four walks at the 10.0 mm plunger length. Participant #2 reached only the second deepest notch (notch 5) during the first walk at the 3.5 mm plunger length, but in all other walks he reached the deepest pin notch (notch 6).

3.4. Out-of-lab take-home tests

Participants #1, #2, and #4 spent 32%, 45%, and 46%, respectively, of their sum prosthesis day time conducting walks and shifts (**Figures 7A–C**). Participant #1 spent 32% of his time partially or fully doffed, while participants #2 and #4 spent only 2% and 7%, respectively, of their time partially or fully doffed.

The mean stance phase minimum was 2.5 mm for participant #1, 9.4 mm for participant #2, and 2.4 mm for participant #3 (**Table 2**). Participant #2's pin height was higher during the out-of-lab test compared with the in-lab test; he was at pin notch 4 instead of notch 6 during the out-of-lab test. The air gap during stance phase during the out-of-lab tests was 1.5–3.1 mm for participant #1; 7.3–9.7 mm for participant #2; and 1.0–3.2 mm for participant #4. The coefficient of variation (standard deviation divided by the mean) for stance phase minimum pin height was 10.4% for participant #1, 0.7% for participant #2, and 16.9% for participant #4, while the coefficient of variation for swing phase maximum pin height was less, 2.3%, 0.4%, and 3.3% for participants #1, #2, and #4, respectively.

For all participants during the out-of-lab tests, the mean stance phase weight bearing force delivered to the bottom of the residual limb was under 5.0% BW (range 1.1% to 6.4%), and the mean of the maximum tissue pressure delivered was 12.8 kPa or less (right column, **Table 2**). The coefficient of variation in distal weight bearing and tissue pressure was higher than that for pin height because the zero reference for the pin height was at the

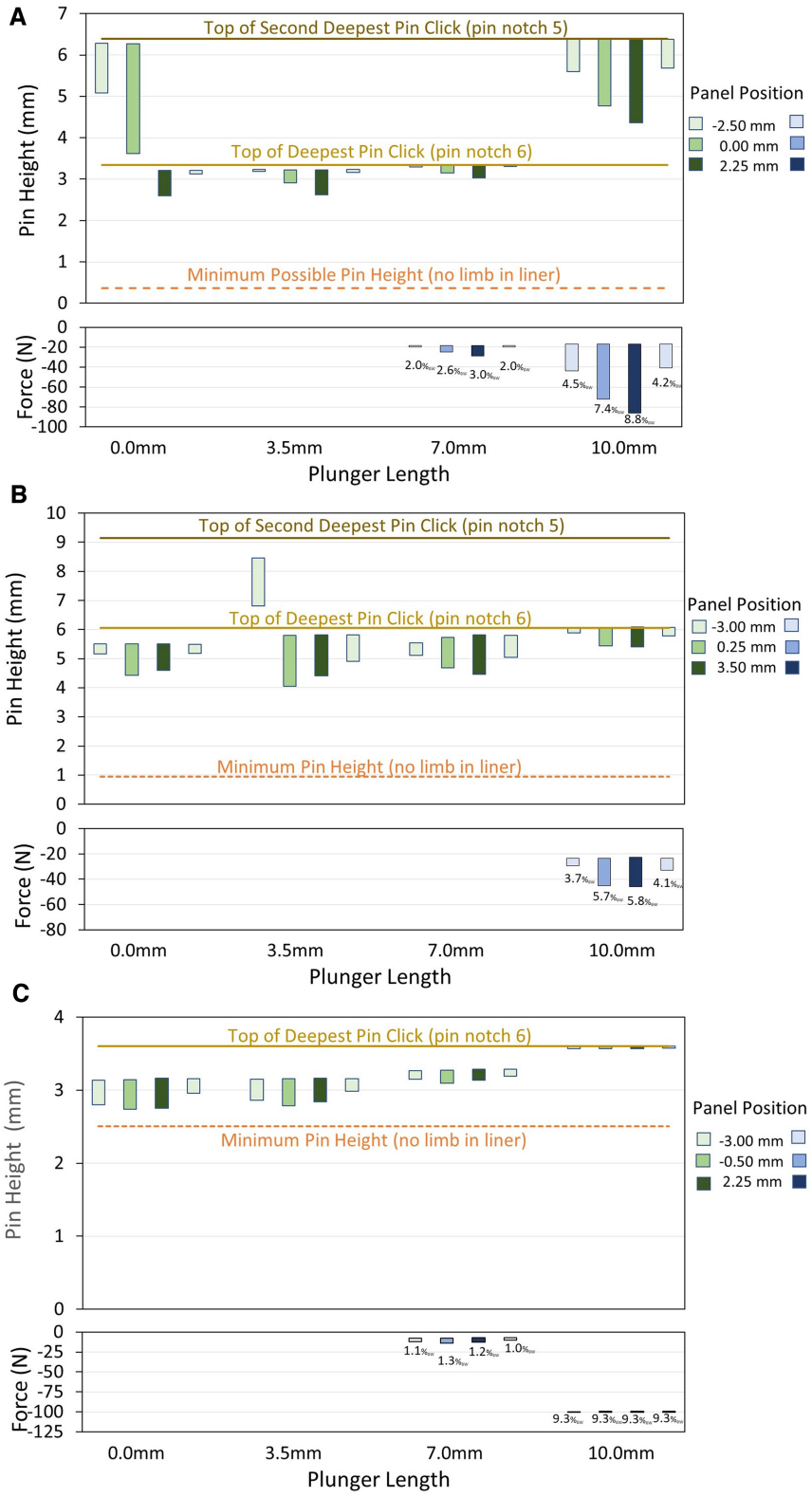

FIGURE 5
(A–C) in-lab test results. Data for participant #1 (A), #2 (B), and #3 (C) are shown. The upper plots are pin height in mm, and the lower plots are distal weight bearing in *N*. In the pin height plots, the bar plots span the range from the mean minimum to the mean maximum pin height for all steps within the 2-min walk. The transitions between pin notches are shown as solid yellow horizontal lines. The minimum possible pin height (dashed orange horizontal line) is the maximum depth of the liner umbrella in the socket without the residual limb in the liner. In the distal weight bearing plots, the mean percent body weight (% BW) during stance phase is printed underneath the bar for each 2-min walk. Once the plunger length was high enough for the pin to contact the plunger and apply force to the springs during stance phase, participants showed a decrease in pin height and an increase in percent weight bearing when the panels were loosened from the tightest to both the midpoint and loosest positions, and they showed an increase in pin height and a decrease in percent weight bearing when the panels were tightened from the loosest to the tightest position.

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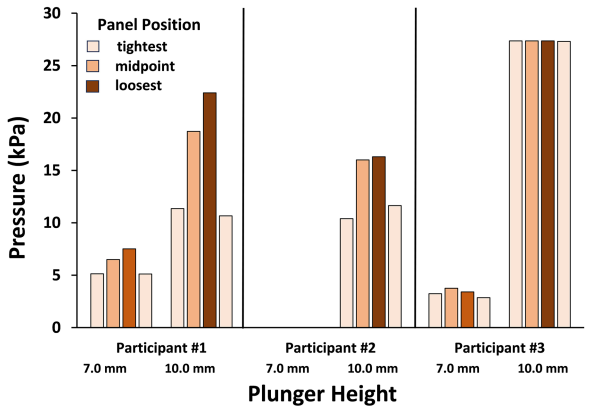

FIGURE 6
Pressures on the distal residual limb during the in-lab test. It is assumed that the applied force was evenly distributed over the umbrella surface. Data for the 7.0 and 10.0 mm plunger lengths are shown for the three participants. Participant #3 at the 10.0 mm plunger length demonstrated relatively consistent pressure compared to participants #1 and #2 presumably because the difference between the swing phase maximum and stance phase minimum was low, and the force applied to the shuttle lock to hold the pin at the deepest notch was relatively high.

top of the pin lock while that for weight bearing and tissue pressure was the pin height at which the springs began to compress. The coefficient of variation for stance phase percent distal weight bearing and tissue pressure was 37% for participants #1, 25% for participant #2, and 43% for participant #4. In many of the steps during swing phase for participants #1 and #4, the pin was at the top of the displacement range, i.e., the notch was against the ratchet, which restricted further proximal motion of the pin (dashed blue line in Figures 8A–C).

Pin pistoning (maximum—minimum pin height) during all walking bout steps was a mean of 0.6 mm for participant #1, 0.1 mm for participant #2, and 0.8 mm for participant #4. The histograms of pistoning distance for all days combined were normally distributed for participant #1, right skewed for participant #2, and bimodal for participant #4 (Figures 9A–C). Histogram data separated by day were relatively normally distributed for participant #1, right-skewed for participant #2, and bimodal on 4 of the 7 days for participant #4 (Supplementary Figure F2), consistent with the all walking steps plots in Figures 9A–C.

Pin height plotted against sensed distance for the six sensors positioned in the socket wall did not show strong linear relationships (Supplementary Figure F3). Higher pin heights tended to show higher sensed distances for some of the days and locations (e.g., Supplementary Figure F3A, anterior distal) but on other days and locations the plots were relatively flat (e.g., Supplementary Figure F3C, posterior mid-limb lateral). The upper edge of the pin notch was visible in data from some days (e.g., as a boundary at 9.6 mm pin height in Supplementary Figure F3B). Many days showed clusters of data (e.g., Supplementary Figure F3A, posterior mid-limb medial), indicating groups of steps at different sensed distances or at different pin heights. The range of pin heights across a day was lowest for participant #2 and highest for participants #1 and #4. Participant #4 noted that he felt less pistoning than normal during the take-home part of the out-of-lab test.

4. Discussion

The developed instrument has the potential to help researchers and practitioners better understand how prosthesis design variables and participant characteristics affect limb motion and distal weight bearing in people using locking pin suspension. Monitored data may prove useful in clinical care. Potentially, the signal could be part of a feedback control system for an auto-adjusting socket to maintain a certain distal weight bearing level that improved outcome. Results from the present study on a small group of participants demonstrated that the instrumentation measured distal weight bearing with good sensitivity and the magnitude of distal weight bearing could be controlled via adjustment of the plunger length in the mechanism that supported the locking pin.

Changes in limb fluid volume during the in-lab protocols may explain why participants #1 and #2 were at different pin notch settings during some of the 2-min walks at the 0.0 mm and 3.5 mm plunger lengths (Figures 5A,B). Studies on people with

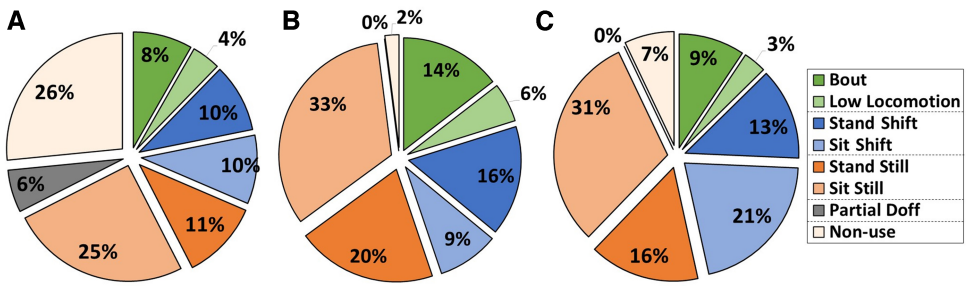

FIGURE 7
(A–C) participant activity during take-home testing. Data for participant #1 (A), #2 (B), and #4 (C) are shown. Data are presented as a percentage of the sum of the prosthesis day duration. Participants spent 32%–46% of their prosthesis day duration conducting walks and shifts (blue and green sections) but varied considerably as to their distributions among the activities.

TABLE 2 Out-of-lab data.

Partic.	Variable	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	All steps
#1	Min depth (mm)	2.3 (0.3)	2.4 (0.2)	2.4 (0.2)	2.6 (0.2)	2.8 (0.1)						2.5 (0.3)
	Max force (*N*)	−31.3 (10.5)	−30.6 (8.8)	−30.4 (7.9)	−21.5 (8.0)	−13.2 (4.6)						−26.9 (9.9)
	Max DWB (%BW)	3.2 (1.1)	3.1 (0.9)	3.1 (0.8)	2.2 (0.8)	1.4 (0.5)						2.7 (1.0)
	Max tiss Pr (kPa)	8.1 (2.7)	8.0 (2.3)	7.9 (2.1)	5.6 (2.1)	3.4 (1.2)						7.0 (2.6)
#2	Min depth (mm)	9.5 (0.03)	9.4 (0.08)	9.4 (0.05)	9.4 (0.05)	9.5 (0.03)	9.5 (0.03)	9.5 (0.03)	9.5 (0.02)	9.4 (0.04)	9.5 (0.05)	9.4 (0.06)
	Max force (*N*)	−9.0 (1.2)	−12.0 (3.3)	−11.0 (1.8)	−10.3 (1.8)	−8.9 (1.2)	−8.4 (1.0)	−8.6 (1.3)	−8.9 (1.0)	−10.0 (1.4)	−9.1 (1.9)	−10.1 (2.4)
	Max DWB (%BW)	1.1 (0.1)	1.5 (0.4)	1.4 (0.2)	1.3 (0.2)	1.1 (0.2)	1.1 (0.1)	1.1 (0.2)	1.1 (0.1)	1.3 (0.2)	1.1 (0.2)	1.2 (0.3)
	Max tiss Pr (kPa)	3.2 (0.4)	4.3 (1.2)	3.9 (0.6)	3.6 (0.6)	3.2 (0.4)	3.0 (0.4)	3.1 (0.5)	3.2 (0.3)	3.5 (0.5)	3.2 (0.7)	3.6 (0.9)
#4	Min depth (mm)	1.9 (0.3)	2.4 (0.4)	2.4 (0.4)	2.6 (0.3)	2.2 (0.2)	2.5 (0.4)	2.3 (0.3)				2.4 (0.4)
	Max force (*N*)	−55.6 (12.6)	−35.9 (15.4)	−34.2 (14.4)	−28.6 (10.8)	−42.5 (9.2)	−30.5 (14.3)	−36.5 (11.7)				−36.1 (15.5)
	Max DWB (%BW)	6.4 (1.5)	4.2 (1.8)	4.0 (1.7)	3.3 (1.2)	4.9 (1.1)	3.5 (1.7)	4.2 (1.4)				4.2 (1.8)
	Max tiss Pr (kPa)	19.7 (4.5)	12.7 (5.4)	12.1 (5.1)	10.1 (3.8)	15.0 (3.3)	10.8 (5.1)	12.9 (4.1)				12.8 (5.4)

Mean (SD) stance phase results for each day and for all steps.

transtibial amputation have typically shown a gradual decrease in limb fluid volume during ambulation right after donning (13). The range in pin height [swing phase maximum minus stance phase minimum (length of the green bars in **Figures 5A–C**)], decreased when participants transitioned to the next deeper serration in the ratchet (pin notch). Once participants transitioned to a deeper notch, the top of their range was lower in the socket, restricting pin proximal displacement during swing phase.

Results from the in-lab tests (**Figures 5A–C**) demonstrated that adjusting the plunger length had the expected effect on the pin height and distal weight bearing measurements. At high plunger lengths (7.0 and 10.0 mm for participants 1 and 3; 10.0 mm for participant #2) the springs compressed, and load bearing on the distal end of the residual limb occurred. For each participant, the pin positions for the 7.0 mm plunger length were higher than those for the 3.5 mm plunger length, and the pin positions for the 10.0 mm plunger length were higher than those for the 7.0 mm plunger length. Participant #1 was pushed up a pin notch (to pin notch 5) at the 10.0 mm plunger length. The force applied through the springs to the bottom of the residual limb at the 10.0 mm plunger length varied considerably across participants, in part reflecting their BMI. The force was 41.0–86.2 N (4.2–8.9% BW) for participant #1 (33.0 kg/m^2 BMI), 29.4–46.1 N (3.0–4.7% BW) for participant #2 (24.7 kg/m^2), and 100.3–100.5 N (10.3–10.3% BW) for participant #3 (34.7 kg/m^2). Participant #3's range was less than the other two participants, presumably because his stance phase minima was just under the pin position transition to the next serration in the rastered pin (notch 6) (**Figure 5C**). The compressive force applied to the pin to transition to notch 6 and for the shuttle lock to hold it there, was relatively high. The umbrella for participant #3's investigational prosthesis, unlike that for participant #1 and #2, was slightly smaller than the umbrella in his traditional socket, which may have contributed to his elevated distal weight bearing.

If a researcher or prosthetist sought to use this system to monitor distal weight bearing with minimal disruption compared to the participants' regular socket, then setting the start of the spring resistive force just above the lowest pin notch the user experiences during regular use may be appropriate, as performed in the out-of-lab tests in this study. Using a lower spring stiffness would further reduce the applied distal weight bearing force though with an increased risk of bottoming out the springs in the mechanism. If it were of interest to increase distal weight bearing to investigate its potential benefit towards participant well-being, enhancing blood flow via a pumping effect on distal limb tissue for example (1), then the spring resistive force should be started at a high plunger length, essentially shortening the socket, or spring stiffness should be increased.

The day-to-day differences in stance phase distal weight bearing measured in the take-home part of the out-of-lab study were well within the range of the sensor's measurement capabilities. The day-to-day fluctuation in pin position could have been due to day-to-day changes in several variables including limb fluid volume, sock thickness, the type of activity conducted, or some other variable. All distal weight bearing forces measured in the out-of-lab study (daily means ranged from 1.1 to 6.4% BW) and their standard deviations were relatively low (**Table 2**). Because they were so much less than the threshold pain tolerance for people with transtibial amputation reported in the literature [13%–48% of maximum vertical ground reaction force for Katz et al. (3); 17.2% BW (SD 13.1) for Persson and Liedberg (4)], it is unlikely participants would find the system at these plunger lengths painful or disruptive. No complaints were reported during take-home use. Participant #4, however, did report that he experienced less pistoning than with his normal prosthesis during take-home use which he found favorable. This may have been because the distal contact helped reduce motion of the limb in the socket in the sagittal plane. It is also possible that low level distal weight bearing improved proprioception. These conclusions are conjecture and would need to be tested through rigorous scientific investigation.

When we calculated distal limb pressure by assuming the distal limb force was evenly distributed over the relatively stiff bottom part of the participant's liner umbrella, mean tissue pressures were up to 27.4 kPa for the in-lab study and up to 12.8 kPa for

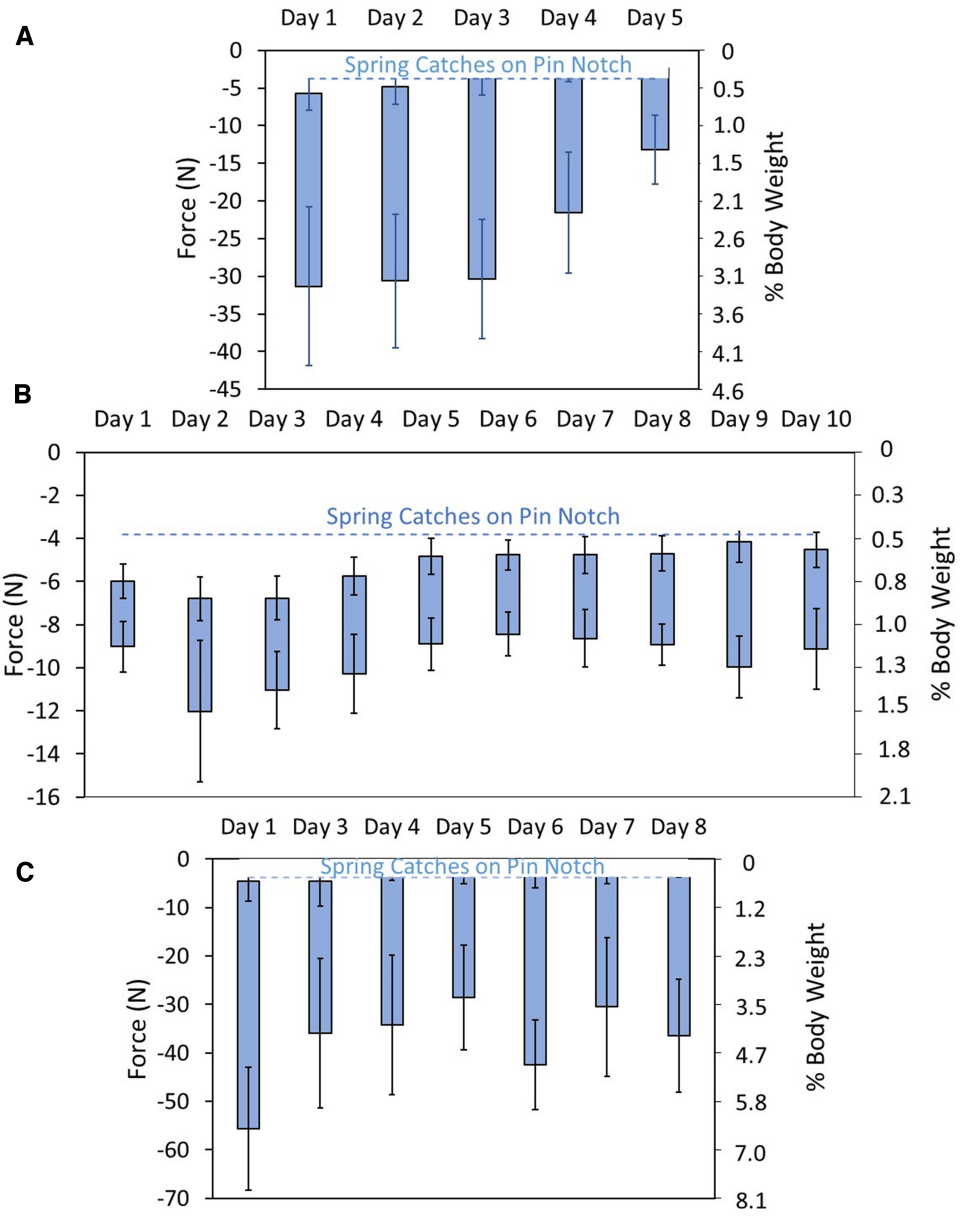

FIGURE 8
(A–C) distal weight bearing during take-home testing. Data are shown in units of force (*N*) (left axis) and % BW (right axis). The dashed blue line is the pin height at which the pin transitioned to the participants' deepest notch. The coefficient of variation for stance phase percent distal weight bearing and tissue pressure was 37% for participants #1 (A), 25% for participant #2 (B), and 43% for participant #4 (C).

the out-of-lab study. The reason that pressures were higher for in-lab than out-of-lab is that the plunger lengths were higher (trials 3 and 4), essentially shortening the length of the socket more than for the out-of-lab test. In circulatory studies conducted in 12 able-bodied participants (no co-morbidities) over the anterior lateral proximal aspect of the tibia, Sangeorzan et al. (14) found that a mean pressure of 9.5 kPa was sufficient to occlude blood flow in the skin. It is thus possible that blood flow was occluded during the stance phase of some steps in the take-home participants. However, pressures that intermittently occlude blood flow (e.g., during stance phase within a step) may be acceptable and even favorable provided the blood vessels re-open and the tissue re-perfuses during swing phase, and reactive hyperemia is not induced. This interpretation is conjecture and the clinical impact of intentionally increasing intermittent distal weight bearing would need to be thoroughly studied before it is implemented in clinical care.

The coefficient of variation in stance phase minima in the walking bouts during the out-of-lab tests (10.4%, 0.7%, and 16.9%, respectively) was considerably greater than that in the 2-min bouts during the in-lab tests (<3.0% for all participants). This difference likely reflects changes in walking style, speed, terrain, direction of ambulation, and bout duration in participants' take-home environments compared with the treadmill walking in the lab.

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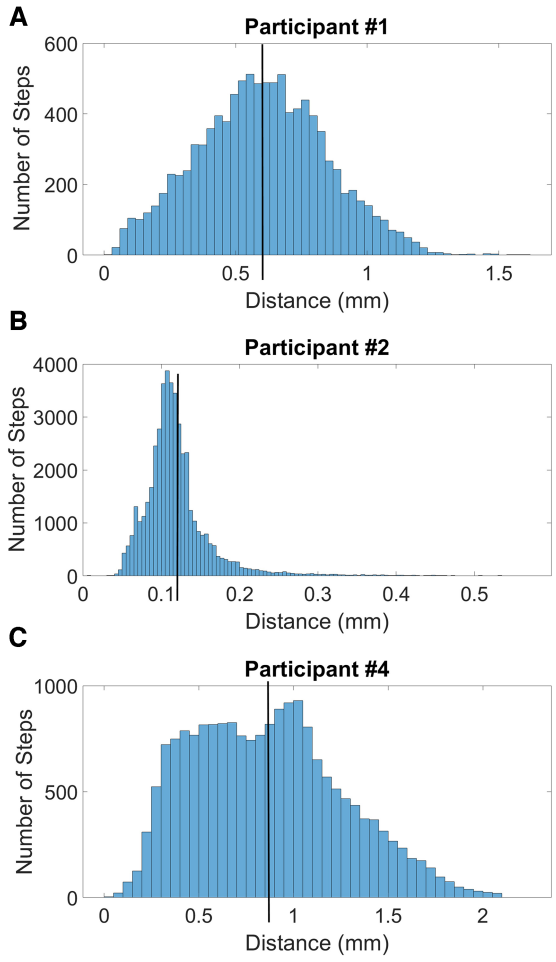

FIGURE 9
(A–C) histograms of swing phase maximum minus stance phase minimum during all steps during take-home testing. The black vertical lines indicate the mean pistoning magnitudes for all steps. The histogram for participant #1 (A) is relatively normally distributed, participant #2 (B) is right-skewed, and participant #4 (C) is bimodal.

Changes in limb fluid volume may also have contributed. Repeatability tests measuring pylon force data in the laboratory have shown considerable variability, leading Zahedi et al. to suggest that field-collected data variability should be evaluated and that information considered in clinical decision making (15). Similar to Zahedi et al. (15), we conclude that pin height and distal weight bearing data may be useful in clinical care. Investigations are needed to quantify and rank the sources of within-day and between-day variability in field-collected force data (16). Achieving that understanding would facilitate determining how to use field-collected data to improve patient outcome.

To be capable of distal weight bearing adjustment during clinical use, the mechanical design of the device would need to be advanced, e.g., an adjustable knob placed on the outside of the device or a wireless device such as a fob or phone app. Potentially, an automated system could be created to adjust the plunger length based on the distal weight bearing measurement, keeping it within a certain percentage body weight range specified by the prosthetist.

At the time of Katz et al.'s (3) and Persson and Liedberg's (4) studies, before elastomeric liners and locking pin suspension were commonly used in clinical practice, practitioners considered some distal weight bearing necessary to reduce edema in the distal residual limb (1). The cyclic distal loading during walking was intended to have a pumping effect on the distal limb, driving out edematous fluid. Elastomeric liners, however, which are nowadays commonly used in clinical practice, introduce an additional strategy to help limit edema in distal limb tissues—radial compressive stress is applied via the elastic properties of the liner polymer. Implementation of edema management using elastomeric liners may have discouraged practitioners from designing sockets to meaningfully cyclically load the distal end of the residual limb. However, in clinical practice sockets are designed to achieve at least some distal weight bearing. It is unknown if no distal weight bearing using locking-pin elastomeric liners, is less favorable to residual limb tissue health than some cyclic distal weight bearing, i.e., cyclic pumping, during ambulation. It is also unknown to what degree no distal weight bearing occurs in clinical practice.

The air gap, the vertical distance between the umbrella and the ledge near the bottom of the socket (**Figure 2B**), may allow the distal end of the residual limb to translate anterior-posterior, particularly if proximal residual limb enlargement is the source of the air gap. During the present investigation, two of the four participants made unsolicited comments that the socket was more comfortable with distal weight bearing than without it. It is possible that load applied to the bottom of the residual limb reduced distal limb sagittal plane motion and thus reduced local stresses over the anterior distal tibia. In other words, contact with the bottom of the socket may have stabilized the distal residual limb. It is also possible that some cyclic distal weight bearing facilitated blood flow in distal residual limb tissues, improving tissue oxygenation, proprioception, and participant comfort. These possibilities are conjectures and would need to be tested through rigorous scientific investigation.

A next step to bring this technology closer to everyday clinical use is to develop a clinical fitting procedure to determine target values and ranges for distal weight bearing. In preliminary efforts conducted since completing this study, we found that participants with protective sensation were able to discern a 0.50-mm change in plunger length, corresponding to a 19.2 N change in force and a 2.7% BW change for a 72 kg (160 lb) participant. Thus, we propose that 0.50-mm increments, using 38.7 N/mm stiffness springs, should be used in initial studies to develop clinical fitting procedures.

There was not a strong linear relationship between sensed liner-socket distance and pin height (**Supplementary Figure F3**), suggesting that variables other than limb vertical position affected their relationship. Variables that may have changed during the day and interacted with each other include residual limb volume, thickness of socks worn, activities conducted, tissue mechanical property changes, and friction between the limb and liner or between the liner and socket, to name a few. It would be interesting to determine what caused some of the data to cluster

at different sensed distances and pin heights during take-home testing (**Supplementary Figure F3**).

A limitation of the spring pin system used in this investigation is that the weight of the system may have affected how participants used the test prosthesis. The added weight (326.4 g for the in-lab system (**Figure 1A**), and 241.0 g for the out-of-lab system (**Figure 1B**) was comparable to an electronic elevated vacuum system. The short-term nature of the investigation and the limited number of participants tested limit generalized application of the study results, but they do provide a base from which to design larger clinical studies.

5. Conclusion

The developed instrument had sufficient resolution to pick up detailed information about distal weight bearing in the present investigation, for example detecting changes in distal weight bearing when socket size was adjusted as well as sensing day-to-day fluctuations. The degree of distal weight bearing was adjustable, and some participants preferred greater distal weight bearing than that in their traditional socket. Future studies should investigate sources of variability in take-home test data and its relevance to patient outcomes. A clinical fitting procedure to establish target values and ranges should be pursued.

Data availability statement

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by the University of Washington Human Subjects Division. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

AK: Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation, Visualization, Writing – review & editing. MW: Investigation, Methodology, Writing – review & editing. JM: Data curation, Formal analysis, Software, Validation, Visualization, Writing – review & editing. KA: Formal analysis, Investigation, Methodology, Writing – review & editing. BL: Conceptualization, Funding acquisition, Investigation, Methodology, Writing – review & editing. NM: Software, Visualization, Writing – review & editing. JG: Conceptualization, Formal analysis, Funding acquisition, Writing – review & editing. JS: Conceptualization, Formal analysis, Funding acquisition, Project administration, Writing – original draft, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article.

This research was supported by the National Institute of Child Health and Human Development, National Center for Medical Rehabilitation Research of the National Institutes of Health under award number R01HD060585. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fresc.2023.1322202/full#supplementary-material

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frontiers | Frontiers in Health Services

TYPE Policy and Practice Reviews
PUBLISHED 21 December 2023
DOI 10.3389/frhs.2023.1213752

OPEN ACCESS

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RECEIVED 16 June 2023
ACCEPTED 04 December 2023
PUBLISHED 21 December 2023

CITATION
Jones H, Chadwell A and Dyson M (2023) Evidencing the effectiveness of upper limb prostheses: a multi-stakeholder perspective on study requirements.
Front. Health Serv. 3:1213752.
doi: 10.3389/frhs.2023.1213752

Evidencing the effectiveness of upper limb prostheses: a multi-stakeholder perspective on study requirements

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The provision of upper limb prosthetic devices through the National Health Services (NHS) within the United Kingdom is driven by national policies. NHS England have recently published a new policy to provide multi-grip myoelectric hands. The policy highlighted that there was limited evidence to support its deployment and it will be reviewed should new information arise. The clear identification of the evidence gap provides an opportunity for the academic research community to conduct studies that will inform future iterations of this and other upper limb prosthetic related policies. This paper presents a summary of findings and recommendations based on two multi-stakeholder workshops held in June 2022 and July 2022, which explored the design requirements for policy-driven research studies. The workshops involved people from a broad range of stakeholder groups: policy, academia, NHS clinical and management, industry, and a person with upper limb absence. The workshop discussions focused on the research questions that NHS England identified in the policy evidence review: (1) Clinical Effectiveness; (2) Cost Effectiveness; (3) Safety; and (4) Patient Subgroups. The recommendations based on stakeholder discussions included the need to gather qualitative and quantitative research evidence, use goal-based outcome measures, and conduct longitudinal studies. Future research studies also need to address the complexities of conducting national and international policy-driven research, such as clinical resource capacity and participant involvement.

KEYWORDS
upper limb prosthetics, policy, stakeholder engagement, outcome measures, quality of life

1. Introduction

Upper limb prosthetic policy in England is in a state of transition. For many years, the most advanced prosthetic hands available on the National Health Service (NHS) were limited to opening and closing in a pinch grip controlled by signals generated from a person's muscles, named as standard myoelectric. In September 2022, following an evidence review and needs assessment undertaken at a national level, NHS-England made the decision to routinely provide patients across England with more advanced prostheses called multi-grip myoelectric hands (1). This process of reviewing the needs, planning and prioritising funding, and subsequently monitoring and reviewing the clinical service, is known within the NHS as the commissioning process (2). During the commissioning

process, the NHS Specialised Services Clinical Panel who review the documents, highlighted that, there is currently limited evidence on the clinical and cost effectiveness of multi-grip myoelectric hands, but that the policy proposition would address a gap in equity (3). The decision was therefore made to change the stance across the NHS to make multi-grip myoelectric hands routinely available. However, the Clinical Commissioning Policy stated that a review of the policy will be conducted when new information is received indicating that the policy requires revision (1). The associated Evidence Review states: "Further research, preferably involving the randomisation of participants to different groups, is required to further understand the clinical effectiveness, safety and cost effectiveness of myoelectric multi-grip prosthetics compared to standard prosthetics" (4). This current state-of-play presents a pertinent opportunity for the research community to design, develop, and conduct studies that aim to better inform this and other future upper limb prosthetics policies. This paper summarises findings from a consensus-based process aimed at improving the design of research studies, which, we believe is a first step towards addressing this evidence gap.

This consensus-based process aims to minimise long-term research costs and improve the quality of the research studies. Upper limb prosthesis provision is complex, the patient population is heterogenous, and rehabilitation goals vary by person. As such, a strong evidence-base involving the randomisation of participants would require large-scale research studies to be undertaken, however, due to the population size, access to a significant participant pool has historically been difficult. Studies often include small numbers of participants local to a research institution and vary widely in their approaches to evaluation. Furthermore, the provision of upper limb prostheses is costly, which also impacts upon the cost of running research studies that use advanced devices such as multi-grip myoelectric hands. It is therefore critical to gain a consensus on the study designs that would be suitable to generate the evidence required by policymakers and device funders prior to running studies.

This paper presents a summary of discussions from two multi-stakeholder workshops that highlighted areas of consideration when designing research studies to inform upper limb prostheses policies. The discussions were broadly based on the research questions that NHS England identified in the policy evidence review: (1) Clinical Effectiveness; (2) Cost Effectiveness; (3) Safety; and (4) Patient Subgroups (4).

2. Workshop design

Two multi-stakeholder workshops were held; one online in June 2022 and one in-person in July 2022, which had 14 and 24 people in attendance, respectively. Each workshop was held over the course of one day: online 5.5 h, in-person 6 h (the agendas are available in **Supplementary Material A**). The online workshop had shorter topic discussions to minimise fatigue during online interaction.

The recruitment for the workshops was conducted online via e-mail invitations to the steering group's professional networks (for example, through the International Society of Prosthetics and Orthotics UK), and advertisement with a workshop flyer on Twitter. The project steering group includes members from upper-limb prosthetics academic research groups across the UK and Ireland, policymakers, and leading charitable and professional organisations. Pre-read material was sent to all participants prior to the workshops, which outlined background information about current methods of measuring clinical effectiveness of upper limb prostheses. This material was sent to provide an opportunity for participants to become familiar with the terms of reference that would be used within the workshops.

The workshops involved adults (18 years or older) from the UK and Ireland: people with experience of policy, academia, NHS clinical and management, upper limb absence, and industry (**Table 1**), one of whom had lived experience of upper-limb absence and prosthesis use; please note that some attendees fell into multiple stakeholder groups. Workshop attendees were pre-allocated into groups that, where possible, had representation from each stakeholder group to enable a range of perspective to be discussed. The online workshop had 3 groups and the in-person workshop had 4 groups.

The discussions at each workshop were facilitated by trained facilitators. The discussions were captured on post-it notes by both the attendees and the facilitators. During the online workshop each author took part in a different group and during the in-person workshop, two authors were facilitators, whilst the third moved between groups listening to an overview of the discussions across the room. This approach ensured that all the authors had a depth of knowledge of the content that was captured during both workshops to inform the analysis. Information captured from the online workshop discussions was documented on a digital whiteboard (**Supplementary Material B**). Information captured from the in-person workshop discussions were documented on paper-based worksheets (**Supplementary Material C**). Photographs of workshop content were captured to assist the analysis. Neither workshop was audio or video recorded.

The analysis of findings from both workshops was conducted by the authors based on a thematic approach (5) to identify main discussion areas and recommendations. Authors agreed on the thematic approach and each author independently analysed the findings within the agreed framework. Authors shared the analysis between themselves and identified common discussion areas and recommendations. The analysis was discussed collectively and reviewed based on the workshop findings. Authors addressed their own biases throughout this process by sharing findings with the wider project steering group, providing an opportunity for critique and discussion.

TABLE 1 Workshops 1 and 2 participant stakeholder groups.

Stakeholder group	Number of participants
People with upper limb absence	1
Policy	2
Academia	14
NHS Clinical and Management	22
Industry	2

2.1. Workshop topics

The workshop discussion topics were designed by the authors with the support of 5 senior academics from other UK and Ireland universities who were involved in the wider project steering group. The starting point of identifying the workshop topics began with the research questions from the NHS England evidence review (4), which explore multi-grip myoelectric hands through the lens of: (1) Clinical Effectiveness; (2) Safety; (3) Cost Effectiveness; and (4) Patient Subgroups. The evidence review (4) also separates clinical effectiveness into critical and important outcomes. Under critical, they include functional outcome measures, activities of daily living, and quality of life; under important, they list prosthetic abandonment, patient satisfaction, prosthetic acceptability, device durability and frequency of replacement and/or re-fitting.

The authors and members of the steering group agreed that the research expertise in the UK and Ireland was likely to lean towards the assessment of Clinical Effectiveness, therefore this topic was given a higher time weighting in the workshops. It was also agreed that to effectively cover the critical outcomes, Clinical Effectiveness should be split into two sub-topics: (1) function and (2) lived experience (which encompasses topics such as quality of life). Safety, Cost Effectiveness and Patient Subgroups were also used as discussion topics within the workshops. In addition to the questions posed by NHS England, the lack of participant and clinician engagement with upper limb prosthetics research have been identified as hurdles to the success of policy-driven research studies. We therefore also asked the workshop participants to discuss methods of engaging people with these types of research studies.

2.2. Workshop questions

All groups were asked the same questions for each topic at both workshops (**Supplementary Material B** and **C**).

Clinical Effectiveness was the first topic at both workshops, where participants were asked to discuss how function and lived experience might be assessed to inform policy. Prompt questions for functional assessment included what outcome measures work, what does not work, what needs validation and what needs improvement? Prompt questions for lived experience assessment were around the challenges to the way lived experience is currently assessed. Both function and lived experience discussions within the Clinical Effectiveness topic included questions on identifying gaps and opportunities for assessment.

The second topic of the workshops explored which Patient Subgroups should be considered for research studies. In addition, to help guide the study designs, this session brought in a broader conversation around Patient Involvement and Engagement in research studies. The participants focused on aspects such as challenges and incentives, as well as how and where people could find out about getting involved in studies. This discussion topic also explored the importance of having clinical collaboration and input into research studies and what challenges currently exist in terms of the practicalities, such as resource capacity and time constraints.

The third and fourth topics of the workshops addressed the questions around Cost Effectiveness and Safety collectively. These were combined due to time constraints and an awareness that many aspects of these two areas of discussion were likely to be addressed at a manufacturer level rather than through the research studies which were to be designed as an outcome of this work. Prompts included: how is Cost Effectiveness evaluated; patient safety; patient comfort; risk of harm; and the regulation process involved in certifying medical devices, such as CE marking in Europe (Conformité Européenne).

Throughout the workshops there were opportunities for each group to give feedback on their main discussion points to the wider group.

Each workshop concluded with a consolidation activity where participants were provided with a policy impact matrix (**Supplementary Material C**). Reflecting on the discussions from the rest of the day, participants were asked "what research could generate evidence which would inform policy in the short, medium and long term?". Groups were then asked to map these initial research study ideas onto a matrix where the perceived policy impact was mapped against the time taken to undertake the work.

The actionable recommendations within this paper are informed by the workshop discussions and this concluding activity from both workshops. The workshops were part of a patient and public involvement exercise to contribute to the design of research studies. Ethical approval to undertake these workshops was given by the Newcastle University Faculty of Science Agriculture and Engineering Ethics Committee (reference: 18659).

3. Summary of workshop discussions

3.1. Clinical effectiveness

This section summarises the discussions on two Clinical Effectiveness sub-topics: (1) function; and (2) lived experience. This section is based on the first research question posed by NHS England surrounding the Clinical Effectiveness of multi-grip myoelectric hands (4).

Outcome Measures. There was a general consensus from workshop participants that existing outcome measures do not provide a holistic view of the success of a prosthesis. When assessing prosthesis performance, it is important that measures enable a combination of quantitative and qualitative data to be captured, sourced from both patients and clinicians. Workshop discussions were centred on outcome measures that go beyond categorisation and measure a range of activities, including functional performance and lived experience.

There were several challenges outlined relating to current outcome measures. The main challenge was a lack of measures that are specifically developed for people with upper limb loss or absence. For example, clinicians highlighted that quality of life measures, such as EQ-5D, are used within upper limb prosthetics clinics, but were originally designed to assess the impact of disease and health at a more generic level (6). By conducting such measures, patients and clinicians may not have a comprehensive overview of the impact on quality of life. For example, a recent study found patients with multi-grip hands to

rate their quality of life higher than the norm (7). Furthermore, with measures such as the EQ-5D, patients scores often plateau, especially after adjusting to limb absence.

It was noted that workshop participants shared that there is a general bias within the field towards quantitative metrics. However, a mixed methods approach that combines quantitative and qualitative metrics may be required due to the broad definition of a successful prescription. It was highlighted that such an approach needs to ensure that qualitative measures, such as observational techniques and open-questions that enable people to share their lived experience, are sufficiently objective to inform upper limb prosthetics policy at a national level. Studies that go beyond traditional clinical measures, and/or use qualitative data were identified as gaps when discussing the assessment of prosthesis functionality. Observational research, which may not be hypothesis-driven, was raised by workshop participants as an equivalent when discussing how to measure lived experience.

Two main areas of improvement for current outcome measures were raised by the workshop participants: (1) increase uniformity in how measures are conducted such that comparisons can be made across patients; and (2) enable assessment over longer periods of time whilst remaining realistic on what measures will be undertaken and who will conduct the required assessment(s). It is pertinent to highlight that the latter point is dependent upon the capacity of clinical staff to contribute to longitudinal assessments, as raised by clinicians during the workshops. In addition, three best practice approaches for measuring function were raised: (1) the use of life course measurement approaches and/or assessing specific life events (e.g., becoming a parent or starting a new job) during a patient pathway; (2) tailoring assessments dependent on the stage of a patient's amputation journey (e.g., initial period post amputation such as 1 and 3 month clinical reviews); and (3) iterative testing with regular follow-ups.

Goal setting was discussed as a tool to contribute towards assessing functionality and lived experience by workshop participants. This may often involve individual goals, and/or goals related to roles within a family that change over time. It was noted that a trained professional needs to assess each patients' goals, and manage unrealistic goals and expectations. Workshop participants shared that a balance must be maintained between self-development and achievement of goals, to reduce the likelihood that people change their lifestyle to achieve prosthesis related goals. Furthermore, measuring patient progress against their personal goals was proposed as a potential method of standardising experimental analysis across patients.

It was highlighted that a quantitative method for assessing and monitoring individual goals is required. Furthermore, a validation of the Patient-Specific Functional Scale (PSFS) for use in upper limb prosthetics is an area of improvement that needs to be addressed.

Longitudinal assessment of the rehabilitation journey. Overall, there was an opinion from workshop participants that a better understanding of the success of prosthetic interventions can be gained by conducting more regular or continual assessment of clinical effectiveness over longitudinal periods. Current measures represent patient data from a relatively narrow timeframe (e.g., within clinic appointments), whereas patients' experience of limb loss or absence may vary daily, and assessment goals can change over time. It was highlighted that although every patient journey is described as unique, there are a series of relatively fixed stages across patient groups, for example starting rehabilitation, ending rehabilitation, and returning to work or school. Workshop participants shared that the experience someone has at these time points can be instrumental in determining what may happen in terms of their future prosthesis usage. A clinician during a workshop shared that if a patient becomes depressed after leaving rehabilitation and does not have the option to access clinical support, they tend to reduce use or entirely reject their prosthesis. While this comment was based on clinical experience, the observation may in part be explained by maladaptive coping strategies when adjusting to limb loss (8). The main challenge that emerged from these discussions was how to allocate sufficient time and resources to conduct measurements at appropriate stages of a rehabilitation pathway, and how to identify what these timepoints may be. Furthermore, the variability between people and different age brackets across children, young people, and adult populations, makes quality of life quantification difficult to achieve.

The broader context of clinical effectiveness included participant discussions that explored how a variety of factors feed into defining or reflecting upon lived experience. For example, psychological factors should be a part of assessments and family members could provide a valuable source of additional information. This could lead to decisions that are informed by several factors, rather than solely on the functional performance of how someone uses a prosthesis.

3.2. Safety

This section summarises the workshop discussions on the Safety topic. This section is based on the second question posed by NHS England (4) exploring the safety of prosthetic devices. The NHS England evidence review highlighted that there was no evidence of the safety of a myoelectric controlled multi-grip upper limb prosthesis compared with standard upper limb prostheses or no prosthetic use (4).

The European legislation conformity confirmation process, known as CE marking was discussed by several workshop participants as prohibiting new components coming to market, due to the timescales for completing this process; however, it was noted by one workshop group that despite these limitations the process remains essential. Prosthetic hands are generally classed in the United Kingdom as Class 1 medical devices (9) requiring a UKCA (United Kingdom Conformity Assessed), CE or CE UKNI (United Kingdom Northern Ireland) mark. This means that manufacturers and healthcare establishments who supply them must follow the UK medical device regulations. The timescale of CE marking was identified as a barrier, as was the notion that the CE marking process may prevent new components reaching market. It was also noted that CE marked devices often reach the market with limited evidence of functionality and once modified, liability for the device lies with the prosthetic clinical rehabilitation service.

Training was raised in numerous domains by participants including training clinicians to inform and guide patients through the decision making process of prescribing a prosthesis; prosthetic device training to reduce abandonment; training in CE safety; patient education and ensuring prosthetics training includes modern socket design.

Physical and psychological patient comfort was raised during the workshop discussions, particularly by clinicians, academics and the person with limb absence. Patient comfort, in terms of the socket-patient interface and fit, was acknowledged as a common problem and an important overall outcome which receives limited research attention. Understanding current methods to reliably measure comfort was raised multiple times, as well as the need to develop new comfort metrics.

3.3. Cost effectiveness

This section summarises the workshop discussions on the Cost Effectiveness topic. This topic is the third question posed by NHS England (4). The NHS England evidence review highlighted that there was no evidence of the cost effectiveness of a myoelectric controlled multi-grip upper limb prosthetic compared with standard upper limb prostheses or no prosthetic use (4).

Clinical factors included quantifying the time, resources and expertise necessary to deliver a specific prosthesis and administer outcome measures required both by the health service and as part of research studies. There were also discussions from participants that stressed the importance of cost in clinical decision making. Participants highlighted how different centres may use different budgeting approaches as this will be guided by their local trust and this can factor into the treatment approach and the devices they prescribe to patients. Further the financial setup may differ across different clinical centres. For example, some prosthetists are employed directly by the NHS, and others may be employed by private companies that either deliver prosthetic services within the NHS or alternatively serve the private patient sector. This scenario factors into the ability to cost these roles in to grant applications, as different clinical centres may have varying budgeting structures. All of these factors can add complexity to research studies. Clinical stakeholders also highlighted the cost associated with purchasing and delivering outcome measure assessments, including the time taken to train clinicians.

Hidden costs in the provision of prostheses often fall into a separate budget line and may not be identified as part of the overall cost of a device. Therefore, there are currently challenges in how cost is measured. For example, a prosthesis that has been used for decades appears to be cost effective, but parts of the device may have been replaced multiple times on a separate budget line. This might include out of warranty replacements, repairs, wear-and-tear, and consumables such as replacement gloves. These costs, alongside costs related to device abandonment were all raised by participants as being rarely reviewed and/or having limited information available. The demand for consumables affects the often high spend on upper limb prosthetic devices. Replacement costs were identified by academic and clinical workshop participants as being particularly complex in paediatric prosthetics as children outgrow devices.

The long-term cost of prescribing a prosthesis was noted by participants as being difficult to track and measure. Two outline approaches were proposed: (1) evidencing long term achievements and contributions to society of people with upper limb absence; and (2) evidencing the long-term implications of not using an upper limb prosthesis. More specific measurements proposed included assessing: quality of life over a longitudinal period, patient income before and after prosthesis fit, rates of adverse events, and the impact on other healthcare services within the NHS, such as social services.

3.4. Patient subgroups

This section summaries the workshop discussions on the Patient Subgroup and Patient Involvement topics. The fourth research question posed by NHS England queried whether there were subgroups of patients who may benefit more from a multi-grip myoelectric upper limb prosthetic than the wider population of interest. The NHS England evidence review highlighted that there was no evidence to support this either way (4). Rather than directly addressing which subgroups of patients may experience additional benefits from a multi-grip myoelectric upper limb prosthesis, workshop questions explored what patient subgroups existed and should be considered when designing representative research studies.

A wide range of subgroups were identified by workshop participants. The diverse nature of patient demographics and geographical location were frequent topics. The remaining topics of conversations were summarised into two groups, those that were generally described as discrete categories or groups and continuous ranges that patients fall somewhere within.

Discrete categories of patients were discussed during both workshops by participants. Although age was considered continuous, young people were described according to distinct groups ranging from infants through to teenagers. Other discrete categories included the reason for a patient's limb absence, i.e., whether the individual had a congenital absence or had acquired limb loss; the number of limbs impacted and their laterality; the discrete level of limb absence (e.g., above/below elbow); whether or not surgical interventions such as osseointegration or muscle reinnervation had been performed; whether an individual was a prosthesis user or not; and whether people were engaged with the medical system or not. Individuals were also catergorized based on their local relationships, i.e., whether they had support from family, siblings or a carer, and these relations were also raised by workshop attendees as potential research participants who could provide insight into the quality of a patient's rehabilitation journey.

Continual ranges used to describe patients covered a range of factors. The overall length of the residual limb used for functional control of upper limb myoelectric devices was discussed as a continuum. Other ranges included the recency of a patients' limb absence and how long they had spent interacting with healthcare services. A range of factors related to individual patient's lifestyles were raised by workshop participants, which generally focused on

patients' levels of physical activity, such as their involvement in sports, and in factors that may influence their levels of physical activity, such as their employment status and job role.

3.5. Stakeholder engagement

This section summarises the workshop discussions about participant and clinical engagement in policy-focussed upper limb prosthetics research studies.

Engagement from a clinical perspective. Participants highlighted that clinicians should be encouraged and supported to have an active role in research studies. Authorship opportunities and Continuing Professional Development hours were presented as potential incentives by workshop participants. Time and funding were key topics of discussion; it was noted by clinicians that administering a study using clinical hours is challenging and should not infringe on the delivery of services, such as patient appointments. It was also noted that friction can be generated when clinical resources are redirected to research. Dedicated funding for prosthetists, clinicians and innovation/Research and Development departments to support research were raised as a possible solution by NHS clinicians and management at the workshops. It was noted that clinicians and academics at the workshops shared that NHS ethics for multi-site studies will be multi-faceted, and capacity should be included to manage and co-ordinate the ethical approval process for such studies.

Engaging and involving a wider cross section of participants was raised as a challenge to research study recruitment by workshop attendees. People who are happy with their prosthesis, or people who do not use their prosthesis do not necessarily engage regularly with a prosthetics centre, which depending on the recruitment process can bias the participant pool. It was suggested that patient groups and patient advocates should be involved in participant recruitment. It was noted that workshop participants felt expert patient ambassadors are not necessarily always representative of the broader patient community, and it is important to recognise the value of having shared project goals between all stakeholders. Furthermore, academic stakeholders at the workshop stressed that the research community needs to establish how to involve people during the experimental design process in a way that does not bias a study if the same group of people become research participants during the study.

4. Actionable recommendations

The following actionable recommendations are informed by the authors' summary of discussions from both workshops. The recommendations could span more than one of the commissioning research question areas (Clinical Effectiveness, Safety, Cost Effectiveness, and Patient Subgroups). The recommendations are not presented in priority order and may be applicable to both paediatric and adult population groups. Although the recommendations are presented under separate headings, crossovers can be identified, especially when considering the longitudinal pathway that people experience living with limb absence or limb loss. For example, outcome measures are informed by the identification and monitoring of personal goals, which influences prosthesis performance, which in turn change personal goals over time (Figure 1).

4.1. Gather qualitative and quantitative research evidence

Quantitative and qualitative research is required to generate evidence on the effectiveness of multi-grip myoelectric hands on both an individual and a national scale.

The implementation of qualitative techniques would allow for a deeper insight into patients' perspectives on how successful their prescription has been. It is worth highlighting that the NHS multi-grip myoelectric hand policy assigns 30% weighting for prosthetic provision on the patient experience view (1). It is recommended that an upper limb prosthesis specific quality of life measure is developed, which can be incorporated into mixed method studies that gather both quantitative and qualitative research findings.

4.2. Use of goal-based outcome measures

It was commonly agreed and highlighted by all groups that the best method to assess the effectiveness of prosthetic intervention would depend on individual personal goals. It was also highlighted that goals could change over time as people become more experienced and skilled with their prosthesis or as their personal circumstances change. Progression against personal goals was proposed more than once as a valuable outcome measure and it is recommended that this should be included in any research studies aiming to inform policy decisions. By doing so, outcomes could develop from the standard categorisation model towards incorporating qualitative data that demonstrates progress against

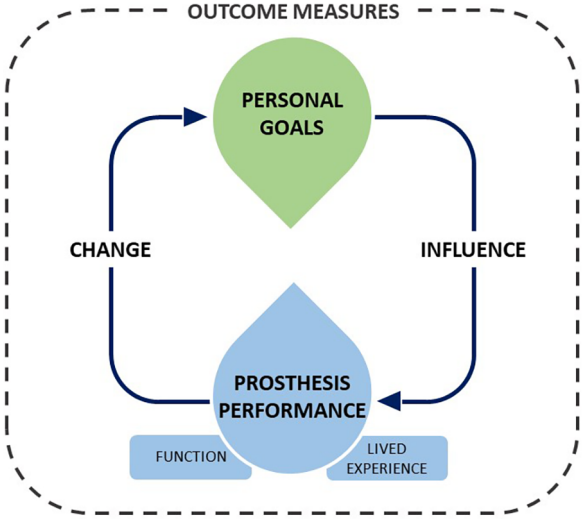

FIGURE 1
Representation of the dynamic relationship between outcome measures and prosthesis performance.

personal goals. A suggestion was made that this could be a patient reported outcome measure, but this can be challenging to utilise on a broader scale when exploring the overall clinical effectiveness of an intervention. Alternative methods should therefore also be sought and where needed validated. Where possible, clinically meaningful difference values should be developed. In addition, methods for capturing individual progress and utilising this to inform the collective success of an intervention should be explored. It was noted that personal goals may change based on prosthesis performance (Figure 1) and that these changes may therefore highlight meaningful indicators of how a person perceives the functionality of their prosthesis.

4.3. Conduct longitudinal studies

Each experience of limb loss or absence is unique and lasts throughout a person's lifetime. During this normally multi-decade long experience, people may fluctuate in the level of health and care services they receive from upper limb prosthetic clinics. However, there can be common stages that more than one person experiences. For example, when somebody first has an amputation, there can be a set of fixed stages as part of an intensive clinical rehabilitation pathway. These pathways may take several months, if not years to navigate through, with prolonged periods of time at home or within the community and/or workplace or school. Over this course of time, peoples' goals and needs may change, alongside their prosthesis usage patterns. It is recommended to gather qualitative and quantitative research data over the course of a rehabilitation pathway; findings relating to the clinical and cost effectiveness can then inform commissioning policy. Such studies will involve remote prosthesis data collection and patient reported outcomes when patients return home and adapt to life within a community, and/or workplace or school.

4.4. Measure wider social costs

The complexity of assessing the wider societal cost of commissioning prosthetic devices requires assessment of multiple interacting cost centres. For this reason, research should investigate savings and expenditure in: the wider social care associated with prosthesis use; associated clinical centres which may also be utilised; any associated co-morbidities or physical activities related to prosthetics; and in more general long-term prosthesis use. To effectively direct investment, it would also be valuable to identify whether specific devices or outcome measures are appropriate for different patient subgroups such as paediatrics.

4.5. Establishing baseline data

There is no current database characterising the population of people living with limb difference in the UK. There is a need to access and coalesce existing retrospective data from siloed sources to understand the current population and their usage patterns. This work would include utilising existing national data sources, such as the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS), and by sourcing data from individual organisations, such as prosthetics service centres. In addition to understanding the demographics of the UK's limb different population, there is a need to monitor the supply, repair, refit and changes to prosthesis provision such that current costs and clinical workload can be accurately measured. This information is particularly needed in paediatric upper limb prosthetics, which remains an underserved and understudied area.

4.6. Educate and train

It is recommended that research studies assess current methods and develop new training-based interventions to enhance clinical services, and patients' experience of using a prosthesis. Education and training should focus on a broad range of stakeholders to improve overall expertise. Education and training sessions for clinical teams across several rehabilitation centres may deliver a cost-effective method of understanding the existing skill base. Sustainable and cost-effective training, such as self-management courses, may address the learning requirements of patients and their close family and/or friends. This could facilitate patient engagement with their clinical pathway and potentially enhance the experience of using a prosthesis.

4.7. Conduct data logging

Many of the ideas for research studies shared during the consolidation activity involved the use of logging technology to record prosthesis usage data. There was a general view amongst workshop participants that prosthetics manufacturers log and retain data of how their devices are used, but choose not to publish it. However, there was limited consensus on how useful data solely logged from prostheses would be for understanding real-world use. Consequently, a common feature of these discussions was how to create a form of activity monitoring in real-world conditions, outside of the laboratory. In comparison to prosthesis logging systems, said activity monitoring systems would also acquire contextual information such that performance metrics can be derived. Additional research is required to ensure that these approaches, especially those involving bespoke systems, and any associated methods of acquiring real-world data are sufficiently robust for large scale data collection.

5. Discussion

This paper presents a summary of discussion points sourced from two multi-stakeholder workshops held in June 2022 and July 2022, which explored questions raised within the current NHS England commissioning policy for myoelectric multi-grip prosthetic hands (1, 4). The workshops involved people from a range of stakeholder groups: policy, academia, NHS clinical and

management, industry, and a person with upper limb absence. These workshops formed part of the early stakeholder involvement aspect of a broader, open and collaborative, policy-led research study design project.

Understanding and quantifying a successful prosthetic prescription is complex (10). Consequently, identifying appropriate outcome measures to use is also complex. Clinicians and researchers who participated in the workshops were keen that outcome measures assessed the goals of the patient. If the measure of success is how quickly someone can move an object from one place to another, but their original goal was to have a prosthesis which allowed them to brush their hair, then the measure is not useful for that purpose. This is likely why some occupational therapists in the workshops were strong advocates of measures such as the Canadian Occupational Performance Measure (COPM) and Assessment of Capacity for Myoelectric Control (ACMC), which are bespoke to a person's goals. Although these measures are useful on an individualistic level, they can be harder to integrate into an overall assessment of the success of the technology. In addition, these types of measures can take a long time to administer, and within the NHS, clinicians are limited in the time they are able to spend with patients. It is therefore important that if outcome data is to be centrally captured as part of the standard rehabilitation pathway (as is recommended within the NHS multi-grip myoelectric hand policy), then this data must also contribute and inform clinical practice. When measuring an individual's goals, it should be remembered that these may be relatively short-term and goals can change over time. If COPM is only conducted once every 12 months, the results may not be representative of the person's experiences. Living with limb absence is present throughout an individual's life course, where their needs and requirements may change. This journey should be reflected in the design of any research studies measuring the effectiveness of prosthesis provision.

People with upper limb absence can experience an onset of multiple long-term physical and mental health conditions, such as chronic pain and depression (11, 12). These changes can have an impact on peoples' health and overall quality of life (13). As these changes emerge, the impact of prescribing multi-grip myoelectric hands may positively or negatively affect the prosthesis user, and other health and care services, such as physiotherapy and mental health. Furthermore, such a prescription may impact upon the responsibilities and emotional burden of carers or family members, which may increase over time as multiple conditions emerge (13). This scenario necessitates multiple investigations into the cost effectiveness and the lived experience of prosthesis users and carers based on the prescription of multi-grip myoelectric prostheses over a longitudinal period, which is reflected in the recommendations outlined within this paper. For this to be realised, collaboration with multiple stakeholders must be conducted, including policy makers, academics, health economists, clinicians, and prosthesis users.

Conducting collaborative research can lead to impactful outcomes for health-related research (14). The National Institute of Health and Care Research, advocates the importance of involving patient and public stakeholders in research studies, in addition to the emerging initiative of community and public engagement (15). In the field of policy development, considering the views, opinions, and experiences of multiple stakeholders could lead to positive change (16). However, implementing collaborative research in practice is complex. During both workshops, there were several discussions about identifying what benefit patients would gain from being involved in research studies. The benefits of involving patients in research are highly documented, however there are emerging academic perspectives on the potential ethical implications of doing this in practice for health-related research (17). There is also the reality of the relatively slow pace of research progress, which can impact upon the experience of being involved in research, in terms of patient fulfilment and participant retention. It is therefore critical that research studies clearly set out realistic study aims and expectations when recruiting and involving patients (18). Collaboration between researchers, NHS rehabilitation centre managers and clinicians, and patients will be key to the success of patient recruitment and involvement initiatives. However, capacity and capability building will be a core component in conducting such an approach. For example, patient groups may need support in developing health literacy, clinicians may need access to usable datasets, and researchers may require a knowledge exchange platform that facilitates collaboration with participants. These areas of capacity and capability building have been highlighted in a recent World Health Organisation framework for engagement (19). Furthermore, the UK Government Policy Lab has established a range of collaborative methods, which have the potential to be applied to policy-driven research studies (20). The methods can be linked to the emergence of *Design for Policy* over the past decade, which has permeated across multiple policy sectors (21, 22). These maturing initiatives are particularly relevant for involving users in policy-driven research; to ensure that methods are used to involve people by collaborating towards a shared goal (23).

This paper presents a summary of the first step towards addressing a shared goal in generating a consensus-based process to designing policy-led research studies. Based on the workshop discussions, there are several underserved areas with limited academic literature that need to be addressed before this goal can be achieved from a clinical and academic perspective. The areas identified were myoelectric training, prosthesis and socket comfort, the design and testing of outcome measures, and using qualitative approaches as measures in upper-limb prosthetic research. These areas are difficult to address and require an extensive degree of testing with people with limb absence. In terms of training, there is limited scientific evidence for some existing methods. In particular, the relationship between training myoelectric control in isolation and improvements in functional prosthesis use remains contentious, and this is a complex area and is difficult to validate (24, 25, 26). Regarding the assessment of comfort, neither of the most applied scales, the "Socket Comfort Score" or the "Comprehensive Lower-Limb Amputee Socket Survey", are validated for upper-limb use (27, 28). Furthermore, socket comfort relates to socket fit and therefore myoelectric prosthesis function (29). Thus, socket comfort cannot be assessed in isolation, and likely requires a holistic approach where comfort is evaluated

alongside functional gains. The Upper Limb Prosthetic Outcome Measures (ULPOM) working group made significant steps forward in identifying the most appropriate outcome measures for upper limb devices (30, 31). Although ULPOM made recommendations, there is still limited academic or clinical consensus on the use of outcome measures.

5.1. Limitations and future study considerations

The content presented within this manuscript is based on a project that is in an early phase of development. The project is a relatively new field of policy-driven research for upper limb prosthetics being run in the context of NHS policy. The reader should be aware of both the wider context of this project, and potential limitations with respect to the workshops from which these recommendations were drawn.

One such consideration is that the content presented in this paper is primarily based on the views and opinions shared by professionals, rather than users of prosthetic devices. The workshops focused on early-stage discussions around the design of research studies based on questions and background information sourced from policy documentation (1–4). The second stage of the project, which is currently on-going, comprises tailored workshops that involve a larger cohort of people with upper limb absence (adults and children) and their family and/or support network. This approach may minimise potential power dynamics which could occur in a multi-stakeholder workshop with policymakers, researchers, clinicians, and industry. Potential study designs based on the recommendations presented within this manuscript will be shared during the second stage workshops to inform the development of this body of work. Furthermore, to enhance stakeholder engagement during these workshops, digital and health literacy is a consideration that must also be addressed via approaches such as online and paper-based visual mediums (e.g., project animations, scenario mapping, and comic-book style print-outs) to facilitate collaboration and communicate the project before, during, and after a workshop.

Another limitation is that due to rail strike action in the United Kingdom, it was not possible to conduct the first workshop in-person, as planned. For methodological consistency, ideally a series of workshops should be conducted in one format, i.e., all online or all in-person, unless a mixed methods approach is used. Due to the difference in workshop format, it was decided to not audio or video record either workshop, so that the analysis of notes from both workshops was consistent. Furthermore, due to the anonymity of data collection and the scope of the funded project, comparisons between stakeholder groups cannot be identified from the content presented within this manuscript. Conducting workshops is a valuable method to elevate a variety of stakeholder opinions and ideas. However, workshops are limited to time, and discussions require high levels of concentration for all involved. The approach also requires a significant amount of time from the workshop participants, which can limit who has the capacity to attend across all stakeholder groups. A suggestion for future studies would be to apply a mixed methods approach including workshops, surveys, and one-to-one interviews to provide people the opportunity to engage in a format that best suits their needs and schedule.

By taking a national approach to research (involving stakeholders from across the United Kingdom and Ireland), it will be possible to generate evidence on a larger scale than previously achievable and ensure methodological consensus. This collaborative approach to evidencing policy decisions could be beneficial for other rare medical conditions involving specialised technology-based interventions.

Author contributions

All authors conceived the study and delivered both workshops. All authors analysed the workshop content. HJ wrote the original draft manuscript. All authors contributed to the article and approved the submitted version.

Funding

This project was funded in parts by Research England QR Policy Support Fund from Newcastle University, project titles: [2022] “Developing UK/Ireland Consensus on studies to inform upper limb prosthetic policy” and [2023] “User Involvement in Policy-Driven Research for Upper Limb Prosthetics”.

Acknowledgments

The authors acknowledge the valuable contributions from all participants at both workshops and the members of the steering group.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher’s note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2023.1213752/full#supplementary-material

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Perspective
PUBLISHED 16 January 2024
DOI 10.3389/fresc.2023.1335966

OPEN ACCESS

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RECEIVED 09 November 2023
ACCEPTED 29 December 2023
PUBLISHED 16 January 2024

CITATION
Gavette H, McDonald CL, Kostick-Quenet K, Mullen A, Najafi B and Finco MG (2024) Advances in prosthetic technology: a perspective on ethical considerations for development and clinical translation. Front. Rehabil. Sci. 4:1335966. doi: 10.3389/fresc.2023.1335966

Advances in prosthetic technology: a perspective on ethical considerations for development and clinical translation

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Technological advancements of prostheses in recent years, such as haptic feedback, active power, and machine learning for prosthetic control, have opened new doors for improved functioning, satisfaction, and overall quality of life. However, little attention has been paid to ethical considerations surrounding the development and translation of prosthetic technologies into clinical practice. This article, based on current literature, presents perspectives surrounding ethical considerations from the authors' multidisciplinary views as prosthetists (HG, AM, CLM, MGF), as well as combined research experience working directly with people using prostheses (AM, CLM, MGF), wearable technologies for rehabilitation (MGF, BN), machine learning and artificial intelligence (BN, KKQ), and ethics of advanced technologies (KKQ). The target audience for this article includes developers, manufacturers, and researchers of prosthetic devices and related technology. We present several ethical considerations for current advances in prosthetic technology, as well as topics for future research, that may inform product and policy decisions and positively influence the lives of those who can benefit from advances in prosthetic technology.

KEYWORDS

ethics, perspective, prosthesis, amputees, rehabilitation, clinic, research, translation

1 Introduction

As prosthesis use has increased, technology has continued to advance, resulting in many scientific breakthroughs over the last decade. A few examples include haptic feedback to restore sensation (1, 2), componentry that can provide active power (3) and machine learning for prosthetic control (1, 3). These and similar advances in prosthetic technology have the potential to revolutionize prosthetic care (2, 3); however, ethical concerns of development and implementation into current clinical practice are often not discussed, contributing to a widening gap between research and clinical practice as well as wasted research costs. For example, actively powered knee and ankle prostheses have encountered multiple challenges (e.g., being too heavy, being too bulky, being inefficient, not providing enough power to actively support the patient's weight and

activity) that have limited commercialization (4). Providing developers and manufacturers of prosthetic technology an overview of ethical concerns related to development and clinical translation could help prevent wasted research costs and maximize potential benefits of prosthetic technology as advances continue.

In this perspective article, we present the author's viewpoints on several ethical considerations for advances in prosthetic technology, as well as topics for future research. Specifically, we discuss topics within device development and translation to clinical practice. While not an exhaustive list, we hope the ethical considerations discussed in these sections can help bridge existing gaps between clinicians and developers, manufacturers, and researchers, to ultimately inform user-centered design, establish policy guidelines, and reduce wasted research costs. Most importantly, proactively addressing ethical considerations from both a research and clinical perspective can help ensure that people who receive prosthetic care actually benefit from current and continued advancements in prosthetic technology.

2 Device development

The development of advanced prosthetic technology is generally conducted with little input from users or clinicians. In this section, we highlight the importance of considering user-centered design principles, participatory action research, reported needs of prosthesis users, and clinician perspectives to optimize device development.

2.1 Utilize user-centered design and participatory action research

User-centered design, also termed co-creation or human-centered design and along the same paradigms as value sensitive design (5), is the process in which developers include the needs, values, opinions, and concerns of end-users throughout the design and implementation of a novel idea or product (6). Without user-centered design in prosthetics, developers risk wasting resources towards the production of new devices that may be unusable or undesirable among end-users. More importantly, participatory action research allows a shift from thinking of people as "end-users" towards integrating them as equal members of the team developing the technology (i.e., making technology *with* people instead of *for* them), ensuring development from idea generation to implementation is relevant to their lived experiences (7). Several studies have reported the perspectives of prosthesis users in the context of current clinically available prosthetic technology, such as cosmesis (making the prosthesis aesthetically pleasing), prosthetic fit/comfort, functionality, and specific prosthetic componentry that may help clinicians provide the best services for their patients (8–21). However, there is limited research focusing on user perspectives regarding future technology to guide the development of new prosthetic devices (22–25). As advanced technologies continue to enter the field of prosthetics, these user perspectives must be reported to ensure the technologies are beneficial before they are made readily available. Yet, user expectations for prosthetic technology may be unrealistically high and unattainable, so it is important to properly educate individuals on inherent trade-offs of design to collect informed perspectives. Of equal concern, including a diverse user group that is representative of the larger target audience is challenging, yet must be considered when collecting these perspectives. Additionally, user-centered design frameworks (6, 23, 26–28), the Usability Metric for User Experience (UMUX) (29), and the Technology Acceptance Model (TAM) (30) should be utilized in future studies to guide new technology design and assess its acceptance by users.

2.2 Determine user needs

In a recent review of lower limb prosthesis (LLP) user needs, pain reduction, mobility, social integration, independence, and the ability to walk were the *most frequently reported* needs while safety was reported as another important need (31). Some of the advanced technology currently used in the clinical setting has resulted in improvements in these areas (32–35) but further development is necessary to meet these needs (31). Although limited, user-centered design as a component of advancing LLP technology has been reported (22, 23), Fanciullacci et al. found that transfemoral amputees reported they would like their powered robotic prosthesis to assist in ascending stairs and inclines, but not running (22). Similarly, Beckerle et al. utilized a human-machine-centered design process that considers both the technical and user needs, weighs their importance in the overall design of the technology, and proposes the priorities to guide the development process (23). Approaches similar to these studies should be implemented in the development of advanced LLP technology to help ensure the technology's acceptance and success in the hands of the users. Further, future LLP technology must meet or exceed the benefits of current technologies in the realm of end-user mobility, independence, comfort, and safety to promote adoption.

Upper limb prosthesis (ULP) users have reported unique needs compared to lower-limb prosthesis users. A recent review reported ULP users require more functionality (e.g., grasping, manipulation, and strength), better cosmesis, and better comfort out of their devices regardless of device type (body powered, myoelectric, passive) or level of limb loss/difference (36). Additionally, users request sensory feedback, higher battery and electrode reliability and durability, less dependence on visual attention while using their prosthesis, accurate anthropomorphic dimensions, less heat retention, and less motor noise (36). Although more recent developments in ULP technology have sought to resolve these issues, these needs are nearly identical to those reported in a study published over 20 years ago (37). Similarly, device abandonment in ULP users has been a concern for decades, yet current prosthetic technology still has not improved abandonment rates (38, 39). In a recent survey, 44% of ULP

users rejected the use of their prosthesis despite almost 93% of them having been prescribed one of the most advanced ULP technologies clinically available (myoelectric control) (38). Reasons for abandonment are due to discomfort (too heavy, too hot, causing excessive sweating), non-ideal function (inhibited control, no sensory feedback), and users being more independent without a prosthesis (39). In addition, advanced prosthetic technology requires various levels of training to deliver optimal user benefits, and overlooking prosthetic training can lead to abandonment (40). Developers and manufacturers can combat abandonment and excessive training needs by developing more intuitive control mechanisms, rather than entirely new devices, and offer clear instructions that physical and occupational therapists can also use to help patients adapt to their devices. As much as ULP technology development has grown over recent decades, it is clear that more must be done to meet the needs of prosthesis users. Further, assessment of the needs and perspectives of prosthetic users regarding advanced ULP technology is sparse. Engdahl et al. found that users are more interested in current clinically available, non-invasive myoelectric prostheses and the ability to complete more basic functions, rather than undergo surgery or the ability to complete advanced functions that would be included with new technologies (24). However, Kelley et al. suggests that users are willing to accept the risks associated with the new technologies if there is a significant functional benefit such as sensory feedback, improved user control, and reduced training time and maintenance (25). Nonetheless, these findings conclude that user perspectives towards advanced ULP technologies must be researched further to help guide technology development.

2.3 Include clinician perspectives

Prosthetic device development should also involve the perspectives of the clinicians, (e.g., prosthetists, physical therapists, occupational therapists, and others) who are members of the interprofessional healthcare team. In a focus group involving clinicians, users, researchers, and device manufacturers, Klute et al. determined fit, comfort, function, performance, and stability were important LLP user needs that the authors suggest can be improved by developing standardized outcome measures (41). Additionally, non-technical features, like improved patient education about the rehabilitation process, improved communication, improved evidence-based guidelines, and improved patient support systems, are just as important (41). Rekant et al. investigated clinician perspectives on current and prospective ULP technology and found that clinicians emphasized the user's needs for completing activities of daily living, participating in hobbies, device reliability and safety, in-hand object manipulation, finger flexion/extension, greater wrist range of motion, and thumb abduction/adduction (42). However, compared to users, clinicians were more skeptical of invasive surgeries (42). Additionally, since prosthetists in the US are reimbursed per device rather than per clinical service, prosthetists often must consider a business perspective that may conflict with their clinical perspective. Nonetheless, further information regarding clinician perspectives on and needs for advanced prosthetic technology is necessary to guide technology development.

2.4 Promote health equity

Promoting health equity can help ensure people who use prostheses have access to advanced technologies that can improve their quality of life (43). To promote health equity in prosthetic design, it's critical to acknowledge that socioeconomic factors (e.g., age, race, ethnicity, gender, living in a rural environment) and other social determinants of health (e.g., racism) can contribute to health disparities in amputation rates, as well as prosthetic technology development and access (38, 43–53). Additionally, especially in the US, reduced access to quality health insurance and a lack of affordability of copays and deductibles have been found to widen disparities (54–56). It is possible that advanced prosthetic technology could continue to widen these existing health disparities. For instance, technology often requires a stable internet connection, compatible hardware and software, as well as technology literacy, training, and technical support for effective use. However, current billing practices in prosthetics dictate that any follow-up care is bundled into a lump-sum payment for the device, and providers are not reimbursed for follow-up care outside of this base rate. Additionally, people who are older adults, belong to systematically marginalized groups, or live in rural communities are often underrepresented in prosthetics literature (57–59), including technology development. To elucidate health disparities, researchers must first collect and report detailed socioeconomic information, as a recent review determined 84% of the 420 manuscripts reviewed did not report race or ethnicity of the participants (60). Collecting and reporting detailed socioeconomic information is an essential first step to begin understanding and addressing existing disparities. Researchers can also pursue topics that center people who are underrepresented in current prosthetics literature, and use recruitment strategies (i.e., participant payment for travel and/or childcare) to mitigate participation barriers and help ensure development and subsequent access to technologies are equitable.

3 Translation to clinical practice

Clinicians and researchers must collaborate to integrate new advanced prosthetic technology into the market and clinical practice, ensuring the greatest benefit to the user, justifying the resources spent to develop the technology, and advancing the field as a whole (61–65). Making novel prosthetic technology readily available in clinical practice requires a sustained effort of numerous resources over multiple years. For instance, microprocessor knees (MPKs) began development in the 1980's (66–68), were not commercially available in the US until 1999, and were not covered by Medicare until 2005 (69). Additionally,

many patient and situational factors affect prosthetic prescription in clinical practice. For example, MPKs may not be suitable for some patients, such as individuals who are not cognitively capable of using and taking care of the MPK (70). Further, some patients, such as those classified as limited community ambulators (K2 Medicare functional classification level), may be unable to receive an MPK due to insurance coverage restrictions, though current research has demonstrated benefits to this population (68, 70). This section discusses practical considerations and potential barriers of translating new advanced prosthetic technology into clinical practice.

3.1 Understand reimbursement and coverage

Arguably the most critical aspect of technology translation into prosthetic patient care is device coverage. To prosthetic users and clinicians alike, cost is a crucial concern and must be accounted for in prosthetic technology development (31, 36, 41, 42, 71). As all authors are based in the US, only US coverage guidelines will be discussed, though international challenges in prosthetic coverage have also been reported (72). Kannenberg et al. discuss how insurance companies (including the Centers for Medicare and Medicaid services) have recently called for greater evidence with high-quality methods to document the clinical benefit of prosthetic technology and guide payment rates (72, 73). Although it is difficult to mask participants and randomize study groups in prosthetics research, high-quality evidence is crucial to justify the need and subsequent reimbursement of prosthetic technology. As manufacturers and developers continue to produce novel technologies, the cost of high-quality research can be priced into the product to account for this need. Additionally, insurance companies can dictate whether cheaper technologies provide equal benefit and will therefore be sufficient for the patient (72). Thus, new prosthetic technology must have a documented added benefit in order to receive adequate reimbursement, and developers and manufacturers should await the publication of this documented benefit prior to marketing the technology. Negotiating reimbursement with third party payers would also be easier if developers and manufacturers defined a specific target population rather than using the traditional yet vague K-Level classifiers or "product for all" approach. Furthermore, the ability of prosthetists to bill for time spent manufacturing, aligning, repairing, or otherwise managing a prosthetic device is limited. Thus, it may be unwise to develop prosthetic technology that requires extensive maintenance as clinicians may reject it on the basis of losing time, effort, and money. Cosmetic devices, though they have been documented to positively impact personal identity and overall quality of life (8, 17, 31, 74–78) are generally regarded as not medically necessary and are not covered by insurance. Despite the struggle to obtain suitable reimbursement for prosthetic devices, clinicians and patients rely on insurance coverage as any remaining costs must be covered out-of-pocket by the patient or sometimes charitable organizations. Finally, it is important to ensure that new prosthetic technology is accessible to all individuals regardless of financial status. Though they may not provide all the same benefits as their higher-end counterparts, more cost-effective options are necessary to meet the needs of all individuals. Ultimately, it is important to keep these funding structures in mind during the development of new prosthetic technology, as device payment is needed for device utilization. If not already doing so, developers could also help advocate for changes in the billing and coding system to improve coverage and reimbursement.

3.2 Abide by regulatory and education standards

An additional step in transitioning new prosthetic technology to the market is abiding by regulatory, manufacturing, and education standards. For instance, the use of digital technology to fabricate prostheses has risen with the advent of computer aided design and manufacturing and 3D printing technology. Both people receiving prosthetic care and prosthetists have expressed concerns regarding durability, safety, and aesthetics of 3D printed lower-limb prosthetic sockets (79). Compliance with manufacturing standards, such as ISO/TC 168 (80) and FDA 21CFR890 (81), ensure the device is safe and suitable for use. Additionally, while digital technologies can be excellent tools to integrate into clinical practice, concern remains over a lack of certification regulations for people who attempt to fit prosthetic devices who have not received the education (currently a Master's degree) or who are not subject to regulations (state licensure or certification required of prosthetists). Though a global shortage in training programs and certified prosthetists is evident (82–84), governing bodies such as the World Health Organization (85), the International Society for Prosthetics and Orthotics (86), and the National Commission on Orthotic and Prosthetic Education (87) have advocated for increased education standards and improved prosthetist training. Furthermore, the emphasis of evidence-based practice in prosthetic education (84, 88), equipping prosthetist educators with tools for effective teaching (84, 89), and utilizing internships and residencies to transition students into skilled clinicians (84, 90) have also improved prosthetic education. Companies, individuals, and researchers who are not prosthetists can seek to include certified prosthetists in their business model or research team to ensure the safety of prosthesis users. Following ethical design, regulatory, and manufacturing processes not only provides protection of the technology and its developers from liability issues, but also improves user safety and user trust in the technology, further improving its acceptance and adoption in clinical practice.

3.3 Encourage patient autonomy

Patient autonomy and informed consent are of utmost importance in clinical practice and should, likewise, be of importance to researchers in prosthetic technology development.

Complete transparency about the design process, intended functionality, benefits and drawbacks, costs, and maintenance requirements for prosthetic devices should always be conveyed by researchers, to help clinicians convey these aspects transparently to patients. Additionally, regardless of whether a patient will be able to afford or effectively utilize a specific prosthetic technology, the patient is still entitled to know all of their options. Prosthetists may act as gatekeepers to device options, potentially only presenting prosthetic technology that they deem appropriate. Decisions about appropriate prosthetic technology may be influenced by implicit and explicit biases. To bridge this gap, shared decision-making models help clinicians improve communication, understand patient values, utilize their clinical experience, and clarify the prosthetic journey for the patient (91–94). Researchers and developers can develop more decision-making models as well as provide greater information and education on new technologies to aid clinicians in this endeavor. Novel technologies are commonly more complex than previous technologies, so developers must find a means of helping clinicians fully explain these complexities to patients. Decision-making aids are one tool within knowledge translation, which is the field of study dedicated to expediting the implementation of research into clinical practice (95). Despite the value that knowledge translation research could bring to effective clinical translation (96), it remains underexamined by researchers in prosthetics literature. Lastly, for future implications of advanced prosthetic technology, it is important to inform patients that their data (collected for monitoring and secondary data use) may be used in ways that are not known at the time they are giving consent.

3.4 Consider data collection and privacy

While not yet integrated into standard clinical practice, several studies have demonstrated that wearable sensors, machine learning, and artificial intelligence could potentially be used in clinical practice to improve prosthetic care (97–100). However, many challenges still exist in integrating these technologies into clinical practice (e.g., privacy concerns with data collection and storage, maintaining software updates, data collection and storage, cost-effectiveness, clinician scope of practice, health equity) (101–105). While standards and guidelines are still emerging, commitment and regulation from developers is crucial, yet difficult to enforce. Researchers and policymakers in prosthetics can look at practical applications, such as governance models, that other fields have recently raised (101). While some advances that could utilize machine learning or artificial intelligence (e.g., brain-computer interfaces, ability to feel temperature or pressure) have not yet left a research setting, they have clear applications for improving functionality (e.g., increased perceptions of prosthetic embodiment, more intuitive control of the device) or remotely monitoring rehabilitation. It is important to consider how integrating these technologies into prosthetic devices could inform clinical decision-making to further prevent complications, manage comorbidities, and improve long-term health of prosthesis users. Specifically, future studies could determine how advanced prosthetic technologies could help monitor and predict rehabilitation adverse events (e.g., falls) to improve overall patient care, while also considering how this could influence clinician scope of practice. Additionally, since limb loss and difference are expected to be permanent disabilities, devising methods to make long-term digital healthcare accessible are also crucial for patient success, and promoting health equity (106, 107).

4 Summary

Figure 1 summarizes the ethical considerations and action items discussed in this perspective article. Developers, manufacturers, and researchers can implement these considerations throughout the process of developing advanced prosthetic technology. Utilizing user-centered design frameworks, as well as centering the needs of people with limb loss and difference and clinician perspectives, are crucial to ensure prosthetic technology will be beneficial to those who will use it. Additionally, determining the need for and benefit of a new prosthetic technology can ultimately prevent wasted research costs. Understanding the barriers to translating advances in prosthetic technology to clinical care before and throughout development can help ensure the technology will be safe to use, accessible, and successful on the market to improve patient outcomes.

5 Conclusion

Although each of the points summarized in Figure 1 are crucial to consider throughout development of novel prosthetic technology, many may conflict. For instance, it may be difficult to balance the need for technology that abides by regulatory standards and employs high-quality research, but also remains inexpensive and accessible to all potential users. Further, members of interdisciplinary teams developing new prosthetic technology may have varying priorities, which may also differ by situation or change over time. Research is needed to incorporate these various design criteria into priority-ranking frameworks, like the one proposed by Beckerle et al. (23), to help developers, manufacturers, and researchers realistically implement these considerations as prosthetic technology advances. Additionally, decision-making and decisional support guides must be developed to aid clinicians in understanding and incorporating new technologies into their practices. Advances in prosthetic technology have the potential to revolutionize care for prosthetic patients, but it is imperative that these technologies are designed ethically and in consideration of end users.

6 Author positionality

Most authors of this article are prosthetists and/or researchers of people with limb loss and difference, as detailed in the abstract. It is essential to note that none of the authors have limb loss or

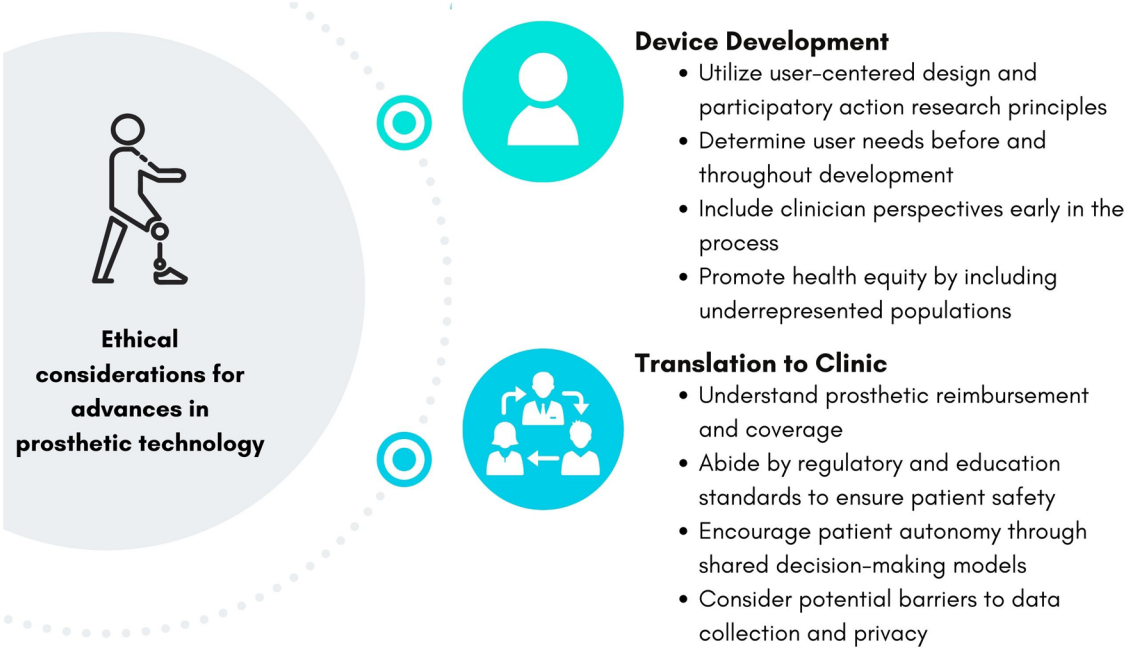

FIGURE 1
Ethical considerations and action items for the development and translation of prosthetic technology.

difference, so we have not personally encountered consequences of ethical barriers related to prosthetic technology. This article represents an effort to critically examine and evaluate ethical barriers related to prosthetic technology in our professional community. We aim to foster greater transparency, equity, and inclusivity throughout the development and translation of prosthetic technology in our community and in our own work.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Author contributions

HG: Writing – original draft, Writing – review & editing. CM: Writing – review & editing. KK-Q: Writing – review & editing. AM: Writing – review & editing. BN: Writing – review & editing. MF: Conceptualization, Supervision, Visualization, Writing – review & editing.

Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 29 January 2024
DOI 10.3389/fresc.2024.1353077

OPEN ACCESS

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RECEIVED 09 December 2023
ACCEPTED 16 January 2024
PUBLISHED 29 January 2024

CITATION
Maas B, Van Der Sluis CK and Bongers RM (2024) Assessing the effectiveness of serious game training designed to assist in upper limb prosthesis rehabilitation.
Front. Rehabil. Sci. 5:1353077.
doi: 10.3389/fresc.2024.1353077

Assessing the effectiveness of serious game training designed to assist in upper limb prosthesis rehabilitation

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Introduction: Controlling a myoelectric upper limb prosthesis is difficult, therefore training is required. Since training with serious games showed promising results, the current paper focuses on game design and its effectivity for transfer between in-game skill to actual prosthesis use for proportional control of hand opening and control of switching between grips. We also examined training duration and individual differences.
Method: Thirty-six participants were randomly assigned to one of three groups: a task-specific serious game training group, a non-task-specific serious game training group and a control group. Each group performed a pre-test, mid-test and a post-test with five training sessions between each test moment. Test sessions assessed proportional control using the Cylinder test, a test designed to measure scaling of hand aperture during grabbing actions, and the combined use of proportional and switch control using the Clothespin Relocation Test, part of the Southampton Hand Assessment Procedure and Tray Test. Switch control was assessed during training by measuring amplitude difference and phasing of co-contraction triggers.
Results: Differences between groups over test sessions were observed for proportional control tasks, however there was lack of structure in these findings. Maximum aperture changed with test moment and some participants adjusted maximum aperture for smaller objects. For proportional and switch control tasks no differences between groups were observed. The effect of test moment suggests a testing effect. For learning switch control, an overall improvement across groups was found in phasing of the co-contraction peaks. Importantly, individual differences were found in all analyses.
Conclusion: As improvements over test sessions were found, but no relevant differences between groups were revealed, we conclude that transfer effects from game training to actual prosthesis use did not take place. Task specificity nor training duration had effects on outcomes. Our results imply testing effects instead of transfer effects, in which individual differences played a significant role. How transfer from serious game training in upper limb prosthesis use can be enhanced, needs further attention.

KEYWORDS

prosthesis, rehabilitation, serious games, upper limb prosthesis, task specificity

Introduction

The ability to perform goal directed movements in daily life of individuals with upper limb absence is lower compared to an able-bodied person (1). The use of a state-of-the-art prosthesis should be able to restore at least part of the functionality, but rejection rates have not been reduced in the last two decades (2–7), despite substantial technological developments. A possible reason that prostheses do not provide functionality to an acceptable level might be due to low levels of prosthesis control, which in turn might result in rejection (2, 8). This conjecture is in line with the idea that using an upper limb prosthesis to perform a task is difficult because the prosthesis is controlled in a different way than a natural hand. Control can be practiced using serious game training, although in the current literature there is still a debate on what training is most effective (9–20). The current paper focuses on what type of serious game training could improve prosthesis control most effectively.

Current state-of-the-art prostheses consist of a bionic hand with multiple grip possibilities. Such a type of bionic hand is controlled by electromyography (EMG) signals produced by activity of the remnant muscles in the stump (i.e., a myoelectric upper limb prosthesis). The electric current that is produced by activating muscles can be used to operate the motors in the prosthesis hand and is called a myosignal. In most current-day applications of myoelectric upper limb prostheses muscle activity is measured by two electrodes attached to the skin above the flexors and extensors. To control the multi-grip hand of a myoelectric prosthesis in a most dexterous way two types of control are needed, proportional and switch control (21). Proportional control means that the amount of muscle activation is proportional to the speed with which the prosthetic hand opens and closes. Switch control means that when the user provides a correct trigger, for example a co-contraction (when the wrist flexor and extensor are activated at the same time following a simultaneous activation signal), the prosthetic hand switches from one grip type to another (for example from the tripod grip to the lateral grip). Most users of multi-grip prosthesis hands need to learn to master both proportional and switch control to use their bionic hand to its full potential; a skill that can be trained as shown by previous research (22–29). However, producing adequate myosignals is not an easy skill to learn (13, 14). Using serious games as training could provide interesting opportunities due to benefits such as more autonomy for users, more engagement, and less need for assistance of a therapist compared to conventional training programs.

Training

Serious games are most often computer games that can be used for education or training, with entertainment being a secondary purpose (30, 31). Benefits of using serious games for training are increased motivation compared to conventional training, inclusion of individualized and augmented feedback and a relative independence in executing the rehabilitation program (32, 33). Furthermore, serious games allow for training of the control of the prosthesis before the prosthesis is available. This enables users to start training early since it might take weeks or months before a prosthesis becomes available. Such training might have benefits since it could exploit neural plasticity processes at work after an amputation (Di Pino et al., 2009; Malone et al., 1984.). Hence, serious games seem to provide ample advantages over conventional training of prosthesis use, especially in the pre-prosthetic phase.

The serious games used in the domain of upper limb prostheses use myosignals to control the avatar in the game in a similar manner as these signals are used to control an actual prosthesis (11, 12, 33, 34–36). Therefore the assumption is that when one improves their myocontrol in the game, the learned skill will transfer to actual prosthesis use and as a consequence users will improve their ability to control the prosthesis. Even though several studies have been performed on serious game training for upper limb prosthesis in the past decade (11, 12, 16, 17, 19, 20, 29, 34, 37–39), the most effective game design to facilitate transfer from the game to actual prosthesis use has not been established. One reason for this might be that people differ in the way their individual motor learning processes are stimulated best as well as in their overall motor learning capacities (40–45). An important advantage of serious games is that in-game performance immediately affects the feedback provided to the user, hence these games are inherently individualized. Moreover, the different levels that can be presented allow for opportunities to tailor training conditions (e.g., variations in order of training tasks or type of feedback) to each individual to optimize transfer of training to actual prosthesis use. How the design of serious games affects transfer is currently unknown, hence, the current paper takes inspiration from motor learning principles to design games that may optimize transfer.

Motor learning: perception-action coupling

Previous research has shown that individuals differ in the performance on different myocontrol tasks (14). These results indicate that performance is specific for the relation between perception (i.e., the perceptual information exploited to perform a specific task) and action (i.e., the movements or muscle activations to complete a task) (46, 47). This means that when a new task has to be learned, a new coupling between perception and action has to be learned. Transfer of skill will only occur when the same perception-action coupling is present in both the training and the actual task.

A task-specific serious game for prosthesis control should resemble tasks that a prosthesis user might encounter in their day-to-day life, such as opening and closing of a prosthesis hand (i.e., proportional control) or switching between different grips (i.e., switch control) (10, 17, 21). Transfer effects were found previously after training with a task-specific serious game, but not after training with a non-task-specific serious game (9).

Until now, task-specificity in prosthesis use has only been investigated for proportional control. It is questionable what task-specific training means for switch control, in particular since Heerschop et al. has shown that different perception-action couplings seem to underly proportional control and switch control (14). Moreover, in a setting where both proportional and switch control were required, Tabor et al., 2018 suggested that transfer of skill does not depend on task-specificity but on the duration of the training period. Tabor et al. indicated that the short duration of the training in Van Dijk et al. was responsible for not finding transfer effects after practicing with the non-task-specific serious game. However, Tabor et al. did not test the transfer of training effects in actual prosthesis use since no pre-test post-test design was used and their analyses were restricted to the change in the myosignals. Hence, an experimental design in which task-specificity, duration of training, functional testing with an actual prosthesis and analyses of the myosignals are combined would enable us to make more decisive conclusions.

Research questions

Does the transfer from myocontrol training in a serious game to actual prosthesis use differ among three training groups (task-specific serious game, non-task-specific serious game, and control group), does the transfer differ between shorter and longer training programs, and do these factors interact? These research questions were asked for tasks in which only proportional control was required as well as for tasks in which both proportional and switch control were used. For the tasks in which both proportional and switch control were required it was also examined whether individual participants differed in learning.

Furthermore, we investigated whether during training the features of the myosignal, used to produce a switch, differed between both serious gaming groups, between the different training durations and how these factors interacted.

Methods

Ethical approval

The study was approved by the Local Ethical Committee of the department of Human Movement Sciences of the University Medical Center Groningen, Groningen, the Netherlands (local Research Registry number: 201900815). All participants received an information letter prior to the pre-test and were asked to sign an informed consent before the start of the experiment.

Participants

Participants were recruited from the student population of the University Medical Center Groningen and University of Groningen. Eligibility criteria were that they were able-bodied, right-handed, had corrected to normal vision, were free of any disorders to their arm or upper body and had no prior experience with a myoelectric prosthesis simulator. Handedness was tested using the Edinburgh Handedness Inventory (48).

Design

The experiment was conducted in 13 sessions which consisted of three test sessions (pre-test, mid-test and post-test) and ten training sessions, with five training sessions between each test session. Sessions were conducted on separate days with a minimum of three and a maximum of five sessions per week. Participants were randomly assigned using a random number generator to one of three groups: the Task-Specific (TS) group, the Non-Task-Specific (NTS) group and the Control (C) group. Participants all performed the same tests in the test sessions but the training differed based on their group.

A power analysis was performed with G*Power using the data from (9) to determine the number of participants needed. The analysis showed that to reach a power of 0.85 and an alpha of 0.05 the number of participants needed was 33.

Materials and procedures

For the pre-test, mid-test and post-test, participants used a myoelectric prosthesis simulator in order to closely resemble a below-elbow myoelectric prosthesis. The simulator consisted of an iLimb Ultra Revolution hand (2013, Touch Bionics, Össur) that was placed distal to the user's hand and was attached to a splint with an open cast wherein the participants' forearm could be placed. The splint was adjustable in length and the cast was attached to the participants' forearm using a leather sleeve which was closed using Velcro straps (26, 27). Two electrodes (13E200 electrodes, MyoBock, Otto Bock Healthcare products, Austria) were embedded in the Velcro leather sleeve around the arm. The electrodes were placed on the most prominent muscle bellies of the wrist flexors and extensors during contractions, which were found using palpation after instructing each participant to move their wrist. The location was marked with a waterproof pen in the pre-test and was repeated over the training sessions if the marking faded. Participants also took a waterproof pen home to be able to keep the marking visible. The electrodes measured muscle activation so that the prosthetic hand could be closed and opened by activating the wrist flexors and extensors respectively, which is similar to the control of an actual upper-limb prosthesis. In addition, by contracting the flexor and extensor at the same time in a short burst, i.e., a co-contraction, the prosthetic hand could change the grip types. The requirements for a correct co-contraction were that both contraction peaks of the wrist flexors and extensors needed to reach the threshold of 40% of maximum voluntary contraction and within 350 ms of each other.

To assess prosthesis control in the pre-test, mid-test and post-test the following tests were used: the Cylinder test (49), part of the activities of daily living (ADL) section of the Southampton Hand Assessment Procedure (SHAP (50);, the Clothespin Relocation Test (CRT (51); and the Tray test (52).

Cylinder test

The Cylinder test was the same test used by (9, 49). For this test, participants had to grasp three different wooden cylinders with the prosthesis simulator in five trials (order was block randomized), while the angle of the hand opening was measured by a goniometer (sampling rate 2000 Hz, Cermet PC300 potentiometer, Contelec, Switzerland). Two legs were attached to the goniometer, one to the housing and one to the slider. The leg of the housing was attached to the thumb of the prosthesis hand and the leg of the slider was attached to the index finger. The potentiometer was connected to an NI-USB 6009 data acquisition device (National Instruments Corporation, USA). The angle measured by the potentiometer was sent to a laptop. The wooden cylinders were 10 cm in height and had a diameter of either 2 cm, 4 cm or 6 cm. Before the test started, participants had to maximally open and close the prosthesis hand to calibrate the signals of the goniometer to the maximal and minimal aperture. Participants had to start with a closed prosthesis hand resting on a pressure sensor located to the right of the cylinder and at the closer edge of the table. They were then asked to grasp a wooden cylinder, which was placed in front of them at 21 cm from the edge of the table, lift a grasped cylinder about 5 cm, and place it back down. The cylinder was constantly within the participants' sight and the movement to grasp the cylinder was made parallel to the frontal plane. Therefore participants did not have to open the hand in order to see the cylinder, as sometimes is necessary in daily life when grasping objects. Participants were instructed to be as accurate as possible while grasping the cylinders and not focus on speed. The maximum opening angle of the hand was measured during the grasping of each cylinder.

SHAP

Two tasks from the ADL section of the SHAP were used: page turning and key turning. These tasks were chosen to push participants to learn difficult tasks in which they could improve their performance, although in daily life the prosthesis is not often used for these tasks. An important reason to use these tasks is that they enabled to test both proportional and switch control at the same time. For each task the prosthesis hand was initially placed in a tripod grip and it was at the participant's choice to switch to a lateral grip to complete the task. The tasks were to use the prosthesis hand to flip over a paper and to turn over a key in a lock, respectively. The completion time of each separate task was recorded by the participant by pressing the button on the timer (which was provided in the SHAP test) with the hand of the prosthesis simulator to start the task, and pressing the button again after they completed the task.

CRT

For the CRT the standard equipment was used which was a set-up with a vertical and a horizontal rod with six red clothespins, three on each rod. Participants started in a tri-pod grip and were asked to grab a clothespin from the vertical rod and place it back on the same rod. Subsequently, participants needed to switch to a lateral grip and were asked to grab a clothespin from the horizontal rod and place it back on the same rod. Then participants had to switch back to the tri-pod grip and grab the second clothespin on the vertical rod. This process was repeated until all six clothespins were grabbed and placed back. The total completion time of all six clothespins was recorded with a stopwatch by the researcher.

Tray test (52)

The set-up for the Tray test consisted of two shelves that were adjustable in height, a tray and a wooden cylinder (10 cm in height, 4 cm in diameter). Before the Tray test started, the top shelf was placed at the participant's shoulder height and the bottom shelf was placed at their waist height (55% body height). Then the cylinder (i.e., "object to be manipulated", see Figure 1) was placed on the top shelf and the tray on the bottom shelf. Participants started in a tri-pod grip and were asked to use the prosthesis hand to grab the cylinder and place it on the tray, then switch to a lateral grip and use both their prosthesis hand and intact hand to place the tray on the top shelf. The completion time of one single trial was recorded using the timer from the SHAP test. The Tray test was developed by Franzke et al. (52) and added to include a bimanual task, since it is known that most prosthesis users use their device mainly for bimanual tasks (4, 53).

In between test sessions, participants performed ten (two times five) training sessions using a serious game. The TS group and the NTS group trained myocontrol without the use of the prosthesis simulator, but in the same way as an actual prosthesis is controlled. The C group used a computer mouse and keyboard to play the games. Muscle activity was measured using electrodes (13E200 electrodes, MyoBock, Otto Bock Healthcare products,

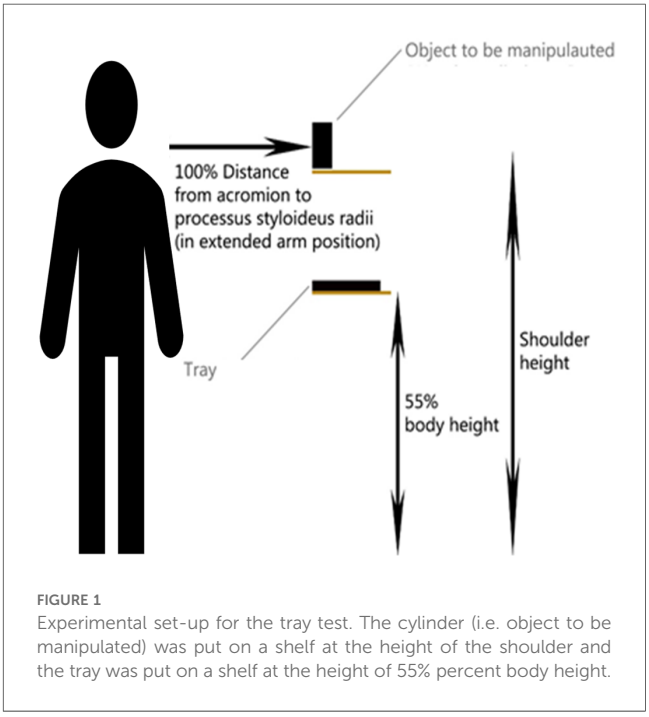

FIGURE 1
Experimental set-up for the tray test. The cylinder (i.e. object to be manipulated) was put on a shelf at the height of the shoulder and the tray was put on a shelf at the height of 55% percent body height.

Austria) that were placed, after cleaning and dampening with an alcohol swab, on the location that was marked in the pretest and were held in place using a sweatband. The electrodes had a gain setting which was set at 4 initially and was adjusted if necessary for each participant individually at the start of the training session. The electrodes were connected to a MyRio (National Instruments, USA), on which custom-built LabView soft-ware (National Instruments Corporation, USA) digitally filtered the signals (band filter, cut-off frequency 10 Hz; low-pass filter, cut-off frequency 35 Hz). After the electrodes were placed, the myosignal needed to be calibrated which was done by determining the amplitude of the myosignal maximum voluntary contraction (MVC). The myosignal was then scaled so that the minimum movement speed in the games was 10% of the MVC and the maximum movement speed was 75% of MVC (9).

The task-specific group

The game used in the training sessions of the Task-Specific group consisted of three parts with an overall objective to control an avatar, either a platform or a grabber, see Figure 2. The participant could move or open and close the avatar by using proportional control, meaning that the speed of the avatar was proportional to the amplitude of the myosignal. The avatar could switch from the platform into the grabber by using switch control (i.e., a co-contraction).

In the first part (see Figure 2A), the objective was to move the platform horizontally to follow a beam of light coming from a barrel located at the top of the screen. The direction in which the light beam would move was indicated by an arrow pointing either to the right or the left. The platform could move to the left or the right by activating the flexors or extensors of the wrist, respectively. The goal was to move the platform at such a speed that it stayed within the light beam until it reached the edge of the screen. When this was done correctly, lightning would appear and points would be scored, as can be seen in the figure.

In the second part (Figure 2B), the objective was to make a co-contraction in a set amount of time indicated by the hour glass at the top of the screen. If a correct co-contraction was made within the time limit, the platform changed into a grabber. If an incorrect co-contraction was made, the grabber would "break" which meant that the third part of the game could not be played. If this happened, the game would continue and show the third part with a block falling from the barrel, but the participant would be unable to open or close the grabber because it was "broken".

In the third part (Figure 2C), the objective was to use the grabber to catch a falling block from the top of the screen. The grabber could be opened and closed by activating the extensors and flexors of the wrist using proportional control. The participant needed to adapt the aperture of the grabber to the width of the blocks. If the grabber was opened 1.7 times the width of the block, the grabber would vibrate and shoot sparks (see bottom right of Figure 2C), as an indication that the hand opened too far. If the grabber opened 1.9 times the width of the block, the grabber would "break" and stop working. This particular feature was added to the game to guide participants to scale the aperture of their prosthesis hand to the object that

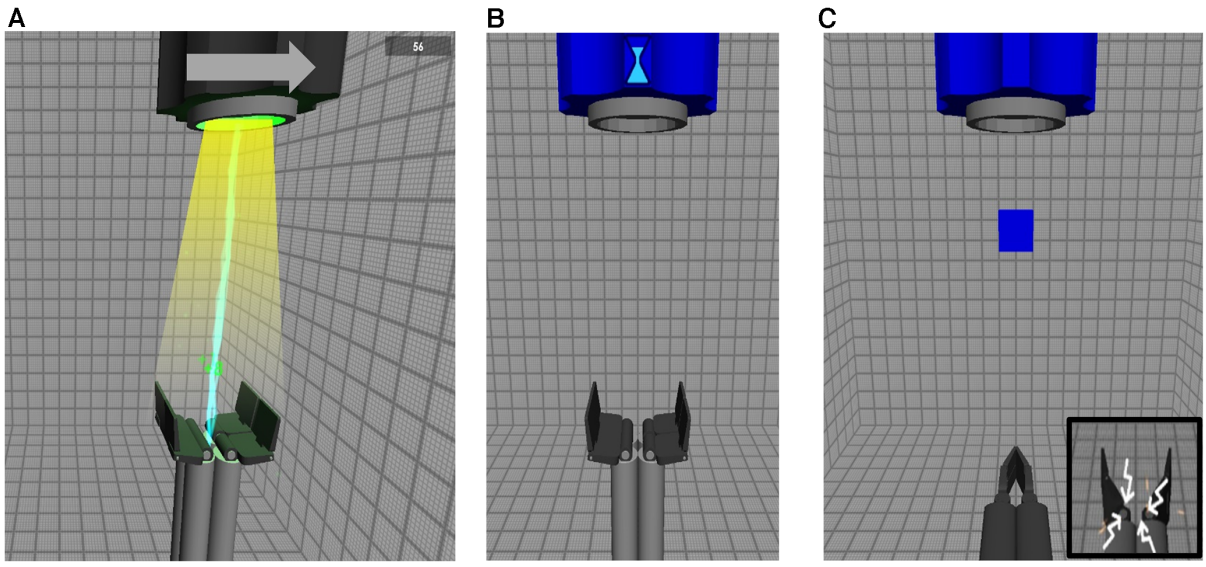

FIGURE 2
All three parts of the task-specific game. (**A**) The arrow at the top indicated whether the barrel at the top would move to the left or to the right. The platform, at the bottom, is controlled by the participant using myosignals and the participant is instructed to follow the light beam with the correct speed which made the lightning appear from the barrel. When the lightning appeared, the participants were scoring points shown in green overlapping the lightning. (**B**) An hourglass is shown at the top of the screen which is slowly depleting. This represented the amount of time the participants had to make a correct co-contraction. (**C**) After a correct co-contraction is made, the platform changes into a grabber that can open and close using the same myosignals. A block is dropped from the barrel at the top of the screen and the participants were instructed to catch the block by opening and closing the grabber. If the grabber would open too far (i.e. 1.7 times the width of the block) the grabber would shoot out sparks (bottom right).

should be grasped since this ability is an indication of better prosthesis control (see Bouwsema, Sluis, et al., 2010; Van Dijk et al., 2016b. The diameter of the falling blocks came in three sizes which were presented in random order. The blocks also varied in fragility, which was indicated by the number of cracks on the block. Blocks with more cracks would break more easily if they were grabbed with too much force. This required the user to vary in the closing speed of the grabber, since a higher closing speed implied a higher grasping force. After the third part the game would restart from the beginning.

Participants trained for twenty minutes in each training session. Three levels of the game were created to increase motivation of the participants. The levels increased in difficulty by moving the beam of light faster, dropping the blocks faster and making them more fragile. Participants trained in the first five training sessions for ten minutes with level one, then ten minutes with level two. In the last five training sessions they trained for ten minutes with level two and for ten minutes with level three.

Non-task-specific group

The game used in the Non-Task-Specific group was the Breakout game (Figure 3) as was used by Van Dijk et al., 2016b. The objective of the game was to keep the ball from hitting the ground by moving the paddle horizontally while at the same time hitting the blocks at the top of the screen. The paddle could be moved left and right by activating the flexors and extensors of the wrist, respectively, using proportional control. Subsequently, participants trained making co-contractions for three minutes. This was done by asking participants to look at the computer screen where their myosignal was shown and making as many co-contractions as possible. A correct co-contraction was indicated on the screen. Feedback on how to improve was provided by the researcher if necessary.

Participants trained for seventeen minutes with the Breakout game. The game consisted of three levels where the number of blocks increased with each level. During a training session, participants would complete all levels in ascending order and then start again at level one. In the seventeen minutes participants played each level two or three times.

FIGURE 3
The breakout game. The paddle at the bottom was controlled by myosignals of the flexor (for moving left) and the extensor (for moving right) of the wrist. The paddle was used to break the blocks at the top. Some blocks were stronger and needed to be hit twice, indicated by a darker color. There were three levels with each level increasing in number of blocks and stronger blocks.

Control group

Participants in the control group played both games from the TS and the NTS groups for 10 min each, but used a computer mouse and keyboard instead of muscle activation to control the avatar.

Data analyses

All outcome measures presented in this section were computed with customized scripts using Matlab (2020a, The Mathworks Inc., USA). The Cylinder test was analyzed in a similar manner as Van Dijk et al. 2016. To this end, the maximum opening angle of the hand during grasping was normalized based on the minimum and maximum angle of the hand. Then, a regression line was plotted through the normalized maximum opening angle data over the five trials for each cylinder size and test moment separately, for each individual. The slopes of these regression lines and the normalized maximum opening angles were used as separate outcome measures of proportional control.

During co-contractions to produce a switch, each of the two myosignals shows a peak. The phasing and amplitude difference of these two peaks in the myosignals during training of the TS and the NTS groups were used as outcome measures for switching control (21). Phasing was defined as the difference in time between the peak of the flexor and extensor of the wrist, respectively, where we considered a time difference between both peaks to be negatively related to skill level in switch control (21). The amplitude difference was defined as the difference in height of the peaks in the myosignal during co-contraction. The smaller the difference in peak amplitude, the higher the skill level in switch control (21). The average phasing and amplitude difference per participant was calculated for each training session. For the TS group the myosignal data of level two was used since that level was played in all training sessions. For the NTS group the three minutes of co-contraction training were used.

Statistical analyses

Statistical analyses were performed using SPSS (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp) and R (R version 4.3.1 (2023-06-16 ucrt), packages lme4, haven, ggplot2, dplyr, broom, plotrix and mice. Significance per effect and interaction was tested by comparing the model to a "null" model where that particular effect or interaction was removed. Testing the significance of the random effect was done by comparing the mixed effects model with a linear model using only fixed effects. Missing values were filled in R using multiple imputation using the "mice" package using predictive mean matching.

Proportional control (effects of transfer, duration and individual differences)

In separate analyses of the Cylinder Test, the slopes of the regression lines and the averages of the normalized aperture were tested for normality with the Kolmogorov-Smirnoff test. For each outcome measure, a linear mixed model analysis was performed with Group, Test Moment and Cylinder Size as fixed effects and individual participants as random effect. Also, interaction effects were tested in the model. We chose to analyze both outcome measures in order to be able to compare the results with Van Dijk et al., 2016b.

Proportional and switch control (effects of transfer, duration and individual differences)

After testing for normality with the Kolmogorov-Smirnoff test, a linear mixed effects model was chosen to analyze the CRT, SHAP (key turning and page turning) and Tray Test together. Group and Test Moment were taken as fixed effects and individuals were taken as a random effect. To this end, the results of the tests were first normalized using *z*-scores. Also, interaction effects were tested in the model.

Myosignals of switch control during training

After testing for normality with the Kolmogorov-Smirnoff test, a linear mixed effects model was chosen to analyze the amplitude and phasing differences with a fixed effect of Group and Training Session and a random effect of individual differences.

Results

Descriptives

Thirty-six participants were included, 13 participants were assigned to the TS group [4 males, average age 20.8 (SD 1.3) years, 91% right handed], 12 participants to the NTS group [3 males, average age 20.0 (SD 0.9) years, 84% right handed] and 11 participants to the C group [3 males, average age 21.1 (SD 1.4) years, 93% right handed].

Proportional control (effects of transfer, duration of training and individual differences)

The linear mixed effects model of the slopes of the regression lines from the Cylinder test showed a significant interaction between Group and Test Moment [$\chi^2(2) = 9.21$, $p = .01$]. As can be seen in Table 1, the direction of the slopes computed over the five trials was different per group for each separate test moment and differed also in direction over the test moments within each group (see Table 1 and Figure 4). We could not find a structure in the variation the directions or magnitudes of the slopes over conditions, making it difficult to interpret this interaction effect. Importantly, none of the effects of cylinder sizes were significant. No significant random effect of participants was found.

TABLE 1 Mean slope of the change in maximum aperture during pre-test, mid-test and post-test.

Group	Test	Slope[a] (SEM)
Task-specific group	Pre-test	0.90 (0.37)
	Mid-test	−0.85 (0.58)
	Post-test	0.05 (0.61)
Non-task-specific group	Pre-test	−0.54 (0.44)
	Mid-test	0.72 (0.57)
	Post-test	−0.40 (0.52)
Control group	Pre-test	−1.39 (0.68)
	Mid-test	0.34 (0.68)
	Post-test	1.10 (0.76)

[a]For presentation purposes, the slope (and the SEM) were multiplied by 100.

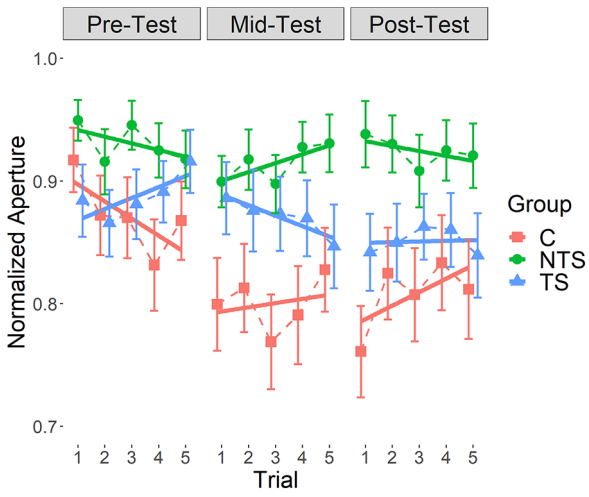

FIGURE 4
The normalized aperture collected during the cylinder test for each test moment, with standard error of the mean. Each data point is the mean across cylinder sizes per trial for each group individually connected with dashed lines, indicated with different colors and symbols. The continuous lines are the regression lines fitted through these data points, also for each group individually. The slopes of these lines are presented in Table 1. TS: Task Specific group; NTS: Non-Task Specific group; C: Control group.

The linear mixed effects model of the aperture data from the Cylinder test revealed a significant interaction effect between Group and Cylinder size [$\chi^2(4) = 58.3$, $p < .001$], see Figure 5A. Figure 5A indicated a large variation in maximum aperture among participants and this variation seemed less for the NTS group compared to the TS and the C group. Furthermore, we see a trend as expected, suggesting that several participants had a smaller maximum aperture for smaller objects indicating that they scaled their maximum aperture to the object sizes. However, this scaling of maximum aperture to object size was not present in all participants, a substantial group of participants always opened the hand maximally or close to maximal, independent of the object size.

We also found a significant main effect of Test Moment [$\chi^2(1) = 5.22$, $p = .02$], shown in Figure 5B, indicating that the maximum aperture decreased over the test moments.

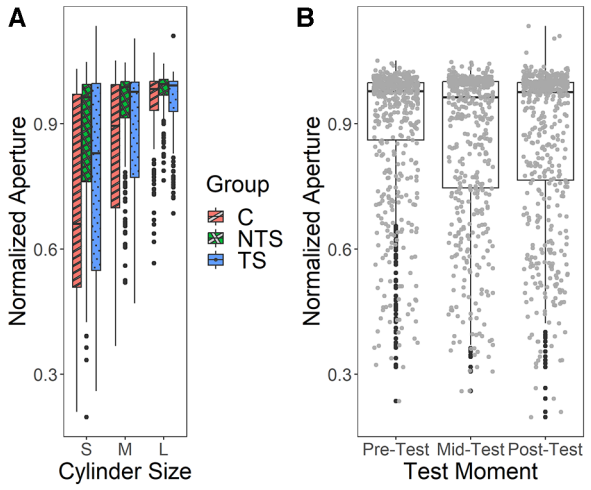

FIGURE 5
(A) The normalized aperture during the cylinder test for the different groups and cylinder sizes. S, small, M, medium, L, large, C, control, NTS, non-task-specific, TS, task-specific. (B) The normalized aperture of the Cylinder test for each test moment. Individual data points are presented in grey, outliers in black.

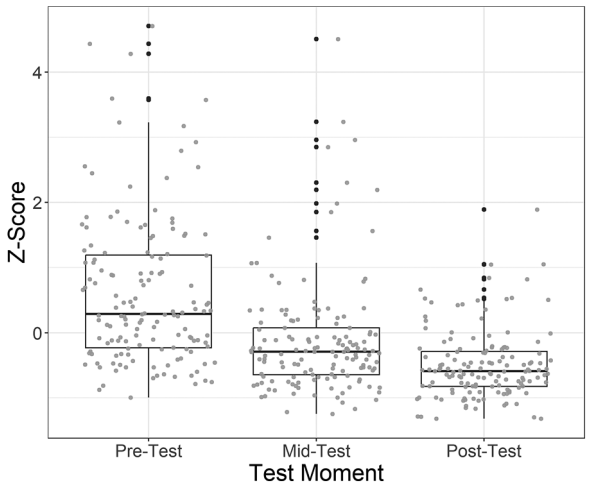

FIGURE 6
The main effect of test moment in the linear mixed effects model using the *z*-scores of the CRT, SHAP and tray test. Individual data points are represented in grey, outliers in black.

This demonstrated that over the testing the maximum aperture was adapted to the object size with the mid-test showing overall the smallest maximum aperture. As can be seen in Figure 5B, a few data points in the post-test exceeded a 100% opening, this was due to a calibration error. Interestingly, we saw a huge individual variation which was confirmed by an overall significant main effect of individual participants [$\chi^2(3) = 907.2$, $p < .001$], indicating that participants differed significantly. As the control group did not differ from both experimental groups, transfer could not be shown.

Proportional and switch control (effects of transfer, duration of training and individual differences)

The linear mixed effects model on the data of the SHAP, CRT and Tray test showed that there was a significant fixed effect of Test Moment [$\chi^2(2) = 48.44$, $p < .001$, see Figure 6], where scores improved over test moments. Figure 6 also shows the large variation among participants, which was confirmed by the significant random effect [χ^2 $(6) = 36.09$, $p < .001$]. None of the effects with Group were significant, implying that we could not show any transfer effect.

Switch control during training

The data about co-contractions of the ten training sessions showed missing values (33 out of 250 total training sessions) because some participants were at times unable to produce any correct co-contraction during a training session. In total 10 participants (3 in the TS group and 7 in NTS group) produced missing values variably across all 10 sessions (Supplementary Material Table S2).

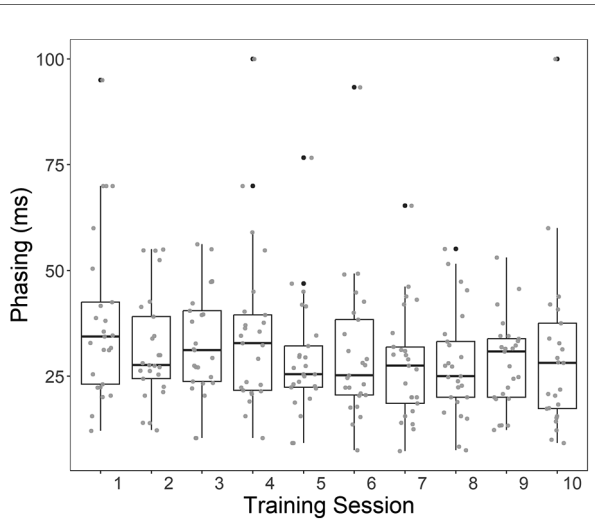

FIGURE 7
Boxplots of the phasing between the wrist flexors and extensors during co-contraction (i.e. the time difference between the peaks). Lower Phasing indicates better switch control. Individual data points are presented in grey, outliers in black.

For the amplitude differences between the two peaks of the co-contraction myosignal none of the effects were significant. For the phasing a significant effect of Training-session was found [$\chi^2(9) = 17.23$, $p = .045$], where participants improved over the ten training sessions (Figure 7). None of the effects of Group was significant. The results showed a significant effect for individual differences [$\chi^2(1) = 66.50$, $p < .001$], showing the high variation among participants.

Discussion

The current paper aimed to establish how the training of modern bionic prosthetic hands using serious games should be organized to foster transfer from training to actual use of the prosthesis. To this end questions regarding differences in transfer among three training groups, the number of training sessions and the interaction of these factors, as well as individual differences, were addressed. These questions were asked for tasks where only proportional control applied and for tasks where both proportional and switch control were required. Overall, we found no group effects indicating that the training groups did not differ from the control group. This implies that the training did not have an effect and the differences between test moments most likely resulted from a test-effect. Since we found no training effect, the research question whether longer or shorter duration of training leads to better transfer, could not be answered. The analyses on the changes in the myosignal features in switch control training showed an increase in the alignment in of the two peaks of the co-contraction, implying that learning over training occurred for switch control. Importantly, for all the outcome measures we found large differences among individuals.

The discussion of the results below will revolve around four issues: why we did not find training effects on transfer and on duration of training, what group effects we found and what those imply for proportional control, how our results regarding learning switch control relate to the current literature and the consequences of our findings about individual differences.

Transfer of training and duration of training

A transfer effect would imply that after a specific training, improvement in the test increases as a function of the training and not from the learning to perform tests. We did find differences between test moments in the slopes of the regression lines of the change in hand aperture in the Cylinder test, the absolute aperture and in the performance scores of the SHAP, CRT and the Tray test. However, for all these outcome measures there was no difference among the three groups on any of the three test moments. This finding implies that the control group improved as much in the tests as the two training groups, which is an indication that training did not add anything to the improvements in the test results. As such, the improvements seen over the test moments should be interpreted as a test-effect (i.e., improvement as a result of the fact that the tests have been practiced three times) and not as a result of the training. To be able to answer our research question on the duration of training, an effect of training needed to be present. However, since we found no training effect we could also not compare the differences in effect between a short and a long training duration.

Our question related to the duration of training was inspired by the work of Tabor et al. (2018) arguing that there might be beneficial effects of training of the myosignal for longer durations that usually is done in studies. They argue that these longer trainings could also lead to transfer of skill because the myocontrol skill could reach a higher level. However, in their study the transfer to actual prosthesis use was not explicitly tested. Therefore, we set out to test the interaction between the different training groups and duration of training and subsequently measure the outcomes in the functional use of the prosthesis. Importantly, our results regarding phasing in switch control during training are in agreement with the findings of Tabor et al. However, despite that we found an increase in the timing of the phasing of the two co-contraction peaks in the myosignals during training, we did not find a training effect of the two games. Hence, we concluded that the myocontrol skills in the two training games did not transfer to actual prosthesis use.

Interestingly, Van Dijk et al. found transfer results using comparable serious games as we did (9). They included four different groups; an Adaptive Catching group (comparable to our TS group), a Free catching and an Interceptive catching group (both comparable to our NTS group) and a Control group. In their study, only the Adaptive Catching group improved in prosthesis control after training which supported their claim that transfer was found due to the task specificity introduced in the game the Adaptive Catching group utilized. Therefore, the results of Van Dijk et al. were different than ours in that they found a transfer effect for the groups training the task-specific task. One explanation for this finding could be that the serious game used in the current study was slightly altered compared to theirs. In our version participants could only catch the falling block after a correct co-contraction was made, a requirement that turned out to be difficult for most participants especially in the first training sessions. This requirement was not incorporated in the game used by Van Dijk et al. which could have allowed their participants more practice with the falling block than participants in our study, most probably resulting in more task-specific training trials and perhaps therefor transfer. It might be that the game needs to be designed in such a way that performance in one type of training (proportional control) does not depend on the other performance (switching control) to ensure that both types of training are done.

Group effects

Interestingly, a few group effects were found. The Group and Test moment interaction on the slopes of the regression lines in the Cylinder test was found to be statistically significant. However, no systematicity in the interaction could be revealed and further interpretation is not possible. On the absolute aperture we found an interaction effect between Group and Cylinder size. It was surprising to see that the C-group performed quite similar as the TS group. Although the C-group trained playing both serious games and were exposed to the grasping task, the grabber was controlled with a computer mouse and keyboard presses. This implies that although the C-group did not train myocontrol, they received a lot of visual feedback (i.e., the same sparks presented in the TS group) on how their hand opening scaled to the object size as the TS group did. Furthermore, participants in the C-group were able to start catching the blocks in the task-specific serious game much quicker than participants in the TS-group. This might

be explained by the fact that the C-group did not have to make a correct co-contraction first, which was a difficult requirement for the TS-group. The C-group was exposed to the block catching mechanics consistently from the start. It might be that this feedback in training helped the C-group to scale the hand aperture of the prosthesis simulator in the test sessions.

With such a finding the question should be asked if this result has any clinical applications. For example, can participants train with a joystick and a version of this game to set up a perception-action coupling based on the primary information provided by the game? And might that training transfer to actual prosthesis control? It could be the case that primary information of a serious game can be picked up regardless if it is controlled by myosignals or a computer mouse and keyboard. This might be partially supported by another study where transfer is thought of as calibration of an existing perception-action coupling based on the information presented during training (46). It might be possible that playing the serious game trains the function that is being performed (grasping an object) and that this function is more primary than the movements with which this function is controlled. Whether this phenomenon could play a role in transfer from serious game training to actual prosthesis control cannot be answered with our results and needs to be investigated in the future.

Switch control

Like Tabor et al. we found that over sessions a general improvement in phasing occurred, although in our study the decrease in the time difference of the two myosignal peaks occurred in the first training sessions while participants in Tabor et al. mostly improved in the later sessions (see Figure 7). Note that also Heerschop et al. (2022) found that participants improved in their phasing mostly in the first five sessions after training with a serious game. As to why phasing improved but amplitude did not could partly be related to how the system detected correct co-contractions. For a correct co-contraction both peaks of the myosignal needed to be 40% of maximum voluntary contraction and within 350 ms of each other. These set of restrictions allow for much more variability in amplitude difference than in phasing because a change in amplitude difference does not have a direct effect on whether a co-contraction is correct or not, and the phasing does. In other words, participants can vary wildly in amplitude difference as long as both peaks are above 40% while varying in phasing can only be done up to a difference of 350. Therefore the nature of the control might push the neuromotor system to improve their phasing while amplitude differences are less restricted.

Individual differences

We found individual differences in almost all analyses using a linear mixed effects model, indicating a substantial amount of variation in the data that did not come from the experimental conditions. The fact that individuals can differ in both their initial conditions and in their improvement is not a new finding (e.g. (28, 40, 54, 55), however when developing training programs for upper limb prosthesis use it might deserve more attention. A first step might be to switch from analyses on mean behavior to appreciating individual difference. Although this entails methodological challenges that need to be overcome (cf. Anderson & Williams, 2022), the current findings indicate that this is the route to go. Such individual analyses might help in creating profiles or categories of participants based on their individual learning process. A next step could then be that a specific motor learning training could be created specifically tailored to each profile. Then individual differences would not be an additional factor of variability but a phenomenon that could be exploited to enhance learning for every type of motor learner. Anecdotally it was found in the current study that some participants could quickly learn to play the game while others had troubles with learning to play the game throughout the training sessions. What determined this difference would be an interesting topic for further research.

The inclusion of serious games in this process could be exceptionally beneficial, since the type of game can be tailored to the specific profile of a user. Note that perhaps a game can be used as a screening tool to distinguish different motor learning profiles early in the rehabilitation process. Moreover, a game can be designed to provide varied feedback or challenges to different performances, for instance, difficulty levels or type of feedback can be individualized. Including such a serious game would ensure that everyone would receive the type training best suited for them, without the need for therapists to create different training schedules per person.

Limitations

A few limitations in the current study can be identified. First, motivation during training could have been affecting the participants' performance. They were asked to train several sessions with the serious games. Based on informal conversations with participants it was found that the serious games in their current form were limited in their motivation to progress. In many cases, participants got demotivated over time and found themselves distracted while playing the games in the later training sessions. This could have influenced their performance in a negative way. Future studies should design serious games that have more to offer, such as different types of feedback, levels, competition systems or a leaderboard. This could increase motivation, engagement and hopefully this could lead to transfer to actual prosthesis use after training with a serious game. Second, the eligibility criteria could have affected the generalizability of our study. All participants were able bodied students recruited from the university, while a large part of the population of prosthesis users is much older. Able-bodied persons are not entirely comparable to prosthesis users, although research has shown that there are similarities in myosignals between able-bodied persons and prosthesis users (56). However, the difference in age could be a factor in the effectiveness of using a serious game as a training tool for prosthesis control, something that needs to be investigated further. Therefore, future studies should also include actual prosthesis users. Furthermore, a suggestion for real world

applicability of further research would be to study the ratio of successful and unsuccessful co-contractions. In addition, it would be interesting to explore whether providing participants with the option to adjust the co-contraction requirements to their personal preferences would result in improved outcomes.

Conclusions

We found that for proportional control there were differences in improvement between training groups. However, there was no structure found in these differences so we were unable to say which training group improved more than both other games. For tasks where proportional and switch control were needed and for only proportional control tasks we found that participants of all groups improved over the testing sessions. This indicated that not a transfer effect but a testing effect was found in the current study. For the learning of switch control we also found no difference between groups even though an overall improvement was observed. An important finding across all analyses was that significant individual differences were found throughout our study which not just means that motor learning is different for each person but that these individual differences should be taken into account in future studies in prosthesis use and in its translation to rehabilitation practice.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation. To receive the raw data, please contact the corresponding author.

Ethics statement

The studies involving humans were approved by Local Ethical Committee, Department of Human Movement Sciences, University Medical Center Groningen, The Netherlands. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

BM: Writing – original draft. CV: Writing – review & editing. RB: Writing – review & editing.

Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fresc.2024.1353077/full#supplementary-material

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 02 February 2024
DOI 10.3389/fresc.2024.1339856

OPEN ACCESS

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RECEIVED 16 November 2023
ACCEPTED 12 January 2024
PUBLISHED 02 February 2024

CITATION
Herrin KR, Kwak ST, Rock CG and Chang Y-H (2024) Gait quality in prosthesis users is reflected by force-based metrics when learning to walk on a new research-grade powered prosthesis.
Front. Rehabil. Sci. 5:1339856.
doi: 10.3389/fresc.2024.1339856

Gait quality in prosthesis users is reflected by force-based metrics when learning to walk on a new research-grade powered prosthesis

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Introduction: Powered prosthetic feet require customized tuning to ensure comfort and long-term success for the user, but tuning in both clinical and research settings is subjective, time intensive, and the standard for tuning can vary depending on the patient's and the prosthetist's experience levels.
Methods: Therefore, we studied eight different metrics of gait quality associated with use of a research-grade powered prosthetic foot in seven individuals with transtibial amputation during treadmill walking. We compared clinically tuned and untuned conditions with the goal of identifying performance-based metrics capable of distinguishing between good (as determined by a clinician) from poor gait quality.
Results: Differences between the tuned and untuned conditions were reflected in ankle power, both the vertical and anterior-posterior impulse symmetry indices, limb-force alignment, and positive ankle work, with improvements seen in all metrics during use of the tuned prosthesis.
Discussion: Notably, all of these metrics relate to the timing of force generation during walking which is information not directly accessible to a prosthetist during a typical tuning process. This work indicates that relevant, real-time biomechanical data provided to the prosthetist through the future provision of wearable sensors may enhance and improve future clinical tuning procedures associated with powered prostheses as well as their long-term outcomes.

KEYWORDS

gait, wearable, robotics, sensors, prosthetics, outcome measures

Introduction

There is mixed evidence on the benefits associated with the use of powered prosthetic feet compared with passive feet (1, 2). Some studies reported increases in preferred walking speed with the use of powered feet (3), while others found no differences in speed in the lab or in daily life (4). Some studies have shown benefits over passive prosthetic feet for select user groups in regard to metabolic cost (3, 5), while others found no difference (4). Some studies have shown improvements in symmetry (6), while others showed increased asymmetry with the use of a powered foot (7). Some studies reported improvements in pain scores with the use of a powered prosthesis (8), while others

noted subject-specific reports of an increase in pain (4). While the evidence is indeed conflicting, the outcomes reported in these studies have important implications for a patient's overall quality of life. The self-selected walking speed is known to have a heavy influence on a patient's quality of life and independence (9), metabolic cost influences a patient's mobility ability level (10, 11), and gait asymmetries are tied to longer-term secondary issues such as osteoarthritis and low back pain (12), which also influence quality of life. Efforts have been made to understand the unequal effectiveness of these prosthetic feet among patients, with some evidence pointing toward the lack of coordination between the human body and the device (1, 13), as well as the limitations in transferring energy from the prosthetic foot to the center of mass and the lack of proper tuning (13). Despite the mixed evidence on powered prosthetic feet, for any benefits to be realized during the use of a powered prosthetic foot, it must be appropriately custom-tuned to the individual with the amputation such that they are comfortable, the gait is as normative as possible, and it will allow for a long-term successful wear.

In clinical practice, prosthetists have a significant influence on the outcomes for individuals with lower limb amputation (14). Powered devices by nature are complex (5), and in research settings, it can take an engineer several hours to manually tune a device for each individual (14, 15). Tuning is an applied skill in which the prosthetist uses an observational gait analysis along with patient-reported feedback to customize the parameters selected for a specific individual (5); tuning also functions as an iterative process requiring collaboration between the patient and the prosthetist. Tuning in both clinical and research settings is subjective, time-intensive, and the standard by which the prosthetist tunes can vary depending on the experience levels of both the patient and the prosthetist (16). Furthermore, if the treating prosthetist is inexperienced with the technology, the tuning of powered, commercially available feet may require the involvement of a manufacturer representative with more extensive device knowledge (5), which may introduce barriers to initial access for the advanced technology and/or barriers to long-term functional gains in the event of changes in patient functional status. In the face of these challenges, a better understanding of the biomechanics underlying the tuning process could help clinicians identify specific areas to focus on, while also providing researchers with relevant data to study.

It is with this motivation that we studied the tuning process and subsequent metrics of gait quality associated with a research-grade powered prosthetic foot in both clinically tuned and untuned conditions. In this study, we investigate the ability of eight metrics of gait quality, as described below, to distinguish between a tuned and untuned powered prosthetic foot, with the goal of identifying the metrics capable of distinguishing between what is clinically known to be good and poor gait quality. We hypothesize that the metrics with a more comprehensive assessment of gait will have the highest probability of detecting the differences following tuning of a research-grade powered prosthetic foot, given the known influence of prosthetic componentry on the functional walking performance of a patient (17, 18).

Methods

Participants

The inclusion criteria for participants with amputation were as follows: aged between 18 and 69 years, at least 12 months post-transtibial amputation, classified as a K3–K4 walker, capable of walking with a prosthesis without assistive devices, and not using a solid ankle, cushion heel (SACH) foot as clinically prescribed. The participants were excluded if they met any of the following criteria: presence of dementia or inability to give informed consent, significant loss of hip, knee, or ankle joint motion, history of dizziness and/or balance problems, and currently pregnant.

Experimental procedures

The participants were fit with a commercially available tethered research-grade powered prosthetic foot (Humotech PRO-001, Humotech, Pittsburgh, USA) as described in (19–21) by a certified prosthetist. The foot was attached to the participant's current socket and aligned until both the user and prosthetist were satisfied with the alignment and motion in all planes, similar to the methods described by Ingraham et al. (22). While standing, the participants were instructed to push into the device to gain comfort and familiarity with the stiffness level of the foot prior to any tuning or walking. Retroreflective markers were placed on anatomical landmarks using a modified Helen Hayes marker set (23) as shown in Figure 1. The subjects then walked on a split-belt treadmill at a predetermined speed (1.0 m/s) while lower limb and trunk biomechanics were collected, first wearing their clinically prescribed passive prosthetic foot for approximately 1 min and switching to the powered prosthetic foot. The speed of 1.0 m/s was selected as it falls within the previously reported values for transtibial prosthesis users during treadmill walking (24). The walking trial in the passive prosthetic foot provided the opportunity for the participants to gain comfort walking on a treadmill at the selected speed, and the data are solely intended for the purpose of comparison. Lower body and trunk kinematics were collected using a 36-camera motion capture system (Vicon, Centennial, CO; Visual 3D, C-Motion, Germantown, MD). Ground reaction forces were recorded from under each foot using an instrumented split-belt treadmill (Bertec, Columbus, OH, USA) (25, 26). Synchronized, optical video data were also recorded in both the sagittal and frontal planes (Vicon Bonita cameras). During the walking trials with the powered prosthetic foot, the study team, which included an experienced certified prosthetist, iteratively tuned the foot according to current clinical practice methods that include an observational gait analysis and patient feedback, similar to the methods described by Ingraham et al. (5, 22). The participants were encouraged to try to maintain equal step lengths and stance times throughout the tuning procedure when possible. We used the default settings of the device with a correction for the body weight of the individual participant as the untuned baseline

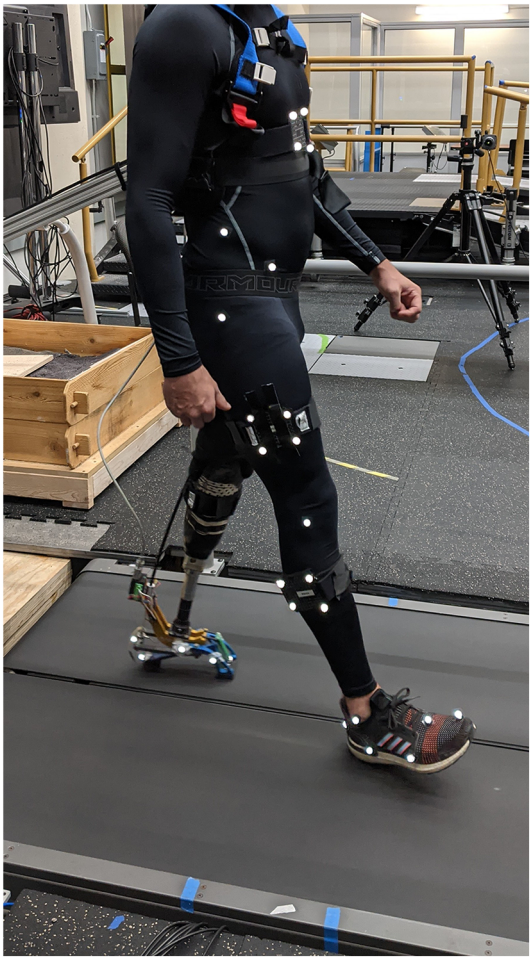

FIGURE 1
Showing experimental setup inclusive research-grade powered prosthetic foot, motion capture marker placement, and instrumented Bertec treadmill.

TABLE 1 Descriptions of the 15 tuning parameters that were altered during the tuning process.

Parameter	Parameter description
MaxDorsi (deg)	Changes the peak angle (in degrees) at which the device will exert peak torque.
MaxPlantar Dorsi (deg)	Changes the starting angle (in degrees) of the walking cycle.
MaxPlantar Plantar (deg)	Changes the angle (in degrees) of the end point of the plantarflexion part of the walking cycle.
HorizShift (deg)	Shifts the graph and all control points along the ankle angle axis (in degrees).
Shape Dorsi	Changes the control point for the dorsiflexion curve, the control point will move perpendicular to the straight line between the dorsiflexion starting and end points. Changes whether work done is positive or negative.
Shape Plantar	Changes the control point for the plantarflexion curve, the control point will move perpendicular to the straight line between the plantarflexion starting and end points. Changes whether work done is positive or negative.
Max Torque (Nm)	Changes the peak torque (in Newton-meters) value of the control curve during a walk cycle.
Min Torque Dorsi (Nm)	Changes the starting torque (in Newton-meters) of the walking cycle.
Min Torque Plantar (Nm)	Changes the torque (in Newton-meters) of the end point of the plantarflexion part of the walking cycle.
Toe_Clear (deg)	Angle targeted at the ankle during swing state.
Tau_thresh	The minimum requirement (in Newton-meters) that signals to the walking controller the beginning of a step. Raising the value will make steps start later because of the higher load requirement, and lowering the value will make steps start sooner but also be susceptible to false positives due to signal noise.
Plantar Trans Tor	Like tau_thresh, it is the minimum threshold of ankle torque (in Newton-meters) required to pass into the plantarflexion state.
Plantar Trans Pow Now	The minimum power output (ankle torque * ankle angle velocity) in the current timestep required to pass into the plantarflexion state.
Plantar Trans Pow Previous (W)	The minimum power output (ankle torque * ankle angle velocity) in the previous timestep required to pass into the plantarflexion state.
Plantar Trans T (sec)	The minimum length of time (in seconds) required to be in dorsiflexion before the transition to plantarflexion can be allowed.

condition. This trial was captured prior to any tuning and was deemed the untuned baseline condition. Following the baseline condition, we iteratively tuned the features of dorsiflexion stiffness, dorsiflexion and plantarflexion range of motion, timing of plantarflexion torque, and magnitude of plantarflexion torque. The participants were encouraged to share any information with the team at each parameter change. If a particular feature of the foot caused discomfort, it was immediately re-tuned in the next parameter change trial. For example, if the timing of plantarflexion torque was being tuned and the participant reported feeling uncomfortable due to dorsiflexion stiffness, this was immediately tuned in the next trial. Following each parameter tuning change, the participant was given approximately 30 s to acclimate to the change, and a 15 s walking trial was recorded. Due to the iterative nature of the tuning process, it was possible for some parameter changes to unintentionally have a negative impact on the participant's gait and/or comfort. It was also possible for a single parameter value to be trialed more than once by a participant, and features such as dorsiflexion stiffness and the timing of the plantarflexion torque may have been revisited multiple times.

There were 15 tunable parameters as described in Table 1 that were manipulated with an average of 8 ± 1 of the 15 parameters altered for each participant. All participants were able to walk in the baseline condition. An average of 24 ± 5 iterative parameter changes were required before the tuning process of the powered prosthetic foot was deemed complete by the full research team, which included the participant. The baseline and tuned parameter values are detailed in Supplementary Table S1 for each participant. The tuning process proceeded until the participant's gait was noted to be visually acceptable and the participant reported feeling comfortable, similar to other studies that have relied on user preference for the fine-tuning of powered foot parameters (4, 5, 22). Participant feedback was critically valued in the tuning process during this study. Visually, the team continually assessed for prosthetic gait deviations (i.e., vaulting, early heel rise, excessive varus/valgus, swing phase clearance,

swing phase whips, controlled plantarflexion at heel strike, appropriate positioning of the foot at heel strike), changes in spatiotemporal symmetry, perceived congruity of the device with the participant and limb positioning during the mid and late stance, and appropriateness of the plantarflexion torque timing with each parameter change similar to (15). Finally, the tuning process concluded when the study team determined that no other tuning changes would further improve the participant's gait visually or in comfort level and the participant confirmed that they felt most comfortable with the selected parameters; this trial was deemed the tuned condition.

Data processing and gait metrics

The Visual 3D software was used to filter data (fourth-order Butterworth with cut-off frequencies at 6 Hz for the force and marker data), as well as to calculate inverse kinematics and kinetics. Data were exported to MATLAB (R2022b, Mathworks, Inc.) for additional processing. To compare between the untuned and final-tuned condition, metrics that were calculated included unified deformable ankle–foot (UDAF) peak power, leg work, impulse symmetry in the vertical and anterior–posterior planes, positive ankle work, limb-force alignment (LFA), the gait quality index (GQI), the prosthetic observational gait score (POGS), and lateral sway. These metrics were selected to provide a broad range of perspectives in the field of biomechanics and gait analysis with some metrics more biomechanically comprehensive, some more computationally intensive, and some more simple in approach. Below is a description of how we defined these gait metrics.

Unified deformable ankle–foot positive work and peak power

The unified deformable (UD) method for determining joint power, particularly ankle power, has become a preferred method for determining the mechanics of a prosthesis. In this study, ankle work and peak power for both the prosthetic and sound sides were calculated using the unified deformable segment model method and normalized to participant body mass. A key benefit of the UD method is that it does not require the determination of a specific ankle joint, which is typically required in classical inverse dynamics equations. This makes it a useful method for characterizing the mechanics of a prosthesis, which lacks a specific axis of rotation. UDAF power was calculated in Visual3D for both the prosthetic and sound limbs, and the positive power near the end of stance (i.e., push-off) was integrated to determine push-off work. More details on the UD calculation can be found in (27).

Leg work

Leg work refers to the positive mechanical work done on the center of mass over a single stride and calculated using inverse dynamics based on the ground reaction forces collected on the instrumented treadmill with a custom code in Matlab, similar to the one used by Selgrade and colleagues (28), and was normalized to the body mass of the participant.

Impulse symmetry

Impulse symmetry was calculated using the following equation (29):

$$\text{Impulse symmetry} = \frac{\text{Impulse}_{\text{Sound}} - \text{Impulse}_{\text{Prosthesis}}}{\frac{1}{2}(\text{Impulse}_{\text{Sound}} + \text{Impulse}_{\text{Prosthesis}})}\ 100\%$$

A value of zero is indicative of complete symmetry between the prosthesis and sound side limbs. Positive values are indicative of larger impulses on the sound side, whereas negative values are indicative of larger impulses on the prosthesis side.

We show the force impulse symmetry index calculated from both the vertical and anterior–posterior components of ground reaction force.

Limb-force alignment

The LFA is a novel metric that is determined by dividing the angle of the sagittal plane ground reaction force by the angle of the trailing limb (30) at the time of peak force production as follows:

$$\text{Limb-Force Alignment} = \text{Trailing Limb Angle}/\text{GRF Angle}$$

A score of 100% is equivalent to complete the alignment between these two vectors. The alignment of these vectors is relevant because it allows for reduced joint moments and muscle forces and therefore a more effective mechanical advantage given the more efficient force application directed along the leg (31–34). The angle of the ground reaction force was calculated as the angle of the force vector in the sagittal plane at the time of peak anterior force. Vertical angles were set equal to zero, and thus greater angles are more anteriorly directed. Trailing limb angle was calculated at the same time point and defined as the sagittal plane angle of the fictional segment connecting the center of pressure to the retroreflective marker over the greater trochanter of the femur, as in (30), with 0 degrees indicative of vertical orientation and values greater than 0 degrees indicative of the greater trochanter being more anterior to the center of pressure.

Gait quality index

The GQI was calculated using the method reported in (35) and provides a summary score of gait quality, which encompasses kinematics, kinetics, and spatiotemporal measures, with scores closer to zero indicative of a more normative gait quality. The

GQI is an average of subscores calculated from a temporal-spatial quality index, a kinematic quality index, and a kinetic quality index, with scores closer to zero indicative of a normative gait pattern. The temporal-spatial quality index is composed of velocity, cadence, bilateral step and stride lengths, and step width, all normalized to height with the exception of cadence. The kinematic quality index is composed of the sagittal and frontal plane measures of the trunk, pelvis, and hip and the sagittal plane measures of the knee and ankle, and the kinetic quality index is composed of hip moments in the frontal and sagittal planes and knee and ankle moments in the sagittal plane.

The control population used for the comparison in the GQI calculation consisted of nine able-bodied individuals who were matched in terms of age, weight, and height (age 39.3 ± 16.8 years, weight 78 ± 12.8 kg, height 1.7 ± 0.1 m). These individuals provided written, informed consent to participate in a prior lab trial under the same protocol as the participants with amputation herein. Because the powered prosthetic foot did not have a conventional ankle joint, we used the same unified deformable segment model method (27) described above for the ankle moment calculations on both limbs for the control population. More details on the GQI calculation can be found in (35).

Prosthetic observational gait score

The prosthetic observational gait score (POGS) was calculated for the prosthetic side using the method reported in (36) with a score of 32 indicative of a poorer quality gait and a score of 0 indicative of a better gait quality. There are 16 aspects of a patient's gait that are scored as part of the POGS calculation including arm swing, vaulting in stance, lateral and anterior/posterior trunk lean, hip extension and flexion in stance and swing, knee extension in stance, knee flexion in terminal stance, initial swing and terminal swing, step symmetry, first ankle rocker, foot rotation at initial contact, width of the base of support, circumduction, and whips. The video footage of participants walking in the robotic foot was blinded and scored by a clinician with the aid of an on-screen digital goniometer for improved accuracy. The passive prosthetic foot condition was not blinded due to the visual nature of the metric, and again, it is provided for visual reference only.

Lateral sway

The lateral sway was calculated for each stride by taking the difference in the maximum and minimum values of the mediolateral trajectory of a sternal chest marker cluster in the coronal plane as in the following equation:

$$\text{Lateral sway} = \text{Maximum position- Minimum position}$$

Paired *t*-tests were completed with statistical software (Minitab 19.2020.1, State College, PA) to compare the impact of tuning on the gait metrics between the untuned and tuned conditions. We defined alpha 0.05 throughout our analysis. Metrics were additionally calculated for the clinically prescribed passive foot condition. Due to the numerous differences in the two styles of feet (i.e., wear/use time, inconsistent shoe use, foot length, tethered capacity), formal statistical comparisons are not provided and are shown in the analysis that follows for visual reference only.

Results

Participants

Two females and five males (age 37.0 ± 10.5 years, weight 81 ± 8.8 kg, height 1.8 ± 0.1 m) with unilateral transtibial amputation were recruited for this study and provided written, informed consent prior to participating in this study according to the Georgia Institute of Technology Institutional Review Board protocol H17290. The average time since amputation for all subjects was 4 years, 7 months ± 2 years. All participants wore total surface bearing socket designs with either pin, suction, or vacuum suspension systems. All participants had a passive, dynamic-response, and energy storage and return clinically prescribed prosthetic foot. Six of the seven participants were amputated on the left side.

UDAF positive work, peak power, and leg work

Tuning the prosthesis increased the prosthetic side positive ankle peak power ($t = -3.79$ $p = 0.009$) and ankle work ($t = -4.33$, $p = 0.005$), but did not increase the overall prosthetic side leg work ($t = -1.92$, $p = 0.103$) as depicted in Figure 2. No significant differences were observed between the tuned and untuned conditions for the sound side for ankle peak power and work ($t = 1.75$, $p = 0.131$ and $t = 1.45$, $p = 0.198$, respectively).

Impulse symmetry

We found significantly reduced symmetry indices in the vertical ($t = 3.97$, $p = 0.007$) and AP planes ($t = 3.62$, $p = 0.011$) in the tuned condition compared with the untuned condition as depicted in Figure 2, indicating an increased symmetry in the generation of force impulse on the ground.

Limb-force alignment

An increased alignment was observed in the limb-force alignment with tuning compared with the untuned condition on the prosthesis side ($t = 2.96$, $p = 0.025$) as depicted in Figure 3. These changes are attributed to the changes in the ground reaction force angle measured on the prosthetic side that was directed significantly more anteriorly ($t = -2.92$ $p = 0.027$) in the tuned condition compared with the untuned condition. No

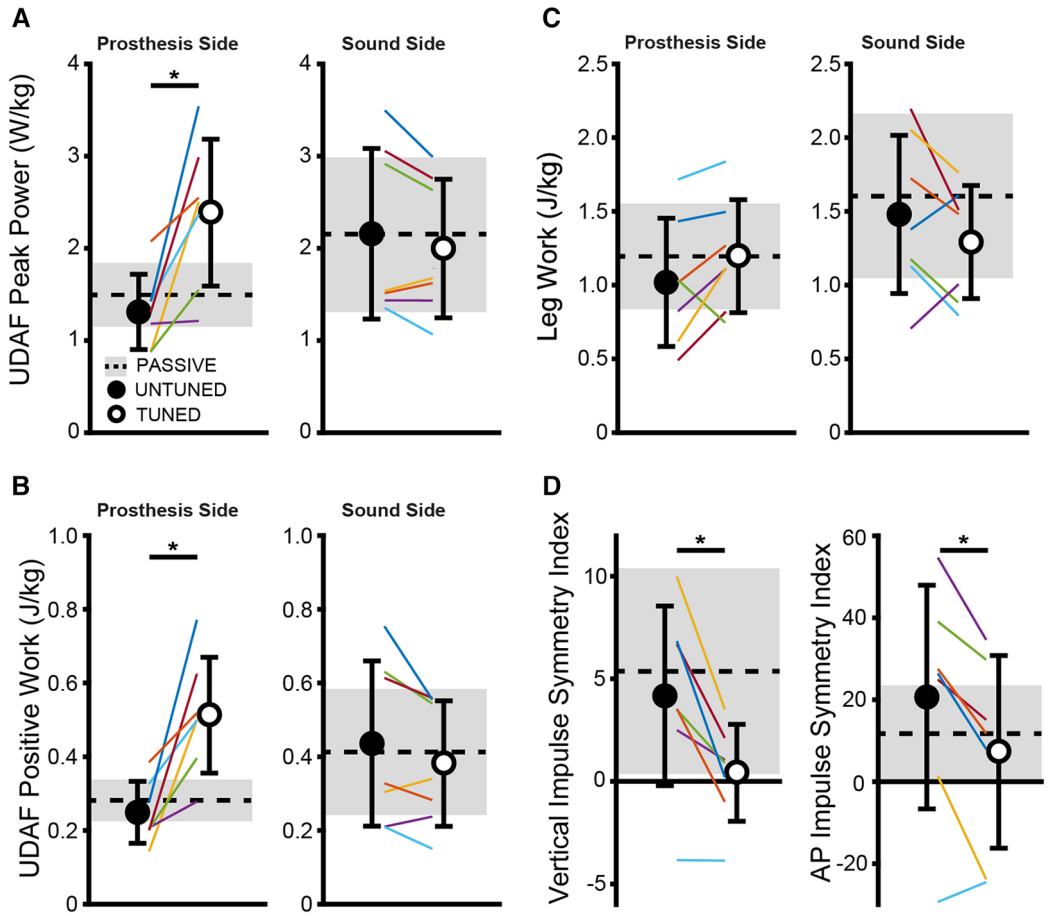

FIGURE 2
The tuned condition shows significantly greater ankle peak power (A) and positive work (B) on the prosthetic side compared to the untuned condition but does not alter metrics on the sound side or change overall prosthesis or sound side leg work (C). The vertical and AP impulse symmetry indices (D) improved with tuning of prosthesis compared to the untuned condition. Individually colored lines represent individual subjects. *indicates significant differences ($p < 0.05$) between the untuned and tuned conditions.

significant differences were found in the prosthetic side trailing limb angle between the tuned and untuned condition ($t = -1.49$, $p = 0.186$). No changes were observed in the limb-force alignment on the sound side with tuning ($t = 0.31$, $p = 0.768$).

GQI, POGS, and lateral sway

As depicted in Figure 4, no significant differences were seen between the tuned and untuned conditions for GQI ($t = 1.52$, $p = 0.18$), POGS ($t = 1.92$, $p = 0.103$), and lateral sway ($t = -0.01$, $p = 0.993$) between the tuned and untuned conditions. Cadence, step and stride lengths, and step width are provided for the untuned and tuned conditions in Supplementary Table S2.

Discussion

The tuning of a powered prosthetic foot is an iterative process that involves significant collaboration between the treating clinician and the patient. A clinician can visually assess a user's gait but also must be able to listen and translate a patient's perceptions into meaningful changes in the mechanical function and behavior of the prosthetic foot. The process is subjective, involves tradeoffs between the patient and clinician, and can necessitate a large amount of trial and error. This process may be exhausting and frustrating for a user and challenging for new and/or time-restricted clinicians. We investigated the response of different gait parameters as we tuned a research-grade powered prosthetic foot to see if any gait metrics could potentially be implemented in the future for a real-time, objective feedback during the tuning process to streamline the process for clinicians and patients alike.

Our data show an increase in positive ankle work and power, which indicates an improvement in the push-off capability following the tuning procedure, which was expected given that some of the parameters tuned by the research team are intended to affect the push-off power (e.g., max torque, min torque plantar). Notably, the peak prosthetic ankle power and work in the tuned condition become more similar in value to the sound side peak ankle power and work, indicative of more normative ankle kinetics after the tuning procedure. Improvements were also seen in the vertical and anterior–posterior impulse

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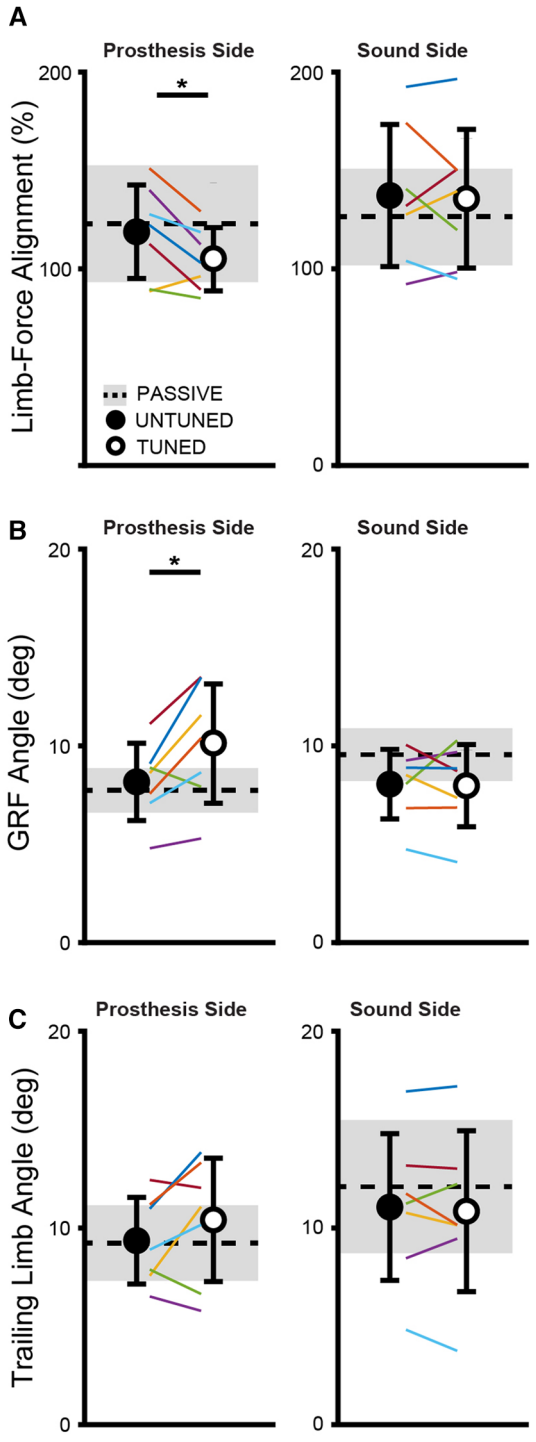

FIGURE 3
The tuned condition shows significantly enhanced alignment of the limb-force alignment (A) on the prosthetic side, which is the alignment between the angle of the sagittal plane ground reaction force (B) and the trailing limb angle (C). Changes in the limb force alignment are attributed to changes in the ground reaction force angle (B) and not the trailing limb angle (C). Individually colored lines represent individual subjects. *indicates significant differences ($p < 0.05$) between the untuned and tuned conditions.

symmetry indices as well as the limb-force alignment metrics with the tuned condition compared with the untuned condition. Several studies have shown asymmetrical loading patterns between the sound and prosthetic limbs in individuals with amputation (37–39), and asymmetrical loading during walking may be linked to osteoarthritis and associated pain (40). Interestingly, both impulse symmetry and limb-force alignment relate to the timing of force generation during walking, which is information not traditionally accessible to a clinician during the prosthetic tuning process. The timing of force generation is critical when tuning powered prostheses; if the plantarflexion torque is delivered at the proper time, it will act to push the user forward, allowing the user to convert the external assistance into forward propulsion (41). In contrast, if delivered at the wrong time, the torque may instead push the user upward and/or lead to walking instability. Access to the force timing data through the use of future technology, such as wearable sensors, could allow for several benefits during the tuning process, including more normative biomechanics on the prosthetic side as well as increased symmetry between limbs. In addition, access to these data in a real-time clinical setting may speed up the tuning process by allowing for fewer tuning iterations.

Despite improvements seen in prosthetic side ankle work with the use of the tuned prosthetic foot, we found no improvements in overall prosthetic side leg work. This could be attributed to the loss of work within the prosthetic side knee and hip and the relatively short period of time in which participants wore the research-grade powered prosthetic foot, which was a limitation in this study. Prior work has shown the importance of the coordination of the human body and machine interface when a patient is interacting with a powered prosthetic foot (1), and our data suggest a reduction or tradeoff in prosthetic side knee power occurring during the tuned prosthetic foot condition (see Supplementary Figure S1). Further, the literature is highly varied in the reported duration of acclimation (42–44) required for a new prosthesis, and additional time may be necessary when transitioning from a passive system to a powered system. Our acclimation time to each parameter change in this study was relatively short (less than 1 min); however, because each change was performed iteratively, the participants had walked on the foot for approximately 30 min when the final-tuned condition was selected. The participants in this study, who were all experienced users of passive prosthetic feet, may have benefited from the additional acclimation time to adequately harness the push-off power provided by the powered prosthetic foot. Along with acclimation time, an additional limitation of this study is that the research team included a single prosthetist; a more clinically diverse research team (i.e., additional health professionals such as physical therapists and physiatrists) may have reached a different optimally tuned condition.

Our other metrics of gait quality (GQI, POGS, and lateral sway) are largely influenced by an individual's kinematics rather than kinetics and showed no significant differences between the untuned and tuned conditions of the powered prosthetic foot.

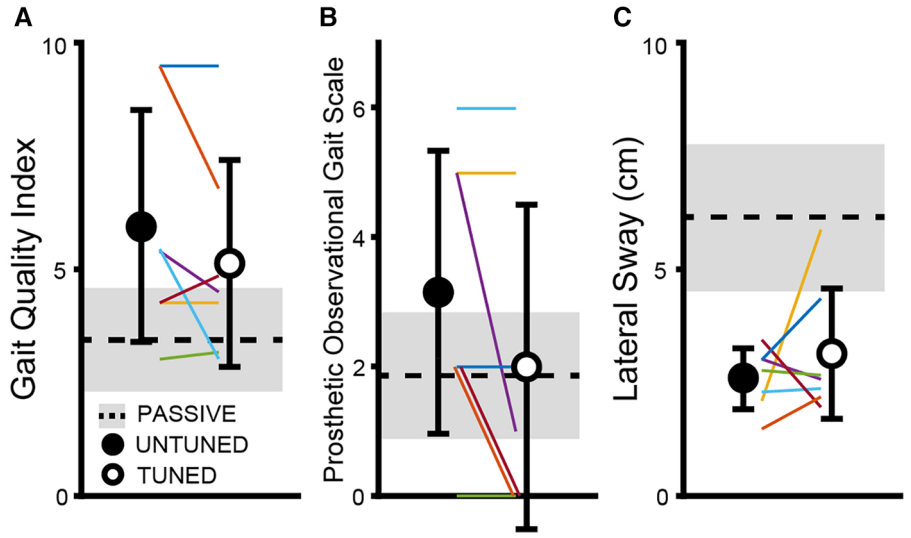

FIGURE 4
No significant differences are observed between the untuned and tuned conditions for the GQI (**A**), POGS (**B**,**C**), and lateral sway metrics. Individually colored lines represent the individual subjects.

The POGS is a clinical outcome measure that was initially developed in 2010 with the intent of providing clinicians with a more objective means for analyzing the changes in the overall gait. It includes visual assessment from the head (vaulting) and arms (arm swing) to all the joints of the lower extremities (36). However, there is no scoring aspect of the POGS that captures the differences between the powered and passive prosthetic feet—specifically, the ability to provide push-off assistance at terminal stance and varying range of motion (i.e., plantarflexion range of motion) and support provided during the mid- to late-stance transition. Although POGS evaluates the first ankle rocker of gait, it does not assess the second or third ankle rocker—key motions in powered prosthetic foot technology. In addition, some gait deviations assessed by POGS, such as vaulting and swing phase whip, may be less related to the tuning of a prosthetic foot and may instead be more reflective of learned habits or prosthesis alignment issues and thus not influenced by either good or bad tuning of a powered foot. Therefore, POGS may be inadequate to assess the nuanced changes in gait with the use of a powered prosthesis; updating the POGS outcome measure to include the assessment of the changes in gait that are common with the use of powered prosthetic technology may allow for greater discrimination during the use of varying powered technology. Alternatively, combining a secondary metric with the POGS that is sensitive to push-off kinetics may augment the POGS when assessing gait with the use of powered technology (45). The overall higher mobility level of the participants in this study may have influenced the lack of changes observed in lateral sway, POGS, and GQI. All participants were highly active, K3–K4 level walkers; this level of ability may allow them to adapt more readily to forced changes in their walking, particularly as it relates to kinematics. The task prescribed to the subjects was relatively simple—the subjects walked at a fixed speed constrained by the dimensions of the treadmill—so the difficulty associated with this task may not have been enough to impact the lateral sway (46). Further, all participants were able to maintain this walking speed in a safe manner throughout the duration of the trial even though the trajectory from the untuned condition to the final-tuned condition did not occur in a linear manner (i.e., some parameter changes made the performance worse). Notably, even when participants encountered parameter changes that were uncomfortable, all participants were able to continue walking.

Overall, our data show changes in the peak power, impulse symmetry, and LFA following the tuning procedure, forcing us to reject our hypothesis that more comprehensive metrics, such as GQI and POGS, would be able to detect changes following the tuning of a powered prosthetic foot. It is instead the metrics that focus on a single limb or the ankle joint alone that best reveal changes between the untuned and tuned conditions.

Our study is limited by several factors, including a relatively small sample size; a larger participant pool may have potentially shown some additional metrics to be of significant use for reflecting differences between the two conditions. Given that our selected foot is a tethered design, the tuning procedure was limited to the treadmill. Therefore, the results herein may not translate to tuning procedures conducted clinically, which typically occur in overground settings (47, 48). Further, we did not measure self-selected walking speed in the clinically prescribed prosthesis and required all participants to walk at a speed of 1.0 m/s for all trials. This set speed may have impacted our results and prevented the participants from naturally increasing their self-selected walking speed with the added push-off power from the device. While we had hoped that our selected clinical measure, the POGS, would reveal differences between the untuned and tuned conditions, it was not sensitive enough to

show differences between the two conditions. An additional clinical outcome such as the 2-min walk test or timed up and go test conducted at the baseline and final-tuned condition may have shown clinically meaningful improvements; however, the tethered nature of the foot prevented our ability to conduct such tests. Because of this, we are forced to rely on the biomechanical metrics (positive ankle work and power), but these metrics may not necessarily reflect true improved clinical outcomes. We therefore relied on user feedback and clinical judgment throughout the procedure, which mimics common clinical practices; however, common clinical practice standards would greatly benefit from the administration of clinically meaningful outcomes before and after tuning these types of devices. Importantly, the results shown here are focused on biomechanical optimization of tuning; further research is needed to understand if these improvements translate to improvements in other performance-based and patient-reported outcomes. The results shown here, if operationalized in the form of wearable sensors that provide and/or fuse kinematic and kinetic data in real-time, could underscore the value of the expertise required for tuning a prosthesis and may facilitate changes to current reimbursement practices. In addition, we selected a single walking speed of 1.0 m/s, which falls within previously reported values for transtibial prosthesis users during level walking (24) to ensure that our participants would be able to maintain the speed throughout the duration of the study. However, testing of additional higher speeds may have revealed more positive outcomes in some of our other selected metrics, especially given that some evidence suggests that walking speeds can increase with the use of powered feet (3). Finally, familiarity with the research-grade prosthetic foot over the length of the trial may have influenced the outcomes, and a repetition of the initial baseline untuned trial after the final-tuned trial would have allowed for comfort and familiarity to be removed as a variable associated with the final-tuned trial.

Interestingly, the device was tuned in this study through standard clinical methods, which only include observational gait analysis and participant verbal feedback. Despite the lack of real-time biomechanics data, significant improvements were noted in several metrics related to force timing. However, as previously noted, these improvements took approximately 24 iterations of parameter tuning to achieve. Our results suggest that this force timing information may be impactful in aiding clinicians in helping their patients achieve a more biomechanically normative and symmetrical gait. In addition, a real-time provision of this data in the future through the use of wearable sensors may augment the ability of a clinician to tune a prosthesis for an individual patient with greater ease and speed than relying on current methods alone.

Conclusion

Our expectation is that this work may extend beyond applications of powered feet in users with transtibial amputation and may also be useful during the prosthetic fitting process for users with transfemoral amputation as well as more commonly prescribed passive devices. The prescription and selection of prosthetic components, as well as the alignment process, are critical aspects for long-term user success and comfort. Indeed, it is known that the alignment of prosthetic components can have an influence on a patient's metabolic cost (11), their overall comfort within the prosthetic socket (49), and, more importantly, their gait and posture (17, 18). Relevant data provided to the prosthetist can enhance and improve the current clinical process associated with the fitting and delivery of prostheses, as well as their long-term outcomes. The metrics detailed herein are not exclusively designed for usage with powered devices and could be used to enhance the prosthetic tuning process and the overall clinical outcomes for patients.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the Institutional Review Board of Georgia Institute of Technology. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

KH: Data curation, Formal Analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. SK: Data curation, Formal Analysis, Investigation, Methodology, Visualization, Writing – review & editing. CR: Data curation, Formal Analysis, Investigation, Visualization, Writing – review & editing. YC: Conceptualization, Funding acquisition, Project administration, Resources, Supervision, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article.

This work was supported by a grant from the National Science Foundation, NSF-NRI 1734416.

Acknowledgments

The authors gratefully acknowledge the Georgia Tech EPIC and PoWeR labs for the use of their laboratory space for this experiment.

In addition, the authors acknowledge the efforts of Margaret Berry and Navya Katragadda in the processing of the Vicon data.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fresc.2024.1339856/full#supplementary-material

SUPPLEMENTARY FIGURE S1
UDAF, knee, hip, and leg power traces are shown for a representative subject for the prosthetic and sound sides.

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 07 February 2024
DOI 10.3389/fresc.2024.1331005

OPEN ACCESS

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RECEIVED 31 October 2023
ACCEPTED 23 January 2024
PUBLISHED 07 February 2024

CITATION
Leister KR, Burke SE, Kim JY, Duenas VH and Barreira TV (2024) Comparison of daily step count between the Fitbit Inspire 3 and the activPAL 3 in adults with transtibial amputation. Front. Rehabil. Sci. 5:1331005. doi: 10.3389/fresc.2024.1331005

Comparison of daily step count between the Fitbit Inspire 3 and the activPAL 3 in adults with transtibial amputation

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Introduction: Physical activity has significant positive effects on health. Accelerometers can be used to track daily physical activity. The Fitbit Inspire 3 is a commercially available health and fitness tracker, but its validity for tracking steps among individuals with transtibial amputation has not been examined. Therefore, the purpose of this study was to evaluate the concurrent validity of the Fitbit Inspire 3 for assessing free-living daily steps in adults with transtibial amputation.
Methods: Participants ($n = 79$) completed a general health survey and were provided with a Fitbit Inspire 3 and activPAL 3 accelerometer to wear concurrently for seven days in their home environment. Relationships between the activPAL and Fitbit Inspire 3 were examined using Pearson's Correlation. Paired samples t-tests, mean difference, mean absolute difference, and equivalence testing were used to compared daily step counts between Fitbit Inspire 3 and activPAL 3.
Results: Average step counts were 5,768 ± 3,750 (mean ± SD) and 4,674 ± 3,081 by the Fitbit Inspire 3 and activPAL, respectively. A high correlation ($r = 0.93$) but significant mean difference was found between the activPAL 3 and Fitbit Inspire 3 ($p < 0.001$). The mean absolute difference between the devices was 1,347 ± 1,184 steps. On average, the Fitbit Inspire 3 counted 1,094 ± 1,423 more daily steps than the activPAL 3. Equivalency could not be claimed between the devices.
Discussion: The Fitbit Inspire 3 counted more steps compared to the activPAL. Because of the significant mean differences and the large mean absolute difference between the devices, the activPAL 3 and Fitbit Inspire 3 are not interchangeable for estimating physical activity in individuals with transtibial amputation. However, due to the high correlation, the devices will produce similar classification rankings based on step counts.

KEYWORDS

physical activity, fitbit, activPAL, amputation, steps, validity

1 Introduction

Mobility and physical activity (PA) influence one's functional status, which is a primary determinant of independence and quality of life (1). This is especially true among lower extremity prosthesis users, who often present with reduced mobility post-amputation. After lower extremity amputation, mobility limitations inherent with limb

loss and prosthesis use typically manifest. Given these challenges, several studies have reported decreased PA among individuals with amputation (2, 3).

Decreased PA among this population is problematic because it may result in increased sedentary time and the development of additional comorbidities. As such, assessing daily PA and mobility within the home environment is a clinically relevant objective. Accurately measuring PA may help to identify an individual with transtibial amputation (TTA) who may be at risk for further health deterioration after surgery. This information may also inform prosthetic rehabilitation efforts.

Accelerometers are simple, innocuous, wearable devices that can be used to monitor daily levels of ambulatory PA, and, therefore, represent feasible tools for assessing physical behaviors (4). A device's cost, availability, and ease of use should be considered when selecting an accelerometer to monitor PA in special populations, including those with an amputation. In addition, the device's concurrent validity should be evaluated before interpreting data output that may be used to inform clinical decisions.

Concurrent validity is a subtype of criterion validity that assess the extent of the agreement between two measurements taken simultaneously (5). The primary objective of concurrent validity is to compare the results of a new device or measurement instrument with those of an already established criterion (6). Concurrent validity is an important aspect of psychometric evaluation that provides evidence for the accuracy and effectiveness of the new measurement instrument compared to an established criterion measure. Based on these factors, investigating concurrent validity is an important objective and should be prioritized.

The activPAL 3 is a thigh-worn, research-grade accelerometer that has been extensively used to measure physical behaviors and has demonstrated strong validity in capturing walking, sedentary behavior, and sleep activity measurements in adults (7, 8). The activPAL has also been used in studies featuring individuals with amputation (9–11). Deans et al. assessed the criterion-related validity of the activPAL for measuring various step parameters among a group of adults with unilateral lower extremity amputation (12). In the study, the activPAL's validity was compared with direct observation of steps taken during a series of laboratory-based tasks. Findings supported that the activPAL was a valid instrument for detecting purposive stepping among prosthesis users within a laboratory setting.

While the activPAL has been used in various studies featuring individuals with amputation, the validity of the commercially available Fitbit Inspire 3 has not been extensively tested in this group. The Fitbit Inspire 3 is a wrist-worn health and fitness tracker that can be purchased at many commercial retailers, making it more accessible to the general public than research-grade devices such as the activPAL. In addition to greater accessibility, the Fitbit Inspire 3 is water-resistant and less costly than many research-grade wearables. These features make the Fitbit Inspire 3 a more attractive option for individuals with amputation who are interested in monitoring their daily PA.

The Fitbit Charge 2, Fitbit Ultra, and Fitbit Inspire HR have been validated in various clinical populations, but step count accuracy assessment is currently limited among individuals with TTA (13–15). Assessing the Fitbit Inspire 3's concurrent validity among this group is essential because The Fitbit Inspire 3 represent a more feasible, cost-effective, and intuitive option for clinicians to assess rehabilitative outcomes outside of the clinical setting. The Fitbit Inspire 3 may also serve as a motivation tool for a prosthesis user interested in enhancing their daily PA.

Considering these potential benefits, this study aimed to investigate the concurrent validity of the Fitbit Inspire 3 for assessing free-living daily step count among individuals with TTA. To address this aim, daily step data collected via the Fitbit Inspire 3 were compared with the research-grade activPAL 3 accelerometer in adults with TTA.

2 Materials and methods

2.1 Participants

The study was conducted according to the Declaration of Helsinki. All participants provided written informed consent in accordance with Syracuse University's Institutional Review Board approved protocol. As part of a larger multicenter study, a cross-sectional design was used to investigate the concurrent validity of the Fitbit Inspire 3 to assess daily steps among individuals with TTA in their free-living environment. All participants were recruited from a network of orthotic/prosthetic clinics across the United States. Inclusion/exclusion criteria were determined after evaluating responses on a self-reported medical history questionnaire.

2.1.1 Inclusion criteria

All participants were between the ages of 18 and 80 and had a unilateral TTA. All participants had used a prosthesis for at least three months before beginning the experimental protocol. It is estimated that 28.2% of amputations occur at the transtibial level, making it the second most common amputation type, trailing only toe/partial foot amputation (33.2%) (16–18). Thus, recruitment was limited to individuals with TTA to increase general applicability and recruitment feasibility.

2.1.2 Exclusion criteria

Participants were provided with a list of movement disorders as part of a comprehensive medical history questionnaire and were asked to identify any movement disorders that may have drastically impacted their mobility (i.e., stroke, Parkinson's disease, spinal cord injury, traumatic brain injury). Participants who self-reported a movement disorder that may have impacted their mobility were excluded. This criterion was established as various movement disorders may further perturb gait biomechanics beyond what is typically noted with prosthesis use, which may confound device validation efforts (19, 20).

2.2 Study design

The experimental protocol was initiated during one encounter at the clinic where the participant regularly received prosthetic care. During the encounter, participants completed a general health survey and were provided with activPAL 3 and Fitbit Inspire 3 devices to wear concurrently for seven days in their home environment. Participants were asked to return the devices to the same location or send the devices via the postal service in a self-addressed stamped envelope.

2.2.1 Health screening

Baseline screening information including ethnicity, sex, age, height (measured with a stadiometer), weight (measured with an electronic scale), and BMI were computed for each participant. Participants were then asked specific questions pertaining to their amputation and current prosthesis (cause of amputation, amputation date, years of prosthesis utilization, age of current prosthesis). Information regarding the participant's type 2 diabetes status, including the date of diagnosis and treatment modality, was also collected during the initial screening. Information pertaining to each individual's type 2 diabetes status was collected as type 2 diabetes is the leading cause of all nontraumatic amputations and was therefore considered an important metric in which to classify the sample (21, 22).

2.2.2 activPAL 3 assignment

Each participant was provided with an activPAL 3 (software version 8.11.1.63, analysis algorithm CERA v1.3). Prior to assigning each activPAL, it was visually confirmed in the device's software suite that each device was using identical software and algorithm versions. The activPAL 3 is a triaxial accelerometer with a sampling frequency of 20 Hz and a dynamic range of ±2 gravitational units (8). The device weighs 20 g (5 cm × 3.5 cm × 0.7 cm) and estimates sitting, standing, walking, and daily steps using proprietary algorithms based on acceleration measurements. The activPAL was attached to the sound side (non-amputated) thigh with Hypafix tape, per Deans et al.'s recommendations (12). The activPAL's validity and accuracy for assessing walking activity among lower extremity prosthesis users has been evaluated and confirmed by Salih et al. (11).

2.2.3 Fitbit Inspire 3 assignment

Each participant was also provided with a Fitbit Inspire 3 (software version 1.188.58). Prior to assigning each Fitbit Inspire 3, it was confirmed that each device was using identical software versions. The Fitbit Inspire 3 is a microelectromechanical triaxial accelerometer that collects data in 60 sec epochs and converts raw acceleration information to step counts using proprietary algorithms. The device weighs 23 g (14 cm × 17.6 cm × 1.4 cm) and measures standard PA metrics, including step count, distance, active minutes, and sleep. Per the manufacturer's recommendation, the Fitbit Inspire 3 was worn on the non-dominant wrist. All devices were linked to a corresponding research account (rather than a personal account) only accessible to the researchers. Participants could, however, track their daily steps by viewing the device's output screen. Daily step count data recorded by the Fitbit Inspire 3 were extracted by logging into the research account and analyzing the software's daily step count log.

Various Fitbit models have been validated for overground walking among special populations. Fulk et al. reported that the Fitbit Ultra was a valid, low-cost option for measuring stepping activity in level, predictable environments for people with stroke (ICC = 0.73) (13). In a second study featuring individuals with obesity, McVeigh et al. found that the Fitbit Charge 2 had high correlation when compared with the ActiGraph GT3X + (r = 0.94) for assessing daily steps. These studies suggest that the Fitbit Ultra and Charge 2 may be valid tools for assessing step count in these clinical populations (14).

2.2.4 activPAL 3 and Fitbit Inspire 3 wear protocol

Written and verbal donning/doffing instructions were provided to each participant. Both the Fitbit Inspire 3 and activPAL 3 were simultaneously temporally synchronized. The same computer, power cord, and docking system were utilized to synchronize the devices within their respective software suites. After temporal synchronization, participants donned each device and were instructed to wear both devices at all times for seven days, only removing when in contact with water. A minimum of four days was necessary for participants to be included in the data analysis. activPAL 3 and Fitbit Inspire 3 data were manually matched for waking wear periods according to the activPAL 3 data. Thus, only valid wear time during waking hours simultaneously recorded on both devices was included for statistical analyses. Once the same periods were identified across the same days, each device's average step count value (per day) was compared. The daily step counts from at least four valid days were averaged, resulting in a single step count value for each participant for each device.

2.3 Statistical analysis

The relationships between the activPAL 3 and Fitbit Inspire 3 were examined using a Pearson correlation. Based on previously published standards, an observed correlation coefficient between 0.40–0.59, 0.60–0.79, and 0.80–1.00 was considered moderate, moderately high, and high, respectively (23).

A paired samples t-test was conducted to identify mean differences between the activPAL 3- and Fitbit Inspire 3-assessed step daily counts. Mean difference and mean absolute difference (MAD) were calculated to determine differences between methods.

Equivalence testing using the confidence interval method was conducted to compare activPAL 3 vs. Fitbit Inspire 3 daily step counts (24). Step values from the Fitbit Inspire 3 were statistically equivalent (at an $\alpha = 0.05$) if the 95% confidence intervals of the mean step value fell within the equivalence zone. The equivalence zone was set at ±10% of the mean activPAL 3 data.

A Bland-Altman plot was created by adding reference lines to a scatterplot. The mean difference and upper and lower reference lines representing the 95% confidence interval for the measures were represented in the plot. All statistical analyses were conducted using SPSS, and the level of significance was defined as $p < 0.05$.

3 Results

A total of 79 adults with TTA (58.1 ± 14.8 years; mean ± SD; 22 females) provided valid Fitbit Inspire 3 and activPAL 3 data; see Table 1 for summary demographics. A high correlation was found between the devices ($r = 0.93$) (Table 2). However, the paired samples t-test revealed a significant mean difference ($t_{78} = -6.83$, $p < 0.001$) (Table 2). The activPAL 3 estimated an average of 4,674 ± 3,081 daily steps, whilst the Fitbit Inspire 3 estimated 5,768 ± 3,750 daily steps. The mean difference and MAD between the activPAL 3 and Fitbit Inspire 3 were −1,094 ± 1,423 and 1,347 ± 1,184 steps, respectively (Table 2).

The 95% confidence interval for the discrepancy between the Fitbit Inspire 3 and activPAL fell entirely outside of the previously specified interval for equivalency, indicating that equivalency could not be claimed (lower 95% confidence interval: $t_{78} = 9.75$, $p < 0.001$; upper 95% confidence interval: $t_{78} = 3.91$, $p > 0.99$).

Bland-Altman plots comparing activPAL 3 to the Fitbit Inspire 3 yielded four data points outside the 95% limit of agreement (±1.96 SD) (Figure 1).

TABLE 1 Demographic and clinical characteristics of participants (mean ± SD).

Characteristic	Value
Total sample age (Years)	$n = 79$ 58.1 ± 14.8
Sex	22 female
Ethnicity	
Asian	2
Black or African American	12
Hispanic or Latino/a	2
White	63
Amputation cause	
Vascular Disease/Diabetes	39
Injury/Trauma	26
Infection (Without diabetes)	7
Cancer/Tumor	3
Congenital/Birth	3
Other	1
Body mass index	30.7 ± 6.0
Years of prosthesis utilization	11.8 ± 13.9
Age of current prosthesis	2.13 ± 1.9

4 Discussion

Regular PA is an important component of health and well-being, particularly in individuals who present with decreased mobility, such as individuals with TTA (2, 25). Accurately measuring PA is fundamental for evaluating a rehabilitative intervention's effectiveness and understanding mobility's impact on health outcomes. In this study, the concurrent validity of the Fitbit Inspire 3 health and fitness tracker step counts measure was evaluated. The activPAL 3 and Fitbit Inspire 3 were highly correlated, indicating that both devices are related and capable of measuring similar constructs. However, the statistically significant paired samples t-test and large mean difference and MAD between the devices indicate that the activPAL 3 and Fitbit Inspire 3 may not be interchangeable for measuring free-living daily steps for individuals with TTA.

The Fitbit Inspire 3 recorded an average of 1,094 more daily steps than the activPAL 3, suggesting it may be more sensitive when capturing steps. These findings imply that while both devices can measure PA, caution should be exercised when comparing step count data between the activPAL 3 and Fitbit Inspire 3 to inform clinical decisions.

The discrepancy of 1,094 steps represents a 23% difference between the two devices. When contextualizing this difference within the framework of established benchmarks for clinical significance, a 10% difference has conventionally been considered acceptable (26). However, it is crucial to recognize that the interpretation of what constitutes a clinically meaningful difference can vary based on the population's specific characteristics and the nature of the outcome measure.

From a clinical standpoint, a meta-analysis conducted by Kang et al. concluded that a 2,600 step per day increase may be expected with accelerometer-based PA interventions among healthy individuals without amputation (27). Applying this comparison to individuals with TTA is challenging given wide variability in daily steps among this population. Further, the relationship between health outcomes and daily step count remains unclear for individuals with TTA. Nevertheless, considering the percentage difference and observed improvements in interventions with accelerometers, a 1,094-step disparity may indeed be noteworthy.

The lack of equivalency between the devices also highlights the importance of selecting the appropriate device for individuals with TTA. While the Fitbit Inspire 3 may be a more user-friendly, cost-effective option, it does not appear to provide comparable estimates to the activPAL for this group. Clinicians should consider these differences when selecting an appropriate device for patients interested in monitoring their daily PA, as measurement inaccuracies could impact treatment outcomes.

TABLE 2 Analysis results for activPAL 3 and Fitbit Inspire 3 daily step count (mean ± SD).

Device	Mean step counts per day	Difference (steps)	Absolute difference (steps)	Correlation	t	p
activPAL 3	4,674 ± 3,081	−1,094 ± 1,423	1,347 ± 1,184	0.93	−6.83	<.001
Fitbit Inspire 3	5,768 ± 3,750					

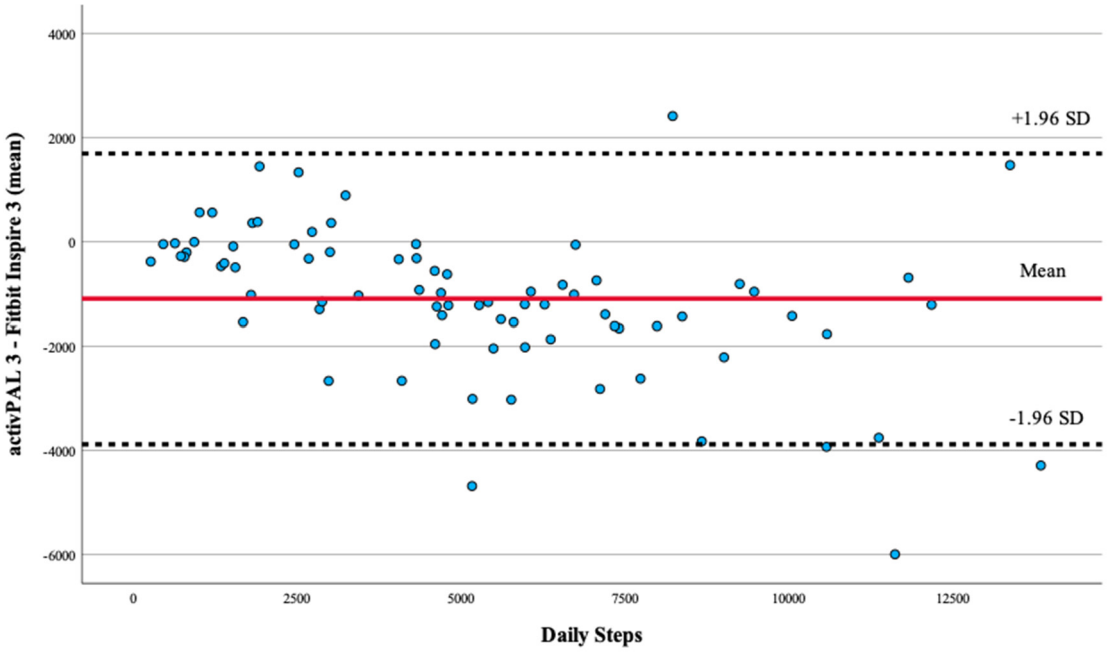

FIGURE 1
Bland–Altman plot of activPAL 3- and Fitbit Inspire 3-counted daily step count values. Bland–Altman plots comparing activPAL vs. the Fitbit Inspire 3 yielded four participant data points outside the 95% limit of agreement (±1.96 SD).

One possible explanation for the observed differences may be attributed to each device's anatomical placement. In the current study, the Fitbit Inspire 3 was worn on the non-dominant wrist, while the activPAL 3 was worn on the thigh of the non-amputated limb. Although wrist-worn devices are popular for monitoring daily steps due to their convenience and wide availability, they may overestimate steps in certain situations, such as when the arms are moving and the lower extremities are stationary or when an individual is handling or manipulating objects while in a seated or static standing position (28–31). These phenomena are highlighted by Nelson et al., who reported that wrist-worn accelerometers can overestimate steps during free-living conditions by 10%–35% when compared to devices worn on the lower body (31). In contrast, thigh-worn devices are less prone to such inaccuracies, as the lower extremity typically accelerates only during ambulatory activities (6, 32).

These observations are also supported by Montoye et al., who found that thigh-worn accelerometers more accurately predicted light- and moderate-intensity PA and sedentary behavior compared to wrist- and hip-worn devices (33). In the study, participants completed three sedentary and 10 non-sedentary activities for 3–10 min each. Direct observation was used as the criterion measure of each activity, and a machine learning model was created for each accelerometer to predict the PA intensity category. The sensitivity and specificity were higher for the thigh-worn device compared to the wrist- and hip-worn accelerometers (>99%). Ultimately, the thigh-worn device provided a more accurate PA assessment under all conditions, while all other accelerometers overestimated PA.

Biomechanical differences often observed among individuals with TTA may offer a second potential explanation for the discrepancies noted between the devices. It widely accepted that individuals with TTA face unique challenges, including decreased mobility, increased energy expenditure, and altered gait biomechanics (34–36). Individuals with TTA often walk at a slower cadence than healthy individuals, which may exacerbate discrepancies between wrist- and thigh-worn devices (37). Hermodsson et al. reported that individuals with TTA secondary to vascular and traumatic etiology had significantly reduced walking speeds compared to healthy individuals during an overground walking test on an instrumented force platform (vascular: 0.85 ± 0.2 m/s; trauma: 0.99 ± 0.2 vs. healthy: 1.42 ± 0.2 m/s) (37). Given the decreased gait velocities exhibited by individuals with TTA, selecting an accelerometer that can capture slower movement signals is essential. The activPAL has been shown to be superior for capturing steps performed at a slower cadence, which may make it a more accurate option for tracking steps in individuals with TTA (6, 38, 38).

The current study had several strengths including a relatively large sample size ($n = 79$), which permits a more diverse representation within the study group. By including a diverse group of individuals with TTA, the study becomes more generalizable to the broader population of individuals with TTA. This, in turn, enhances the external validity of the research, allowing the findings to be applied to a wider range of individuals with similar characteristics. The study's real-world setting represents a second strength. Capturing daily step count within the participant's home environment enhances the study's

ecological validity, as participants may be more likely to engage in their typical daily activities and routines when monitored at home. This captures an individual's natural behavior, providing a more accurate representation of their mobility profile.

Although carefully conducted, there are noteworthy limitations to the current study. One potential limitation is that the sample was only comprised of individuals with TTA. Future studies featuring individuals with amputations at other levels (transfemoral, hip disarticulation, etc.) are needed to determine the accuracy and equivalency of the activPAL 3 and Fitbit Inspire 3 for individuals with amputation levels other than transtibial. The study did not explore the potential factors that could contribute to the differences in step count estimates between the two devices, such as differences in placement, attachment, or algorithm sensitivity. Future studies should be conducted to examine these factors. Lastly, a direct measure of steps was not utilized amongst the sample and therefore the true daily step counts are unknown. While direct measures are not always feasible for all free-living activities, they can provide valuable insights into the device's accuracy, especially during shorter periods when direct step measurement is reasonable. Despite this limitation within the current study, the activPAL 3 has been shown to be accurate in short bouts of PA in this population in previous research (11, 12).

Overall, the findings of this study suggest that individuals with TTA should be cautious when selecting and interpreting data from commercially available wearable activity monitors. Although these devices can be valuable tools for monitoring PA and tracking mobility progress, inter-device comparisons may be nuanced and not always provide accurate and/or interchangeable data. This study highlights the importance of acknowledging the incongruities between commercially available and research-grade accelerometers.

5 Conclusions

The present study provides important insights into the validity of the Fitbit Inspire 3 for estimating step count for individuals with TTA. While a strong relationship was found between the activPAL 3 and Fitbit Inspire 3, the Fitbit Inspire 3 likely counted more daily steps relative to the research-grade activPAL 3, indicating that the devices may not be equivalent or interchangeable in this population. Therefore, researchers and clinicians should consider these findings when selecting a device to monitor step count for individuals with TTA and interpreting data obtained from the Fitbit Inspire 3.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Syracuse University Institutional Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

KL: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. SB: Conceptualization, Formal Analysis, Methodology, Supervision, Writing – review & editing. JYK: Formal Analysis, Supervision, Writing – review & editing. VD: Formal Analysis, Supervision, Writing – review & editing. TB: Conceptualization, Formal Analysis, Project administration, Resources, Software, Supervision, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article.

This research was supported by grant funding through the Bernard D. and Louise C. Rostker Institute for Veterans & Military Families Dissertation Research Fund.

Acknowledgments

The content of the manuscript has previously appeared online as part of K. Leister's dissertation.

Conflicts of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 28 February 2024
DOI 10.3389/fresc.2024.1290092

OPEN ACCESS

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RECEIVED 06 September 2023
ACCEPTED 14 February 2024
PUBLISHED 28 February 2024

CITATION
Tacca JR, Colvin ZA and Grabowski AM (2024) Low-profile prosthetic foot stiffness category and size, and shoes affect axial and torsional stiffness and hysteresis.
Front. Rehabil. Sci. 5:1290092.
doi: 10.3389/fresc.2024.1290092

Low-profile prosthetic foot stiffness category and size, and shoes affect axial and torsional stiffness and hysteresis

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Introduction: Passive-elastic prosthetic feet are manufactured with numerical stiffness categories and prescribed based on the user's body mass and activity level, but mechanical properties, such as stiffness values and hysteresis are not typically reported. Since the mechanical properties of passive-elastic prosthetic feet and footwear can affect walking biomechanics of people with transtibial or transfemoral amputation, characterizing these properties can provide objective metrics for comparison and aid prosthetic foot prescription and design

Methods: We characterized axial and torsional stiffness values, and hysteresis of 33 categories and sizes of a commercially available passive-elastic prosthetic foot model [Össur low-profile (LP) Vari-flex] with and without a shoe. We assumed a greater numerical stiffness category would result in greater axial and torsional stiffness values but would not affect hysteresis. We hypothesized that a greater prosthetic foot length would not affect axial stiffness values or hysteresis but would result in greater torsional stiffness values. We also hypothesized that including a shoe would result in decreased axial and torsional stiffness values and greater hysteresis.

Results: Prosthetic stiffness was better described by curvilinear than linear equations such that stiffness values increased with greater loads. In general, a greater numerical stiffness category resulted in increased heel, midfoot, and forefoot axial stiffness values, increased plantarflexion and dorsiflexion torsional stiffness values, and decreased heel, midfoot, and forefoot hysteresis. Moreover, for a given category, a longer prosthetic foot size resulted in decreased heel, midfoot, and forefoot axial stiffness values, increased plantarflexion and dorsiflexion torsional stiffness values, and decreased heel and midfoot hysteresis. In addition, adding a shoe to the prosthetic foot resulted in decreased heel and midfoot axial stiffness values, decreased plantarflexion torsional stiffness values, and increased heel, midfoot, and forefoot hysteresis.

Discussion: Our results suggest that manufacturers should adjust the design of each category to ensure the mechanical properties are consistent across different sizes and highlight the need for prosthetists and researchers to consider the effects of shoes in combination with prostheses. Our results can be used to objectively compare the LP Vari-flex prosthetic foot to other prosthetic feet to inform their prescription, design, and use for people with a transtibial or transfemoral amputation.

KEYWORDS

prostheses, amputation, prescription, rehabilitation, materials testing

1 Introduction

To walk, people with a transtibial or transfemoral amputation typically use passive-elastic prosthetic feet, which are comprised of carbon fiber or fiberglass, and allow elastic energy storage and return during the stance phase. The mechanical properties of passive-elastic prosthetic feet, such as stiffness and hysteresis, affect kinematics, kinetics, muscle activity, metabolic cost, moments acting on the residual limb, and user preference during walking (1–9). Yet, these mechanical properties are not typically reported by the manufacturer. Instead, prosthetic manufacturers use numerical stiffness categories (e.g., 1–9) to delineate each prosthesis where a higher numerical stiffness category corresponds to a stiffer prosthesis and prescribe stiffness categories based on the user's body mass and activity level (10). However, stiffness categories and differences in stiffness values between categories are not consistent across manufacturers or between models (11, 12). Current prosthetic prescriptions rely on manufacturer recommendations and subjective feedback from prosthetists and people with amputation. Therefore, to better inform prosthetic foot prescription, objective values for mechanical properties of prosthetic feet such as stiffness values and hysteresis should be provided. These values will inform dynamic function and can be implemented in future prosthetic designs.

Previous studies have characterized passive-elastic prosthetic feet mechanical properties (11–20) and found that force-displacement and torque-angle profiles are well described by linear (13, 16) or curvilinear (11, 15, 17–19) relationships, which are used to calculate axial (kN/m) and torsional (kN*m/rad) stiffness values. These studies provide axial stiffness values for compressive forces applied to a prosthetic foot heel, midfoot, and forefoot, which affect the biomechanics of the user during walking (1). For example, a study that varied the heel and forefoot stiffness values of an experimental passive-elastic prosthetic foot found that greater heel stiffness values resulted in a higher ground reaction force loading rate, greater knee flexion angle in early stance, and greater knee extension moment, and that greater forefoot stiffness values resulted in a greater knee extension angle in mid-stance and greater knee flexor moment during walking at a range of speeds (0.7–1.5 m/s) for people with unilateral transtibial amputation (1). Therefore, determining the heel, midfoot, and forefoot axial stiffness values for a passive-elastic prosthetic foot would provide objective values for comparing prosthetic feet and better predict the dynamic effects of using different stiffness passive-elastic prosthetic feet on walking biomechanics.

Characterizing torsional stiffness values of passive-elastic prosthetic feet can provide additional information to derive function and can be compared to the biological ankle-foot system. A biological ankle can behave mechanically like a torsional spring and damper system during walking at 1.2 m/s (21) and typically has a curvilinear torque vs. angle relationship during the stance phase so that the torsional stiffness increases with greater ankle dorsiflexion (concave shape) (21, 22). Some previous studies have characterized torsional prosthetic foot stiffness properties (6, 16, 22–24). One method of characterizing the torsional stiffness of prosthetic feet is to calculate the average torsional stiffness when dorsiflexion and plantarflexion torques are applied to the prosthesis by a materials testing machine (16). Another method to characterize the torsional stiffness of prosthetic feet is to measure the ankle torque and angle during the stance phase of walking and determine how well or if the torque-angle curve matches the concave shape of a biological ankle torque-angle curve (i.e., Index of Anthromorphicity) (22). In addition, another previous study found that prosthetic foot length affects torsional stiffness values since longer feet have a longer moment arm and have greater torsional stiffness values than shorter feet for a given applied force and angle change (24).

Furthermore, the prosthetic foot energy returned during the push-off phase of stance depends on stiffness values (3) and hysteresis, or energy loss (17, 25). Passive-elastic prosthetic foot energy return is related to the energy stored and can affect walking biomechanics, where lower energy return can result in decreased affected leg work during push-off, increased unaffected leg work during collision, and increased hip work (7, 26). Hysteresis has been reported for some passive-elastic prosthetic feet (13, 17–19) and likely depends more on material properties rather than stiffness categories of prosthetic feet (13). Ultimately, characterizing the passive-elastic prosthetic feet axial and torsional stiffness values and hysteresis will better inform prosthetic prescription and function by allowing objective comparisons between different prosthetic foot models, stiffness categories, and sizes.

Most people with a transtibial or transfemoral amputation wear shoes over their prosthetic foot during walking and this likely affects stiffness values and hysteresis compared to prosthetic feet alone (27). Major et al. found that adding shoes to prosthetic feet resulted in lower axial stiffness values at the heel and midfoot but not at the forefoot compared to prosthetic feet alone (27). Moreover, Major et al. found that adding shoes to prosthetic feet resulted in greater hysteresis compared to prosthetic feet alone (27). Since adding shoes to prosthetic feet changes the mechanical properties compared to prosthetic feet alone and because shoes are commonly used when people with a transtibial or transfemoral amputation walk, shoes should be considered when characterizing prosthetic feet mechanical properties.

There are many prosthetic foot models that are commercially available to people with a transtibial or transfemoral amputation. One such model is the Össur low-profile (LP) Vari-flex (Össur, Reykjavik, Iceland), which is a passive-elastic prosthetic foot made of carbon-fiber with a short build height (0.068 m) (10) so that it can be used by people with long residual limbs. It has also been used within a stance-phased powered prosthesis (28). Characterizing the mechanical properties of LP Vari-flex feet can provide objective measures that can be used to compare these prostheses to other available prosthetic feet (11–20), inform dynamic function, and influence future prosthetic design that includes stance-phase powered prostheses. Therefore, it is important to determine the axial and torsional stiffness values and hysteresis of a wide range of different stiffness categories and

sizes of prosthetic feet. Moreover, since shoes can affect the mechanical properties of prosthetic feet, it is also important to determine the axial and torsional stiffness values and hysteresis of prosthetic feet with and without shoes.

The Össur Vari-flex (higher profile version of the LP Vari-flex, Össur, Reykjavik, Iceland) prosthetic foot exhibits a curvilinear force-displacement profile (11), thus we expected that the axial and torsional stiffness of all the stiffness categories of the LP Vari-flex would be better characterized by a curvilinear force-displacement profile than a linear force-displacement profile independent of a shoe. We assumed that because a greater numerical stiffness category is prescribed to people with greater body mass and higher activity levels, a greater stiffness category would result in higher axial stiffness values when force is applied at the heel, midfoot, and forefoot, and higher torsional stiffness values when plantarflexion and dorsiflexion torque are applied to the prosthetic foot but would have no effect on hysteresis with or without a shoe. Since manufacturers recommend the same LP Vari-flex prosthetic foot stiffness category for a given body mass and activity level regardless of prosthetic foot size, we hypothesized that greater passive-elastic prosthetic foot length (size) would have no effect on axial stiffness values when force is applied at the heel, midfoot, and forefoot, and hysteresis within a given category with or without a shoe. However, since increasing prosthetic foot size increases the length and moment arms of the prosthesis, we hypothesized that greater passive-elastic prosthetic foot length (size) would result in greater torsional stiffness values when plantarflexion and dorsiflexion torque are applied to the prosthetic foot with or without a shoe. Based on results from a previous study that found adding a shoe to prosthetic feet resulted in lower axial stiffness values at the heel and midfoot but not at the forefoot (27), we hypothesized that adding a shoe to the prosthetic foot would result in lower axial stiffness values when force is applied at the heel and midfoot and increase hysteresis but not affect axial stiffness values when force is applied at the forefoot or torsional stiffness values when plantarflexion and dorsiflexion torque are applied to the prosthetic foot and shoe compared to without a shoe.

2 Methods

2.1 Prosthetic feet

LP Vari-flex prosthetic feet are manufactured in a range of different stiffness categories (1–9) and foot sizes (22–30 cm) that are prescribed to people with a transtibial or transfemoral amputation who have a range of body mass (45–166 kg) and low to high impact (activity) levels (10). We determined the axial stiffness (kN/m) values, torsional stiffness (N*m/rad) values, and hysteresis (%) of 33 different LP Vari-flex prosthetic feet with different stiffness categories (Categories 1–8) and sizes (24–29 cm; Table 1) in compression using a materials testing machine (MTM; Instron Series 5859, Norwood, MA). We determined axial stiffness values and hysteresis with a force applied at the heel, midfoot, and forefoot of each prosthetic foot including the rubber cosmesis with and without a standard walking shoe (New Balance MA411, Boston, MA). Then, we determined torsional stiffness values when plantarflexion and dorsiflexion torque were applied to each prosthetic foot including the rubber cosmesis with and without a standard walking shoe (New Balance MA411, Boston, MA). For two prosthetic foot sizes (27 and 29), we did not have a New Balance MA411 shoe, so we instead used New Balance MW928 shoes. Both the New Balance MA411 and MW928 are designed for walking and have similar mass and construction. Thus, we assumed that the mechanical effects of these walking shoes would not differ.

2.2 Axial stiffness

We constructed a custom aluminum base and low-friction roller system for the MTM to measure the heel, midfoot, and forefoot axial stiffness values of the prosthetic feet. We used a low friction roller between the base and each prosthetic foot to minimize torque on the uniaxial load cell of the MTM (Figure 1). A rigid pylon was aligned vertically and attached to the MTM. Each prosthetic foot was attached to the rigid pylon and the bottom of the prosthetic foot was aligned perpendicular to the pylon. We set the base at −15°, 0°, and 20° relative to horizontal, which corresponds to the angles required for heel, midfoot, and forefoot axial stiffness testing, respectively (29) (Figure 1). For each test, we preloaded the prosthetic foot with 4–6 N so that the platform (grey in Figure 1) would not slide out between the low friction roller and prosthetic foot in between each cycle and used the MTM to apply a force along the pylon at 100 N/s (29) for four consecutive compressive loading and unloading cycles. Each prosthetic foot stiffness category is recommended for a user within a range of body mass values by the manufacturer (Table 1). For each prosthetic stiffness category, we used the highest body mass within the recommended range to estimate the peak ground reaction force applied on the heel, midfoot, and forefoot of the prosthetic foot during walking. We set the maximum force of each test to a value based off the first and second peak vertical ground reaction forces on the affected leg of a person with a transtibial amputation walking on level ground at 1.75 m/s to estimate the ground reaction force that could be applied to a particular prosthesis during walking (30). When a person with a transtibial amputation walks on level ground at 1.75 m/s using a passive-elastic prosthesis, they apply a first peak vertical ground reaction force that is 1.3 times their body weight (BW) for their affected leg (30). Thus, we applied a maximum force of 1.3 times BW of the heaviest person within the recommended range for each prosthetic stiffness category at a moderate impact level for the heel and midfoot tests (base at −15° and 0°). When a person with a transtibial amputation walks on level ground at 1.75 m/s using a passive-elastic prosthesis, they apply a second peak vertical ground reaction force that is 1.0 times their body weight (BW) for their affected leg (30). Thus, we applied a maximum force of 1.0 times BW of the heaviest person within the recommended

TABLE 1 Low-profile Vari-flex prosthetic foot (10) stiffness category, size, shoe, average manufacturer recommended body mass for a moderate impact level, maximum manufacturer recommended body mass for a moderate impact level, 1.3 times the maximum recommended body weight (BW; maximum force threshold for the heel and midfoot tests), and 1.0 times the maximum recommended BW (maximum force threshold for the forefoot test).

Foot	Stiffness category	Size (cm)	Shoe (US Size)	Average body mass (kg)	Maximum body mass (kg)	1.3 BW (N)	1.0 BW (N)
1	1	24	MA411 (7)	48.5	52	662	510
2	1	25	MA411 (8)	48.5	52	662	510
3	1	26	MA411 (9)	48.5	52	662	510
4	2	24	MA411 (7)	56	59	752	578
5	2	25	MA411 (8)	56	59	752	578
6	2	26	MA411 (9)	56	59	752	578
7	3	24	MA411 (7)	64	68	866	666
8	3	25	MA411 (8)	64	68	866	666
9	3	26	MA411 (9)	64	68	866	666
10	3	28	MA411 (11)	64	68	866	666
11	3	29	MW928 (12.5)	64	68	866	666
12	4	24	MA411 (7)	73	77	981	755
13	4	25	MA411 (8)	73	77	981	755
14	4	26	MA411 (9)	73	77	981	755
15	4	27	MW928 (10)	73	77	981	755
16	4	28	MA411 (11)	73	77	981	755
17	4	29	MW928 (12.5)	73	77	981	755
18	5	24	MA411 (7)	83	88	1,121	862
19	5	25	MA411 (8)	83	88	1,121	862
20	5	26	MA411 (9)	83	88	1,121	862
21	5	27	MW928 (10)	83	88	1,121	862
22	5	28	MA411 (11)	83	88	1,121	862
23	5	29	MW928 (12.5)	83	88	1,121	862
24	6	25	MA411 (8)	94.5	100	1,274	980
25	6	26	MA411 (9)	94.5	100	1,274	980
26	6	27	MW928 (10)	94.5	100	1,274	980
27	6	28	MA411 (11)	94.5	100	1,274	980
28	6	29	MW928 (12.5)	94.5	100	1,274	980
29	7	26	MA411 (9)	108.5	116	1,478	1,137
30	7	27	MW928 (10)	108.5	116	1,478	1,137
31	7	28	MA411 (11)	108.5	116	1,478	1,137
32	7	29	MW928 (12.5)	108.5	116	1,478	1,137
33	8	27	MW928 (10)	123.5	130	1,656	1,274

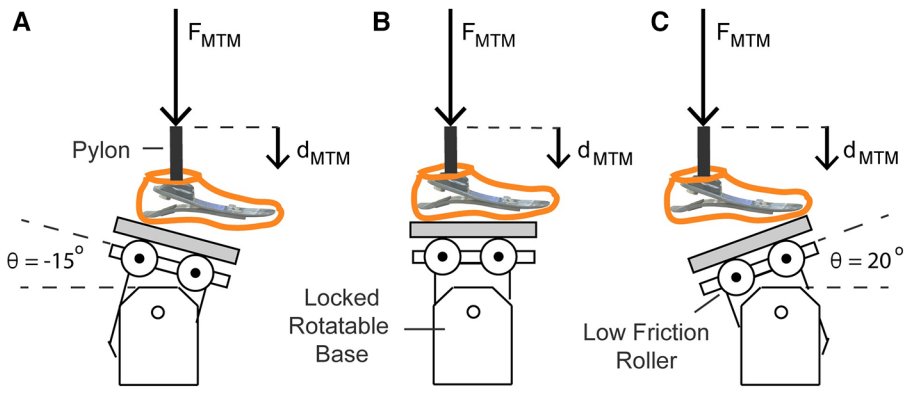

FIGURE 1
Illustration of axial stiffness testing for the (A) heel, (B) midfoot, and (C) forefoot of each prosthetic foot. The materials testing machine (MTM) applied force (F_{MTM}) vertically at 100 N/s along the pylon to compress the prosthetic foot. F_{MTM} and vertical displacement (d_{MTM}) were measured by the load cell and MTM. A low friction roller was placed beneath the prosthetic foot to minimize the torque applied on the load cell of the MTM. For the axial tests on the heel, midfoot, and forefoot, the rotatable base was locked at –15°, 0°, and 20° relative to horizontal, respectively.

range for each prosthetic stiffness category at a moderate impact level for the forefoot test (base at 20°).

We determined the axial stiffness values of each prosthetic foot as the quotient of the normal force and displacement applied by the base onto the bottom of the prosthesis (Figures 1, 2). The normal force (F_{norm}) equals the quotient of the F_{MTM} and the cosine of the angle of the base relative to the prosthetic foot (θ) (Figures 1, 2; Equation 1):

$$F_{norm} = \frac{F_{MTM}}{\cos(\theta)} \quad (1)$$

The displacement of the prosthetic foot normal to the base (d_{norm}) equals the product of the vertical displacement of the materials testing machine (d_{MTM}) and the cosine of the angle of the base relative to the prosthetic foot (θ) (Figures 1, 2; Equation 2):

$$d_{norm} = d_{MTM}\cos(\theta) \quad (2)$$

Therefore, the axial stiffness value of the prosthetic foot (k_{pros}) equals F_{MTM} divided by the product of d_{MTM} and cos $(\theta)^2$ (Equation 3):

$$k_{pros} = \frac{F_{norm}}{d_{norm}} = \frac{F_{MTM}}{d_{MTM}\cos(\theta)^2} \quad (3)$$

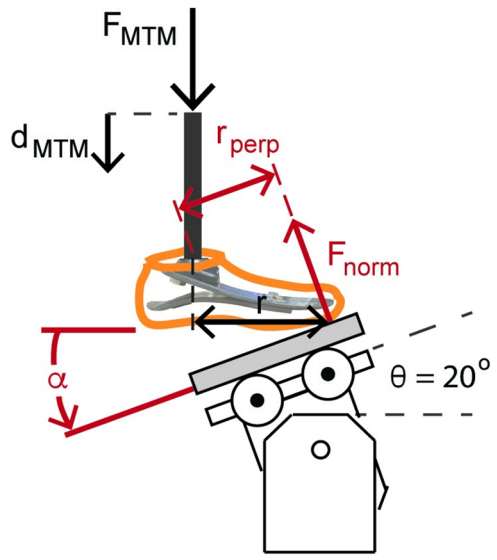

FIGURE 2
Illustration of the forefoot prosthetic axial stiffness testing and dorsiflexion torsional stiffness testing. The MTM applied force (F_{MTM}) and displacement (d_{MTM}) vertically along the pylon. The reaction force applied to the bottom of the prosthetic foot is the normal force (F_{norm}) relative to the base. For the heel, midfoot, and forefoot axial stiffness testing, the rotatable base was locked at −15°, 0°, and 20° relative to horizontal, respectively. F_{norm} equals $F_{MTM}/\cos(\theta)$. The displacement of the prosthetic foot normal to the base (d_{norm}) equals $d_{MTM} \times \cos(\theta)$. Therefore, axial prosthetic stiffness (k_{pros}) equals the quotient of F_{MTM} and $d_{MTM} \times \cos(\theta)^2$. We estimated torsional stiffness values from the quotient of the product of F_{norm} and the perpendicular moment arm ($r_{perp} = r \times \cos(\theta)$) and the angular displacement of the foot $\left(\alpha = \tan^{-1}\left(\frac{d_{MTM}}{r}\right)\right)$.

2.3 Torsional stiffness

We determined torsional stiffness values by dorsiflexing and plantarflexing the prosthetic feet. Plantarflexion and dorsiflexion torsional stiffness values of each prosthetic foot were measured as the quotient of the torque and angular displacement of the prosthesis calculated from the force and displacement measured during the heel and forefoot axial stiffness tests when the rotatable base was locked at −15° and 20°, respectively (Figure 1). For plantarflexion torsional stiffness, we estimated the moment arm as the horizontal distance between the point of contact of the heel during the heel axial stiffness test and the pylon (r) and multiplied it by cosine of the base angle (−15°) to calculate the perpendicular moment arm (r_{perp}). The point of contact was the location where the heel of the prosthesis contacted the base when the prosthetic foot was preloaded with 4–6 N. For dorsiflexion torsional stiffness, we estimated the moment arm as the horizontal distance between the point of contact of the forefoot during the forefoot axial stiffness test and the pylon (r; Figure 2) and multiplied it by the cosine of the base angle (20°) to calculate the perpendicular moment arm (r_{perp}; Figure 2). The point of contact was the location where the forefoot of the prosthesis contacted the base when the prosthetic foot was preloaded with 4–6 N and corresponded with the start of the forefoot axial stiffness test. We calculated torque throughout compression as the product of the normal force (F_{norm}) and r_{perp} (Figure 2). We assumed the point of contact and thus r_{perp} was constant throughout loading and unloading due in part to the low friction roller placed beneath the prosthesis. We calculated the angle of the prosthetic foot (α) as the inverse tangent of the vertical displacement of the MTM (d_{MTM}) divided by the horizontal distance of the point of contact and the pylon (r; Figure 2). Thus, torsional stiffness ($k_{pros,torsion}$) equals the quotient of the change in torque (τ) and angle (α in rad) of the prosthetic foot (Equation 4):

$$k_{pros,torsion} = \frac{\tau}{\alpha} = \frac{F_{norm} \times r_{perp}}{\tan^{-1}\left(\frac{d_{MTM}}{r}\right)} \quad (4)$$

2.4 Hysteresis

We calculated hysteresis for each loading and unloading cycle as the percentage of energy lost during unloading (difference between the energy returned during unloading and the energy stored during loading) compared to the energy stored during loading. Hysteresis was calculated as the quotient of the difference in the area under the loading and unloading curves and the area under the loading curve (Equation 5):

$$\text{Hysteresis} = \frac{\int_0^{\max d_{norm}} F_{norm}(d_{norm})dd_{norm} - \int_{\max d_{norm}}^0 F_{norm}(d_{norm})dd_{norm}}{\int_0^{\max d_{norm}} F_{norm}(d_{norm})dd_{norm}} \times 100\% \quad (5)$$

where F_{norm} is the normal force, d_{norm} is the displacement of the prosthetic foot, and dd_{norm} is the differential of the displacement of the prosthetic foot.

2.5 Data analysis

We used a custom MATLAB script (Mathworks Inc., Natick, MA, USA) to fit linear and quadratic curves to the force-displacement and torque-angle data, calculated average axial and torsional stiffness values, and calculated hysteresis. We used a 20 N F_{norm} threshold to define the start and end of each loading and unloading cycle and set the maximum F_{norm} or torque value of each cycle as the end of the loading phase of the cycle. Then, we fit linear and quadratic least-squares curves to the normal force-displacement and torque-angle data from the loading phases of the last three cycles for each prosthetic foot at the heel, midfoot, and forefoot. So that our results are comparable to previous studies that characterized Vari-flex prosthetic feet (the higher profile version of the LP Vari-flex prosthesis) (11, 20), we calculated average axial and torsional stiffness values from the discrete value of the slope of the force-displacement and torque-angle curve from a minimum value of 50 N to 1.0 × body weight (BW) for the average body mass recommended for the moderate impact level (Table 1). We averaged that value for the last three test cycles for each foot and test condition. Finally, we averaged the hysteresis from the last three cycles from the normal force-displacement and torque-angle data for each prosthetic foot and test condition.

2.6 Statistical analysis

We calculated adjusted R^2 values (31, 32) for the linear and quadratic curves for each prosthetic foot at the heel, midfoot, and forefoot. We used adjusted R^2 values because the adjusted R^2 corrects for added degrees of freedom in the model and allows comparison of the goodness of fit between the linear and quadratic curves (31, 32). The axial and torsional stiffness of the prosthetic foot was determined to be better characterized by a linear or quadratic force-displacement or torque-angle curve if the adjusted R^2 was greater. Then, we constructed eight linear regression models (33) to determine the effect of prosthetic foot stiffness category, prosthetic foot size, and shoe or no shoe on the average axial stiffness values and hysteresis at the heel, midfoot, and forefoot, and torsional stiffness values in the plantarflexion and dorsiflexion directions. We set average axial stiffness values, torsional stiffness values, or hysteresis as the dependent variable and stiffness category (numerical; 1–8), size (numerical; 24–27 cm), and shoe vs. no shoe (categorical; shoe = 1, no shoe = 0) as independent variables (dependent variable = intercept + B_1 × stiffness category + B_2 × size + B_3 × shoe/no shoe). We report unstandardized model coefficients B_1, B_2, and B_3, which represent the change in dependent variable (average axial stiffness value, average torsional stiffness value, and hysteresis at the heel, midfoot, or forefoot) corresponding to a 1 category change in stiffness category, 1 cm change in size, and use of a shoe compared to no shoe, respectively. For each comparison, we controlled for the remaining fixed effects. We visually inspected regression model assumptions of linearity, normality, and homoscedasticity (34), and report 95% confidence intervals for each model coefficient and R^2 values for each regression model. A unit change in hysteresis (%) is a percentage point (p.p.) where one p.p. refers to a 1% unit, such that an increase from 5% to 6% is a 1 p.p. increase as opposed to a 20% increase (i.e., *not* $\frac{6\%-5\%}{5\%} \times 100\% = 20\%$). We used a significance level of $p < 0.05$. All statistical analyses were performed in RStudio (Boston, MA, USA).

3 Results

For every prosthetic foot, we found that the adjusted R^2 was higher when force vs. displacement was represented as a quadratic compared to a linear curve (average adjusted R^2 across all tests–quadratic: 1.00, linear: 0.95). Therefore, prosthetic foot force-displacement curves were better described by a quadratic compared to linear fit. The prosthetic foot force-displacement curves were well described by a progressive, quadratic force-displacement curve, meaning that axial stiffness increased with greater force applied (Figures 3, 4).

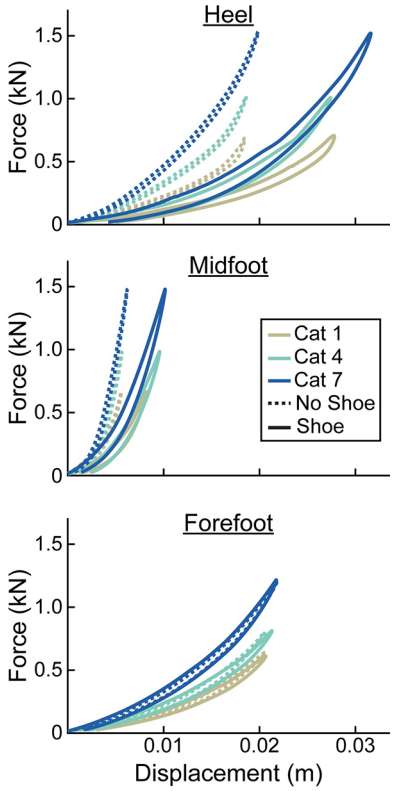

FIGURE 3
Representative force (kN) vs. displacement (m) curves of the heel, midfoot, and forefoot of size 26 cm LP Vari-flex prosthetic feet. The colors represent different stiffness categories (categories 1, 4, 7). The dashed lines are for the tests without a shoe and the solid lines are for the tests with the shoe. Curves go in a clockwise direction from the start to the end of a cycle.

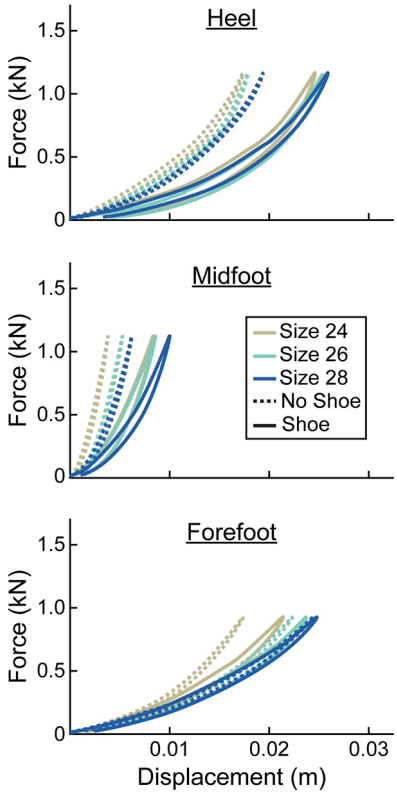

FIGURE 4
Representative force (kN) vs. displacement (m) curves of the heel, midfoot, and forefoot of stiffness category 5 LP Vari-flex prosthetic feet. The colors represent different sizes (24 cm, 26 cm, 28 cm). The dashed lines are for the tests without a shoe and the solid lines are for the tests with the shoe. Curves go in a clockwise direction from the start to the end of a cycle.

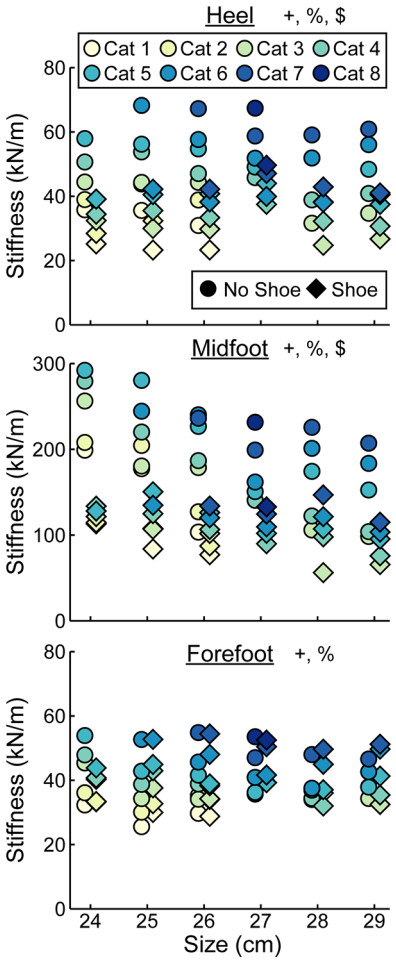

FIGURE 5
Average axial stiffness values (kN/m) vs. LP Vari-flex prosthetic foot size in cm. The colors represent different stiffness categories (categories 1–8), the circles represent average axial stiffness values without a shoe, and the diamonds represent average axial stiffness values with a shoe. Symbols are offset for no shoe and shoe for clarity. The *y*-axis differs for the midfoot compared to heel and forefoot axial stiffness values. + indicates a significant effect of stiffness category, % indicates a significant effect of size, and $ indicates a significant effect of shoe.

At the heel, average prosthetic foot axial stiffness values increased by 4.6 kN/m for every 1 stiffness category increase ($p < 0.001$), decreased by 1.7 kN/m for every 1 cm increase in size ($p < 0.001$), and decreased by 13.5 kN/m with the shoe compared to without the shoe ($p < 0.001$; Figure 5; Table 2). At the midfoot, average prosthetic foot axial stiffness values increased by 15.6 kN/m for every 1 stiffness category increase ($p < 0.001$), decreased by 19.4 kN/m for every 1 cm increase in size ($p < 0.001$), and decreased by 81.4 kN/m with the shoe compared to without the shoe ($p < 0.001$; Figure 5; Table 2). At the forefoot, average prosthetic foot axial stiffness values increased by 3.8 kN/m for every 1 stiffness category increase ($p < 0.001$) and decreased by 1.6 kN/m for every 1 cm increase in size ($p < 0.001$; Figure 5; Table 2). However, we did not detect a statistically significant effect of adding a shoe on the average forefoot prosthetic foot axial stiffness value ($p = 0.46$; Figure 5; Table 2).

When force was applied at the heel, average prosthetic foot plantarflexion torsional stiffness values increased by 0.01 kN-m/rad for every 1 stiffness category increase ($p < 0.001$), increased by 0.02 kN-m/rad for every 1 cm increase in size ($p < 0.001$), and decreased by 0.04 kN-m/rad with the shoe compared to without the shoe ($p < 0.001$; Figures 6–8; Table 3). When force was applied at the forefoot, average prosthetic foot dorsiflexion torsional stiffness values increased by 0.12 kN-m/rad for every 1 stiffness category increase ($p < 0.001$) and increased by 0.09 kN-m/rad for every 1 cm increase in size ($p < 0.001$; Figures 6–8; Table 3). However, we did not detect a statistically significant effect of adding a shoe on the average prosthetic foot dorsiflexion torsional stiffness value ($p = 0.31$; Figure 8; Table 3).

Hysteresis at the heel decreased by 0.3 percentage points (p.p.) for every 1 stiffness category increase ($p < 0.001$), decreased by 1.0 p.p. for every 1 cm increase in size ($p = 0.01$), and increased by 13.8 p.p. with the shoe compared to without the shoe ($p < 0.001$; Figure 9, Table 4). Hysteresis at the midfoot decreased by 0.3 p.p. for every 1 stiffness category increase ($p = 0.04$), decreased by 0.5 p.p. for every 1 cm increase in size ($p = 0.01$), and increased by 11.0 p.p. with the shoe compared to without

TABLE 2 Linear regression parameters for fixed effects of LP Vari-flex prosthetic foot stiffness category, size, and shoe or no shoe on the axial stiffness values (kN/m) at the heel, midfoot, and forefoot. Coefficient estimates, 95% confidence intervals for coefficient estimates (CI), coefficient standard errors (SE), *t* values (*t*), and *p* values (*p*) are listed for each stiffness category (1–8) and size (24–29 cm). The shoe vs. no shoe coefficient is in reference to the no shoe condition.

Heel axial stiffness (kN/m)	Estimate (B)	CI	SE	*t*	*p*
Intercept	72.85	[59.34, 86.35]	6.75	10.79	**<0.001**
Stiffness category	4.64	[4.17, 5.11]	0.23	19.77	**<0.001**
Size [cm]	−1.67	[−2.20, −1.13]	0.27	−6.22	**<0.001**
Shoe vs. no shoe	−13.51	[−15.13, −11.90]	0.81	−16.76	**<0.001**
$R^2 = 0.92$					
Midfoot axial stiffness (kN/m)	**Estimate (B)**	**CI**	**SE**	***t***	***p***
Intercept	635.26	[539.35, 731.17]	47.98	13.24	**<0.001**
Stiffness category	15.63	[12.29, 18.96]	1.67	9.37	**<0.001**
Size [cm]	−19.39	[−23.21, −15.58]	1.91	−10.17	**<0.001**
Shoe vs. no shoe	−81.35	[−92.80, −69.91]	5.73	−14.21	**<0.001**
$R^2 = 0.85$					
Forefoot axial stiffness (kN/m)	**Estimate (B)**	**CI**	**SE**	***t***	***p***
Intercept	66.47	[53.62, 79.33]	6.43	10.34	**<0.001**
Stiffness category	3.84	[3.39, 4.29]	0.22	17.18	**<0.001**
Size [cm]	−1.63	[−2.14, −1.12]	0.26	−6.39	**<0.001**
Shoe vs. no shoe	0.57	[−0.97, 2.10]	0.77	0.74	0.464
$R^2 = 0.83$					

Bold values indicate significance ($p < 0.05$).

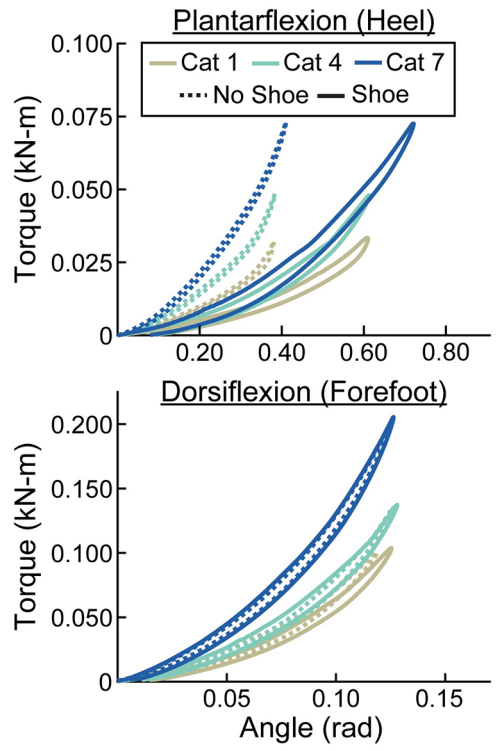

FIGURE 6
Representative torque (kN-m) vs. angle (rad) curves for plantarflexion (heel) and dorsiflexion (forefoot) of size 26 cm LP Vari-flex prosthetic feet. The colors represent different stiffness categories (categories 1, 4, 7). The dashed lines are for the tests without a shoe and the solid lines are for the tests with the shoe. The *x*- and *y*-axes differ for the plantarflexion and dorsiflexion torque and angle values.

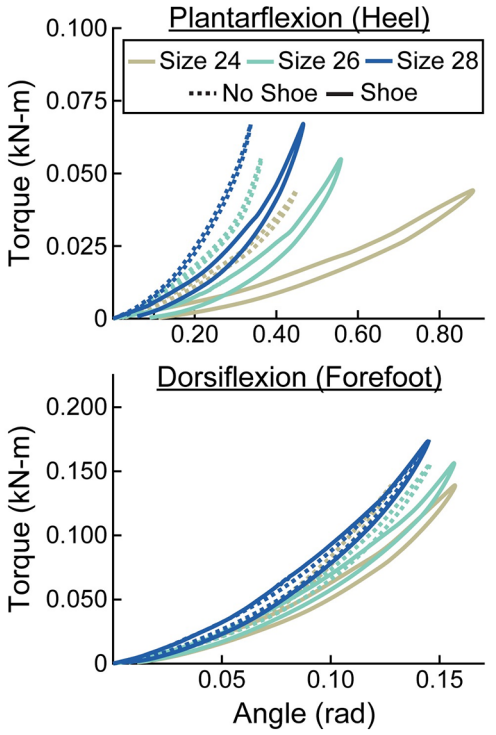

FIGURE 7
Representative torque (kN-m) vs. angle (rad) curves for plantarflexion (heel) and dorsiflexion (forefoot) of category 5 stiffness LP Vari-flex prosthetic feet. The colors represent different sizes (24 cm, 26 cm, 28 cm). The dashed lines are for the tests without a shoe and the solid lines are for the tests with the shoe. The *x*- and *y*-axes differ for the plantarflexion and dorsiflexion torque and angle values.

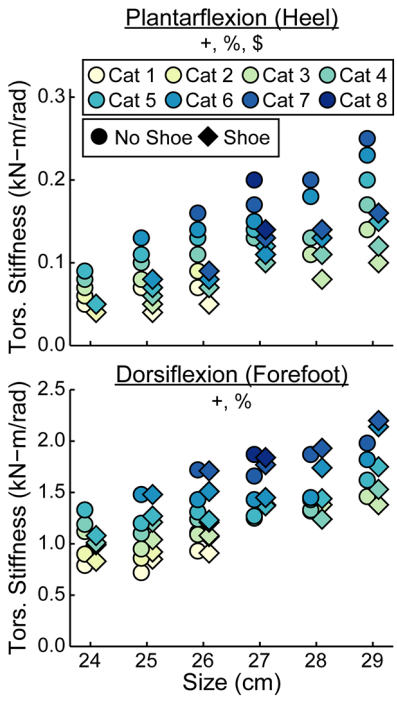

FIGURE 8
Average torsional (tors.) stiffness values (kN-m/rad) vs. LP Vari-flex prosthetic foot size in cm for plantarflexion (heel) and dorsiflexion (forefoot). The colors represent different stiffness categories (categories 1–8), the circles represent average torsional stiffness without a shoe, and the diamonds represent average torsional stiffness with a shoe. Symbols are offset for no shoe and shoe for clarity. The *y*-axis differs for the plantarflexion and dorsiflexion torsional stiffness values. + indicates a significant effect of stiffness category, % indicates a significant effect of size, and $ indicates a significant effect of shoe.

the shoe ($p < 0.001$; Figure 9, Table 4). Hysteresis at the forefoot decreased by 0.3 p.p. for every 1 stiffness category increase ($p = 0.01$) and increased by 7.0 p.p. with the shoe compared to without the shoe ($p < 0.001$; Figure 9, Table 4). However, we did not detect a statistically significant effect of prosthetic foot size on hysteresis at the forefoot ($p = 0.48$; Figure 9, Table 4).

4 Discussion

In support of our hypothesis, the force-displacement curves of the LP Vari-flex prosthetic foot at the heel, midfoot, and forefoot (Supplementary Material: Force-Displacement Equations) and the plantarflexion and dorsiflexion torque-angle curves (Supplementary Material: Torque-Angle Equations) exhibited a curvilinear profile and were well-described by a quadratic curve (average adjusted R^2 for all tests: 1.00). These results are similar to the curvilinear stiffness exhibited by the higher profile prosthetic model, the Vari-flex (11), likely because both prostheses have a similar design and are made of carbon fiber. The LP Vari-flex prosthetic foot force-displacement and torque-angle curves have a steeper slope with greater applied forces and torques and thus stiffen with displacement. This suggests that the stiffness of the prosthetic foot differs during dynamic tasks where forces change and thus prosthetists may need to consider the activity when prescribing a given prosthetic foot stiffness category. For example, based on the force-displacement equations (Supplementary Table S4), we estimate that when a 70 kg person uses a category 4, size 27 prosthesis inside of a walking shoe, the axial stiffness at the heel is 35.1 kN/m for a load consistent with walking at 0.75 m/s [1.0 BW first peak vertical ground reaction force (30)], but this value increases to 40.5 kN/m for a load consistent with walking at 1.75 m/s [1.3 BW first peak vertical ground reaction force (30)]. The change in axial stiffness at the heel between low and high loading (5.4 kN/m) is similar to the change in average axial stiffness at the heel for a 1 category increase (4.6 kN/m; Table 2), suggesting that it is meaningful to consider the curvilinear nature of LP Vari-flex prosthetic feet.

We found that a greater numerical stiffness category of the LP Vari-flex prosthetic foot resulted in increased average axial stiffness values at the heel, midfoot, and forefoot by 4.6, 15.6, and 3.8 kN/m per one category increase, respectively. The change in heel stiffness values between categories of the LP Vari-flex prosthetic foot were similar to the changes in the higher profile prosthetic foot model (Vari-flex), where heel axial stiffness values increase by about 6–7 kN/m per one category increase (11, 19). In general, we found

TABLE 3 Linear regression parameters for fixed effects of LP Vari-flex prosthetic foot stiffness category, size, and shoe or no shoe on the torsional stiffness values (kN-m/rad) in plantarflexion (heel) and dorsiflexion (forefoot). Coefficient estimates, 95% confidence intervals for coefficient estimates (CI), coefficient standard errors (SE), *t* values (*t*), and *p* values (*p*) are listed for each stiffness category (1–8) and size (24–29 cm). The shoe vs. no shoe coefficient is in reference to the no shoe condition.

Plantarflexion (Heel) torsional stiffness (kN-m/rad)	Estimate (B)	CI	SE	*t*	*p*
Intercept	−0.36	[−0.42, −0.30]	0.03	−12.56	**<0.001**
Stiffness category	0.01	[0.01, 0.01]	0.00	11.85	**<0.001**
Size [cm]	0.02	[0.01, 0.02]	0.00	14.56	**<0.001**
Shoe vs. no shoe	−0.04	[−0.05, −0.03]	0.00	−11.63	**<0.001**
$R^2 = 0.92$					
Dorsiflexion (Forefoot) torsional stiffness (kN-m/rad)	**Estimate (B)**	**CI**	**SE**	***t***	***p***
Intercept	−1.65	[−2.10, −1.20]	0.23	−7.30	**<0.001**
Stiffness category	0.12	[0.11, 0.14]	0.01	15.75	**<0.001**
Size [cm]	0.09	[0.07, 0.11]	0.01	10.28	**<0.001**
Shoe vs. no shoe	0.03	[−0.03, 0.08]	0.03	1.03	0.305
$R^2 = 0.91$					

Bold values indicate significance ($p < 0.05$).

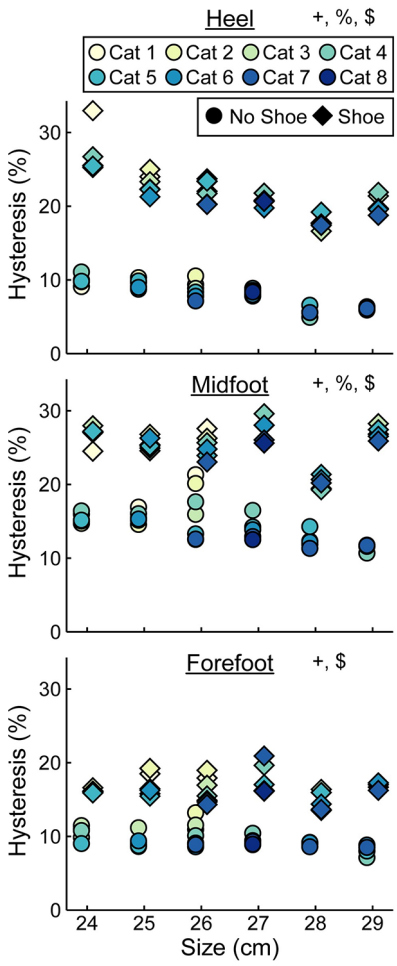

FIGURE 9
Average hysteresis (%) vs. LP Vari-flex prosthetic foot size in cm. The colors represent different prosthetic foot stiffness categories (categories 1–8), the circles represent average hysteresis without a shoe, and the diamonds represent average hysteresis with a shoe. Symbols are offset for no shoe and shoe for clarity. + indicates a significant effect of stiffness category, % indicates a significant effect of size, and $ indicates a significant effect of shoe.

that the heel and forefoot axial stiffness values of the LP Vari-flex prosthetic foot for a given stiffness category are stiffer than the higher profile Vari-flex prosthetic foot model. For example, the average axial stiffness value of the heel for a size 27 LP Vari-flex without a shoe ranges from 49.1 to 58.7 kN/m for categories 5–7, whereas the average axial stiffness value of the heel for a size 27 Vari-flex prosthetic foot without a shoe ranges from 37.5 to 45.4 kN/m in Turner et al. (20) and 36.4 to 47.1 kN/m in Ruxin et al. (11) for categories 5–7. Moreover, the average axial stiffness value of the forefoot for a size 27 LP Vari-flex without a shoe ranges from 36.2 to 47.0 kN/m for categories 5–7, whereas the average axial stiffness value of the forefoot for a size 27 Vari-flex prosthetic foot without shoes for categories 5–7 ranges from 29.1 to 38.5 kN/m in Turner et al. (20) and 28.6 to 40.0 kN/m in Ruxin et al. (11). These differences in stiffness values between the same category of the LP Vari-flex and Vari-flex may be clinically meaningful. The average forefoot stiffness of the size 27 category 5 LP Vari-flex prosthesis is 7.6 kN/m or 26.6% greater than the Vari-flex prosthesis (11). A previous study suggested that a 10% change in prosthetic foot stiffness is the minimum clinically important difference (22). Furthermore, a previous study of people with amputation walking with an experimental prosthesis at 0.7–1.5 m/s suggests that a 7.6 kN/m increase in forefoot stiffness can increase the magnitude of unaffected leg negative center-of-mass work by 0.9 J on average (1), which may increase the risk of osteoarthritis in the unaffected leg knee (35). Ultimately, the differences in heel and forefoot axial stiffness values between the LP Vari-flex and Vari-flex prosthetic feet suggest that prosthetists should prescribe a lower stiffness category for the LP Vari-flex prosthesis than they would for the Vari-flex prosthesis. Furthermore, the changes in axial stiffness values of the LP Vari-flex prosthetic foot without a shoe between prosthetic stiffness categories for the heel, midfoot, and forefoot were variable (Figure 5). Previous studies that characterized commercially available passive-elastic prosthetic feet found similar results (11, 19). The variable changes in axial stiffness values between stiffness categories highlight the need for objective measurements of prosthetic foot stiffness values within and between manufacturers because our results show that an increase in the stiffness category may not always result in an actual increase in the stiffness of the prosthesis. Such measurements would improve the understanding of the mechanical function provided by prostheses.

We also found that a greater stiffness category of the LP Vari-flex prosthetic foot resulted in an increased average torsional stiffness value for plantarflexion (heel) and dorsiflexion (forefoot) by 0.01 and 0.12 kN-m/rad, respectively. Major et al. estimated the torsional stiffness values of three commercially-available prosthetic feet, the SACH foot, Seattle foot, and Flex-foot, and found that the plantarflexion (heel) and dorsiflexion (forefoot) stiffness values ranged from 0.09 to 0.20 kN-m/rad and 0.39 to 1.40 kN-m/rad, respectively (6). Similarly, we found that plantarflexion (heel) stiffness values of the LP Vari-flex foot without a shoe ranged from 0.05 to 0.25 kN-m/rad and dorsiflexion (forefoot) stiffness values of the LP Vari-flex foot without a shoe ranged from 0.72 to 1.98 kN-m/rad across the tested stiffness categories and sizes. Different torsional stiffness values of prosthetic feet can affect the joint angles, peak ground reaction forces, and metabolic cost of people with unilateral transtibial amputation during walking (6), so characterizing the torsional stiffness values of prosthetic feet can be a useful tool for predicting how different prosthetic feet will affect walking biomechanics. Moreover, since a biological ankle can behave mechanically like a torsional spring and damper system during walking at 1.2 m/s (21), torsional stiffness values of prosthetic feet provide information that can be compared to the biological ankle-foot system (36) to derive function and potentially inform biomimetic prosthetic prescription and design.

In contrast to our prediction, we found that a greater LP Vari-flex prosthetic foot stiffness category resulted in a 0.3 percentage point decrease in hysteresis for the heel, midfoot, and forefoot, which is a relatively small effect. The hysteresis at the heel, midfoot, and forefoot of the LP Vari-flex prosthetic feet without

TABLE 4 Linear regression parameters for fixed effects of LP Vari-flex prosthetic foot stiffness category, size, and shoe or no shoe on the hysteresis (%) at the heel, midfoot, and forefoot. Coefficient estimates, 95% confidence intervals for coefficient estimates (CI), coefficient standard errors (SE), *t* values (*t*), and *p* values (*p*) are listed for each stiffness category (1–8) and size (24–29 cm). The shoe vs. no shoe coefficient is in reference to the no shoe condition.

Heel hysteresis (%)	Estimate (B)	CI	SE	*t*	*p*
Intercept	36.56	[29.95, 43.17]	3.31	11.06	**<0.001**
Stiffness category	−0.31	[−0.54, −0.08]	0.12	−2.70	**0.009**
Size [cm]	−1.03	[−1.29, −0.76]	0.13	−7.81	**<0.001**
Shoe vs. no shoe	13.81	[13.02, 14.60]	0.39	35.00	**<0.001**
$R^2 = 0.96$					
Midfoot hysteresis (%)	**Estimate (B)**	**CI**	**SE**	***t***	***p***
Intercept	28.40	[18.96, 37.84]	4.72	6.01	**<0.001**
Stiffness category	−0.34	[−0.66, −0.01]	0.16	−2.05	**0.045**
Size [cm]	−0.48	[−0.85, −0.10]	0.19	−2.54	**0.014**
Shoe vs. no shoe	10.99	[9.86, 12.12]	0.56	19.49	**<0.001**
$R^2 = 0.87$					
Forefoot hysteresis (%)	**Estimate (B)**	**CI**	**SE**	***t***	***p***
Intercept	12.78	[7.22, 18.34]	2.78	4.60	**<0.001**
Stiffness category	−0.28	[−0.47, −0.08]	0.10	−2.85	**0.006**
Size [cm]	−0.08	[−0.30, 0.14]	0.11	−0.71	0.479
Shoe vs. no shoe	6.99	[6.32, 7.65]	0.33	21.05	**<0.001**
$R^2 = 0.88$					

Bold values indicate significance ($p < 0.05$).

a shoe averaged across sizes ranged from 6.9% to 10.3%, 12.1% to 18.1%, and 8.8% to 10.7%, respectively. Therefore, it is unclear if the effect of LP Vari-flex prosthetic foot stiffness category on hysteresis is clinically meaningful. Future studies should examine the independent effects of prosthetic hysteresis on kinematics, kinetics, muscle activity, metabolic cost and user preference during walking to determine the clinically meaningful difference in prosthetic hysteresis. Nonetheless, prosthetists may want to consider that LP Vari-flex prosthetic feet with stiffer categories have less hysteresis than less stiff categories when prescribing prosthetic feet.

We partially reject our hypothesis that an increase in prosthetic foot size would have no effect on axial stiffness values or hysteresis but would increase torsional stiffness values. We found that a 1 cm increase in the size of the LP Vari-flex prosthetic foot resulted in a 1.7, 19.4, and 1.6 kN/m decrease in axial stiffness values at the heel, midfoot, and forefoot, respectively, an 0.02 and 0.09 kN-m/rad increase in plantarflexion (heel) and dorsiflexion (forefoot) torsional stiffness values, respectively, and a 1.0 and 0.5 percentage point decrease in the hysteresis at the heel and midfoot, respectively. As hypothesized, an increase in prosthetic foot size resulted in an increase in torsional stiffness values due to an increase in the moment arm of the prosthesis. Despite the fact that manufacturers recommend the same LP Vari-flex prosthetic foot stiffness category for a given body mass and activity level regardless of prosthetic foot size (10), prosthetic foot size does affect axial stiffness values, torsional stiffness values, and hysteresis. Since axial stiffness values, torsional stiffness values, and hysteresis can affect kinematics, kinetics, muscle activity, metabolic cost and user preference during walking (1–7), prosthetists should consider that an increase in the size of the LP Vari-flex prosthetic foot can decrease axial stiffness values, decrease hysteresis, and increase torsional stiffness values when prescribing prosthetic feet. Furthermore, manufacturers should design prosthetic feet to have similar mechanical properties for a given prosthetic foot stiffness category regardless of the prosthetic foot size.

In support of our hypothesis, we found that adding a shoe to the LP Vari-flex prosthetic foot decreased axial stiffness values at the heel and midfoot by 13.5 and 81.4 kN/m, respectively, and increased hysteresis at the heel, midfoot, and forefoot by 13.8, 11.0, and 7.0 percentage points, respectively. Our results are similar to those of Major et al. who found that adding an athletic shoe to the prosthetic foot decreased heel and midfoot axial stiffness values by 20.5 kN/m and 151.6 kN/m, respectively, and increased hysteresis at the heel, midfoot, and forefoot by 7.4, 9.3, and 3.4 percentage points, respectively, compared to values for a prosthetic foot without a shoe (27). Moreover, similar to Major et al., we found that adding a shoe did not affect forefoot axial stiffness values (27). Ultimately, adding a shoe to a prosthetic foot affects the heel and midfoot axial stiffness values and heel, midfoot, and forefoot hysteresis, so footwear should be considered when determining how different prosthetic feet affect kinematics, kinetics, muscle activity, metabolic cost, and user preference of people with transtibial or transfemoral amputation.

In contrast to our hypothesis that adding a shoe to the LP Vari-flex prosthetic foot would not affect torsional stiffness values, we found that adding a shoe resulted in a decrease of plantarflexion (heel) torsional stiffness by 0.04 kN-m/rad but did not affect dorsiflexion (forefoot) torsional stiffness. Overall, adding a shoe to the LP Vari-flex prosthetic foot affects heel and midfoot axial stiffness values, heel, midfoot, and forefoot hysteresis, and plantarflexion (heel) torsional stiffness values. Previous studies have found that different types of footwear can have different effects on stiffness and hysteresis (27). This highlights the need to consider footwear when choosing and aligning prosthetic feet

and predicting how different prosthetic feet may affect kinematics, kinetics, muscle activity, metabolic cost, and user preference of people with transtibial or transfemoral amputation during walking.

Our study had some potential limitations. We used a uniaxial load cell (Instron 2580-201, Norwood, MA), so we were unable to measure off-axis forces on the load cell during the heel and forefoot tests. We used a low-friction roller system to reduce off-axis forces on the load cell and derived equations (1)–(3) to estimate the actual force applied to the prosthetic foot based on the force measured by the uniaxial load cell (Supplementary Material: Derivation and Verification of Equations 1–3). However, since the low-friction roller system is not perfectly frictionless, we may have overestimated the force on the prosthetic foot (Supplementary Material: Derivation and Verification of Equations 1–3). We conducted a *post hoc* analysis of the forefoot test with one prosthetic foot using a multi-axis force transducer (MC3A-500, AMTI, Watertown, MA, USA) and found that our estimate of the force applied to the prosthetic foot from equation (1) overestimated the actual force measured by the multi-axis force transducer by 1% (Supplementary Material: Derivation and Verification of Equations 1–3). Another potential limitation is that we estimated the torque and angle of each prosthetic foot assuming a constant moment arm (r) from the point of contact of the foot to the pylon when the prosthesis was preloaded to 4–6 N for the heel and forefoot tests. However, the moment arm may have decreased as the prosthetic foot was plantarflexed during the heel test and dorsiflexed during the forefoot test despite the low friction roller system. Therefore, we may have overestimated the torque on the prosthetic foot.

For our study, we only tested the effects of one type of walking shoe, which does not represent all types of footwear that people with amputation wear during daily life. Major et al. characterized the stiffness and hysteresis of different prosthetic feet inside several different types of footwear that included a hiking boot, athletic shoe, leather dress shoe, and flat shoe (27). The shoe that we tested is similar to the athletic shoe described in Major et al. (27). Major et al. found that of all the tested shoes, the athletic shoe resulted in the greatest change in stiffness and hysteresis relative to the condition without a shoe (27). Therefore, we expect that the differences in stiffness and hysteresis between prostheses with and without a shoe that we found in our study are likely greater than if we had tested a hiking boot, leather dress shoe, or flat shoe. Future studies should measure the effects of different types of footwear on the mechanical properties of LP Vari-flex feet or measure the prosthetic ankle torque-angle curves during walking with different footwear to provide characterization of the mechanical properties of prosthetic feet.

In addition to the mechanical properties of passive-elastic prosthetic feet, the alignment of the prosthesis relative to the socket can affect the function of the prosthesis during walking and is important for prosthetists to consider when prescribing prosthetic feet (37). When prescribing prosthetic feet, prosthetists often adjust the alignment of the prosthesis depending on if the person with amputation feels the prosthesis is too compliant or too stiff. Objective stiffness values of prosthetic devices can be used by prosthetists when choosing the prosthetic device, but the prosthesis can be further adjusted by changing its alignment. Future studies should examine how different alignments of the prosthesis relative to the socket can affect the mechanical properties of LP Vari-flex feet and provide guidelines for aligning prosthetic feet.

In conclusion, we characterized the axial stiffness values, torsional stiffness values, and hysteresis of LP Vari-flex prosthetic feet with a range of stiffness categories and sizes without and with shoes. In general, a greater prosthetic foot stiffness category resulted in an increase in heel, midfoot, and forefoot axial stiffness values, an increase in plantarflexion and dorsiflexion torsional stiffness values, and a decrease in heel, midfoot, and forefoot hysteresis. Moreover, an increase in prosthetic foot size resulted in a decrease in heel, midfoot, and forefoot axial stiffness values, an increase in plantarflexion and dorsiflexion torsional stiffness values, and a decrease in heel and midfoot hysteresis. Finally, adding a shoe to the LP Vari-flex prosthetic foot resulted in a decrease in heel and midfoot axial stiffness values, a decrease in plantarflexion torsional stiffness values, and an increase in heel, midfoot, and forefoot hysteresis. Thus, estimating the dynamic function of prosthetic feet without and with a shoe may be affected by the manufacturer-recommended prosthetic foot stiffness category and size as well as the footwear used in combination with the prosthesis. Future research and/or manufacturers should characterize the mechanical properties of prosthetic feet and footwear prior to experimental testing or prescription to better understand the resulting effects of mechanical properties on the user's walking biomechanics, preferences, daily activities, and the usability and acceptability of the prosthesis.

Overall, the axial and torsional stiffness values, hysteresis, and force-displacement equations of LP Vari-flex prosthetic feet with and without a shoe can be used to objectively compare LP Vari-flex prosthetic feet to other prosthetic feet to inform their prescription and design and use by people with a transtibial or transfemoral amputation. Prosthetists can compare our objective stiffness values to values reported for other prosthetic feet (11) rather than using manufacturer-defined categories that can be inconsistent or subjective. For example, the recommended stiffness category of the Vari-flex prosthesis for a 70 kg person with a moderate impact level is a category 4, which has an average stiffness of 35.7 kN/m at the heel and 26.7 kN/m at the forefoot for the size 27 prosthesis (20). If a prosthetist wants to prescribe an LP Vari-flex prosthesis of the same size with similar characteristics as the Vari-flex prosthesis, they could use the equations from Table 2 (average stiffness = intercept + $B_1 \times$ stiffness category + $B_2 \times$ size + $B_3 \times$ shoe/no shoe) to determine which category LP Vari-flex prosthesis has the same heel and forefoot stiffness as the Vari-flex prosthesis. Our results suggest they should prescribe the category 2 prosthesis, which has an average stiffness of 37.0 kN/m at the heel (from Table 2: average heel stiffness = $72.85 + (4.64 \times 2) + (-1.67 \times 27) + (-13.51 \times 0)$) and 30.14 kN/m at the forefoot (from Table 2: average forefoot stiffness = $66.47 + (3.84 \times 2) + (-1.63 \times 27) + (0.57 \times 0)$). Similarly,

since prosthetists typically choose the prosthetic foot size to match the size of the biological foot, a prosthetist can use our results in Tables 2–4 to ensure consistent characteristics for people of similar weight and impact level for a range of different foot sizes. Future work should synthesize our results and previous studies to create tables with objective stiffness values for different prostheses so prosthetists can compare different prosthetic foot categories, sizes, and models. In addition, our results can be used by researchers conducting studies on the effects of prosthetic feet with different mechanical properties on walking biomechanics, such as kinematics, kinetics, muscle activity, and metabolic cost. Moreover, researchers can use the force-displacement and torque-angle equations to design experimental prosthetic feet with mechanical properties that match commercially available prosthetic feet.

Data availability statement

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

Author contributions

JT: Data curation, Formal Analysis, Investigation, Validation, Visualization, Writing – original draft, Writing – review & editing, Methodology. ZC: Investigation, Writing – review & editing, Data curation, Methodology. AG: Conceptualization, Funding acquisition, Resources, Software, Supervision, Validation, Writing – review & editing, Methodology.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article.

This study was funded by a Department of Veterans Affairs Rehabilitation Research and Development Service merit review award (I01 RX002941).

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fresc.2024.1290092/full#supplementary-material

DATA SHEET 1
Code for statistics and figures.

DATA SHEET 2
Average axial and torsional stiffness and hysteresis data.

DATA SHEET 3
Derivation and verification of Equations 1–3.

DATA SHEET 4
Information about Data.

DATA SHEET 5
Force-displacement equations during the loading phase for the heel, midfoot, and forefoot tests with and without a shoe.

DATA SHEET 6
Torque-angle equations during the loading phase for the heel and forefoot tests with and without a shoe.

DATA SHEET 7
Force-displacement equations during the unloading phase for the heel, midfoot, and forefoot tests with and without a shoe.

DATA SHEET 8
Torque-angle equations during the unloading phase for the heel and forefoot tests with and without a shoe.

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 04 March 2024
DOI 10.3389/fresc.2024.1345364

OPEN ACCESS

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RECEIVED 27 November 2023
ACCEPTED 23 February 2024
PUBLISHED 04 March 2024

CITATION
Simon AM, Newkirk K, Miller LA, Turner KL, Brenner K, Stephens M and Hargrove LJ (2024) Implications of EMG channel count: enhancing pattern recognition online prosthetic testing.
Front. Rehabil. Sci. 5:1345364.
doi: 10.3389/fresc.2024.1345364

Implications of EMG channel count: enhancing pattern recognition online prosthetic testing

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Introduction: Myoelectric pattern recognition systems have shown promising control of upper limb powered prostheses and are now commercially available. These pattern recognition systems typically record from up to 8 muscle sites, whereas other control systems use two-site control. While previous offline studies have shown 8 or fewer sites to be optimal, real-time control was not evaluated.
Methods: Six individuals with no limb absence and four individuals with a transradial amputation controlled a virtual upper limb prosthesis using pattern recognition control with 8 and 16 channels of EMG. Additionally, two of the individuals with a transradial amputation performed the Assessment for Capacity of Myoelectric Control (ACMC) with a multi-articulating hand and wrist prosthesis with the same channel count conditions.
Results: Users had significant improvements in control when using 16 compared to 8 EMG channels including decreased classification error ($p = 0.006$), decreased completion time ($p = 0.019$), and increased path efficiency ($p = 0.013$) when controlling a virtual prosthesis. ACMC scores increased by more than three times the minimal detectable change from the 8 to the 16-channel condition.
Discussion: The results of this study indicate that increasing EMG channel count beyond the clinical standard of 8 channels can benefit myoelectric pattern recognition users.

KEYWORDS

below-elbow amputation, artificial hand, channel reduction, muscle signals, myoelectric control, outcome measures, surface electromyography

1 Introduction

Myoelectric pattern recognition control is a commercially available option for upper limb prosthesis control. Following transradial amputation, the most common major upper limb amputation (1), users can make physiologically appropriate muscle contractions of their phantom hand or wrist. Measurement via surface electromyography (EMG) of their residual forearm muscles and identification of these patterns of activity can be used to intuitively control similar prosthesis movements. For transradial users, the use of myoelectric pattern recognition, particularly after a period of home usage, has shown improvements over two-site agonist-antagonist control in some studies (2, 3), while other laboratory-based studies controlling fewer movements demonstrate similar outcomes between the two systems (4). Due to the amount of

dexterity lost in the missing hand, there is still much room to improve users' control and functional capabilities with any of these prosthetic systems.

Multiple review articles cover decades of pattern recognition research aimed at increasing the accuracy of powered upper limb devices including investigating various features and classification techniques, arm position, electrode shift during don-doff cycles (i.e., the process of putting on and taking off a prosthetic device), and proportional control (5–7). The EMG measurement system is an important part of the upper limb prosthetic system, and often channel optimization or channel reduction investigations are a subsection of pattern recognition studies. In a study quantifying control of hand and wrist using 12 uniformly placed surface EMG channels, authors indicate that offline analyses show that six optimally chosen channels only reduced accuracies from 93.1% to 91.5% for 6 movements (8). When investigating the impact of arm position and integrating EMG with accelerometer data, researchers noted that for five individuals with a transradial amputation, offline classification error only minimally increased when the number of channels was reduced from eight to two (9). When classifying finger movements for transradial users, a subset of 6 EMG channels classified 12 different individual finger movements with 90% accuracy, which was very similar to the accuracy when using all 11 channels (10). Using the dataset from (10), independent component analysis and clustering methods were used to find a reduced set of four EMG sensors that did not reduce overall accuracy (11). Similar results classifying finger movements were observed using a genetic algorithm to reduce features and channels: data from one individual with a transradial amputation and five with no limb absence indicated that 8–11 of the 16 EMG channels recorded in the study could be eliminated without sacrificing classification accuracy (12). Our own prior work using offline analyses suggested that finding an optimal subset of 3 channels from a set of 16 channels does not provide statistically significant reduction in classification accuracy (13).

While these surface EMG channel reduction results are encouraging and could reduce complexity of the pattern recognition EMG socket, these results are from offline analyses. Offline analysis may not always have a strong correlation with online pattern recognition performance metrics (14, 15). Although high offline accuracy may be necessary, it alone may not confirm good functional real-time control of a pattern recognition prosthesis (15). Alternatively, real-time control of a virtual prosthesis may be used to enhance offline analyses. For example, virtual prosthesis control has been found to be predictive of functional performance with a physical prosthesis: control of a virtual prosthesis on the Target Achievement Control (TAC) Test (16) was correlated with control of a physical prosthesis during several clinical outcome measures including the ACMC, the Southampton Hand Assessment Procedure, and the Box and Blocks test (17). Additionally, channel reduction studies use pre-gelled silver/silver chloride electrodes as an EMG interface, whereas clinical interfaces usually involve dry stainless steel domes embedded in a socket. This difference may also affect results. Therefore, investigation of performance with a clinical interface and in real-time is necessary to expand insight on whether or not reducing the number of EMG channels truly affects control.

The three upper limb pattern recognition systems that earned Food and Drug Administration (FDA) class II clearance (18–20) currently record up to 8 EMG channels. At the time they first became available, this was an increase from two-site agonist/antagonist control. Maintaining good skin contact with all 8 bipolar EMG channels (up to 17 domes embedded in a socket) was initially a concern. The success of these commercial systems indicates that good well-fitting sockets with 8 channels can be achieved. Clinical practice of electrode placement involves muscle palpation and selecting sites that have underlying muscle that maintain good contact during use (21). Clinical selection of these 8 channel locations is likely different than the optimal reduced channel sets found in the literature. If space is limited due to residual limb length, electrode contact points can even be shared between EMG channels. If space is not limited, the impact of more contact points and more EMG channels embedded in a prosthetic socket is untested.

The effect of EMG channel count on real-time prosthesis control with users in the limb loss population has not been directly investigated. This study serves to fill that knowledge gap for below-elbow prosthesis control. Individuals with no limb absence and individuals with unilateral transradial amputation controlled a virtual prosthesis in real-time using pattern recognition configured with 8 and 16 channels of EMG. Individuals with transradial amputation additionally used a physical prosthesis to complete the ACMC under the same channel conditions. We hypothesized that increased EMG channel count would result in improved control of both the virtual and physical prostheses. If supported, users may gain functional benefits of increasing the number of EMG channels in clinically available pattern recognition systems.

2 Methods

2.1 Participants

Individuals with no limb absence and individuals with a transradial amputation between the ages of 18 and 95 were recruited at the Shirley Ryan AbilityLab in Chicago, IL, for this study. Inclusion criteria for the individuals with an amputation also included history of a unilateral upper limb amputation below the elbow, the ability to use a prosthesis under myoelectric control, and residual limb length large enough to accommodate 33 electrode contacts. Exclusion criteria included cognitive impairment, evaluated subjectively during the consenting process that would interfere with their understanding of study requirements or any significant comorbidity that would preclude completion of the study. The study was approved by the Northwestern Institutional Review Board (STU00216244 and STU00015912), and all participants provided written informed consent to participate.

2.2 EMG configuration and study prosthesis

For all participants, 33 electrodes were placed on the surface of the forearm in order to measure from 16 bipolar EMG channels with one reference (i.e., ground) electrode. For individuals with no limb absence, silver/silver chloride electrodes were placed with an approximate 3 cm inter-electrode distance in two circumferential bands: 8 pairs in a band at the proximal portion of the residual forearm around the apex of the muscle bulge and another 8 pairs in a band distal to the first (Table 1). All 16 EMG channels were recorded for all trials. For the 8-channel condition, all 8 channels of EMG in the proximal band were used to train to the pattern recognition system. EMG signals were amplified and digitized using a Texas Instruments ADS1299 chip sampled at 1,000 Hz.

For individuals with a transradial amputation, custom sockets were fabricated (Figure 1) for use during both the virtual and physical prosthesis testing. Existing, well-fitting sockets were duplicated and a new socket was fabricated with a flexible inner liner. A clinician palpated the residual limb according to clinical practice to determine the locations of the bulk of the forearm muscles. Two circumferential bands of electrodes with an approximate 3–5 cm inter-electrode distance, based on residual limb length, shape and scar tissue, were selected over the forearm muscles: a proximal band consisting of twelve electrode pairs and a distal band of four electrode pairs. All 16 EMG channels were recorded. For the 8-channel condition, six electrode pairs from the proximal band and two pairs from the distal band were used to train the pattern recognition system. Electrode locations were transferred to the flexible inner liner, and stainless steel dome electrodes were installed (Figure 1, *left*). The study prosthesis consisted of the flexible inner liner and rigid vivak frame with 3D printed connections to a custom two-degree-of-freedom wrist and the Psyonic Ability Hand (22) (Figure 1, *right*). This prosthesis was used for both virtual and physical prosthesis testing.

2.3 Channel count evaluation

2.3.1 Virtual prosthesis testing

Participants with a transradial amputation wore the study prosthesis, but hand and wrist motors were turned off. The raw EMG measured from the flexible liner was sent to a desktop computer and displayed on a monitor to verify electrode contact and to control a virtual prosthesis displayed in front of the individual. The virtual (i.e., graphical) environment used in this study was non-immersive.

All participants trained a pattern recognition system to recognize hand and wrist movements using verbal and screen-guided prompts, making natural muscle contractions that

TABLE 1 Protocol overview.

Participants	EMG setup	Virtual TAC Test	Physical ACMC and survey
No limb absence	• Silver/silver chloride pre-gelled electrodes • 3 cm inter-electrode distance • Two circumferential bands of electrodes: 8 pairs in proximal band and 8 pairs in distal band	$N = 6$	
Transradial amputation	• Custom socket fabrication • Stainless steel dome electrodes • 3–5 cm inter-electrode distance • Two circumferential bands of electrodes: 12 pairs in proximal band and 4 pairs in distal band	$N = 4$	$N = 2$

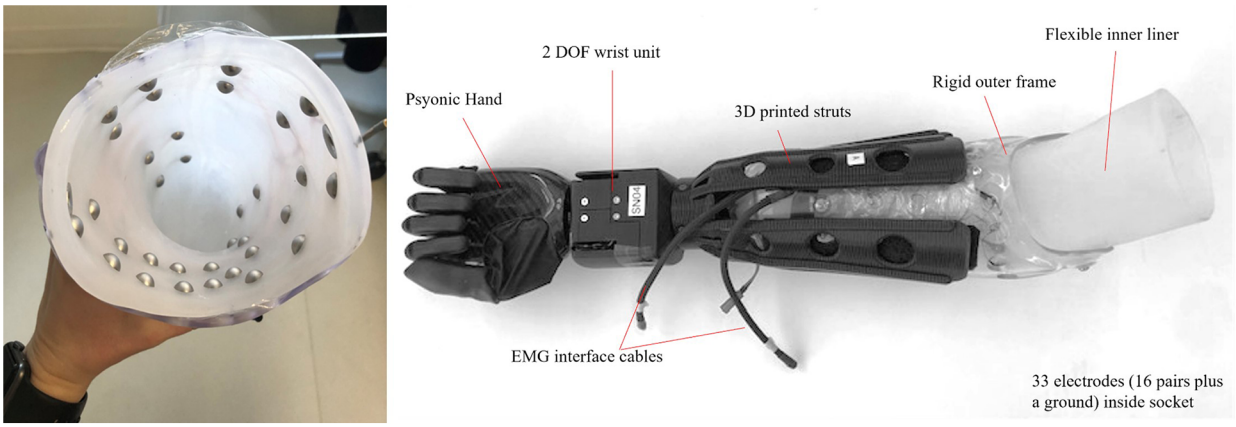

FIGURE 1
Physical prosthesis fabrication including (*left*) flexible inner liner with 33 electrode domes and (*right*) Psyonic Ability Hand and custom powered wrist.

mimicked a sequence of pictures on the monitor (23). All users were instructed to keep their forearm unsupported during calibration and training. Individuals with no limb absence trained hand open and close, wrist pronation and supination, wrist flexion and extension, and rest. Individuals with a transradial amputation trained hand open, hand close in chuck and key grip, wrist pronation and supination, and rest. During this seated calibration participants held each contraction for 3 s and repeated each motion four times. For individuals with a transradial amputation, training data collection was also prompted by a clinician, and one grip was trained first before adding the second grip. Additionally, for these individuals all virtual prosthesis use (calibration and testing) occurred with the physical prosthesis donned, forearm unsupported to create a weighted environment within the prosthetic socket, and hand/wrist motors turned off.

The pattern recognition classification system used was well established (24, 25) and similar to what is clinically available. EMG data from 8 or 16 channels were segmented into 200 ms analysis windows with a 25 ms update rate, four time domain and six auto-regressive features were extracted, and a linear discriminant analysis classifier (5, 26, 27) used to decode hand and wrist movements. Movement speed was proportional to EMG amplitude (28), and a decision-based velocity ramp was used to limit speed if movement decisions were not consistent (29).

After calibration, participants had sequential control of the trained movements and controlled a virtual prosthesis in a real-time non-immersive virtual environment. EMG quality was monitored to promptly identify and resolve obvious sources of noise (all participants) or socket-fit issues (transradial participants). When multiple grips were calibrated, users had to fully open the virtual hand to switch grips. After they demonstrated control of the virtual prosthesis, they practiced repetitions of the Target Achievement Control (TAC) Test. During the TAC Test, participants are instructed to move the virtual prosthesis such that it matches a target posture (Figure 2) within an acceptable tolerance on each trained degree of freedom (±5 degrees for participants with no limb absence and ±10 degrees for participants with transradial amputation). All participants had at least one practice session prior to testing.

Data collection began with two screen-guided calibrations, which were used to train the virtual prosthesis. Similar to practice, each calibration had two repetitions of 3 s contractions for each movement and a rest period of 2 s between movements. After participants re-acclimated to controlling the virtual prosthesis, they performed six repetitions of each one-degree-of-freedom movement target in the TAC Test. Each condition (8 and 16 channels) was randomized as were the repetitions within each condition trial. Breaks were provided as necessary between TAC Test trials with a longer break between channel conditions. A single researcher set the channel condition during testing. The participant and other individuals in the room (prosthetist, occupational therapist, and additional researchers) were blinded to channel condition throughout the testing. At the end of the session, four more repetitions of each motion were collected via screen-guided calibration for offline analysis.

After each condition, participants in the transradial group completed a questionnaire aimed at assessing the user's perceived control, which asked them to rank on a scale from 1 (very easy) to 5 (very hard) how difficult it was to move the prosthesis in each of the five movements (wrist supination, wrist pronation, hand open, chuck grip, and key grip). A total score of 5 indicated that all movements were easy to achieve and, a total score of 25 indicated all movements were very hard.

TAC Test performance metrics were averaged across all movements. Metrics included: failure rate (the percentage of trials participants failed to achieve the target posture within 20 s), completion time (for successful trials, the time to achieve the target posture), and path efficiency (the shortest path to the

FIGURE 2
Target Achievement Control (TAC) Test. Participants moved a virtual prosthesis into target posture. The virtual hand turned green when target was reached within acceptable tolerances. Participants with transradial amputation wore the study prostheses during virtual testing. All users were instructed to keep their forearm unsupported during testing.

target posture divided by the total distance traveled during the trial). Additionally, the two reserved calibrations collected at the end of the experiment were used to calculate offline classification error. Since some users had delayed onset or early termination of their muscle contractions, classification error was calculated as a false activation rate: muscle contraction movements that were incorrectly classified as rest were not included as errors.

2.3.2 Physical prosthesis testing

In an additional testing session on a separate day, individuals with a transradial amputation used the study prosthesis with the 8- and 16-channel conditions. The Psyonic Ability Hand had the capability to close in multiple grips, but only key and chuck grip were calibrated for this preliminary testing. Additional custom post-processing was necessary to ease how the hand physically changes grips because the Psyonic Hand does not need to be fully open to change grip patterns. Pilot testing indicated that if grip decisions were not consistent, the hand would change to a different grip even if an object was being held. Previous approaches to resolve this issue include requiring the user to fully open the hand and/or perform a hand open signal for a set time duration before allowing the system to change grips (30). In this study, users were required to perform a strong hand open signal for a set duration prior to the hand changing grips. Clinician and user feedback was used to set the strength and duration thresholds of the hand open contraction for each user.

Like the virtual session, participants donned the study prosthesis and calibrated the same set of movements. After the device was calibrated, the hand and wrist motors were turned on to allow the participant to practice using the prosthesis. Practice involved working with an occupational therapist to control each motion of the prosthesis, stacking blocks, folding a towel, and other tasks in both a seated and standing position.

A single researcher set the channel condition in a randomized order so all other individuals, including the user, were blind to the channel condition. After the channel condition was set, participants practiced with the prosthesis for an additional 5 min. Re-calibration was allowed based on the clinical discretion of the blinded occupational therapist/prosthetist. Participants performed a single trial of the ACMC with each channel condition. The ACMC is an observational assessment measuring the user's quality of prosthetic hand movements during a two-handed functional task (31, 32). The ACMC outcome was videotaped while users packed luggage, gathering items from various size containers and locations, packing and folding them into a suitcase. After each channel condition, participants completed the same questionnaire aimed at assessing their perceived control. If the participant recalibrated during the previous condition, the system was reverted to the original calibration data prior to starting the 5-min practice with the other channel condition (again with the opportunity to recalibrate), thus establishing a standard baseline of control for each condition. At the end of the session, four more repetitions of each motion were recorded via screen-guided calibration for offline analysis. A certified occupational therapist who was also blinded to the channel condition scored the assessment using the video.

2.3.3 Statistical analysis

Analysis of variance statistical analyses were conducted utilizing Minitab Statistical Processing Software (Version 21) to assess the impact of EMG channel count on various measures associated with the TAC Test, including classification error rate, failure rate, completion time, and path efficiency. To accommodate the hierarchical structure of our data, where multiple measurements were taken from each participants, linear mixed effects models were employed. Participant was incorporated as a random effect to account for inter-subject variability, while population (categorized into no limb absence or transradial amputation) and channel count (8 or 16) were included as fixed effects to evaluate their influence on the dependent variables.

For each dependent variable, a separate linear mixed effects model was specified. The model fitting process involved the estimation of fixed effects to understand the relationship between the dependent variables and our predictors, while random effects were used to model the variability attributable to differences across participants. The significance of fixed effects was determined using likelihood ratio tests, comparing the full model containing the predictors with a reduced model excluding the effect in question. This approach allowed for the assessment of whether EMG channel count, as well as the population category, significantly affected the outcomes of interest.

3 Results

3.1 Participants

Ten individuals (six with no limb absence and four with a unilateral transradial amputation) participated in this study (Table 1). The no limb absence group consisted of 3 males and 3 females, were all right-handed, and all used their right arm to control the virtual prosthesis. The transradial group was all male, and all reported limb loss secondary to trauma. Additional demographics for participants with transradial amputation are listed in Table 2.

3.2 Virtual prosthesis results

All participants successfully completed the virtual environment testing. Offline classification error significantly decreased for the 16-channel system compared to the 8-channel system ($p = 0.006$). There were no differences between population ($p = 0.785$). For users with the no limb absence, false activation error rates for six movements were 7.0% [6.1, S.D.] for 8 channels and 3.0% [2.6] for 16 channels. For users with transradial amputation, false activation error rates for five movements were 8.8% [7.5] for 8 channels and 2.9% [4.1] for 16 channels. Confusion matrices for these conditions are displayed in Figure 3.

TABLE 2 Demographics of individuals with a transradial amputation.

ID	Age	Years since amputation	Prosthesis side	Previous handedness	Residual limb length	TMR	PR experience	Recent home prosthesis use
S1	36	9	Left	Right	Long (300 mm)	Y	Y	Non-user
S2	60	44	Right	Right	Medium (210 mm)	N	Y	Myoelectric (2-site), 8+ h/day, 7 days/week
S3	29	3	Left	Right	Medium (245 mm)	N	Y	Myoelectric (2-site), 4-8 h/day, 5-7 days/week
S4	34	6	Left	Right	Medium (225 mm)	Y	Y	Myoelectric (PR) or BP, <4 h/day, 1–7 days/week

TMR, targeted muscle reinnervation (24); PR, pattern recognition; 2-site, two-site agonist-antagonist control; BP, body-powered prosthesis.

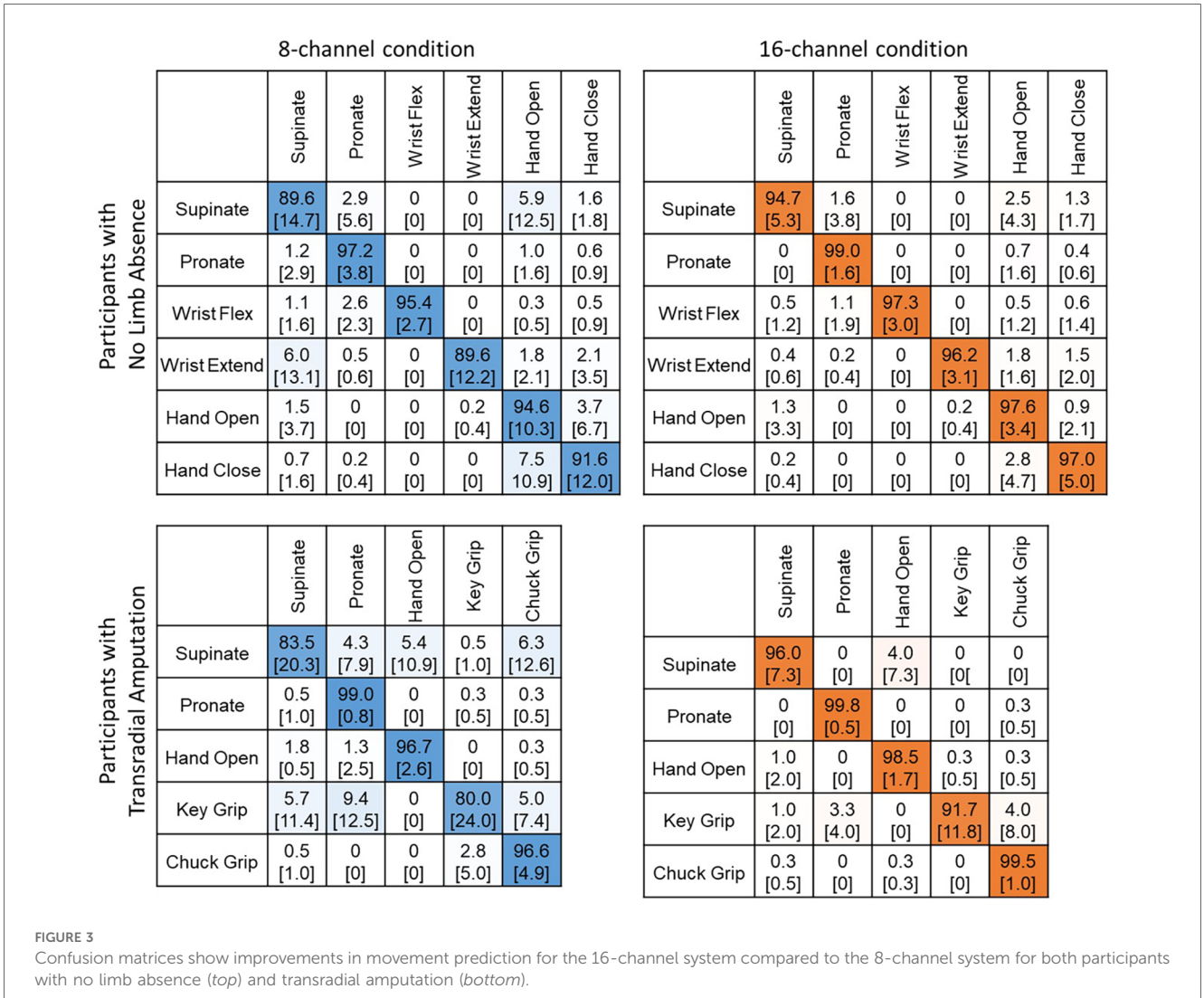

FIGURE 3
Confusion matrices show improvements in movement prediction for the 16-channel system compared to the 8-channel system for both participants with no limb absence (*top*) and transradial amputation (*bottom*).

TAC Test metrics for both groups showed an overall improvement in control for the 16-channel count condition compared to the 8-channel count (Figure 4). When using 16 channels compared to 8 channels, average failure rates decreased from 6.2% [8.8] to 0.3% [0.8] for the group with no limb absence and from 8.3% [12.3] to 2.5% [3.2] for the group with transradial amputation. However, these changes were not statistically significant between channel count ($p = 0.082$) or population ($p = 0.525$). Completion times decreased from 7.3 s [2.9] to 4.4 s [1.8] and 4.6 s [1.7] to 3.7 s [0.9]. These changes were statistically significant for channel count ($p = 0.019$) but not population ($p = 0.962$). Path efficiency increased from 74.8% [10.9] to 85.1% [9.3] and 75.9% [11.3] to 84.5% [5.3] for the groups with no limb absence and transradial amputation, respectively. These changes were statistically significant for channel count ($p = 0.013$) but not for population ($p = .962$).

3.3 Physical prosthesis results

Two individuals with a transradial amputation (S1 and S4) successfully completed the physical prosthesis testing. The other

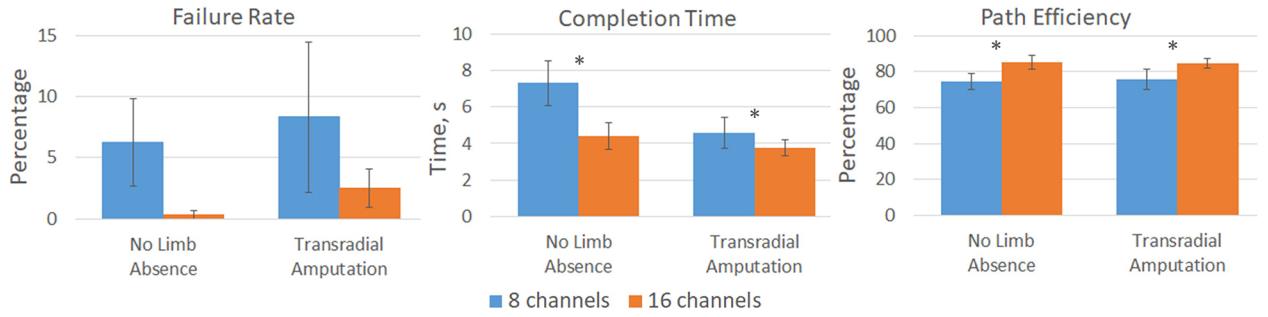

FIGURE 4
Virtual prosthesis TAC Test results for participants with no limb absence and with transradial amputation for both the 8-channel (*blue*) and 16-channel (*orange*) systems. Significant improvements, denoted by *, in completion time ($p = 0.019$) and path efficiency ($p = 0.013$) were measured for the 16-channel system compared to the 8-channel system. Failure rate was not statistically significant between channel count ($p = 0.082$).

two participants' (S2 and S3) residual limb became quite fatigued when practicing using the study prosthesis, likely due to its length and weight. Since they were at elevated risk for fatigue and proximal joint discomfort, they did not attempt the ACMC.

Participants S1 and S4 demonstrated increased capabilities with the 16-channel system compared to the 8-channel system (Figure 5). S1 score increased from 48.7 to 56.3 and S4 increased from 44.6 to 52.8. Offline false activation rate error slightly decreased for the 16-channel system, 10.0% [2.4], compared to the 8-channel system, 12.8% [4.2].

3.4 Transradial user questionnaire results

Since individuals with an amputation were the target population, they were the only group surveyed on their perception of control between the two different channel conditions. They were wearing and subjected to the weight of the study prosthesis for both the virtual and physical prosthesis testing but only interacting with the device for the physical testing. Figure 6 shows that, on average for the virtual testing, users perceived easier control with the 16-channel system compared to the 8-channel. A similar trend was seen for the physical prosthesis but with a much larger gap in ease of use between the two different channel conditions.

4 Discussion

To the authors' knowledge, this is the first study that evaluates EMG channel count during real-time pattern recognition control with end users. Results support our hypothesis that real-time control with a pattern recognition system configured with 16 EMG channels provides better control than one configured with 8 EMG channels. Both groups of participants (individuals with no limb absence and with unilateral transradial amputation) were able to

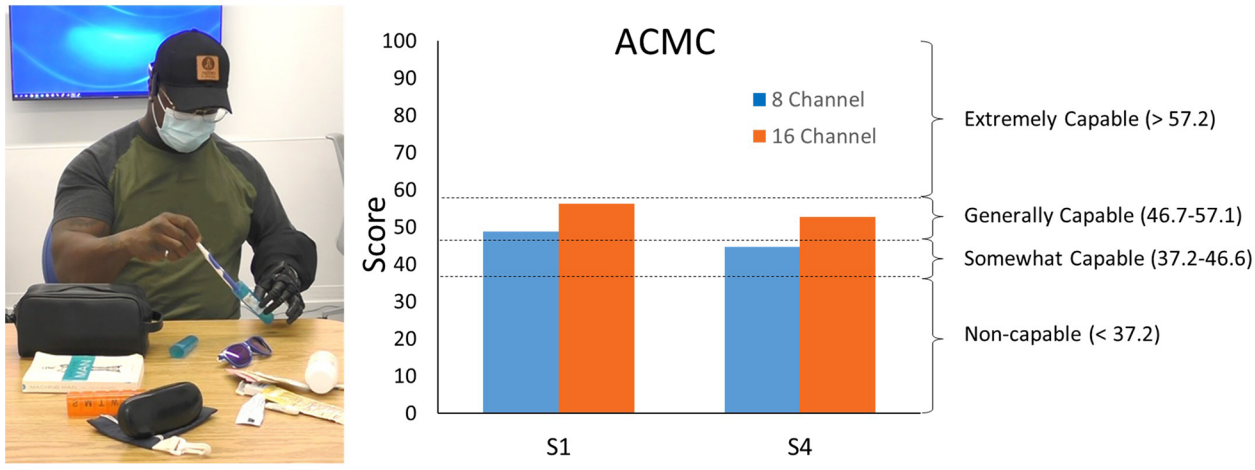

FIGURE 5
Individual with a transradial amputation packing luggage items (*left*) as a part of the ACMC. ACMC scores demonstrate increased capabilities with the 16-channel system compared to the 8-channel system (*right*).

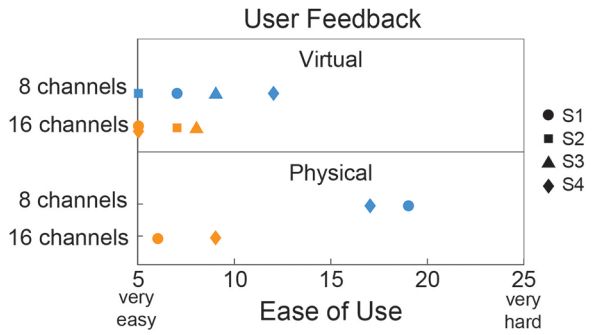

FIGURE 6
Ease of use questionnaire given to individuals with transradial amputation for both the virtual ($N = 4$) and physical ($N = 2$) prosthesis testing. A total score of 5 indicated that all motions were "very easy" and a total score of 25 indicated that all motions were "very hard".

complete TAC Test trials in significantly less time with significantly increased path efficiency with the 16-channel system. Participants with a transradial amputation also demonstrated increased capabilities while using a physical prosthesis to perform an outcome measure with the 16-channel system. Furthermore, survey results from transradial users indicate that they can perceive this control improvement in both the virtual and physical environment.

Physical prosthesis testing showed improvements in the ACMC score when using the system with more EMG channels: both participants' scores increased (S1 by 7.6 points and S4 by 8.2 points). This increase in ACMC score is more than three times the minimal detectable change of 2.5 for the ACMC scored by a single rater. This outcome measure demonstrates that these improvements in control are clinically relevant as one user's scores indicated a move from a category of "somewhat capable" to "generally capable". Survey results also indicate an expected shift in decreased ease of use from the virtual to the physical environment. Physical prosthesis control is more difficult because weight, limb position, and fatigue likely have a larger impact. Notably, EMG channel count had a much larger impact on ease of use with a physical device compared to a virtual prosthesis. S2 and S3's inability to complete physical prosthesis testing likely is a result of the selection of physical device. Despite participants S2 and S3 having residual limb lengths similar to S4, during use the device weight and length led to substantial muscle fatigue for them, making it impractical for use under either channel condition. An alternative study device or device configuration (e.g., single degree-of-freedom hand with two degree-of-freedom wrist) might have led to reduced device weight or length or different weight distribution, potentially enabling these participants to complete the channel condition study with a physical prosthesis.

False activation rates in this study were within the ranges of offline errors previously published for transradial users (i.e., classification accuracy converted to error rate). Error rate for the 8-channel condition was 8.8% for five movements (i.e., two wrist movements, hand open, and two grips): Li et al. found six optimally placed EMG channels resulted in an 8.5% error rate for six movements (four wrist movements, hand open, and hand close) (8), and Geng et al. (9) found 7.3% error for 6 intra-limb movements (four wrist movements, hand open and hand close). Error rates measured in this study, 2.9% with 16 EMG channels, are lower than these previously published results.

This work investigated channel count as it relates to an input into pattern recognition systems. However, there are other alternative methods of EMG prosthetic control. For example, multi-channel EMG signals can be decomposed to identify individual motor unit activity (33). This type of approach uses source separation techniques and often requires higher channel counts than typical pattern recognition systems. When successfully implemented, this approach has been used with individuals with no limb absence and two with limb difference (one transradial congenital absence and one with transradial amputation) to decode six wrist motions, showing hat on average 16 ±7 motor units were identified per motion with greater than 85% accuracy (34) and can occur in real-time (35). For individuals with no limb absence, dimensionality-reduction using a nonlinear autoencoder has shown promise for control of a high-dimensional virtual hand with only four EMG signals (36). It is possible that incorporating more channels into such a system may further improve performance, perhaps at the expense of a more extensive training data set for configuration of the autoencoder.

Virtual performance metric trends for the TAC Test were similar between groups even though the systems between groups were not the same. While the electrodes used for each population were different (i.e., pre-gelled silver/silver chloride for the group with no limb absence and dry stainless steel domes for the group with a transradial amputation) they both represent common electrode types used in upper limb pattern recognition research. Results are promising in that the trend towards improved control with 16 EMG channels was independent of these electrode differences. Stainless steel dome electrodes (i.e., the clinical interface for EMG controlled transradial prostheses) have higher impedance, poorer skin/electrode impedance matching and more electrode liftoff compared to the pre-gelled silver/silver chloride self-adhesive electrodes. Channel arrangement was slightly different: the 8-channel condition for individuals with no limb absence included only the proximal ring of electrodes whereas the 8-channel condition for individuals with transradial amputation included six channels in the proximal ring and two in the distal ring. Both of these EMG configurations are reasonable choices that potentially could be clinically implemented and both lead to similar improvements for the 16- vs. 8-channel conditions for completion time and path efficiency. They are, however, different than channel reduction studies that often reduce the number of channels to an optimal set of four to eight found via a search algorithm. In this way, the 8-channel condition may be slightly underestimating control performance of an optimal 8-channel system. But, this may be more clinically relevant since, currently, there is no quantitative mechanism to select optimal channels for individual users in the clinic. Another difference involves the trained and tested movements: the no limb absence group controlled a virtual two degree-of-freedom

wrist and a one degree-of-freedom hand, whereas the transradial amputation group controlled a virtual one degree-of-freedom wrist and hand with two grips. The TAC Test was programmed to be slightly more difficult for the no limb absence group (i.e., smaller window of acceptable tolerances of all degrees-of-freedom). These variations were included to test differences more broadly in channel count.

A clinically-relevant choice during testing was to use the same EMG interface during virtual prosthesis testing that individuals with a transradial amputation would use during physical prosthesis testing. These participants wore and supported the weight of the study prosthesis during virtual testing. While a custom socket is not always available for real-time virtual testing, when available, it does provide a more real-world environment for measuring EMG. Additionally, it was important to confirm that 33 dome electrodes could be installed into an upper limb socket. It was noteworthy that inclusion in this study required having a residual limb length large enough to accommodate 33 domes; therefore there is a subset of users in which there is not enough room. These results, however, would indicate from a merely channel count perspective, to include more than 8 and up to 16 channels if possible.

Clinically, these results may be challenging to implement as it doubles the complexity of the EMG-socket interface. Maintaining good electrode contact during home use is difficult (30); EMG channels are susceptible to signal noise. While the reliability of surface EMG recordings over time may be challenging, research into automatic noise detection and fault-tolerant systems is showing promise to allow users to maintain reliable control even if and when EMG signal noise occurs (37, 38). This is true regardless of the control strategy employed.

This study had some limitations including the low number of participants with transradial amputation and limitation on running statistics. The protocol involved making a socket with embedded electrodes for each participant and having the participant wear the prosthesis for both the virtual and physical testing. For two participants, the prosthesis weight and length was too much for them to support during physical prosthesis use. It is possible that if either the custom wrist or the Psyonic Ability hand was swapped out for a shorter or lighter version, they may have been able to complete the ACMC. Another limitation to this study of channel count was that we only included participants who had enough room in their socket for 33 EMG domes. Although untested in this study, it would be valuable to know if utilizing electrode contact sharing to achieve 16 EMG channels for users with shorter residual limbs results in similar control improvements above the now standard 8 EMG channels.

5 Conclusion

Contrary to the standard 8 EMG channels currently used for commercial upper limb pattern recognition systems, our results indicate that increasing the number of EMG channels can lead to improvements in both offline and online control. Our work does not imply that existing control systems work poorly, merely that more capable systems could be created in the future. Importantly, these results are consistent for individuals with transradial amputation during both virtual and physical prosthesis testing. Improvements were not only perceptible to the end users but also measurable by means of the TAC Test and ACMC.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Northwestern University Internal Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

AS: Formal Analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing, Project administration, Data curation, Supervision. KN: Investigation, Methodology, Visualization, Writing – original draft, Writing – review & editing, Formal Analysis. LM: Investigation, Methodology, Project administration, Writing – review & editing. KT: Investigation, Methodology, Writing – review & editing, Project administration. KB: Investigation, Resources, Software, Writing – review & editing. MS: Investigation, Resources, Software, Writing – review & editing. LH: Formal Analysis, Funding acquisition, Methodology, Project administration, Supervision, Validation, Writing – review & editing, Conceptualization, Data curation, Resources, Software.

Funding

The author(s) declare that financial support was received for the research, authorship, and/or publication of this article.

Funding for this study was provided by the National Institutes of Health (NIH) R01 HD094861, the Department of Defense (DoD) W81XWH2210431, Discretionary laboratory funding, and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) 90REGE0003. NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this report do not necessarily represent the policy of NIDILRR, ACL, or HHS, and you should not assume endorsement by the Federal Government.

Conflict of interest

LH has a financial interested in Coapt, LLC, however no Coapt products were used in the completion of this research project.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 15 March 2024
DOI 10.3389/fresc.2024.1336115

OPEN ACCESS

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RECEIVED 10 November 2023
ACCEPTED 06 March 2024
PUBLISHED 15 March 2024

CITATION
Gladish JR, Dearth CL, Beachler MD, Potter BK, Forsberg JA and Hendershot BD (2024) Mechanical loading of bone-anchored implants during functional performance tests in service members with transfemoral limb loss.
Front. Rehabil. Sci. 5:1336115.
doi: 10.3389/fresc.2024.1336115

Mechanical loading of bone-anchored implants during functional performance tests in service members with transfemoral limb loss

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Introduction: For individuals with limb loss, bone-anchored implants create a direct structural and functional connection to a terminal prosthesis. Here, we characterized the mechanical loads distal to the abutment during several functional performance tests in Service members with transfemoral (TF) limb loss, to expand on prior work evaluating more steady-state ambulation on level ground or slopes/stairs.
Methods: Two males with unilateral TF limb loss and two males with bilateral TF limb loss participated after two-stage osseointegration (24 and 12 months, respectively). Tri-directional forces and moments were wirelessly recorded through a sensor, fit distal to the abutment, during six functional tests: Timed Up and Go (TUG), Four Square Step Test (FSST), Six Minute Walk Test (6MWT), Edgren Side-Step Test (SST), T-Test (TTEST), and Illinois Agility Test (IAT). Additionally, participants performed a straight-line gait evaluation on a 15 m level walkway at a self-selected speed (0.93–1.24 m/s). Peak values for each component of force and moment were extracted from all six functional tests; percent differences compared each peak with respect to the corresponding mean peak in straight-line walking.
Results: Peak mechanical loads were largest during non-steady state components of the functional tests (e.g., side-stepping during SST or TTEST, standing up from the ground during IAT). Relative to walking, peak forces during functional tests were larger by up to 143% (anterior-posterior), 181% (medial-lateral), and 110% (axial); peak moments were larger by up to 108% (flexion-extension), 50% (ab/adduction), and 211% (internal/external rotation).
Conclusions: A more comprehensive understanding of the mechanical loads applied to bone-anchored implants during a variety of activities is critical to maximize implant survivability and long-term outcomes, particularly for Service members who are generally young at time of injury and return to active lifestyles.

KEYWORDS

amputation, biomechanics, kinetics, military, osseointegration, periprosthetic fracture

1 Introduction

Despite substantial technological advancements in prosthetic components, suboptimal human-device interaction can diminish functional performance and overall clinical outcomes for persons with limb loss. Specifically, residual limb tissues are not evolutionarily designed for weight bearing and thus the mechanical environment within a conventional prosthetic socket often results in poor skin health (1, 2). Poor residual skin health can limit prosthesis use, thereby reducing mobility and independence. Osseointegration, by direct skeletal attachment, mitigates many common drawbacks of conventional prosthetic sockets (e.g., inadequate fit/suspension, heat, moisture)—while also enhancing sensory feedback, movement quality, and prosthesis embodiment—for many resulting in greater prosthesis use, mobility, and quality of life (3).

Service members with limb loss are generally young at time of injury and often return to active lifestyles. To mitigate risk for periprosthetic fracture and component damage/failure (4), it is critical to understand the mechanical loads applied to the bone-anchored implant during a variety of activities. Compared to traditional biomechanical evaluations, wireless sensors incorporated into the endoskeletal prosthesis capture more direct measurement of mechanical loading at the implant-femoral interface, and can facilitate such evaluations in non-laboratory settings. Such an approach has been used to characterize forces and moments at the bone-anchored implant among individuals lower limb loss during steady-state walking (in a straight line and circles), as well as ramp/stair ascent and descent (5–7). The purpose of this study was to further characterize mechanical loading of the bone-anchored implant among Service members with unilateral and bilateral transfemoral (TF) limb loss, specifically during several functional performance tests that would be difficult to measure with traditional biomechanical methods (i.e., instrumented walkways) and are otherwise lacking in the current literature [e.g., (8)]. It was expected that mechanical loads measured during functional tasks would be larger than steady-state ambulation (i.e., walking in a straight line). Ultimately, such an effort will contribute to a more complete understanding of implant survivability in highly active populations with TF limb loss.

2 Methods

2.1 Participants

Four males with traumatic TF limb loss (Table 1), two unilateral ("UTF1" and "UTF2") and two bilateral ("BTF1" and "BTF2"), participated after osseointegration (OPRA^{TM} implant system; Integrum, Sweden). All participants wore microprocessor knee(s) with a dynamic response foot-ankle device(s), and were able to independently ambulate without the use of assistive devices (e.g., cane, crutches, walker). All participants consented to procedures approved by the local Institutional Review Board.

2.2 Procedures

Approximately one hour prior to data collection, a certified prosthetist fit a wireless 6DOF load sensor (iPecs^{TM}; RTC Electronics Inc., Dexter, MI, USA) just distal to the failsafe mechanism (Axor II^{TM}; Integrum, Sweden). Note, both participants with bilateral TF limb loss could only accommodate a sensor on the right side due to limited clearance between the left prosthetic knee and failsafe (i.e., could not preserve limb length and alignment). Prior to data collection, the load sensor was zeroed with the prosthesis unloaded.

Tri-directional forces and moments were wirelessly recorded (850 Hz) during six functional performance tests: (1) Timed Up and Go (TUG), (2) Four Square Step Test (FSST), (3) Six Minute Walk Test (6MWT), (4) Edgren Side-Step Test (SST), (5) *T*-Test (TTEST), and (6) Illinois Agility Test (IAT). Additionally, the same forces and moments were recorded while participants completed an overground gait assessment along a 15 m walkway, at a self-selected speed. Self-selected walking speeds were 1.18 m/s (UTF1), 1.24 m/s (UTF2), 1.09 m/s (BTF1), and 0.93 m/s (BTF2).

2.3 Analyses

Raw forces and moments were output using the provided calibration matrix and analyzed with custom scripts in MATLAB (MathWorks, Natick, MA, USA). Raw forces and moments were normalized to body weight (BW and BW-m). The sensor was oriented such that forces and moments were resolved in anatomical coordinates of the residual limb: anterior-posterior, medial-lateral, and axial; corresponding moments in flexion-extension, ad/abduction, and internal/external rotation. Peak values within each direction/component of force and moment were identified and extracted from each functional test; for the gait evaluation, means of these peaks were computed across all steps (~15 steps per participant). To provide a relative measure of the mechanical loads imposed during the functional tests, percent

TABLE 1 Demographics for each participant with unilateral (UTF) and bilateral (BTF) transfemoral limb loss, at time of evaluation after osseointegration (OI).

		Age (yr)	Body mass (kg)	Stature (cm)	Time since amp (mo)	Time since OI (mo)
Unilateral	UTF1	50	86.5	174.5	114	24
	UTF2	42	106.0	176.0	204	24
Bilateral	BTF1	30	73.3	180.5	98	12
	BTF2	38	106.5	185.0	112	12

All participants wore microprocessor knees (X3®; Ottobock) and dynamic response ankle-foot prostheses (UTF1, Kinterra®, Proteor; UTF2, Pro-Flex® LP Torsion, Ossur; BTF1, Variflex XC®, Ossur; BTF2, Soleus Tactical®, College Park Industries).

differences were computed for all peak forces and moments with respect to the corresponding mean peaks from the gait evaluation.

3 Results

Peak medial-lateral forces were largest in the SST, anterior-posterior forces in the IAT and T-Test, and axial forces in the SST (Table 2). Flexion-extension moments were largest in the 6MWT, ab/adduction moments in the SST, and internal/external rotation moments in the IAT (Table 3).

Compared to straight-line walking, peak forces during functional tests were larger by up to 143% (anterior-posterior), 181% (medial-lateral), and 110% (axial; Figure 1); peak moments were larger by up to 108% (flexion-extension), 50% (ab/adduction), and 211% (internal/external rotation; Figure 1).

Persons with UTF vs. BTF generally performed better on most functional tests (Table 4).

4 Discussion

This study characterized peak mechanical loads during several functional performance tests, after osseointegration, in Service members with unilateral and bilateral TF limb loss. These peak loads tended to be largest during transient components of the functional performance tests, with peak forces and moments respectively up to 181% and 211% larger than during straight-line walking. In the sagittal plane, peak anterior-posterior forces tended to occur during initiation (e.g., standing up from the ground; IAT) or when weaving between cones (IAT); similarly, peak flexion-extension moments occurred during initiation or change of directions within the IAT and TTEST. In the frontal plane, peak medial-lateral forces tended to occur during side stepping (SST); peak ab/adduction moments also occurred during side stepping or directional changes at the far ends of the SST course. In the transverse plane, peak axial forces tended to occur during sidestepping or directional changes in the TTEST or SST; peak internal/external rotation moments occurred when turning (TUG) or weaving (IAT).

Comparing straight-line walking, peak forces and moments measured in the current study are generally comparable to prior work in persons with both transtibial and transfemoral limb loss (5–7). While smaller loads during more repetitive activities like walking (level, slopes, stairs) can accumulate over time, and thus play a role in the fatigue life of system components [e.g., perhaps necessitating prophylactic exchange/replacement; (9)], larger peak values during more transient activities remain important for minimizing unexpected breakaway or risk for unsafe load transmission. Here, despite several occurrences of non-body weight normalized peak flexion-extension moments (67–80 Nm) and internal/external rotation moments (13–25 Nm) exceeding the respective fail-safe release threshold in flexion/bending (70 ± 5 Nm) and axial twist (15 ± 2 Nm), none of these resulted in an actual release during testing. As suggested previously (7), relatively large between-subject variability supports the notion of a personalized

TABLE 2 Peak forces by functional performance test for each participant with unilateral (UTF) and bilateral (BTF) transfemoral limb loss. Forces are normalized to body weight (BW).

	Medial-lateral				Anterior-posterior				Axial			
	UTF1	UTF2	BTF1	BTF2	UTF1	UTF2	BTF1	BTF2	UTF1	UTF2	BTF1	BTF2
TUG	0.183	0.100	0.118	0.142	0.272	0.240	0.267	0.252	1.059	1.460	1.741	1.165
4SST	0.168	0.098	0.110	0.145	0.191	0.213	0.200	0.170*	1.085	1.388	1.835	1.510
6MWT	0.182	0.116	0.211	0.165	0.291	0.215	0.350	0.236	1.118	1.383	2.102	1.285
SST	0.151	0.166	0.302	0.153	0.164	0.196	0.171	0.129*	1.603	2.165	2.264	1.482
TTEST	0.196	0.148	0.232	0.153	0.308	0.276	0.279	0.220	1.326	1.971	1.978	1.563
IAT	0.193	0.121	0.148	0.188	0.419	0.233	0.546	0.255	1.280	1.688	1.888	1.250
SSW	0.163	0.090	0.108	0.134	0.239	0.193	0.225	0.160	0.867	1.094	1.077	1.042

TUG, timed up and go; FSST, four square step test; 6MWT, six minute walk test; SST, edgren side-step test; TTEST, T-test; IAT, illinois agility test; SSW, self-selected walk. Asterisks (*) indicate two occurrences where the peak force was posterior vs. anterior for all other tests.

TABLE 3 Peak moments by functional performance test for each participant with unilateral (UTF) and bilateral (BTF) transfemoral limb loss. Moments are normalized to body weight (BWm).

	Flexion/extension				Ab/adduction				Internal/external rotation			
	UTF1	UTF2	BTF1	BTF2	UTF1	UTF2	BTF1	BTF2	UTF1	UTF2	BTF1	BTF2
TUG	0.050	0.057	0.093	0.056	0.046	0.066	0.057	0.040	0.014	0.021	0.027	0.016
4SST	0.057	0.053	0.090	0.050	0.058	0.070	0.069	0.041	0.011	0.014	0.016	0.014
6MWT	0.058	0.053	0.111	0.059	0.058	0.072	0.088	0.052	0.012	0.016	0.029	0.012
SST	0.039	0.055	0.082	0.043	0.064	0.098	0.086	0.049	0.008	0.011	0.017	0.008
TTEST	0.064	0.071	0.104	0.059	0.057	0.082	0.074	0.048	0.012	0.019	0.016	0.010
IAT	0.053	0.066	0.097	0.064	0.053	0.080	0.073	0.042	0.015	0.024	0.034	0.019
SSW	0.031	0.040	0.054	0.036	0.051	0.056	0.059	0.038	0.007	0.013	0.011	0.007

TUG, timed up and go; FSST, four square step test; 6MWT, six minute walk test; SST, edgren side-step test; TTEST, T-test; IAT, illinois agility test; SSW, self-selected walk.

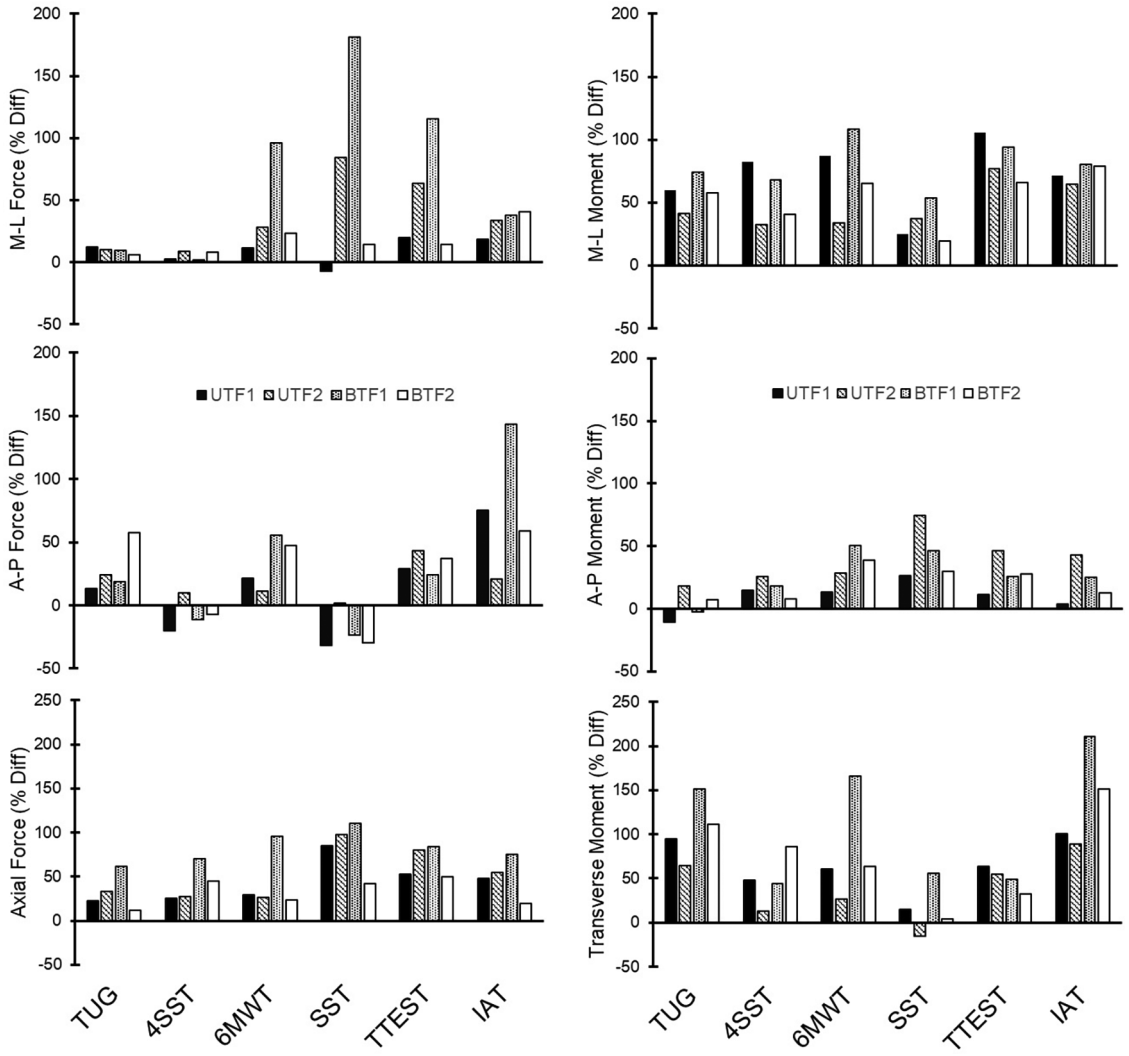

FIGURE 1
Percent differences (% Diff) in peak forces and moments, by functional performance test relative to corresponding peaks from the gait evaluation, for each participant with unilateral (UTF) and bilateral (BTF) transfemoral limb loss. TUG, timed up and go; FSST, four square step test; 6MWT, six minute walk test; SST, edgren side-step test; TTEST, T-test; IAT, illinois agility test.

TABLE 4 Outcomes by functional performance test for each participant with unilateral (UTF) and bilateral (BTF) transfemoral limb loss.

		TUG (s)	4SST (s)	6MWT (m)	SST (pts)	TTEST (s)	IAT (s)
Unilateral	UTF1	8.8	9.6	446.0	8	53.0	67.4
	UTF2	7.2	8.3	445.1	10	35.8	46.3
Bilateral	BTF1	9.2	12.7	496.3	9	43.7	58.0
	BTF2	14.8	17.0	347.5	7	60.2	74.7

TUG, timed up and go; FSST, four square step test; 6MWT, six minute walk test; SST, edgren side-step test; TTEST, T-test; IAT, illinois agility test.

approach to the design, prescription, and evaluation of components to adequately protect the implant and/or bone. Insufficient spacing between abutment/failsafe and prosthetic knee to accommodate the load sensor (height = 46 mm)—without affecting limb length/alignment—ultimately excluded a large majority of individuals with TF limb loss who have received osseointegration at our institution. Future work should aim to continue load characterization across a variety of activities in larger and more diverse samples (e.g., transtibial or transfemoral with other implant systems).

Of note, the four participants in the current sample were generally high-functioning per the scoring criteria of each functional performance test. For example, TUG scores here ranged from 7.2–8.8 s for UTF and 9.2–14.8 s for BTF [K3 = 12.8 ± 0.5 s and K4 = 9.5 ± 0.8 s; (10)]. 4SST scores here ranged from 8.3–9.6 s for UTF [10.4 ± 5.3 s; (11)] and 12.7–17.0 s for BTF [22.0 ± 10.2 s; (12)]. 6MWT here ranged from 348 to 496 m [K3 = 299 ± 102 m and K4 = 419 ± 86 m; (13)].

In summary, the current study which characterized mechanical loading of the bone-anchored implant during functional

performance tests extends traditional biomechanical assessments (i.e., measuring ground reaction forces with force platforms, often during steady-state ambulation), and is a first step toward establishing benchmarks of peak loading during such activities. Wireless sensor approaches could enable broader surveillance of mechanical loads in the home and community, further improving ecological validity. In a larger sample, future work should also consider evaluating relationships of these mechanical loads with limb characteristics [e.g., bone quality, residual limb length; (14)], time since amputation and/or osseointegration, and prosthetic components (6, 15). Broader understanding of the mechanical loads applied to the abutment following osseointegration is critical to maximize implant survivability and long-term outcomes, particularly for Service members who are generally young at time of injury and return to active lifestyles.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by Walter Reed National Military Medical Center Institutional Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

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Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article.

This work was supported, in part, by the Congressionally Directed Medical Research Program (Award # W81XWH-17-2-0060).

Acknowledgments

The authors would like to thank members of the Limb Optimization and Osseointegration Program and the Extremity Trauma & Amputation Center of Excellence for their assistance with project coordination and data collection. The views expressed herein are those of the authors and do not reflect the official policy or position of the Uniformed Services University of the Health Sciences, Army/Navy/Air Force, the US Department of Defense, nor the US Government. The identification of specific products or scientific instrumentation does not constitute endorsement or implied endorsement on the part of the authors, the Department of Defense, or any component agency.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Systematic Review
PUBLISHED 02 April 2024
DOI 10.3389/fresc.2024.1336042

OPEN ACCESS

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RECEIVED 09 November 2023
ACCEPTED 05 February 2024
PUBLISHED 02 April 2024

CITATION
Rehani M, Stafinski T, Round J, Jones CA and Hebert JS (2024) Bone-anchored prostheses for transfemoral amputation: a systematic review of outcomes, complications, patient experiences, and cost-effectiveness. Front. Rehabil. Sci. 5:1336042. doi: 10.3389/fresc.2024.1336042

Bone-anchored prostheses for transfemoral amputation: a systematic review of outcomes, complications, patient experiences, and cost-effectiveness

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Introduction: Bone-anchored prostheses (BAP) are an advanced reconstructive surgical approach for individuals who had transfemoral amputation and are unable to use the conventional socket-suspension systems for their prostheses. Access to this technology has been limited in part due to the lag between the start of a new procedure and the availability of evidence that is required before making decisions about widespread provision. This systematic review presents as a single resource up-to-date information on aspects most relevant to decision makers, i.e., clinical efficacy, safety parameters, patient experiences, and health economic outcomes of this technology.

Methods: A systematic search of the literature was conducted by an information specialist in PubMed, MEDLINE, Embase, CINAHL, Cochrane Library, the Core Collection of Web of Science, CADTH's Grey Matters, and Google Scholar up until May 31, 2023. Peer-reviewed original research articles on the outcomes of clinical effectiveness (health-related quality of life, mobility, and prosthesis usage), complications and adverse events, patient experiences, and health economic outcomes were included. The quality of the studies was assessed using the Oxford Centre for Evidence-Based Medicine Levels of Evidence and ROBINS-I, as appropriate.

Results: Fifty studies met the inclusion criteria, of which 12 were excluded. Thirty-eight studies were finally included in this review, of which 21 reported on clinical outcomes and complications, 9 case series and 1 cohort study focused specifically on complications and adverse events, and 2 and 5 qualitative studies reported on patient experience and health economic assessments, respectively. The most common study design is a single-arm trial (pre-/post-intervention design) with varying lengths of follow-up.

Discussion: The clinical efficacy of this technology is evident in selected populations. Overall, patients reported increased health-related quality of life, mobility, and prosthesis usage post-intervention. The most common complication is a superficial or soft-tissue infection, and more serious complications are rare. Patient-reported experiences have generally been positive. Evidence indicates that bone-anchored implants for prosthesis fixation are cost-effective for those individuals who face significant challenges in using socket-suspension systems, although they may offer no additional advantage to those who are functioning well with their socket-suspended prostheses.

KEYWORDS
bone-anchored prosthesis, osseointegration, lower extremity, transfemoral, treatment outcome, postoperative complications, patient experience, cost-effectiveness analysis

Introduction

Lower-limb amputation severely impacts physical function, psychological well-being, and social participation (1–8). Following a transfemoral (above-knee) amputation, the standard of care for restoring mobility is to fit the individual with a prosthesis that consists of a socket-suspension system to which the prosthetic components (such as the knee and foot) are attached. Approximately 86% of people with major lower-limb amputation are fit with a socket prosthesis (9). A trained prosthetist is required to custom-design the socket for each user according to the condition and shape of their residual limb. Suction to the residual limb or strapping around the pelvis is necessary for a socket to fit properly. Although prosthetic socket-suspension systems have evolved over the past few decades with substantial technological advancements, there are still limitations to their use. The socket must fit firmly to the residual limb to ensure comfort, transmit forces of the skeleton to the ground, and enable the movement of the residual limb to control the position of the prosthetic limb. The interface between the socket and the residual limb is one of the most crucial factors for the success of the prosthesis; however, discomfort and problems related to socket fit are common and have been shown to negatively affect the quality of life and mobility of the user (10–13). The problems that plague many prosthetic users are the lack of comfort, skin ulcers (14), inadequate or fluctuating suspension (15), tissue irritation, excessive heat and perspiration (14), poor control due to the motion of the soft tissue within the socket, and low confidence with mobility (12). Chronic skin problems and pain caused by friction between the residual limb and the prosthesis have been reported in 34%–63% of socket prosthesis users, reducing the use and function of the prosthetic device, quality of life, and body image satisfaction (12, 16–19). In addition, the socket can restrict the range of movement of the hip, leading to difficulties in sitting or participating in the activities of daily living. If the user experiences poor outcomes and problems with the socket, repeat visits to a physician or the prosthetist are required for assessment and adjustment. By some estimates, frequent refitting is typical in up to three-quarters of socket prosthesis users (11). Individuals who are unable to use the socket-suspension systems due to recurrent problems may completely abandon their prostheses (20, 21).

These problems spurred the development of new techniques to attach prosthetic components directly to a titanium implant that is inserted into the bone of the residual limb, obviating the need for a socket interface. Since titanium is naturally biocompatible (non-toxic and non-allergenic), titanium implant integrates with living bone tissue. This process, termed *osseointegration* (OI), results in a bone-anchored prosthesis in which the implant that extends percutaneously, i.e., through the skin, allows a direct functional and structural connection to the prosthetic components (22, 23). Bone-anchored implants have been used for dental and maxillofacial reconstructions for decades, and since the 1990s, they have been used for prosthetic reconstructions for individuals with transfemoral amputations (24). Bone-anchored prosthesis is a treatment option for various amputation levels in several areas worldwide.

Types of implants for bone-anchored prostheses

Implants and protocols for bone-anchored prostheses have emerged and evolved over the past several years. Currently, there are two main types of fixations in use, namely, the screw-type (threaded) and press-fit type. Based on these two types of fixations, there are six types of implants for which evidence is available in the peer-reviewed literature (25). The first surgery for a person with transfemoral amputation occurred in 1990 in Sweden with the earliest design [called Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA)] (26). This is the only type of implant that relies on a screw-type fixation. As the name suggests, the titanium alloy implant is secured to the femur using a threading tool to cut spiral groove threads in the intramedullary cortex of the residual bone and then screwed into the femur. The OPRA technique is characterized by two surgical stages spaced 6 months apart. The success of the osseointegrated prostheses in Sweden spurred the design of implants in Germany in the late 1990s. This implant design diverted from screw-type fixation to intramedullary press-fit alloy devices similar to those used in joint arthroplasty. This led to the design of the Integral Leg Prosthesis (ILP; Orthodynamics, Germany), which was called the Endo-Exo Prosthesis (EEP; ESKA Orthopaedic, Germany) in its earlier iterations. In its latest iteration, the "third generation" of EEP is called Transcutaneous Osseointegrated Prosthetic Systems (TOPS) (27). The EEP and its successor ILP also rely on a two-stage surgical procedure, but the time between surgeries is reduced to 4–6 weeks. The Osseointegrated Prosthetic Limb (OPL; Permedica S.p.A., Italy) evolved from the experience with the ILP and is used in either a two- or single-stage surgery. More recently, the Bone Anchoring Device for Artificial Limbs (BADAL X) attachment using OTN Implants (the Netherlands) has been reported (28). Details on the varying designs and surgical and rehabilitation approaches are published elsewhere (25). Each type of implant has varying levels of evidence in the published literature on clinical efficacy outcomes and complications (25, 29, 30).

Two other types of implants are reported in the literature but are not the focus of this review since they are still in the development stage and/or lack adequate published literature for review. The Compress Device (Zimmer Biomet) was initially designed as a solution for large-gap limb salvage for patients with bone tumors, which is still used for that purpose (25). Since the Compress Device is a newer system, surgical techniques or rehabilitation guidelines have not yet been published. Despite having just finished its clinical trial,

the Intraosseous Transcutaneous Amputation Prosthesis (ITAP; Stryker Orthopaedics; ClinicalTrials.gov no. NCT02491424) not be released due to a reported higher risk of infection and implant failure (31, 32).

Since the original surgeries in the 1990s in Sweden, various centers have begun providing BAP and publishing reports on clinical outcomes and complications, including centers in Germany, the Netherlands, Australia, the UK, the USA, and Canada. With the growing body of evidence on the outcomes of BAP from various groups around the world, there is increasing pressure on publicly and privately funded health insurance systems to make this procedure more widely available to all patients who could benefit. Implementation in new centers has been sporadic, typically facility determined, with discrepancies across private and publicly funded health systems. Inequitable access could be partly due to the unavailability of a single resource that brings together information on aspects most relevant for policymakers when making decisions about the provision of this new technology. Systematic reviews have covered outcomes (33–35), complications (36, 37), and implant design (25, 37); however, given the rapidly evolving evidence in this field, this review responds to the need for a single resource that presents an updated systematic review (by type of implant, where reported) of clinical efficacy outcomes, complications, patient preferences, and cost-effectiveness.

This review aims to present a systematic review to answer the four main questions that regulatory bodies and policymakers pose: What are the (a) clinical efficacy, (b) safety, (c) patient experience, and (d) cost-effectiveness of bone-anchored implants that enable attachment of prosthetic devices for persons with transfemoral amputations?

Methods

We conducted a systematic review that adhered to the PRISMA 2020 checklists (Supplementary Appendices S1, S2) (38). An a priori protocol was drafted according to the PRISMA-*P* guidelines (39) and was made available online (40). An experienced medical information specialist developed and tested the search strategies through an iterative process in consultation with the review authors. Using the multifile and deduplication tool options in OVID, we searched Ovid MEDLINE ALL, including ePub Ahead of Print, In-Process & Other Non-indexed Citations, and Embase. In addition, we searched the Cochrane Library (Wiley), CINAHL (Ebsco), Web of Science Core Collection, and PubMed. All searches were performed on 14 March 2021 and updated on 31 May 2023. The strategies utilized a combination of controlled vocabulary (e.g., "bone-anchored prosthesis," "osseointegration," "bones of the lower extremity") and keywords (e.g., "OPRA," "osseo-anchor," "femur"). Vocabulary and syntax were adjusted across the databases, and no language or date restrictions were imposed, although animal-only records were removed where possible. The results were downloaded and deduplicated using EndNote version 9.3.3 (Clarivate Analytics) and uploaded to Covidence (41). We performed a gray literature search using CADTH's Grey Matters and Google Scholar to ensure that no primary articles of interest were missed. The reference lists of the articles selected for full-text or included in this review were also searched for additional sources. Specific details regarding the strategies appear in Supplementary Appendix S3. Title and abstract screening and primary exclusion upon full-text review were carried out by two reviewers (MR and TS). Any conflicts at these stages were handled by consensus (between MR and TS), and a third reviewer (JSH) served as an arbiter when needed. Secondary exclusion upon full-text review was conducted by one reviewer (MR) and verified by another (JSH) who is a subject matter expert in prosthesis research.

PICOTS elements

Population: Individuals with a unilateral or bilateral transfemoral amputation.
Intervention: Percutaneous osseointegrated/bone-anchored implants to which external prosthetic components are attached.
Comparator: Socket-suspension prosthesis systems or no prostheses.
Outcomes: (1) To assess clinical outcomes, health-related quality of life (HRQoL), and functional outcomes, such as mobility, and prosthesis usage, (2) clinical complications and adverse events, (3) patient experiences of benefits and challenges, and (4) any health economic variable.
Time: No restriction.
Studies: Articles published in peer-reviewed journals that were as follows: (1) experimental or observational studies with outcomes data on an intervention group and the comparator and studies with a pre-/post-design, (2) studies reporting specifically on complications and adverse events, (3) studies exploring patient experiences using qualitative methods, and (4) health economic evaluations based on, but not limited to, cost-comparison, cost–benefit analysis, cost-minimization analysis, cost-effectiveness analysis, or cost-utility analysis.

Inclusion criteria

Primary peer-reviewed research reports meeting the PICOTS criteria were included.

Primary exclusion criteria

Articles not meeting the PICOTS criteria were excluded at this stage. Other health technology assessments, literature reviews, case reports, opinion pieces, and editorials were also excluded.

Secondary exclusion criteria

At this stage, articles that (1) reported on the same patients as those included in other studies, (2) did not report data for the transfemoral level separately, (3) self-identified as interim reports of longer-term follow-up studies, (4) described a bone-anchored prosthesis intervention not of interest, or (5) did not report data on the comparator group were also excluded.

Data analysis and synthesis

Information was extracted by one reviewer (MR) from included studies only. Essential characteristics of the studies, e.g., implant type, city and country of the center publishing the study, funding source, study type, comparator, length of follow-up, details about external prosthetic components, number of participants, sex ratio, numbers of participants with unilateral or bilateral amputation, age of participants at treatment, time between amputation and surgery, etiology of the patients, and outcomes of interest, were extracted. Quantitative data on outcome measures of clinical efficacy were extracted, collated, and presented in tables.

Quality and risk of bias assessment of included studies

To assess the quality of the literature, studies on clinical efficacy were reviewed by two reviewers (MR and TS) who assigned the Oxford Centre for Evidence-Based Medicine (OCEBM) Levels of Evidence (42) by consensus and carried out The Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) (43). ROBINS-I is a tool designed to evaluate the risk of bias in the estimates of effectiveness or safety in studies that do not randomize the allocation of participants. It is well suited to cohort studies and single-arm trials as it assesses the risks to external validity due to confounding bias, selection bias, information bias, and reporting bias. The severity of these risks of bias is evaluated based on pre-established criteria and rated as "low," "moderate," "serious," "critical," and "no information," where applicable.

The quality of literature focusing on complications was assessed by determining the OCEBM Levels of Evidence by one reviewer (MR) and verified by another (TS).

Results

Search results

Figure 1 shows the study selection process as a PRISMA diagram. In total, 3,294 references were found in the 8 databases after removing the duplicates. After title and abstract screening by two reviewers, 132 articles were selected for full-text review. Eighty-two articles were excluded based on the primary exclusion criteria; however, an additional 12 were excluded based on the secondary exclusion criteria. Finally, 38 studies were included in this review. Twenty-one were on clinical efficacy outcomes (HRQoL, mobility, or prosthesis usage) with single-arm trial (pre-/post-intervention follow-up) design or cohort studies; nine case series (prospective or retrospective) and one cohort study were specifically reported on infectious or serious complications, two reported on patient experiences based on qualitative research methods, and five reported on health economic evaluations. Table 1 shows the list of studies (by implant type) included for evaluating clinical efficacy outcomes and information on study characteristics. Supplementary Table S1 shows the list of studies excluded at the secondary exclusion stage and the reasons for exclusion.

Commonly reported outcomes

Commonly reported outcomes of clinical efficacy were HRQoL (as measured by patient-reported outcome measures such as SF-36, EQ-5D, and the Questionnaire for Persons with a Transfemoral Amputation; Q-TFA), mobility (as measured by a trained observer/clinician using instruments such as 2-min Walk Test; 2MWT, 6-min Walk Test; 6MWT, 10-min Walk Test; 10MWT, Timed-Up-and-Go Test; TUG), self-perceived mobility (as measured by PLUS-M), prosthesis usage, and safety parameters (which included the number and types of complications and adverse events). SF-36 was the most commonly reported generic HRQoL outcome measure. Q-TFA is a condition-specific HRQoL outcome measure to assess transfemoral prosthesis users' quality of life and overall prosthetic situation (64). 2MWT, 6MWT, 10MWT, and TUG are performance-based tests administered and scored by a clinician. They measure the ambulatory potential of persons with lower-limb amputation with and without a prosthesis (65, 66).

Types of studies and follow-up

Most of the included studies on clinical efficacy reported comparing outcomes before surgery (when patients used the comparator, i.e., socket-suspension systems or no prostheses) and after surgery with varying lengths of follow-up. Please refer to Figure 2 for a Gantt-chart-type depiction of the timeline of surgeries and follow-up in the included literature on the various bone-anchored implant types. Seventeen of the 21 studies were single-arm trials with pre-/post-intervention follow-up designs (where participant served as their own control) and 4 were cohort studies (where the comparisons were made between two distinct groups, the OI intervention group and the socket group). The shortest length of follow-up in the single-arm trials was 1 year postsurgery, and the longest was 15 years postsurgery. Twelve studies were either 1-year or 2-year postsurgery follow-ups. All seventeen single-arm trials of the 21 included studies on clinical efficacy outcomes also reported on complications in varying detail; the other four that did not were cohort studies. The two qualitative research studies were based on phenomenological methods. Two of the five health economic evaluations were based on cost-comparison analysis and three on cost-utility analyses.

Quality of included studies and risk of bias

The quality of the included single-arm trials (pre-/post-intervention follow-up) and cohort studies was assessed using the OCEBM Levels of Evidence and ROBINS-I. The quality of the included case series was assessed using OCEBM Levels of Evidence.

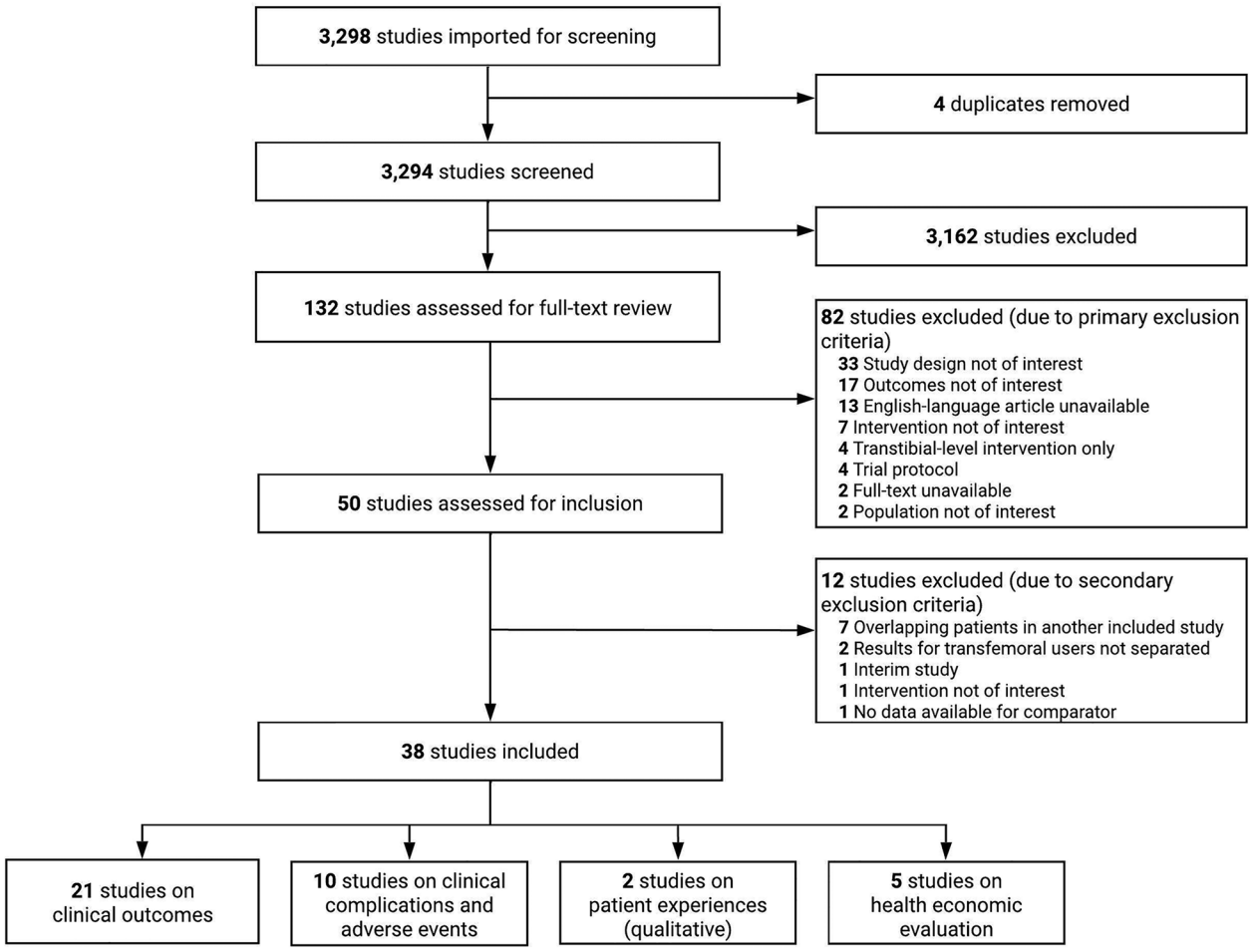

FIGURE 1
PRISMA flow diagram for the selection of studies for this review.

Supplementary Table S2 shows the quality assessment results for the studies on clinical outcomes. The general quality of evidence ranged from OCEBM Level 2 to 4, as most studies were single-arm trials or observational case series. The single-arm trials in this review were generally rated at Level 2 as they were deemed similar to well-designed clinical trials with several objective outcome measures and pre-/post-data on patients serving as their own controls. Cohort studies and case series (prospective or retrospective) were rated at Levels 3 and 4, respectively. Current practice patterns preclude study designs of higher methodological quality (such as RCTs) as difficulty with the socket-suspension system is generally considered a requirement for bone-anchored implants. Single-arm trials or cohort studies are therefore considered a methodologically robust and ethical way of comparing socket-suspension to bone-anchored implants.

The risk of bias (assessed using the ROBINS-I) was evaluated over four domains. The risk of confounding bias was generally considered moderate for most studies. In single-arm trials with pre-/post-design, the impact of any baseline confounding is typically minimal. In cohort studies, the risk of baseline confounding exists. One of the potential confounders identified in this review was the reporting of external prosthetic components that are attached to the bone-anchored implant. In studies where information about external prosthetic components was not reported, this risk was unknown and could have contributed to unmeasured confounding, therefore resulting in a moderate rating of confounding bias for several studies. The risk of selection bias was generally low. A lack of consistent reporting of how missing data was handled made the assessment of selection bias due to missing data challenging. Information bias due to the classification of interventions was considered low but was generally considered moderate due to the selection of outcome measures. The risk of reporting bias was generally rated as moderate but serious in two studies. The details on the choice of rating and rationale are presented in Supplementary Table S2.

Patient selection criteria

The literature reported fairly consistent requirements for individuals to be selected for transfemoral OI surgery. Table 2

TABLE 1 Included studies on clinical outcomes.

Study	Implant type	OCEBM level of evidence	Country (city)	Funding source	Study type	Comparator	Length of follow-up reported	External prosthetic components (number of participants)	Number of patients (sex ratio) [unilateral: bilateral]	Mean age ± SD (if reported) at treatment (range or IQR) in years	Mean time ± SD (if reported) since amputation (range) in years	Etiology
Screw-type fixation												
Hagberg et al. (44)	OPRA	Level 2	Sweden (Mölndal)	Non-profit and commercial (Integrum AB)	Single-arm trial (pre-/post-comparison)	Socket (15/18) No prosthesis (3/18)	2 years	NR	18 (8 M: 10 F) [16:2]	45.44 (22–62)	15 (10m–33)	12 trauma, 5 tumor, 1 arterial embolus
Brånemark et al. (45)	OPRA	Level 2	Sweden (Mölndal)	Non-commercial[a]	Single-arm trial (pre-/post-comparison)	Socket (42/51) No prosthesis (9/51)	2 years	NR	At baseline: 51 (28 M: 23 F) [45:6] At follow-up: 48 (NR) [NR]	44 ± 12 (20–65)	12 (1–42)	33 trauma, 12 tumor, 6 other
Brånemark et al. (46)	OPRA	Level 2	Sweden (Mölndal)	Non-profit and government grants[a]	Single-arm trial (pre-/post-comparison)	Socket (42/51) No Prosthesis (9/51)	5 years	NR	At baseline: 51 (28 M: 23 F) [45:6] At follow-up: 40 (NR) [NR]	44 (20–65)	12 (1–42)	33 trauma, 12 tumor, 6 other
Matthews et al. (47)	OPRA	Level 2	United Kingdom (London)	No funding	Single-arm trial (pre-/post-comparison)	Socket	5 years	NR	18 (15 M: 3 F) [18:0]	34.77 (21–49)	NR	18 trauma
Zaid et al. (48)	OPRA	Level 2	USA (San Francisco)	NR	Single-arm trial (pre-/post-comparison)	Socket	1 year	NR	9 (7 M: 2 F) [NR]	45 (21–61)	12.9 (0–45)	4 trauma, 4 tumor, 1 infection
Hagberg et al. (49)	OPRA	Level 2	Sweden (Mölndal)	Non-profit and government grants[a]	Single-arm trial (pre-/post-comparison)	Socket	15 years	NR	At baseline: 111 (78 M: 33 F) [111:0] At follow-up: 11 (NR) [NR]	44.6 (17–70)	11.1 ± 10.8 (0–43)	75 trauma, 23 tumor, 3 emboli, 10 infection
Hagberg et al. (50)	OPRA	Level 2	Sweden (Mölndal)	Non-profit and government grants	Single-arm trial (pre-/post-comparison)	Socket (31/37) No Prosthesis (6/37)	10 years	NR (noted the lack of systematic documentation of external prosthetic device details as a limitation of the study)	At baseline: 51 (28 M: 23 F) [45:6] At follow-up: 37 (19 M: 18 F) [32:5]	44 (20–65)	12 ± 11 (1–42)	At baseline: 33 trauma, 12 tumor, 4 infection, 2 arterial embolus At follow-up: 25 trauma, 9 tumor, 1 infection, 2 arterial embolus

(*Continued*)

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TABLE 1 Continued

Study	Implant type	OCEBM level of evidence	Country (city)	Funding source	Study type	Comparator	Length of follow-up reported	External prosthetic components (number of participants)	Number of patients (sex ratio) [unilateral: bilateral]	Mean age ± SD (if reported) at treatment (range or IQR) in years	Mean time ± SD (if reported) since amputation (range) in years	Etiology
Press-fit type fixation												
Van de Meent et al. (51)	ILP	Level 2	The Netherlands (Nijmegen)	Non-commercial	Single-arm trial (pre-/post-comparison)	Socket	1 year	*Knee* Mechanical knee joint (3/22) Microprocessor-controlled knee; MPK (19/22) Did not report change in components post-intervention *Foot* NR	22 (18 M: 4 F) [21:1]	46.5 ± 10.7 (23–67)	16.4 ± 14.8 (2–45)	20 trauma, 2 tumor
Reetz et al. (52)	ILP	Level 2	The Netherlands (Nijmegen)	Non-profit and government grants	Single-arm trial (pre-/post-comparison)	Socket (38/39) No prosthesis (1/39)	5 years	NR	39 (30 M: 9 F) [38:1]	48.7 ± 13.9 (22–80)	12 (1–52)	29 trauma, 6 tumor, 3 infection, 1 other
Gailey et al. (53)	ILP	Level 3	United States (Miami, FL)	Government grant	Cohort study	Socket	N/A	*Knee* Mechanical knee joint (1/22) Group not specified MPK (21/22) *Foot* Dynamic response prosthetic foot (22/22)	22 OI group: 11 Socket group: 11 (Almost equal sex ratio reported in each group but numbers not reported for either group.)	Age (in years) at inclusion reported. OI group: 44.7 ± 14.9 Socket group: 49.6 ± 16.0	Mean time (in months) since amputation reported. OI group: 86.7 ± 102.3 Socket group: 149.7 ± 193.8 Mean time since OI for OI group not reported	Across both groups: 15 trauma, 3 tumor, 4 dysvascular disease
Al Muderis et al. (54)	ILP or OPL	Level 3	Australia (Sydney)	Commercial (Orthodynamic GmbH, Lübeck, Germany; Permedica S.p.A, Milan, Italy)[a]	Single-arm trial (pre-/post-comparison)	Socket (36/50) No prosthesis/wheelchair-bound (14/50)	Minimum: 1 year Mean: 21.5 months	NR (Authors mentioned that clinical outcomes may have been impacted due to fitting of superior external prosthetic components post-intervention)	50 (34 M: 16 F) [50:0]	48.4 (24–73)	NR	32 trauma, 8 tumor, 5 infection, 3 blast injury, 2 congenital
Leijendekkers et al. (55)	ILP or OPL	Level 2	The Netherlands (Nijmegen)	No funding[a]	Single-arm trial (pre-/post-comparison)	Socket (21/31) No prosthesis/wheelchair-bound (10/31)	1 year	Reported that all participants had the same prosthetic components post-intervention as they	31 (17 M: 14 F) [29:2]	Median: 56 (IQR: 45–59)	Median: 6 (IQR: 3–26)	17 trauma, 7 tumor, 3 dysvascular disease, 4 other

(*Continued*)

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TABLE 1 Continued

Study	Implant type	OCEBM level of evidence	Country (city)	Funding source	Study type	Comparator	Length of follow-up reported	External prosthetic components (number of participants)	Number of patients (sex ratio) [unilateral: bilateral]	Mean age ± SD (if reported) at treatment (range or IQR) in years	Mean time ± SD (if reported) since amputation (range) in years	Etiology
								did pre-intervention (Details NR)				
Al Muderis et al. (56)	OPL	Level 3	Australia (Sydney)	Commercial (Permedica S.p.A, Milan, Italy; AQImplants GmbH, Ahrensburg, Germany; Osseointegration International Pty Ltd., Sydney, Australia)[a]	Single-arm trial (pre-/post-comparison)	Socket (12/22) No prosthesis/ wheelchair-bound (10/22)	1 year	NR	22 (17 M: 5 F) [22:0]	46.2 (20–67)	NR	16 trauma, 4 tumor, 2 infection
McMenemy et al. (57)	OPL	Level 2	United Kingdom (Birmingham)	NR	Single-arm trial (pre-/post-comparison)	Socket	2 years	NR	7 (7M) [0: 7]	Median: 28 (IQR: 24–33)	Median: 96 months (IQR: 79–101)	7 trauma
Reif et al. (58)	OPL	Level 2	United States (New York, NY)	No funding	Single-arm trial (pre-/post-comparison)	Socket or none	6 months and 1 year	NR	18 (11 M: 7 F) [NR]	49.6 ± 12.0 (NR)	7.8 ± 8.8 (NR)	13 trauma, 3 infection, 2 vascular injury
Pospiech et al. (59)	EEP	Level 3	Germany (Lübeck)	No funding	Cohort study	Socket	N/A	*Knee* Mechanical knee joint (0/39) MPK (OI group: 22/22 Socket group: 17/17) *Foot* Triton (OI group: 16/22 Socket group: 12/17) C-Walk (OI group: 2/22 Socket group: 2/17) Kinterra (OI group: 2/22 Socket group: 1/17) Vari-Flex (OI group: 2/22 Socket group: 2/17) Reported no	39 OI group: 22 (17 M: 5 F) [NR] Socket group: 17 (12 M: 5 F) [NR]	Age (in years) at inclusion reported. OI group: 48.7 ± 8.3 (NR) Socket group: 47.0 ± 12.3 (NR)	Mean time (in months) since amputation: OI group: 230 ± 138 (NR) Socket group: 241 ± 17 (NR) Mean time since OI for OI group: 66.8 ± 42.4 months (NR)	OI group: 15 trauma, 3 tumor, 4 other Socket group: 12 trauma, 4 tumor, 1 other

(*Continued*)

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TABLE 1 Continued

Study	Implant type	OCEBM level of evidence	Country (city)	Funding source	Study type	Comparator	Length of follow-up reported	External prosthetic components (number of participants)	Number of patients (sex ratio) [unilateral: bilateral]	Mean age ± SD (if reported) at treatment (range or IQR) in years	Mean time ± SD (if reported) since amputation (range) in years	Etiology
								significant difference between groups based on type of prosthetic knees and feet				
Örgel et al. (60)	EEP	Level 3	Germany (Hannover)	No funding	Cohort study	Socket	N/A	NR	69 OI group: 33 (17 M: 16 F) [NR] Socket group: 36 (18 M: 18 F) [NR]	Age (in years) at inclusion reported. OI group: 52.1 ± 9.7 (NR) Socket group: 48.6 ± 13.0 (NR)	NR Mean time since OI for OI group: 30.5 ± 41.5 months (NR)	OI group: 21 trauma, 3 tumor, 1 infection, 4 dysvascular disease, 4 other Socket group: 23 trauma, 3 tumor, 2 infection, 4 dysvascular disease, 4 other
Welke et al. (61)	EEP	Level 3	Germany (Hannover)	Government grant	Cohort study	Socket	N/A	*Knee* Mechanical knee joint (OI group: 0/20 Socket group: 0/17) MPK (OI group: 20/20 Socket group: 17/17) *Foot* NR	37 OI group: 20 (12 M: 8 F) [20: 0] Socket group: 17 (13 M: 4 F) [17:0]	Age (in years) at inclusion reported. OI group: 54.0 ± 8.2 (NR) Socket group: 62.0 ± 14.6 (NR)	OI group: 23.7 ± 13.2 (NR) Socket group: 25.2 ± 18.7 (NR) Mean time (in years) since surgery for the OI group: 6.6 ± 2.4 (NR)	OI group: 12 trauma, 4 tumor,1 infection, 2 dysvascular disease, 1 other Socket group: 9 trauma, 4 tumor, 0 infection, 3 dysvascular disease, 1 other
Atallah et al. (28)	OTN (reported as OFI-C for long femur and OFI-Y for short femur)	Level 2	The Netherlands (Nijmegen)	No funding[a]	Single-arm trial (pre-/post-comparison)	Socket	1 year	NR	69 (49 M: 20 F) [66:3]	OFI-C; $n = 53$ 57 ± 14 OFI-Y; $n = 16$ 50 ± 15	OFI-C; $n = 53$ 6 (4–17) OFI-Y; $n = 16$ 17 (8–28)	36 trauma, 8 tumor, 10 infection, 9 dysvascular disease, 3 congenital, 6 other[b]
Sinclair et al. (62)	POP	Level 2	United States (Salt Lake City, UT)	Government grant	Single-arm trial (pre-/post-comparison)	Socket	1 year	Reported that all participants had the same prosthetic components post-intervention as they did pre-intervention (Details NR)	10 (10 M: 0 F) [10:0]	48.8 ± 12.1 (32–68)	9.4 ± 5.7 (1–18)	5 blast injury, 2 motor vehicle collision, 3 other trauma

(*Continued*)

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TABLE 1 Continued

Study	Implant type	OCEBM level of evidence	Country (city)	Funding source	Study type	Comparator	Length of follow-up reported	External prosthetic components (number of participants)	Number of patients (sex ratio) [unilateral: bilateral]	Mean age ± SD (if reported) at treatment (range or IQR) in years	Mean time ± SD (if reported) since amputation (range) in years	Etiology
Davis-Wilson et al. (63)	Unspecified	Level 2	United States (Aurora, CO)	NR	Single-arm trial (pre-/post-comparison)	Socket	1 year	*Knee* Mechanical knee joint (0/9) MPK (9/9) *Foot* Dynamic carbon fiber (9/9) Reported no change to components post-intervention	9 (4 M: 5 F) [9:0]	47.67 ± 7.6 (38–58)	16.7 ± 12.4 (3–39)	NR trauma, NR tumor, 0 dysvascular disease, NR congenital limb deficiency

OPRA, Osseointegrated Prostheses for the Rehabilitation of Amputees; ILP, Integral Leg Prosthesis; OPL, Osseointegrated Prosthetic Limb; EEP, Endo-Exo Prostheses; POP, Percutaneous Osseointegrated Prosthesis.
NR, Not reported.
[a]Some authors of this study have declared a potential financial conflict of interest in the company supplying the implant.
[b]Etiology reported in this study combined data for 69 persons with transfemoral and 3 persons with through-knee amputation.

shows the inclusion and exclusion criteria in each of the included studies. The most common inclusion criteria are recurrent problems or the inability to use socket prostheses (28, 44–52, 54–58, 63), mature skeleton (28, 44, 45, 47–49, 52), or normal residual skeletal anatomy (44, 45, 47), the ability to comply with the treatment and follow-up requirements (45–48, 52, 54, 56, 62), and pre-surgical evaluation by a clinical team (44, 46, 51, 52, 57, 63) along with physical and medical examinations and imaging (44, 45, 47). There also are several contraindications to the OI surgery. The most common exclusion criteria are severe peripheral vascular disease (44–47, 49–52, 54, 56, 57), diabetes mellitus (28, 44–46, 49–52, 54, 56, 57, 62), treatment with chemotherapy (44–46, 49, 50, 52, 54, 56, 57, 63), exposure of the amputated limb to radiation (28, 52, 54, 56–58, 63), current treatment with corticosteroids (44–46) or immunosuppressive drugs (28, 54, 56, 57, 62), and pregnancy (44–46, 54, 56). The most common age range reported for patient selection in the included studies was between 18 and 70 years.

Clinical efficacy

Table 3 summarizes the results from the included studies on the clinical efficacy outcomes of interest (HRQoL, mobility, and prosthesis usage) for each type of implant. The participants in most included studies underwent OI surgery in their mid-40s, had unilateral transfemoral OI surgery, and underwent primary amputation due to trauma. Time between amputation and the OI surgery varied greatly between studies and ranged from 10 months (44) to 52 years (52). Three studies declared receiving funds, in whole or part, from commercial entities; whereas, 10 studies declared funding, in whole or part, from non-commercial and non-profit sources or government grants. Six declared having received no funding and three did not report having funding sources. The authors of seven studies declared a financial conflict of interest in the companies that supplied the implants. Seven studies were based on implants with screw-type fixation and 14 on those with press-fit fixation. All types of implants (screw-type or press-fit type) showed an improvement to varying degrees in HRQoL, mobility, and prosthesis usage when the pre-surgical condition (with socket prosthesis) of the patients is compared to their postsurgical condition. Most studies were based on the duration of follow-up of 1 year (28, 48, 51, 54–56, 58, 62, 63) or 2 years (44, 45, 57) post-intervention. There were three studies based on a 5-year follow-up (46, 47, 52) and one study each for 10-year (50) and 15-year (49) follow-ups, respectively, post-intervention.

Health-related quality of life

Compared to baseline, an improvement in SF-36 physical component score (PCS) was reported at 1-year (54, 56), 2-year

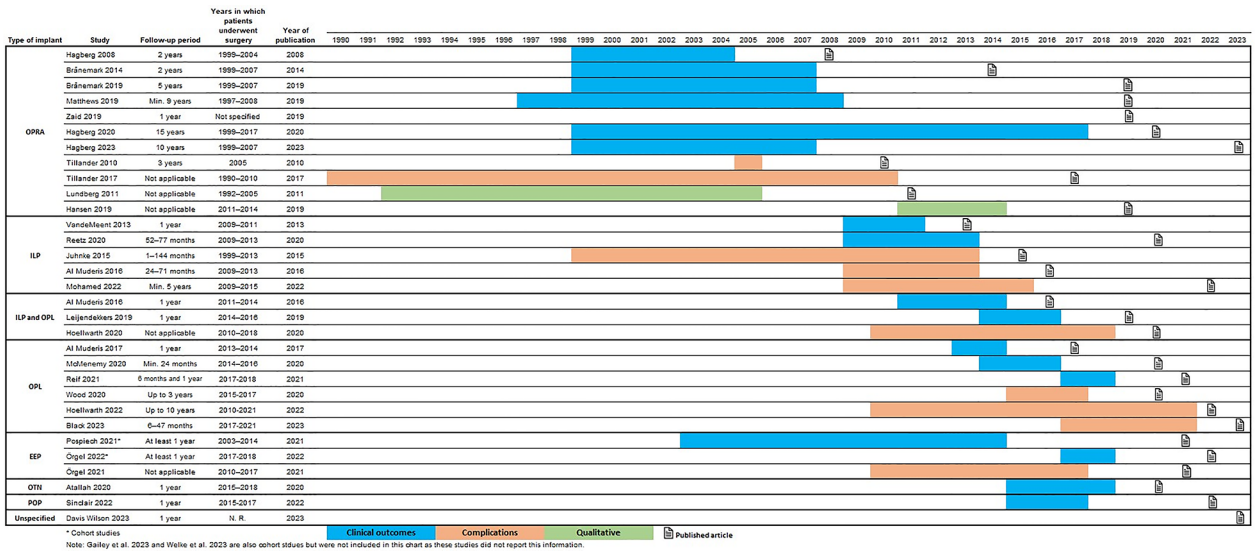

FIGURE 2
Lengths of follow-up of outcomes and complications and years of publication (by implant type).

(44–47, 57), 5-year (46, 47), and 10-year (50) follow-ups. The SF-36 mental component score (MCS), however, was reported to have improved at a 2-year (57) follow-up in one study but did not consistently show improvements in other studies. The condition-specific HRQoL measure, Q-TFA global score, showed an improvement at 1-year (28, 51, 54–56, 58, 62), 2-year (44, 45), 5-year (46, 47, 52), 10-year (50), and 15-year (49) follow-up. Reduction in problems due to the prosthesis, measured by Q-TFA problem score, was reported at 1-year (48, 58, 62), 2-year (44, 45), 5-year (46, 47), 10-year (50), and 15-year (49) follow-up. Two articles (46, 47) presented 5-year follow-up data and reported the interim 2-year follow-up data. They reported that the differences between 2- and 5-year follow-ups for all SF-36 domains and Q-TFA subscales were not statistically significant. Similarly, there were no significant differences in these measures between 5- and 10-year follow-ups (50). A significant reduction in disability (as measured by the WHODAS 2.0) was also reported at 1-year follow-up (63).

Out of the four cohort studies, three reported on the differences in HRQoL outcomes between bone-anchored prosthesis and socket prosthesis users (59–61). Two studies (59, 60) reported that condition-specific HRQoL, as measured by the Q-TFA global score, was significantly higher, and problems related to prosthesis use were also significantly lower in the bone-anchored prosthesis cohort than those in the socket prosthesis cohort. One study (61) found no differences in these variables or the PCS and MCS in SF-36 or the Q-TFA global score. Out of the two cohort studies that also reported EQ-5D results (59, 60), one study (59) reported no significant difference in HRQoL between groups, whereas the other (60) showed a significant increase in the bone-anchored cohort than the socket cohort at 1-year follow-up. This increase could perhaps be due, in part, to a greater sample size (69 patients) in the latter study (60) than in the former (59), which had 39 patients, or because the individuals in the socket group in the former study (59) indicated that they were satisfied with their prostheses, whereas this was not controlled for in the latter study (60).

Mobility and prosthesis use

Improvements in mobility were reported widely, as evident by the significant improvements in the distance walked during the 2MWT at 1-year follow-up (58) and 6MWT at 1-year (51, 54–56, 58, 62) and 2-year (57) follow-ups and improvements in TUG at 1-year follow-up (51, 55, 56). Studies on press-fit implants more commonly used performance-based outcome measures that specifically measured mobility and function. Although observer-based mobility performance measures were not used or reported by the studies on screw-type implants (44–50), information on mobility and prosthesis usage in these studies based on the self-reported Q-TFA did show improvements. Prosthesis use as measured by Q-TFA prosthetic use score was reported to have increased significantly at 1-year (28, 55, 58), 2-year (44, 45), 5-year (46, 47, 52), and 10-year (50), but not at 15-year (49), follow-up. Improved perceived mobility (measured by PLUS-M), balance (measured by ABC), and functional capacity were also reported at 1-year follow-up (63), as were significant reductions in time to don and doff the prosthesis (62).

Out of the four cohort studies, three reported on the differences in mobility between cohorts of bone-anchored prosthesis and socket prosthesis users (53, 60, 61). Gailey et al. (53) and Welke et al. (61) reported no significant differences in mobility between the two groups, as measured by the 10 MWT (53), 6 MWT (61), and TUG (53, 61) or

TABLE 2 Patient selection/inclusion and exclusion criteria in included studies on clinical outcomes.

Patient selection/inclusion criteria	Patient exclusion criteria
Transfemoral amputation (28, 44–52, 54–58, 62)	Severe peripheral vascular disease (44–47, 49–52, 54, 56, 57)
Patients with chronic pain or extremity dysfunction electing to undergo amputation with primary OI reconstruction (58)	Diabetes mellitus (44–46, 49–52, 54, 56, 57, 62) or severe diabetes (including medical history of multi-organ failure) (28)
Age below 70 years (44–47, 50)	Current treatment with chemotherapy (44–46, 49, 50, 52, 54, 56, 57, 63) or within 3 months of OI surgery (28)
Difficulty in using socket prosthesis (28, 44–52, 54–58, 63)	Exposure of amputated limb to radiation (52, 54, 56–58, 63) or within 3 months of OI surgery (28)
Previous or current use of a socket prosthesis (62)	Current treatment with corticosteroids (44–46) or immunosuppressive drugs (28, 54, 56, 57, 62)
Ability to comply with treatment and follow-up requirements (45–48, 52, 54, 56, 62)	Active infection (28, 48, 57, 62, 63) or within 6 months before the OI surgery (62)
Cause of primary amputation was congenital (55, 62, 63), trauma (55, 62, 63), tumor resection (55, 62, 63), or stable vascular disease (55)	Body weight more than 100 kg (44, 47, 48) or BMI $\geq$ 30 kg/m^2 (62)
Mature skeleton (28, 44, 45, 47–49, 52)	Current pregnancy (44–46, 54, 56)
Normal residual skeletal anatomy (44, 45, 47)	Skin disease involving the amputated limb (45, 46)
"Sufficient" residual skeletal dimensions (49, 50)	Age less than 18 years (28, 54–56, 62, 63)
Assessment by a clinical team (orthopedic surgeon, physiotherapist, prosthetist) (44, 46, 51, 52, 57, 63)	Age less than 20 years (45, 46, 50)
Suitability for surgery assessed by medical and physical examinations and imaging (44, 45, 47)	Ongoing tobacco use (48, 54, 56, 57, 62)
Agreement to refrain from participation in high levels of physical activity (62)	Residual femoral length less than 9 cm (48)
Current or anticipated use of non-propulsive, passive microprocessor-regulated devices or passive non-microprocessor-regulated devices (62)	Residual femoral length less than 8 cm (51)
	Severely osteoporotic bone (58)
	Mental illness (52), psychological instability (56), disabling psychiatric disorder (54, 55, 58), or medical history of severe cognitive or psychiatric disorders (51)
	Bone deformity, dysplasia, metabolic disorders (28)
	Patients with opioid dependence not responsive to treatment (58)
	Demonstrated risk of substance abuse (62, 63)
	Non-traumatic etiology (63)
	Unstable heart condition (63)

self-perceived mobility, as measured by PLUS-M (53). Gailey et al. (53) reported on a small sample size (22 patients, 11 in each group) and did not report on the mean duration since the OI surgery for those in the bone-anchored prosthesis group. Additionally, the selection of participants is a limitation in Welke et al. (61). Individuals in the socket group in this study reported a high level of functional mobility and are not comparable to those socket users who face significant mobility issues due to their socket and may go on to benefit from bone-anchored prosthesis. Overall, cohort studies that report on comparisons of bone-anchored prosthesis users with socket users should be taken with caution, as individuals who are successful prosthesis users with a socket prosthesis are generally not considered candidates for bone-anchored prostheses.

Four out of seventeen single-arm trials (51, 55, 62, 63) and three out of the four cohort studies (53, 59, 61) reported on external prosthetic components. In the single-arm trials, three (55, 62, 63) reported that participants were fit with the same external components with the bone-anchored implant that they used with their pre-intervention socket system. One single-arm trial (51) did not clearly report this. In the three cohort studies that included details of external prosthetic components, the authors reported that the types of components were similar in both groups (OI and socket).

The evidence suggests that quality of life, mobility, prosthesis use, and satisfaction with the prosthesis improve with bone-anchored implants compared to the patients' condition as socket prosthesis users. However, socket prosthesis users who do not face significant challenges with their sockets and already have a higher degree of mobility may not benefit as much, even if they opt for bone-anchored implants for prosthesis fixation.

Complications and adverse events

Information on complications and their time frame can be useful in informing clinical decision-making, planning, and informing health economic models. Moreover, 17 out of the 21 articles on outcomes also reported on complications faced by patients. Table 4 summarizes the adverse events and complications reported in these articles. Nine case series and one cohort study reported only on infectious and other serious complications but presented no other outcomes of interest. Table 5 shows the findings of these studies and the odds of complications (where available) by implant type. The most commonly reported complication is superficial (skin/soft tissue) infections that occur in all types of implants from as few as 11% (44) to as much as two-thirds (52) of the patients. These complications are usually managed with oral or intravenous (parenteral) antibiotics or surgical intervention (such as

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TABLE 3 Reported clinical outcomes and results of quality of life, mobility outcomes, and prosthetic usage (by implant type).

Study	Implant type	Outcomes reported	Results (HRQoL)	Results (mobility)	Results (prosthetic usage)	Other
Screw-type fixation						
Hagberg et al. (44)	OPRA	Q-TFA, SF-36	Mean scores: **Q-TFA** Subscore / Pre / Post / Sig PUS: 51.06 / 82.89 / $p = 0.013$ Mobility: 57.53 / 65.94 / $p = 0.001$ Problem: 38.07 / 16.53 / $p = 0.002$ Global: 37.73 / 72.12 / $p = 0.002$ **SF-36** Subscore / Pre / Post / Sig PCS: 31 / 44 / $p = 0.001$ MCS: 55 / 50 / n.s. PF: 31 / 60 / $p = 0.001$ RP: 38 / 68 / $p = 0.003$ BP: 53 / 72 / $p = 0.029$ GH: 75 / 79 / n.s. VT: 61 / 62 / n.s. SF: 80 / 83 / n.s. RE: 78 / 73 / n.s. MH: 76 / 77 / n.s. • Overall improvement was reported in condition-specific HRQoL (as measured by Q-TFA) • More generally, the improvement in SF-36 physical component score, physical functioning, physical role, and bodily pain subscales indicate an improved self-report of physical health • Slight decrease in SF-36 mental component score but not significant	• Q-TFA prosthetic mobility score improved significantly, which indicates a reduction in reliance on walking aids and an improvement in walking ability and walking habits	• Q-TFA prosthetic use score improved significantly ($p = 0.013$) from a mean (SD) of 51.06 (41.52) at baseline to 82.89 (26.88) at follow-up • 17/18 using OI prosthesis with no restrictions at 2-year follow-up • 1/18 could not due to severe pain during weight bearing. This patient was reported to have implant loosening due to osteoporosis	NR
Brånemark et al. (45)	OPRA	Q-TFA, SF-36, fixture cumulative survival rate	Mean scores: **Q-TFA** Subscore / Pre / Post / Sig PUS: 47 / 79 / $p < 0.001$ Mobility: 52 / 70 / $p < 0.001$ Problem: 44 / 17 / $p < 0.001$ Global: 38 / 77 / $p < 0.001$ **SF-36** Subscore / Pre / Post / Sig PCS: 74 / 76 / $p < 0.001$	• Mean Q-TFA prosthetic mobility score improved significantly	• Mean Q-TFA prosthetic use score improved • 47/51 patients using OI prosthesis at follow-up • 89% using prosthesis daily compared to 57% prior to OI	Cumulative survival rate at 2 years was 92%

(*Continued*)

TABLE 3 Continued

Study	Implant type	Outcomes reported	Results (HRQoL)				Results (mobility)	Results (prosthetic usage)	Other
			MCS	53	50	n.s.			
			PF	35	58	$p < 0.001$			
			RP	41	63	$p < 0.001$			
			BP	55	61	n.s.			
			GH	78	77	n.s.			
			VT	60	63	n.s.			
			SF	78	79	n.s.			
			RE	75	75	n.s.			
			MH	74	76	n.s.			
			• Q-TFA: Improved prosthetic use, mobility, global situation, and fewer problems • SF-36: Significant improvement in physical component scores and physical function and role physical subscales • Slight decrease in SF-36 mental component score but not significant						
Brånemark et al. (46)	OPRA	Q-TFA, SF-36, fixture cumulative survival rate, revision-free rate	Mean scores:				• Q-TFA prosthetic mobility score improved significantly between baseline and at 5-year follow-up	• Q-TFA prosthetic use score improved significantly between baseline and at 5-year follow-up • At baseline 29/42 (69%) used their prostheses on a daily basis for at least 13 hours/day. At 5-year follow-up, 28/40 (70%) patients used their prosthesis for that long on a daily basis	• The 5-year fixture cumulative survival rate was 92% and the revision-free rate was 45%
			Q-TFA						
			Subscore	Pre	Post	Sig			
			PUS	47	86	$p < 0.0001$			
			Mobility	53	67	$p < 0.0001$			
			Problem	44	17	$p < 0.0001$			
			Global	38	74	$p < 0.0001$			
			SF-36						
			Subscore	Pre	Post	Sig			
			PCS	32	41	$p < 0.0001$			
			MCS	53	51.1	n.s.			
			PF	35	60	$p < 0.0001$			
			RP	41	62	$p < 0.0001$			
			BP	55	61	n.s.			
			GH	78	82	n.s.			
			VT	60	64.3	n.s.			
			SF	78	83	n.s.			
			RE	75	78	n.s.			
			MH	74	77	n.s.			
			• At 5-year follow-up statistically significant improvements compared to baseline in all four Q-TFA scores and in the Physical Function, Role Physical, and Physical Component scores on the SF-36						

(*Continued*)

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TABLE 3 Continued

<table>
<tr><th>Study</th><th>Implant type</th><th>Outcomes reported</th><th>Results (HRQoL)</th><th>Results (mobility)</th><th>Results (prosthetic usage)</th><th>Other</th></tr>
<tr><td></td><td></td><td></td><td>• Improvements noted above were the same as (45) but no significant improvement between 2-year and 5-year follow-ups was reported</td><td></td><td></td><td></td></tr>
<tr><td>Matthews et al. (47)</td><td>OPRA</td><td>Q-TFA, SF-36</td><td>Mean scores:
Q-TFA
Subscore | Pre | Post | Sig
PUS | NR | NR | p = 0.0001
Mobility | NR | NR | p = 0.0028
Problem | NR | NR | p = 0.0004
Global | NR | NR | p = 0.0001
SF-36
Subscore | Pre | Post | Sig
PCS | NR | NR | p = 0.004
MCS | NR | NR | n.s.
PF | NR | NR | p = 0.0001
RP | NR | NR | n.s.
BP | NR | NR | n.s.
GH | NR | NR | n.s.
VT | NR | NR | n.s.
SF | NR | NR | n.s.
RE | NR | NR | n.s.
MH | NR | NR | n.s.
• HRQoL showed significant improvements up to 5 years after implantation
• There were no significant differences between 2 years postsurgery and 5 years post-implantation
• The physical scores, physical functioning, and physical component score in the SF-36 improved significantly from preoperative status and 2- and 5-year follow-ups
• However, SF-36 scores did not change significantly between 2 and 5 years postoperatively</td><td>• Q-TFA prosthetic mobility score improved significantly between baseline and 5-year follow-up
• There were no significant differences between 2 years postsurgery and 5 years postimplantation</td><td>• Q-TFA prosthetic use score improved significantly between baseline and at 5-year follow-up
• There were no significant differences between 2 years postsurgery and 5 years postimplantation</td><td>NR</td></tr>
</table>

(*Continued*)

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TABLE 3 Continued

Study	Implant type	Outcomes reported	Results (HRQoL)	Results (mobility)	Results (prosthetic usage)	Other
			• In the Q-TFA, there were significant improvements in all of the main scores between the preoperative period and 2- and 5-year post-implantation			
Zaid et al. (48)	OPRA	Q-TFA, SF-36 subscales	Mean scores: **Q-TFA** Subscore / Pre / Post / Sig PUS: 32.9 / 62.8 / n.s. Mobility: 52.3 / 65.4 / n.s. Problem: 43.6 / 22.2 / $p = 0.02$ Global: 34.5 / 77.4 / n.s. **SF-36** Subscore / Pre / Post / Sig PCS: NR / NR / N/A MCS: NR / NR / N/A PF: 44 / 63.6 / n.s. RP: 35 / 60 / n.s. BP: NR / NR / n.s. GH: NR / NR / n.s. VT: 51.7 / 61.5 / $p = 0.009$ SF: 68.6 / 85.7 / $p = 0.02$ RE: NR / NR / n.s. MH: 70 / 77 / $p = 0.002$ • There was a significant improvement in the Q-TFA problem subscore • There was a trend toward improvement for all other subscores of the Q-TFA, although none reached significance • There were significant increases in three SF-36 health-related subscales (vitality, social functioning, and mental health)	• Q-TFA prosthetic mobility score showed no significant change between baseline and 1-year follow-up	• Q-TFA prosthetic use score showed no significant change between baseline and 1-year follow-up	NR
Hagberg et al. (49)	OPRA	Q-TFA	Mean scores: **Q-TFA** Subscore / Pre / Post / Sig PUS: NR / NR / n.s. Mobility: NR / NR / n.s. Problem: NR / NR / $p = 0.020$ Global: NR / NR / $p = 0.004$ • Compared with before treatment, the patient-reported HRQoL was significantly better and remained so over the 15-year timeframe • Patients reported fewer problems and an improved overall situation at follow-up	• The activity grade was higher at each time point as compared with the baseline. The activity grade (0–4) was assigned to each patient at each follow-up by the physiotherapist in the treating team, where 0 is no prosthetic activity and 4 is daily prosthesis use for full days without walking aids	NR	• The survival rate of the osseointegrated implant (the fixture) was 89% and 72% after 7 and 15 years, respectively • A total of 61 patients (55%) had mechanical complications

(*Continued*)

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TABLE 3 Continued

Study	Implant type	Outcomes reported	Results (HRQoL)	Results (mobility)	Results (prosthetic usage)	Other
Hagberg et al. (50)	OPRA	Q-TFA, SF-36	Mean scores: **Q-TFA** Subscore / Pre / Post / Sig PUS / 46.7 / 80.6 / $p < 0.001$ Mobility / 52.5 / 65.8 / $p < 0.001$ Problem / 43.9 / 16.3 / $p < 0.001$ Global / 37.7 / 74 / $p < 0.001$ **SF-36** Subscore / Pre / Post / Sig PCS / 33 / 39 / $p = 0.001$ MCS / 53 / 52 / n.s. PF / 35 / 58 / $p < 0.001$ RP / 41 / 53 / n.s. BP / 55 / 57 / n.s. GH / 78 / 74 / n.s. VT / 74 / 80 / n.s. SF / 75 / 74 / n.s. RE / 78 / 80 / n.s. MH / 60 / 65 / n.s. • At 10-year follow-up, statistically significant improvements in all four Q-TFA scores and in the Physical Functioning and the Physical Component scores on the SF-36	• Q-TFA prosthetic mobility score improved significantly between baseline and at 10-year follow-up	• Q-TFA prosthetic use score improved significantly between baseline and at 10-year follow-up	NR
Press-fit type fixation						
Van de Meent et al. (51)	ILP	Q-TFA global score, prosthesis use in hours, 6MWT, TUG, prosthesis use (in hours)	Mean score: **Q-TFA** Subscore / Pre / Post / Sig Global / 39 / 63 / $p = 0.001$ • The Q-TFA mean global score improved significantly from 39 to 63	Mean scores: **6MWT (in meters)** Pre / Post / Sig Distance / 321 / 423 / $p = 0.002$ **TUG (in seconds)** Pre / Post / Sig Time / 15.1 / 8.1 / $p = 0.002$ • Significant improvements in 6MWT (27% increase) and TUG (44% faster)	Mean score: **Prosthesis use (in hours/week)** Pre / Post / Sig Hours/week / 56 / 101 / $p < 0.001$ • Prosthesis use improved by 45% and increased to 101 hours/week with OI compared to 56 hours/week with socket	• Q-TFA global score (68% higher) and prosthesis use (45% higher) significantly improved with OI prosthesis compared to socket prosthesis
Reetz et al. (52)	ILP	Q-TFA prosthetic use score and global score	Median scores: **Q-TFA** Subscore / Pre / Post / Sig	NR	• The Q-TFA median prosthetic use score improved significantly from 71 to 100	NR

(*Continued*)

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TABLE 3 Continued

Study	Implant type	Outcomes reported	Results (HRQoL)	Results (mobility)	Results (prosthetic usage)	Other
			PUS 71 100 $p < 0.001$ Global 33 75 $P < 0.001$ • The Q-TFA median global score improved significantly from 33 to 75 • Bone-anchored press-fit prostheses lead to greater prosthesis use and overall health-related quality of life even up to 5-years postsurgery follow-up			
Gailey et al. (53)	ILP	10 MWT[a], TUG, Activities-specific Balance Confidence (ABC) Scale, PLUS-M	NR	Mean scores: 10MWT (in meters/second) OI group / Socket group / Sig Speed 0.81 / 0.96 / n.s. TUG (in seconds) OI group / Socket group / Sig SSWS 12.39 / 11.27 / n.s. FWS 9.72 / 9.5 / n.s. PLUS-M OI group / Socket group / Sig T-score 59.17 / 53.50 / n.s. • No significant differences found between groups in TUG (at self-selected walking speed; SSWS, or fastest walking speed; FWS), or PLUS-M	NR	• No significant differences found between groups in Activities-specific Balance Confidence (ABC) Scale
Al Muderis et al. (54) (Numbers of patients receiving ILP or OPL not specified)	ILP or OPL	Q-TFA, SF-36, AMPRO, 6MWT, TUG	Mean scores: Q-TFA Subscore / Pre / Post / Sig PUS NR NR N/A Mobility NR NR N/A Problem NR NR N/A Global 47.82 83.52 $p < 0.001$ SF-36 Subscore / Pre / Post / Sig PCS 37.09 47.29 $p < 0.001$ MCS NR NR N/A PF NR NR N/A RP NR NR N/A	Mean scores: 6MWT (in meters) Pre / Post / Sig Distance 281 419 $p < 0.001$ TUG (in seconds) Pre / Post / Sig Time 14.59 8.74 $p < 0.01$ • All 14 participants who were wheelchair bound preoperatively could not perform the TUG and 6MWT were able to do so postoperatively • Their postoperative scores were comparable with those of the patients who were walking preoperatively	NR	NR

(*Continued*)

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TABLE 3 Continued

Study	Implant type	Outcomes reported	Results (HRQoL)	Results (mobility)	Results (prosthetic usage)	Other
			BP NR NR N/A GH NR NR N/A VT NR NR N/A SF NR NR N/A RE NR NR N/A MH NR NR N/A • Significant improvement in SF-36 physical component summary and Q-TFA global score			
Leijendekkers et al. (55) (17 ILP, 15 OPL)	ILP or OPL	Q-TFA prosthetic use, Q-TFA global, 6MWT, TUG, prosthetic comfort score	Median score: **Q-TFA** Subscore Pre 6m Post 12m Post Sig PUS 52 90 100 N/A Mean score: **Q-TFA** Subscore Pre 6m Post 12m Post Sig Global 48 69 70 $p < 0.001$ • HRQoL (measured by Q-TFA global score) increased significantly at 6- and 12-month follow-up compared to baseline	Mean scores: **6MWT (in meters)** Pre 6m Post 12m Post Sig Distance 319 284 313 $p = 0.038$ **TUG (in seconds)** Pre 6m Post 12m Post Sig Time 13.0 12.8 11.3 $p = 0.005$ • TUG showed no change at 6-month follow-up but improved significantly at 12-month follow-up compared to baseline • Out of the 31 transfemoral, 10 were wheelchair-bound before OI surgery, at 6 months and 12 months postsurgery 0 patients were wheelchair-bound	• Q-TFA prosthetic use score increased at 6- and 12-month follow-ups compared to baseline	• Mean prosthetic comfort score (1–10) increased significantly ($p < 0.001$) from 5.4 to 8.2 between baseline and 12 months
Al Muderis et al. (56)	OPL	Q-TFA,SF-36, 6MWT, TUG	Mean scores: **Q-TFA** Subscore Pre Post Sig Global NR NR $p < 0.05$ **SF-36** Subscore Pre Post Sig PCS NR NR $p < 0.05$ MCS NR NR N/A PF NR NR N/A	Mean scores: **6MWT (in meters)** Pre Post Sig Distance NR NR $p < 0.05$ **TUG (in seconds)** Pre Post Sig Time NR NR $p < 0.05$ • 6MWT showed significant improvement (128%) at follow-up over preoperatively	NR	N.R.

(*Continued*)

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TABLE 3 Continued

Study	Implant type	Outcomes reported	Results (HRQoL)	Results (mobility)	Results (prosthetic usage)	Other
			RP NR NR N/A BP NR NR N/A GH NR NR N/A VT NR NR N/A SF NR NR N/A RE NR NR N/A MH NR NR N/A • Q-TFA global and SF-36 physical component scores were significantly higher at follow-up than preoperatively	• TUG showed a significant reduction (30%) at follow-up than preoperatively		
McMenemy et al. (57)	OPL	SF-36, 6MWT, TUG	Mean scores: **SF-36** Subscore Pre Post Sig PCS 34.65 54.5 $p = 0.018$ MCS 41.55 58.19 $p = 0.018$ • The physical component score (PCS) and mental component score (MCS) of the SF-36 demonstrated a statistically significant improvement representing a change from "below" or "well below" to "same or above" level expected of an age- and gender-matched able-bodied population	Mean score: **6MWT (in meters)** Pre Post Sig Distance 248 402 $p = 0.018$ Median score: **TUG (in seconds)** Pre Post Sig Time N/A 10.6 N/A • The distance covered in the 6MWT improved by 154 m from baseline to 24-month follow-up • Preoperatively, no patient was able to perform the TUG test reliably and safely due to stump and balance problems. At the last postoperative review, all patients were able to perform the test with a median time of 10.6 s	NR	NR
Reif et al. (58) (*Data on individuals with transfemoral amputation provided by the corresponding author*)	OPL	Q-TFA, PROMIS (Function, Pain Intensity, Pain Interference), LD-SRS[b], 2MWT[c], 6MWT, and EQ-5D	Mean scores: **Q-TFA** Subscore Pre Post Sig PUS 49.77 75.23 Yes (*p*-value NR) Mobility 45.55 66.29 Yes (*p*-value NR) Problem 51.00 20.17 Yes (*p*-value NR) Global 17.60 77.08 Yes (*p*-value NR)	Mean scores: **2MWT (in meters)** Pre Post Sig Distance 195.4 336.4 Yes (*p*-value NR) **6MWT (in meters)** Pre Post Sig Distance 564.6 955.0 Yes (*p*-value NR)	• Q-TFA prosthetic use score increased at follow-up compared to baseline	**PROMIS** Scale Pre Post Sig Function 34.00 40.53 Yes (*p*-value NR) Pain Intensity 46.60 44.39 Yes (*p*-value NR) Pain Interference 57.10 52.39 Yes (*p*-value NR)

(*Continued*)

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TABLE 3 Continued

Study	Implant type	Outcomes reported	Results (HRQoL)	Results (mobility)	Results (prosthetic usage)	Other
			EQ-5D Pre: Index 0.62; Post: Index 0.66; Sig: Index n.s. • Q-TFA prosthetic use score, mobility score, and global score were significantly improved at follow-up compared to baseline • Q-TFA Problem score was significantly reduced at follow-up compared to baseline. • EQ-5D scores were not significantly different at follow-up • PROMIS Function score significantly improved at follow-up compared to baseline	• 2MWT and 6MWT scores improved significantly at follow-up compared to baseline		
Pospiech et al. (59)	EEP	Q-TFA, EQ-5D-3L	Mean scores: **Q-TFA** PUS: OI group 89, Socket group 87, Sig n.s. Mobility: OI group 87, Socket group 79, Sig $p = 0.05$ Problem: OI group 7, Socket group 18, Sig $p < 0.001$ Global: OI group 81, Socket group 69, Sig $p = 0.022$ **EQ-5D-3L** Index: OI group 0.89, Socket group 0.93, Sig n.s. VAS: OI group 84.32, Socket group 82.59, Sig n.s. • Patients with bone-anchored press-fit implants had a higher prosthesis-associated QoL when assessed with the Q-TFA • HRQoL as assessed with EQ-5D-3L was not different between groups	NR	• Patients with OI experienced fewer prosthesis-associated problems than socket prosthesis users. General quality of life, as assessed with the Problem score of the Q-TFA	• Patients with bone-anchored press-fit implants and patients with a socket-suspension system were group-matched for age, body mass index and mobility grade
Örgel et al. (60)	EEP	Q-TFA, EQ-5D-5L, SAT-PRO[d], PMQ[e] 2.0, FIM[f]	Mean scores: **Q-TFA** PUS: OI group NR, Socket group NR, Sig n.s. Mobility: OI group NR, Socket group NR, Sig n.s. Problem: OI group NR, Socket group NR, Sig $p < 0.001$ Global: OI group NR, Socket group NR, Sig $p < 0.001$	Mean score: **PMQ 2.0** Score: OI group NR, Socket group NR, Sig $p < 0.001$ • Q-TFA mobility score showed a significant difference between the TOPS (OI) group and	NR	• Greater mobility reported by the TOPS (OI) group and reduced problems score could possibly influence the higher level of satisfaction in this group

(*Continued*)

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TABLE 3 Continued

<table>
<tr><th>Study</th><th>Implant type</th><th>Outcomes reported</th><th>Results (HRQoL)</th><th>Results (mobility)</th><th>Results (prosthetic usage)</th><th>Other</th></tr>
<tr><td></td><td></td><td></td><td>
EQ-5D-5L
<table>
<tr><td>Subscore</td><td>OI group</td><td>Socket group</td><td>Sig</td></tr>
<tr><td>Index</td><td>NR</td><td>NR</td><td>$p < 0.004$</td></tr>
<tr><td>VAS</td><td>NR</td><td>NR</td><td>$p < 0.035$</td></tr>
</table>

Q-TFA problem score showed a significant difference between the TOPS (OI) group and socket group; the socket group reporting more problems
Q-TFA total score showed significant difference between the TOPS (OI) group and socket group; the TOPS group reporting better outcomes
EQ-5D-5L health and total scores showed a significant difference between the TOPS (OI) group and socket group. Higher scores were reported by the TOPS group

</td><td>
socket group; the TOPS group reporting greater mobility

Significantly higher PMQ 2.0 scores for the TOPS (OI) group than the socket group

</td><td></td><td></td></tr>
<tr><td>Welke et al. (61)</td><td>EEP</td><td>Q-TFA, SF-36, 6MWT, TUG</td><td>
Mean scores:
Q-TFA
<table>
<tr><td>Subscore</td><td>OI group</td><td>Socket group</td><td>Sig</td></tr>
<tr><td>PUS</td><td>85.0</td><td>89.2</td><td>n.s.</td></tr>
<tr><td>Mobility</td><td>82.1</td><td>84.8</td><td>n.s.</td></tr>
<tr><td>Problem</td><td>10.3</td><td>17.3</td><td>n.s.</td></tr>
<tr><td>Global</td><td>69.6</td><td>74.0</td><td>n.s.</td></tr>
</table>
SF-36
<table>
<tr><td>Subscore</td><td>OI group</td><td>Socket group</td><td>Sig</td></tr>
<tr><td>PCS</td><td>46.3</td><td>46.9</td><td>n.s.</td></tr>
<tr><td>MCS</td><td>50.2</td><td>53.7</td><td>n.s.</td></tr>
<tr><td>PF</td><td>NR</td><td>NR</td><td>N/A</td></tr>
<tr><td>RP</td><td>NR</td><td>NR</td><td>N/A</td></tr>
<tr><td>BP</td><td>NR</td><td>NR</td><td>N/A</td></tr>
<tr><td>GH</td><td>NR</td><td>NR</td><td>N/A</td></tr>
<tr><td>VT</td><td>NR</td><td>NR</td><td>N/A</td></tr>
<tr><td>SF</td><td>NR</td><td>NR</td><td>N/A</td></tr>
<tr><td>RE</td><td>NR</td><td>NR</td><td>N/A</td></tr>
<tr><td>MH</td><td>NR</td><td>NR</td><td>N/A</td></tr>
</table>

No significant differences between groups reported in SF-36 or Q-TFA scores

</td><td>
Mean scores:
6MWT (in meters)
<table>
<tr><td></td><td>OI group</td><td>Socket group</td><td>Sig</td></tr>
<tr><td>Distance</td><td>321.7</td><td>315.5</td><td>n.s.</td></tr>
</table>
TUG (in seconds)
<table>
<tr><td></td><td>OI group</td><td>Socket group</td><td>Sig</td></tr>
<tr><td>Time</td><td>11.0</td><td>11.2</td><td>n.s.</td></tr>
</table>

No significant differences between groups reported between groups in 6MWT or TUG

</td><td>NR</td><td></td></tr>
</table>

(*Continued*)

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TABLE 3 Continued

Study	Implant type	Outcomes reported	Results (HRQoL)	Results (mobility)	Results (prosthetic usage)	Other
Atallah et al. (28)	OTN (reported as OFI-C for long femur and OFI-Y for short femur)	Q-TFA Prosthesis wearing time (PUS), health-related quality of life (GS)	Mean scores: **Q-TFA** **OFI-C ($n = 52$)** Subscore / Pre / Post / Sig PUS / 59 / 86 / $p < 0.01$ GS / 42 / 67 / $P < 0.01$ **OFI-Y ($n = 16$)** Subscore / Pre / Post / Sig PUS / 31 / 93 / $p < 0.01$ GS / 31 / 79 / $P < 0.01$ • The Q-TFA mean PUS and GS improved significantly at 1-year follow-up	NR	• The Q-TFA mean prosthetic use score improved significantly at 1-year follow-up	• This study included those individuals who received modified ILP implants, i.e., curved osseointegration femur implant (OFI-C) indicated for a long femoral remnant and gamma osseointegration femur implant (OFI-Y) indicated for a short femoral remnant
Sinclair et al. (62)	POP	Q-TFA, 6MWT, Don/doff time	Mean scores: **Q-TFA** Subscore / Pre / Post / Sig PUS / 78 / 96 / n.s. Mobility / 64 / 81 / n.s. Problem / 25 / 3 / $p < 0.001$ Global / 62 / 92 / $p < 0.001$	Mean score: **6MWT (in meters)** Pre / Post / Sig Distance / 481 / 584 / $p < 0.001$	NR	Mean score: **Don/doff time (in seconds)** Pre / Post / Sig Don / 112.5 / 9.7 / $p < 0.05$ Doff / 24.4 / 7.1 / $p < 0.05$
Davis-Wilson et al. (63)	Unspecified	WHODAS 2.0[g], PLUS-M, ABC[h]	NR	Mean score: **PLUS-M** Pre / Post / Sig T-score / 48.67 / 58.60 / $p < 0.001$	NR	Mean scores: **WHODAS 2.0** Pre / Post / Sig Score / 11 / 5.33 / $p = 0.008$ **ABC** Pre / Post / Sig Score / 72.78 / 88.67 / $p = 0.013$

NR, Not reported.
[a]10 MWT, 10 m walk test.
[b]LD-SRS, Limb Deformity–Scoliosis Research Society.
[c]2MWT, 2 min walk test.
[d]SAT-PRO, satisfaction with prosthesis questionnaire.
[e]PMQ 2.0, prosthesis mobility questionnaire 2.0.
[f]FIM, functional independence measure.
[g]WHODAS 2.0, World Health Organization Disability Assessment Schedule 2.0.
[h]ABC, activity-specific balance scale.

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TABLE 4 Adverse events and complications reported in included studies on clinical outcomes.

Study	Implant type	Uneventful course	Superficial/soft tissue infections	Deep infections	Periprosthetic fractures	Implant loosening	Implant breakage	Implant removal	Mechanical complications	Other
Screw-type fixation										
Hagberg et al. (44)	OPRA	NR	• In 2/18 patients	NR	NR	• In 1/18 patients	NR	NR	• 1/18 patients had a broken external component	NR
Brånemark et al. (45)	OPRA	NR	• 41 events in 28/51 patients (treated with oral antibiotics)	• In 4/51 patients (3 treated with antibiotics, 1 implant removal)	0	• In 3/51 patients leading to implant removal	NR	• In 4/51 patients (3 due to implant loosening, 1 due to deep infection)	• 4/51 patients experienced complications with the abutment and/or the abutment screw • Damaged components were replaced • No mechanical complications with the fixture	• 5 patients suffered episodic pain during rehabilitation, without loosening • 4 patients with 5 fractures; 3 in the ipsilateral hip, 1 below the elbow, and 1 vertebral compression
Brånemark et al. (46)	OPRA	NR	• 70 events in 34 patients(treated with oral antibiotics)	• 14 events in 11 patients (9 treated with oral antibiotics, 1 implant removal, 1 unresolved)	NR	• In 3/51 patients leading to implant removal	NR	• In 4/51 patients (3 due to implant loosening, 1 due to deep infection)	• 43 complications in 15 patients • Damaged abutment and/or the abutment screw were replaced • Incidences increased between 2- and 5-year post-OI	• Stump revisions in 3/51 patients • One of the deep infections caused early loosening/failure of the fixture
Matthews et al. (47)	OPRA	NR	• In 11/18 patients (treated with oral antibiotics)	• In 5/18 patients (2 patients treated with oral antibiotics, 3 requiring implant removal)	• 2 fractured the neck of the femur due to a fall	• In 1/18 patients (requiring removal)	NR	• In 5/18 patients (3 due to deep infections, 1 due to chronic pain, 1 due to implant fracture)	• 2 patients fell and fractured the abutment • 5 patients fractured the abutment-retaining bolt • 11 patients experienced abutment bending • Fractured components were replaced • 12 patients required surgery for abutment changes	• 1 of the superficial (soft-tissue) infection required operative debridement
Zaid et al. (48)	OPRA	NR	• 4 events in 4/9 patients (treated with oral antibiotics)	• In 1/9 patients (requiring implant removal)	• 1 intertrochanteric fracture close to the implant due to a fall	NR	NR	• In 1/9 patients due to deep infection	• 8/9 patients experienced problems with the connector, resulting in the replacement of the connectors	NR
Hagberg et al. (49)	OPRA	NR	NR	NR	NR	0	NR	NR	• Over 15 years, 61/111 patients had mechanical	NR

(*Continued*)

TABLE 4 Continued

Study	Implant type	Uneventful course	Superficial/soft tissue infections	Deep infections	Periprosthetic fractures	Implant loosening	Implant breakage	Implant removal	Mechanical complications	Other
									complications, resulting in the exchange of the percutaneous implant parts	
Hagberg et al. (50)	OPRA	NR	• Reported as 1.88 per 10 person-years	• In 16 patients (15 treated with antibiotics, 1 implant removal)	NR	• In 3 patients (in the first 5 years leading to removal)	• In 4 patients (requiring removal between 5 and 10 years)	• In 8 patients (3 due to implant loosening, 1 due to deep infection, 4 due to implant breakage)	• Mechanical complications of outer components (i.e., abutment or abutment screw) significantly increased ($p = 0.001$) in the 5–10-year period compared to the first 5 years after implantation	NR
Press-fit fixation										
Van de Meent et al. (51)	ILP	NR	• In 8/22 patients (managed by extensive cleaning with hydrogen peroxide and antibiotics as needed)	NR	NR	NR	NR	NR	NR	NR
Reetz et al. (52)	ILP	• In 9/39 patients	• 148 events in 26/39 patients (46 events did not require treatment, 85 events treated with oral, 7 with parenteral antibiotics, and 10 with surgical intervention)	• 8 events in 4/39 patients (1 did not require treatment, 5 events treated with oral antibiotics, and 2 with surgical intervention)	NR	• 1/39 patients experienced aseptic loosening within 1 year • 0/39 patients experienced septic loosening	• In 2/39 patients within 2 years (revised successfully)	• In 2/39 (due to pain)	• 12 dual-cone adapters broke in 9 patients and were replaced	• 30 events of soft-tissue refashioning in 14/39 patients due to stoma-redundant tissue. 1 patient experienced 9 events • 13 events of stoma hypergranulation in 8/39 patients
Gailey et al. (53)	ILP	No information on complications provided								
Al Muderis et al. (54)	ILP or OPL	• In 23/50 patients	• In 21/50 patients (13 treated with oral antibiotics, 5 to parenteral antibiotics, and 3 requiring debridement)	0	• In 4/50 patients due to falls (resolved successfully without removing the implant)	NR	NR	NR	NR	• Soft-tissue refashioning in 10/50 patients to avoid impingement, skin irritation, and infection

(*Continued*)

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TABLE 4 Continued

Study	Implant type	Uneventful course	Superficial/soft tissue infections	Deep infections	Periprosthetic fractures	Implant loosening	Implant breakage	Implant removal	Mechanical complications	Other
										• Revision of the implant was required in 2/50 patients; 1 due to failure of OI as a result of an undersized device, and 1 due to implant fatigue failure at 3.5 years
Leijendekkers et al. (55) *(information extracted from online supplemental materials accompanying the article)*	ILP or OPL	• In 19/31 patients (10 OPL, 9 ILP)	• 9/31 (2 OPL, 7 ILP) had low-grade soft-tissue infections treated with oral antibiotics • 1/31 (ILP) had high-grade soft-tissue infection requiring surgical intervention	NR	• In 4/31 (2 OPL, 2 ILP) patients due to falls	0	0	NR	• 2 dual-cone breakages with the ILP (none with the OPL), all successfully replaced	• Stoma hypergranulation in 2/31 patients (1 OPL, 1 ILP)
Al Muderis et al. (56)	OPL	NR	• 12 cases in 10/22 patients of low-grade soft-tissue infection • 3 cases in 2/22 patients of high-grade soft-tissue infection	0	0	0	0	0	NR	• 6/22 patients required refashioning surgery
McMenemy et al. (57)	OPL	NR	• Each patient had been prescribed a minimum of 1 course of empirical antibiotics for superficial infection	0	• In 1/7 patients (surgically stabilized with a dynamic hip screw which healed uneventfully)	0	NR	0	• 1/7 patients experienced a broken dual cone (after weightlifting), which was replaced	• 3/7 patients required refashioning of the stoma or stump 12–16 months postoperatively with no subsequent stump complications
Reif et al. (58)	OPL	NR	• 15 events in 9/18 patients. All treated with oral antibiotics	NR	• In 2/18 patients	0	0	0	• 6/18 patients experienced a broken attachment, which was replaced • 3/18 patients needed a longer dual cone	• 1/18 patients underwent stoma revision
Pospiech et al. (59)	EEP	No information on complications provided								
Örgel et al. (60)	EEP	No information on complications provided								

(*Continued*)

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TABLE 4 Continued

Study	Implant type	Uneventful course	Superficial/soft tissue infections	Deep infections	Periprosthetic fractures	Implant loosening	Implant breakage	Implant removal	Mechanical complications	Other
Welke et al. (61)	EEP	No information on complications provided								
Atallah et al. (28)	OTN (reported as OFI-C for long femur and OFI-Y for short femur)	NR	• In 13/68 patients (7 in OFI-C and 6 in OFI-Y)	NR	• In 2/68 patients (2 in OFI-C)	0	0	NR	• 3/68 patients experienced dual-cone adapter breakage	• Soft-tissue refashioning due to stoma-redundant tissue in 1/68 patients in the OFI-Y group • No individuals experienced multiple events of infections of the same grade
Sinclair et al. (62)	POP	NR	• 2 events in 1 patient	NR	• In 1/10 patients	• In 1/10 patients	NR	• In 2/10 patients (1 due to implant loosening, 1 due to periprosthetic fracture)	• 5 events in 2 patients (loose adaptors or outer adaptor bolts) which were replaced	• 2 patients underwent skin revisions to reduce redundant skin • 4 events of residual limb muscle pain, soreness in the residual limb, and anterior distal muscle pain
Davis-Wilson et al. (63)	Unspecified	NR	NR	NR	NR	NR	NR	NR	NR	• 1/9 patients experienced stoma hypergranulation and underwent soft tissue revision surgery • 1/9 patients experienced stoma pain • 1/9 patients experienced stoma erythema • 1/9 patients experienced stoma hematoma • 1/9 of patients experienced muscle spasms

NR, Not reported.

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TABLE 5 Studies focusing specifically on complications and safety parameters.

Study	Implant type	Study design	OCEBM Level of Evidence	Aims/design	Number of patients	Findings	Odds of complications	Comments
Screw-type fixation								
Tillander et al. (36)	OPRA	Prospective case series	Level 4	• To explore infectious complications • The study group was followed prospectively for an average of 3 years to identify implant infections and cross-sectionally surveyed twice (at inclusion and after approximately 3 years) for bacterial presence, local infection, and antibiotic use	• 39 (33 with transfemoral level of amputation)	• 2/39 patients had infections at baseline and 7/39 patients had experienced infections at follow-up • 7 patients had a local infection at the skin penetration area in the 6-month period preceding baseline. Out of these 4 were treated with short-term oral antibiotics • 11 patients had a history of local infection at the skin penetration area during the 6-month period before follow-up. Out of these 6 patients were treated with short-term oral antibiotics • The most common bacteria found around the skin-implant interface were Staphylococcus aureus, coagulase negative staphylococci, and streptococci group A, B, or G	• This information was presented in another paper (67)	• These adverse events were not compared with those of conventional socket prostheses
Tillander et al. (67)	OPRA	Retrospective case series	Level 4	• To quantify the risk of osteomyelitis • To characterize the clinical effect of osteomyelitis (including risk of implant extraction and impairments to function) • To determine whether common patient factors (age, sex, body weight, diabetes, and implant component replacements) are associated with osteomyelitis in patients with transfemoral amputations	• 96	• Osteomyelitis occurred in 16/96 patients • Out of the 16, 10 patients underwent extraction of the fixture • Out of the remaining 6, prosthetic use was temporarily impaired in 4 patients with infection who did not undergo implant extraction	• The 10-year cumulative risk of implant-associated osteomyelitis was 20% (in 16/96 patients) • No significant association between osteomyelitis and age (being elderly), overweight (BMI >25 kg/m^2), sex, or smoking	• None
Press-fit fixation								
Juhnke et al. (68)	ILP	Retrospective case series	Level 4	• To explored changes in clinical outcomes during the evolution of device designs and concurrent refinement of operative techniques: three systematic and empirically driven iterations over 15 years	• 69 • 30 in Group 1 (Design A or B) • 39 in Group 2 (Design C)	*Group 1:* • Only patients in this group needed reoperations or revisions due to infection • 1 structural failure of implant, 4 explanations, 3 fractures, 77% had intervention due to soft-tissue stoma and 80% due to "any unplanned intervention"	NR	• Retrospective comparative analysis of patients treated over 14 years with three types of implant design • Implant design changes determined by clinical outcomes to reduce infection at the stoma and deep bone and implant interface

(*Continued*)

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TABLE 5 Continued

Study	Implant type	Study design	OCEBM Level of Evidence	Aims/design	Number of patients	Findings	Odds of complications	Comments
						Group 2: • 5 needed unplanned interventions. None of these surgeries were secondary to infections • No structural failures or explantations, 2 peri-implant fractures (did not require implant removal), and 1 intervention due to a soft-tissue stoma		
Al Muderis et al. (69)	ILP	Prospective case series	Level 4	• To report on the safety of press-fit osseointegrated implants used in Australia and the Netherlands	• 86 (65 males)	• 31/86 had an uneventful course with no complications • 29/86 developed low-grade or high-grade soft tissue infections that were managed with oral or parenteral antibiotics or surgical intervention (such as debridement) • 26/86 did not develop an infection but had one or more other complications requiring intervention, including stoma hypergranulation (17), soft-tissue redundancy (14), proximal femoral fracture (3), inadequate OI leading to implant replacement (1), implant breakage (2) • Mechanical complications: breakage of the pin used as a fail-safe mechanism (25) • 0/86 developed deep peri-implant infection • 1/86 underwent removal of the implant due to inadequate OI resulting from an undersized implant. This patient was re-treated with a larger-diameter implant	• Significant association between: ◦ Sex and risk of severe infection ◦ Females have a sixfold increase in risk • BMI or >25 kg/m^2 and risk of mind infection. Threefold increase in risk of mild infections in these patients • Smoking and recurrent infections. Sevenfold increase in risk in these patients	• Participants were recruited in 2 centers (Australia and the Netherlands) and underwent the two-stage surgical procedure • This article developed and launched a classification system for infection based on clinical and radiographic signs to allow prospective incidence reporting, severity assessment • No significant association was observed between other characteristics and the risk of complications. Similar infection rates were observed at the two centers
Mohamed et al. (70)	ILP	Retrospective case series	Level 4	• To identify risk factors which lead to revision surgery after implant breakage • Rate and causes of revision surgery • Location of mechanical failure and septic loosening (intramedullary versus dual-cone adapter)	• 58 (41 males)	• 20/58 patients experienced implant failures • 7/20 had a failed intramedullary stem (6 due to breakages and 1 due to septic loosening). All 7 underwent revision surgery to have a larger-diameter OPL intramedullary stem because initial	NR	• Cold welding of the taper connection to the intramedullary stem was observed • After 9 years, the cumulative implant survival probability was 78% • Median implant survival time was 6 (IQR: 4) years

(*Continued*)

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TABLE 5 Continued

Study	Implant type	Study design	OCEBM Level of Evidence	Aims/design	Number of patients	Findings	Odds of complications	Comments
						broken stem changed intramedullary space • 13/20 sustained dual-cone adapter breakages (9 due to weak-point breakage, 3 due to distal taper breakage, and 1 broke both). These were revised in an outpatient setting without the need for anesthesia • Factors associated with revision surgery identified as (1) stem failures due to smaller stem diameter, and (2) number of infectious events in a patient • Authors could not find evidence for any factor associated with dual-cone adapter weak-point or distal taper failure		
Hoellwarth et al. (71)	ILP or OPL	Retrospective case series	Level 4	• To assess the risk of periprosthetic fractures by a retrospective review identified 518 OI procedures which were undertaken in 458 patients between 2010 and 2018 for whom complete medical records were available • Potential risk factors including time since amputation, age at OI, bone density, weight, uni/bilateral implantation and sex were evaluated	• 313 with 347 femoral implants (279 unilateral, 34 bilateral) • 9 with 18 mixed transfemoral/ transtibial implants	• No fractures occurred spontaneously • No patients required removal of implants • 22 periprosthetic fractures reported, representing 6.3% of 347 femoral implants • Fractures united in 21 out of 22 patients (95.5%) • 19/22 fractures due to ground-level fall, 2/22 due to twist, 1/22 due to kicking • The vast majority (19/22, 86.4%) occurred within 2 cm of the proximal tip of the implant and after a fall • Fixation most commonly involved dynamic hip screws (10) and reconstruction plates (9)	• Significant association between periprosthetic fractures and: ◦ Sex, a 3.89-fold increased risk of fracture for females ◦ Weight, a 1.02-fold increased risk of fracture per kg above a mean of 80.4 kg ($p = 0.046$) • No increased risk for bilateral implants time from amputation to OI, age at surgery, or bone density	• Mobility level and prosthesis wear time were negatively affected after fixation of the fracture in any patient • Given that the rate of fractures in lower-limb amputees using traditional socket prostheses has been reported to be 2% to 3%, OI consistently provides a better quality of life compared with traditional socket prostheses, and that even after a fracture mobility is likely to remain better compared with a traditional socket prosthesis
Wood et al. (72)	OPL	Prospective case series	Level 4	• To examine pain and pain management for up to 3 years after surgery in military persons with severe complex trauma-related (blast) injuries • Pain assessment using 4-point verbal rating scale (VRS) conducted (1) preoperatively, the day before surgery; and postoperatively at (2)	• 7 bilateral (all males)	• Progressive decrease in the use of regular analgesics • 6/7 patients reported no to mild pain on discharge from hospital to rehabilitation center (on average 17 days later) • 5/7 patients required some analgesic at 6 weeks postsurgery • 3/7 patients needed long-term pain management with opiates	NR	• Perioperative venous thrombosis or pulmonary embolism did not occur • 6/7 patients experiences systemic inflammatory response postoperatively • 1/7 patients experienced femoral shaft fracture during surgery which was managed conservatively • 3/7 patients had recurrent soft tissue complications. Two of these

(*Continued*)

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TABLE 5 Continued

Study	Implant type	Study design	OCEBM Level of Evidence	Aims/design	Number of patients	Findings	Odds of complications	Comments
				discharge from hospital, (3) 6 weeks, (4) 3 months, and (5) 6 months		postoperatively. 2 were still using ay 3 months, and 1 continuing at 14 months postsurgery • 1/7 patients experienced persistent pain after discharge		underwent revision surgeries within 18 months postsurgery • 3/7 patients experienced femoral fractures after discharge. 1 due to fall, 1 due to twist while standing, and 1 due to increased physical activity
Hoellwarth et al. (73)	OPL	Retrospective case series	Level 4	• To investigate the association between bone-anchored implants and mortality and assess the potential risk factors	• 485 (331 transfemoral, 154 transtibial)	• No deaths occurred intraoperatively or during inpatient recuperation or acute recovery after OI • 19 patients died after the OI procedure at a mean of 2.2 years after surgery (range: 58 days to 5 years) • 17 participants died of causes unrelated to OI • 2 died of direct OI-related infectious complications originating from the stoma site • Leading causes of death were cardiac issues (5/19), cancer (4/19), pulmonary issues (3/19), suicide (3/19), osseointegrated-related infection (2/19), and trauma (1/19)	• Factors that increase the risk: increased age (hazard ratio: 1.06), vascular disease (OR: 4.73), or amputation due to infectious causes (OR: 3.87) • Notable factors not associated with mortality risk included post-OI infection and sex	• Most patients who have had OI will most likely survive, but die of unrelated medical or accidental events • The incidence of suicide in this cohort highlights that those who have undergone amputation have long been recognized as a population at risk for mental health issues

Black et al. (74)	OPL	Retrospective case series	Level 4	• To assess the incidences, timelines, and risk factors of soft tissue complications in patients with lower limb prosthetic implants	• 60 (33 unilateral transfemoral, 2 bilateral transfemoral)	• Out of the 60 patients (combined data for transfemoral and transtibial levels):
						  ○ 25 developed soft tissue infections
						  ○ 5 developed osteomyelitis
						  ○ 6 had symptomatic neuromas
						  ○ 7 required soft tissue revisions
						• 47% of soft tissue infections occurred in the 1 month after implantation, and 76% occurred in the first 4 months
							• Soft tissue infections were positively correlated with obesity (RR: 2.01) and female sex (RR: 2.15)
							• Neuroma development was associated with increased age at OI (RR: 1.09)
							• Osteomyelitis was positively correlated with decreased center experience (RR: 7.42)
								• Patients were followed for an average of period of 21.8 months
								• Soft tissue infections were observed the soonest after implantation, with a median onset of 36 days after surgery
								• Deep infections of the bone and/or hardware occurred later in time, at a median of 157 days after surgery
								• Soft tissue redundancy and symptomatic neuromas appeared around 8 months and up to 18 months postoperatively
								• Hypertension, diabetes mellitus, tobacco use, and alcohol use did not have significant associations with poor outcomes
								• Increased center experience can reduce the risk of osteomyelitis

(*Continued*)

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TABLE 5 Continued

Study	Implant type	Study design	OCEBM Level of Evidence	Aims/design	Number of patients	Findings	Odds of complications	Comments
Örgel et al. (75)	EEP	Retrospective cohort study	Level 3	• To investigate the impact of periprosthetic fractures in persons who got an EEP between 2010 and 2017 at the 2 centers in Germany by comparing the outcomes in mobility [Prosthesis Mobility Questionnaire (PMQ), AMP K-level] and prosthesis wear time in hours in patients with a periprosthetic fracture to patients without a periprosthetic fracture • To derive a classification system and treatment algorithm of periprosthetic fractures related to TOPS	• 34 (15 in fracture group, 19 in control group)	• 15 periprosthetic fractures (5 intraoperative and 10 postoperative) • All postoperative fractures were treated with implant-retaining osteosynthesis • No implants required removal	• Sex- and age-related differences could not be evaluated as this study mainly consisted of younger (mean age: 48.7 years) and predominantly male (73.5%) patients	• For both the fracture and control group, a significant increase of the PMQ and K-level was observed before and after the OI treatment • Periprosthetic fractures do not worsen outcomes • A significantly higher increase of the PMQ before and after OI treatment for the group BMI $\geq$ 25 kg/m^2 than for the group BMI < 25 kg/m^2, regardless of a periprosthetic fracture • There was no significant improvement in the rehabilitation results for the K-level in favor of the overweight patients compared to the normal weight patients

NR, Not reported.
RR, Relative Risk.
OR, Odds Ratio.

debridement) (36). Soft-tissue refashioning (28, 52, 54, 56–58, 62, 63) and stoma hypergranulation (52, 55, 63) are other complications often reported. Mechanical complications, including the breakage of external parts, also occurred in third (58) to half (49) of the patients treated with BAP and were reported to be managed by exchanging percutaneous implant parts as needed. Such mechanical complications have been reported to increase between 5 and 10 years after implantation (50). More serious complications, such as implant loosening, implant breakage, and implant failure (requiring removal), were reported and were rarer in individuals treated with press-fit implants (ILP or OPL). Implant loosening has been reported to occur more frequently in screw-type implants and in the first 5 years following implantation. Implant removal occurred in 8 out of 51 patients in the OPRA (screw-type) study cohort (50) and as few as 2 out of 39 patients who were fitted with the ILP (press-fit type) implants (52). In the OPRA study cohort, half of the implant removals occurred in the first 5 years following implantation and the other half between 5 and 10 years (50).

Deeper infections affecting the residual femur are rare and appear more prevalent in screw-type implants, although it should be noted that the duration of follow-up is generally longer for these studies than for press-fit implants. The risk of osteomyelitis (deep infection of the bone) was studied in individuals with screw-type OPRA implants, and the 10-year cumulative risk was 20% (67). There was no significant association between osteomyelitis and advanced age, being overweight, patient's sex, or smoking. However, in a retrospective study of complications with the press-fit ILP implant, Al Muderis et al. (69) reported a threefold increase in the risk of mild infections in persons with overweight or obesity, a sixfold increase in the risk of severe infection in female patients, and a sevenfold increase in recurrent infections in patients who were smokers. The increased risk of soft-tissue infections in persons with obesity and in females who were treated with press-fit implants was also reported by another study (74).

Spontaneous periprosthetic fractures were reported to have not occurred with the OPL (71) in a retrospective case series of 347 patients. Periprosthetic fractures due to falls were rare and occurred in as low as 6.3% of patients treated with the OPL implant; however, the follow-up duration of these studies was short (1 or 2 years). The most common cause for a periprosthetic fracture is falling, and the most common location is close to the proximal tip of the implant (71). Females have approximately a fourfold greater increase in the risk of periprosthetic fractures; however, time from amputation to OI surgery, age at OI surgery, or bone density were not reported to be associated with increased risk for fractures (71). Periprosthetic fractures were reported to be managed successfully in most cases by uniting the bone with dynamic hip screws or reconstruction plates (71, 75) and have been reported to not worsen outcomes (75).

One study specifically examined pain and pain management for up to 3 years after OI surgery (72). This was conducted in a group of seven patients with military service experience who experienced severe complex trauma-related injuries and underwent bilateral transfemoral OI surgeries with the press-fit OPL implant. In this group, five patients were required to take analgesic at 6 weeks postsurgery, three needed long-term pain management with

opiates (out of which only one continued opiate use at 14 months postsurgery), and one had persistent pain after discharge. A progressive decrease in the use of regular analgesics was reported.

The cumulative survival rate for the ILP implant after 9 years was reported to be 78% in a retrospective case series of 58 patients (70). In this group of 58 patients, approximately 35% experienced implant failures either due to intramedullary stem failure (12%) or mechanical complications, such as dual-cone adapter breakage (23%). Those who experienced stem failure underwent revision surgery to have a larger-diameter OPL stem implanted, and those who experienced mechanical complications were revised in an outpatient setting without anesthesia. It was determined that common factors that lead to implant/stem failure are the initial implantation of a smaller diameter stem or the number of infectious events in a patient. Improvements to the design of the implant have been credited to the reduction in unplanned interventions and structural failure requiring the removal of the implant (68).

A retrospective analysis of mortality in a cohort of 485 patients who received the OPL implant reported that no deaths occurred intraoperatively or during inpatient recuperation or recovery after OI surgery; however, 19 patients in this cohort died within 5 years after the OI surgery (73). Moreover, 17 out of these 19 died due to causes unrelated to OI surgery, and 2 died of infectious complications originating at the stoma site. One of these two deaths occurred between 2 and 5 years following the OI surgery and the other over 5 years after the surgery. Notably, among the seventeen patients in this cohort, three died of suicide, highlighting the need for mental health evaluation and support in persons with amputation. Although not included in the data extraction, there was a case report of a patient who died during the EEP surgical implantation due to a pulmonary embolism, which could have been related to a pre-existing risk of deep vein thrombosis and wheelchair immobilization. This case report recommended that additional preventive measures such as preoperative scoring systems and, in exceptional cases, using an inferior vena cava filter should be considered in patients with a high risk of developing venous thromboembolism.

Patient experiences (qualitative literature)

Two research studies reported on the lived experiences of patients who received screw-type implants. Specific patient quotes from the qualitative studies to elucidate changes and challenges in the lives of the patients due to bone-anchored prostheses are included in Table 6. One study included three persons with upper-limb amputation (two transhumeral and one transradial) and ten persons with transfemoral amputations who used a bone-anchored prosthesis (76). The users described living with a bone-anchored prosthesis as a revolutionary change beyond functional improvements. Some users also described embodying the prosthetic leg as a part of them. The seven transfemoral BAP users in the other study (77) described the feeling of being *whole* again and described improvements in aspects of social participation, which greatly improved their quality of life. Both studies mentioned some challenges of being a bone-anchored prosthesis user, specifically due to the fear of infections, falling, and breaking the implant.

Cost-effectiveness (health economic literature)

Five studies addressing the health economic impacts associated with bone-anchored implants for transfemoral prosthetic fixation were included. Table 7 outlines the study characteristics, main findings, and limitations. Two were cost-comparison studies (78, 82) and three were cost-utility studies (79, 81, 83). Two studies were based on the screw -type implant (78, 79), one on the OPL (81), and both did not specify the type of implant (82, 83). Another health economic evaluation was found but excluded as it combined the data for transfemoral and transtibial levels of BAP and separate data for transfemoral users was not available (84). To explore the cost-effectiveness of transfemoral BAP, it is essential that this information be analyzed separately.

Handford et al. (81) reported the cost of bilateral transfemoral OI to be £123,008 and unilateral to be £81,008. Haggstrom et al. (78) reported fewer visits to the prosthetist by those who use BAP vs. socket-suspended prostheses. Despite this, they reported that the costs of prosthetic materials and components were higher for BAP, which made the annual mean costs for bone-anchored and socket prostheses similar. The results of the three cost-utility studies vary greatly due to their methodological approaches. Hansson et al. (79) reported an ICER of €83,374 (in 2009 Euros) per QALY gained by bone-anchored prosthesis users over socket users. Frossard et al. (83) reported an AUD 16,632/QALY gained, and Handford et al. (81) reported £40,040.92/QALY 6 years after the OI surgery due to a steady increase in the patient-reported health utility value (HUV) in the 6 years postsurgery. The cost data in Frossard et al. (83) was based on a 6-year horizon for the press-fit implant, but the utility estimates were based on 2-year follow-up data with screw-type implant (44, 45) and multiplied over the 6 years to obtain differences in QALYs. Handford et al. (81) also presented the results of a subgroup analysis of patients grouped based on preoperative EQ-5D HUV being less or more than 0.60. The mean preoperative HUV of the group that had an HUV of <0.60 was 0.41, which reached 0.77 by 5 years and yielded a cost/QALY of £25,334.87. This, they reported, met the cost-effectiveness threshold of £30,000/QALY advised by NICE (85). The cost continued to fall in this group to neutrality with the comparator at 10.5 years. They concluded that those who perform poorly with socket prosthesis (typically those with an HUV of <0.60) are likely those who face significant challenges in walking or do not walk at all. Osseointegration offers the greatest benefit to these individuals as they continually show improvements in HUV and cost-effectiveness within 5 years. Conversely, in those with a preoperative HUV of >0.60, the gain in HUV and cost-effectiveness is less compelling.

Neither of the two cost-utility studies based on modeling (79, 83) included discounting of costs or outcomes. There is a notable range of prescribed rates for discounting costs and outcomes based on countries or regions (86–88), but these studies

TABLE 6 Patient perspectives from qualitative research studies.

Study	Implant type	Patient quotes
Lundberg et al. (76)	OPRA	*Changes in life due to bone-anchored prostheses:* "I can feel that it's (bone-anchored prosthesis) not as good as a healthy leg, but it's far more normal than the old one (socket prosthesis). This is perhaps 70% as compared to a real leg and a real leg being 100% and an old prosthesis is perhaps 25%." "The prosthesis (bone-anchored prosthesis) is a part of me since it works so well, and you don't have to think that it's a problem and that it should be hard and so forth … it's more like a substitute, my "pretend leg"" "There is something missing, one part of me is missing and I miss it physically in a way I haven't done before, not after the accident either. And this happened after I got the prosthesis (bone-anchored prosthesis) that is more me than ever, that makes me feel more whole as a person." "I don't think about having the prosthesis in that it doesn't feel like a prosthesis. With this kind of technology you can't feel it. I sit just as much on this leg as on the other leg and the scary thing was this week when I didn't have my leg on, and when I suddenly stood up I felt I had on the prosthesis. It has come so far that the brain has also gradually begun to believe that I have a real leg" "…there is a fixture properly anchored, femur is reinforced with marrow and bone from the pelvis, it's anchored with material from my own body, with the only purpose to give me the possibility to walk. It's very concrete. As opposed to a traditional prosthesis that is slipped on to the outside of the body. But here I can feel when I put the foot down, so that I can feel the shock throughout the body, not in an unpleasant way but I feel it and it gives me a positive experience of my body as a whole." "One part of the body is trapped in this vacuum-packed socket, that's the way it's. To be let out of this entrapment, just to feel the sun towards the thigh or the air that surrounds the thigh instead of this heat and the sweating that is coming. It was like … it was my definition of freedom, that and to not have to think about the suspension" "The other prosthesis ruled my life, it was my master in a way, it's inevitable … it affected my mood and my interest in doing things that I knew would demand an extra effort. You had to weigh the pros and cons and that's all gone now. Now it's actually me … I am in command and not the left leg (S-prosthesis) and that's a big difference." *Challenges with bone-anchored prostheses:* "The disadvantage (with the OI-prosthesis) is that if you got stuck with the foot for instance which has happened a number of times, the leg is twitching (the fail-safe attachment device) and then you can't turn it right unless you get to the prosthetic workshop and then you feel much more handicapped instead.'"
Hansen et al. (77)	OPRA	*Changes in life due to bone-anchored prostheses:* "I got sores from using the socket prosthesis, and I had major problems securing it because my limb is so short. Sometimes when I was working the prosthesis would just fall off. This one is easy to attach, and it does not fall off. Also, you don't get any sores. Before the prosthesis was a barrier (socket-suspended prosthesis), now it's a great help (osseointegrated prosthesis)" "The socket prosthesis cut me in the groin. It was very unpleasant, and I couldn't do much. I couldn't vacuum clean or mop the floors, it was impossible, I just couldn't handle it. Today I can do all these things, and I don't need help anymore." "I used to do a lot of weight-lifting in the gym, and sometimes during the training my socket prosthesis would just fall off, and I just couldn't live with that, because then I had to start all over again! When I have a prosthesis it has to work, and this new one does!" "And if we go for a walk, I'm able to hold my wife's hand. I haven't been able to do that for eight to ten years. Some people might think that isn't a big deal, but to me it means a lot." "This osseointegrated prosthesis has given me far more freedom and quality of life. I do not get chafes anymore, and I am not in pain. This means that I am able to do stuff with my kids again, and I am happier than before. Also, when I am together with my family and friends I am able to go for a walk after dinner instead of just staying at home reading a magasin." "Well, I can't deny the fact that I'm disabled. That's obvious because I'm missing a leg. But with all the opportunities I've been given with this osseointegrated prosthesis, well, it almost makes up for my disability." *Challenges with bone-anchored prostheses:* "I am an experienced dive instructor, but I am not able to go to the public pool, because there is an increased risk of infection if I jump into the water. That is a major disadvantage for me." "I don't go outside during winter as much as before after I got this prosthesis. If I fall my socket prosthesis would just fall off, but if I fall with this osseointegrated prosthesis there is a risk of breaking the implant. Therefore during winter I stay inside more, which of course is annoying."

did not address discounting. As the failure of bone-anchored implants has been reported to be rare, the implants are estimated to maintain their effectiveness throughout the lifetime of an individual. Contrary to this, the majority of costs occur in the first year postsurgery. Due to this, the absence of discounting could potentially artificially inflate the reported ICER. Hansson et al. (79) presented alternative scenarios based on anticipated declines in utility in users of socket-suspension systems, as worsening of symptoms is expected and could cause a continuing decline in HRQoL in these users. This resulted in the cost per QALY gained of €37,020, €24,662, and €18,952, for a 1%, 2%, and 3% decline, respectively, over 20 years. Lastly, none of these studies take a societal perspective on costs and outcomes, which can be complex to acquire but provide a more holistic picture of the economic impact of bone-anchored prosthesis use.

Discussion

Overall, bone-anchored implants that enable the direct attachment of prosthetic devices for individuals with transfemoral amputation who have failed conventional socket-suspension systems show promising results. The similarities in the patient selection criteria and the improved outcomes across the included studies add to the credibility of the findings on clinical efficacy. The evidence on clinical efficacy available on different implant types and on shorter (1- or 2-year) and longer (5-, 10-, and 15-year) follow-ups indicates that those who have been fitted with these implants consistently report improvements in quality of life, mobility, satisfaction with the prosthesis, and an overall improvement in situation as a person with an amputation. At 15-year postsurgery follow-up, approximately

TABLE 7 Health economic studies on bone-anchored implants for transfemoral prosthesis fixation.

Study (country)	Implant type	Aims	Funding	Patient population	Study design	Costs	Outcomes measured	Findings	Limitations and comments
Screw-type fixation									
Haggstrom et al. (78) (Sweden)	OPRA	To investigate the differences in prosthetic costs and service of osseointegrated prostheses compared to socket-suspended prostheses	Government and non-profit grants	50 patients with unilateral transfemoral amputation (36 socket-suspended prostheses, 20 osseointegrated prostheses, 6 patients used both kinds of prostheses)	Retrospective cost-analysis and survey on the number of visits	Retrospective costs over a 10-year period from one prosthetic workshop *Costs included*: New prostheses, services, adjustments, and repairs	Number of visits over a 10-year period from one prosthetic workshop	• 3.1 visits/year vs. 7.2 visits/year (cost-analysis), 3.4 visits/year vs. 9.2 visits/year (survey) • Mean total annual cost of new prostheses, services, repairs and adjustments was 14% lower for OI prostheses than socket prostheses (€3,149 and €3,672. respectively, n.s.) • Cost of material accounts for 92.5% for OI prostheses and 70% for socket prostheses	*Limitations*: • Did not include the costs of the bone-anchored implant, surgeries, hospital stay, postsurgical follow-up, rehabilitation, and the possible costs of dealing with complications
Hansson et al. (79) (Sweden)	OPRA	To compare the cost-effectiveness of treatment with a bone-anchored prosthesis and a socket-suspended prosthesis for patients with a transfemoral amputation	Government and non-profit grants	39 transfemoral prosthesis users followed for 2 years (80), no control group	Cost-utility analysis Perspective: Swedish healthcare system Time Horizon: 20 years Markov model based on clinical input from a 2-year follow-up study (80)	Costs acquired from hospital data, literature, and expert opinion *Costs included*: Socket: Acquired from (78), i.e., new prostheses, services, adjustments, and repairs Bone-anchored: Acquired from hospital data. OPRA implant, surgery, postsurgical care, medications, laboratory tests, and imaging	Health utility based on SF-6D were taken from a previous study by the same group (80)	• ICER (in 2009 euros): for bone-anchored prostheses was €83,374 per QALY gained compared with socket prostheses • Sensitivity analysis: the probability of bone-anchored prosthetic implants being cost-effective was reported to be 0.40 for a willingness-to-pay value of €48,000	*Limitations*: • Small sample size and they were only followed for 2 years, requiring extrapolation of the effects over time
Press-fit fixation									
Handford et al. (81) (UK)	OPL	To compare the cost of bone-anchored prostheses to the annual cost of a poorly-fitting socket	NR	80 transfemoral prosthesis users	Cost-utility based on retrospective analysis of costs and prospectively collected PROMs for health utility	Based on the UK Ministry of Defense fiscal costing. *Costs*: Bilateral Bone-anchored: £123,008 Unilateral Bone-anchored: £81,008 Socket: £9,624/year *Costs included*: Socket: Cost of multiple visits to the prosthetist, new molds, and	Health Utility based on SF-36 scores converted to EQ-5D Health Utility Value	• Mean preoperative EQ-5D HUV was 0.64 which rose to 0.73 at 5 years and 0.78 at 6 years resulting in a cost/QALY of £96,129.71 and £40,040.92, respectively	*Limitations*: • To mitigate the impact of considerable variability in follow-up time points and the number of times each individual was followed up, the mean of all individuals EQ-5D-HUV was used for analysis. This could explain the failure to reach statistical significance in the pooled data, necessitating a subgroup analysis • Assumed that the ongoing high- cost of external

(*Continued*)

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TABLE 7 Continued

Study (country)	Implant type	Aims	Funding	Patient population	Study design	Costs	Outcomes measured	Findings	Limitations and comments
						prostheses Bone-anchored: Preoperative assessment, initial surgery, implant cost, hospital length of stay, two 4-week inpatient stays at a rehabilitation facility, seven follow-up appointments at a hospital, prosthetic follow-up, DEXA Scan, radiographs, and blood tests			components would be similar in socket and BAP users
Frossard et al. (82) (Australia)	Unspecified	Cost-comparison between socket and bone-anchored prostheses	NR	NR	Cost-comparison between socket and bone-anchored prostheses with three different types of knees	Historical costs based on administrative data from the Queensland Artificial Limb Service for provision of socket prostheses and simulated costs for bone-anchored prostheses over a 6-year cycle *Costs included*: Socket: liner, socket, knee unit, and foot unit Bone-anchored: Connector, knee unit, and foot unit	None	Bone-anchored prostheses were reported to be cost-saving by at least AUD 1,600 even with the most expensive knee, the microprocessor-controlled knee	*Limitations*: • Only ongoing costs associated with prostheses were considered and compared • Did not include the costs of the bone-anchored implant, surgeries, hospital stay, postsurgical follow-up, rehabilitation, and the possible costs of dealing with complications
Frossard et al. (83) (Australia)	Unspecified	To report the incremental costs, heath gain, and cost-effectiveness of BAP compared to socket-suspended prostheses	None	16 transfemoral prosthesis users	Cost-utility analysis Perspective: Queensland, Australia Time Horizon: 6 years	Costs based on administrative data from the Queensland Artificial Limb Service	Utility estimates from 2-year follow-up data from literature (44, 45) and multiplied over 6 years to obtain differences in QALYs	• ICER in 2016 AUD: AUD 16,632 per QALY gained • Bone-anchored prostheses were cost saving for 19% of patients and cost effective for 88% of patients	*Limitations*: • The analysis was based on a small convenient sample size and narrow case-mix • The cost data was based on a 6-year horizon for press-fit implants but the utility estimates were based on 2-year follow-up data with screw-type implants • Missing actual yearly costs were replaced with estimated costs based on their previous work (82) • Did not include the costs of the bone-anchored implant, surgeries, hospital stay, postsurgical follow-up, rehabilitation, and the possible costs of dealing with complications • No sensitivity analysis but presented ICERs based on scenarios varying the utility values

NR, Not reported.

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64% of patients mentioned that osseointegration improved their overall situation as a person with amputation (49). It is noteworthy that studies that presented interim 2-year and 5-year follow-up data (46, 47) revealed no significant differences in HRQoL (measured by SF-36 domains and Q-TFA subscales) between these two time points. Similarly, there were no significant differences in these measures between 5- and 10-year follow-ups (50). These findings suggest that most advantages of bone-anchored prostheses can be expected within the first 2 years and are maintained beyond that. It is interesting to note that the mobility improvements may contribute to the concomitant improvements in patient-reported health-related quality of life. Mobility has been previously reported to be strongly positively correlated with general satisfaction and HRQoL in individuals with lower-limb prostheses (89). Improvements in mobility are further supported by other studies on BAP users who reported a higher daily step count and daily stepping time when assessing mobility in daily activities, i.e., not in a controlled lab setting (90). In addition, even those with bilateral transfemoral BAP after on average 7 years reported improved mobility (91).

It should be noted that although an improvement in quality of life has been reported, this often does not translate into an improvement in the mental health of BAP users. Only one study (57) reported an improvement in the mental component score of the SF-36, and none employed an instrument specifically designed to address changes in mental health. Mental health is a known challenge within the amputation and prosthesis-user communities (92–94). Depression has been reported to affect as many as one-third of persons with lower-limb amputation (92). More research is required to explore the mental health changes that accompany BAP use, as adequate evaluation and treatment of mental health concerns in this population may improve HRQoL.

Soft tissue infection is the most common complication consistently reported across studies, which is typically managed conservatively. The incidence of hypergranulation and the need for refashioning of the stoma or for soft tissue redundancy suggest that continuous efforts are required to improve and track soft tissue management. Of utmost concern is to continually track serious complications requiring implant removal. Survival rates of implants in the literature ranged from 78% to 99% for studies using press-fit implants (28, 52, 62, 70) and 72% to 92% for studies using screw-fit implants (45–47, 49). There seems to be an equal probability of implant loss for screw-type implants in the first 5 years and the subsequent 5 years in the one study that examined implant loss (50), so a longer-term tracking of these complications is crucial. Mechanical complications are common across implant types but were often reported to be managed by replacing external parts as needed. The incidences of mechanical complications increase between 5 and 10 years after implantation (50), and the cost of replacing external parts may lead to an increase in prosthetic care expenses over time. It has also been reported that at 5- and 10-year follow-ups, mechanical complications tend to be significantly correlated with prosthetic mobility or the occurrence of deep infections. Improved mobility that BAP offers to prosthesis users may therefore inadvertently contribute to mechanical complications (49). The statistics on mechanical complications of external parts need to be considered in the context of the expected longevity of any mechanical prosthesis component, which also needs periodic replacement in active socket prosthesis users.

Patient-reported experiences in the literature are based on screw-type implants and generally positive. In the future, additional qualitative studies on individuals who receive press-fit implants may be beneficial to enable the comparisons of patient perspectives and experiences. In addition, it would be beneficial to explore the changes and challenges that a patient experiences preoperatively and after receiving a BAP. The use of longitudinal qualitative research methods (95, 96) may be well positioned to understand the issues that socket prosthesis users experience and to articulate the changes that they experience when they transition to bone-anchored prosthesis.

The two cost-comparison studies (78, 82) have limited applicability for decision-making on increasing the availability of BAP. Cost-analysis or cost-comparison studies are considered appropriate when the outcomes of the intervention and the comparator are identical (97). It is evident from the information presented here that the outcomes of the socket-suspension and bone-anchored prostheses are not identical. The reports based on pre-/post-study designs illustrate that quality of life or mobility often changes when a previous socket-suspension system user becomes a bone-anchored prosthesis user. However, these two studies present useful information on some of the costs that are considered in the health economic evaluation of this technology.

Economic models/frameworks for evaluating costs and health outcomes differed across studies. The two cost-comparison studies (78, 82) and one of the cost-utility studies (83) did not include the costs of the bone-anchored implant, surgeries, hospital stay, postsurgical follow-up, and rehabilitation or the possible costs of dealing with complications. The results of these studies have limited usefulness and generalizability because of the narrow frame of costs (only prosthetic care costs) included for analysis. Without accounting for the upfront costs associated with bone-anchored implants (such as costs of the surgery, hospital stay, and postsurgical follow-up) and appropriate ongoing costs (such as those related to prosthetic care or dealing with complications), the results from these studies should be interpreted with caution. Not accounting for these costs likely led to an underestimation of the ICER. Hansson et al. (79) included these costs associated with bone-anchored implants, but they did not include the costs of many common complications, and their Markov model did not include many tunnel states in which patients often find themselves during their journey toward becoming BAP users. Handford et al. (81) included a broad list of costs in their analysis. The outcomes measured varied from the number of visits to a prosthetist (78) to utility values based on SF-6D (79) and EQ-5D (81).

Overall, the results from these health economic studies are mixed and complex to interpret. This necessitates future studies in this field to have health economics as a forethought and

ideally be based on prospective real-world administrative data over a reasonable time horizon (at least 5 years). This may become increasingly feasible in the future with the growing adoption of electronic medical records. To acquire a more realistic picture of the cost-effectiveness of bone-anchored implants, the costs considered for analysis should include the cost of the implant, surgery, postsurgical care, rehabilitation, regular follow-up, and management of complications and should be compared against the costs borne by the system to service the needs of the socket-suspension system users, including their need for prosthetic services, medical follow-up, complication management, and surgical revisions. The HRQoL outcomes should be collected prospectively and should be generic to allow the calculation of utility values. The comparison of costs and outcomes should ideally be made with the patients' pre-intervention state of socket prosthesis use, but in the absence of the availability of this information, to a control group matched on several parameters including similar functional mobility restrictions and similar types of prosthetic components. If modeling is deemed a more suitable tool to assist in decision-making, then it should account for many states to more accurately reflect the typical patient trajectory.

Nonetheless, overall, it appears that bone-anchored prostheses involve a higher upfront cost to the healthcare system but yield a longer-term gain, as evident by the improvements in health-related outcomes and reduced problems due to socket systems. Other groups, such as Ontario Health in Canada, concluded in their health technology assessment that bone-anchored implants are a cost-effective intervention (98). However, it is possible that this intervention is mostly cost-effective for those who stand to gain the most out of it, i.e., those who face significant challenges due to socket-suspension systems, and not suitable as primary treatment for prosthetic fixation.

The technology has evolved since the early 1990s with consistent revisions in design and improvements in outcomes for patients. Screw-type implants have longer follow-ups and have been around for a longer time, and the press-fit implants have higher reported case numbers and more comprehensive tracking of outcomes and complications. The press-fit implants have demonstrated a reduced risk of complications with concomitant improvements in quality of life and mobility. The latest iterations of both types of implants can also be used with individuals with a long or short length of the residual femur (28). The surgery can be done as a one-stage procedure that may reduce the burden on the patient and the healthcare system. A recent review presents evidence in favor of the one-stage approach owing to the lower incidence of postsurgical complications with this approach (99). Some work has been done to develop a comprehensive and systematic framework for tracking complications (69, 100) and a systematic outcomes-tracking framework (101, 102); however, not all centers follow the same guidelines for reporting. Future studies in this field can also further improve the quality of evidence by reporting on potential confounders (such as external prosthetic components, pre-existing pain, residual limb length, or bone mineral density) and addressing them by conducting and reporting subgroup analyses or other appropriate statistical tools, if statistical power allows.

As the number of cases increases across centers worldwide, there is also an opportunity to further explore changes in the mental health of prosthesis users and the factors/experiences contributing to changes in the perceptions of patients about their health-related quality of life. Well-designed mixed methods studies (103, 104) could address this need and contextualize the perceived changes in quality of life with patients' experiences and challenges in their everyday lives. Future research on the lived experiences of patients and their caregivers and the impact of bone-anchored prostheses on productivity and vocational/employment situations will lead to a richer and more wholesome understanding of the change in the lives of patients that bone-anchored prostheses appear to promise.

The studies included in this review present considerable variability in follow-up duration, the type of variables on which data are collected, and the reported outcomes. The resultant inability to do a meta-analysis/synthesis may be perceived as a challenge for policymakers when deciding on the value of providing this technology; however, there is evidence that BAP seems to be a worthwhile alternative for those who are experiencing recurring issues with their socket prosthesis and can have a long-lasting impact on the individual's quality of life, function, and participation in society. As the body of evidence on clinical efficacy and complications evolves in this area, it would be prudent to adopt a standard suite of outcome measures and complication tracking at regular time points and for a longer term and to establish data reporting standards by consensus within the various centers around the globe offering this intervention. This will enable comparisons of outcomes across centers worldwide and across implant types. With such data in the future, a meta-analysis may also become feasible. When policymakers and regulatory bodies approve or implement this technology as a funded alternative intervention to socket prostheses for individuals experiencing recurring issues with their socket prostheses, it is essential that well-designed and planned cost-utility studies be conducted.

Limitations

There were a few limitations of this review, primarily due to the types of study designs and reporting of information in the included studies. Despite similar measures being reported in studies with a pre-/post-design, a meta-analysis was not feasible due to the varying lengths of follow-up and the variability in how results were reported in the literature. Some articles only reported the statistical significance of the difference between the pre- and post-intervention but not actual values (47, 49, 56, 60), whereas others reported median scores and not mean scores (52, 55, 57). One of the issues that may impact the reported health-related quality of life was the persistence of phantom limb pain. This issue could not be fully explored in this review as this phenomenon is inconsistently reported in the included literature. Other potential confounders, such as residual limb length and

type of prosthetic components, are insufficiently reported to allow accurate analysis of their potential impact on outcomes. It should be noted that this review excluded papers on gait parameters as this was recently reviewed (105) and the relationship between gait parameters and clinical outcomes needs to be further examined. Lastly, two of the included studies were reported to have been conducted as a clinical trial (48, 62), and one of these is under regulatory oversight by the FDA (62). These studies may be subject to different obligations to report outcomes and adverse events; however, we assessed their quality and risks of bias using appropriate tools.

Conclusion

Overall, based on the information available presently, the clinical efficacy of bone-anchored prostheses is well established as hundreds of cases have been performed worldwide with beneficial outcomes for patients and complications being managed effectively. Patients also report positive changes in their lived experience. The evidence points to the cost-effectiveness of this technology for those who suffer poor outcomes with standard-of-care socket prostheses, although further work is needed to collect sufficient data for rigorous health economic analysis. Standardizing outcome tracking would help with synthesizing evidence across centers. This paper presents a single resource on data collected in this population that can be used for decision-making on the implementation of BAP for transfemoral amputation.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material; further inquiries can be directed to the corresponding authors.

Author contributions

MR: conceptualization, funding acquisition, investigation, methodology, project administration, validation, visualization, writing – original draft, writing – review and editing. TS: investigation, methodology, supervision, validation, writing – review and editing. JR: validation, writing – review and editing. AJ: validation, writing – review and editing. JH: conceptualization, funding acquisition, methodology, supervision, validation, writing – review and editing.

Funding

The authors declare financial support was received for the research, authorship, and/or publication of this article.

MR is supported by grants from the University Hospital Foundation (RES0046327) and the Glenrose Rehabilitation Hospital Foundation (RES0049057), both of which are based in Edmonton, AB, Canada.

Acknowledgments

The authors are grateful to Becky Skidmore (information specialist consultant, Ottawa Hospital Research Institute) for carrying out the literature search for this systematic review.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fresc.2024.1336042/full#supplementary-material

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 04 April 2024
DOI 10.3389/fresc.2024.1354144

OPEN ACCESS

EDITED BY
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RECEIVED 12 December 2023
ACCEPTED 05 March 2024
PUBLISHED 04 April 2024

CITATION
Klute GK and Mulcahy CW (2024) Sagittal and transverse ankle angle coupling can influence prosthetic socket transverse plane moments. Front. Rehabil. Sci. 5:1354144. doi: 10.3389/fresc.2024.1354144

Sagittal and transverse ankle angle coupling can influence prosthetic socket transverse plane moments

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Introduction: The intact foot and ankle comprise a complex set of joints that allow rotation in multiple planes of motion. Some of these motions are coupled, meaning rotation in one plane induces motion in another. One such coupling is between the sagittal and transverse planes. For every step, plantar- and dorsi-flexion motion is coupled with external and internal rotation of the shank relative to the foot, respectively. There is no prosthetic foot available for prescription that mimics this natural coupling. The purpose of this study was to determine if a sagittal:transverse ankle angle coupling ratio exists that minimizes the peak transverse plane moment during prosthetic limb stance.
Methods: A novel, torsionally active prosthesis (TAP) was used to couple sagittal and transverse plane motions using a 60-watt motor. An embedded controller generated transverse plane rotation trajectories proportional to sagittal plane ankle angles corresponding to sagittal:transverse coupling ratios of 1:0 (rigid coupling analogous to the standard-of-care), 6:1, 4:1, 3:1, and 2:1. Individuals with unilateral transtibial amputation were block randomized to walk in a straight line and in both directions around a 2 m circle at their self-selected speed with the TAP set at randomized coupling ratios. The primary outcome was the peak transverse plane moment, normalized to body mass, during prosthetic limb stance. Secondary outcomes included gait biomechanic metrics and a measure of satisfaction.
Results: Eleven individuals with unilateral transtibial amputations participated in the study. The 6:1 coupling ratio resulted in reduced peak transverse plane moments in pairwise comparisons with 3:1 and 2:1 coupling ratios while walking in a straight line and with the prosthesis on the outside of the circle ($p < .05$). Coupling ratio had no effect on gait biomechanic metrics or satisfaction.
Discussion: The general pattern of results suggests a quadratic relationship between the peak transverse plane moment and coupling ratio with a minimum at the 6:1 coupling ratio. The coupling ratio did not appear to adversely affect propulsion or body support. Subjects indicated they found all coupling ratios to be comfortable. While a mechatronic prosthesis like the TAP may have limited commercial potential, our future work includes testing a robust, passive prosthetic foot with a fixed coupling ratio.

KEYWORDS

prosthesis, lower limb, amputation, residual limb, torsion adapter, transverse plane rotation adapter

1 Introduction

Ambulatory individuals with a lower limb amputation are prone to pain and injury caused by loads applied to the residual limb through the prosthetic socket (1–5). Epidermoid cysts, for example, are painful lesions of the residual limb caused by shear stress where the skin of the residual limb rubs against the brim of the socket (6). The high stress at the prosthesis-residual limb interface may also cause decreases in venous return and reduce lymphatic drainage, which can be detrimental to amputees with compromised vascular systems (2, 6, 7). Transverse plane moments applied by the prosthetic socket to the residual limb, can peak during turning maneuvers and exacerbate the problem (8, 9). If turning maneuvers were uncommon, little emphasis on this problem would be warranted. However, turning maneuvers comprise a sizeable fraction of the steps taken during typical daily activities (10–12). Amputees also experience back pain at a higher rate than the general population (13), resulting in part from an asymmetric gait (14). Undesirable transverse plane moments may be a factor in asymmetrical, compensatory gait.

The need to ameliorate transverse plane moments between the residual limb and socket was recognized as early as 1947 by Eberhart (15) who wrote that transverse plane motions and their frictional effects "are a major source of discomfort and the chief cause of dissolution of the skin." Three decades later, Lamoureux and Radcliffe (16) presented a prosthesis with an elastomeric spring allowing axial rotation in between the ankle and the socket and found that its use provided "dramatic relief of skin abrasions and epidermoid cysts in some cases". In addition to reducing the transverse plane moment, they also reported improved gait symmetry. Today, transverse plane rotation adapters as a standalone device are commercially-available and can increase transverse plane rotation and decrease transverse plane moments (8, 17). They can also reduce the energy consumption of unilateral amputees at walking speeds above normal (18). This transverse rotation function can also be found in other commercially available devices such as shock absorbing pylons and multiaxial feet.

These observations suggest that prescription of transverse plane rotation adapters may lead to greater mobility for lower limb amputees. However, their use is not widespread and if excessively compliant, may reduce gait stability (19). Cost, weight, prosthesis build height, and the inability for the user to adjust the stiffness may all play a role in their lack of adoption, but it may also be that the transverse plane rotation is not coupled with the sagittal plane. With these devices, motion only occurs in the transverse plane when a transverse plane torque is applied. In contrast, the intact foot and ankle contain a complex set of joints that allows rotation in all three planes, and some are coupled together (20, 21), meaning rotation in one plane induces motion in another. In particular, the axis of rotation of the talo-crural joint during ankle flexion is inclined downwards and laterally relative to horizontal, and the rotation ranges from 10 to 26 degrees among individuals (22). The rotation about this inclined axis couples plantar- and dorsi-flexion motion with external and internal rotation of the shank relative to the foot, respectively (23). This sagittal:transverse ankle angle coupling is not replicated in prosthetic feet and ankles.

Ambulatory individuals with a lower limb amputation take thousands of steps on their prosthesis each day (24, 25) and none feature coupled motion between the sagittal- and transverse planes. The absence of this natural coupling may be related to the high incidence of residual limb soft tissue injuries (6, 7), the need for compensatory gait (14), and overall dissatisfaction with their prostheses (26, 27).

The purpose of this study was to determine if a sagittal: transverse ankle angle coupling ratio exists that minimizes the peak transverse plane moment (socket torque), normalized to body mass, during prosthetic limb stance. A novel, torsionally active prosthesis (TAP) was used to couple sagittal and transverse plane motions using a 60-watt motor (28). An embedded controller generated transverse plane rotation trajectories proportional to sagittal plane ankle angles corresponding to sagittal:transverse coupling ratios of 1:0 (rigid coupling analogous to the standard-of-care), 6:1, 4:1, 3:1, and 2:1. Thus, for a 6:1 coupling ratio, if a subject generates a sagittal plane motion of six degrees with their prosthesis, the TAP will generate a transverse plane motion of one degree. Individuals with unilateral transtibial amputation walked in a straight line and in both directions around a circle with the TAP set at different coupling ratios (blinded and randomized). The primary outcome was the peak transverse plane moment, normalized to body mass, during prosthetic limb stance. Secondary outcomes included gait biomechanic metrics and a measure of satisfaction.

2 Materials and methods

To discover the influence of coupled motion on the gait biomechanics of individuals with lower limb amputation, we built a novel, Torsionally Active Prosthesis (TAP) whose transverse plane motion (driven by a motor) could be controlled in proportion to sagittal plane motion (driven by the wearer) using real-time feedback and an on-board microcontroller. This novel prosthesis was then fitted to participants who provided informed consent to an Institutional Review Board approved human subjects experiment.

2.1 Torsionally active prosthesis

The TAP is based on a series elastic actuator composed of a 60-watt brushed, direct current, battery powered motor (RE30, Maxon Precision Motors, San Mateo, CA) in series with a 100:1 harmonic drive transmission (CSF14-2XH-F, Harmonic Drive, Hauppauge, NY), and an aluminum motor housing that acts as both a torsion spring and a torque transducer [first-generation TAP is described in (28)]. The second-generation TAP (see Figure 1) replaced an obsolete microcontroller with a 32-bit, 180 MHz microcontroller (Teensy 3.6, PJRC, Sherwood, OR) and strain gages to provide a robust estimate of the sagittal plane ankle angle. Body weight load tests were performed on different

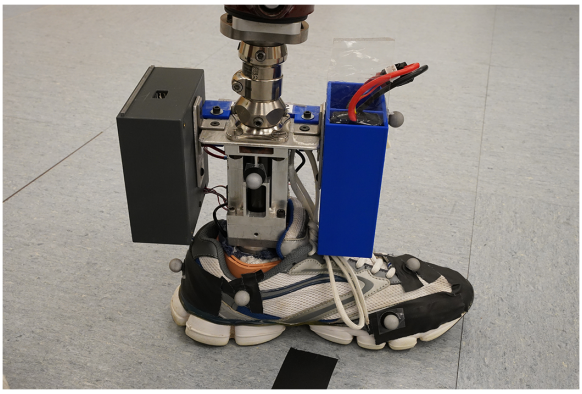

FIGURE 1
The second-generation TAP.

stiffness category prosthetic feet (Vari-Flex Low Profile, Össur, Reykjavik, Iceland) with strain gages mounted on the forefoot keel and heel keel. Individuals are prescribed feet with a specific stiffness category based on their body weight and activity level. Data from these non-human subject tests were used to obtain prosthetic foot category-dependent transfer functions to convert measured strain to an estimation of the sagittal plane ankle angle. The transverse plane angle was calculated using a magnetic encoder (Encoder MR, Type L, Maxon Precision Motors) that measured motor position. Using the experimentally derived transfer functions (one for each category stiffness prosthetic foot and motor position), the system software (see Figure 2) calculates the target transverse plane rotation trajectories corresponding to sagittal:transverse coupling ratios of 1:0 (rigid), 6:1, 4:1, 3:1, and 2:1 (the independent variable), which are then used in a proportional-integral-derivative (PID) controller tuned by a combination of Ziegler-Nichols (29) and manual tuning heuristics. The PID controller provides motor inputs used to achieve the desired coupling ratio during ambulation. The controller operated at a 1 kHz loop rate. A magnetic encoder (Encoder MR, Type L, Maxon Precision

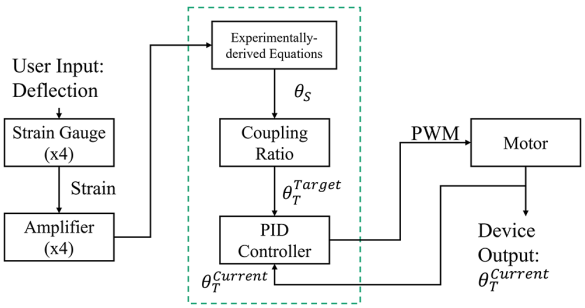

FIGURE 2
TAP system architecture. Proportional integral derivative (PID), pulse width modulation (PWM), sagittal plane angle (θ_S), target transverse plane angle (θ_T^{Target}), actual transverse plane angle ($\theta_T^{Current}$).

Motors, San Mateo, CA) with 1,024 counts per turn was used to calculate transverse plane rotation. Motor current was used to calculate transverse plane moments normalized to body mass. Data was logged on to a micro-SD card at a sampling rate of 100 Hz.

To power the TAP, an on-board 11.1-volt 3-cell lithium polymer battery (20C 4,000 mA, Venom, Rathdrum, ID) allowed 60–90 min of operation. At 2.9 kg, the ready-to-test configuration (including shoe) was not expected to influence oxygen consumption, heart rate, or gait efficiency (30–32). The TAP can meet the operational requirements (<29 Nm transverse plane torque) of straight and circle walking activities (8, 33) of a 75th percentile male adult (~100 kg) (34) who can accommodate a prosthesis with a minimum build height of 22 cm.

System operation tests using a boot cast arrangement boot cast arrangement enabling individuals without amputation to walk using the TAP over the range of coupling ratios. The most challenging condition is the 2:1 sagittal:transverse coupling ratio as it demands the largest transverse plane rotation. During early stance, the difference between the target and feedback driven response was very small and the performance profile closely followed the target (see Figure 3). During late stance, the difference between the target and feedback driven response remains relatively small and the performance profile follows the target but not as closely (see Figure 3). This late stance drop in performance is to be expected as the load on the motor is much greater. The error, the difference between the target (setpoint) and the feedback driven response, during a complete gait cycle was only 0.269° RMS. Another key metric of performance is the amount of current required during system operation. Large currents place much greater performance requirements on the electronic components and battery. Peak current was less than 30 amperes and averaged 7.5 amperes over the gait cycle. The range of transverse angles achieved varied by coupling ratio (see Figure 4 for a representative test subject result).

2.2 Human subject experiment

2.2.1 Participants

Eleven males with unilateral transtibial amputation (age: 53 ± 15 years, height: 1.76 ± 0.06 m, mass: 92 ± 11 kg, etiology: 8 trauma, 2 diabetic, 1 infection; see Table 1 for as-prescribed prosthetic prescription) participated. All were free of contractures, had been fitted with a prosthesis and had used a prosthesis for at least six months, wore their prosthesis at least 4 h per day, and were moderately active by self-report suggesting all were capable of community ambulation. Each provided informed consent approved by the governing Institutional Review Board.

2.2.2 Study prosthesis

Each subject was fit with the TAP in series with a size and stiffness category appropriate Vari-Flex Low Profile prosthetic foot and foot cover by a certified prosthetist. The prosthetic pylon height was adjusted such that the build height of the study prosthesis was equivalent to the subject's as-prescribed prosthesis.

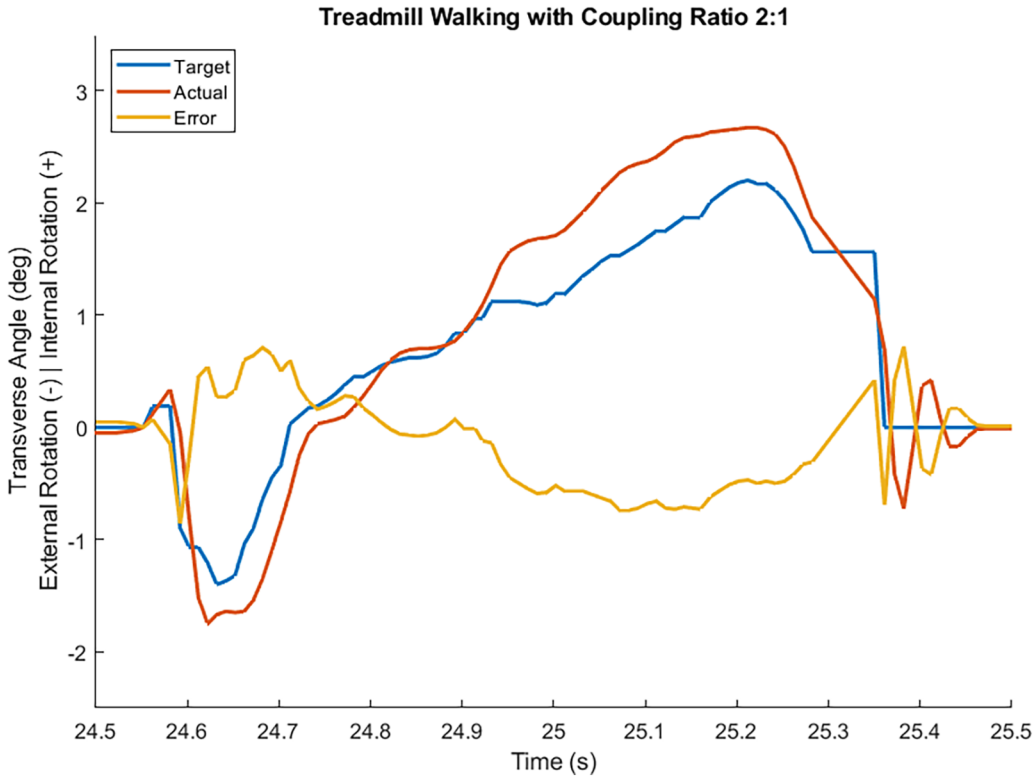

FIGURE 3
Transverse plane angle target, feedback driven actual response, and error while an individual without an amputation walked at self-selected speed wearing a boot cast arrangement in a straight line with coupling ratio 2:1. Heel contact occurred at 24.55 s and toe off occurred at 25.36 s.

2.2.3 Instrumentation

Data for biomechanic outcomes were measured with embedded force plates and a motion capture system. Eight force plates (BP400600, AMTI, Watertown, MA) mounted flush to the floor measured ground reaction forces (GRF) at 2,000 Hz and were filtered with a bidirectional Butterworth filter with a 25 Hz cutoff. All subjects were provided with tight fitting spandex shorts and shirts to wear during data collection. The same researcher placed 14 mm reflective tracking markers on each subject using Vicon's standard Plug-in-Gait marker set, with additional markers placed bilaterally on the medial elbow, medial knee epicondyle, medial malleolus, tibial tuberosity, fibular head, and first and fifth metatarsal heads. Clusters of four markers were also placed bilaterally on the upper arms and thighs. The markers on the prosthetic limb mirrored the intact limb. TAP-specific markers were added to the anterior and posterior faces of the device as well as the medial and lateral base of the motor housing. A 16-camera motion capture system (Vantage V8, Vicon Motion Systems, Oxford, UK) recorded marker trajectories at 100 Hz which were filtered with a bidirectional Butterworth filter with a 6 Hz cutoff.

Satisfaction for each condition was captured with a single score on a 0–10 scale. Zero represented the most uncomfortable socket fit the subject could imagine, and ten represented the most comfortable socket fit.

2.2.4 Protocol

Self-selected walking speeds (SSWS) were calculated from the mean of three trials while the subjects wore their as-prescribed prosthesis to walk at their own pace 20 m in a straight (ST) line and while walking around a 2 m diameter circle marked with a dashed line on the floor with their prosthesis on the inside (PI) and outside (PO) of the circle. Subject height, body mass, and demographics were also recorded. The TAP was then fit and aligned by a licensed and certified prosthetist using standard clinical procedures. The pylon length was adjusted to accommodate the build height of the TAP as needed. Each subject wore their as-prescribed socket and suspension system except for one whose foot was mounted posteriorly directly to the socket. For this subject, a duplicate socket was made with a conventional pyramid adapter with which to mount the TAP. Although there is no consensus on how much accommodation time is necessary for acclimation to a new prosthetic foot (35), we allowed each subject at least 15 min to walk straight and around the 2 m circle with the TAP to learn how each coupling ratio performed and felt.

Subjects were block randomized to the order in which they walked ST, PI, and PO. Sagittal:transverse coupling ratios of 1:0, 6:1, 4:1, 3:1, and 2:1 were also block randomized and blinded to the subject. At least ten trials each of ST, PI, and PO were performed with a minimum of two trials at each coupling ratio.

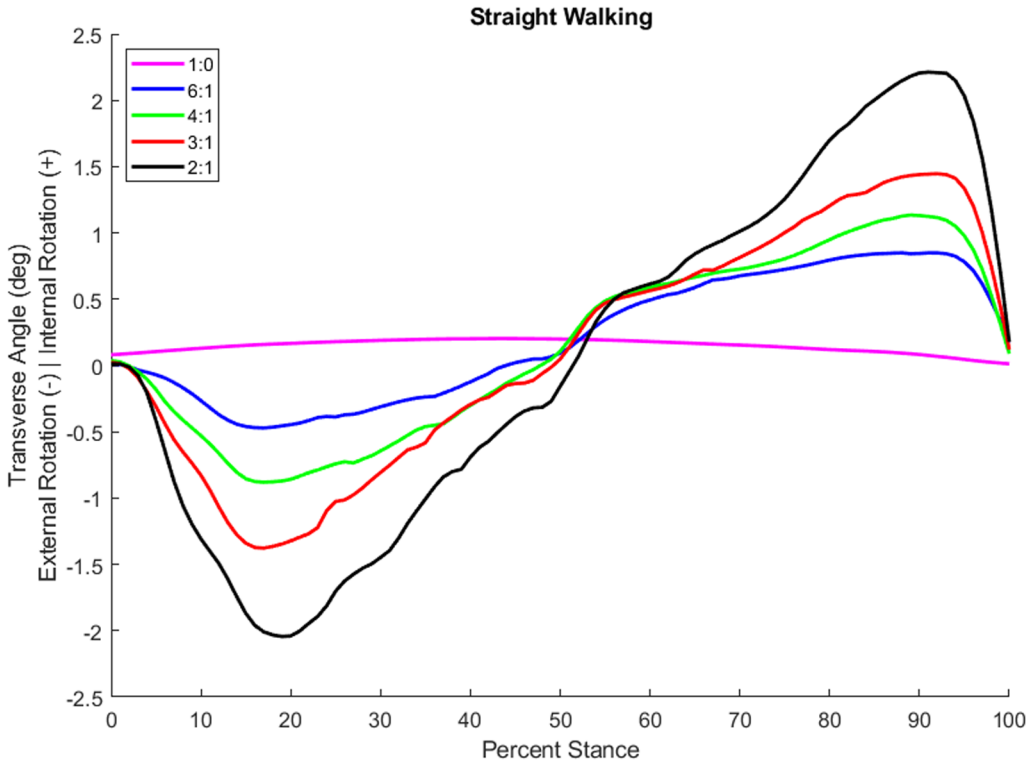

FIGURE 4
Transverse plane rotation angle during stance of an individual with a transtibial amputation while walking at self-selected speed in a straight line with different coupling ratios.

TABLE 1 Sample demographics and as-prescribed prosthetic prescription. patellar-tendon-bearing (PTB), total surface bearing (TSB).

Subject	Age (years)	Height (m)	Mass (kg)	Etiology	Prescribed Foot	Liner	Socket
1	58	1.68	84	Trauma	College Park Tru Step	ALPS 26	Hybrid PTB
2	55	1.75	89	Infection	Össur Proflex XC Torsion	Willowood Alpha Silicone	TSB
3	70	1.86	83	Trauma	Fillauer All Pro	Willowood Alpha Classic	Hybrid PTB
4	57	1.78	86	Trauma	Cheetah Explorer	Össur Iceross Comfort	TSB
5	72	1.75	86	Diabetes	Echelon VT	Willowood Alpha Classic	TSB
6	31	1.84	100	Trauma	College Park Tactical	Össur Iceross	TSB Boa System
7	29	1.65	83	Trauma	Össur XC Torsion	Össur Iceross	Modified PTB
8	60	1.79	112	Trauma	Össur Pivot	Willowood Alpha Classic	TSB
9	70	1.79	83	Diabetes	College Park Tru Step	Willowood Alpha Classic	PTB
10	42	1.81	111	Trauma	IBEX Filauer	Össur Iceross Comfort	PTB
11	40	1.71	97	Trauma	Össur LP Proflex	Össur Iceross	TSB with adjustable posterior panel

Acceptable trials were within ± 10 percent of their self-selected walking speed and had at least one single limb foot-ground contact wholly on a force plate for each limb. However, while wearing the TAP, some subjects ($n = 5$) consistently had difficulty walking at their SSWS previously measured while wearing their as-prescribed prosthesis. For these subjects, their SSWS was recalculated while wearing the TAP and walking at their own pace for 6 m in a ST line and while walking around a 2 m diameter circle as previously described. After each set of trials at a specific coupling ratio, the subject was asked to rate their satisfaction. Rest breaks were provided as needed. If all planned trials could not be completed within 4 h, the subject returned for a second visit after at least one overnight rest period.

2.3 Analysis

The marker trajectories and GRFs were processed in Visual 3D (C-Motion, Boyds, MD) to calculate gait kinematics, kinetics, and gait event timings. Knee and hip joint angles and powers were calculated using a 15-segment whole body model (head, torso, Visual 3D Composite pelvis, and bilateral upper arm, forearm,

hand, thigh, shank, and foot). Prosthetic ankle power was calculated using the unified deformable segment model (36). The coordinate systems were transformed to the subject's torso coordinate system to maintain alignment with the direction of progression. Each segment's mass was estimated as a percentage of whole-body mass (37), and the inertial properties and center of mass positions were based on geometric approximations calculated in Visual 3D. The prosthetic shank mass was reduced to 35% of the intact shank, and the prosthetic CoM location was moved 35% closer to the knee joint (38). All GRFs were normalized by subject body mass (kg). Initial heel contact and toe-off events were automatically detected based on force plate loading threshold of 25 N and kinematic pattern recognition. These events were also inspected visually and corrected if needed.

The primary outcome was the peak transverse plane moment, normalized to body mass, during prosthetic limb stance. To discover if varying the coupling ratio influenced the subject's gait or their satisfaction with their prosthesis, secondary outcomes were calculated. Discretized gait biomechanic metrics included the intact and prosthetic hip and knee power during push-off [known as H3 and K3, respectively (39)], and the prosthetic ankle power during push-off. Kinematic metrics included peak hip extension angle during pre-swing and peak knee flexion during weight acceptance. The vertical and anterior-posterior GRF during weight acceptance were also analyzed. All outcomes including satisfaction were aggregated with project specific software (MathWorks, Natick, MA).

Linear mixed effects regression was used to test for an association between each outcome (dependent variable) by coupling ratio. Coupling ratio was the independent fixed effect (modeled as categorical using 4 dummy variables). Study participant and study participant by coupling ratio interaction were random effects. To address the variability in outcome variance among participants, maximum penalized likelihood estimation was used (40). Hypothesis testing for the association between outcome and coupling ratio was carried out using conditional F-tests with degrees of freedom estimated using the Kenward-Roger method. Pairwise hypothesis testing was carried out with adjustments for multiple comparisons using Tukey's method. Results are summarized as outcome means (±standard error) by coupling ratio, and pairwise mean differences in outcome by coupling ratio category accompanied by standard errors and 95% confidence intervals (CI). Analyses were carried out using R 4.2.1 (41), and packages tidyverse, lme4, blme and emmeans (40, 42–44). Statistical analyses on satisfaction results were not performed due to the small sample size and the higher expected variances of qualitative data.

3 Results

The subjects' ST, PI, and PO SSWS were 1.24 ± 0.19 m/s (mean ± standard deviation), 0.44 ± 0.08 m/s, and 0.42 ± 0.07 m/s, respectively. Eleven subjects completed all trials walking ST and PI. A device malfunction prevented one subject from completing the PO trials.

There were significant differences in the mean maximum transverse plane moments while ST and PI walking (see Table 2). The general pattern suggest a quadratic relationship between transverse plane moments and the sagittal:transverse ankle angle coupling ratio with a minimum at 6:1 (see Figure 5). Coupling ratios greater than 6:1 (i.e., 4:1, 3:1, and 2:1) appear to increase the transverse plane moment when compared to the rigid condition (1:0). However, only the 6:1 vs. 3:1 and the 6:1 vs. 2:1 coupling ratios during ST and PO walking were statistically different ($p < .05$) in pairwise comparisons (see Table 3). The general pattern also suggests the transverse plane moments were lowest during ST and highest PI walking (see Figure 5).

Biomechanical outcomes did not exhibit any statistical differences across coupling ratios during ST, PI, and PO walking (see Table 4).

Satisfaction results did not appear to exhibit any general patterns other than participants felt their prosthesis was comfortable as mean scores for the different coupling ratios ranged from a low of 7.1 to a high of 8.5 (see Table 5). Multiple

TABLE 2 Mean (±SE) maximum transverse plane moment normalized to body mass (Nm/kg) while walking straight (ST) and around a 2 m diameter circle with the prosthesis on the inside (PI) and on the outside (PO) at five different sagittal:transverse coupling ratios.

	Sagittal:transverse coupling ratio					
	1:0	6:1	4:1	3:1	2:1	*p*-value
ST	0.299 ± 0.025	0.292 ± 0.013	0.312 ± 0.011	0.323 ± 0.012	0.350 ± 0.019	**0.029**
PI	0.340 ± 0.026	0.324 ± 0.023	0.331 ± 0.023	0.343 ± 0.019	0.349 ± 0.021	0.340
PO	0.306 ± 0.026	0.298 ± 0.026	0.322 ± 0.025	0.336 ± 0.021	0.358 ± 0.021	**0.040**

Bold font indicates a statistically significant difference at $p < 0.05$.

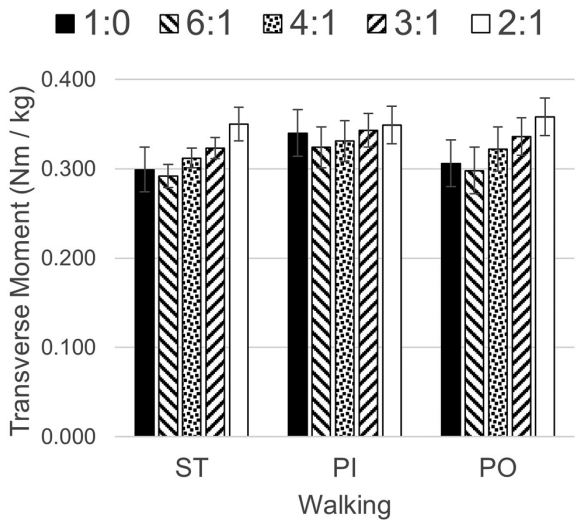

FIGURE 5
Transverse plane moments while walking straight (ST) and around a 2 m diameter circle with the prosthesis on the inside (PI) and on the outside (PO) at five different sagittal:transverse coupling ratios.

TABLE 3 Mean pairwise difference (± SE), 95% CIs and *p*-values in maximum transverse plane moment normalized to body mass (Nm/kg) among sagittal:transverse coupling ratios while walking straight (ST) and around a 2 m diameter circle with the prosthesis on the inside (PI) and on the outside (PO).

Coupling ratios	ST	PI	PO
1:0–6:1	0.006 ± 0.018 (−0.054, 0.067) 1	0.017 ± 0.014 (−0.031, 0.064) 0.78	0.008 ± 0.015 (−0.044, 0.060) 0.99
1:0–4:1	−0.013 ± 0.018 (−0.072, 0.045) 0.94	0.009 ± 0.015 (−0.041, 0.060) 0.97	−0.016 ± 0.015 (−0.068, 0.036) 0.83
1:0–3:1	−0.024 ± 0.021 (−0.092, 0.044) 0.77	−0.003 ± 0.020 (−0.068, 0.063) 1	−0.031 ± 0.015 (−0.083, 0.021) 0.33
1:0–2:1	−0.051 ± 0.023 (−0.128, 0.025) 0.26	−0.008 ± 0.017 (−0.064, 0.048) 0.99	−0.052 ± 0.021 (−0.122, 0.018) 0.17
6:1–4:1	−0.02 ± 0.009 (−0.048, 0.009) 0.24	−0.007 ± 0.009 (−0.035, 0.021) 0.91	−0.024 ± 0.009 (−0.053, 0.006) 0.14
6:1–3:1	**−0.031 ± 0.009 (−0.061, 0) 0.047**	−0.019 ± 0.012 (−0.06, 0.021) 0.55	**−0.038 ± 0.011 (−0.074, −0.002) 0.036**
6:1–2:1	**−0.058 ± 0.014 (−0.105, −0.011) 0.016**	−0.025 ± 0.014 (−0.07, 0.021) 0.42	**−0.06 ± 0.016 (−0.113, −0.006) 0.028**
4:1–3:1	−0.011 ± 0.008 (−0.038, 0.016) 0.69	−0.012 ± 0.011 (−0.048, 0.024) 0.8	−0.015 ± 0.01 (−0.048, 0.018) 0.57
4:1–2:1	−0.038 ± 0.014 (−0.083, 0.007) 0.11	−0.018 ± 0.009 (−0.049, 0.014) 0.39	−0.036 ± 0.014 (−0.082, 0.01) 0.14
3:1–2:1	−0.027 ± 0.010 (−0.06, 0.006) 0.13	−0.006 ± 0.011 (−0.043, 0.032) 0.99	−0.021 ± 0.010 (−0.055, 0.013) 0.29

Bold font indicates a statistically significant difference at $p < 0.05$.

subjects failed to discern any differences by coupling ratio. During ST walking, 4 of the 11 subjects gave the same score for each coupling ratios. During PI walking, only 2 of 11 subjects felt no differences across coupling ratios, but during PO walking 5 of 10 who completed all trials could not distinguish any differences in satisfaction.

4 Discussion

The study investigated the effects of varying the sagittal: transverse coupling ratio on individuals with a unilateral transtibial amputation while they walked straight and in both directions around a 2 m circle.

4.1 Interpretation

The ST SSWS for the participants in this study is comparable to the speeds reported for an identical task and similar population [1.24 ± 0.19 m/s vs. 1.19 ± 0.16 m/s (33), respectively]. However, the turning SSWS of the current population was slower than that previously reported [PI: 0.44 ± 0.08 m/s and PO: 0.42 ± 0.07 m/s m/s vs. mean of both directions: 0.88 ± 0.10 m/s (33), respectively]. The difference could be due to the greater mass of the TAP than the as-prescribed prostheses worn in (33).

The mean maximum transverse plane moments general pattern (see Figure 5) suggests a coupling ratio of 6:1 may reduce transverse plane moments during straight and circle walking, while a coupling ratio of 2:1 or 3:1 may increase them. The slower PI and PO speeds of the participants in this study may have reduced the magnitude of these moments (45). Subjects who walk faster around a circle may exhibit larger transverse plane moments. The transverse plane moments reported here are in general somewhat larger than those observed by subjects wearing a rigid pylon or a commercially-available transverse plane rotation adapter (8). The higher moments may be due to the greater mass of the TAP.

The joint powers (hip, knee, and prosthetic ankle) and kinematics (hip angle) during push-off and the kinematics (hip angle) during pre-swing were not affected by the coupling ratio. This suggests that the coupling ratios explored in this study do not adversely affect propulsion. The kinematics (knee angle) and GRFs (vertical and anterior-posterior) during weight acceptance were also not affected by the coupling ratio. This suggests the coupling ratios explored in this study do not adversely affect body support.

The satisfaction ratings were also not influenced by the coupling ratio. Likert scales like the one used in this study can allow for a range of responses from one extreme to the other as well as no opinion. The results here suggest the subjects were comfortable with their prosthesis and the coupling ratio had no discernible effect. More advanced methods may need to be adapted for use with the TAP to explore this issue (46).

4.2 Implications

For individuals with lower limb amputation who are capable of locomotion, their clinician must choose among several hundred available prosthetic feet when prescribing a prosthesis. While these products have many different distinguishing features, none mimic the coupled motion exhibited by the natural limb. The results of this study suggest a coupling ratio exists that minimizes transverse plane moments without adversely affecting key gait metrics or satisfaction with their prosthesis. The target population for this device is the limited and unlimited community ambulator. Household ambulators may have challenges associated with balance and the coupled transverse plane motion could potentially induce instability in these individuals. At the other end of the spectrum, the athletic ambulator with high impact loads and large sagittal plane motions might generate excessive coupled transverse plane motions which could cause skin irritation or injury arising from high shear stresses.

4.3 Limitations

Limitations of this research include a small sample population ($n = 11$), a short acclimation period to a novel intervention

TABLE 4 Mean (± SE) kinetic and kinematic biomechanical outcomes by sagittal:transverse plane coupling ratio while walking straight (ST) and around a 2 m diameter circle with the prosthesis on the inside (PI) and on the outside (PO).

	Sagittal:transverse coupling ratio					
	1:0	6:1	4:1	3:1	2:1	*p*-value
Peak Hip Power (H3) Intact Limb (W/kg) during push-off						
ST	0.88 ± 0.12	0.86 ± 0.13	0.84 ± 0.12	0.87 ± 0.13	0.92 ± 0.14	0.49
PI	0.75 ± 0.11	0.7 ± 0.1	0.79 ± 0.13	0.77 ± 0.11	0.71 ± 0.11	0.45
PO	0.47 ± 0.05	0.49 ± 0.07	0.48 ± 0.05	0.45 ± 0.05	0.5 ± 0.06	0.85
Peak Hip Power (H3) Prosthetic Limb (W/kg) during push-off						
ST	0.55 ± 0.09	0.55 ± 0.08	0.53 ± 0.09	0.59 ± 0.08	0.56 ± 0.09	0.28
PI	0.6 ± 0.07	0.62 ± 0.07	0.63 ± 0.07	0.65 ± 0.08	0.61 ± 0.08	0.69
PO	0.34 ± 0.06	0.34 ± 0.05	0.35 ± 0.07	0.33 ± 0.05	0.32 ± 0.05	0.95
Peak Knee Power (K3) Intact Limb (W/kg) during push-off						
ST	−1.3 ± 0.15	−1.25 ± 0.16	−1.21 ± 0.16	−1.27 ± 0.18	−1.26 ± 0.17	0.59
PI	−0.84 ± 0.11	−0.81 ± 0.1	−0.79 ± 0.09	−0.78 ± 0.11	−0.88 ± 0.12	0.68
PO	−1.12 ± 0.17	−1.1 ± 0.18	−1.13 ± 0.22	−1.09 ± 0.16	−1.12 ± 0.2	1.00
Peak Knee Power (K3) Prosthetic Limb (W/kg) during push-off						
ST	−1.24 ± 0.19	−1.16 ± 0.19	−1.17 ± 0.16	−1.23 ± 0.16	−1.2 ± 0.17	0.82
PI	−0.64 ± 0.09	−0.69 ± 0.1	−0.73 ± 0.11	−0.7 ± 0.1	−0.66 ± 0.1	0.55
PO	−1.23 ± 0.12	−1.22 ± 0.18	−1.3 ± 0.13	−1.3 ± 0.19	−1.24 ± 0.13	0.87
Peak Prosthetic Ankle Power (W/kg) during push-off						
ST	−0.15 ± 0.03	−0.15 ± 0.03	−0.15 ± 0.03	−0.16 ± 0.03	−0.16 ± 0.03	0.70
PI	−0.16 ± 0.04	−0.16 ± 0.04	−0.17 ± 0.04	−0.17 ± 0.04	−0.17 ± 0.05	0.78
PO	−0.15 ± 0.03	−0.14 ± 0.04	−0.16 ± 0.03	−0.13 ± 0.03	−0.15 ± 0.03	0.16
Peak Extension Hip Angle Intact Limb (°) during push-off						
ST	−18.3 ± 3.4	−17.9 ± 3.2	−18 ± 3.4	−18.5 ± 3.2	−18.5 ± 3.2	0.55
PI	−10.3 ± 3.7	−9.8 ± 3.6	−10 ± 3.7	−11.2 ± 3.7	−10.9 ± 3.8	0.50
PO	−10.3 ± 3.7	−9.9 ± 3.8	−10.5 ± 3.7	−10.1 ± 3.6	−10.1 ± 3.7	0.72
Peak Hip Extension Angle Prosthetic Limb (°) during push-off						
ST	−13.7 ± 3.3	−13.5 ± 3.1	−13.7 ± 3.3	−13.3 ± 3.4	−13.3 ± 3.4	0.70
PI	−6.6 ± 3.7	−6.4 ± 3.9	−7.1 ± 3.4	−6.9 ± 3.6	−6.9 ± 3.6	0.96
PO	−7.4 ± 3.3	−7.8 ± 3.4	−8 ± 3.2	−7.4 ± 3.5	−7.9 ± 3.4	0.75
Peak Knee Angle Intact Limb (°) during weight acceptance						
ST	12.8 ± 2.7	12.8 ± 2.7	12.9 ± 3	13.2 ± 2.6	12.7 ± 2.6	0.92
PI	8.5 ± 2.4	8.7 ± 2.4	8.9 ± 2.4	8.6 ± 2.4	8.4 ± 2.4	0.85
PO	12.4 ± 2.6	11.6 ± 2.4	12.6 ± 2.1	12.4 ± 2.6	11.9 ± 2.6	0.80
Peak Knee Angle Prosthetic Limb (°) during weight acceptance						
ST	7.8 ± 3.5	8.7 ± 3.3	7.4 ± 3.4	7.9 ± 3.6	8.8 ± 3.8	0.59
PI	8.5 ± 3.3	8 ± 3	8.4 ± 3.3	8.9 ± 2.9	8.8 ± 2.9	0.90
PO	9 ± 3.2	9.6 ± 2.9	9.8 ± 2.9	10.4 ± 2.8	9.6 ± 2.8	0.44
Vertical Ground Reaction Force (N/BW) during weight acceptance						
ST	1.11 ± 0.04	1.08 ± 0.03	1.08 ± 0.04	1.07 ± 0.05	1.1 ± 0.04	0.61
PI	1 ± 0.03	1 ± 0.03	1.01 ± 0.02	1.02 ± 0.03	1.02 ± 0.02	0.85
PO	1.03 ± 0.04	1.02 ± 0.04	1.03 ± 0.04	0.98 ± 0.04	1.03 ± 0.05	0.59
Anterior (braking) Ground Reaction Force (N/BW) during weight acceptance						
ST	−0.15 ± 0.03	−0.15 ± 0.03	−0.15 ± 0.03	−0.16 ± 0.03	−0.16 ± 0.03	0.70
PI	−0.16 ± 0.04	−0.16 ± 0.04	−0.17 ± 0.04	−0.17 ± 0.04	−0.17 ± 0.05	0.78
PO	−0.15 ± 0.03	−0.14 ± 0.04	−0.16 ± 0.03	−0.13 ± 0.03	−0.15 ± 0.03	0.16

TABLE 5 Mean (± SD) satisfaction scores on a 0–10 scale where 0 represents the most uncomfortable socket fit the subject could imagine, and 10 represents the most comfortable socket fit.

	Sagittal:transverse coupling ratio				
	1:0	6:1	4:1	3:1	2:1
ST	8.0 ± 1.3	8.2 ± 1.3	8.0 ± 1.0	7.7 ± 1.2	8.5 ± 1.0
PI	7.5 ± 1.3	7.9 ± 1.1	7.1 ± 1.7	7.5 ± 0.7	8.1 ± 1.3
PO	7.7 ± 1.7	7.9 ± 1.2	7.4 ± 1.3	7.8 ± 1.1	7.7 ± 1.5

(15 min), a heavier intervention than the participant's as-prescribed prosthesis, and a limited selection of tested coupling ratios (five). A larger sample population might produce additional results with statistical significance. A longer acclimation period might result in subjects walking faster around the 2 m circle. A longer acclimation period might also enable the subjects to be more nuanced in their opinions resulting in observable differences in satisfaction scores between conditions. The TAP is approximately three times as

heavy as a conventional prosthetic foot. While prescription of a conventional transverse plane rotation adapter would reduce this difference, a heavier study intervention might bias satisfaction ratings. Finally, while this study explored five different coupling ratios, the TAP could be programmed to explore a range more closely centered on the 6:1 coupling ratio.

4.4 Future work

The clinical significance of this research lies in the development of a passive (i.e., not mechatronic) version of the TAP and measure its safety and effectiveness in a long-duration, field-based clinical trial. A clinical trial comparing a passive version of the TAP to a rigid pylon and a transverse plane rotation adapter would illuminate key differences.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Veterans Affairs Puget Sound Healthcare System IRB #2. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

GK: Conceptualization, Funding acquisition, Methodology, Writing – original draft, Writing – review & editing. CM: Formal Analysis, Investigation, Methodology, Software, Writing – review & editing.

Funding

The author(s) declare that financial support was received for the research, authorship, and/or publication of this article.

This study was supported by awards I01 RX002456 and IK6 RX002974 from the United States Department of Veterans Affairs Rehabilitation Research & Development Service. Support was also provided by the US Dept. of Veterans Affairs, Technology Transfer Office (BRAVE).

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 02 May 2024
DOI 10.3389/fresc.2024.1342370

OPEN ACCESS

EDITED BY
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RECEIVED 21 November 2023
ACCEPTED 15 April 2024
PUBLISHED 02 May 2024

CITATION
Klenow TD, Lundstrom RL, Morris A, Patterson S, Simpson C, Trejo EG and Kannenberg A (2024) An enhancement of the Genium™ microprocessor-controlled knee improves safety and different aspects of the perceived prosthetic experience for unilateral and bilateral users.
Front. Rehabil. Sci. 5:1342370.
doi: 10.3389/fresc.2024.1342370

An enhancement of the Genium™ microprocessor-controlled knee improves safety and different aspects of the perceived prosthetic experience for unilateral and bilateral users

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Introduction: Bilateral microprocessor-controlled prosthetic knee (MPK) users have unique needs in traversing environmental barriers compared to unilateral users. An enhancement to the Genium™/Genium X3™ MPK which included an updated ruleset, hydraulics, and new bilateral parameter presets was made to improve safety while stumbling and the smoothness of gait for all users while also improving the experience of bilateral users. The purpose of the study was to evaluate the effectiveness of the enhancements in a sample with unilateral and bilateral amputation.

Methods: A convenience sample of MPK users was recruited from two sites in the USA in two phases. Assessments included the *L*-Test of Functional Mobility, Activity-specific Balance Confidence Scale, Prosthetic Limb User Survey of Mobility, a study-specific questionnaire, and the Comparative Activities of Daily Living (ADL) Questionnaire. Statistical significance of extracted data was tested with the Wilcoxon Rank-Sum Test for independent data and Wilcoxon Signed-Rank for paired data with an *a priori* significance level of $p < 0.05$. Unilateral subjects were age-matched to the group of bilateral subjects for between-groups and within-groups analyses.

Results: Twenty-six subjects ($n = 26$) were enrolled. Stumble frequency reduced 85% from 16.0 ± 39.7 to 2.4 ± 2.3 ($p = 0.008$) between baseline and final assessment overall. The bilateral group reported 50% ($p = 0.009$) and 57% ($p = 0.009$) greater relative improvement in patient-reported ease and safety, respectively, of completing ADLs compared to the unilateral group. The unilateral group reported residual limb pain and low back pain reduced from 2.3 to 1.4 ($p = 0.020$) and 3.8 to 1.8 ($p = 0.027$), respectively, whereas the bilateral group did not.

Discussion: Substantial reductions in stumbles, residual limb pain, and back pain were shown overall. These reductions were driven by the unilateral group who also showed improvements in comfort, exertion, and concentration while

10.3389/fresc.2024.1342370

walking. The enhancements to the knee likely reduced some gait asymmetry for unilateral users. Improvements in patient-reported ease and safety of completing ADLs were shown overall and were driven by the bilateral group. This study shows further improvement in patient experience is achievable through innovation in MPK technology even for patients who appear to be functioning well.

KEYWORDS

amputee, rehabilitation, transfemoral, MPK, ADL-Q, mechatronic, biomedical

1 Introduction

Individuals with lower extremity amputation (LEA) are a relatively small population in allied health. Those with transfemoral amputation (TFA) constitute a smaller proportion of the population compared to patients with transtibial amputation (TTA), and those with bilateral TFA make up an even smaller proportion yet (1). TFA patients often have poor rehabilitation outcomes due to the absence of two major biological joints in both lower extremities (2, 3). Significant efforts have brought technological advancements to patients with TFA in the form of microprocessor-controlled knee (MPK) joints (4). Most MPKs on the market today utilize some application of a hydraulic cylinder which dampens flexion and extension of the joint during stance and swing phases of gait and standing (5). The degree of dampening is controlled by a microprocessor which accepts input from various sensors and opens or closes hydraulic valves in response to a decision tree called a ruleset. The Genium^{TM} (Ottobock Healthcare Products GmbH, Vienna, AT) (Figure 1) was introduced in 2011 containing an advanced control concept, additional sensors, and improved algorithms enabling a range of new functions for MPK users (4). Specific technological modifications for bilateral users have not yet been developed, however.

Invariably, the needs of bilateral and unilateral users differ in response to similar gait events due to absence or presence of a sound limb. The most notable gait events are ramp and stair negotiation where the unilateral prosthesis users can use the sound limb to control the speed of slope or stair descent and rely on it as a primary stability point (6). However, the bilateral user is solely reliant on the capability of assistive technology to complete these activities of daily living (ADLs) (5). Most commercially available MPKs have a programming selection for bilateral users, but this option often alters only the appearance of the graphical user interface (GUI) for the device, the reporting function, or the ability to connect the GUI to multiple devices but not the ruleset parameters. A functional difference between groups is thereby created because the identical functionality for both groups results in a relatively poorer prosthetic experience for patients with bilateral TFA than with unilateral TFA (3). The lack of specific functional options may force bilateral users to preemptively avoid problematic situations (7). Situation avoidance leads to activity avoidance and reductions in social and community participation which ultimately results in reduced

FIGURE 1
Genium and Genium X3 images, reprinted with permission from Otto Bock Healthcare LP.

quality of life (7–10). However, these reductions may be avoided if features are created to improve the experience of bilateral users because previous research has shown relative fulfilment of rehabilitative potential has a greater impact on mental health and quality of life than the laterality of amputation (11, 12).

A recent enhancement to the Genium and Genium X3 was made to improve safety during stumbling and improve everyday walking for users. An additional objective was to introduce bilateral parameter presets for the rulesets of these MPKs. Therefore, the purpose of this study was to investigate the effectiveness of the enhancements to improve safety during stumbling and to improve everyday walking in a group of subjects with both unilateral and bilateral TFA. It was hypothesized that the enhancements would reduce stumbles and falls and would improve gait stability and comfort overall. An additional purpose was to investigate whether the introduction of bilateral parameter presets improve the prosthetic experience of bilateral prosthesis users. It was hypothesized that the enhancements would result in greater improvements in patient-reported ease and safety of ADL completion in a group of bilateral users compared to a control group of unilateral users following the final update.

2 Materials and methods

The Institutional Review Board approval of the study protocol was provided by WCG IRB (WCG #20171027). The clinical trial was divided into two phases (Figure 2). Phase I included proof of concept testing of developmental ruleset changes in a small group of MPK end-users. Investigational Genium and Genium X3 knees featured enhanced rulesets including specific parameter presets for bilateral users in Phase I. Phase II included a larger sample for testing prior to commercialization. Devices in phase II featured the specific parameter presets for bilateral subjects as well as updated rulesets and hydraulics for all users. Direct feedback was provided by subjects and prosthetists to design engineers at the beginning of phase II. Indirect feedback was provided through outcome measures (OMs) collected at various points as detailed below. This feedback was integrated prior to implementation of the final ruleset update which was uploaded to all investigational MPKs two months prior to the final assessment.

2.1 Subject recruitment

A convenience sample of MPK users was recruited from two participating clinics in Oklahoma and Florida in the United States. Inclusion criteria were:

- History of TFA, knee disarticulation (KD), or hip disarticulation (HD)
- 6 months prior experience with a Genium or Genium X3
- Current prosthetic use >8 h per day
- Demonstrated ability to walk at different speeds
- Ability to ascend and descend ramps and stairs
- Medicare Functional Classification Level K2, K3 or K4
- Use of a compatible conventional prosthetic interface (socket)
- Willingness to use the study MPK with a smartphone app

Exclusion criteria were:

- <18 years old
- Serious health risks which may prevent participation (e.g., unstable cardiovascular conditions, terminal cancer, etc.)
- History of chronic skin breakdown of residual limb
- Falls once per week for reasons not related to prosthetic use (e.g., vestibular disorders)
- Current pregnancy
- Current or anticipated participation in another clinical trial

Sites were asked to enroll a minimum of three subjects with bilateral TFA or KD in Phase I and at least seven bilateral subjects in Phase II for a total of 10. Sites were asked to enroll seven subjects with unilateral amputation in Phase I and at least 7 in phase II for a total of 14. Subjects from Phase I continued participation through Phase II.

2.2 Device assignment, fitting, and assessments

Following informed consent, each subject's existing prosthesis was evaluated for fit and function by the site principal investigator and the sponsor's clinical specialist. Subjects then completed a screening assessment to ensure compliance with inclusion and absence of exclusion criteria. All existing prostheses had a commercially-available Genium or Genium X3 knee and a prosthetic foot from the Triton™ product line (Ottobock SE & Co. KGaA; Duderstadt, GER) or the TaiLor Made™ (Prosthetic & Orthotic Associates; Orlando, FL, USA) except for one subject who used a Flex Foot Junior (Ossur, Reykjavik, ISL) due to foot size limitations. The baseline assessment included collection of demographics, a general health questionnaire, several validated outcome measures (OMs), and the Study-Specific Questionnaire (SSQ) described below in Section 2.3.

Following the baseline assessment, subjects entered Phase I where they were provided an investigational Genium or Genium X3, corresponding to their existing knee model, with the enhanced ruleset. Bilateral subjects used the bilateral parameter presets as part of their initial programming. In Phase II, subjects were fit with a new investigational Genium or Genium X3 with an enhanced ruleset and updated hydraulics. Bilateral subjects again used the bilateral parameter presets as part of their initial programming. At the end of Phase II, subjects completed the protocol with the assessment of the same outcome measures completed at baseline along with the comparative Activities of Daily Living Questionnaire (ADL-Q) described below in Section 2.3.

2.3 Outcome measures

The OMs used in the baseline and final assessments are described below:

Subject-reported stumbles and falls were collected by asking subjects to recall the frequencies of each in the previous 8 weeks using the following categories: never, once, 2–5 times, once per week, 2–5 times weekly, once per day, or 2–5 times per day.

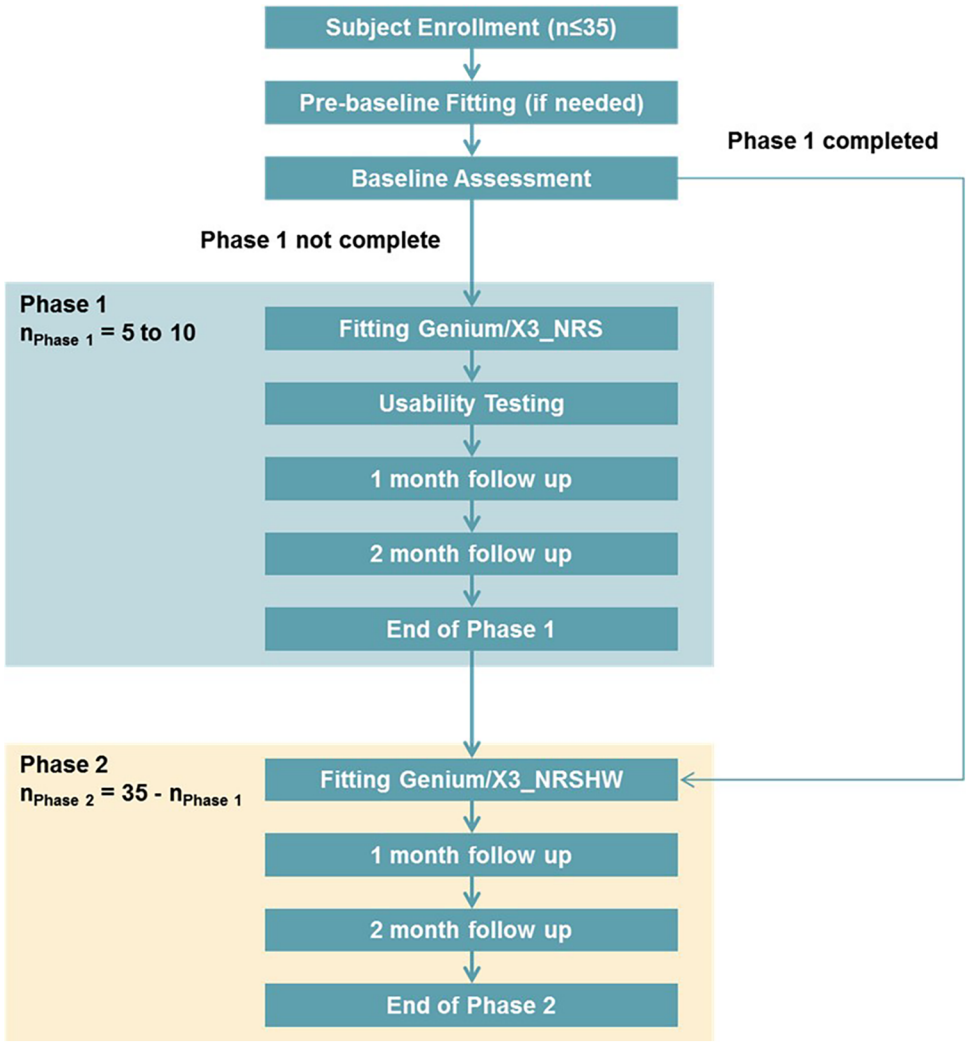

FIGURE 2
Study subject flow.

The answers were converted to estimated numbers of falls or stumbles over the previous 8-week period, taking the midpoint of the range of each response category where applicable.

The Numeric Pain Rating Scale (NPRS) is a single-point evaluation of the highest pain experienced in the last week at the low back and in the residual limb on a continuous scale from 0 to 10. It has a minimally clinically important difference (MCID) of 1 for individuals with chronic pain and other musculoskeletal disorders (13–17). Excellent internal consistency has been demonstrated for young (Cronbach alpha = 0.88) and elderly subjects (Cronbach alpha = 0.87) alike as well as excellent inter-rater reliability (18).

The *L*-Test is a modified version of the Timed-up-and-go (TUG) test that increases the total distance and number of turns. Experienced MPK users were expected to encounter a ceiling effect or insufficient challenge in the TUG test. Since the *L*-Test has reduced the ceiling effect of the TUG by 52% and also highly correlates with it (Pearson $r = 0.93$), the *L*-test was considered more appropriate for the subjects in this study (19). The *L*-test has an MCID of 4.5 s for individuals with lower extremity amputation as established by Rushton et al. (20) and a fall-risk threshold of >25.5 s for healthy elderly people (21).

The Activities-specific Balance Confidence (ABC) Scale is 16-item self-reported measure designed to identify balance confidence issues (22). Each of the 16 activities is rated on a 10-point scale between 0% and 100% in 10% increments, with greater scores indicating better balance confidence. The total score is then averaged across the 16 activities. A fall-risk threshold of <67% has been established for elderly people (23).

The Prosthetic Limb Users Survey of Mobility (PLUS-M) is a self-report instrument for measuring mobility of adults with lower limb amputation. The PLUS-M 12-item short form provides T-scores that range from 21.8 to 71.4 (24). Higher T-scores indicate better mobility. A T-score of 50 is equal to the mean of the development sample and every 10 points correspond approximately to one standard deviation (25). For example, a patient with a PLUS-M T-score of 60 is one standard deviation above the average respondent from the original ($n = 1,091$) sample.

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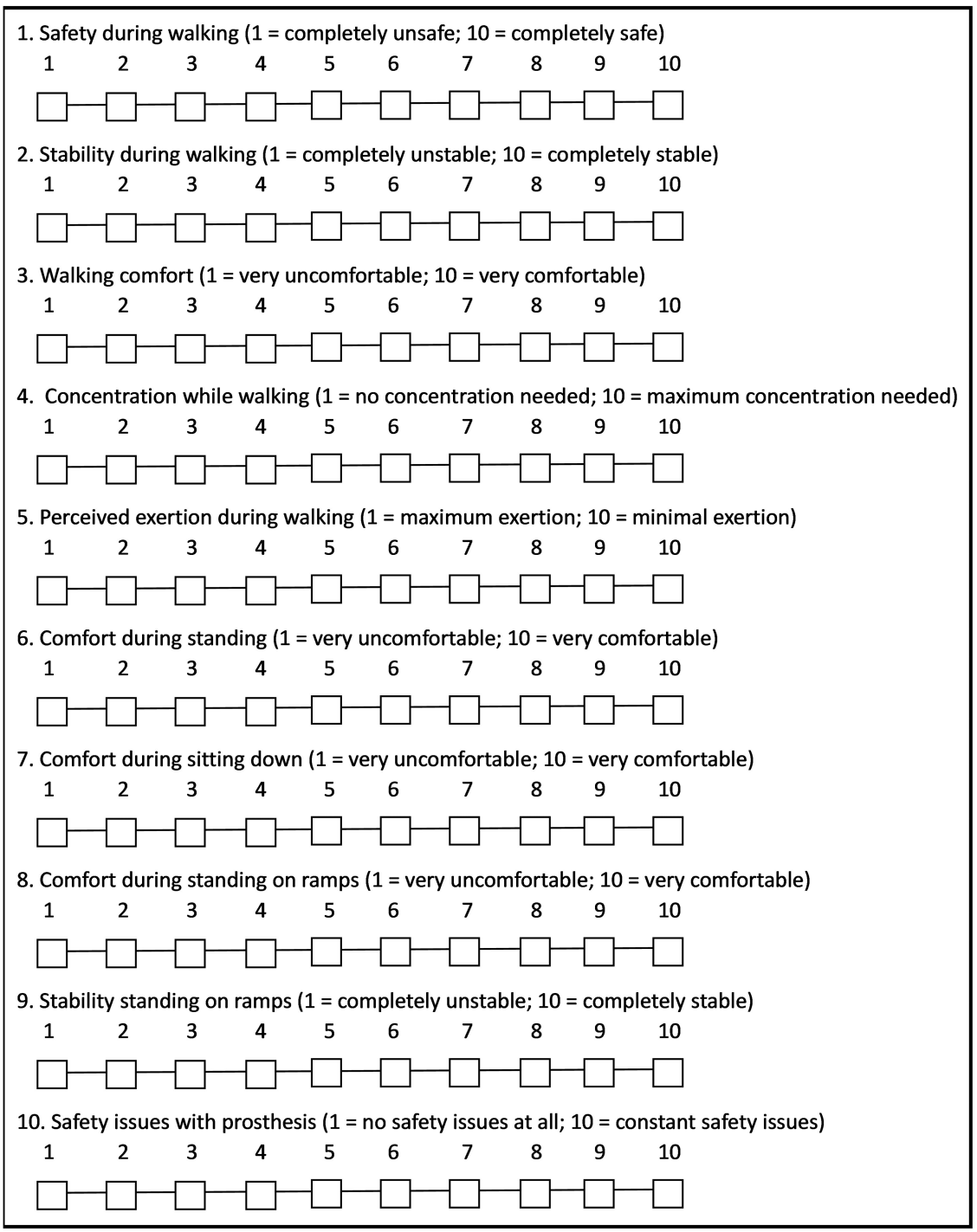

FIGURE 3
Study-specific questionnaire.

A study-specific questionnaire (SSQ) was created and used to evaluate the effect of specific aspects of the enhancements on subjects' experience during common prosthetic tasks. Questions in the SSQ included patient-reported ratings of walking safety, walking stability, walking comfort, concentration while walking (autowalk), exertion while walking, standing comfort, sitting comfort, comfort standing on ramps, stability standing on ramps, and use of the stair and ramp functions rated on a 10-point scale (Figure 3). The SSQ was administered at baseline and final assessments as well as at various points throughout the study period to provide feedback to product developers. Only baseline and final scores will be reported in this article.

TABLE 1 Demographics.

Demographic	Aggregate	Unilateral (age-matched)	Bilateral
Number of subjects	26	9	9
Gender	2 Female, 24 Male	1 Female, 8 Male	0 Female, 9 Male
Age (years)	35.1 ± 12.6	29.3 ± 7.1	29.3 ± 5.1
Prosthetic experience			
Mean time since amputation (years)	15.0 ± 12.2	11.4 ± 5.6	12.3 ± 11.3
Mean time using MPK (years)	3.7 ± 2.2	4.4 ± 2.8	2.8 ± 1.9
Etiology			
Trauma	20	8	6
Congenital	3	1	2
Tumor	1		
Vascular	1		
Rhabdomyolysis	1		1
Amputation level			
Hip disarticulation	1		
Transfemoral	22	8	7
Knee disarticulation	3	1	2
Study knee			
Genium	8	3	4
X3	18	6	5

The Comparative Activities of Daily Living Questionnaire (ADL-Q) is a 45-item questionnaire related to ADLs grouped into seven categories: personal care and dressing, family and social roles, leisure time activities, mobility, transportation, health related exercise, and other activities (26). Subjects reported perceived ease and safety of completing ADLs on a 5-point Likert scale ranging from much improvement with the existing knee joint (−2 pts) to much improvement with investigational knee joint (+2 pts). The ADL-Q has been used in studies evaluating advanced MPKs in the past (4, 26). A threshold for clinically significant change of 0.5 was suggested by Kannenberg et al. in 2013 (26). The comparative ADL-Q was administered at the final assessment.

Subjects were also asked if they used functions of the knee including yielding down slopes and stair ascent mode both for ascending stairs and stepping over obstacles. These questions were asked at the baseline and final assessments.

2.4 Statistical analysis

All results were described with measures of central tendency (e.g., means, standard deviations). Comparisons were made between the baseline and final assessments on aggregate. A subset of unilateral subjects was age-matched to the group of bilateral subjects for a between-groups analysis. Means and standard deviations at baseline and final assessment between groups and within each of the age-matched groups were calculated and compared.

Statistical significance was tested with the Wilcoxon Rank-Sum Test for independent data and Wilcoxon Signed-Rank test for paired data with an *a priori* significance level of $p < 0.05$. Calculations were completed in Python statistical analysis software SciPy 3.11 (Python Software Foundation; Fredericksburg, VA, USA).

3 Results

Twenty-six ($n = 26$) subjects were enrolled in the study. Ten ($n = 10$) were enrolled in Phase I and an additional 16 were

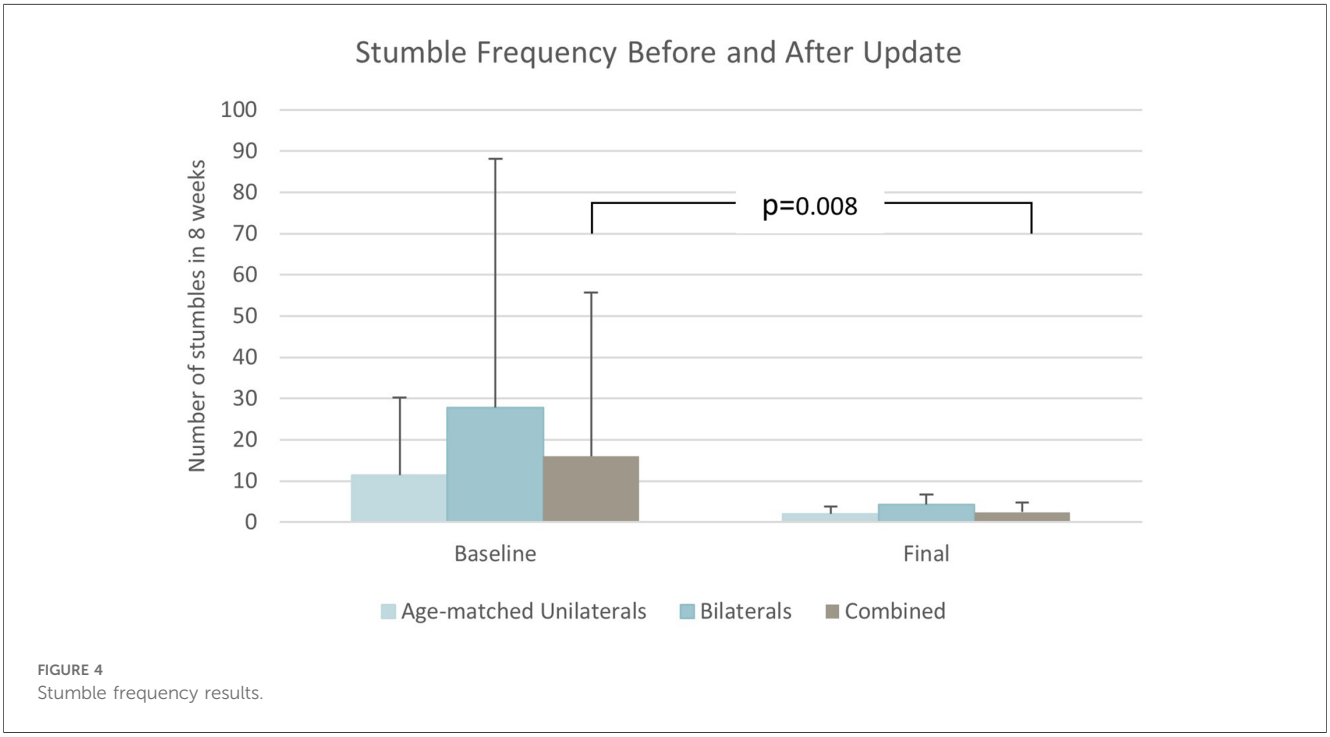

FIGURE 4
Stumble frequency results.

TABLE 2 Falls and Stumbles in the previous 8 weeks.

Measure	Aggregate		Age-matched Unilateral		Bilateral	
	Baseline	Final	Baseline	Final	Baseline	Final
Falls	1.16 ± 1.41	0.74 ± 1.70	0.72 ± 1.15	0.22 ± 0.44	1.89 ± 1.51	1.72 ± 2.59
	$\Delta = -0.42$; $p = 0.133$		$\Delta = -0.50$; $p = 0.179$		$\Delta = -0.17$; $p = 0.713$	
Stumbles	16.0 ± 39.7	2.4 ± 2.3	11.3 ± 18.9	1.9 ± 1.8	27.8 ± 60.3	4.2 ± 2.4
	$\Delta = -13.5$; $p = 0.008$		$\Delta = -9.4$; $p = 0.115$		$\Delta = -23.6$; $p = 0.246$	

Δ = change from Baseline after update.

enrolled in Phase II. One unilateral subject dropped out due to worsening of pre-existing back pain in Phase II and was not included in the analysis. One subject had a history of unilateral TFA and contralateral TTA and was excluded from the between-group analysis but included in the aggregate analysis. Demographic data is shown in Table 1.

3.1 Aggregate analysis

Stumble frequency (Figure 4) reduced significantly by 85% from baseline to final assessments ($p = 0.008$) as shown in Table 2. Fall frequency was low at baseline already, so the observed further reduction at final assessment did not attain statistical significance (Table 2). Low back pain ($p = 0.022$) (Figure 5) and residual limb pain ($p = 0.002$) (Figure 6) were reduced as shown in Table 3. No statistically significant change was observed in *L*-Test, PLUS-M or ABC (Table 3). In the SSQ, subjects reported statistically significant improvements ranging from +0.7 to +1.6 for walking safety ($p = 0.046$), walking comfort ($p = 0.002$), exertion while walking ($p = 0.010$), concentration while walking ($p = 0.006$), standing comfort ($p = 0.010$), sitting comfort ($p = 0.040$), stability standing on ramps ($p = 0.001$), and overall prosthetic safety ($p = 0.009$) (Table 4). In the comparative ADL-Q (Figure 6), clinically meaningful improvements (>0.5) were demonstrated in both safety and ease of ADL completion in the areas of Family Role, Social and Leisure Activities, Shopping, Mobility, Transportation, Health-Related Exercise, and Other Activities as shown in Table 5.

3.2 Between-groups analysis

No significant differences between unilateral and bilateral users were observed for stumble or fall frequency between groups (Table 2). Subjects with unilateral amputation demonstrated faster times on the *L*-Test than the bilateral group at baseline ($p = 0.007$) and final assessments ($p = 0.027$) as shown in Table 3. No statistically significant differences were shown between groups for the PLUS-M or ABC. For the SSQ, the unilateral group reported lower scores (Figure 7) than the bilateral group only on the item of perceived concentration while

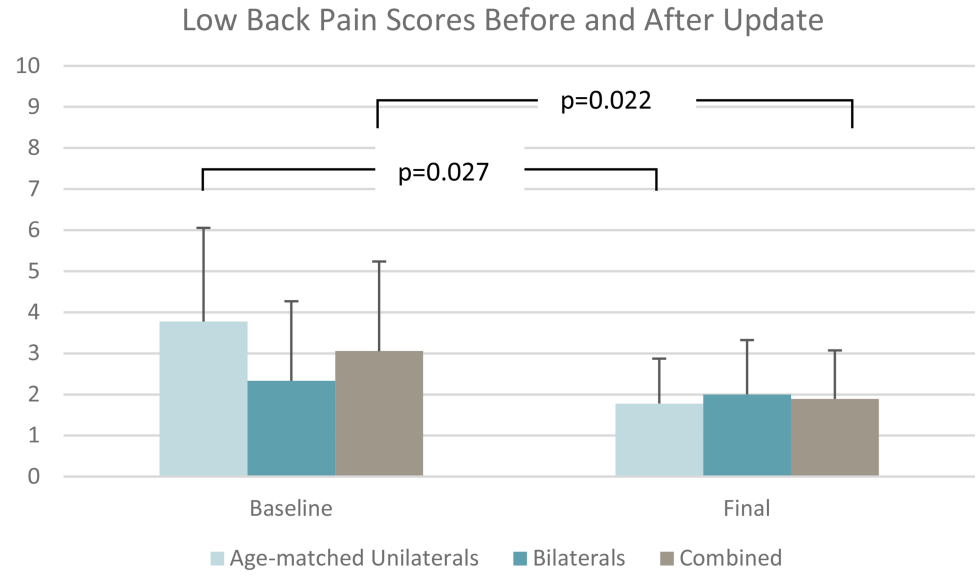

FIGURE 5
Low back pain scores.

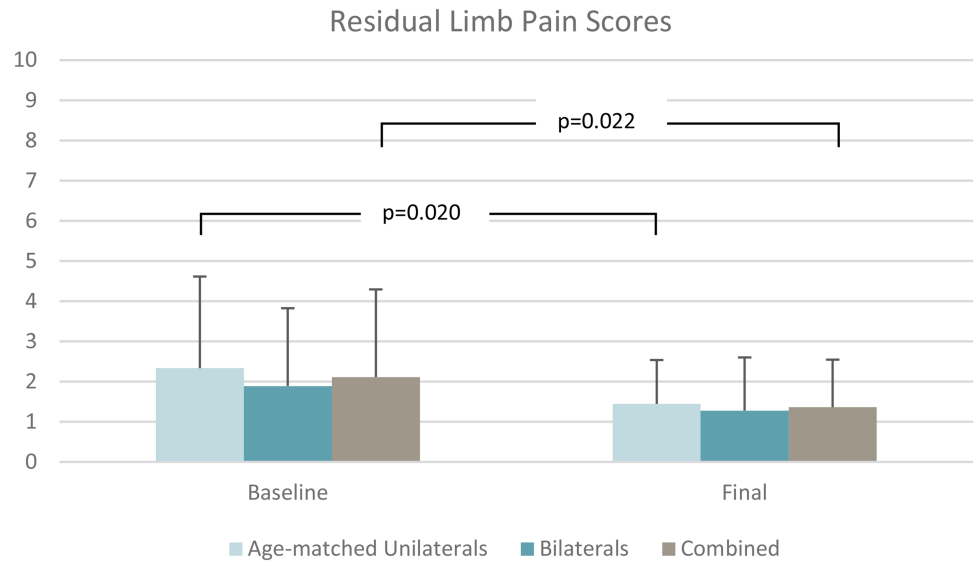

FIGURE 6
Residual limb pain scores.

walking at the final assessment ($p = 0.026$) as shown in Table 4; no other statistically significant differences were shown. Regarding the comparative ADL-Q, the bilateral group reported 50% greater improvement in ease ($p = 0.009$) and 57% greater improvement in safety ($p = 0.009$) of ADL execution compared to the unilateral group with the investigational (Table 5). In the activity categories (Figure 8), the bilateral group improved more than the unilateral group in ease and safety with statistically significant relative improvements in ease of Family Role ($p = 0.0006$), Social and Leisure Activities ($p = 0.0001$), Shopping ($p = 0.0001$), Mobility ($p = 0.0004$), and Transportation ($p = 0.027$), as well as safety in Family Role ($p = 0.0005$), Social and Leisure Activities ($p = 0.00008$), Shopping ($p = 0.00008$), Mobility ($p = 0.0001$), Transportation ($p = 0.021$), Health-Related Exercise ($p = 0.004$), and Other Activities ($p = 0.043$). Bilateral subjects reported greater utilization of optimized stair ascent and stepping over obstacles compared to the age-matched unilateral group as shown in Table 6.

3.3 Within-groups analysis

Subjects with unilateral TFA experienced reduced low back pain ($p = 0.027$) (Figure 5) and residual limb pain ($p = 0.020$) (Figure 6) from baseline to final assessment whereas the bilateral group did not (Table 3). Regarding the SSQ, subjects with unilateral TFA reported improved walking comfort ($p = 0.020$), exertion while walking ($p = 0.040$), concentration while walking ($p = 0.023$), and stability standing on ramps ($p = 0.031$) (Table 4). No other statistically significant differences were found.

TABLE 3 Results for all subjects, age-matched unilateral group, and bilateral subjects.

Measure	Aggregate		Age-matched unilateral		Bilateral	
	Baseline	Final	Baseline	Final	Baseline	Final
L-test (sec)	24.0 ± 4.7	23.6 ± 4.8	21.0 ± 4.7	20.9 ± 4.6	26.1 ± 4.7***	25.7 ± 4.7*
	Δ = −0.5; $p = 0.462$		Δ = −0.1; $p = 0.932$		Δ = −0.4; $p = 0.750$	
ABC (%)	86.6 ± 13.5	88.8 ± 10.9	87.8 ± 13.8	92.2 ± 6.2	86.5 ± 17.6	85.3 ± 14.4
	Δ = + 2.2; $p = 0.201$		Δ = + 4.4; $p = 0.164$		Δ = −1.2; $p = 0.400$	
PLUS-M (t-score)	57.4 ± 7.7	57.2 ± 6.1	57.4 ± 7.6	59.6 ± 6.6	59.1 ± 8.3	55.6 ± 6.2
	Δ = −0.2; $p = 0.783$		Δ = + 2.2; $p = 0.426$		Δ = −3.4; $p = 0.249$	
Residual limb pain	2.1 ± 1.4	1.5 ± 1.0	2.3 ± 1.2	1.4 ± 0.5	1.9 ± 1.7	1.3 ± 0.8
	Δ = −0.6; $p = 0.002$		Δ = −0.9; $p = 0.020$		Δ = −0.6; $p = 0.109$	
Low back pain	2.9 ± 2.1	2.0 ± 1.3	3.8 ± 2.3	1.8 ± 1.1	2.3 ± 1.9	2.0 ± 1.3
	Δ = −1.0; $p = 0.022$		Δ = −2.0; $p = 0.027$		Δ = −0.3; $p = 0.593$	

Δ = change from Baseline after update.
*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, for between group comparisons (age-matched unilateral vs. bilateral).

TABLE 4 Results for SSQ items.

Item	Aggregate		Age-matched unilateral		Bilateral	
	Baseline	Final	Baseline	Final	Baseline	Final
Exertion during walking	3.0 ± 2.2	1.8 ± 1.1	3.2 ± 2.0	1.7 ± 0.7	2.8 ± 2.2	2.1 ± 1.6
	Δ = −1.2; $p = 0.012$		Δ = −1.6; $p = 0.041$		Δ = −0.7; $p = 0.380$	
Concentration during walking	2.4 ± 1.8	1.7 ± 1.4	2.2 ± 1.3	1.2 ± 0.7	2.3 ± 2.3	2.3 ± 2.2*
	Δ = −0.8; $p = 0.006$		Δ = −1.0; $p = 0.024$		Δ = 0.0; $p = 1.000$	
Walking safety	8.4 ± 2.6	9.7 ± 0.6	9.6 ± 0.7	9.7 ± 0.4	8.0 ± 3.0	9.8 ± 0.4
	Δ = +1.2; $p = 0.046$		Δ = +0.1; $p = 0.705$		Δ = +1.8; $p = 0.141$	
Walking stability	8.7 ± 2.1	9.6 ± 0.6	9.3 ± 0.7	9.7 ± 0.5	7.7 ± 3.2	9.6 ± 0.7
	Δ = +0.9; $p = 0.060$		Δ = +0.3; $p = 0.257$		Δ = +1.9; $p = 0.136$	
Walking comfort	8.3 ± 2.1	9.6 ± 0.6	8.6 ± 0.9	9.7 ± 0.4	7.8 ± 3.2	9.7 ± 0.7
	Δ = +1.4; $p = 0.002$		Δ = +1.1; $p = 0.020$		Δ = +1.9; $p = 0.136$	
Standing comfort	8.5 ± 1.8	9.5 ± 0.8	8.7 ± 1.3	9.4 ± 0.9	8.2 ± 2.7	9.6 ± 0.7
	Δ = +1.0; $p = 0.015$		Δ = +0.8; $p = 0.068$		Δ = ±1.3; $p = 0.197$	
Sitting comfort	8.7 ± 2.3	9.4 ± 1.1	9.2 ± 1.1	9.3 ± 0.5	8.8 ± 3.0	9.8 ± 0.4
	Δ = +0.7; $p = 0.039$		Δ = +0.1; $p = 0.564$		Δ = +1.0; $p = 0.414$	
Stability standing on ramps	7.0 ± 2.1	8.6 ± 1.7	8.1 ± 1.5	9.4 ± 0.8	5.8 ± 2.7	7.7 ± 2.5
	Δ = +1.6; $p = 0.001$		Δ = +1.3; $p = 0.031$		Δ = +1.9; $p = 0.074$	
Comfort standing on ramps	7.8 ± 1.8	8.4 ± 1.8	8.2 ± 1.6	9.0 ± 0.9	7.3 ± 2.3	7.7 ± 2.5
	Δ = +0.6; $p = 0.232$		Δ = +0.8; $p = 0.161$		Δ = +0.3; $p = 1.000$	
Overall prosthesis safely	8.2 ± 2.8	9.8 ± 0.4	8.6 ± 2.6	9.7 ± 0.4	8.0 ± 3.3	10.0 ± 0.0
	Δ = +1.6; $p = 0.009$		Δ = +1.1; $p = 0.236$		Δ = +2.0; $p = 0.109$	

Δ = change from Baseline after update.
*$p < 0.05$, for between group comparisons (age-matched unilateral vs. bilateral).

4 Discussion

The purpose of this study was to investigate the effectiveness of enhancements to the Genium and Genium X3 MPK to improve safety during stumbling and everyday walking in a group of subjects with both unilateral and bilateral TFA, and specifically to improve the prosthetic experience of bilateral prosthesis users. The first hypothesis that the enhancements would reduce stumbles and falls and would improve gait stability and comfort in the sample was partially supported in that stumbles were greatly reduced, and comfort and stability of walking improved as measured by the SSQ and ADL-Q but not by PLUS-M, ABC, and *L*-test. The already low baseline number of falls was also reduced, but not to a level of statistical significance. The second hypothesis that the enhancements would improve patient-reported ease and safety of ADL completion in a group of bilateral users compared to a control group of unilateral users was also partially supported. The subjects with bilateral amputation showed significantly greater improvements in ADL-Q results compared to unilateral users, but not with the other outcome measures. Device performance did not diminish following implementation of the enhancements which is evident in the absence of significant aggregate or within-group declines in outcomes during the study period.

The most notable improvement overall was observed in stumble reduction. Stumbles significantly decreased 85% on aggregate. As fall frequency was quite low for this sample at baseline, the further decrease by 36% with the investigational Genium was not statistically significant. It is possible the reduction in stumbles may have translated to a statistically significant reduction in falls with a larger sample or longer study period because stumbles have led to falls in up to 57% of subjects in previous studies (27).

TABLE 5 ADL-Q results.

Category	Ease			Safety		
	Aggregate	Age-matched unilateral	Bilateral	Aggregate	Age-matched unilateral	Bilateral
Personal care and dressing	0.09 ± 0.35	0.06 ± 0.33	0.14 ± 0.42	0.1 ± 0.36	0.06 ± 0.23	0.17 ± 0.51
Family role	0.99 ± 0.86	0.74 ± 0.81	1.56 ± 0.70***	1.08 ± 0.81	0.81 ± 0.62	1.56 ± 0.75***
Social and leisure activities	1.07 ± 0.74	0.89 ± 0.65	1.51 ± 0.73***	1.1 ± 0.78	0.89 ± 0.75	1.58 ± 0.69***
Shopping	1.07 ± 0.74	0.89 ± 0.65	1.51 ± 0.73***	1.1 ± 0.78	0.89 ± 0.75	1.58 ± 0.69***
Mobility	0.97 ± 0.78	0.88 ± 0.74	1.25 ± 0.81***	1.02 ± 0.81	0.9 ± 0.76	1.32 ± 0.82***
Transportation	0.6 ± 0.76	0.49 ± 0.69	0.93 ± 0.89*	0.63 ± 0.79	0.51 ± 0.69	1.00 ± 0.93*
Health related exercise	0.8 ± 0.82	0.73 ± 0.69	1.05 ± 0.85	0.8 ± 0.84	0.57 ± 0.77	1.22 ± 0.92**
Other activities	0.7 ± 0.76	0.65 ± 0.70	0.91 ± 0.82	0.71 ± 0.77	0.62 ± 0.73	0.98 ± 0.89*

*$p < 0.05$.
**$p < 0.01$.
***$p < 0.001$, for between group comparisons (age-matched unilateral vs. bilateral).

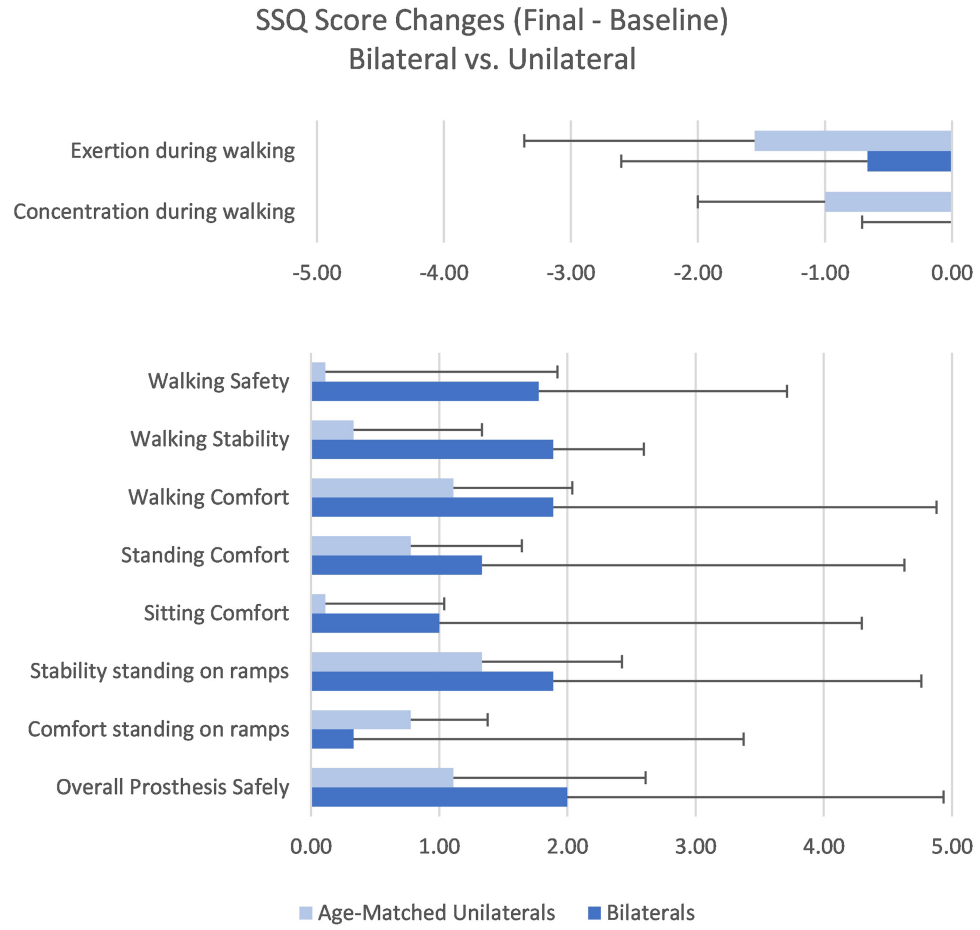

FIGURE 7
Study-specific questionnaire change scores.

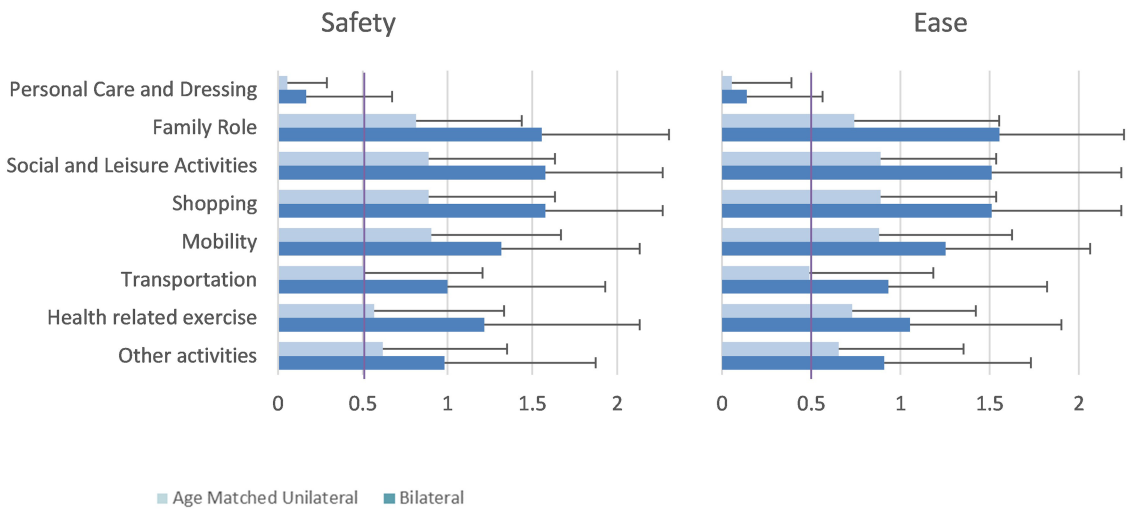

FIGURE 8
Comparative ADL-Q results.

TABLE 6 Utilization of MPK functions.

Function	Unilateral			Bilateral		
	Baseline	Final	±	Baseline	Final	±
Knee yielding down slopes	9	8	−1	9	9	0
Optimized stair ascent						
- Stair ascent	2	3	+1	7	8	+1
- Stepping over obstacles	3	5	+2	6	6	0

The baseline frequency from this sample is slightly less than a group of ($n = 19$) subjects with unilateral TFA using C-Leg MPKs reported by Kahle et al. in 2008 who fell 1 ± 2 times in a similar period (28). Much attention has been given to fall prevention as a safety concern in recent years due to associated healthcare cost and mortality. The Centers for Disease Control and Prevention reports $50B in costs associated with non-fatal falls and $754M with fatal falls in the United States each year (29). A study by researchers from The Mayo Clinic found cost associated with falls by individuals with TFA to be more expensive than falls in the able-bodied, $25,652 compared to $18,091 respectively (30).

Pain has a significant influence on quality of life worldwide, but especially in the United States where it is the single most heavily-weighted dimension of the EQ-5D index (31). Chronic low back pain and residual limb pain are of unique interest for individuals with amputation, particularly those with TFA (16, 17). Mean differences reflected improvement for residual limb pain and low back pain on aggregate as a result of the enhancements. This was mainly driven by an improvement in unilateral subjects as shown by the mean differences in the age-matched unilateral group. The improvements approached the level of clinical meaningfulness for residual limb pain and reached a level of "much better" improvement for lower back pain (32). While not specifically addressed in the study, the pain reduction in unilateral subjects may have been the effect of improved everyday walking with increased symmetry, either in gait parameters or ground reaction forces, which in turn would have the potential to reduce low back pain and residual limb pain in unilateral subjects through more symmetric muscle activation. Improvements in gait symmetry is a common conclusion from studies with Genium use (4). The links between unilateral amputation, TFA, and increased rates of gait asymmetry, low back pain, and stump pain have been established previously (33). Changes to prosthetic knee joints are not expected to improve symmetries in bilateral subjects when both knee joints are the same. This finding likely explains why unilateral subjects reported improved comfort, exertion, and concentration while walking in the SSQ, while bilateral users did not. Pain is a subjective perceptive phenomenon involving cognitive processing; therefore, if an aspect of prosthetic gait is causing discomfort, then concentration is directed there (34). Pain has also negatively influenced perceived exertion levels in other reports (35, 36). Reductions in pain can have meaningful impact not only in the lives of individual patients but also the general healthcare system because pain is responsible for higher costs annually than diabetes and heart disease in the United States with the largest portion of that being attributable to low back pain (37). Similar trends are found throughout the world (38).

While improvements in several areas were noted for all subjects, the user experience of the bilateral group was particularly insightful. While improvements in ease and safety of ADL execution were noted in all categories of the comparative ADL-Q in the aggregate analysis, the bilateral group experienced significantly greater relative improvements in ease of performing ADLs in five categories and safety of performing ADLs in all seven categories than the age-matched unilateral users. This is similar to prior work by Kannenberg et al. where ease and safety of all ADL-Q categories improved or did not reduce in a sample of subjects with TFA comparing the C-Leg™ MPK to Genium, although that sample had only unilateral users (26). The ADL-Q serves as an informative tool regarding patient-reported ease and safety of ADL completion and research is needed to evaluate its psychometric properties. As with the ADL-Q ratings, the bilateral group also reported greater improvements in most items of the SSQ and particularly for walking safety and stability compared to the unilateral group. Although the changes were not statistically significant, it is important to note that at the end of the study these ratings were all very close to the maximum possible score with all subjects in the bilateral group reporting a 10 out of 10 for "overall prosthesis safety." In contrast, the unilateral and bilateral groups were similar at baseline for "perceived exertion" and "concentration during walking," but the mean rating of the unilateral group improved by over 45% for both items whereas the bilateral group mean remained constant.

The lack of significant differences between the bilateral and unilateral groups with the PLUS-M, ABC, and SSQ suggests similarity in patient-reported end-user experience in all areas tested except for actual physical performance measured with the *L*-test. The functional gap between individuals with history of bilateral and unilateral TFA was noted both at baseline and at the final assessment which is consistent with the literature (39, 11, 12). *L*-test times found here were similar to those reported by Deathe, et al. who observed ($n = 46$) subjects under the age of 55 with unilateral TTA and TFA ambulating with a prosthesis required an average of 25.4 ± 6.8 s to complete the *L*-Test (19). The Deathe sample included only unilateral subjects at both the TFA and TTA levels (19). A fall risk threshold of 25.5 s for healthy elderly subjects has been established, and there is no corresponding value for individuals with amputation (20). The bilateral group in this study performed near this threshold while the unilateral group performed well under (21). The observation of a persistent gap in physical performance between groups is probably due to the absence or presence of an unaffected leg, respectively, and supports the exemption of patients with bilateral limb loss from the MFCL K-level system (40). This exemption was also emphasized by the Lower Limb Prosthetics Inter-agency workgroup in 2017 (41).

The combination of improvements measured by the ADL-Q and SSQ and lack of any real decline in the validated patient-reported measures between-groups shows there were improvements to the patient experience of bilateral TFA users which are not or cannot be captured with currently available validated outcome measures. The validated measures used in this study, the *L*-test, PLUS-M, and ABC, while not an exhaustive list, evaluate diverse aspects of

mobility, walking performance, and safety. This contrast of results between validated and study-specific OMs shows there is room for improvement in patient experience and product performance which can be achieved specifically when technological advancements are tailored to unique needs of sub-populations such as bilateral users, even when the users already appear to be functioning well. Further, current and commonly-used validated OMs may not be capturing discernable improvements in product function and aspects of daily life which are important to the end-user, specifically user-perceived safety, comfort, and ease of completing ADLs. Moreover, this discrepancy demonstrates the need for continual product improvement, even in the most advanced microprocessor-controlled components, to restore functional capacity and independence for patients—especially individuals with bilateral TFA.

4.1 Limitations

Since this study was supporting a product enhancement to determine its feasibility, sample size was based on stated needs of the product developers and not on a sample size calculation which is typically done in randomized clinical trials. Therefore, the overall sample of users with TFA ($n = 25$) and smaller sub-sample of bilateral subjects ($n = 9$) may have resulted in the study being underpowered. Further, users of the Genium and Genium X3 are usually MFCL K3 or higher and typically walk well, so there is not much room for improvement in functional performance which was evident in the baseline scores. While the mixed sample was necessary to determine the efficacy of this update, the heterogeneity somewhat limits the generalizability of aggregate findings for either group since they are clinically different.

A limitation of the Comparative ADL-Q is its direct comparison of recalled and concurrent experience which inherently introduces a bias. The experience with the existing prosthesis is recalled over an extended period whereas the experience with the experimental prosthesis is concurrent. Recalled ratings are often less accurate than concurrent ratings since the latter is fresh in the subjects' minds. This may also have affected the final question in the ABC regarding confidence walking on icy sidewalks because the baseline assessments occurred in spring and summer whereas final assessments occurred in winter. In this case the baseline assessment would be recalled and final assessment concurrent. This was the item of greatest improvement in the ABC, improving 46.9%–60.8%.

Subjects are also known to have an affinity for new technology which is referred to as pro-innovation bias (42). A common mitigation strategy is blinding. While blinding is typically not feasible in prosthetic studies due to the obvious differences in appearance of components, this enhancement was mostly internal and, hypothetically, could have been blinded (43). Lack of randomization or a crossover component also increases bias. However, the primary objective of the project was to confirm the feasibility of the enhancement. Therefore, the comparison of the enhancement between bilateral users and a control group of similar unilateral subjects was the most pragmatic solution.

An additional limitation was the use of the SSQ and ADL-Q in this study since the clinical meaning of unvalidated measures is obscure. Since this sample was high-functioning at baseline, a change in OMs validated in the population with limb loss was not expected and did not occur. However, the purpose of the enhancement was not necessarily to improve physical performance but rather to improve stability and comfort in several specific situations which would translate to improvements in perceived ease and safety of ADL completion. The ADL-Q has been used successfully in other studies comparing different MPKs (26). Further research to determine its psychometric properties may be warranted.

5 Conclusion

This study evaluated the implementation of a ruleset and hydraulics upgrade as well as bilateral parameter presets to the Genium^{TM} and Genium-X3^{TM}. Marked reductions in stumbles, residual limb pain, and back pain were shown overall. These reductions were driven by the results of the subjects with unilateral amputation who also showed improvements in comfort, exertion, and concentration while walking. Improvements in patient-reported ease and safety of completing ADLs were shown overall and were driven by the results of the subjects with bilateral amputation who had significantly greater relative improvements compared to the unilateral users. Finally, performance of the MPKs did not decrease following the enhancement.

Data availability statement

The datasets presented in this article are not readily available because the dataset is property of Otto Bock Healthcare LP. Requests to access the datasets should be directed to Tyler Klenow, tyler.klenow@ottobock.com.

Ethics statement

The studies involving humans were approved by WCG IRB, 212 Carnegie Center, Suite 301. Princeton, NJ 08540, USA. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

TK: Writing – original draft, Writing – review & editing. RL: Formal Analysis, Supervision, Visualization, Writing – review & editing. AM: Formal Analysis, Writing – review & editing. SP: Investigation, Writing – review & editing. CS: Investigation, Writing – review & editing. ET: Project administration, Writing – review & editing. AK: Writing – review & editing.

Funding

The authors declare financial support was received for the research, authorship, and/or publication of this article.

This study was funded by Ottobock Healthcare Products GmbH, Vienna, AT.

Conflict of interest

TK, RL, AM, and AK are employees of Otto Bock Healthcare LP, a subsidiary of Ottobock SE & Co. KGaA, the parent company of Ottobock Healthcare Products GmbH, which is the manufacturer of the Genium^{TM}, sponsored the study. EG is an employee of Ottobock Healthcare Products GmbH, which is the manufacturer of the Genium^{TM}. SP owns Prosthetic & Orthotic Associates and CS was employed by Dream Team Prosthetics, LLC which were compensated by the sponsor to participate as sites.

The authors declare that this study received funding from Ottobock Healthcare Products GmbH, Vienna, AT. The funders had the following involvement in the study: study design, data collection and analysis, and decision to publish.

Publisher's note

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 27 June 2024
DOI 10.3389/fresc.2024.1354115

OPEN ACCESS

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RECEIVED 11 December 2023
ACCEPTED 11 June 2024
PUBLISHED 27 June 2024

CITATION
Hovorka CF, Kogler GF, Chang Y-H and Gregor RJ (2024) Selective orthotic constraint of lower limb movement during walking reveals new insights into neuromuscular adaptation.
Front. Rehabil. Sci. 5:1354115.
doi: 10.3389/fresc.2024.1354115

Selective orthotic constraint of lower limb movement during walking reveals new insights into neuromuscular adaptation

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Introduction: A concern expressed by the clinical community is that the constraint of motion provided by an ankle foot orthosis (AFO) may lead the user to become dependent on its stiffness, leading to learned non-use. To examine this, we hypothesized that using an experimental AFO-footwear combination (exAFO-FC) that constrains ankle motion during walking would result in reduced soleus and tibialis anterior EMG compared to free (exAFO-FC) and control (no AFO, footwear only) conditions.
Method: A total of 14 healthy subjects walked at their preferred speed (1.34 ± 0.09 m·s-1) for 15 min, in three conditions, namely, control, free, and stop.
Results: During the stance phase of walking in the stop condition, ipsilateral soleus integrated EMG (iEMG) declined linearly, culminating in a 32.1% reduction compared to the control condition in the final 5 min interval of the protocol. In contrast, ipsilateral tibialis anterior iEMG declined in a variable fashion culminating in an 11.2% reduction compared to control in the final 5 min interval. During the swing phase, the tibialis anterior iEMG increased by 6.6% compared to the control condition during the final 5 min interval. The contralateral soleus and tibialis anterior exhibited increased iEMG in the stop condition.
Discussion: An AFO-FC functions as a biomechanical motion control device that influences the neural control system and alters the output of muscles experiencing constraints of motion.

KEYWORDS

ankle foot orthosis, neuromuscular, soleus, tibialis anterior, footwear

1 Introduction

Ankle foot orthoses (AFOs) are one of the most commonly prescribed orthoses (1), designed to provide stability to a user during standing while also optimizing gait when functional deficits (e.g., loss of dorsiflexion and loss of plantarflexion) are present. An AFO combined with footwear (AFO-FC) controls joint motion at the ankle and the

Abbreviations
Ag/Ag-Cl, silver/silver chloride; AFO, ankle foot orthosis; AFO-FC, ankle foot orthosis-footwear combination; ANOVA, analysis of variance; CPO, certified prosthetist and orthotist; EMG, electromyography; exAFO-FC, experimental ankle foot orthosis-footwear combination; Hz, Hertz; iEMG, integrated electromyography; IC, initial contact; *N*, sample size; SENIAM, European standards of surface EMG for non-invasive assessment of muscles; SOL, soleus; TA, tibialis anterior; TO, toe off; 3D, three dimensional.

knee in a prescribed manner to improve walking performance by minimizing or eliminating undesirable compensatory pathological gait patterns (2–16). Current clinical practice is informed by basic and intuitive mechanical solutions in movement control (e.g., assist, resist, and stop) (17) that have relatively predictable outcomes in gait mechanics. Unfortunately, this limited clinical perspective with a focus on joint position and mechanical control overlooks the neuromuscular and sensorimotor response mechanisms associated with ankle joint control. A small number of studies using passive AFOs (18) and footwear have examined subjects' neuromuscular output of muscles that act on the ankle by using electromyography (EMG) or other measures to describe the magnitude of muscle response (19–32). The goal of this investigation was to improve our understanding of neuromuscular output during the early adaptation period to the constraint of ankle joint motion by an AFO-FC. Our strategy was to use EMG to monitor muscle activation output based upon the premise that EMG records electrical signals in the muscle action potential and hence provides a window of nervous system control of muscle activation during movement. Accordingly, we sought to better understand the consequential neuromuscular considerations between constrained and unconstrained ankle motion using an AFO combined with footwear, by collecting EMG activity of lower limb muscles during treadmill walking in healthy subjects.

A concern expressed by the clinical community is that the constraint of motion provided by an orthosis may lead the user to be dependent on the stiffness and stability provided by the orthosis to the lower limb during standing and walking. This continued dependence over a prolonged period of AFO and footwear use will lead to learned non-use (33) and muscle atrophy (22, 31). Of these studies, the largest cohorts of subjects that used AFO-FCs were hemiparetic stroke survivors during the subacute phase of recovery. Reported results are conflicting. Murayama and Yamamoto (22) showed that subjects' use of an AFO-FC elicited differences in the EMG magnitude of the tibialis anterior muscle over 16 weeks, whereas Nikamp et al. (23) reported no difference in the magnitude of tibialis anterior activity after 26 weeks of AFO-FC use. Geboers et al. examined patients with lower limb peripheral neuropathy and reported a modest 6% decline in the EMG magnitude of the tibialis anterior muscle after 6 weeks of use of an AFO compared to a 20% decline in the EMG of the tibialis anterior muscle in patients that did not use an AFO (19). The optimal prescription recommendation for any individual type of AFO-FC design, including the dose of use (e.g., frequency, intensity, and duration), is critical to any schedule of neuromotor rehabilitation. To begin addressing these concerns, this study sought to characterize and quantify a relationship between the constraint of joint motion and neuromuscular output using EMG and motion capture. We hypothesized that the use of an experimental AFO-footwear combination (exAFO-FC) that constrained ankle motion during walking would reduce the magnitude of tibialis anterior and soleus muscle EMG compared to a free (exAFO-FC) condition and a control (no AFO, footwear only) condition.

2 Materials and methods

2.1 Subjects

A total of 14 healthy subjects with right leg dominance [eight females; six males; mean (standard deviation) ages, 21.04 (0.89) years; height, 171.19 (4.11) cm; mass, 65.74 (4.72) kg] gave written informed consent to participate in a protocol approved by the Georgia Institute of Technology Institutional Review Board.

2.2 Instrumentation, limb segment modeling, and computation

The study involved a 3D gait lab using six high-speed cameras (Vicon, Oxford, UK; 120 Hz) and 16 retroreflective markers (14 mm diameter) taped to the pelvis and lower limbs of subjects using a method modified by Kadaba et al. (34) to record joint motion. Specific anatomical sites for marker placement were as follows: anterior superior iliac spine, posterior superior iliac spine, thigh segment, knee joint center, shank segment, lateral malleolus, calcaneus, and second metatarsophalangeal joint (34). Because the visibility of markers attached to the skin of subjects' shank and foot regions was impeded by the AFO, to restore visibility, we attached markers to the exterior of the orthosis at the shank, lateral ankle joint, heel strap at the calcaneus, and forefoot strap at the dorsum of the second metatarsophalangeal joint.

A custom dual belt treadmill with embedded force plates, one under each belt (AMTI, Watertown, MA, USA; 1,080 Hz), was used to collect ground reaction forces, joint moments, and temporospatial parameters (i.e., stance duration, swing duration, and cadence). All data were collected in the Vicon workstation and motion data were processed using the plug-in-gait model to identify and label markers. All data were imported to MATLAB version 7.11.0 (The MathWorks Inc., Natick, MA, USA) for additional processing. Raw force signals were filtered (fourth-order Butterworth low-pass filter with a cutoff frequency of 20 Hz) and analyzed to determine ground reaction components and joint moments during the stance phase and to identify the duration of stance and swing phases. Motion data were filtered (fourth-order Butterworth low-pass filter with a cutoff frequency of 10 Hz) and analyzed to determine the angular motion of the ankle joint. All motion and force data were synchronized and time normalized to 100% of the gait cycle and analyzed using standard inverse dynamic calculations and estimated inertial characteristics based on subject-specific anthropometrics (35). Because the dominant motions of the ankle joint complex occur through the talocrural articulation as plantarflexion and dorsiflexion during gait, analysis of ankle motion was restricted to the sagittal plane (36, 37).

Activation of the tibialis anterior and soleus muscles was sampled on both legs using wireless electromyography (EMG) (Noraxon USA, Scottsdale, AZ, USA; 1,500 Hz) and bipolar Ag/Ag-Cl adhesive electrodes (Danlee Medical Products, Syracuse, NY, USA) incorporating 20 mm inter-electrode spacing were

adhered to the skin of subjects. We recorded kinematic, kinetic, and EMG data from each subject during the first 30 s of every minute as they walked on a treadmill at their self-selected speed.

2.3 Leg dominance and EMG

To account for any gait variations (38–40) (e.g., dominant vs. non-dominant) that may contribute to muscle adaptation, the dominant leg of each subject was identified by administering three motor tasks (ball kick, step ascent, and standing balance recovery) (41–44). Subjects with right leg dominance were selected for the study. We collected surface EMG of the principal single-joint muscles that provide ankle motion during walking (ipsilateral and contralateral soleus and tibialis anterior) because these muscles are likely to be influenced by the AFO (45) The surface electrode locations were determined by the principal investigator (CH) in accordance with the European standards of surface EMG for non-invasive assessment of muscles (SENIAM) to minimize impedance and maximize EMG signal fidelity (46). A ground electrode was attached to the skin of each subject's left leg at the proximal anteromedial plateau of the tibia. To minimize the risk of motion artifact, pre-amplifiers and EMG cables were wrapped and secured to the subjects' legs and adjusted to allow a typical range of hip, knee, and ankle motion for walking. To ensure fidelity and minimize cross talk, we visually inspected the EMG signals of each participant during manual muscle tests and 5 m overground walking tests prior to treadmill walking, moving electrode placement if needed.

2.4 Preferred walking speed

Preferred walking speed was determined by administering three trials of the 10 m walk test for overground walking (47). The mean overground walking speed was then matched to individuals' treadmill speeds by adapting a method described by Amorim et al. (48).

2.5 Experimental AFO and footwear

An experimental AFO (exAFO) with integrated footwear (total mass of 1.76 kg) was designed and created to fit the right (dominant side) leg of all subjects. To achieve this, the AFO included sufficient adjustability at the foot and shank to provide an intimate fit and to provide multiple motion control conditions including maximum constraint of ankle motion in a stop condition and free ankle motion in a free condition through an adjustable clamp and low-friction sliding bearing system (3). To minimize the variability of footwear and limb length and to maintain rollover dynamics when the ankle was constrained by the AFO, we integrated a footwear system. The motion control performance of the experimental AFO-footwear combination (exAFO-FC) was validated in quasistatic loading experiments using cadaveric limbs and human subject treadmill walking experiments in an instrumented gait lab (3).

To ensure proper fit of the exAFO-FC and congruency between the anatomical and orthotic ankle joints, subject inclusion criteria specified a range for individual foot length, ankle height, and calf girth. More specifically, key design features were included in the experimental AFO-FC to minimize displacement of subjects' shank and foot. For example, an adjustable heel strap secured the hindfoot, an adjustable dorsal foot strap secured the midfoot, a rigid foot shell secured the forefoot, and a rigid shank shell with an adjustable tibial plate secured the leg. An adjustable linear slide bearing was anchored between the shank and foot shells to maximally constrain ankle motion (clamps secured) or to allow free ankle motion (clamps removed).

Alignment of the exAFO-FC in the stop condition, for all 14 legs, was set at a shank-to-vertical angle 10° incline (i.e., modest ankle dorsiflexion angle) based on the findings reported by Owen (4) to facilitate rollover during stance phase. The experimental AFO-FC was necessary for this study as commercial and custom orthoses with integrated footwear were neither available nor were they validated to meet the rigorous requirements for ankle motion control and stance phase rollover performance for this study.

2.6 Experimental protocol

The subjects were tested walking at their preferred speed (1.34 ± 0.09 m·s-1) for 15 min, in three conditions, namely, control (bilateral footwear combination, no AFO), free (use of contralateral footwear with ipsilateral AFO-FC in no constraint condition), and stop (use of contralateral footwear with ipsilateral AFO-FC in maximal constraint) (Figure 1). To wash out the carryover effects between the stop and free conditions, the subjects walked at their preferred speed (1.34 ± 0.09 m·s-1) for 15 min in the control condition. The order of the two exAFO-FC conditions was randomized to minimize the order effects.

2.7 Data processing and analysis

All motion and force data in the sagittal plane and all EMG data were synchronized, filtered, and time normalized to 100% of the gait cycle. The mean ground reaction force, moments, and angles, for the stop and free conditions and the 95% confidence interval for the control condition were calculated. The mean ankle range of motion (ROM) in each condition was analyzed using repeated measures ANOVA with Bonferonni *post hoc* comparison.

Raw EMG data for all subjects' soleus and tibialis anterior muscles were synchronized with force and motion data in the Vicon workstation and were exported offline to MATLAB version R2009a (The MathWorks Inc., Natick, MA, USA) for further processing. The raw EMG data (Figure 2A) were adjusted for voltage offsets, full wave rectified, and band-pass filtered with frequency cutoffs at 10–500 Hz (Figure 2B), followed by the application of a fourth-order Butterworth filter with zero lag at a cutoff frequency of 20 Hz to obtain linear envelopes and

FIGURE 1
Experimental AFO and footwear conditions. Subjects treadmill walked in the control condition (use of bilateral footwear, no AFO), stop condition (use of contralateral footwear with ipsilateral AFO and integrated footwear in maximal constraint with clamps installed in linear slide bearing), and free condition (use of contralateral footwear with ipsilateral AFO and integrated footwear in no constraint condition with clamps removed from linear slide bearing).

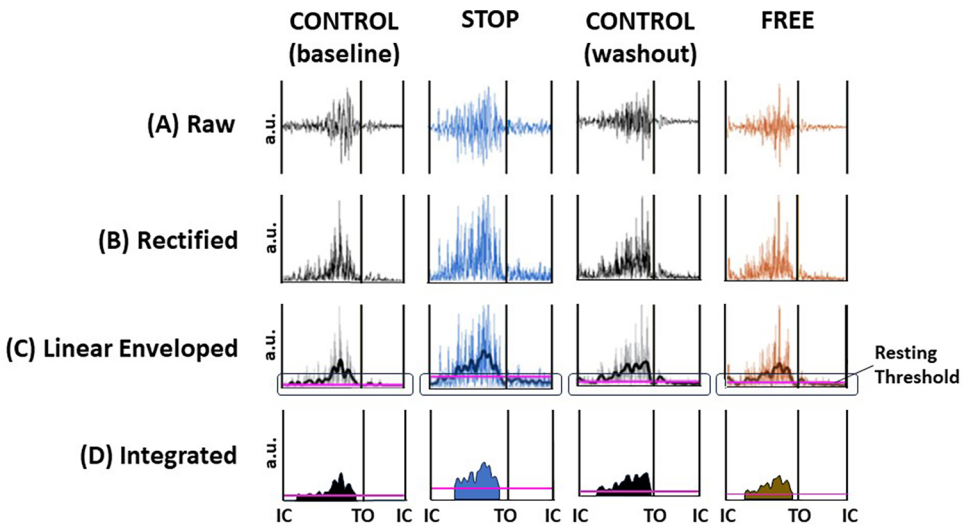

FIGURE 2
Digital signal processing of EMG data. Exemplar data of a subject's ipsilateral soleus muscle during minute 13, gait cycle 9 in the control (baseline), stop, control (washout), and free conditions. (A) raw EMG, (B) full wave rectified EMG, (C) band-pass and low-pass filtering to render a linear enveloped EMG (jagged line). Resting threshold (horizontal purple line encircled) to identify the onset and termination of each burst activation period. (D) Integrated EMG (iEMG) is calculated as the integration of the linear enveloped area of EMG and represents the quantity of the area under the rectified and enveloped EMG and hence the quantity of total activation. Resting threshold (horizontal purple line). The black vertical lines represent initial contact (IC) and toe off (TO) events of the gait cycle; voltage in arbitrary units (au).

rectification to adjust for signal offsets due to enveloping the data (Figure 2C). The cutoff frequency of 20 Hz was selected because it produced smoothed signals that closely represented the shape of each muscle's raw EMG tension curves while still retaining the signals' critical temporal characteristics. A resting threshold was calculated to identify the onset and termination of muscle burst activation (49–52). The area under the rectified and linear enveloped EMG during each burst activation period was calculated as the integrated EMG (iEMG) (Figure 2D). Hence, the iEMG was a representation of the quantity of each muscle's total activation during the burst activation period.

2.8 Analysis of soleus and tibialis anterior iEMG during each step

In the first analysis, we quantified and characterized subjects' tibialis anterior and soleus muscle adaptation during each step in each condition (e.g., control, free, and stop). We calculated each subject's integrated EMG during each burst activation period of the tibialis anterior and soleus muscles of ipsilateral and contralateral legs in the control, free, and stop conditions throughout the 15 min walking period. Due to the occasional loss of EMG signal fidelity, the iEMG data were collapsed into

seven continuous gait cycle intervals. The baseline reference value was calculated as the mean of the pooled iEMG of both legs (ipsilateral and contralateral) of all subjects in the control condition for the entire 15 min walking period. We calculated the mean iEMG of all subjects for the respective leg (ipsilateral and contralateral) and muscle (tibialis anterior and soleus) in each of the seven gait cycle intervals for each condition (control, free, and stop).

2.9 Analysis of the relationship of soleus and tibialis anterior iEMG and ankle ROM during the last 5 min

In the second analysis, we quantified the relationship between subjects' tibialis anterior and soleus muscle and ankle ROM during the final 5 min in each condition (e.g., control, fee, and stop). We selected the final 5 min for comparative analysis. This interval was selected because subjects exhibited the least variability in ankle motion, which is an indication that steady-state gait was achieved. A baseline reference value (mean control) was calculated as the pooled iEMG of both legs (ipsilateral and contralateral) of all subjects ($n = 14$) in the control condition and as the pooled ankle ROM. For all subjects ($n = 14$), we calculated the mean iEMG for each leg (ipsilateral and contralateral), each muscle (tibialis anterior and soleus), and each condition (control, free, and stop). We analyzed the difference in subjects' mean iEMG during each condition (control, free, and stop) using a one-tailed, paired student's *t*-test. We similarly analyzed the difference in the subject's mean ankle ROM. All EMG and muscle activation data were analyzed using SPSS (IBM SPSS Statistics for Windows, version 21.0, Armonk, NY, USA).

3 Results

3.1 Force, motion, and temporal-spatial outputs during gait

Subjects' use of an experimental AFO-footwear combination elicited a substantial decrease in ipsilateral ankle ROM, to within a mean (standard deviation) of 3.7 (2.1)° in stop, compared to 27.7 (4.2)° in control ($p = 0.000$), and 24.2 (3.6)° in free ($p = 0.091$). There were no differences in ipsilateral ankle moments ($p > 0.05$) and no difference in ankle motion and moments in the three conditions on the contralateral leg ($p > 0.05$). Additionally, there were no differences ($p > 0.05$) in step length, but significant ($p < 0.05$) yet modest differences in stance duration (4%) and swing duration (6%) were elicited by subjects during gait, which suggests a near absence of compensatory movements. The force, motion, and temporospatial outputs reported were during the fourth minute of walking, which was the onset of steady-state gait. Steady-state gait was determined as the onset of minimal variability which began in the fourth minute and remained consistent for the remainder of the 15 min walking period. Additional details regarding these findings are available in a prior published study (3).

3.2 EMG of soleus and tibialis anterior muscles during gait

3.2.1 Integrated EMG of soleus and tibialis anterior muscles during continuous stepping

The magnitude of integrated EMG of subjects' tibialis anterior and soleus muscles during continuous stepping revealed notable differences between ipsilateral and contralateral legs and between conditions during the 15 min walking period. Walking in the stop condition, the ipsilateral soleus muscle elicited an immediate decrease in iEMG below baseline and a continued gradual decline through the end of the walking period. Conversely, the magnitude of iEMG of the contralateral soleus muscle in the stop condition elicited an immediate increase above baseline, followed by a gradual return to baseline by the end of the walking period. In the free condition, the magnitude of iEMG of subjects' ipsilateral soleus muscle remained at baseline for the first minute followed by a gradual decline below baseline through the remainder of the 15 min walking period (Figure 3). The magnitude of subjects' iEMG of the contralateral soleus muscle in the free condition elicited an immediate increase above baseline followed by a return to baseline at the fourth minute of walking and remained at baseline for the remainder of the walking period (Figure 3). In the control condition, subjects' iEMG of the ipsilateral and contralateral soleus muscles exhibited an immediate increase above baseline followed by a return to baseline by the fourth minute, which persisted at or near the baseline for both legs for the remainder of the walking period (Figure 3).

Because the tibialis anterior muscle elicited activation in stance and swing, iEMG outputs were evaluated independently in the stance and swing phases of gait. Walking in the stop condition during the stance phase elicited an immediate decrease in subjects' iEMG of the ipsilateral tibialis anterior muscle followed by a pattern of variable increase above baseline and decrease below baseline, which persisted to the completion of the 15 min walking period. Conversely, subjects' iEMG of the contralateral tibialis anterior during the stance phase exhibited an immediate increase above baseline during the first 5 min of walking followed by a pattern of variable increase above and decrease below baseline, which persisted during the final 10 min of walking in the stop condition (Figure 4). The free condition elicited an immediate increase in subjects' iEMG of the ipsilateral tibialis anterior during the stance phase followed by a gradual decline below baseline. Walking in the free condition during the stance phase, subjects' iEMG of the ipsilateral tibialis anterior exhibited an immediate increase above baseline followed by a gradual decline below baseline, which persisted to the 15th minute of walking. In the free condition during the stance phase, subjects' contralateral tibialis anterior muscle iEMG exhibited an immediate yet modest increase in activation above baseline followed by a variable pattern of decrease below baseline and

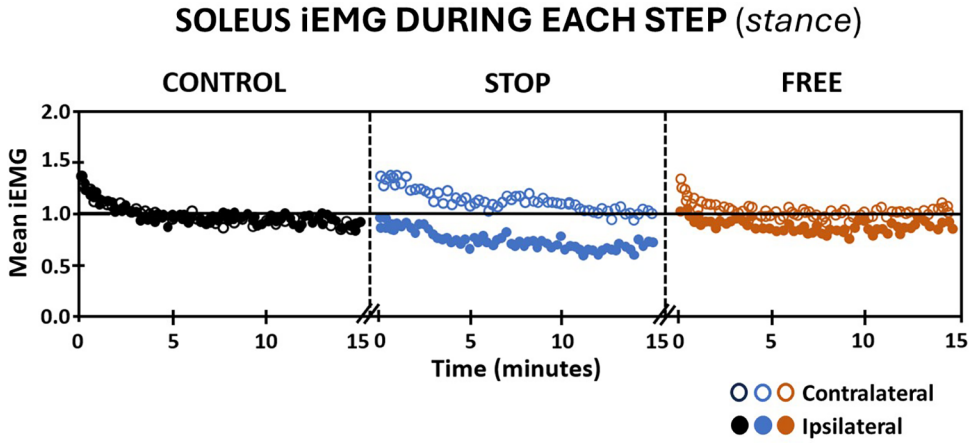

FIGURE 3
Soleus muscle activation (mean iEMG) during each step (stance phase) in the control (black), stop (blue), and free (brown) conditions during walking for all subjects ($n = 14$). Note the ipsilateral leg (closed circles) and contralateral leg (open circles). Each symbol is the mean iEMG for seven continuous gait cycle intervals. Baseline (horizontal black line) is the aggregate mean iEMG of both legs (ipsilateral and contralateral) soleus muscles in the control condition during the entire 15 min walking period.

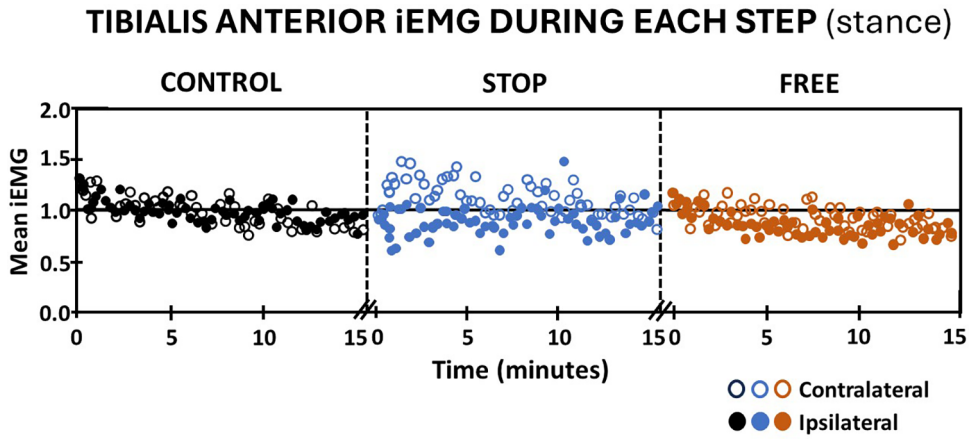

FIGURE 4
Tibialis anterior muscle activation (mean iEMG) during each step (stance phase) in the control (black), stop (blue), and free (brown) conditions during walking for all subjects ($n = 14$). Note the ipsilateral leg (closed circles) and contralateral leg (open circles). Each symbol represents the mean normalized iEMG for seven continuous gait cycle intervals. Baseline (horizontal black line) is the aggregate mean iEMG of both legs (ipsilateral and contralateral) soleus muscles in the control condition during the entire 15 min walking period.

increase above baseline (Figure 4). In the control condition, subjects' iEMG of ipsilateral and contralateral tibialis anterior muscle during the stance phase exhibited an immediate increase followed by a gradual decline to baseline by the 15th minute (Figure 4).

Walking in the stop condition during the swing phase, subjects' iEMG of the ipsilateral tibialis anterior elicited an immediate increase followed by a gradual return to baseline, whereas the contralateral tibialis anterior in the stop condition, elicited an immediate and sustained increase in iEMG above baseline (Figure 5). In the free condition, subjects' iEMG of the ipsilateral tibialis anterior exhibited an immediate and substantial increase followed by a gradual decline that remained above baseline throughout the entire 15 min of walking. On the contralateral leg in the free condition, there was an immediate increase in iEMG of the tibialis anterior during swing followed by a return to baseline by the 15th minute of walking. Subjects' iEMG of ipsilateral and contralateral tibialis anterior muscle in the control condition during the swing phase of gait exhibited an immediate increase above baseline followed by a gradual return to at or near baseline in each leg (Figure 5).

3.2.2 Integrated EMG of soleus and tibialis anterior muscles during final 5 min of walking

To further quantify neuromuscular adaptation during walking, the subjects' mean integrated EMG of tibialis anterior and soleus muscles in the stop and free conditions were calculated relative

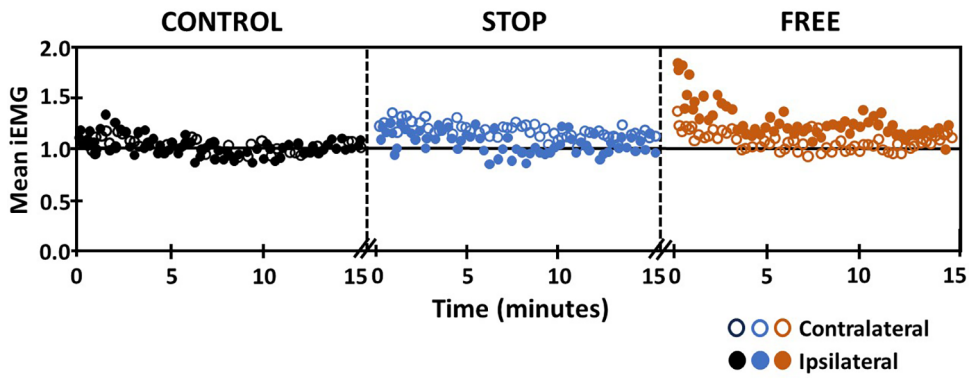

FIGURE 5
Tibialis anterior muscle activation (mean iEMG) during each step (swing phase) in the control (black), stop (blue), and free (brown) conditions during walking for all subjects ($n = 14$). Note the ipsilateral leg (closed circles) and contralateral leg (open circles). Each symbol represents the mean normalized iEMG for seven continuous gait cycle intervals. Baseline (horizontal black line) is the aggregate mean iEMG of both legs (ipsilateral and contralateral) tibialis anterior muscles in the control condition during the entire 15 min walking period.

to the control condition during the final 5 min. The final 5 min was selected for analysis because subjects achieved a steady state of iEMG and ankle ROM during this period compared to the prior 10 min of walking.

During the final 5 min in the stop condition when ankle motion was constrained to mean (standard deviation) 13.1 (2.8)% of the total ROM, subjects' ipsilateral soleus muscle iEMG mean (standard deviation) declined to 67.9 (8.9)% relative to the control condition during the stance phase of gait (Figure 6). In the free condition, when ankle motion was 90.1 (20.1)% of ROM, the ipsilateral soleus muscle iEMG declined to 88.4 (9.2)% relative to the control condition. The difference between ipsilateral soleus iEMG in the stop condition compared to the free condition was significant ($p = 0.000$). On the contralateral leg in the stop condition, the ankle ROM was modestly increased to 104.5 (19.3)% and iEMG was increased to 102.1 (9.4)% in the control condition. In the free condition on the contralateral leg, ankle motion also similarly increased to 107.9 (21.4)% and iEMG increased to 108.1 (8.9)% in the control condition, respectively. There was no difference ($p > 0.05$) in ankle motion and no difference ($p > 0.05$) in iEMG of the soleus muscle between the stop and free conditions on the contralateral leg (Figure 6).

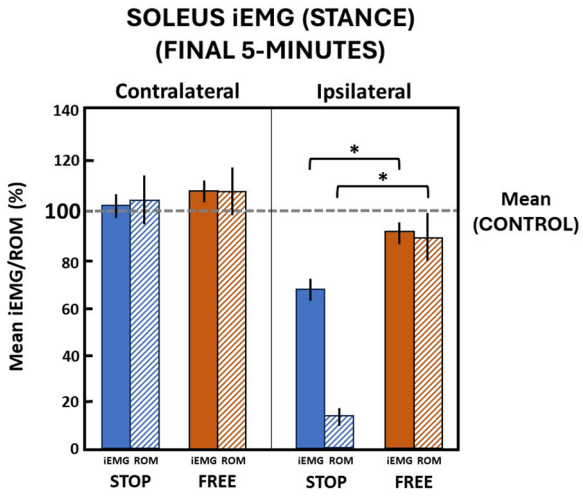

FIGURE 6
Soleus muscle activation (mean iEMG) in the final 5 min during the stance phase. The horizontal dashed line is the aggregate mean of both legs' ROM and iEMG expressed as 100% in the control condition. All values relative to the control condition (%). * indicates significance ($p < 0.05$). Ankle range of motion (ROM) and iEMG (%) in the stop (blue) and free (brown) conditions in the ipsilateral (solid) and contralateral (diagonally hatched) legs of all subjects ($n = 14$) during the last 5 min.

In the final 5 min in the stop condition when ankle motion was constrained to 13.1 (2.8)% of the ROM, subjects' ipsilateral tibialis anterior muscle iEMG declined to 88.8 (15.4)% relative to the control condition during the stance phase of gait (Figure 7). In the free condition, when ankle motion was 90.1 (20.1)% of the ROM, the ipsilateral tibialis anterior muscle iEMG modestly declined to 95.5 (18.6)% relative to the control condition. Despite a significant ($p = 0.000$) difference between ankle motion in stop and free conditions, there was no difference ($p > 0.05$) in the ipsilateral tibialis anterior muscle iEMG between the stop and free conditions.

On the contralateral leg in the stop condition, the ankle ROM was modestly increased to 106.8 (7.5)% and iEMG of the tibialis anterior was increased to 109.1 (8.5)% of the control condition during the stance phase. In the free condition on the contralateral leg during the stance phase, ankle motion increased to 108.7 (10.1)% and iEMG declined to 99.2 (10.3)% in the control condition. There was no difference ($p > 0.05$) in ankle motion and no difference ($p > 0.05$) between iEMG of the tibialis anterior muscle in the stop and free conditions on the contralateral leg during the stance phase (Figure 7).

Walking in the final 5 min in the stop condition when ankle motion was constrained to 13.1 (2.8)% of the ROM, subjects'

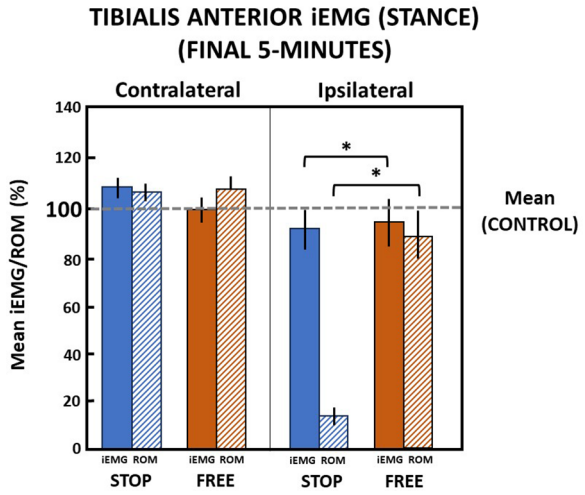

FIGURE 7
Tibialis anterior muscle (mean iEMG) during the stance phase in the final 5 min. The horizontal dashed line is the aggregate mean of both legs' ROM and iEMG expressed as 100% in the control condition. All values relative to the control condition (%). *indicates significance ($p < 0.05$). Percent of ankle range of motion (ROM) and percent of iEMG in the stop (blue) and free (brown) conditions in the ipsilateral (solid) and contralateral (diagonally hatched) legs of all subjects ($n = 14$) during the last 5 min.

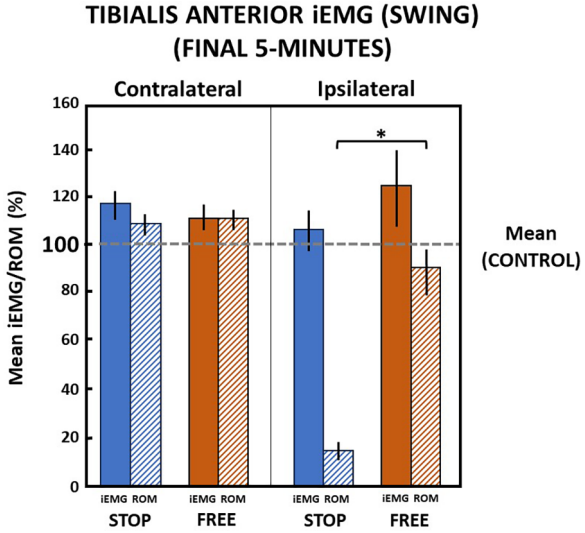

FIGURE 8
Tibialis anterior muscle (mean iEMG) during swing phase in the final 5 min). The horizontal dashed line is the aggregate mean of both legs' ROM and iEMG expressed as 100% in the control condition. All values relative to the control condition (%). *indicates significance ($p < 0.05$). Percent of ankle range of motion (ROM) and percent of iEMG in the stop (blue) and free (brown) conditions in the ipsilateral (solid) and contralateral (diagonally hatched) legs of all subjects ($n = 14$) during the last 5 min.

ipsilateral tibialis anterior muscle iEMG increased to 106.6 (17.1)% relative to the control condition during the swing phase of gait (Figure 8). In the free condition, when ankle motion was 90.1 (20.1)% of the ROM, the ipsilateral tibialis anterior muscle iEMG notably increased to 123.7 (32.4)% relative to the control condition. Despite a significant ($p = 0.000$) difference between ankle motion in stop and free conditions, there was no difference ($p > 0.05$) in the ipsilateral tibialis anterior muscle iEMG between stop and free conditions during the swing phase (Figure 8).

On the contralateral leg in the stop condition, the ankle ROM moderately increased to 110.2 (9.9)% and iEMG of the tibialis anterior moderately increased to 118.5 (12.5)% of the control condition during the swing phase. In the free condition on the contralateral leg during the swing phase, ankle motion similarly increased to 111.9 (9.5)% and iEMG increased to 111.8 (11.2)% in the control condition. There was no difference ($p > 0.05$) in ankle motion and no difference ($p > 0.05$) between iEMG of the tibialis anterior muscle in stop and free conditions on the contralateral leg during the swing phase (Figure 8).

4 Discussion

Traditionally most orthotic interventions are founded on the mechanics of body segment and joint motion control with little or no consideration of the consequential sensorimotor response to a particular orthotic intervention. This narrow clinical perspective is due, in part, to our limited knowledge of the neuromuscular mechanisms associated with the use of orthoses and footwear. Only three studies investigated the lower limb muscle EMG of healthy subjects using an AFO (28, 29, 32). While these investigations evaluated healthy subjects, the methods were substantially different such that they employed non-standardized footwear, substantially different AFO designs providing variable ankle motion control, and different methods of EMG digital signal processing and analysis. Given the numerous differences, comparisons of these studies to findings in our investigation are difficult to interpret.

Data from our investigation supports an emergent theory that when ankle joint motion is constrained by the use of a lower limb orthosis during walking, skeletal muscle activation of uni-articular muscles acting on the constrained ankle joint is altered compared to unconstrained walking. A summary of preliminary findings including a description of the characteristics of an orthosis-induced neuromotor response mechanism due to constraint of ankle motion is described.

The constraint of ankle joint motion of subjects walking in the exAFO-FC altered the activation of the soleus and tibialis anterior muscles. During the stance phase of walking in the AFO and footwear conditions, the ipsilateral soleus muscle iEMG progressively declined linearly over continuous steps, culminating in a 32.1% reduction compared to the control condition in the final 5 min of a 15 min protocol. The ipsilateral tibialis anterior muscle iEMG declined 11.2% in the final 5 min of walking, compared to the control condition. Unlike the linear decline over continued steps observed by the ipsilateral soleus muscle, the iEMG output of the ipsilateral tibialis anterior muscle was highly variable in the same respective test parameters. During the swing phase walking during maximal constraint of ankle joint motion

in the AFO, the ipsilateral tibialis anterior muscle again exhibited a high variation in iEMG during continuous stepping. This culminated in a 6.6% increase in iEMG compared to the control condition during the final 5 min of the 15 min period of walking. Hence, during the swing phase, the tibialis anterior muscle demonstrated an increase in iEMG in the final 5 min compared to declines in iEMG exhibited by the soleus and tibialis anterior muscles during the stance phase of gait.

These findings may not have been observed previously because the study described herein used a novel AFO specifically designed to optimize ankle joint constraint of motion. Additionally, the experimental protocol employed continuous sampling of muscle EMG during walking, which was well-suited to study neuromuscular behavior to the constraint of motion. Further discussion of the soleus and tibialis anterior muscle response coupled with the specialized ankle motion constraint design and performance of the experimental AFO and integrated footwear help explain the clinical implications ascertained from the preliminary results in this investigation.

Our investigation leveraged an AFO that delivered near-total ankle constraint of plantarflexion and dorsiflexion motion during gait. An experimental AFO-footwear combination was developed, rigorously tested, and validated to restrict ankle movement to less than 4° of dorsiflexion and plantarflexion motion (3). The AFO and integrated footwear were assessed in two performance studies: (a) a quasistatic loading study using cadaveric limbs to quantify the motion control capability of the experimental AFO and (b) a gait study involving human subjects to quantify the combined effectiveness of the exAFO and integrated footwear for motion control and preservation of rollover. These studies provided supportive evidence that the footwear design features contribute to maintaining rollover and minimized interruption of forward progression, despite the restriction of ankle motion provided by the exAFO-FC (3).

Our approach to collecting and analyzing muscle EMG was based on the premise that EMG samples the muscle's electrical activity and is representative of muscle action potentials. Hence, sampling and analysis of muscle EMG can provide insights into the neural control system and its influence on neuromuscular output. Based on this premise, we applied a twofold method of examining muscle EMG. First, we characterized the neuromuscular response of the soleus and tibialis anterior muscles to the motion control conditions (control, stop, free) by collecting and analyzing EMG during continuous stepping in a 15 min walking protocol. Second, we quantified the muscle EMG and collapsed these data in the final 5 min interval of walking as a representation of the adaptation of each muscle to the experimental conditions.

The twofold method of examining the EMG of soleus and tibialis anterior muscles during the walking protocol yielded data sets that enabled the interpretation of their neuromuscular behavior and adaptation to the constraint of motion. Key findings from this analysis are that the ipsilateral soleus and tibialis anterior exhibit different patterns of output to the constraint of motion. During the stance phase, the soleus muscle exhibits a linear and non-variable decline during continuous stepping in the AFO and footwear whereas the tibialis anterior muscle exhibits a highly variable decline. The decline in soleus muscle activation is nearly three times the magnitude of the decline in tibialis anterior muscle activation. In the swing phase, the ipsilateral tibialis anterior muscle demonstrates a variable increase (rather than decrease) in activation during the 15 min walking period. This suggests that despite similarities as one-joint muscles that typically engage in eccentric lengthening contraction during the stance phase, the soleus and tibialis anterior muscle iEMG during constraint of motion is altered in a way that regulates the magnitude of activation differently. Furthermore, the phase of gait during constraint of motion may influence the direction of neuromuscular output during constraint of motion (e.g., stance phase decline and swing increase). Finally, the magnitude of the constraint of motion appears to relate to the magnitude of the decline in muscle activation. This is supported by iEMG of subjects walking in the free condition where ankle motion was minimally constrained and was similar to the control condition. During minimal constraint of ankle motion by the AFO in the free condition, the ipsilateral soleus and tibialis anterior muscles exhibited only modest decreases in iEMG during the stance phase of gait. Conversely, walking in the free condition during the swing phase, the ipsilateral tibialis anterior muscle exhibited a substantial increase in activation. This may be due in part to the inertial effects of the AFO evoking increased activation of the muscle to dorsiflex the ankle and lift the mass of the foot and AFO to ensure foot clearance from the ground.

A plausible explanation and perhaps a limitation of the study may relate to the mass of the exAFO-FC. The majority of the mass in the experimental AFO and footwear system was due to the adjustable ankle motion linear bearing component located at the shank. This was a favorable location because it concentrated the mass in a more proximal position on the leg (as opposed to the ankle). We conducted a pilot study of 14 healthy subjects walking in the exAFO and in a control (no AFO) condition to examine the potential for inertial effects. We found no differences ($p > 0.05$) in subjects' heart rate, perceived exertion, preferred overground walking speed, and cadence, yet there were modest but significant ($p < 0.05$) differences in stance duration (4%) and swing duration (6%). A portion of these findings appear in a prior study (3).

Other investigators studied inertial effects by incrementally varying the location of mass added to the leg of healthy subjects and found steadily increasing metabolic costs with more distal placement due to changes in the moment of inertia (53). Skinner and Barrack reported the addition of 1.82 kg mass of a single leg at the ankle of healthy subjects elicited a modest (7%) increase in oxygen consumption but no difference ($p > 0.05$) in velocity, cadence, stride length, gait cycle, and double-limb support time (54). They did report alterations in single limb support time (decreased) and swing phase (increased) compared to the control (no added weight) condition. Based on the comparison of these findings to our study, the concentration of mass in the exAFO-FC at the shank likely minimizes inertial effects and their influence on the gait of subjects. This is supported by subjects demonstrating modest differences in stance (4%) and swing (6%) phase duration and no differences in walking speed, cadence, heart rate perceived exertion, and preferred speed in exAFO-FC compared to the control (no AFO) condition.

A likely explanation for the decline in EMG activity during constraint of joint motion is that the orthosis provides external biomechanical stabilization of the ankle joint, which (without the orthosis) is normally provided through muscular action. During orthosis use, the neural control system responds in a way to minimize the effort needed when the ankle joint can be stabilized without neuromuscular activity. The magnitude of the decline is somewhat proportional to the magnitude of the motion constraint. The greater the constraint of ankle motion (e.g., stop condition) evokes a greater decline in neuromuscular activity, whereas the lower the level of ankle constraint of motion (e.g., free condition) evokes a lower decline in neuromuscular activity. This may not be surprising but in this specific clinically relevant context, the physiological adaptation in response to mechanical constraint results in reduced muscle activity.

Key findings of the contralateral leg iEMG align with findings from the ipsilateral leg iEMG and further support the proposed adaptation to the constraint of motion using the experimental AFO and integrated footwear. During maximal constraint of motion of the ipsilateral leg, iEMG of the contralateral soleus and tibialis anterior muscles during the stance phase exhibited an increase above baseline during continuous stepping that declined near baseline at the end of the 15 min walking period. Similar to the ipsilateral leg, the contralateral soleus muscle exhibited a linear pattern of decline, and the contralateral tibialis anterior exhibited a variable pattern of decline respectively. During the swing phase, the contralateral tibialis anterior iEMG followed a similar pattern as during the stance phase on the contralateral side. Hence, an adaptive change in iEMG output during use of the AFO and footwear occurred in the contralateral soleus and tibialis anterior muscles in a similar fashion to the ipsilateral leg. To further complement these EMG results, the ankle joint motion and moments were no different ($p > 0.05$) in the contralateral leg when subjects walked in the experimental conditions [i.e., AFO in maximal ankle constraint (stop condition) and free ankle motion (free condition)] compared to the control (no AFO) condition (3). This supports that the contralateral leg did not experience notable compensatory movements despite the orthotic constraint of ankle motion on the ipsilateral leg.

The implications of these findings are that unilateral constraint of lower limb motion using an AFO and footwear during walking influences the neuromuscular behavior of skeletal muscles on both lower limbs. Generally, the pattern of behavior is a decline in neuromuscular activity on the ipsilateral constrained leg and an increase in neuromuscular activity on the contralateral leg.

5 Conclusion

When an orthosis constrains ankle joint movement during walking, an adaptative neuromotor response mechanism will alter neuromuscular output with progressive stepping (e.g., 15 min of walking) that changes iEMG activity compared to an unconstrained control. Clinicians need to be cognizant of this adaptive response period when planning treatments, particularly in users who do not have a neuromotor deficit. Additionally, the motion blocking and footwear features incorporated into an orthosis system are likely critical factors to the effectual neuromotor response of the user. Further study of these parameters in clinical populations is needed to confirm the findings in this study of healthy subjects.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the Institutional Review Board of the Georgia Institute of Technology. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

CH: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. GK: Methodology, Writing – original draft, Writing – review & editing. Y-HC: Formal Analysis, Supervision, Writing – review & editing. RG: Writing – review & editing.

Funding

The authors declare financial support was received for the research, authorship, and/or publication of this article.

This research was supported by the American Orthotic and Prosthetic Association, Center for Learning Evidence-Based Practice Grants (COPL-EBP 04310; COPL-EBP 043011 and COPL-EBP 043012), a National Science Foundation Grant HRD-0450303; and the Oak Ridge Institute for Science and Education (ORISE).

Acknowledgments

We would like to thank Mindy Millard-Stafford and Steven Wolf from the Georgia Tech School of Biological Sciences Faculty for their feedback regarding the study, in addition to the members of the Georgia Tech Comparative Neuromechanics Lab (Megan Crawford, Katie Eckert, Morgan Hinchey, Marina Musicus, Anthony Nguyen, Heather Noyes, Simisola Oludare, Nafiz Sheikh, Nitesh Singh, Jaemin Sung, Tiffany Yan, Vladislav Voziyanov, Tracy Norman, and Brian Selgrade) and members of the Georgia Tech School of Biological Sciences (Scott French, T. Richard Nichols, and Teresa Snow) for their assistance.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Original Research
PUBLISHED 12 July 2024
DOI 10.3389/fresc.2024.1354069

OPEN ACCESS

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RECEIVED 11 December 2023
ACCEPTED 25 April 2024
PUBLISHED 12 July 2024

CITATION
Dickinson AS, Steer JW, Rossides C, Diment LE, Mbithi FM, Bramley JL, Hannett D, Blinova J, Tankard Z and Worsley PR (2024) Insights into the spectrum of transtibial prosthetic socket design from expert clinicians and their digital records.
Front. Rehabil. Sci. 5:1354069.
doi: 10.3389/fresc.2024.1354069

Insights into the spectrum of transtibial prosthetic socket design from expert clinicians and their digital records

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Background: Transtibial prosthetic sockets are often grouped into patella tendon bearing (PTB) or total surface bearing (TSB) designs, but many variations in rectifications are used to apply these principles to an individual's personalised socket. Prosthetists currently have little objective evidence to assist them as they make design choices.
Aims: To compare rectifications made by experienced prosthetists across a range of patient demographics and limb shapes to improve understanding of socket design strategies.
Methodology: 163 residual limb surface scans and corresponding CAD/CAM sockets were analysed for 134 randomly selected individuals in a UK prosthetics service. This included 142 PTB and 21 TSB designs. The limb and socket scans were compared to determine the location and size of rectifications. Rectifications were compiled for PTB and TSB designs, and associations between different rectification sizes were assessed using a variety of methods including linear regression, kernel density estimation (KDE) and a Naïve Bayes (NB) classification.
Results: Differences in design features were apparent between PTB and TSB sockets, notably for paratibial carves, gross volume reduction and distal end elongation. However, socket designs varied across a spectrum, with most showing a hybrid of the PTB and TSB principles. Pairwise correlations were observed between the size of some rectifications (e.g., paratibial carves; fibular head build and gross volume reduction). Conversely, the patellar tendon carve depth was not associated significantly with any other rectification, indicating its relative design insensitivity. The Naïve Bayes classifier produced design patterns consistent with expert clinician practice. For example, subtle local rectifications were associated with a large volume reduction (i.e., a TSB-like design), whereas more substantial local rectifications (i.e., a PTB-like design) were associated with a low volume reduction.
Clinical implications: This study demonstrates how we might learn from design records to support education and enhance evidence-based socket design. The method could be used to predict design features for newly presenting patients, based on categorisations of their limb shape and other demographics, implemented alongside expert clinical judgement as smart CAD/CAM design templates.

KEYWORDS

CAD/CAM, PTB, TSB, prosthetic limb design, machine learning, knowledge-based system, expert system

1 Introduction

There are numerous approaches to designing a prosthetic socket to provide a functional body-prosthesis coupling, which transmits tolerable loading to the residual limb during weight-bearing activities. Transtibial prosthetic sockets, for the most common major amputation level, are often grouped by design philosophy. The patella tendon bearing (PTB) approach includes local rectifications to preferentially load relatively tolerant tissues and offload vulnerable sites (1). By contrast, total surface bearing (TSB) sockets are intended to deliver more uniform load distribution and avoid high pressure gradients (2). However, factors like residual limb shape, size, tissue tolerance and desired activity level vary significantly across the heterogeneous population of people with lower limb amputation. In addition, environmental and economic factors need consideration in order to create a comfortable and functional socket, alongside both patient and clinician preference (3).

The International Society for Prosthetics & Orthotics (ISPO) has declared the development of evidence-based socket design to improve fit as a primary objective, in response to calls from prosthetists (4). However, there is limited objective evidence to assist them with design choices for different situations, and often rely on an iterative design process until the prosthesis user finds the limb comfortable (3). The foundational US Veterans' Affairs Automated Fabrication of Mobility Aids (AFMA) project included analysis of rectification practice (5), and enhanced resolution 3D scan data has led to further such insights recently at the transtibial (6, 7), transfemoral (8) and transradial levels (9). However, but there remains a specific knowledge gap in data to guide the choice of size or combination of individual socket rectification features for a given prosthesis user (10).

There are some clinical indications to support the overall PTB-TSB choice. PTB sockets are generally indicated for longer, more bulbous shaped limbs, and this design principle is commonly used in earlier in prosthetic rehabilitation, especially for people with residual limb pain or oedema (11). TSB sockets are preferred for more mature, stable residual limbs without oedema or excessive soft tissue (12, 13), and are often used for more active individuals, combined with elastomeric liners (14). The PTB rectification pattern design depends on prosthetist judgement and skill, typically achieved through a hands-on plaster method. TSB sockets are also produced by hands-on methods, or by "hands-off" shape capture under hydrostatic pressure, although local shape modification may still be required (15). In practice, inspection of population design data indicates that prosthetists may create hybrid sockets with a spectrum of PTB and TSB features employed to differing degrees (6). However, the relationship between rectification variables remains unclear. Both PTB and TSB sockets can also be produced in the Computer Aided Design and Manufacture (CAD/CAM) approach, and digital design records from CAD/CAM practice present an opportunity to learn from experts.

There is established precedent for these concepts. The use of rectification mapping to describe and communicate socket design was published in 1989 (16), and beside free-hand CAD/CAM, the description of databases of "primitive", "reference" or "template" sockets with standard rectifications to inform computer aided socket design also dates back to the 1980s (17–21). In the context of much larger adoption of CAD/CAM technologies with higher spatial resolution 3D scans, and evolving principles of socket design, the present study aims to use data-driven methods to conduct an updated study of transtibial socket designs prescribed to a cohort of individuals with lower-limb amputation. This will be achieved by investigating the choice and size of rectifications used by experienced prosthetists, and the combinations of rectification choices they use across a range of design strategies.

2 Materials and methods

This was an observational cohort study of transtibial socket design, with approval granted by the University of Southampton ethics and research governance office (ERGO, ref.53279A1). In total 163 sockets, designed in Omega (WillowWood, Ohio, USA) and prescribed to 134 individuals (36F:97M)[1] were sampled at random from UK clinical service, through a single multi-centre provider (Table 1). The sockets were fitted between November 2018 and November 2022, and the analysed data represented their design prior to any manual adjustment upon fitting. The individuals' demographics and pre-assessed activity level (K-Level) and a post-fitting socket comfort score (SCS) were provided. The researchers were blinded to these data during limb and socket shape data processing, described below.

Two surface meshes were obtained for each participant, representing a 3D scan of the residuum and the corresponding mould design file shape used to produce the socket (Figures 1A,B). The residuum and rectified socket scan pairs were aligned using the ampscan open source toolbox (22), first coarsely using a calculated principal axis and manually-picked mid patella and distal tibia landmarks, and then more precisely using an automatic, iterative closest point (ICP) process operating on the anterior, sub-patellar portion of the shape. Finally all aligned pairs were inspected by two experienced observers (AD, JS) and small manual adjustments were made where necessary. The shapes were then registered to one-another using ampscan to describe each socket's design as a rectification map (Figure 1C). Clusters of scan mesh vertices representing individual rectifications were identified manually by two experienced observers (AD, JS) (Figure 1D), and within each cluster the rectification "size" was obtained, as the depth of carve or height of build-up from limb to socket surfaces (Figure 1E). The 98th percentile deviation across the vertices in each rectification cluster was used instead of the maximum, to avoid any noise arising from individual vertices. This method was used to describe "design features" of local rectifications at the patellar tendon (PT,

[1]counts which add up to less than the total indicate a missing metadata point. For example there was no record of sex for one person, reason for limb absence for one person, or time since amputation for 3 people

TABLE 1 Demographics of the recipients of the sampled sockets designs, and distributions of activity (K) level and socket comfort score.

			Sex, *n*		Design, *n*			Age, years		Time since, years			K-Level, 1–4					Socket comfort score, 1–10						
		n	F	M	PTB	TSB	PTBSC	Mean	(s.d.)	Med	(range)		1	2	3	4	Mean	5	6	7	8	9	10	Mean
Sex	F	51	51	0	39	9	3	52.9	(16.6)	2.4	0.2	70.3	8	15	28	0	2.4	2	0	6	16	18	7	8.7
	M	111	0	111	95	12	4	59.8	(14.3)	1.0	0.1	53.4	14	46	45	6	2.4	1	3	15	38	29	21	8.4
Design	PTB	135	39	95	135			58.8	(15.4)	0.8	0.1	50.0	20	54	58	3	2.3	2	2	13	47	43	25	8.6
	TSB	21	9	12		21		52.5	(14.0)	10.5	0.3	30.2	2	5	11	3	2.7	1	1	6	6	5	2	8.1
	PTB SC	7	3	4			7	55.6	(16.5)	16.2	6.6	70.3	0	2	5	0	2.8	0	0	2	1	0	1	7.8
Age	19–29	9	4	5	7	1	1	24.2	(3.9)	2.1	0.5	20.9	0	1	7	1	3.0	0	1	0	3	3	1	8.0
	30–39	11	6	5	7	4	0	33.5	(3.5)	2.2	0.2	16.3	1	2	4	4	3.0	1	0	1	6	1	1	7.8
	40–49	28	14	14	24	3	1	47.1	(3.0)	0.8	0.1	50.0	1	8	18	1	2.7	2	0	4	11	6	5	8.0
	50–59	41	11	30	32	7	2	54.7	(2.8)	1.2	0.2	53.4	4	17	20	0	2.4	0	1	8	8	11	12	8.8
	60–69	29	6	23	24	3	2	63.8	(2.5)	0.9	0.2	17.9	1	15	13	0	2.4	0	0	2	11	9	5	8.7
	70–79	39	9	29	35	3	1	74.3	(3.2)	1.8	0.2	70.3	12	15	12	0	2.0	0	1	6	14	15	2	8.3
	>80	6	1	5	5	0	0	86.1	(5.0)	4.0	0.3	17.9	3	3	0	0	2	0	0	0	1	3	2	9.2
Reason for	Dysvascularity	63	11	52	59	3	1	64.8	(12.3)	0.9	0.1	17.9	15	41	6	1	1.9	0	2	8	26	16	10	8.7
	Trauma	47	17	30	32	14	1	51.9	(13.6)	4.6	0.2	46.1	3	10	31	3	2.7	2	1	5	11	16	11	8.7
	Infection	26	10	16	22	2	2	55.3	(18.0)	1.8	0.2	13.6	2	8	16	0	2.5	0	0	2	11	7	3	8.4
	Neuro	10	6	4	10	0	0	53.1	(10.0)	0.6	0.2	6.8	1	1	7	1	2.8	0	0	3	2	4	1	8.2
	Neoplasia	6	4	2	5	1	0	57.7	(22.5)	1.6	0.3	14.0	1	1	3	1	2.7	0	0	0	1	3	2	8.0
	Congenital	3	2	1	2	0	1	29.5	(-)	20.9	0.5	47.8	0	0	3	0	3.0	1	0	0	1	0	0	6.5
Time since amputatn	0–0.25	19	4	15	19	0	0	55.7	(13.3)	0.2	0.1	0.2	3	6	9	1	2.4	0	0	4	9	4	2	8.8
	0.25–0.5	28	8	20	27	1	0	58.5	(14.7)	0.4	0.3	0.5	3	13	11	1	2.4	0	1	4	9	8	5	8.3
	0.5–1	28	6	22	27	1	0	59.0	(15.2)	0.6	0.5	1.0	5	13	9	1	2.2	0	1	3	8	9	5	8.8
	1–2	12	2	10	11	1	0	61.7	(14.9)	1.3	1.0	1.9	2	6	4	0	2.2	0	1	0	5	3	3	8.3
	2–3	12	5	7	12	0	0	52.2	(22.3)	2.4	2.1	3.0	3	3	6	0	2.3	0	0	0	5	4	3	8.8
	3–5	12	6	6	8	4	0	51.1	(13.6)	3.8	3.2	4.8	0	6	6	0	2.5	0	0	3	6	3	0	8.4
	5–10	20	7	12	16	2	1	61.5	(14.9)	7.4	5.3	10.0	4	5	10	0	2.3	1	0	2	5	7	3	8.7
	10–15	13	5	8	7	4	2	62.2	(12.9)	11.5	10.5	14.0	0	4	8	1	2.8	0	0	1	1	5	4	9.0
	15+	17	5	11	8	6	3	57.8	(16.6)	29.0	16.3	70.3	2	2	11	2	2.8	1	0	3	6	5	2	8.0
	Overall	163	51	111	135	21	7	57.7	(15.4)	1.2	0.1	70.3	22	61	74	6	2.4	3	3	21	54	48	28	8.5

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carve), fibula head (FH, build), medial and lateral paratibial areas (MP, LP, carves), the tibial crest (TC, build), distal end elongation (DE, build), and between the lateral and medial supracondylar regions (LMC, carves). Further, a gross socket sizing design variable was calculated as the volume reduction (VR) by finding the mean of cross-sectional area differences between the limb and socket at 10 sections between the mid-patella tendon and distal end of the tibia.

The rectification data were analysed in three stages:

- To characterise the study population and ensure representativeness and coverage, exploratory data analysis inspected the distribution of sex, age, reason for amputation, time since amputation, socket comfort score (SCS) and K-Levels, and prescribed socket design. The population's age distribution was normally distributed so parametric descriptive statistics were used (mean and standard deviation, s.d.). The time since amputation was not normally distributed, and so the median and range were reported.
- To understand general socket design trends, the sizes of PT, FH, LP, MP, TC, DE, SC, and VR rectifications were analysed. Differences in the extent to which the rectifications were used in sockets designed using PTB and TSB approaches was compared using the non-parametric Mann-Whitney *U*-Test (rectification size distributions were not normally distributed). Bonferroni *post hoc* correction to reduce the risk of Type-I errors arising from multiple comparisons.

Finally, associations between the separate rectifications' sizes were assessed, to inspect more subtle trends in expert prosthetists' rectification strategy (Figure 1F):

- First, to evaluate simple correlation between the sizes of pairs of rectifications, Spearman Rank regression was calculated. This method can detect linear correlations but cannot rule out more complex non-linear associations and is highly influenced by outliers. Therefore:
- The probabilistic methods Kernel Density Estimation (KDE) and Gaussian Naïve Bayes classification (23) were applied to further investigate the diversity and frequency of different design approaches, and search for causal relationships between rectifications. These analytical methods estimated the probability of a prosthetist's choice of one rectification size following a prior decision of another rectification size. This enabled interrogation of the expert prosthetist's training datasets to find the probabilities of selecting, for example, a low, medium, or high build at the Fibular Head given a high carve at the Patellar Tendon. These categories were identified by splitting the fitted KDE function at the 33rd and 67th percentiles.

3 Results

3.1 Exploratory data analysis

Exploratory Data Analysis revealed differences in demographics, activity assessment and socket comfort across the population (Table 1). The studied socket designs were prescribed to a population with a widely distributed age ($n = 134$, mean 58.6 years, range 19.6–94.1 years), and were delivered over a range of times since amputation or limb absence ($n = 163$, median 1.2 years, range 0.14–70.3 years). The sockets were prescribed for a range of reasons for limb absence, which included dysvascularity (39%), trauma (29%) and infection (16%). Twenty-one were designed to a TSB principle (13%), 7 as PTB supracondylar sockets (4%) and the rest were "standard" PTBs. The dataset was sparse for people with congenital limb absence (3 individuals), people aged over 80 years (6 individuals), and only included adults.

Compared to the whole cohort, people with amputations due to trauma were observed to have higher activity (mean K level 2.7 vs. 2.4), were longer post-amputation (median 4.6 years vs. 1.2 years), and more likely to use TSB sockets (14/47, 30% vs. 21/163, 13%). People with dysvascularity-related amputations were older (mean 65 years vs. 58 years), had lower activity than the population averages (mean K level 1.9), and had their amputations more recently (median 0.9 years). TSBs were prescribed to people with longer-established amputations than PTBs (median 10.5 years vs. 0.8 years).

3.2 Descriptive statistical analysis of expert socket design practice by rectification

Several design features were used across sockets described during design as PTB or TSB (Figure 2). Local rectifications were typically larger in PTB sockets than TSBs, and this difference was statistically significant for the DE elongation build ($p < 0.05$), LP carve ($p < 0.001$) and approached significance for MP carve ($p = 0.076$). Conversely, the gross volume reduction (VR) was significantly larger for TSBs ($p < 0.05$). However, a considerable overlap was observed between all rectification distributions, and notably the PT carve and FH build rectification sizes were similar across both groups.

The training dataset was observed to contain sockets that were clearly recognisable as PTB or TSB designs, and others which appeared to contain more hybrid features (Figure 3). Therefore, instead of analysing the socket population in discrete groups, design was evaluated using rectification sizes as continuous variables.

Multiple linear correlation (Table 2) revealed several associations between the sizes of rectification pairs. There was a significant positive correlation between LP and MP rectifications ($\rho = 0.66$, $p < 0.001$), which are features that are often performed together. Moderate negative correlations were observed between the off-loading build at the tibial crest (TC) and both MP and LP paratibial carves ($\rho = -0.40$, $p < 0.001$ and $\rho = -0.35$, $p < 0.001$, respectively), features which are often performed together and are more pronounced in nominally PTB sockets. A significant positive correlation was observed between the off-loading build at the fibular head (FH) and the gross volume reduction (VR), ($\rho = 0.38$, $p < 0.001$). This is also expected: a build is used to offload the FH bony prominence in PTB sockets whereas a line-to-line fit is preserved here in TSB sockets, which typically use greater VR to achieve more uniform load transfer. Weaker negative correlations were also observed between builds at the distal end elongation (DE) and at the fibular head (FH) ($\rho = -0.32$, $p < 0.001$). However, the patellar tendon (PT) rectification depth did not correlate significantly with any other rectification, indicating its relative design independence.

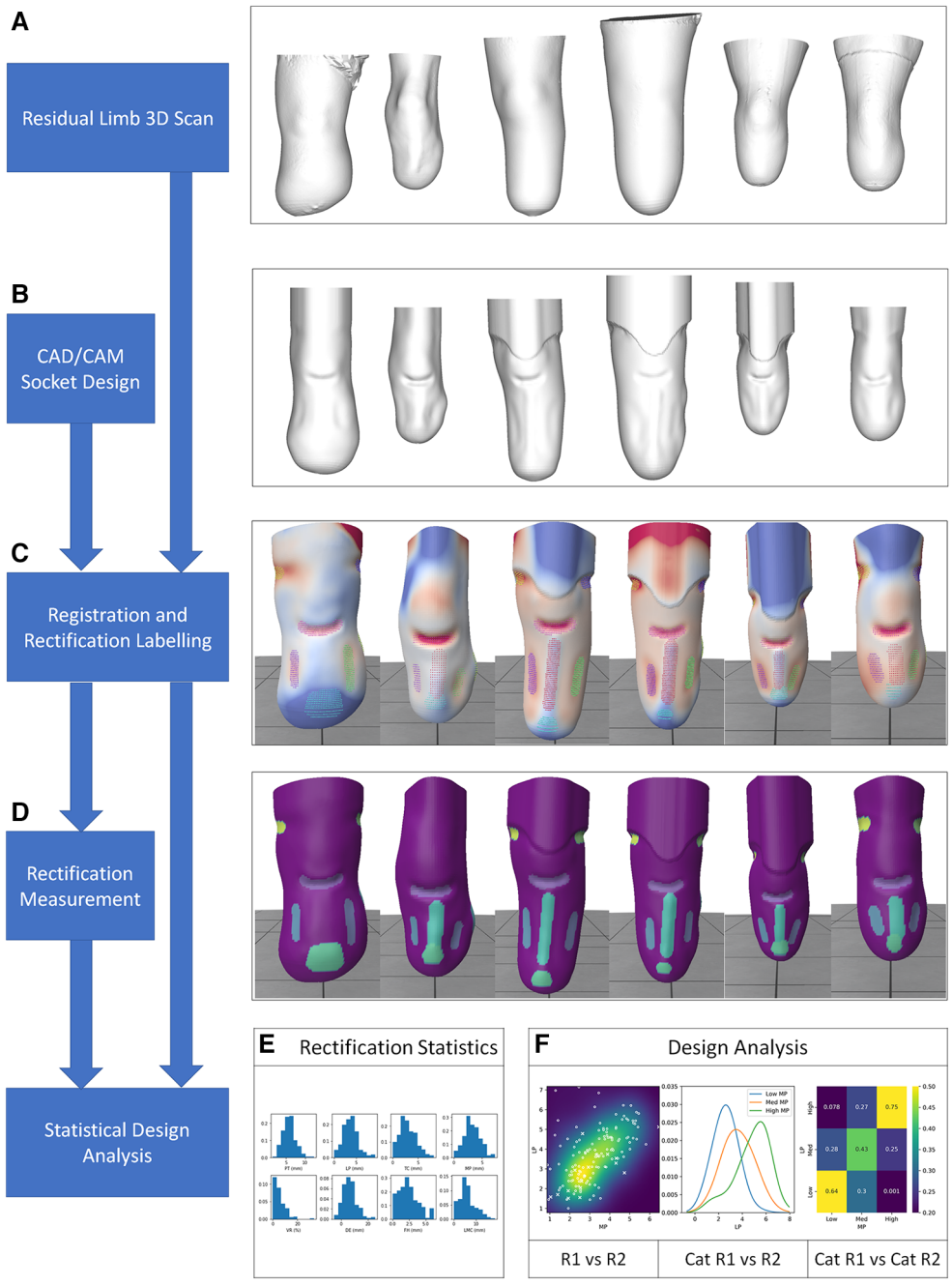

FIGURE 1
Data processing from 3D scan of limb and CAD/CAM socket design, extracted rectification design feature locations and sizes, expressed as design variables, and categorised.

3.3 Probabilistic analysis of socket design practice

The raw dataset carve and build rectification sizes were split into low-, mid- and high-sized categories with limits at the population 33rd and 67th percentiles. These were further reduced to exemplar single values of low- middle- and high-sized rectifications at the 10th, 50th and 90th percentiles (Table 3).

Simple associations existed for some rectification pairs, for example a strong correspondence between the size of medial and lateral paratibial carves (Figure 4 top). This was evidenced by a strong linear correlation, and a low probability from the KDE and NB analyses that a high medial paratibial carve would be used in combination with a low lateral paratibial carve, and vice versa (<10%).

Other rectification pairs were not associated. In particular, the choice of patellar tendon carve depth did not strongly influence any other rectification choice, which was evidenced by weak correlations and similar probabilities in the KDE and NB analyses (minimum 23% and maximum 41%, where random choice between sizes is 33%; Figure 4 middle).

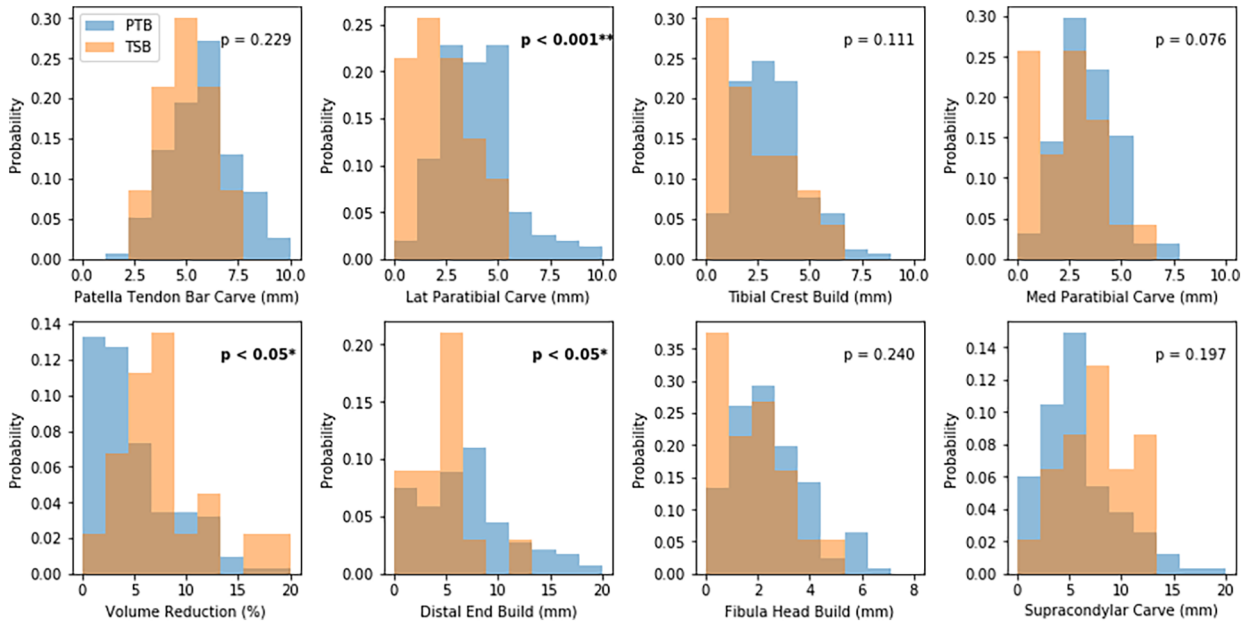

FIGURE 2
Distributions of rectification sizes for sockets described as PTB and TSB designs. "Build" denotes material is added, and "Carve" denotes material is removed.

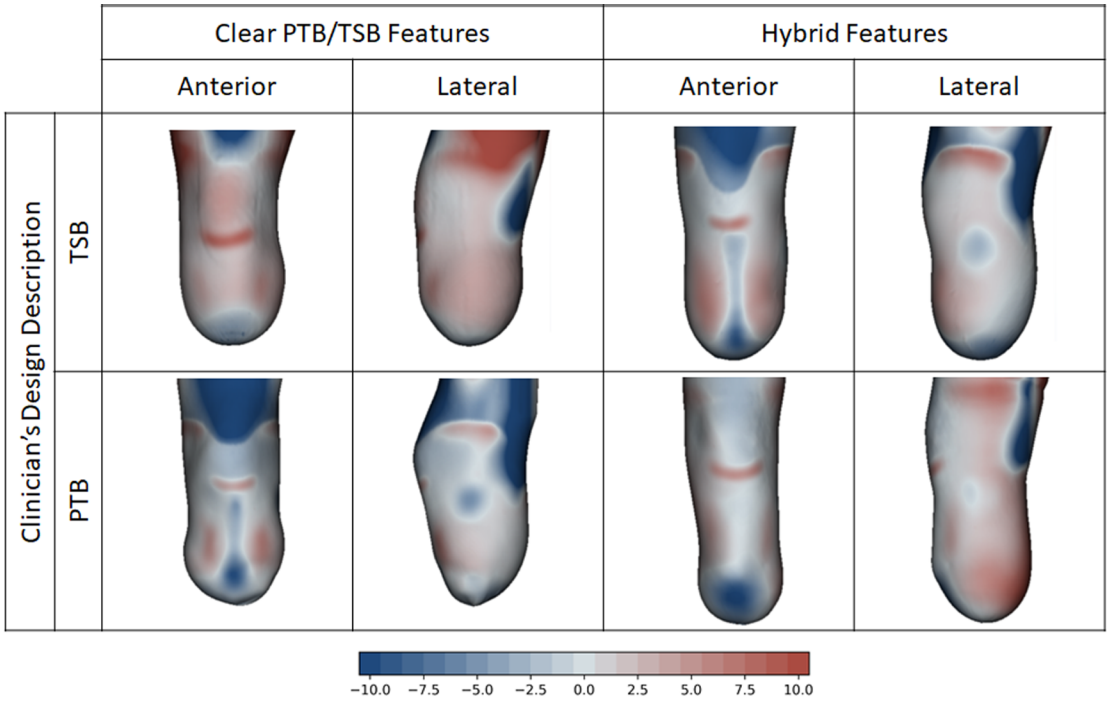

FIGURE 3
Example socket designs to PTB and TSB intent, plotted on the residual limb shape. Some training dataset designs had clear PTB or TSB intent, and others lay on a hybrid spectrum between PTB and TSB. Colour key indicates rectification design map in mm. Positive (red) represents carve, and negative (blue) represents build-up.

TABLE 2 Spearman rank correlations (ρ) between rectification groups.

	PT	MP	LP	FH	DE	VR	TC	LMC
PT	–							
MP	0.18	–						
LP	0.18	0.66**	–					
FH	0.11	−0.17	−0.26**	–				
DE	−0.15	0.05	0.11	−0.32**	–			
VR	−0.17	−0.13	−0.25**	0.38**	−0.19	–		
TC	0.10	−0.40**	−0.35**	0.37**	−0.18	0.21	–	
LMC	−0.20	0.16	−0.07	0.01	−0.09	0.22	−0.14	–

*denotes significance at $p < 0.05$, **at $p < 0.001$. Positive correlations occur where both rectifications are builds or carves, and negative where one is a build and the other is a carve.

However, the associations between some rectification pairs were more complex, and distinctly different clinical strategies were apparent, notably for the gross volume reduction which is often one of the first rectification choices made during the design process. Following the choice of gross volume reduction to apply, clinicians made different choices of whether to elongate the distal end to accommodate displaced soft tissue (Figure 4 bottom). For example, in the case of a low volume reduction, there was some causal link to the choice of distal end elongation (low 44% vs. high 28%), which may reflect a choice to offload the distal tip. However, for a high volume reduction, the causal link was much stronger (low 15% vs. high 50%), supporting the requirement of more space at the distal end to accommodate the soft tissues when they are highly compressed.

Finally, to demonstrate an example use case of these insights from expert clinical practice, the Naïve Bayes classifier was used to create example socket designs with the highest probability to result from an initial clinical decision of a high or low volume reduction. The resulting rectifications were superimposed upon the mean residual limb shape from the training population of 3D scans [Figure 5 (6),]. For sockets with a low degree of volume reduction, prosthetists were most likely to use more pronounced carves at the patellar tendon and paratibials, a high FH offload, a mid-sized tibial crest offload and a mid-to-low distal end elongation, collectively representing more PTB-like design features (Figure 5 top). Conversely, for sockets with a high volume reduction, prosthetists used small carves at the patellar tendon, paratibials and tibial crest, a closer-fitting FH profile, and a large distal end elongation, features commonly used together in more TSB-like sockets, along with lateral-medial carves above the knee condyles (Figure 5 bottom).

TABLE 3 Categorised rectification sizes extracted from the KDE function fitted to the training dataset of 163 socket designs.

Rectification		Category		
		Low (10th %le)	Mid (50th %le)	High (90th %le)
Patellar Tendon, mm	(carve)	4.1	5.8	7.4
Fibular Head, mm	(build)	1.0	2.1	3.8
Medial Paratibial, mm	(carve)	1.9	3.2	4.7
Lateral Paratibial, mm	(carve)	2.1	3.6	5.1
Tibial Crest, mm	(build)	1.4	2.7	4.4
Distal End, mm	(build)	1.5	5.8	10
Lateral-Medial Condyles, mm	(carve)	3.0	5.5	9.3
Volume Reduction, %		1.5	4.3	9.9

4 Discussion

This study set out to enhance our objective understanding of prosthetic socket design. We assessed the spectrum of transtibial socket features in a randomly sampled UK population, by identifying and measuring the selection and size of rectifications used by experienced prosthetists, and associations between these choices.

The study presents quantitative data that express how CAD/CAM sockets designed by expert prosthetists to PTB and TSB approaches do not form clearly separate groups, but lie on a spectrum. Local rectifications were typically smaller, and the volume reduction was typically larger for the TSB group compared to the PTB group. However, across the study population there was considerable overlap between all rectification sizes for PTB and TSB designs, which supports the biomechanical theory that rectifications work together, and therefore associations between chosen rectification sizes were inspected.

Strong linear correlations were observed between the sizes of rectifications which typically feature in combination, in PTB designs. The PT carve depth was not associated with any other rectification, indicating its relative design insensitivity. Similarly, supracondylar carves varied independently from all rectifications, consistent with these being more "optional" design features, consistent with their role in suspension rather than the transfer of stance loads. It was also noteworthy that despite finding no simple correlation between elongation at the residuum's distal end and volume reduction, the variables were associated. For example, a large volume reduction was rarely used without an associated distal elongation to accommodate the displaced soft tissue. Such logical but more complex associations between rectification sizes were not detected by linear regression but were revealed by applying probabilistic approaches.

Rectification practice insights like these might be used in combination with variables of residuum size and shape extracted from a new limb scan, to identify the most likely combination of rectifications that prosthetists have used to design sockets for similar cases in the past. The resulting rectifications could be presented to prosthetists as "templates", to support at the

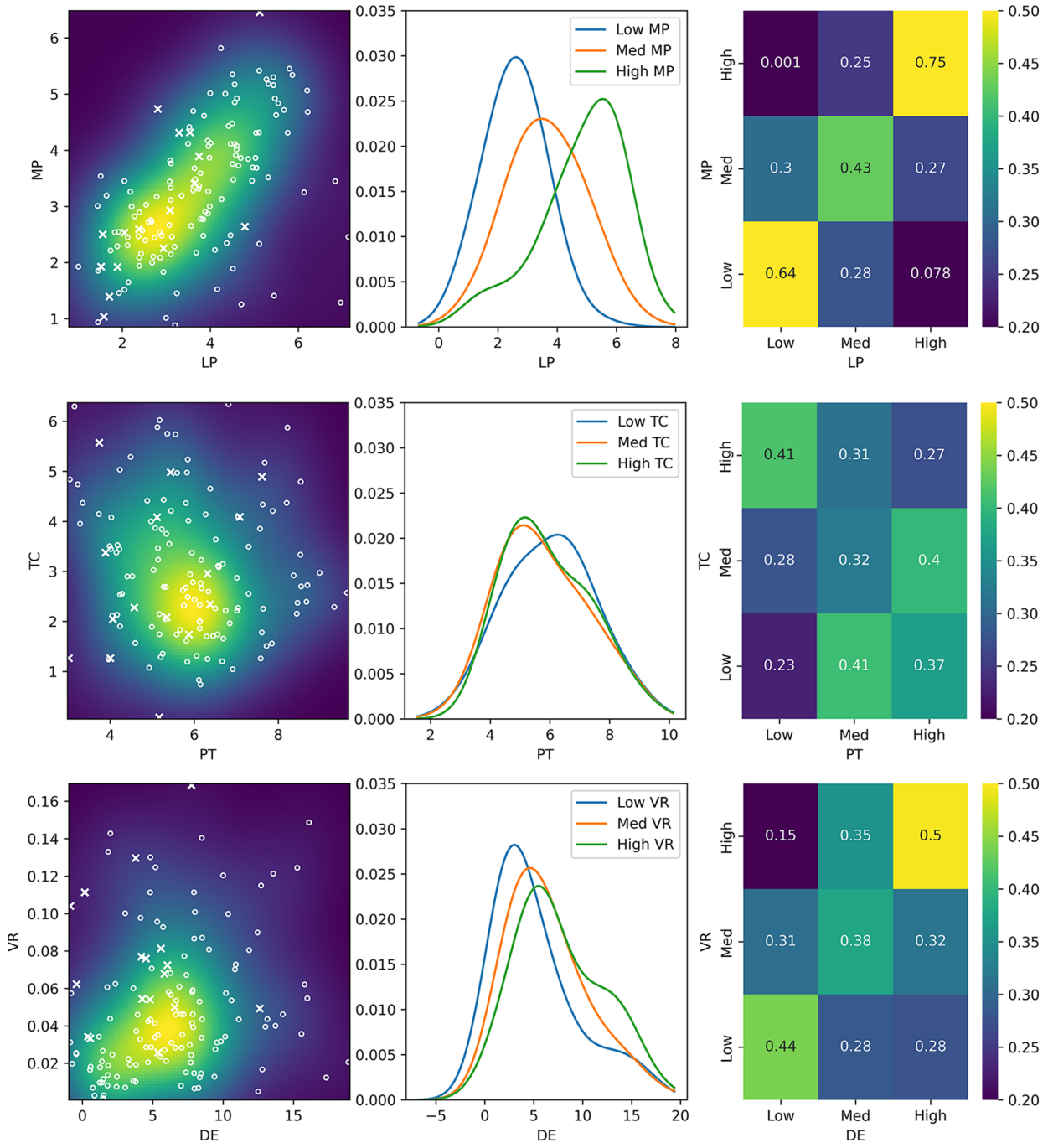

FIGURE 4
Three methods of assessing association between the sizes of three example pairs of rectifications. First, a scatter plot (left) of rectification sizes shows common combinations of rectification sizes, where each point represents one of the 163 training sockets. Both variables are continuous. The probability of combinations calculated by Kernel Density Estimation (KDE) is superimposed as a colour map. Circles represent nominally PTB sockets, and crosses are nominally TSB sockets. Three slices through the dataset are then used (centre) to define low, medium and high values of one rectification. For these categories, the corresponding probability density function of the other rectification is plotted. Finally, the Gaussian Naïve Bayes (NB) classifier is used to show the probability that a prosthetist would choose combinations of low, medium and high sizes of each rectification having previously chosen the size of another rectification (right). Results are shown for a highly associated pair (LP and MP, top), an un-associated pair (PT and TC, middle) and a pair which contains different association options (DE and VC, bottom).

beginning of their design process, incorporating the understanding of the interdependence of these local design decisions. There are considerable evidence, economic, operational and mindset factors involved in implementing digital technologies in prosthetics clinic workflows (24), and many considerations for socket design beyond a person's residual limb size and shape. For this reason, we would never recommend that such analysis of past rectifications is used to automate socket design, and an expert

FIGURE 5
By pre-defining the size of volume reduction across the socket, the Naïve Bayes classifier was used to provide probabilities of the clinician choice of size of the other rectifications across the training dataset. With 3 categories, a probability of 33.3% would represent no preference. This shows clear groups of more PTB-biased socket design associated with a decision to perform low volume reduction (top row) and more TSB-biased features associated with a large-sized volume reduction (bottom row). In rectification map, red represents a carve or volume reduction in the socket design, blue represents build, and white is a close match to the limb shape.

prosthetist should always remain responsible; they know their client best. The rationale is the same as in CAD/CAM, where a 3D surface scan alone will not identify highly person-specific sites of sensitivity or vulnerable tissue such as wounds, scars, grafts and bony prominences or heterotopic ossification. Such cases may explain the outliers visible in Figure 4 (left). Although the great majority of sockets had less than 10% volume reduction and less than 10 mm distal end elongation, the presence of outliers illustrates and reinforces the importance of expert clinical intervention, to meet individual needs for sockets with design features lying outside the normal size range.

Beyond direct residuum-based factors influencing socket design choices, prosthetists will include practical, service-delivery and usability considerations. The cost of current PTB and TSB options is reported to be equivalent in the short term, with PTB costing 40% less initially but requiring a greater number of clinic visits with their associated time and travel costs, over three times as long, to achieve equivalent clinical performance (25). Part of the cost, function and comfort benefits of TSB sockets may be attributed to corresponding vacuum assisted suspension and silicone or elastomer liners, although these are reported to produce more perspiration and require manual skill in donning, which may be more difficult for older individuals and people with impaired manual dexterity (26).

The study uses a retrospective analysis of sockets from 3D scanned residual limb surface and CAD/CAM socket design data alone. As mentioned above, prosthetists also consider soft tissue composition and sensitive or vulnerable sites in their design, based on palpation, but this information was unavailable for the present study. The study's training data also considered only CAD/CAM PTB and TSB sockets, and different findings might be obtained if sockets produced using conventional plaster-based processes were digitised and studied by the same methods. Furthermore, the study also does not provide information on the negative effects of poor design, or undesirable rectification choices, because all sockets included in the training population were relatively comfortable; 80% of the population had an SCS > 7. Other rectification features may also be relevant beyond the size or depth used in this study, such as the rectification zone area, shape and location, but were not considered in this study.

Furthermore, though this study employs a larger population than previously published modelling and socket analysis studies, its generalisability is inevitably limited. The study's exploratory data analysis revealed trends which agreed with previously published research, and the use of PTB and TSB approaches matched clinical guidelines. Comfort level trends agreed with clinical assessments for conventional PTB and hydrocast TSB sockets (higher for PTB, and increasing with time since amputation) (27), and trends in TSB socket users indicated higher activity and higher satisfaction amongst young, active users (28, 29). The exploratory data analysis also showed some heterogeneity in sex, age and reason for amputation which was representative of the UK NHS population (30), but there may be preference for design to different styles in different locations. External validity beyond the present setting may also be limited because other patient groups in different ecogeographic groupings or ethnicities will present different anatomic, pathology and surgical variations, which may require different clinical management. Prosthetists might use the presented methods to perform detailed analysis of their own prior practice or for similar patients seen by colleagues or peers in a practice or region (19), or as in the current exemplar dataset this method might be used to investigate trends across a broader population. The presented methods are built upon open-source software tools and can be applied to other historic design

records, but the results should not in isolation be interpreted as recommendations for clinical practice. Finally, while the study was designed to provide detailed observational descriptions of socket design, it does not provide a direct mechanistic explanation of these designs' load transfer. The results are best interpreted in conjunction with mechanical and clinical tests which attempt to understand these mechanisms (31, 32) and link them to clinical effectiveness in terms of function and quality of life (3, 11, 33), towards the study's stated aim of enhancing our community's evidence-based support for socket design.

5 Conclusion and clinical implications

This study set out to derive objective understanding from population-based socket design records, towards supporting clinicians to reduce the iterative socket design in prosthetic limb provision. Sockets were shown to vary in a spectrum, instead of separate clusters of more pure PTB or TSB approaches, so future clinical studies should look at the design paradigm with continuous variables instead of discrete groups. This understanding might be implemented clinically in the form of initial modified geometry, or as a list of modification sizes which could be applied in a predefined workflow in conventional CAD/CAM software, or in CAD/CAM templates. As described previously, such templates should be selected and adapted to the patient by certified prosthetists (5, 6, 8, 18, 19, 21), and as suggested by Boone et al. in the ShapeMaker system (19) they could also be updated, learning from a prosthetist's individual technique, or data might continue to be pooled for more general insights. Such templates would not substitute clinical training but might free the prosthetist to focus more of their time on the higher value-added, patient-facing part of their practice.

Ultimately the intention of this paper's methodology is to provide a tool for prosthetists to understand their range of decision making and learn more about alternative methods to achieve the same result. Knowledge derived using these methods may also enhance how clinicians share best practice for complex cases, and how less experienced prosthetists and trainees learn from analysing the work of highly skilled prosthetists. The results also provide insights to support engineers in conducting physical testing and biomechanical simulations that represent real-world clinical practice.

Data availability statement

The data analyzed in this study is subject to the following licenses/restrictions: Raw datasets analysed during the study are part of individuals' healthcare data. Ethical approval was granted for the study to access them under Secondary Data Analysis, but the raw data cannot be made publicly available for reasons of individual privacy. Processed data behind the figures is however made publicly available. The dataset supporting the conclusions of this article is available in the University of Southampton repository, https://doi.org/10.5258/SOTON/D2896.

Ethics statement

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Ethics Committee of University of Southampton (protocol code ERGO 53279 on 11th November 2019). Patient consent was waived due to the study's retrospective, anonymised analysis of data collected under routine clinical practice, structured as a service development audit. This approach was supported by a committee chair from the UK National Research Ethics Service (NRES).

Author contributions

ASD: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Visualization, Writing – original draft. JWS: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Software, Visualization, Writing – original draft. CR: Formal Analysis, Investigation, Methodology, Software, Visualization, Writing – review & editing. LED: Investigation, Writing – original draft. FMM: Data curation, Writing – review & editing. JLB: Data curation, Writing – review & editing. DH: Data curation, Validation, Writing – review & editing. JB: Data curation, Validation, Writing – review & editing. ZT: Data curation, Validation, Writing – review & editing. PRW: Conceptualization, Funding acquisition, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article.

This study was funded by the Royal Academy of Engineering (RAEng), grant numbers RF/130 and EF1819\8\24, the Engineering and Physical Sciences Research Council (EPSRC)/ National Institute for Health Research (NIHR) Global Challenges Research Fund, grant number EP/R014213/1, Innovate UK, grant 10014827, and The Alan Turing Institute, grant EP/N510129/1.

Acknowledgments

We acknowledge kind support from Caroline Ward of Opcare Ltd., data previously collected by Emily Pearson of Opcare Ltd., advice from Prof James Batchelor from the University of Southampton, and support from the University of Southampton's Institute for Life Sciences.

Conflict of interest

ASD, JLB, CR, JWS and PRW are co-founders and/or employees and/or shareholders of Radii Devices Ltd., and DH, JB and ZT are employees of Opcare Ltd. However, the authors declare that the research was conducted in the absence of any

commercial or financial relationships that could be construed as a potential conflict of interest, and the research does not involve any products. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Rehabilitation Sciences

TYPE Methods
PUBLISHED 24 July 2024
DOI 10.3389/fresc.2024.1353303

OPEN ACCESS

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RECEIVED 10 December 2023
ACCEPTED 05 July 2024
PUBLISHED 24 July 2024

CITATION
LeCursi NA, Janka BM, Gao F, Orendurff MS, He Y and Kobayashi T (2024) A proposed evidence-guided algorithm for the adjustment and optimization of multi-function articulated ankle-foot orthoses in the clinical setting. Front. Rehabil. Sci. 5:1353303. doi: 10.3389/fresc.2024.1353303

A proposed evidence-guided algorithm for the adjustment and optimization of multi-function articulated ankle-foot orthoses in the clinical setting

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Individuals with neuromuscular pathologies are often prescribed an ankle-foot orthosis (AFO) to improve their gait mechanics by decreasing pathological movements of the ankle and lower limb. AFOs can resist or assist excessive or absent muscular forces that lead to tripping, instability, and slow inefficient gait. However, selecting the appropriate AFO with mechanical characteristics, which limit pathological ankle motion in certain phases of the gait cycle while facilitating effective ankle movement during other phases, requires careful clinical decision-making. The aim of this study is to propose an explicit methodology for the adjustment of multi-function articulated AFOs in clinical settings. A secondary aim is to outline the evidence supporting this methodology and to identify gaps in the literature as potential areas for future research. An emerging class of AFO, the multi-function articulated AFO, offers features that permit more comprehensive, iterative, and reversible adjustments of AFO ankle alignment and resistance to ankle motion. However, no standard method exists for the application and optimization of these therapeutic devices in the clinical setting. Here we propose an evidence-guided methodology applicable to the adjustment of multi-function articulated AFOs in the clinical setting. Characteristic load–deflection curves are given to illustrate the idealized yet complex resistance-angle behavior of multi-function articulated AFOs. Research is cited to demonstrate how these mechanical characteristics can help mitigate specific pathologic ankle and knee kinematics and kinetics. Evidence is presented to support the effects of systematic adjustment of high resistance, alignable, articulated AFOs to address many typical pathomechanical patterns observed in individuals with neuromuscular disorders. The published evidence supporting most decision points of the algorithm is presented with identified gaps in the evidence. In addition, two hypothetical case examples are given to illustrate the application of the method in optimizing multi-function articulated AFOs for treating specific gait pathomechanics. This method is proposed as an evidence-guided systematic approach for the adjustment of multi-function articulated AFOs. It utilizes observed gait deviations mapped to specific changes in AFO alignment and resistance settings as a clinical tool in orthotic treatment for individuals with complex neuromuscular gait disorders.

KEYWORDS

ankle foot orthosis, gait, AFO, kinematics, kinetics, alignment, stiffness, resistance

1 Introduction

Ankle-foot orthoses (AFOs) are common assistive devices used to treat pathologic gait and help facilitate functional gait by improving ankle and knee motion in patients with neuromotor pathologies. In healthy individuals, efficient walking involves muscle activations to control the motion of the ankle and other joints to initiate or resist motion across various phases of the gait cycle (1–5). The ankle must perform a complex series of tasks during walking (6, 7) and the function of the ankle during gait may be described by dividing the gait cycle into foot-centric phases known as the "three rockers of gait" (1, 7, 8) (Figure 1).

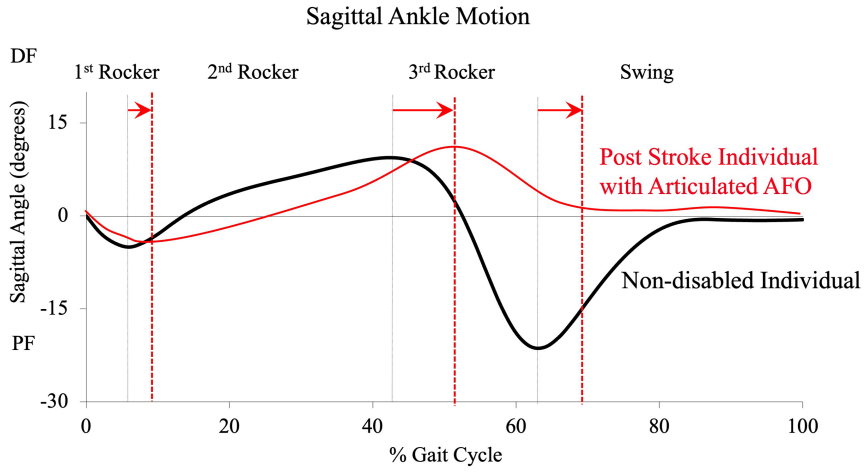
For individuals with compromised neuromusculoskeletal systems, disrupted motion and forces acting at the ankle result in pathologic deviations that are primarily observed in the three rockers of gait, but can also include pathological kinematics and kinetics at the knee and hip. Pathologic ankle biomechanics can be positively influenced by an AFO that resists/assists ankle motion to compensate for impaired muscle function (10–15). Research demonstrates that an AFO can assist the ankle in improving stability and enhancing walking competence, efficiency, and mobility.

The primary indication for AFO prescription is excessive plantarflexion (PF) in swing phase for individuals with foot drop. This can lead to an increased risk of the patient tripping (16, 17). A secondary but related indication is toe-heel or flat foot gait at initial contact. This pathologic gait pattern severely disrupts the forward momentum of the body during ambulation (18). The position of the foot at initial contact, maximum plantarflexion in early stance, maximum ankle dorsiflexion (DF) during mid-stance, ankle push-off during terminal stance, and foot clearance in swing may all benefit from AFOs. Studies indicate that AFOs can improve joint kinematics and kinetics (19–23), walking speed (24), standing stability (24, 25), and energy efficiency (26, 27), leading to improved patient mobility and safety.

However, adjusting the mechanical properties of an AFO in the clinical setting to fully maximize these benefits for the patient is a complex task. This study proposes an evidence-guided algorithm for the adjustment of articulated AFO mechanical characteristics to remediate specific pathologic gait deviations and improve ankle and knee kinematics and kinetics throughout the gait cycle. This work aims to assist clinicians in establishing a more consistent evidence-guided clinical methodology for the adjustment of articulated AFOs. It is anticipated that this evidence-guided methodology may establish a foundation for future research into the method itself, potentially leading to further published evidence on the efficacy of this and other lower limb orthotic interventions.

There is a broad compendium of literature comparing the effectiveness of non-articulated and articulated AFOs in the treatment of gait deficits. Non-articulated AFOs are typically of the solid ankle, posterior leaf spring (PLS), or strut type.

The 3 Rockers of gait are essential for the following functions:
1st Rocker - maintaining forward momentum in early stance,
2nd Rocker - creating support against gravity in single limb stance, and
3rd Rocker - providing propulsive impulses during push-off in late stance.



The 3 Rockers of gait are defined by the minima and maxima of sagittal ankle motion. Sagittal ankle motion of individuals with post stroke often have reduced ankle range of motion, and delayed minima and maxima (red dashed lines with red arrows) due to slow walking speed resulting in an elongated stance phase and shortened swing phase (7, 9).

FIGURE 1
The three rockers of gait are defined by initial contact to first peak plantarflexion (First rocker: heel rocker), peak plantarflexion to peak dorsiflexion (Second rocker: ankle rocker), and peak dorsiflexion to second peak plantarflexion (Third rocker: forefoot rocker) (7, 9).

Articulated AFOs are typically known as hinged AFOs (24–26, 28) and frequently employ metal springs to resist/assist ankle motion. Researchers have investigated the influence of these AFO types when treating pathologic gait deviations, and compared different AFO designs for different patient populations (19, 28–30). More recently, systematic reviews have been conducted (24–26, 28) to compare gait in individuals post-stroke with and without the use of an AFO, regardless of the mechanical characteristics of the AFO or its appropriateness for a specific pathological gait disturbance. Although many studies have taken into account the adjustment of AFO mechanical characteristics on the kinematics and kinetics of the ankle, knee, and hip (8, 9, 11, 13, 15, 22, 31–42), a comprehensive method to adjust the mechanical characteristics of articulated AFOs to address specific observed pathological joint kinematic deviations has not yet been developed.

In clinical practice, there are two fundamental characteristics of an AFO that are commonly considered and adjusted to influence gait biomechanics. One is the AFO's resistance to ankle motion and the other is its ankle alignment angle. The AFO alignment angle is defined as the angle in the sagittal plane between the axes of the footplate and tibial sections without external force applied. A "neutrally aligned" AFO is defined as an AFO with a 90° ankle alignment angle. This alignment is also commonly referred to as a 0° alignment in vernacular terms, indicating that the sagittal plane tibial axis of the AFO is vertically aligned.

The resistance of an AFO is typically measured as the torque or bending moment in Newton-meters (Nm) that the AFO applies to resist ankle motion. The terms resistance and stiffness are sometimes used interchangeably; however, the stiffness of an AFO is more rigorously defined as the change of resistance per unit of ankle articulation and is typically measured in Newton-meters per degree (Nm/deg). Various devices have been developed to measure the stiffness of AFOs (43). These three AFO mechanical characteristics, namely, alignment, resistance, and stiffness, influence ankle motion in distinct ways, though the influence of stiffness as opposed to overall resistance is not yet fully understood. However, when adjusted these AFO characteristics can help mitigate pathologic gait abnormalities for patients with neuromuscular disorders (11, 12, 14).

Several recent studies have compared the biomechanical influence of AFOs with mechanical characteristics systematically adjusted to the unique needs of each individual patient (8, 11, 32–37, 41). Kobayashi et al. evaluated the influence of plantarflexion spring stiffness of articulated dorsiflexion assist-type AFOs and demonstrated a systematic effect on sagittal ankle position at initial contact and subsequent ankle motion throughout the gait cycle in individuals post-stroke (11).

Kobayashi et al. assessed sagittal ankle and knee motion and moments during walking using articulated dorsiflexion assist-type AFOs with varying levels of stiffness (37). Their work showed that for individuals post-stroke with knee hyperextension, this pathologic gait deviation could be ameliorated by increasing plantarflexion spring stiffness. This adjustment encouraged a heel-toe gait pattern at initial contact, resulting in a shifted ankle position toward dorsiflexion rather than plantarflexion, and a dorsiflexor moment at the ankle during early stance. Increasing plantarflexion stiffness also reduced the peak knee flexor moment and knee hyperextension by restricting shank reclination during single-limb stance (37). Their work also showed a systematic increase in both ankle dorsiflexion and knee flexion angles with increased plantarflexion-resist spring stiffness throughout the gait cycle. However, it is important to note that while group results suggested a systematic relationship between stiffness and effects, individual responses to varying stiffnesses were non-linear and specific to each subject.

It remains unclear whether it is most beneficial for an AFO to provide sufficient resistance to plantarflexion to maintain a fixed ankle position throughout the swing phase, while also limiting the maximum plantarflexion resistance to allow ankle plantarflexion at initial (heel) contact where the ground reaction force increases the external plantarflexion moment at the ankle.

Waterval et al. studied the influence of PLS AFOs with five different stiffnesses for 37 participants with neuromuscular disorders and non-spastic calf muscle weakness (15). PLS AFOs initially provide zero resistance to ankle motion. Their resistance to ankle motion is derived from the deflection of the footplate away from the ankle alignment angle, and so ankle alignment may change throughout swing phase. In this study on optimal walking economy, the stiffness of AFOs was highly individualized. A stiffness of 4.3 ± 0.5 Nm/deg was most frequently associated with the best gait economy, but this was observed only in 11 out of 37 participants. The most economical gait was achieved with AFOs having different stiffnesses: 2.8 ± 0.4 Nm/deg in eight participants, 3.5 ± 0.4 Nm/deg in six participants, 5.3 ± 0.7 Nm/deg in five participants, and 6.6 ± 1.1 Nm/deg in six participants. The least efficient AFO stiffness was observed most frequently at 6.6 ± 1.1 Nm/deg in 14 participants and at 5.3 ± 0.7 Nm/deg in 12 participants. Their results demonstrated that AFO stiffness individualized for each participant in the study reduced the energy cost of walking by 11% when compared to the stiffest AFO. It was hypothesized that the stiffest AFO would produce the greatest push-off energy based on calculation of energy stored and lost through bending moment hysteresis, but the stiffest AFO did not result in significantly lower mean walking energy cost (15). These results suggested that adjustment of PLS AFO stiffness for each individual patient is likely more beneficial than simply making an AFO stiffer. It should be noted that this study employed single stiffness settings for each of the different AFOs, with these settings remaining constant throughout the gait cycle. In practice, this approach is difficult to employ for individuals with complex neuromuscular pathologies where ankle motion is dysfunctional at certain points in the gait cycle but functional at other points. Even if a set of prefabricated AFOs with a range of stiffnesses were available at fitting, an appropriate stiffness AFO would still be difficult to prescribe because the guiding outcome of this approach is gait economy, which requires complex metabolic testing with portable O_2 and CO_2 sensor systems. Therefore, it is unlikely that this approach would be applicable to routine orthotic care in the clinical setting due to its expense, time, and effort, and the limitations of the orthotist's scope of practice and experience with respect to energy cost diagnostics. The method would also be susceptible to errors due to confounding variables such as food consumed prior to the test and the difficulty of achieving a steady state during walking.

2 Optimal mechanical characteristics of AFOs

2.1 Customary orthotic practice and challenges in AFO optimization

Determining the optimal mechanical characteristics of an AFO is a complicated task for both the prescribing physician, and the orthotist responsible for providing orthotic care and adjusting the AFO to improve patient ambulatory function. AFO designs that incorporate an adjustable ankle joint rather than requiring an irreversible change to the orthotic design to alter stiffness offer the ability to modify the AFO's mechanical characteristics quickly and reversibly in a clinical setting. These adjustable orthoses also facilitate the adaptation of those characteristics to the patient's evolving needs over time. Adjustability also offers the ability to change the AFO's mechanical characteristics progressively, and iteratively to achieve specific functional objectives. However, optimization requires that the goals of adjustment are clearly defined. In practice, it is often also necessary to prioritize and reconcile optimization goals considering a myriad of competing concerns in orthotic patient management.

The overall aim of AFO optimization is to reduce specific pathologic gait deviations. It is reasonable to assume that the reduction of pathologic gait deviations will improve patient ambulatory function (24–26, 28); therefore normal gait is often used as a comparative reference for adjustment. The adjustment process is typically informed by subjective and objective clinical indicators, e.g., patient verbal feedback and observation of the patient walking, respectively. It is widely accepted that three-dimensional (3D) instrumented gait analysis, including kinetic and kinematic data, is the gold standard of gait assessment. However, this type of motion analysis has limited availability and is costly, time-consuming, and complicated, which makes it impractical in many clinical settings. As a result, customary orthotic practice often relies on basic clinical techniques to evaluate objective clinical indicators. One such technique is the identification of gait deviations through observational gait analysis.

Several studies have demonstrated that observational gait analysis can result in substantial errors when used to identify gait deviations (44–47). However, studies also suggest that if the observer's attention can be focused on a few discrete gait events and the assessment is repeated multiple times, the ability of the observer to reliably identify gait deviations may be improved (48). The use of slow-motion video as an adjunct to observational gait analysis may also help improve the reliability of identifying gait deviations. Therefore, it is possible to improve the accuracy of identifying the orthotic influence on patient gait through iteration of AFO adjustments using repetitive observations of specific gait events with slow-motion video. This is typically done by pausing the motion and scrolling the video repeatedly through the gait event. Establishing the reliability of observational gait analysis is essential if it is to be used to determine whether a specific gait deviation has been reduced or increased through the adjustment of the AFO's mechanical characteristics. Various gait assessment scales have been developed that utilize this concept (49). For example, the Edinburgh Visual Gait Score showed 69% agreement with 3D computerized gait analysis for maximum ankle dorsiflexion in stance, 83% agreement with maximum ankle dorsiflexion in swing, but only 47% agreement with peak knee extension in stance (49). While these observational gait tools may not achieve the same level of accuracy or precision as the gold standard of instrumented motion analysis, they can potentially improve the reliability, sensitivity, and validity of visual gait analysis when instrumented analysis is not feasible.

Therefore, by focusing on a few key gait characteristics, the orthotist's ability to identify a patient's gait deviations reliably and validly may be improved, and by doing so, observational gait analysis may be adequate for the purpose of AFO adjustment and optimization of patient ambulatory function. However, it should be noted that substantial errors may be associated with the less rigorous application of observational gait analysis to AFO optimization. Therefore, an iterative approach to the change of an AFO's mechanical characteristics with repetitive observation is essential to minimize observational errors if the assessment is to be applied to orthotic practice.

2.2 AFO mechanical characteristics

To reduce pathologic gait deviations, the intrinsic sagittal plane mechanical characteristics of an AFO should be adjusted. As aforementioned, these intrinsic mechanical characteristics are the AFO's alignment, resistance, and stiffness. Non-articulated AFOs typically exhibit high structural stiffness, ranging between 8 and 18 Nm/deg, depending on the fabrication method, design, and materials used (50). Following fabrication, the structural stiffness of a non-articulated AFO is fixed unless its shape is permanently changed. The resistance of high stiffness AFOs increases rapidly with deflection of the AFO footplate, although their initial resistance is 0 Nm. By contrast, traditional articulated AFOs use mechanical ankle joints to resist ankle motion. These orthotic components typically resist ankle motion using internal springs with stiffness that is significantly lower than the structural stiffness of a solid AFO. The stiffness of these traditional hinged AFOs may be on the order of 0.25 Nm/deg (11, 35, 39). Traditional hinged AFOs initially present 0 Nm of resistance to ankle motion, and because of their relatively low stiffness, they may only be suitable for managing swing-phase gait abnormalities (e.g., foot drop), where the resistance required to influence pathologic gait is relatively low compared to stance phase.

An emerging class of articulated ankle-foot orthosis with features that facilitate improved control over AFO mechanical characteristics has been recently introduced to the orthotics profession. The first of these devices was the Neuro Swing double-acting ankle joint introduced by Fior and Genz (Lüneburg, Germany) in 2013. In 2016, Becker Orthopedic (Troy, Michigan, United States) introduced the Triple Action multi-function ankle component and in 2019 Otto Bock Healthcare (Duderstadt, Germany) introduced Nexgear Tango.

These advanced orthotic components differ slightly in their feature set, but they all share the defining characteristics of multi-function orthotic ankle components. Multi-function articulated AFOs are well suited for managing both swing-phase and stance-phase gait deficits due to their high resistance to ankle motion and adjustability. The resistance and stiffness of multi-function articulated AFO springs are typically much higher than those found in traditional articulated AFOs. In addition, multi-function articulated AFOs offer the advantage of more precise adjustment, with mechanical characteristics that are de-coupled from one another. This allows for independent adjustment of mechanical characteristics in a way that is more versatile than traditional articulated AFOs. The stiffness of component springs can be changed to accommodate a broader range of patient weights, and these devices possess the unique feature of presenting a resistance threshold, or pre-load torque (Nm) to ankle motion. The resistance threshold of a multi-function articulated AFO is the torque necessary to move the AFO footplate away from its alignment angle against the ankle joint springs. When the torque applied to the AFO footplate is below the resistance threshold, the multi-function articulated AFO presents the high structural stiffness of the orthosis to resist ankle motion and the footplate deflects minimally as would a much higher stiffness non-articulated AFO. However, when the external ankle moment exceeds the resistance threshold of the ankle component, the footplate begins to move away from its ankle alignment angle and the resistance of the AFO continues to increase at a rate determined by the stiffness of the ankle joint springs. This stiffness is typically less than the structural stiffness of a non-articulated, e.g., solid AFO, but significantly higher than the stiffness of a traditional articulated AFO. The maximum range of ankle motion is also adjustable, and when this motion limit is reached, the AFO again presents high structural stiffness to resist ankle motion (Figure 2). Therefore, the total resistance that a multi-function articulated AFO applies to influence ankle motion is determined by its structural stiffness, resistance threshold, and dorsiflexion and plantarflexion spring stiffnesses. This mechanical behavior results in a complex resistance vs. angle curve

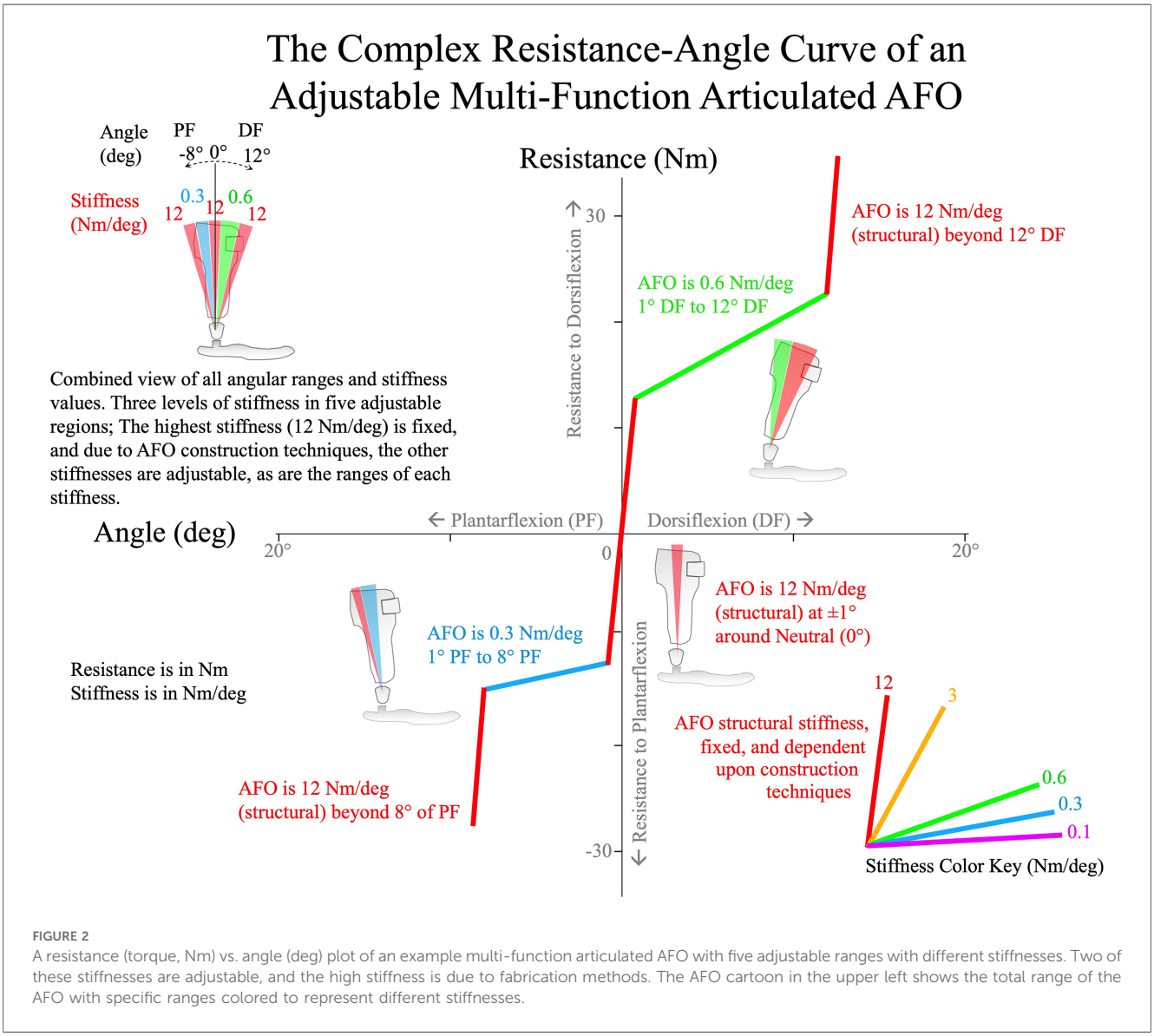


FIGURE 2
A resistance (torque, Nm) vs. angle (deg) plot of an example multi-function articulated AFO with five adjustable ranges with different stiffnesses. Two of these stiffnesses are adjustable, and the high stiffness is due to fabrication methods. The AFO cartoon in the upper left shows the total range of the AFO with specific ranges colored to represent different stiffnesses.

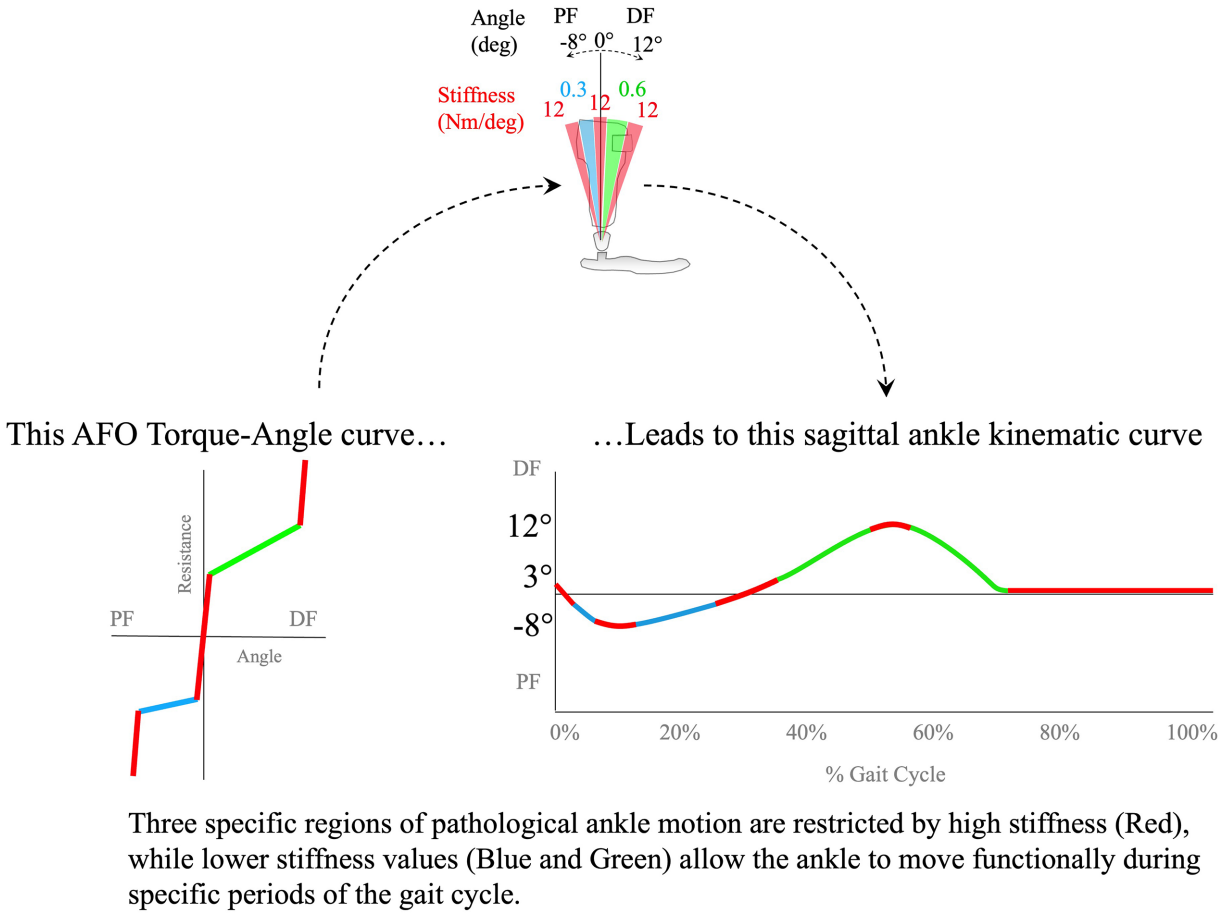


FIGURE 3
A typical multi-function articulated AFO's Resistance vs. Angle curve results in a specific sagittal ankle kinematic curve. The limits to motion caused by the highest stiffness are represented in red (12 Nm/deg) mainly during swing phase in the curve, with blue representing a low stiffness of 0.3 Nm/deg in early stance, and green representing a low stiffness of 0.6 Nm/deg in mid- and terminal stance. The red stiff region as the ankle crosses neutral provides stability in the single-limb stance, but allows ankle motion in both dorsiflexion and plantarflexion as the ankle angle changes.

resembling a sigmoid that exhibits varying stiffness throughout specific and adjustable ankle ranges of motion (Figure 3).

This complex behavior of a multi-function articulated AFO allows functional ankle motion against reduced stiffness while resisting motion through dysfunctional ranges. The multi-function articulated AFO also facilitates the independent adjustment of ankle alignment angle without altering the resistance or stiffness settings (36, 40).

3 Development of an evidence-guided algorithm

3.1 Evidence-guided algorithm for the adjustment of multi-function articulated AFOs in the clinical setting

There is a lack of standardized orthotic adjustment algorithms in orthotic practice. One orthotic algorithm described by Owen involves the optimization of AFOs combined with shoe outsole modification to improve patient ambulatory function. The AFO footwear combination (AFO-FC) is clinically "tuned" by modifying the shoe outsole shape to improve gait in children with cerebral palsy (CP) (51). This method of adjusting the AFO-FC has also been described by Jagadamma et al. for use in post-stroke adults with hemiplegia (22). The method initially focuses on determining the ankle alignment angle by evaluating the patient's passive range of ankle dorsiflexion before fabrication of the rigid AFO. With the rigid AFO and shoes fitted to the patient, optimization for standing balance and knee position is accomplished by adjustment of the heel height of the shoe. The shape of the heel and forefoot rockers of the shoe outsole are subsequently adjusted by abrasive grinding to "tune" the shape of the shoe outsole, reducing pathologic shank and thigh kinematics in both early and late stance phases of gait. The stiffness of an AFO footplate may affect gait patterns as well (52). Owen's method thus focuses on the reduction of pathologic shank and thigh gait deviations with an emphasis on observing these limb segments with respect to the vertical axis.

In contrast to Owen's work, the adjustment algorithm proposed in this present work aims to preserve functional ankle motion while reducing pathologic ankle and knee gait deviations. This algorithm is novel as it is focused on adjusting the mechanical characteristics of a multi-function articulated AFO to associate with and systematically influence specific events throughout the gait cycle (8, 11, 36–42, 53, 54).

Multi-function articulated AFO mechanical characteristics have been found to systematically influence gait kinematics and kinetics of the ankle and knee (8, 11, 33–39, 41). Studies demonstrate that changes to the AFO ankle alignment angle influence ankle angle throughout the gait cycle (8, 11, 33, 34). Studies also demonstrate that resistance to ankle plantarflexion systematically influences ankle and knee sagittal kinematics and kinetics throughout the swing phase and during the first rocker of gait (31, 39). Resistance to ankle dorsiflexion systematically influences the second rocker of gait, mid-stance to pre-swing (36). Evidence also suggests that this influence is mostly isolated, facilitating the association of specific AFO adjustments with particular phases of the gait cycle. Therefore, the algorithm was developed to exploit this isolated influence of AFO adjustments to help establish a clear pathway toward optimization, providing guidelines to associate observed gait deviations with specific multi-function articulated AFO adjustments while remediating undesirable, iatrogenic consequences of the orthotic treatment. Examples of the adjustments that can be made to a multi-function articulated AFO are shown in Figure 4, where each resistance threshold value is adjusted in response to an observed gait deviation.

The algorithm was developed to be used in the clinical setting, where access to a sophisticated gait lab is typically not available. The method relies on observational gait analysis augmented by repeated observation of specific gait events using slow-motion video to increase the reliability of observations and indicated adjustments. Contemporary smartphones equipped with high-resolution slow-motion cameras make this feasible in a clinical setting. Observational gait analysis may be further improved by capturing video from different perspectives, e.g., both the sagittal

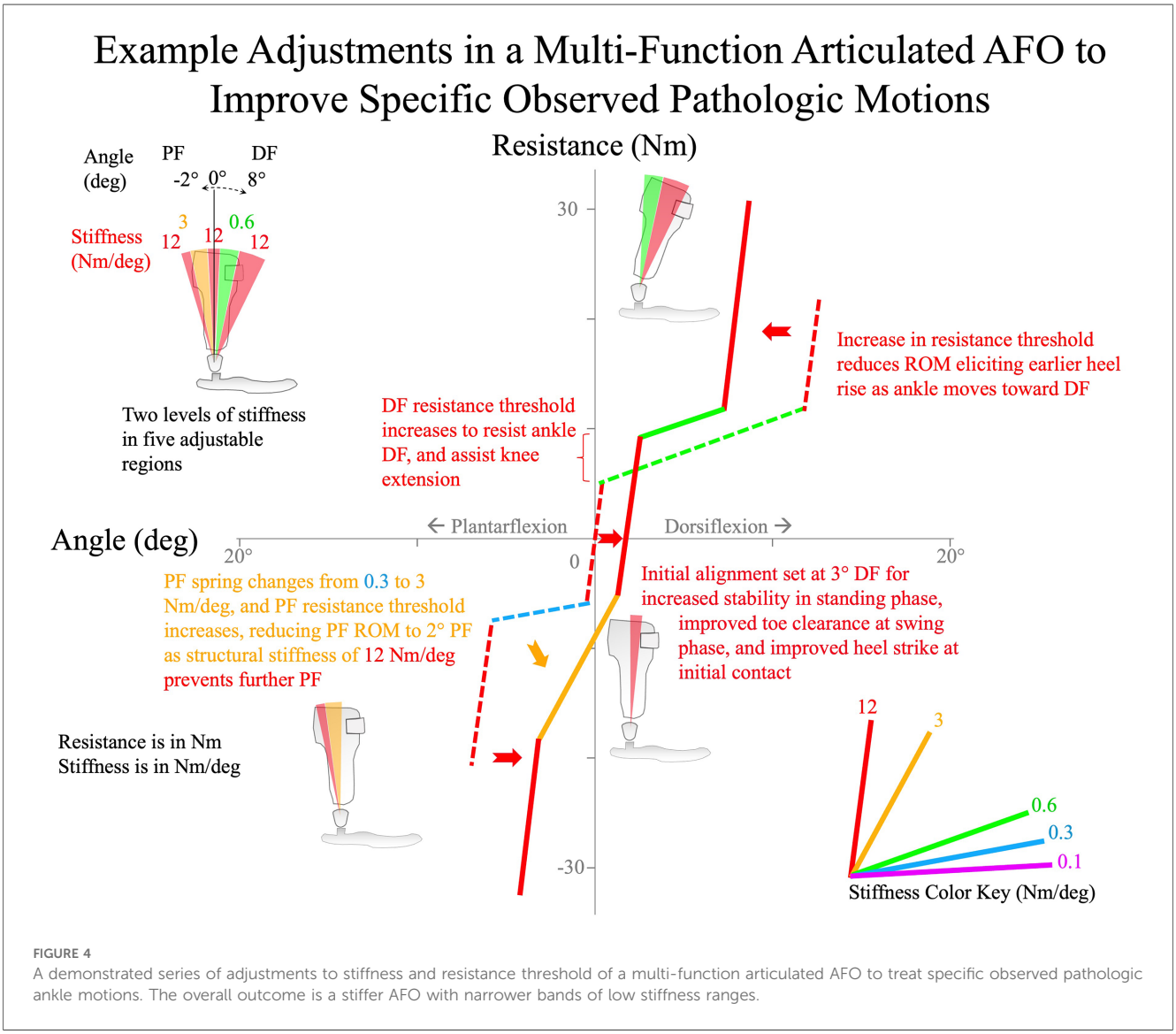


FIGURE 4
A demonstrated series of adjustments to stiffness and resistance threshold of a multi-function articulated AFO to treat specific observed pathologic ankle motions. The overall outcome is a stiffer AFO with narrower bands of low stiffness ranges.

and coronal planes, which may also be helpful to detect changes in gait characteristics as well as to estimate joint angles or step lengths.

A specific and clinically relevant set of gait events was selected for the adjustment algorithm (Supplementary File 1) based on reliability of identification as well as clinical utility:

1. Knee position and shank inclination in static weight bearing.
2. Perceived weight line with respect to ankle, knee, and hip joint anatomical axes in static weight bearing.
3. Toe clearance in mid-swing.
4. Knee extension at terminal swing.
5. Foot position at initial contact.
6. Knee kinematics through the first rocker.
7. Tibial progression through the second rocker.
8. Heel rise at terminal stance through the third rocker.
9. Knee kinematics after mid-stance.
10. Step length and step length symmetry.

Pathologic deviations of these specific gait events inform associated adjustments to multi-function articulated AFO mechanical characteristics. Evidence to support the systematic effects of AFO adjustment intended to influence specific gait characteristics is supported by cited literature in the text and Figures 5–13.

Throughout the subsequently described process, the term *alignment* signifies changing the AFO ankle alignment angle without adjustment of AFO resistance threshold or stiffness, while the term *adjustment* is used to indicate a change of resistance threshold or component stiffness with or without a change of alignment. As previously described, the resistance threshold of the multi-function articulated AFO is adjusted by pre-compressing, or pre-loading the component springs within the ankle joint. AFO component stiffness is adjusted by installing different springs or combinations of springs in the ankle joint, and may scale the range of resistance threshold adjustment according to the weight and biomechanical deficits of the patient. Steps 4 and 5 in the following procedure involve initially setting the AFO resistance range by adjusting spring stiffness, followed by adjusting the resistance threshold to reduce the observed pathologic gait deviations.

3.2 The multi-function articulated AFO adjustment algorithm—the total time to execute the algorithm is approximately 30 min

Step1: bench adjustment (orthosis on the bench)—approximately 3 min

Bench adjustment involves setting the mechanical characteristics of the orthosis to an initial condition in preparation for optimization. The term and procedure are similar in some aspects to the more familiar "bench alignment" originally coined by prosthetists. Prosthetic bench alignment of a

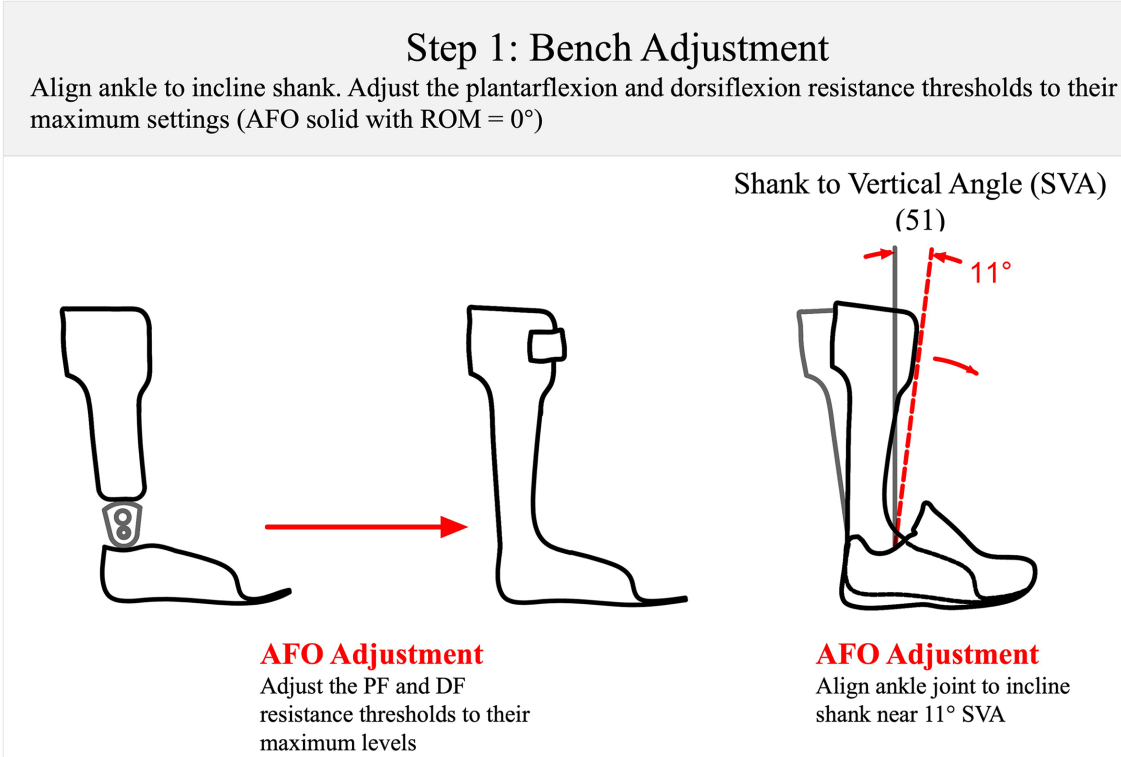


FIGURE 5
Step 1: the bench adjustment of a multi-function articulated AFO at the start of the optimization process. The AFO is set at an incline of 11° of SVA (51) to accommodate a typical shoe. The PF resistance threshold and DF resistance threshold are adjusted to maximum. SVA, shank to vertical angle; PF, plantarflexion; DF, dorsiflexion.

transtibial prosthesis refers to the process of adjusting the initial alignment of the prosthetic socket with respect to the prosthetic foot. While there is an accepted standard for prosthetic bench alignment, accommodation is typically made to the socket angle in cases where the patient has a flexion contracture or atypical joint alignment of the residual limb, and for the anticipated heel height of the shoe.

By contrast, orthotic "bench adjustment" in the algorithm implies setting the initial AFO ankle alignment angle to slightly incline the patient's shank with the AFO and shoe donned (Step 1: Figure 5) and adjusting the resistance of the AFO to "lock" the ankle joint, simulating the mechanical characteristics of a high stiffness, non-articulated AFO. This is done to achieve maximum stability and safety for the patient during "Static Alignment".

Step 2: static alignment (orthosis donned while patient is standing) —approximately 4 min

Static alignment is performed with the AFO and shoes fitted to the patient in quiet standing (Step 2: Figure 6) and the AFO "locked" to simulate a non-articulated AFO. Static alignment changes the ankle angle with concomitant change to knee flexion. The goal of this step of the algorithm is to adjust the initial ankle alignment angle to achieve slight shank inclination and improve the patient's subjective sense of balance in quiet standing. If accommodation is necessary for a plantarflexion contracture to position the ankle within its passive range of motion (ROM), a heel lift under the AFO may be beneficial. During Static Alignment, an objective measure of 10°–12° of shank inclination, e.g., 11° shank to vertical angle (SVA), may be used as a starting point. This angle was originally determined by Owen to be the average shank to vertical angle for optimizing gait kinematics and kinetics in their method (51). Consideration should also be given to the position of the patient's weight line with respect to the imaginary line joining the trochanter, knee, and ankle (TKA). The patient's subjective feedback is critical during static alignment, and their sense of balance, stability, and comfort are assessed as part of this process. Again, a parallel can be drawn to the static alignment of a transtibial prosthesis, which includes

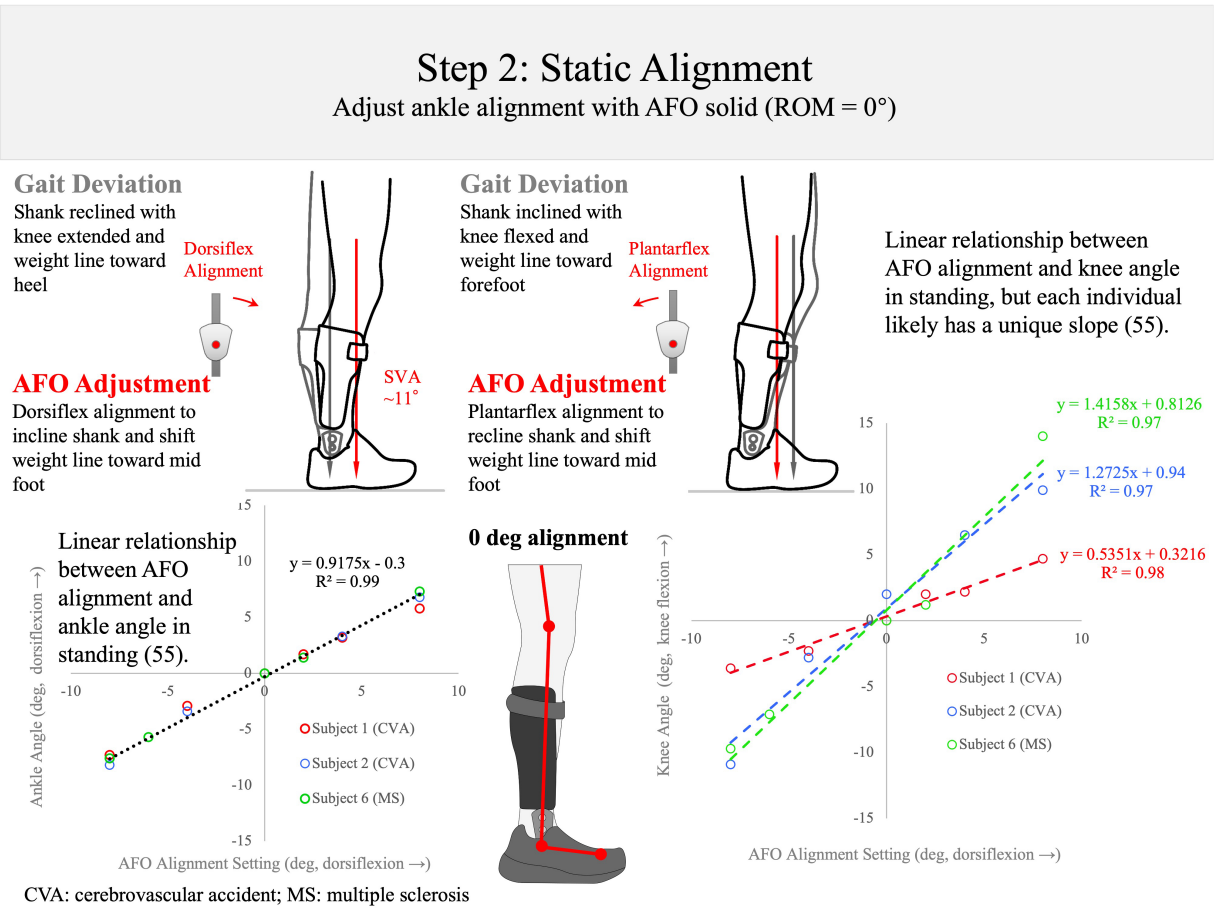


FIGURE 6
Step 2: static alignment. With the AFO range set to 0° of plantarflexion and 0° of dorsiflexion (range of motion: ROM = 0°), the alignment angle of the AFO is set so that the center of mass weight line falls at the middle of the foot (red line). The gray line shows when the AFO is too plantarflexed (left) or dorsiflexed (right). Previous research has shown that the standing ankle angle responds systematically to AFO alignment angle changes, accounting for >99% of the participant's variance (55). The knee also shows a linear relationship to AFO alignment angle ($R^2 > 0.96$), but each individual likely has a unique slope of knee position in standing as AFO alignment angle is altered (55).

anteriorly tilting the prosthetic socket (i.e., flexing the socket) and aligning the knee center anterior to the ankle axis such that the patient's weight line passes through the middle third of the foot (56). A previous study has shown that ankle and knee joint angles respond systematically to AFO alignment angle changes while standing, but each individual likely has a unique profile of knee position as the AFO alignment is changed (55).

Step 3: swing-phase alignment (orthosis donned while patient is walking)—approximately 7 min

When satisfied with the static alignment, the patient is asked to walk to adjust swing phase alignment (Step 3: Figures 7–9). This step of the algorithm is also performed with the ankle joint adjusted to simulate a non-articulated AFO. Published data show that the sagittal ankle angle is systematically changed with ankle alignment of the multi-function articulated AFO. The goal of the swing-phase alignment is to optimize ankle alignment to improve toe clearance in mid-swing, knee extension at terminal swing, and foot position and foot-position symmetry at initial contact. These three gait events are observed and prioritized during swing-phase alignment according to the following guidelines.

During mid-swing, toe clearance is evaluated with a goal of achieving at least 1 cm of clearance between the shoe and the floor (Step 3A: Figure 7). A minimum toe clearance of 1–2 cm has been suggested for the young and elderly adults (16, 17). Ankle alignment may be adjusted toward dorsiflexion to increase toe clearance. Assuming the structural stiffness of the orthosis is sufficient, the kinematic response to this adjustment has been found to be systematic (33).

After alignment for toe clearance, knee extension at terminal swing is observed and compared with the normative value of 175° of the knee popliteal angle, or 5° of knee flexion at terminal swing (Step 3B: Figure 8). If the knee does not fully extend at terminal swing, it could be due to a knee flexion contracture or shortened gastrocnemius, which may be exacerbated by excessive ankle dorsiflexion alignment. If the knee does not achieve full extension, the previous objectives may need to be reconciled by further iterative adjustment of ankle alignment to achieve overall optimization. However, it should be noted that this last objective of full knee extension is not well supported by the published literature. Anecdotal clinical observations do suggest that it may have utility for orthotic optimization; therefore, it is included in the

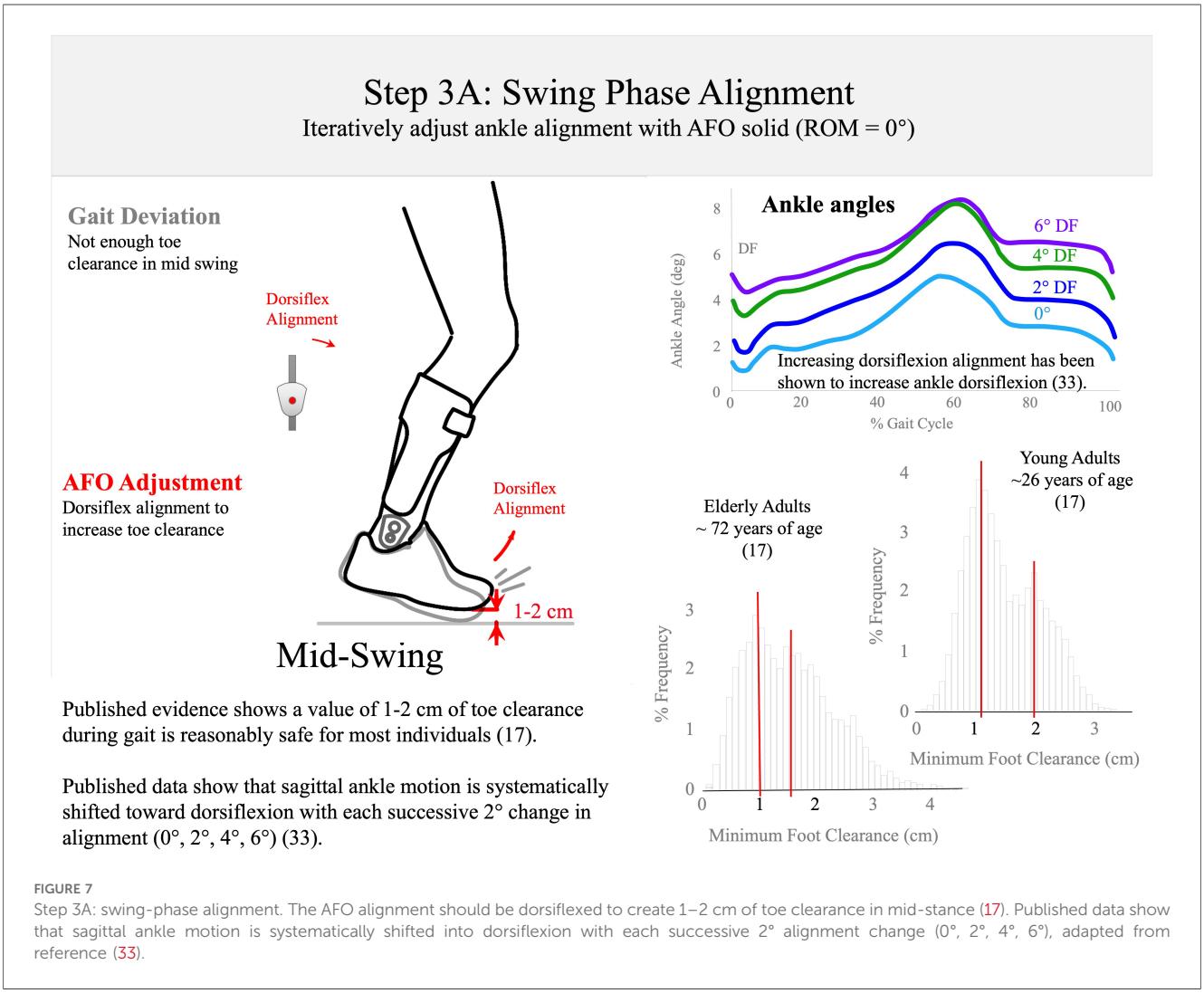


FIGURE 7
Step 3A: swing-phase alignment. The AFO alignment should be dorsiflexed to create 1–2 cm of toe clearance in mid-stance (17). Published data show that sagittal ankle motion is systematically shifted into dorsiflexion with each successive 2° alignment change (0°, 2°, 4°, 6°), adapted from reference (33).

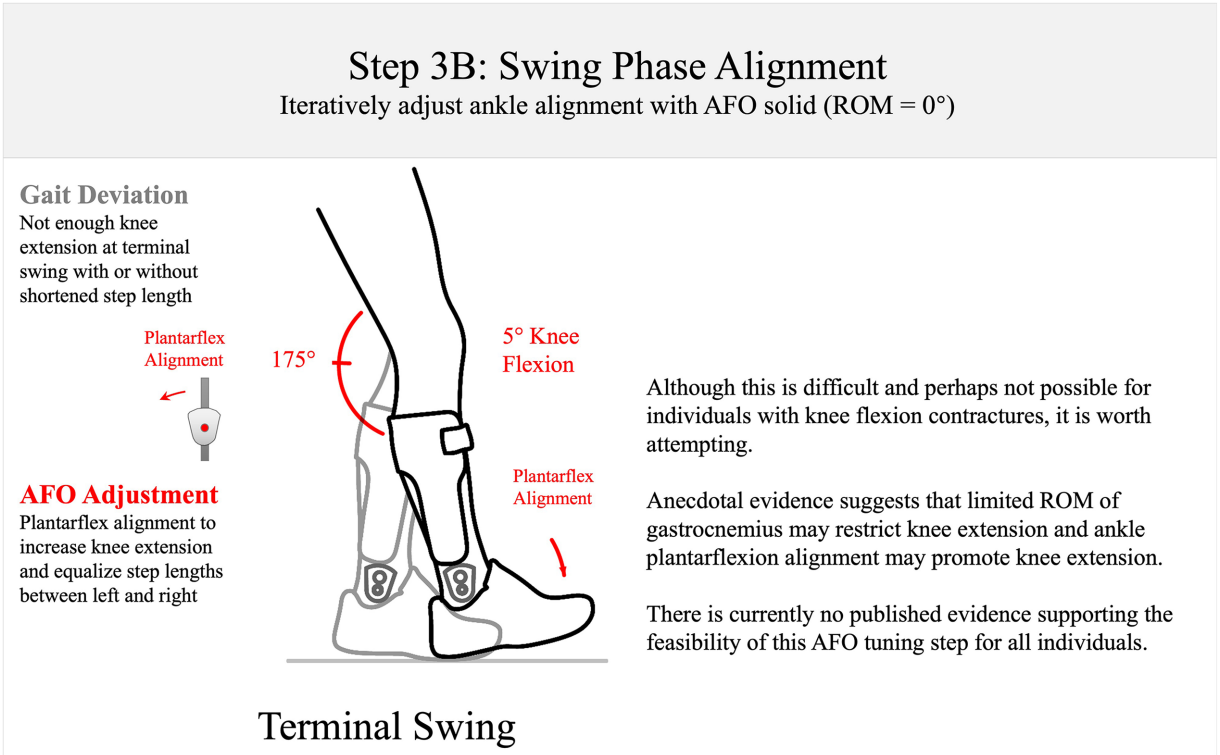


FIGURE 8
Step 3B: swing-phase alignment. The AFO should be aligned to encourage near full knee extension at initial contact. This is a challenging goal, and there is as yet no published evidence to support this goal in optimization of AFOs.

algorithm with the caveat that the measure should be cautiously utilized. However, the clinician should not rely solely on this observation for definitive decision-making during AFO optimization.

The angle between the shoe outsole and the floor at initial contact i.e., foot-to-floor angle, has been described by Perry in normal gait to be 25° at the time of heel strike (6). Vette et al. show a range of 15°–20° of foot-to-floor angle at initial contact (57). Therefore, a range of 10°–25° is used as the goal for swing-phase alignment of the foot position at initial contact and foot-position symmetry (Step 3C: Figure 9). Ankle alignment is optimized to achieve this goal by adjusting ankle alignment toward dorsiflexion or plantarflexion to increase or decrease the foot-to-floor angle, respectively.

To summarize, static- and swing-phase alignment is performed with the multi-function articulated AFO adjusted to its maximum resistance settings (against the dorsiflexion and plantarflexion motion limiting stops); therefore, any pathologic gait deviations observed during the adjustment of swing-phase alignment are reduced by optimizing ankle alignment to balance and prioritize concerns among the observed gait deviations. Toe clearance in mid-swing and foot position at initial contact are prioritized. However, if there is observed restriction of knee extension in terminal swing due to increasing dorsiflexion alignment of the AFO, particularly associated with a shortened gastrocnemius muscle, then optimizing toe clearance and/or foot position at initial contact becomes crucial. This optimization should consider how the knee flexion angle throughout the swing affects the position of the foot with respect to the floor.

Iteration between AFO settings for "Static Alignment" and "Swing-Phase Alignment" may be necessary to reconcile competing concerns between these two steps of the adjustment algorithm and to achieve the optimal alignment setting for balance in quiet standing with improved swing-phase gait mechanics. There may be a point of diminishing benefits to this compromise in reduction between gait deviations as the ankle alignment angle is changed. The algorithm relies on clinical judgment and iterative adjustments to alignment and careful, repeated observations to identify the optimal balance between these potentially competing concerns.

Step 4: early stance–phase adjustment (orthosis donned while patient is walking)—approximately 8 min

During static- and swing-phase alignments, the plantarflexion resistance threshold had been previously adjusted (during bench adjustment) to "lock" the ankle simulating a non-articulated AFO. In this configuration there was no concern that the orthosis would present inadequate resistance to prevent ankle plantarflexion through the swing phase because the orthosis presents the high structural stiffness of a non-articulated AFO to the ankle. However, with the patient walking in a maximally supportive AFO with high resistance to plantarflexion, undesirable rapid knee flexion in the first rocker may be

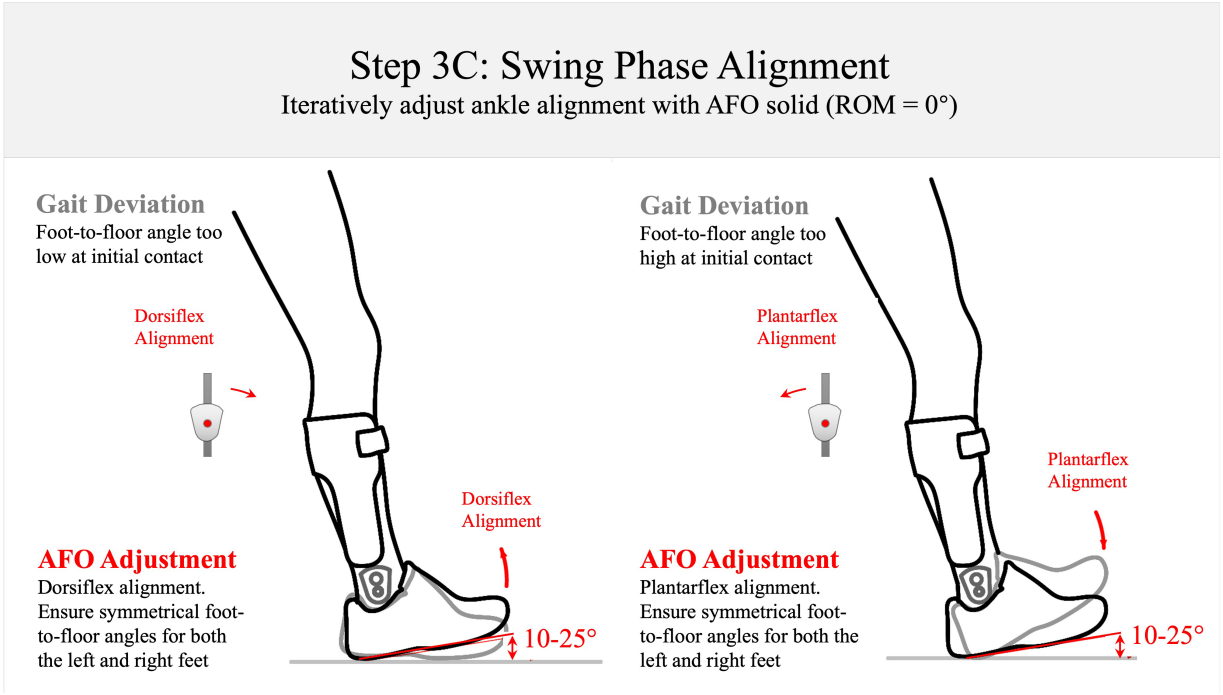


FIGURE 9
Step 3C: swing-phase alignment. The AFO alignment should be adjusted to create a 10°–25° between the foot and the floor at initial contact. 10°–25° foot-to-floor angle is supported by the studies by Perry and Vette et al. (6, 57). Lower angles than this are observed in pathological individuals leading to foot-flat or toe-heel contact (57) that can disrupt weight acceptance and forward momentum preservation in early stance (18).

observed (11, 34, 37, 39). This iatrogenic gait deviation is mitigated by reducing the plantarflexion resistance threshold in the next step of the algorithm (Step 4A: Figure 10).

Early Stance–Phase Adjustment involves reducing the plantarflexion resistance threshold to allow ankle plantarflexion in the first rocker when the ground reaction force from initial contact to loading response exceeds that resistance. When making this adjustment, it is important to maintain the plantarflexion resistance threshold high enough to maintain the ankle position at the ankle alignment angle throughout the swing phase until initial contact. The goal of adjusting the AFO resistance threshold for early stance phase is to encourage controlled knee flexion by permitting resisted ankle plantarflexion during the first rocker of the gait cycle. Therefore, the plantarflexion resistance threshold setting should permit ankle plantarflexion from initial (heel) contact to loading response to facilitate controlled knee flexion as the foot moves toward the floor. If the patient presents with genu recurvatum in early stance, in some cases reduction of the plantarflexion resistance threshold may permit knee hyperextension before mid-stance (39). In such cases, the plantarflexion resistance threshold may need to be increased and iteration of this adjustment may be necessary to determine the best setting to resist knee hyperextension while permitting ankle plantarflexion as much as possible in early stance (Step 4B: Figure 11). The final setting of the plantarflexion resistance threshold should therefore balance and prioritize these concerns and the clinician must decide on the primary gait deficit to be treated while prioritizing the reduction of other gait deviations.

Step 5: late stance–phase adjustment (orthosis donned while patient is walking)—approximately 8 min

The last step of the algorithm involves adjusting the dorsiflexion resistance threshold for the late stance phase of the gait cycle. This adjustment is intended to permit resisted ankle dorsiflexion with knee stability during the second and third rockers (Step 5: Figures 12, 13). The resistance of an AFO to dorsiflexion encourages knee extension after mid-stance and may also help control forward tibial progression during the second rocker (Step 5A: Figure 12). The multi-function articulated AFO will begin resisting dorsiflexion as the ankle attempts to dorsiflex beyond the ankle alignment angle. Resistance to dorsiflexion is essential to compensate for plantarflexor and quadriceps weakness and to encourage full knee extension after mid-stance. However, excessive resistance to dorsiflexion may also result in undesirable knee hyperextension in terminal stance (36). In this step of the algorithm, tibial progression and knee stability are observed from mid-stance through pre-swing.

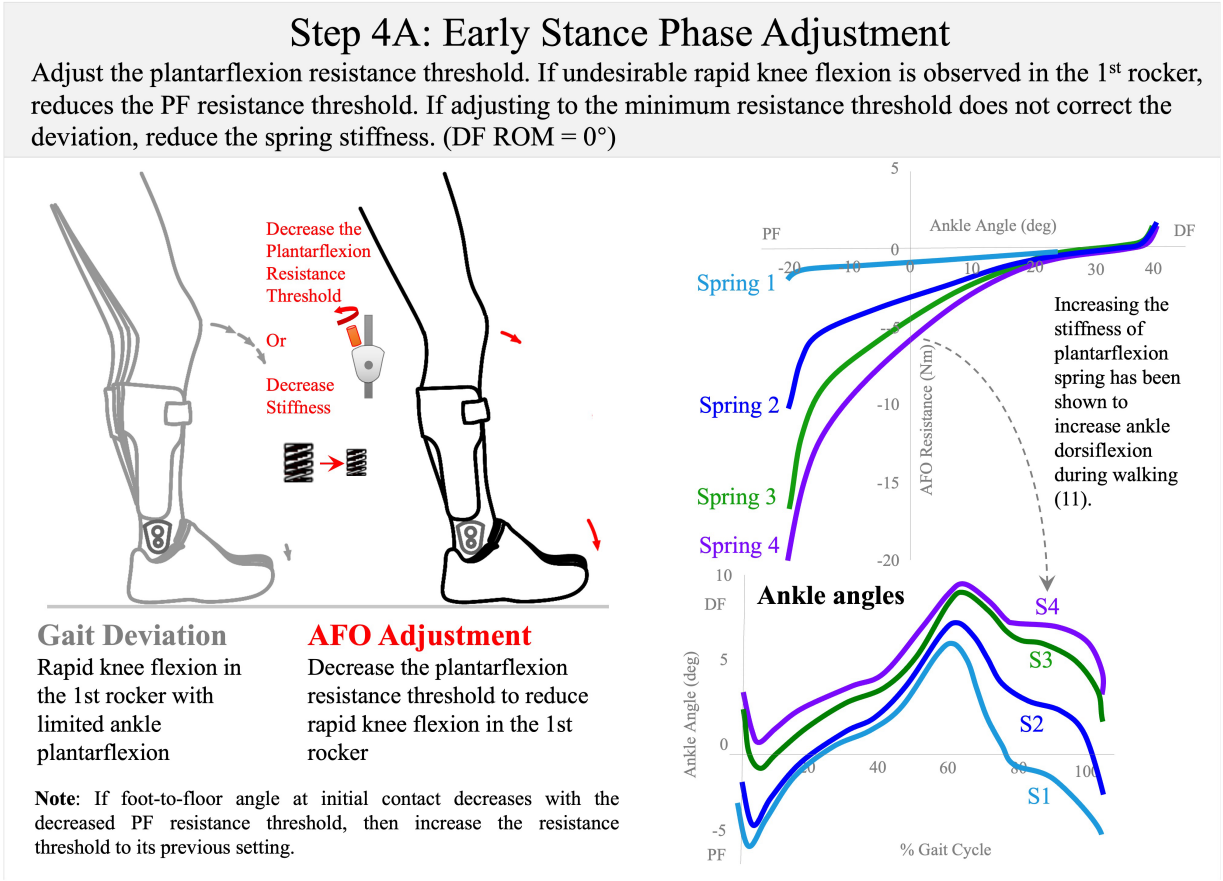


FIGURE 10
Step 4A: early stance-phase adjustment. The AFO plantarflexion range should be adjusted or the spring stiffness changed to allow the first rocker with controlled knee flexion. Dorsiflexion range of motion is set to 0° (DF ROM = 0°). Published data have demonstrated that sagittal ankle motion can be systematically shifted into plantarflexion or dorsiflexion by altering plantarflexion range spring stiffness (11). To control rapid knee flexion in early stance, either decrease the plantarflexion resistance threshold or choose a less stiff spring (3 Nm/deg → 0.6 Nm/deg → 0.3 Nm/deg).

The timing of heel rise is also observed after mid-stance and at the third rocker (Step 5B: Figure 13). It is generally accepted that the appropriate timing of heel off occurs prior to initial contact of the contralateral foot, but after the contralateral foot swings past the stance foot in the sagittal plane (59). Evidence suggests that the timing of heel off may also be affected by ankle dorsiflexion range of motion (58). Excessive knee flexion or late heel off after mid-stance suggests an insufficient dorsiflexion resistance threshold. If these gait deviations are observed, consider increasing the dorsiflexion resistance threshold. Conversely, the observation of excessive knee hyperextension or early heel off after mid-stance suggests that the dorsiflexion resistance threshold should be decreased.

4 Hypothetical case studies

The multi-function Articulated AFO Adjustment Algorithm (Supplementary File 1) is applicable to the orthotic treatment of a broad range of complex neuromotor pathologies. To illustrate the application of this algorithm, two hypothetical clinical cases are presented. These cases are based on the generalized clinical presentation and treatment outcomes of an ensemble of actual patients treated using multi-function articulated AFOs with the adjustment algorithm and by order of a prescribing physician.

4.1 Example 1: a patient with myelomeningocele

Imagine a hypothetical patient, a 15-year-old adolescent boy, who presents to clinic with myelomeningocele (MMC). The underlying pathology results in the functional deficit of absent volition of the plantarflexors with other motor function mostly preserved. Because of the plantarflexor deficit, the patient exhibits no push-off in the late stance phase of gait, and walks with persistent knee flexion throughout the stance phase. It is important to keep these deficits in mind when reviewing slow-motion videos during the optimization process. The patient has a history of orthotic treatment using non-articulated plastic AFOs worn with athletic footwear and native outsoles. However, an iatrogenic gait abnormality of excessive knee flexion in the first

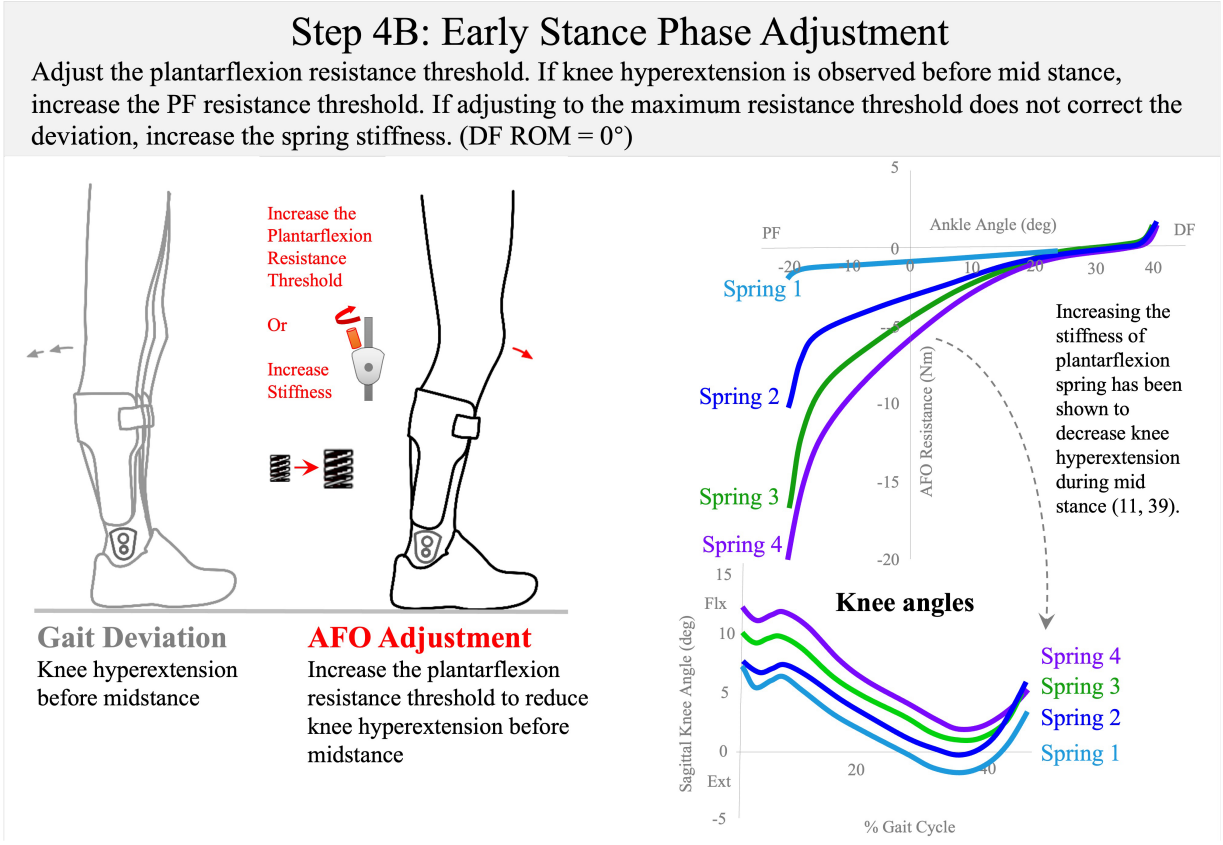


FIGURE 11
Step 4B: early stance-phase adjustment. Published data have shown that a more compliant spring can shift the knee to more extension in early stance (11, 39). To control knee hyperextension in early stance, either increase the plantarflexion resistance threshold or choose a stiffer spring (0.3 Nm/deg → 0.6 Nm/deg → 3 Nm/deg).

rocker is observed and persistent knee flexion throughout the stance phase remains unaddressed in the current orthotic design. The goals of orthotic treatment will be to improve the patient's stance phase gait mechanics while minimizing restriction of the ankle to preserve ankle motion in the first and second rockers, to reduce knee flexion in the first rocker of gait, and to achieve full knee extension without knee hyperextension in the late stance phase.

The patient is molded for bilateral multi-function articulated AFOs (Figure 14). The negative casts are corrected before pouring the positive model to align the sagittal ankle angle of the AFOs. This alignment is intended to promote a slight inclination of the shank when the AFOs are fitted to the patient wearing shoes. The AFOs incorporate features intended to resist the pathologic foot and ankle postural abnormalities.

Step 1: bench adjustment

Prior to fitting, the orthoses are bench adjusted. Bench adjustment is performed by adjusting the ankle alignment angle to its neutral setting (at the angle of fabrication that slightly inclines the shank when fit with the shoes) and the resistance threshold of the multi-function articulated AFO ankle joints to their maximum setting, effectively configuring the AFOs as solid ankle-foot orthoses.

Step 2: static alignment

The patient is seen for orthotic fitting, and the orthoses and shoes are donned. The fit of the orthoses is evaluated and adjusted to provide comfort and postural support without irritation.

The patient is asked to stand, and the ankle alignment angles are adjusted with the patient in static weight bearing. It is observed that the patient's knees are excessively flexed, therefore the static alignment angle is adjusted toward plantarflexion to slightly recline the shank and provide improved standing balance. Reclining the shank is perceived to shift the visualization of the weight line (TKA line) posteriorly. This patient's knee flexion is observed to be very responsive to the adjustment of ankle angle and is easily optimized during static alignment.

Step 3: swing phase alignment

The patient is asked to walk at a comfortable pace while the clinician uses a smart phone to record slow-motion, sagittal plane video. Slow-motion video captures at the high frame rate of 240 frames per second, resulting in a high-resolution video that improves the clarity of stop-motion and scrolled images. The

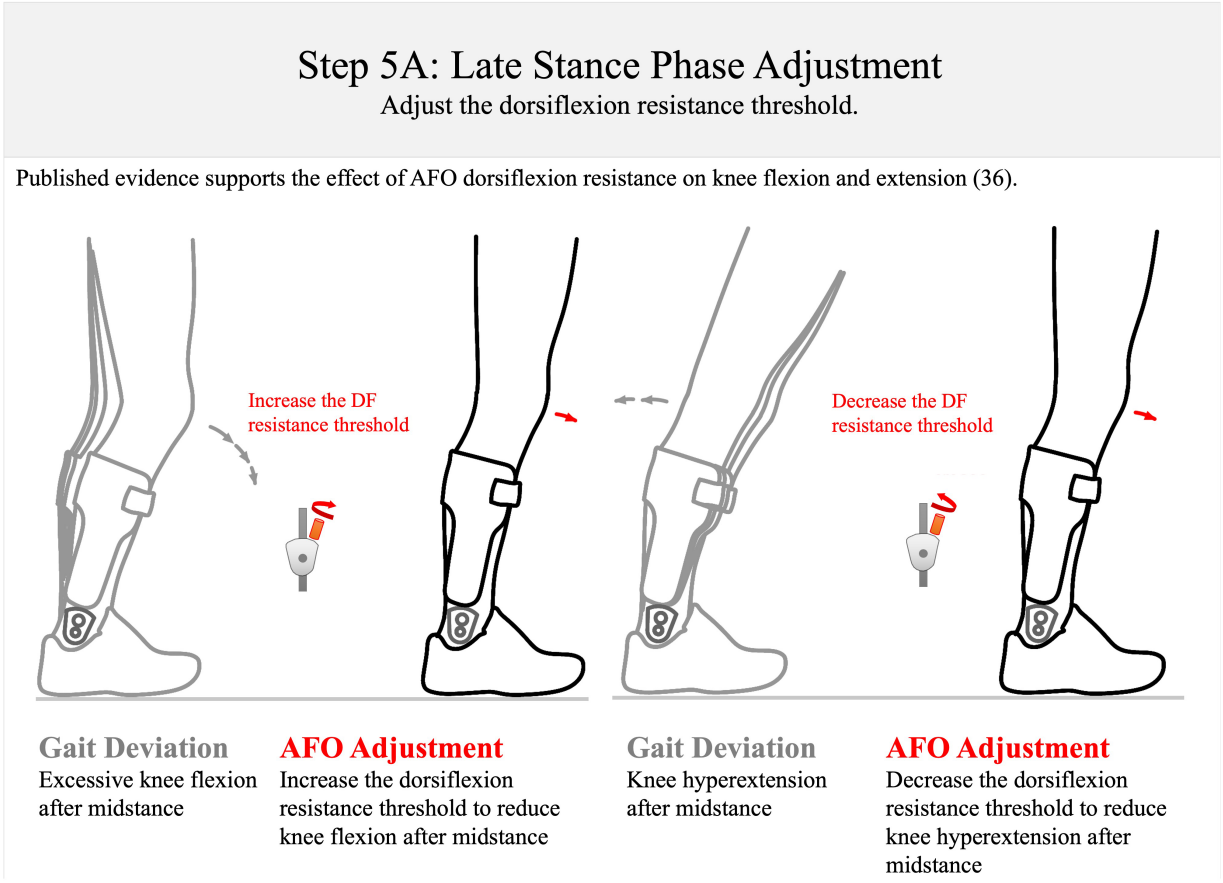


FIGURE 12
Step 5A: late stance-phase adjustment. To reduce excessive knee flexion in stance, the DF resistance threshold should be increased; to control knee hyperextension in the single-limb stance, the dorsiflexion resistance threshold should be decreased. This approach is supported by data from Ref. 36. DF, dorsiflexion.

clinician reviews the video, slowly scrolling the image left and right to analyze toe clearance in mid-swing and foot-to-floor angle at initial contact. This assists in identifying the pathologic gait abnormalities. Through the analysis of multiple steps of the patient walking, it appears that the toe clearance is greater than 2 cm in mid-swing, but the foot position at initial contact appears symmetric between the left and right sides. It is also observed that the foot-to-floor angle is excessive and greater than 25°. The ankle alignment settings of the AFOs are adjusted toward plantarflexion to decrease the foot-to-floor angle at initial contact. The walking trial is repeated, and slow-motion smart phone video confirms that the new alignment setting encourages heel contact with decreased dorsiflexion at initial contact and a foot-to-floor angle of about 20°. There does not appear to be any effect of the adjustment on knee extension at terminal swing. The patient's standing balance is again evaluated in static weight bearing. Shank inclination appears slightly reduced, but the knees do not appear hyperextended, and the ankle alignment setting is verified as the best compromise overall that improves standing balance and the patient's sense of stability in ambulation. The final, best-compromise multi-function articulated AFO alignment setting is 0°.

Step 4: early stance–phase adjustment

During initial adjustment of the AFO, the plantarflexion and dorsiflexion were locked to simulate a non-articulated AFO with high stiffness. Therefore, it is suspected that the high resistance to plantarflexion might result in the iatrogenic gait abnormality of rapid knee flexion in the first rocker. Slow-motion video confirms this suspicion.

To improve early stance-phase knee kinematics, the Early Stance-Phase Adjustment procedure is performed. Because the patient's dorsiflexion strength is preserved, it was anticipated that a lower stiffness, high compliance spring resisting plantarflexion might be appropriate for the patient. Therefore, a spring of 0.2 Nm/deg stiffness had been installed in the component's plantarflexion-resist channels prior to Bench Adjustment. The plantarflexion resistance threshold of the multi-function articulated AFOs are adjusted to 1 Nm permitting 15° of ankle plantarflexion relative to the ankle alignment angle before encountering the plantarflexion stop.

The patient is again asked to walk, and slow-motion video confirms that the toe clearance in mid-swing and foot-to-floor angle at initial contact remain unchanged after reducing the

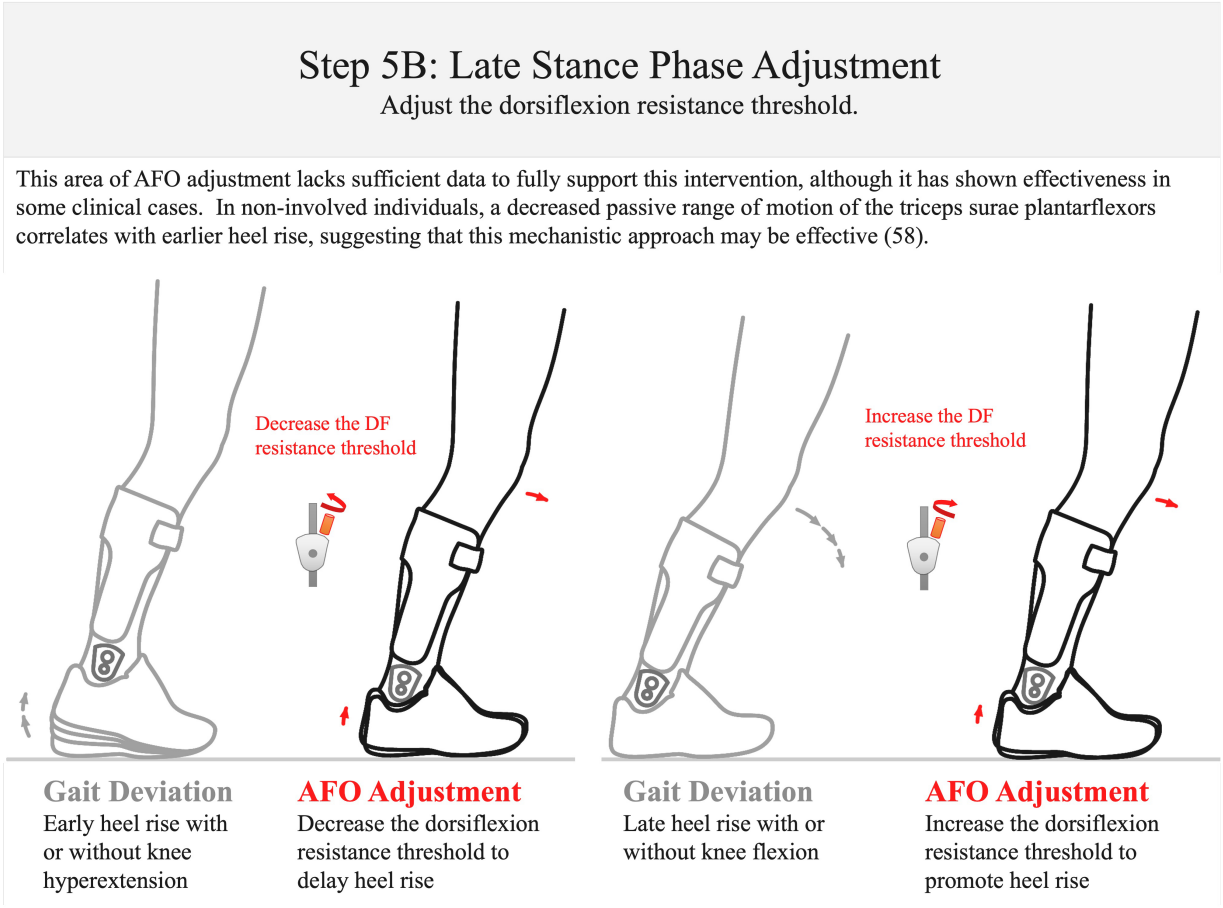


FIGURE 13
Step 5B: late stance-phase adjustment. If heel rise occurs too early in the gait cycle, decrease the DF resistance threshold. If the individual exhibits late heel rise with hyperdorsiflexion, increase the dorsiflexion resistance threshold (58). There is as yet no published evidence that supports or refutes this adjustment. DF, dorsiflexion.

plantarflexion resistance threshold. The excessive knee flexion in the first rocker is again observed and appears reduced following this adjustment but is still present. Therefore, the plantarflexion resistance threshold is further decreased to 0.6 Nm, increasing the compliance of the AFO in plantarflexion. Video analysis is repeated and reveals that this adjustment appears to significantly reduce the rapid knee flexion in the first rocker of gait. Foot position in swing phase and at initial contact remains unchanged, and ankle plantarflexion is clearly observed from initial contact to foot flat. The patient now ambulates with improved foot position throughout the swing phase and at initial contact and with significantly improved knee kinematics and visible ankle plantarflexion during the first rocker.

Step 5: late stance–phase adjustment

Having remediated the iatrogenic gait abnormality of rapid knee flexion in the first rocker, Late Stance Phase Adjustment is performed. A stated goal of orthotic treatment was encouraging full knee extension in late stance phase. The orthosis had been bench adjusted for high structural resistance to dorsiflexion and this setting has not yet been changed. Therefore, the orthosis had been configured to block ankle dorsiflexion beyond the ankle alignment angle that occurs at mid-stance. While achieving full knee extension was a stated goal, knee hyperextension is observed and considered an iatrogenic gait abnormality; therefore, the resistance threshold to ankle dorsiflexion must be decreased.

A 0.3 Nm/deg stiffness spring had initially been installed in the component's dorsiflexion-resist channel to provide assertive resistance to ankle dorsiflexion over a shorter range of motion substituting for the absent plantarflexors. The dorsiflexion resistance threshold is changed to 0.6 Nm, which permits a maximum of 16° of dorsiflexion range of motion relative to the ankle alignment angle before encountering the dorsiflexion stop. The patient is asked to walk, and slow-motion video confirms that the knee hyperextension has decreased after mid-stance, but repeated observations reveal that at this dorsiflexion resistance threshold, full knee extension is achieved only intermittently. Therefore, the dorsiflexion resistance threshold is increased to 1.4 Nm and the patient is again asked to walk. With this adjustment, the video confirms that the patient achieves reliable, full knee extension with smooth tibial progression through mid-stance without knee hyperextension or early heel rise.

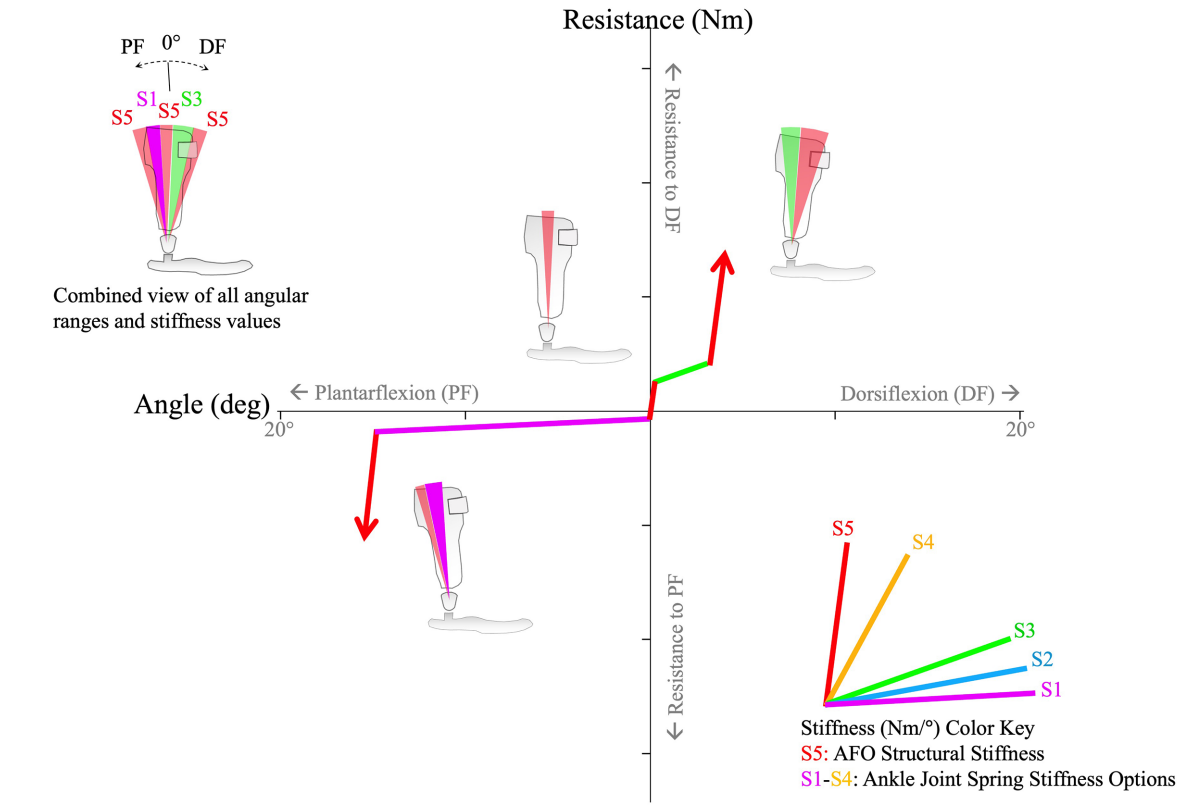


FIGURE 14
A hypothetical case study of the adjustment algorithm for a 15-year-old adolescent boy with sacral level MMC. With highly active dorsiflexors and absent plantarflexors, the multi-function articulated AFO is adjusted to have low stiffness through 15° of plantarflexion and then encounters the high stiffness of the AFO structure. A brief period of high stiffness is set around neutral (0°) for stance-phase stability, with a moderate spring stiffness into ~4° of dorsiflexion where the high stiffness of the AFO was encountered to prevent excessive dorsiflexion in the late stance-phase, and improve knee extension in mid-stance. MMC, myelomeningocele.

After completion of the algorithm, the patient's gait pattern is comprehensively reviewed to determine whether there are additional opportunities for improvement through iteration of multi-function articulated AFO component settings.

4.2 Example 2: a patient with Charcot–Marie–Tooth disease

Imagine a hypothetical 76-year-old elderly man with a history of Charcot–Marie–Tooth (CMT) presents to the clinic with a plantarflexion contracture with maximum dorsiflexion of 0° and quadriceps weakness. The patient's ambulatory function is impaired with several pathologic gait abnormalities including poor foot clearance in swing phase, steppage gait, short step length, and slow walking. Without use of an assistive device, the patient walks with an anterior trunk lean and instability. The patient's chief complaint is decreased activity level and an increased number of falls.

The primary goal of orthotic treatment is to provide support for the quadriceps and decrease the risk of falls. Secondary goals are to improve standing balance in static weight bearing, and to improve toe clearance in swing phase while minimizing restriction of the ankle to preserve ankle motion in the first and second rockers.

The patient is molded for fabrication of bilateral multi-function articulated AFOs (Figure 15). Prior to fabrication, the negative casts are corrected to neutral (0°) dorsiflexion, which would facilitate approximately 5° of shank inclination when fitted with shoes. This ankle angle is the patient's maximum passive dorsiflexion range of motion.

Step 1: bench adjustment

Prior to fitting, the orthoses are bench adjusted. Bench adjustment is performed by adjusting the ankle alignment angle to its neutral setting (at the angle of fabrication) and the resistance threshold of the multi-function articulated AFO ankle

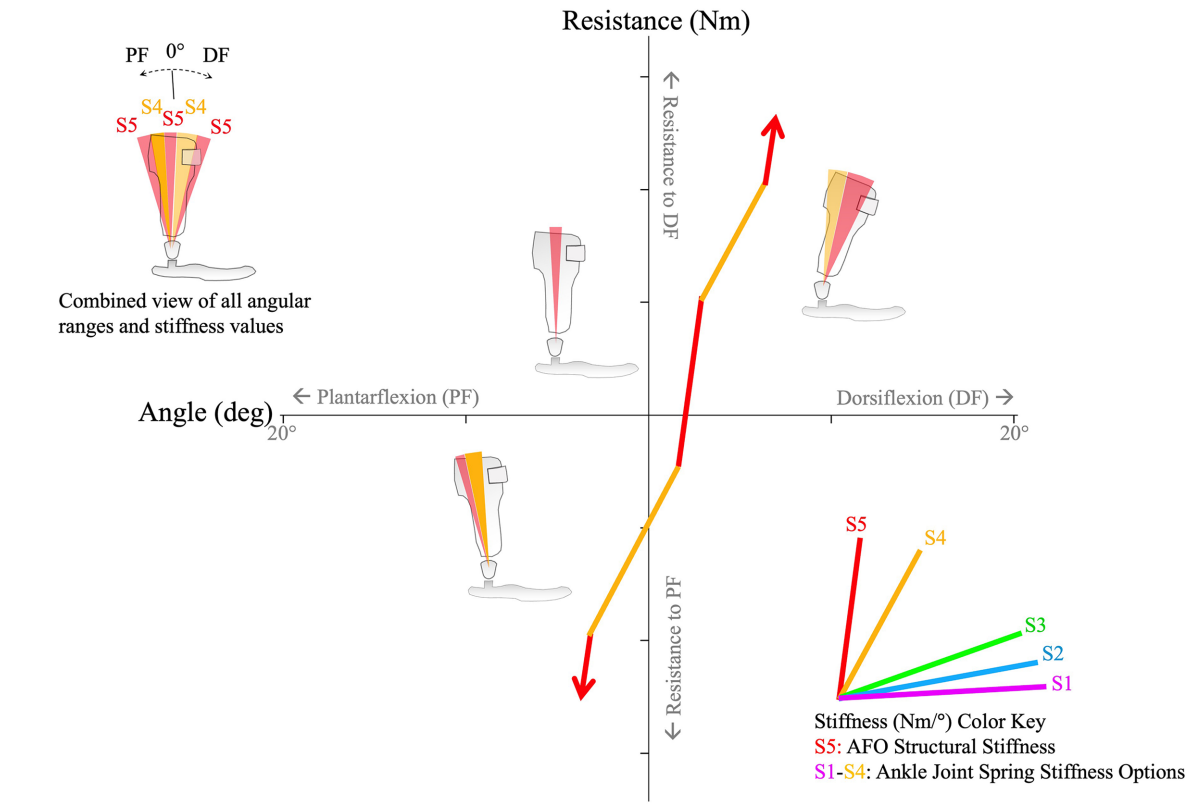


FIGURE 15
A hypothetical case study of the adjustment algorithm for a 76-year-old elderly man with CMT disease. The patient's pathologic gait deviations are the result of bilateral plantarflexion contractures at 0° and quadriceps weakness. After optimization of the ankle alignment angle for balance in static weight bearing, the multi-function articulated AFO is adjusted using the algorithm to allow 8° of resisted plantarflexion against stiff springs. The resistance threshold to dorsiflexion is adjusted to permit the second rocker against high resistance springs to stabilize the knees before encountering the high structural stiffness of the AFO at 5° dorsiflexion. CMT, Charcot-Marie-Tooth.

joints to their maximum resistance setting, effectively configuring the AFOs as solid ankle-foot orthoses.

Step 2: static alignment

The patient is seen for orthotic fitting and the orthoses and shoes are donned. The fit of the orthoses is evaluated and adjusted. After achieving the appropriate fit to provide comfort and postural support without irritation, the patient's AFOs are optimized using the evidence-guided algorithm.

The patient is asked to stand in the orthoses and the ankle alignment angles are adjusted with the patient in static weight bearing. Because the patient's ankle dorsiflexion range of motion is limited, heel lift insoles are added to his shoes plantar to the orthoses to accommodate the contractures and maintain the position of the ankles within their passive range of motion. This facilitates optimization of shank inclination while avoiding alignment of the ankle angle at the patient's end of anatomic dorsiflexion range of motion. The shank inclination is evaluated, and patient feedback is solicited regarding his sense of stability in quiet standing. The final ankle alignment setting is 2° dorsiflexion. This static alignment results in the patient standing in slight knee flexion. Because the orthoses present high resistance to dorsiflexion (with dorsiflexion blocked at bench adjustment), the patient has the sense of improved standing balance, which is objectively observed in a more relaxed and erect trunk and arm position. When solicited for feedback, the patient expresses a feeling of improved stability and comfort.

Step 3: swing-phase alignment

The patient is asked to walk at a comfortable pace. A smart phone is used to record slow-motion video to assist in identifying pathologic gait abnormalities.

Through this analysis it is observed that when walking, the patient has improved toe clearance and foot position at initial contact with the initial bench adjustment, although foot position at initial contact and step length appear slightly asymmetrical between the left and right sides. The ankle alignment settings of the AFOs are adjusted to improve symmetry while ensuring that

the foot-to-floor angle is maintained at approximately 10° at initial contact. Following this adjustment, the patient expresses the feeling of greater stability while walking and this is reflected by the observed decrease in anterior lean and reduced trunk sway during gait. The patient's sense of standing balance is again evaluated in static weight bearing and the ankle alignment setting is verified as the best compromise that overall provides the best standing balance and sense of stability while the patient is walking.

Step 4: early stance–phase adjustment

After the pathologic gait abnormalities of foot clearance in mid-swing, knee extension at terminal swing, foot position at initial contact, and step length symmetry in early stance have been remediated with static- and swing-phase alignment, it is anticipated that the high resistance to plantarflexion of the multi-function articulated AFOs might result in the iatrogenic gait abnormality of rapid knee flexion in the first rocker. This is confirmed by observation. To improve early stance-phase kinematics, the Early Stance-Phase Adjustment procedure is performed.

It was anticipated that a high stiffness spring resisting plantarflexion was appropriate for the patient, due to the patient's weight and the nature of their biomechanical deficits; therefore, a spring of 1.5 Nm/deg stiffness was installed in the component's plantarflexion-resist channels prior to Bench Adjustment.

The plantarflexion resistance thresholds of the multi-function articulated AFOs are adjusted to 4.3 Nm facilitating 5° of plantarflexion range of motion relative to the ankle alignment angle before encountering the plantarflexion motion stop. However, it is observed that knee flexion is still exaggerated in the first rocker from initial contact to loading response at this plantarflexion resistance threshold setting. Therefore, the plantarflexion resistance threshold is further reduced to 1 Nm. The evaluation is repeated and this change in component settings appears to result in improved knee stability in the first rocker with controlled knee flexion through early stance, while maintaining the position of the foot from swing to initial contact.

Step 5: late stance–phase adjustment

Having optimized knee kinematics in the first rocker, attention is lastly focused on Late Stance–Phase kinematics. Tibial progression through mid-stance and knee kinematics at terminal stance are evaluated using slow-motion video.

It was anticipated that a high stiffness spring resisting dorsiflexion would be appropriate for the patient, due to the patient's weight and the weak quadriceps; therefore, a spring of 1.5 Nm/deg stiffness had been installed in the component's dorsiflexion-resist channels prior to Bench Adjustment. With the AFOs still adjusted to block dorsiflexion, repeated observations using slow-motion video of the patient walking confirm that while knee stability appears improved and gait speed is higher, tibial progression is interrupted in the second rocker near the static alignment angle.

Therefore, the resistance threshold to dorsiflexion is decreased to 5 Nm to allow resisted ankle dorsiflexion past the ankle alignment angle after mid-stance, facilitating 4° of resisted dorsiflexion range of motion beyond the ankle alignment angle. Resisted dorsiflexion is intended to support the quadriceps and keep the knee more extended through mid-stance while improving tibial progression in the second rocker until the structural stiffness of the orthosis is encountered at the end of dorsiflexion range of motion.

After completion of the algorithm, the patient's gait pattern is comprehensively reviewed to determine whether there are additional opportunities for improvement through iteration of multi-function articulated AFO component settings.

5 Discussion and limitations of the algorithm

The overarching goal of this AFO adjustment algorithm is to mitigate pathologic gait deviations while minimizing restriction of ankle motion throughout the gait cycle. It is assumed that the mitigation of pathologic gait deviations will improve overall patient function and the least possible ankle restriction will facilitate the most beneficial therapeutic outcome. However, the evidence is limited to the biomechanical principles of the steps for optimizing multi-function articulated AFOs rather than the efficacy of orthotic treatment due to the lack of research in this area.

The method was developed to assist in the optimization of multi-function articulated AFOs in the orthotic treatment of pathologic gait secondary to stroke, CP, traumatic brain injury (TBI), MMC, multiple sclerosis (MS), CMT disease, and other neuromotor pathologies. By adopting the modest ambition of developing a preliminary adjustment algorithm focused on the reduction of pathologic gait deviations when compared to normal gait, the algorithm is intended to serve as a preliminary guideline for the adjustment of AFO mechanical characteristics to streamline the process of AFO adjustment and improve the consistency of the clinician's approach in reducing the pathologic gait deviations that may result from a broad range of underlying pathologies.

Evidence from published research that supported the development of the algorithm suggests that the method could potentially be used to systematically reduce pathologic gait deviations, thereby improving gait, daily activities, and the quality of life for patients with a broad range of underlying pathologies. The focal influence of specific mechanical characteristics of multi-function articulated AFOs on certain kinematic variables, and the reliability of observational gait analysis augmented by repeated observations of specific gait events using slow-motion video, were established and lay the foundation for the method (8, 11, 26, 31, 36, 39, 40, 44–49, 53, 54). However, some observations employed by the algorithm are less well supported including knee extension at terminal swing and timing of heel rise at late stance. Additional research is required to validate the utility of these clinical observations for orthotic adjustment. There is also insufficient evidence to support the efficacy of AFOs in general in the treatment of patients with pathologic gait abnormalities (60, 61). Multi-site studies using an ensemble of metrics including patient activity

level, kinematic measurements, and validated performance-based and patient-reported outcome measures to determine patient satisfaction and quality of life could address these limitations.

Identification of pathologic gait deviations plays an important role in our proposed algorithm. Although there have been significant advances in motion analysis technology, a cost-effective and clinically viable means to quickly and accurately assess gait performance remains unrealized. In clinical practice, orthotists rely heavily on observational gait analysis to assess the impact of orthotic treatment. However, evidence also suggests that the reliability of observational gait analysis may be influenced by the clinician's skill level and personal experience (44, 46). There is also evidence suggesting that this reliability may be improved by focusing the clinician's observations on specific gait events, with repetitive trials using slow-motion video (45, 47–49). A thorough validation of the algorithm is necessary in future studies with a large sample size.

The published research does not support application of a single AFO stiffness for treating the complex gait pathologies observed (39, 62). Therefore, our case examples illustrate how the method could be applied to adjust the mechanical characteristics including stiffness and the resistance threshold of an AFO to the unique needs of the individual patient to achieve the best possible results. This method was developed to be effectively implemented in the clinical setting by orthotists familiar with the basic techniques of customary orthotic practice. Real-world functional gait data that demonstrate the efficacy of orthotic treatment and AFOs optimized using the method are not available; however, this limitation could be overcome by conducting large-scale clinical trials with comprehensive evaluations of a variety of patient populations (63).

Future applications of the algorithm (Supplementary File 1) could involve developing a structured methodology for orthotic clinical care. This could inform research by standardizing orthotic practice, therefore facilitating the isolation of variables essential to experimental design. Such research could focus on efficacy, potentially leading to advancements in care delivery, orthotic design, and ultimately improving patient outcomes.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Ethics statement

The algorithm presented in this study was developed based on literature review and clinical experiences of the team. The "Hypothetical case studies" were presented based on hypothetical patients.

Author contributions

NL: Conceptualization, Methodology, Visualization, Writing – original draft. BJ: Conceptualization, Methodology, Visualization, Writing – review & editing. FG: Methodology, Writing – review & editing. MO: Methodology, Conceptualization, Visualization, Writing – original draft. YH: Methodology, Visualization, Writing – review & editing. TK: Methodology, Visualization, Writing – review & editing, Conceptualization, Supervision.

Funding

The authors declare that this study received funding from Becker Orthopedic. The funder was not involved in the study design, collection, analysis, interpretation of data, the writing of this article, or the decision to submit it for publication.

Acknowledgments

This work has been posted as a preprint on Research Square (64).

Conflict of interest

NL and BJ are employees of Becker Orthopedic, Inc., manufacturer of the Triple Action multi-function ankle joint.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

The authors declared that they were an editorial board member of Frontiers, at the time of submission. This had no impact on the peer review process and the final decision.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fresc.2024.1353303/full#supplementary-material

SUPPLEMENTARY FILE 1
Summary of the adjustment process of multi-function articulated ankle-foot orthoses.

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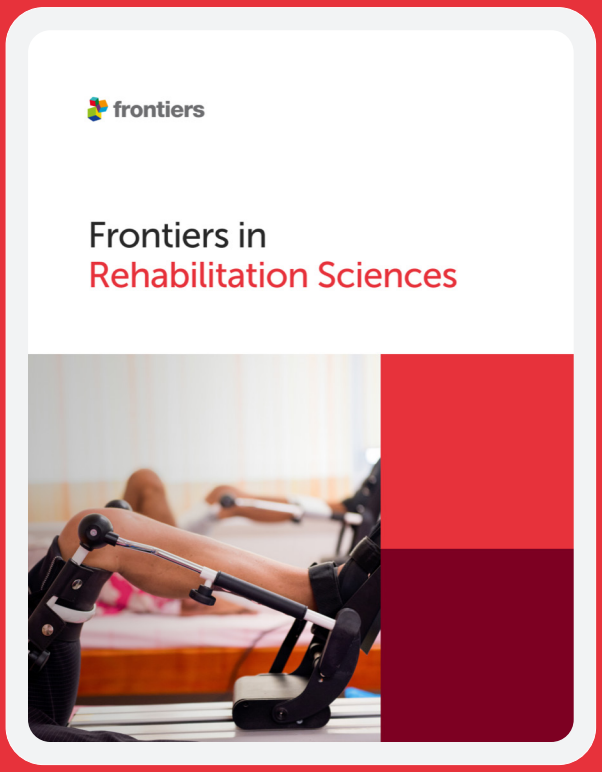

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