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TITLE: A Pilot Clinical Trial to Assess the Effect of Transfemoral Socket Design on Hip Muscle Function

PRINCIPAL INVESTIGATOR: Andrew Sawers, CPO, PhD

CONTRACTING ORGANIZATION: University of Illinois at Chicago

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14. ABSTRACT

The purpose of the proposed research is to evaluate how prosthetic socket design influences hip muscle function in transfemoral prosthesis users. The scope of the proposed research includes evaluating hip muscle function and its contribution to balance and mobility in unilateral lower limb prosthesis users, and testing whether walking with a sub-ischial socket alters hip muscle function in unilateral transfemoral prosthesis users. This is to be accomplished by conducting cross-sectional (aim 1) and longitudinal (aims 2) studies to evaluate hip muscle function in lower limb prosthesis users (aim 1), and test whether it can be influenced by socket design in transfemoral prosthesis users (aim 3). To date we have made reasonable progress on recruitment and enrollment given the COVID-19 pandemic. Specifically, we have recruited, enrolled, and completed data collection on 10 of 14 able-bodied controls, and 6 of 14 transfemoral prosthesis users, and 6 of 14 transtibial prosthesis users in aim 1. We have recruited and enrolled 2 of 8 transfemoral prosthesis users for aim 2, with prospective data collection ongoing. Plans to expand recruitment efforts and adjust to COVID restrictions are underway. Dissemination efforts have resulted in the publication of one manuscript (Hewson et al., 2020), and the submission of a conference abstract (Dent et al., 2020).

15. SUBJECT TERMS
amputee; strength; muscle; recruitment; enrollment

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INTRODUCTION

Owing to their design, standard of care ischial-containment sockets may weaken residual limb hip muscles among transfemoral prosthesis users, potentially limiting balance, and mobility. Our recent work has provided anecdotal evidence that walking with a sub-ischial socket (i.e., one that does not interact with the pelvis) increases residual limb hip muscle size and strength in transfemoral prosthesis users. While an appealing therapeutic possibility, direct evidence that socket design alters residual limb hip muscle function among transfemoral prosthesis users is still needed. Testing this hypothesis is made difficult by gaps in our knowledge of muscle function among people with lower limb amputation. The scope of the proposed research therefore includes first evaluating hip muscle function and its contribution to balance and mobility among transfemoral prosthesis users (Aim 1), and then testing the hypothesis that walking with a sub-ischial socket alters hip muscle function among transfemoral prosthesis users (Aim 2). This is to be accomplished by comprehensively evaluating hip muscle strength and endurance in 14 transfemoral ischial-containment prosthesis users and 14 age- and sex-matched able-bodied persons (Aim 1). Eight of the transfemoral prosthesis users will be fit with a sub-ischial socket (Aim 2), and their muscle strength, endurance, and coordination will be assessed eight and 42-weeks post-fitting to evaluate short- and long-term changes in residual limb hip muscle function. This project will determine whether deficits in hip muscle strength or endurance play a causal role in balance and mobility impairments, and may shift the perception of prosthetic sockets from mechanical interfaces to devices with therapeutic benefit (e.g., increase strength).

KEYWORDS

Amputee; muscle; strength; endurance; socket; prospective; rehabilitation

ACCOMPLISHMENTS

Major goals of the project: The major goals (milestones) of the project as outlined in the SOW were:

Goal 1: Obtain and maintain IRB approvals from UIC, NU, and ORP/HRPO
(*Target date: Y1Q1, Y1Q4 – 100% Completed*).

Goal 2: Study Preparation: recruitment, consent, and data collection materials, equipment, and staff ready for data collection (*Y1Q1- 100% Completed*).

Goal 3: 28 participants enrolled (*Y1Q4 – 66% completed*).

Goal 4: Data collection completed (*Y2Q3 – 50% completed*).

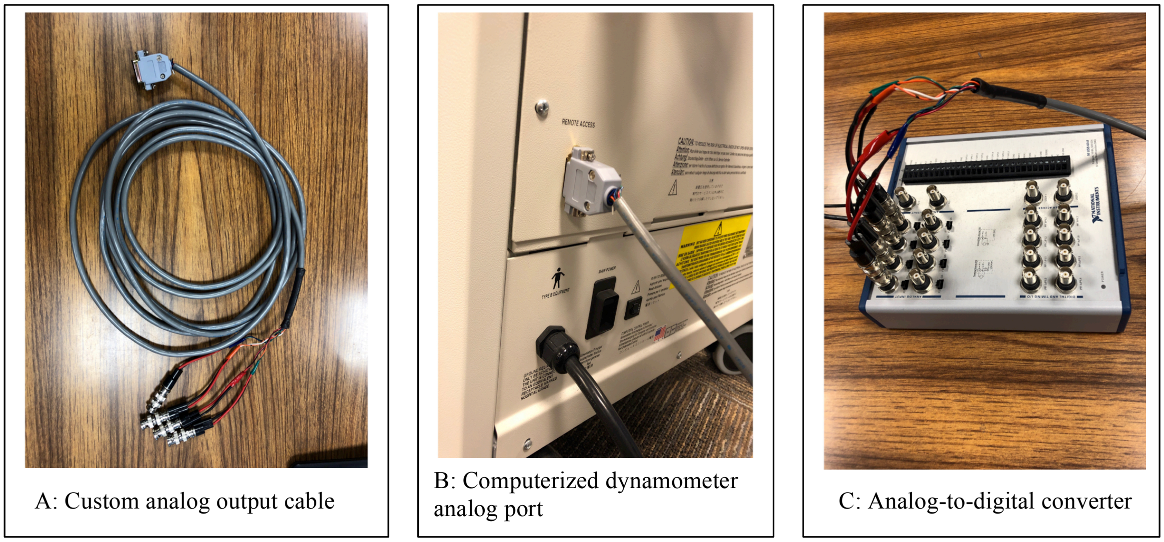
Goal 5: Data entered, processed, and analyzed to address study hypotheses (*Y2Q4 – 35% completed*).

Goal 6: Abstracts presented at scientific conferences, manuscripts prepared and submitted for publication, delivery of training material for clinical implementation NU-FlexSIS socket course. (*Y2Q4 – 15% completed*).

Accomplishments under these goals: For each of the goals/milestones outlined in the SOW, we had made significant and timely progress prior to COVID-19. With additional safety measures in place, we have resumed recruitment, enrollment, and data collection in an effort to achieve the major goals of the project. At the same time we continue to look for additional and novel ways to remain as productive as possible.

Goal 1: The PI and Co-I developed and modified study protocol and consent documents for their local IRBs. Local (UIC and NU) IRB approval was obtained on 10/09/2019. After some delay due to HRPO misplacing the submitted documents, ORP/HRPO approval was obtained on 02/05/2020. Both study sites (UIC and NU) have completed their annual IRB continuing review. Documents for the ORP/HRPO annual continuing review were submitted 07/29/20.

Goal 2: The PI and Co-I of the project finalized all study protocols (e.g., assessment of hip muscle strength, clinical balance and mobility testing, EMG electrode placement), and data collection forms to standardize data collection procedures. Recruitment materials were distributed to clinical collaborators. Research staff at UIC was trained to ensure consistency in data collection and entry procedures across all team members. The PI and other members of the UIC study team built and tested a custom analog cable (figure 1A) to export, convert, and record the raw analog torque signal from a computerized Biodex dynamometer (figure 2B) through an analog-to-digital converter (figure 1C) during strength testing. Access to the raw analog torque signal permits analyses that would otherwise not be possible (i.e., calculate additional metrics of strength).



A: Custom analog output cable

B: Computerized dynamometer analog port

C: Analog-to-digital converter

Figure 1: Custom analog cable and accompanying connections to export and record raw analog signal.

Custom code was written and de-bugged to analyze raw torque time series data. The custom cable and computer code allow us to calculate a variety of strength metrics from the raw torque signal (figure 2) rather than having to rely on the basic and rudimentary metrics generated by the computerized Biodex dynamometer. Finally, we also successfully registered our clinical trial (Aim 2) on ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT04212299).

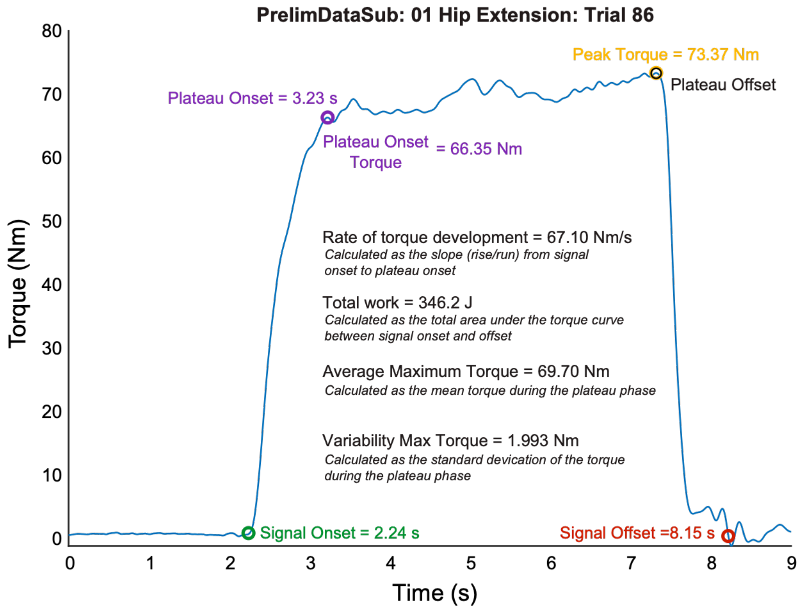


Figure 2: We wrote custom Matlab code to automate the processing and analysis of the raw torque signal. The code detects signal onset plateau onset, plateau offset, and signal offset. From those four time points all strength outcome measures are calculated: peak torque, rate of torque development, total work (angular impulse), average maximum torque, and variability in maximum torque (i.e., torque steadiness).

Goal 3: We met all of our quarterly enrollment targets pre-COVID-19 (i.e., Y1Q2). For aim 1 (i.e., cross-sectional assessment of hip muscle strength) we have recruited and enrolled 10 of 14 able-bodied controls, and 6 of 14 transfemoral prosthesis users. In addition we have recruited and enrolled 6 of 14 transtibial prosthesis users in aim 1. While not originally planned, the inclusion of transtibial prosthesis users in aim 1 provides an additional and important comparison to assess how the level of amputation affects hip muscle function. All financial compensation for participants with transtibial amputation is being provided through the PI's discretionary account. For aim 2 (i.e., prospective pilot clinical trial of sub-ischial socket) we have recruited and enrolled 2 of 8 transfemoral prosthesis users. One of those two transfemoral prosthesis users has received his sub-ischial socket (figure 3), while the second is completing the fitting process.

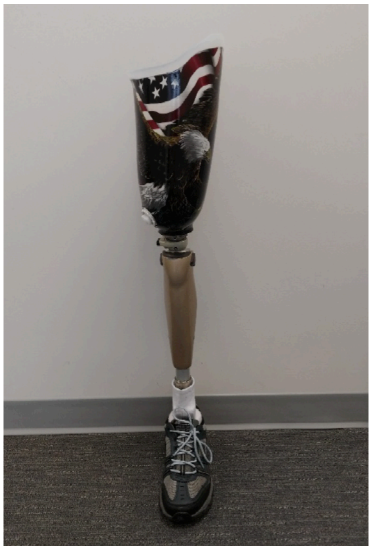


Figure 3: sub-ischial socket delivered to study participant.

We have recently been given permission to re-start in-person human subjects research at our respective institutions. We have implemented additional safety procedures (e.g., mask, minimal personnel). Since implementing these procedures we have recruited one additional participant with transtibial amputation and one with transfemoral amputation, both for aim 1. They will be enrolled in the coming week. Three additional transtibial and one additional transfemoral prosthesis user have expressed interest in participating, but have elected to hold off enrolling until the New Year. While COVID-19 has and continues to hamper our enrollment, we believe that we will be able to catch up as we expand recruitment to additional local prosthetic clinics.

Goal 4: We have collected hip muscle strength, as well as clinical walking and balance data (aim 1) on nearly half of the our planned sample (i.e., 10/14 able bodied controls, 6/14 transfemoral amputees, and 6/14 transtibial amputees). For aim 2 we have collected baseline strength, electromyography, and clinical walking and balance data on a quarter of our planned sample (i.e., n= 2 of 8). We have also completed the 8-week follow-up testing (i.e., hip muscle strength, electromyography, and walking and balance performance) on the transfemoral prosthesis user who has received his sub-ischial socket. As we re-start in-person data collection, we have also begun exploring additional data collection procedures that do not require physical contact but would still serve to advance the research questions posed under the current award. Prior to their addition, any new data collection procedures will be discussed at length with the Science Officer managing this award.

Goal 5: All strength and electromyography data collected to date has been processed and are currently being analyzed. All clinical walking and balance data has been digitized and uploaded from the data collection sheets to a shared REDCap database. In addition to the planned analyses (i.e., comparing hip muscle strength between control, intact, and residual limbs; evaluating the association between hip muscle strength and walking and balance ability; comparing hip muscle coordination patterns between socket designs in transfemoral prosthesis users; as well as evaluating short- and long-term changes in hip muscle strength with sub-ischial versus ischial-containment sockets), two novel analyses have emerged that are highly relevant to the planned analyses. First, while writing our recently published review on muscle strength deficits in people with lower limb amputation, we discovered that to date, methods of normalization, designed to account for differences in body shape and size, have not been applied to the assessment of strength in people with lower limb amputation. As a result, comparisons in the literature between residual and intact legs, as with respect to controls have not accounted for differences in body shape or size. Therefore, any observed differences in strength within the literature may simply reflect differences in body shape or size, not strength. To address this gap we have begun to test whether normalization of strength metrics is necessary in lower limb prosthesis users (i.e., strength measures in lower limb prosthesis users correlate with body shape or size parameters), and whether conventional normalization procedures are sufficient to remove any body-size dependency of strength metrics in lower limb prosthesis users (i.e., they reduce the magnitude and significance of correlations between strength metrics and body size or shape parameters). Preliminary analyses revealed that peak hip extension torque was significantly correlated to body size (i.e., mass x height) in the residual (r=.704, p=.042) and intact (r=.769, p=.044) limbs of transfemoral prosthesis users. In contrast, peak hip extension torque was significantly correlated to height, not body size, in the residual (r=.882, p=.010) and intact (r=.819, p=.023) limbs of transtibial prosthesis users. Both results suggest that peak hip extension torque in lower limb prosthesis users is dependent on body shape or size, and support the need for normalization to remove body size dependency. When peak hip extension torque was normalized by body size (i.e., torque values divided by body size), correlation magnitudes decreased (r≤.24), and were no longer statistically significant p>.10 in either transfemoral or transtibial prosthesis users. This suggests that the body size dependency of peak hip extension torque can be removed via ratio scaling normalization procedures. As we continue to increase our sample size, we will evaluate additional methods of normalization (i.e., ratio versus allometric scaling). The application of normalization procedures to the planned analyses in the current project will ensure that suitable and appropriate comparisons, as well as interpretations, of the data are made.

Second, it would appear that different strength metrics provide unique, non-overlapping information about strength and strength-related deficits in people with lower limb amputation. Historically, only peak torque has been used to examine strength and strength deficits in people with lower limb amputation. We have found however, that several of the strength metrics we computed from the isometric torque signals were highly correlated with each other, while others were not. This resulted in the identification of two unique dimensions of strength: i) how much torque can be generated (e.g., peak torque, max average torque, and total angular impulse), and ii) how consistently torque can be generated (i.e., torque steadiness) (figure 4).

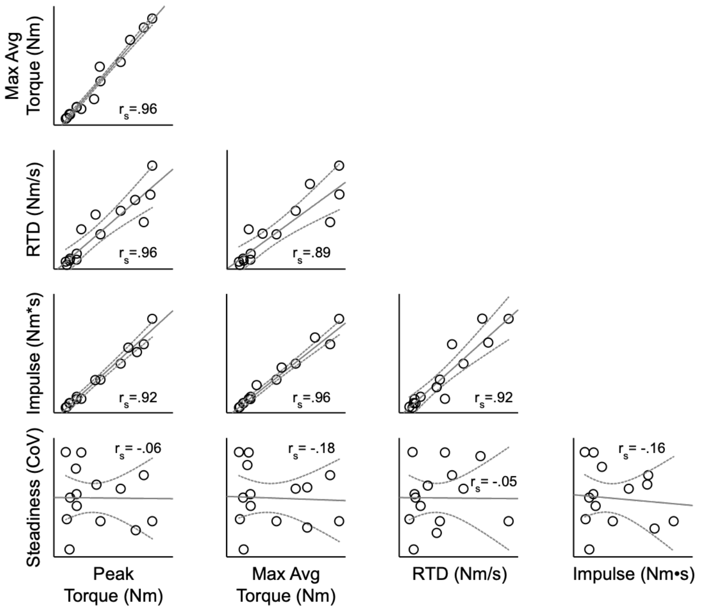


Figure 4: The strong correlations between peak torque, maximum average torque, rate of torque development (RTD), and impulse indicate that they provide redundant information about strength (i.e., they measure the same construct – how much torque can be generated). In contrast, the absence of a correlation between peak torque and torque steadiness (i.e., how consistently torque can be generated) suggests they measure different dimensions of strength. These data are for the hip extension muscles in the residual limb. Analysis of other muscles and legs is ongoing.

We were somewhat surprised to find that the rate of torque development (i.e., RTD) was so highly correlated to measures of how much torque can be generated, and did not form its own dimension (i.e., how quickly torque can be generated). Similarly, muscular endurance, not included in the analysis is likely to form a 3rd dimension of strength. It remains to be determined whether these dimensions of strength are truly independent, associated with different performance outcomes such as balance, mobility, or endurance, and which of them exhibit the largest deficits among people with lower limb amputation compared to able-bodied controls. These preliminary results have generated number of ideas for future research regarding the dimensionality of strength.

Goal 6: In spite of the COVID-19 pandemic, and as we re-start in-person data collections, we have attempted to maintain a productive publication record under this award. To date Dr. Sawers and a graduate student had a scoping review on muscle strength deficits in lower limb prosthesis users accepted in Prosthetics and Orthotics International (see attached for PDF of submitted manuscript). In this review reported strength deficits in lower limb prosthesis users were synthesized, and possible causes, consequences and solutions were discussed, while gaps and future research directions were highlighted. We found that the reviewed studies offered evidence of strength deficits in people with lower limb amputation. Specifically, when compared to controls, and the intact limb, the primary strength outcome, peak torque, was lower in transtibial residual limb knee flexors and extensors, as well as transfemoral residual limb hip muscles. The magnitude of these between limb differences often exceeded a 10% bilateral deficit cited as the norm for controls, and frequently exceeded a 20% threshold often cited as abnormal in other patient populations. Major scientific gaps identified in the literature included the lack of alternative strength metrics previously shown to be critical to balance and mobility outcomes (e.g., rate of torque development, muscle endurance), the validity of clinical performance-based strength tests among lower limb prosthesis users, and the relationship of strength deficits among specific lower limb muscles to balance and mobility outcomes in lower limb prosthesis users. We have also authored a conference abstract based on the preliminary strength normalization data analysis. This abstract will be submitted to the World Congress of the International Society for Prosthetics and Orthotics.

Several other manuscripts are currently in preparation. These include: i) a second review paper synthesizing reported changes in muscle structure with amputation, and ii) a short communication/technical note describing normalization procedures and how they influence the interpretation of strength deficits in people with lower limb amputation.

Opportunities for training and professional development: Nothing to report.

Dissemination of results to communities of interest: Nothing to report.

Plan to accomplish goals during over next reporting period: During the next reporting period, we intend to complete all remaining facets of the study goals. This includes: i) completing participant recruitment and enrollment; ii) completing data collection for Aim 1; iii) completing 75% of data collection for Aim 2; iv) process and review all data pertaining to Aim 1; v) conducting hypothesis testing for Aim 1 and additional questions we have developed; vi) prepare and submit manuscripts related to Aim 1, and vii) present study results to local prosthetists in the Chicago area at the 2021 Scheck and Siress Education Fair, as well as ISPO World Congress. In order to identify a sufficient number of participants willing to participate in in-person data collections we have and continue to broaden our recruitment efforts. This includes reaching out to additional prosthetic clinics and rehabilitation hospitals in the Chicagoland area, posting recruitment materials on patient and clinician list-serves, and possibly purchasing print advertisements in publications from regional and national amputee support groups.

IMPACT: Nothing to report.

CHANGES/PROBLEMS

While we anticipate our enhanced recruitment strategies will pay dividends, many lower limb prosthesis users remain hesitant to participate in-person data collection due to their age accompanying co-morbidities (e.g., diabetes). In light of this challenge we will explore additional ways to collect data that require less physical contact, yet still answer research questions posed under the current award.

PRODUCTS

Journal publications (in this reporting period)

Hewson A, Dent S, Sawers A. Strength deficits in lower limb prosthesis users: A scoping review. *Prosthetics and Orthotics International.* 2020; 44(5):323-340.

Conference presentations (in this reporting period)

Dent A, Fatone S, Caldwell R, Sawers A. Ossur Instructional Course. Normalization is necessary and removes body size dependency of strength measures in unilateral lower limb prosthesis users. 2020 *World Congress of the International Society for Prosthetics and Orthotics*.

PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS

Individuals who worked on the project

Name:	Andrew Sawers, PhD
Project Role:	Principal Investigator (UIC)
Researcher Identifier:	
Nearest person month worked:	1
Contribution to Project:	Dr. Sawers has been responsible for overseeing all aspects of the project (IRB, managing recruitment, enrollment, and data collection, data analysis, and manuscript preparation)
Funding Support:	N/A

Name:	Stefania Fatone, PhD
Project Role:	Co-Investigator (NU)
Researcher Identifier:	
Nearest person month worked:	<1
Contribution to Project:	Dr. Fatone has been responsible for overseeing aspects of the project at the NU study site (IRB, managing recruitment, enrollment, and socket fabrication and fitting).
Funding Support:	N/A

Name:	Shaquitta Dent, MS
Project Role:	Graduate Student (UIC)
Researcher Identifier:	
Nearest person month worked:	1
Contribution to Project:	Ms. Dent has performed work in the area of screening of participants, enrolling participants, consent, data collection, data entry, data analysis, and dissemination at the University of Illinois at Chicago study site.
Funding Support:	N/A

Name:	Ryan Caldwell
Project Role:	Co-I (NU)
Researcher Identifier:	
Nearest person month worked:	<1
Contribution to Project:	Mr. Caldwell has been responsible for overseeing aspects of the project at the NU study site (recruitment as well as socket fabrication and fitting).
Funding Support:	N/A

Change in the active other support for the PD/PI(s) or senior/key personnel

Nothing to report

Other organizations involved as partners

Nothing to report

SPECIAL REPORTING REQUIREMENTS

N/A

APPENDICES

Appendix 1: Quad Chart
Appendix 2: Manuscript

A pilot clinical trial to assess the effect of transfemoral socket design on hip muscle function

OP180022

W81XWH-19-1-0507-OPORP-PORA (Funding Level 1)

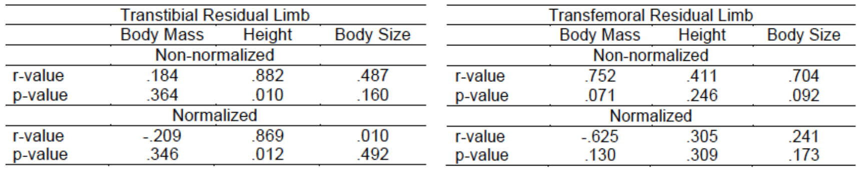
PI: Andrew Sawers, PhD, CPO **Org:** The University of Illinois at Chicago **Award Amount:** $350,000

Study Aim(s)

- Evaluate hip muscle function and its contribution to balance and mobility among unilateral transfemoral prosthesis users.
- Test whether walking with a sub-ischial socket alters hip muscle function among unilateral transfemoral prosthesis users.

Approach

We will conduct cross-sectional (Aim 1) and longitudinal (Aim 2) studies to evaluate hip muscle function in transfemoral prosthesis users, and test whether it can be influenced by socket design. We will compare measures of hip muscle strength between transfemoral amputees and controls, while evaluating the relationship between hip muscle function and walking and balance performance among transfemoral amputees (Aim 1). We will also prospectively assess changes in measures of hip muscle function among transfemoral amputees transitioning from an ischial-containment to a sub-ischial socket (Aim 2).



Transtibial Residual Limb	Body Mass	Height	Body Size
Non-normalized			
r-value	.184	.882	.487
p-value	.364	.010	.160
Normalized			
r-value	-.209	.869	.010
p-value	.346	.012	.492

Transfemoral Residual Limb	Body Mass	Height	Body Size
Non-normalized			
r-value	.752	.411	.704
p-value	.071	.246	.092
Normalized			
r-value	-.625	.305	.241
p-value	.130	.309	.173

Table 1 and 2: Correlation magnitude and statistical significance between residual limb peak hip extension torque and three anthropometric parameters frequently used in strength normalization procedures. While residual limb peak hip extension torque in transtibial prosthesis users was correlated to both height and body size, only normalization to body size (i.e., body mass x height) reduced the magnitude and significance of the correlation. Similarly, while residual limb peak hip extension torque in transfemoral prosthesis users was correlated to both body mass and body size, only normalization to body size (i.e., body mass x height) reduced the magnitude and significance of the correlation.

Timeline and Cost

Activities **CY**	**19**	**20**	**21**
Human subjects approval & train sites	▨		
Participant recruitment		▨	▨
Conduct data collection procedure		▨	▨
Analyze data and disseminate results		▨	▨
Estimated Budget ($K) **$350**	**$100**	**$150**	**$100**

Updated: (01/08/2018)

Goals/Milestones

CY19 Goal – Study preparation and participant recruitment

☑ Obtain local human subjects approval

☑ Finalize protocols, data collection sheets and study database

☑ Equip and train study staff at UIC & Northwestern

CY20 Goals – Ongoing recruitment, data collection, and analysis

☑ Recruit 28 participants for Aim 1 and 8 for Aim 2

☑ Conduct data collection and analysis procedures

☐ Disseminate initial results at national conference

CY21 Goal – Analysis and dissemination

☐ Recruit and collect data from final 10 participants

☐ Analyze final data set

☐ Disseminate final study results

Comments/Challenges/Issues/Concerns

- None to report

Budget Expenditure to Date

$84,400 (including F&A)

Prosthetics and Orthotics International

INTERNATIONAL
SOCIETY FOR PROSTHETICS
AND ORTHOTICS

Review

Strength deficits in lower limb prosthesis users: A scoping review

Prosthetics and Orthotics International
2020, Vol. 44(5) 323–340

DOI: 10.1177/0309364620930176
journals.sagepub.com/home/poi
SAGE

Alex Hewson, Shaquitta Dent and Andrew Sawers

Abstract

Background: Strength deficits may play a central role in the severity of balance, mobility, and endurance impairments in lower limb prosthesis users. A body of literature detailing the scope and specifics of muscle weakness in lower limb prosthesis users is emerging, but has yet to be summarized. A synopsis of strength deficits, and their impact on functional abilities in lower limb prosthesis users, may inform rehabilitation and research needs.

Objectives: Synthesize reported strength deficits in lower limb prosthesis users, and discuss possible causes, consequences, and solutions.

Study Design: Scoping review.

Methods: A search of biomedical databases was performed, and inclusion/exclusion criteria were applied to identify publications relevant to the purpose of the review.

Results: In all, 377 publications were identified, of which 12 met the inclusion/exclusion criteria. When compared with the controls and the intact limb, the primary strength outcome, peak torque, was lower in transtibial residual limb knee flexors and extensors, as well as transfemoral residual limb hip muscles.

Conclusions: The reviewed studies provide evidence of strength deficits in lower limb prosthesis users. These deficits appear to be consequential, as they may contribute to balance, mobility, and endurance impairments. Additional research exploring alternative strength metrics, clinical tests, and causal links to functional impairments is required.

Clinical relevance

Evidence of muscle weakness among lower limb prosthesis users, and its influence on balance, mobility, and endurance, suggests that greater clinical attention and scientific inquiry into physical conditioning of lower limb prosthesis users is merited and required.

Keywords

Amputation, muscle strength, artificial limb, rehabilitation.

Date received: 7 January 2020; accepted: 27 April 2020

Introduction

Lower limb amputation has a substantial effect on an individual's functional ability,[1–4] as evidenced by the 26%–62% of lower limb prosthesis users who regain the ability to walk outdoors.[1] Among the functional challenges faced by lower limb prosthesis users, increased metabolic demand,[5–7] decreased balance ability,[8–12] decreased walking speed,[13,14] increased stumbles and falls,[12,15–17] reduced activity level,[18,19] and difficulty ambulating on hills, stairs, or uneven terrain[20–22] are frequently cited. A wide variety of prosthetic interventions are available and have been used with varying degrees of success,[23–32] to address these balance, mobility, and endurance challenges. Nonetheless, functional challenges persist following lower limb amputation.

In addition to prosthetic design, there is emerging evidence that preserving and/or restoring pre-amputation strength levels may be essential to mitigating or preventing gait and balance deficits associated with lower limb amputation. For example, when matched for age and fitness, unilateral transtibial prosthesis users walk with a metabolic cost equivalent to that of people without lower limb

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Associate Editor: David Rusaw

amputation.[33,34] Furthermore, regardless of prosthetic foot function (i.e. powered or passive), when pre-limb loss muscle strength was maintained in a musculoskeletal model of a transtibial prosthesis user, the metabolic cost of walking was not significantly different post-amputation.[35] In addition to reduced metabolic cost,[36] stronger muscles also appear to be related to better balance,[37,38] as well as greater mobility and endurance[39] among lower limb prosthesis users. These studies suggest that lower limb strength may be a key determinant of balance, mobility, and endurance in lower limb prosthesis users. A comprehensive understanding of strength deficits among lower limb prosthesis users, and any related consequences on balance, mobility, and endurance will be central to further advances in rehabilitation of lower limb prosthesis users.

The body of evidence detailing the scope and specifics of muscle weakness in lower limb prosthesis users has yet to be summarized. This scoping review aims to address this gap in the literature by thoroughly summarizing differences in strength between the residual and intact limbs of people with lower limb amputation, and with respect to unimpaired adults. A comprehensive review of strength deficits among lower limb prosthesis users is critical to providing physiological targets for engineers, surgeons, physical therapists, and prosthetists to develop and implement more effective prosthetic components, surgical procedures, and therapies. This review will also serve to identify gaps in the current body of knowledge from which future research questions can be developed. The objective of this scoping review was, therefore, to synthesize reported strength deficits among lower limb prosthesis users, and discuss their possible causes, consequences, and potential solutions.

Methods

Literature search

A search of the literature in March of 2018 was performed using two bibliographic databases: PubMed (1949 to March 2018), and the Cumulative Index to Nursing and Allied Health Literature Expanded Index (CINAHL; March 1981–March, 2018). Keywords based on the population of interest, “amputee,” and outcome of interest, “strength,” were used in the search across both databases. The syntax used in both PubMed and CINAHL was (“amputee” AND “strength). Additional manuscripts were identified by searching the references of the initially identified publications.

Inclusion and exclusion criteria

Inclusion and exclusion criteria were applied to identify publications relevant to the stated purpose of the review. Only those publications, written in, or translated into, English, and published in peer-reviewed journals were considered (i.e. no dissertations, conference proceedings, White Papers). Only studies that directly compared the strength of the residual, intact, and/or control leg hip and knee muscles were included. Studies whose objective was to evaluate the effectiveness of an exercise or resistance training program were excluded from the results, but considered for later discussion. Studies that did not report results based on the level of amputation or present data in a manner that allowed for its extraction according to level of amputation were also excluded. No exclusion criteria based on the etiology or level of amputation was applied.

Screening and review of publications

To select publications pertinent to the objective of the review, the inclusion and exclusion criteria were applied to the search results by two of the authors (A.H. and A.S.). After removing duplicate publications identified in both databases, each article was screened based on its title, and removed if unrelated to the objective of the review. The contents of the abstracts were then reviewed for details regarding the population of interest (i.e. people with lower limb amputation), and the outcome of interest (i.e. strength). All remaining publications were then reviewed, with their results binned into muscle group (i.e. knee extensors, hip flexors) and level of amputation (i.e. transtibial, transfemoral).

Results

Literature search

The search strategy yielded 377 citations across the two databases; 32 of these publications were selected based on their title and 2 additional publications were added after searching the references of these initial 32 papers. After review of the abstracts, 12 of the 34 publications were found to meet the inclusion and exclusion criteria established for this review. The included publications were found to span the years 1968–2018. Of the 12 publications included for review, nearly 70% were published on or prior to 2002, while nearly 50% were published prior to 2000.

Study demographics and outcomes

Study sample sizes ranged from 7 to 38. The level of amputation studied was predominantly transtibial (i.e. 9 of the 12 studies, and 74% of all study participants; Table 1). The etiology of limb loss across studies was mainly non-dysvascular (i.e. 60% of study subjects). Knee flexor and extensor strength was the most studied outcome among transtibial prosthesis users (i.e. eight studies), while hip strength was the primary outcome in studies involving transfemoral prosthesis users (i.e. three studies). Strength

Table 1. Characteristics of studied samples.

Author (year)	Level of amputation (*n*)	Etiology (*n*)	Time since amputation (years) mean ± SD	RL length (cm) mean ± SD	Sex (*n*)	Age (years) mean ± SD
Bäcklund et al. (1968)[40]	Transtibial (20)	Trauma (20)	12.5	Not reported	Male (18) Female (2)	39.4
James (1973)[41]	Transfemoral (38)	Not reported	18	Not reported	Male (38)	43.3 ± 12.5
Renström et al. (1983)[42]	Transtibial (32)	Dysvascular (20) Infection (3) Cancer (2) Trauma (7)	2.33 ± 1.83	14.8 ± 0.7	Male (24) Female (8)	Male: 61 ± 18 Female: 38 ± 9
Ryser et al. (1988)[43]	Transfemoral (10) Controls (10)	Trauma (7) Cancer (2) Dysvascular (1)	7.8	31.8 ± 5.1	Male (8) Female (2)	LLPU: 41.4 ± 12.5 Control: 41.5 ± 15
Isakov et al. (1996)[44]	Transtibial (18)	Trauma (15) Dysvascular (3)	13.4 ± 14.4	15.1 ± 3.2	Male (12) Female (6)	45.7 ± 14.7
Powers et al. (1996)[45]	Transtibial (22)	Dysvascular (22)	Male: 24.6 Female: 13.0	Not reported	Male (15) Female (7)	Male: 59.6 ± 11 Female: 60.5 ± 5
Moirenfeld et al. (2000)[46]	Transtibial (11)	Trauma (11)	19.6 ± 13.6	9.5 ± 5.9	Not reported	43.7 ± 14.4
Nadollek et al. (2002)[37]	Transtibial (22)	Dysvascular (22)	2.99 ± 1.72	Not reported	Not reported	71.7 ± 9.62
Pedrinelli et al. (2002)[47]	Transtibial (25) Controls (27)	Trauma (14) Dysvascular (7) Infection (4)	Not reported	Not reported	LLPU: Male (17) Female (8) Control: Male (18) Female (9)	LLPU: 36 ± 13.0 Control: 35 ± 9.9
Tugcu et al. (2009)[48]	Transtibial (15)	Trauma (15)	4.8 ± 3.6	Not reported	Male (15)	26.2 ± 3.9
Lloyd et al. (2010)[49]	Transtibial (8) Controls (8)	Trauma (4) Dysvascular (2) Infection (1) Cancer (1)	7.2	Not reported	LLPU: Male (7) Female (1) Control: Male (7) Female (1)	LLPU: 43 ± 13 Control: 45 ± 13
Rutkowska-Kucharska et al. (2018)[50]	Transfemoral (14)	Trauma (7) Cancer (4) Congenital (2) Dysvascular (1)	Not reported	27.1 ± 4.4	Not reported	46 ± 14

n: sample size; RL: residual limb; SD: standard deviation; LLPU: lower limb prosthesis user.

of the tested muscle groups was primarily quantified using peak isometric torque (i.e. eight studies), and to a lesser extent, peak isokinetic torque (i.e. five studies). Only 3 of the 12 studies included a control group of non-lower limb prosthesis users.[43,49,47] In each of these studies, lower limb prosthesis users were matched to non-lower limb prosthesis user controls based on a combination of age, sex, height and/or body mass index. None of the studies matched for underlying comorbidities such as dysvascular disease.

The reviewed studies offer evidence of strength deficits in people with lower limb amputation. Differences in isometric and isokinetic strength between the residual limb, intact limb, and controls are described below, and detailed in Tables 2 to 11. The percentage difference between legs is reported in the text, while study-specific torque values are provided in Tables 2, 3, 5, 6, and 9 for transtibial prosthesis users and Tables 4, 7, 8, 10, and 11 for transfemoral prosthesis users.

Knee flexion and extension strength

There is evidence that across muscle actions (i.e. isometric[37,40,41,43,45,49,50] and isokinetic[42,44,46–48]), test postures (i.e. seated,[40,42,44–48] supine,[49] and prone[49]) knee joint angles (i.e. 20°–90°[40,42,44,45,49]) and angular velocities (i.e. 30–180°/s[42,44,46–48]), knee flexion and extension strength in the residual limb of unilateral transtibial prosthesis users are significantly lower than that of their intact leg or controls (Tables 2

Table 2. Summary of studies investigating knee flexor strength in unilateral transtibial prosthesis users.

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
Bäcklund et al. (1968)[40]	Intact	Isometric	Peak torque	3 s	Prosthesis	Left: mean = 1108 kpcm^{a} Right: mean = 1229 kpcm^{a}	3 trials	Sitting	Knee: 90° flx Hip: 90° flx
Renström et al. (1983)[42]	Residual	Isometric	Peak torque	Not reported	Prosthesis	50 ± 23 Nm^{b,c}	3 trials	Sitting	Knee: 30° flx
					No prosthesis	30 ± 10 Nm^{b}			Hip: 100° flx
					Prosthesis	36 ± 18 Nm^{b,c}			Knee: 60° flx
					No prosthesis	25 ± 9 Nm^{b}			Hip: 100° flx
		Isokinetic (concentric)		30°/s (ROM: 0°–90°)	Prosthesis	39 ± 22 Nm^{b,c}			Hip: 100° flx
					No prosthesis	30 ± 16 Nm^{b}			
				60°/s (ROM: 0°–90°)	Prosthesis	36 ± 21 Nm^{b,c}			Hip: 100° flx
					No prosthesis	27 ± 16 Nm^{b}			
				120°/s (ROM: 0°–90°)	Prosthesis	28 ± 20 Nm^{b}			Hip: 100° flx
					No prosthesis	25 ± 44 Nm^{b}			
	Intact	Isometric		Not reported	N/A	95 ± 31 Nm			Knee: 30° flx Hip: 100° flx
		Isokinetic (concentric)		30°/s (ROM: 0°–90°)		77 ± 25 Nm			Knee: 60° flx Hip: 100° flx
				60°/s		87 ± 27 Nm			Hip: 100° flx
				(ROM: 0°–90°)		81 ± 27 Nm			
				120°/s (ROM: 0°–90°)		63 ± 25 Nm			
Isakov et al. (1996)[44]	Residual	Isometric	Average peak torque	5 s	Not reported	30.3 ± 20.4 Nm^{b}	5 trials	Sitting	Knee: 60° flx Hip: 90° flx
	Intact					52.6 ± 24.3 Nm			
	Residual	Isokinetic (concentric)	Peak torque	60°/s (ROM: unknown)		29.9 ± 20.0 Nm^{b}			
		Isokinetic (eccentric)				64.5 ± 37.3 Nm^{b}			Hip: 90° flx
	Intact	Isokinetic (concentric)				74.6 ± 34.8 Nm			
		Isokinetic (eccentric)				128.2 ± 45.1 Nm			
Moirenfeld et al. (2000)[46]	Residual	Isokinetic (concentric)	Peak torque	120°/s (ROM: 0°–90°)	Prosthesis	49.3 ± 12.3 Nm^{b}	5 trials	Sitting	Hip: 110° flx
	Intact					74.6 ± 25.7 Nm			

(Continued)

Table 2. (Continued)

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
Pedrinelli et al. (2002)[47]	Residual	Isokinetic (concentric)	Peak torque	60°/s (ROM: unknown)	Not reported	43.8 Nm[d]	4 trials	Sitting	Not reported
				180°/s (ROM: unknown)		29.9 Nm[d]	6 trials		
	Intact			60°/s (ROM: unknown)		65.0 Nm[d]	4 trials		
				180°/s (ROM: unknown)		48.0 Nm[d]	6 trials		
	Control (dominant)			60°/s (ROM: unknown)		94.5 Nm	4 trials		
				180°/s (ROM: unknown)		72.2 Nm	6 trials		
	Control (non-dominant)			60°/s (ROM: unknown)		90.5 Nm	4 trials		
				180°/s (ROM: unknown)		75.8 Nm	6 trials		
Tugcu et al. (2009)[48]	Residual	Isokinetic (concentric)	Peak torque	30°/s (ROM: unknown)	Prosthesis	45.9 ± 24.4 Nm[b]	5 trials	Sitting	Hip: 90° flx
				120°/s (ROM: unknown)		33.7 ± 19.2 Nm[b]			
	Intact			30°/s (ROM: unknown)		72.5 ± 26.4 Nm			Hip: 90° flx
				120°/s (ROM: unknown)		52.9 ± 17.5 Nm			
Lloyd et al. (2010)[49]	Residual	Isometric	Peak torque	5 s	Prosthesis	0.36 ± 0.2 Nm/kg[d,e]	3–5 trials	Prone	Knee: 20°flx Hip: 90° flx
	Intact					0.73 ± 0.3 Nm/kg[d,e]			
	Control					0.81 ± 0.3 Nm/kg			

SD: standard deviation; kpcm: kilopound per centimeter; °: degrees; flx: flexion; Nm: newton-meter; °/s: degrees per second; ROM: range of motion; s: seconds; Nm/kg: newton-meter per kilogram.

[a] Left and right intact values reported separately.

[b] Residual limb significantly weaker than intact limb ($p < 0.01$).

[c] Residual limb significantly stronger wearing prosthesis than without ($p < 0.01$).

[d] Significantly weaker than control limb ($p < 0.05$).

[e] Lower limb prosthesis users are significantly more asymmetrical than controls ($p < 0.05$).

Table 3. Summary of studies investigating knee extensor strength in unilateral transtibial prosthesis users.

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
Bäcklund et al. (1968)[40]	Intact	Isometric	Peak torque	3 s	Prosthesis	Left: mean = 2006 kpcm^{a} Right: mean = 1852 kpcm^{a}	3 trials	Sitting	Knee: 90° flx
Renström et al. (1983)[42]	Residual	Isometric	Peak torque	Not reported	Prosthesis	33 ± 4 Nm^{b,c}	3 trials	Sitting	Knee: 30° flx Hip: 100° flx
					No prosthesis	24 ± 3 Nm^{b}			
					Prosthesis	51 ± 7 Nm^{b}			Knee: 60° flx Hip: 100° flx
					No prosthesis	54 ± 5 Nm^{b}			
		Isokinetic		30°/s (ROM: 90°–0°)	Prosthesis	52 ± 6 Nm^{b,c}			Hip: 100° flx
					No prosthesis	37 ± 6 Nm^{b}			
				60°/s (ROM: 90°–0°)	Prosthesis	47 ± 5 Nm^{b}			Hip: 100° flx
					No prosthesis	46 ± 5 Nm^{b}			
				120°/s (ROM: 90°–0°)	Prosthesis	41 ± 4 Nm^{b}			Hip: 100° flx
					No prosthesis	36 ± 4 Nm^{b}			
	Intact	Isometric	Peak torque	Not reported	N/A	79 ± 9 Nm			Knee: 30° flx Hip: 100° flx
						153 ± 13 Nm			Knee: 60° flx Hip: 100° flx
		Isokinetic		30°/s (ROM: 90°–0°)		150 ± 12 Nm			Hip: 100° flx
				60°/s (ROM: 90°–0°)		136 ± 10 Nm			
				120°/s (ROM: 90°-0°)		102 ± 8 Nm			
Isakov et al. (1996)[44]	Residual	Isometric	Average peak torque	5 s	Not reported	46.0 ± 26.4 Nm^{b}	5 trials	Sitting	Knee: 45° flx Hip: 90° flx
	Intact					93.0 ± 34.0 Nm			
	Residual	Isokinetic (concentric)	Peak torque	60°/s (ROM: unknown)		40.4 ± 20.5 Nm^{b}			
		Isokinetic (eccentric)				112.0 ± 47.2 Nm^{b}			Hip: 90° flx
	Intact	Isokinetic (concentric)				76.7 ± 31.0 Nm			
		Isokinetic (eccentric)				171.2 ± 45.4 Nm			
Moirenfeld et al. (2000)[46]	Residual	Isokinetic (concentric)	Peak torque	120°/s (ROM: 90°-0°)	Prosthesis	79.1 ± 40.3 Nm^{b}	5 trials	Sitting	Hip: 110° flx
	Intact					154.3 ± 45.0 Nm			

(Continued)

Table 3. (Continued)

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
Powers et al. (1996)[45]	Residual	Isometric	Peak torque	5 s	No prosthesis	Male: 6.6 ± 2.7 kgm[b] Female: 2.6 ± 1.0 kgm[b]	2 trials	Sitting	Knee: 60° flx Hip: 90° flx
	Intact					Male: 8.6 ± 3.6 kgm Female: 3.1 ± 1.1 kgm			
	Control					Male: 12.9 ± 4.6 kgm Female: 8.9 ± 4.9 kgm			
Pedrinelli et al. (2002)[47]	Residual	Isokinetic (concentric)	Peak torque	60°/s (ROM: unknown)	Not reported	68.9 Nm[d]	4 trials	Sitting	Not reported
				180°/s (ROM: unknown)		44.3 Nm[d]	6 trials		
	Intact			60°/s (ROM: unknown)		124.1 Nm[d]	4 trials		
				180°/s (ROM: unknown)		74.4 Nm[d]	6 trials		
	Control (dominant)			60°/s (ROM: unknown)		178.8 Nm	4 trials		
				180°/s (ROM: unknown)		110.7 Nm	6 trials		
	Control (nondominant)			60°/s (ROM: unknown)		183.5 Nm	4 trials		
				180°/s (ROM: unknown)		112.4 Nm	6 trials		
Tugcu et al. (2009)[48]	Residual	Isokinetic (concentric)	Peak torque	30°/s (ROM: unknown)	Prosthesis	82.1 ± 38.4 Nm[b]	5 trials	Sitting	Hip: 90° flx
				120°/s (ROM: unknown)		53.9 ± 21.9 Nm[b]			
	Intact			30°/s (ROM: unknown)		138.0 ± 42.3 Nm			
				120°/s (ROM: unknown)		85.0 ± 27.1 Nm			
Lloyd et al. (2010)[49]	Residual	Isometric	Peak torque	5 s	Prosthesis	0.35 ± 0.2 Nm/kg[d,e]	3–5 reps	Supine	Knee: 30° flx
	Intact					0.81 ± 0.3 Nm/kg[d,e]			
	Control					1.10 ± 0.3 Nm/kg			

SD: standard deviation; s: seconds; kpcm: kilopound per centimeter; °: degrees; flx: flexion; Nm: newton-meter; °/s: degrees per second; ROM: range of motion; kgm: kilogram-meter; Nm/kg: newton-meter per kilogram.

[a] Left and right intact values reported separately.

[b] Residual limb significantly weaker than intact limb ($p < 0.05$).

[c] Residual limb significantly stronger with prosthesis ($p < 0.01$).

[d] Significantly weaker than control limb ($p < 0.05$).

[e] Lower limb prosthesis users significantly more asymmetrical ($p < 0.05$).

Table 4. Summary of studies investigating intact knee flexor and extensor strength in unilateral transfemoral prosthesis users.

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
Knee flexors									
James (1973)[41]	Intact Control	Isometric	Peak torque	3 s	No prosthesis	11.1 ± 0.45 kpm[a] 14.3 ± 0.49 kpm	3 trials	Sitting	Knee: 90° flx Hip: 90° flx
Knee extensors									
James (1973)[41]	Intact Control	Isometric	Peak torque	3 s	No prosthesis	34.8 ± 1.50 kpm 32.1 ± 1.93 kpm	3 trials	Sitting	Knee: 90° flx Hip: 90° flx

SD: standard deviation; s: seconds; °: degrees; flx: flexion; kpm: kilopound-meters.

[a] Significantly weaker than control limb ($p < 0.001$).

Table 5. Summary of studies investigating hip flexor strength in unilateral transtibial prosthesis users.

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
Bäcklund et al. (1968)[40]	Residual Intact	Isometric	Peak force	3	Prosthesis	mean = 44 kp mean = 45 kp	3 trials	Standing	Not reported
Tugcu et al. (2009)[48]	Residual	Isokinetic (concentric)	Peak torque	30°/s (ROM: unknown)	Prosthesis	109.5 ± 27.0 Nm	5 trials	Sitting	Hip: 90° flx
				120°/s (ROM: unknown)		80.3 ± 16.9 Nm			
	Intact			30°/s (ROM: unknown)		117.8 ± 31.6 Nm			
				120°/s (ROM: unknown)		89.6 ± 25.5 Nm			

SD: standard deviation; kp: kilopounds; °/s: degrees per second; ROM: range of motion; °: degrees; flx: flexion; Nm: newton-meter.

Table 6. Summary of studies investigating hip extensor strength in unilateral transtibial prosthesis users.

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
Bäcklund et al. (1968)[40]	Residual	Isometric	Peak force	3 s	Prosthesis	mean = 45 kp	3 trials	Standing	Not reported
	Intact					mean = 48 kp			
Powers et al. (1996)[45]	Residual	Isometric	Peak torque	5 s	No prosthesis	Male: 12.3 ± 5.6 kgm Female: 5.6 ± 2.9 kgm	2 trials	Supine	Hip: 20° flx
	Intact					Male: 13.0 ± 4.9 kgm Female: 6.4 ± 3.0 kgm			
	Control					Male: 21.4 ± 4.9 kgm Female: 15.4 ± 1.8 kgm			
Tugcu et al. (2009)[48]	Residual	Isokinetic (concentric)	Peak torque	30°/s (ROM: unknown)	Prosthesis	138.9 ± 31.4 Nm	5 trials	Sitting	Hip: 90° flx
				120°/s (ROM: unknown)		118.5 ± 26.9 Nm			
	Intact			30°/s (ROM: unknown)		140.1 ± 45.6 Nm			
				120°/s (ROM: unknown)		117.5 ± 38.0 Nm			

SD: standard deviation; s: seconds; kp: kilopounds; kgm: kilogram-meter; °: degrees; flx: flexion; °/s: degrees per second; ROM: range of motion; Nm: newton-meter.

Table 7. Summary of studies investigating hip flexor strength in unilateral transfemoral prosthesis users.

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
James (1973)[41]	Residual	Isometric	Peak torque	3 s	No prosthesis	10.7 ± 0.76 kpm	3 trials	Standing	Hip: 0° abd
	Intact					20.5 ± 0.72 kpm			
	Control					20.2 ± 0.62 kpm			
Rutkowska-Kucharska et al. (2018)[50]	Residual	Isometric	Peak torque	Not reported	No prosthesis	1.00 ± 0.15 Nm/kg[a]	5 trials	Supine	Not reported
	Intact					1.28 ± 0.21 Nm/kg			
	Residual	Isokinetic (concentric)		60°/s (ROM: unknown)		0.93 ± 0.15 Nm/kg[a]			
				120°/s (ROM: unknown)		0.77 ± 0.15 Nm/kg[a]			
	Intact			60°/s (ROM: unknown)		1.37 ± 0.21 Nm/kg			
				120°/s (ROM: unknown)		1.14 ± 0.15 Nm/kg			

SD: standard deviation; s: seconds; kpm: kilopound-meters; °: degrees; abd: abduction; Nm/kg: newton-meter per kilogram; °/s: degrees per second; ROM: range of motion.

[a] Residual limb significantly weaker than intact limb ($p \leq 0.01$).

Table 8. Summary of studies investigating hip extensor strength in unilateral transfemoral prosthesis users.

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
James (1973)[41]	Residual	Isometric	Peak torque	3 s	No prosthesis	9.3 ± 0.56 kpm[a]	3 trials	Standing	Hip: 0° abd
	Intact					16.7 ± 0.82 kpm			
	Control					20.0 ± 0.74 kpm			
Rutkowska-Kucharska et al. (2018)[50]	Residual	Isometric	Peak torque	Not reported	No prosthesis	1.32 ± 1.44 Nm/kg[a]	5 trials	Supine	Not reported
	Intact					1.77 ± 0.65 Nm/kg			
	Residual	Isokinetic (concentric)		60°/s (ROM: unknown)		1.11 ± 0.97 Nm/kg[a]			
				120°/s (ROM: unknown)		0.90 ± 0.78 Nm/kg[a]			
	Intact			60°/s (ROM: unknown)		1.58 ± 0.24 Nm/kg			
				120°/s (ROM: unknown)		1.14 ± 0.24 Nm/kg			

SD: standard deviation; s: seconds; kpm: kilopound-meters; °: degrees; abd: abduction; Nm/kg: newton-meter per kilogram; °/s: degrees per second; ROM: range of motion.

[a] Residual limb significantly weaker than intact limb ($p \leq 0.05$).

Table 9. Summary of studies investigating hip abductor strength in unilateral transtibial prosthesis users.

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
Powers et al. (1996)[45]	Residual	Isometric	Peak torque	5 s	No prosthesis	Male: 6.0 ± 3.3 kgm Female: 3.6 ± 2.1 kgm	2 trials	Supine	Hip: 0° abd
	Intact					Male: 6.9 ± 3.6 kgm Female: 3.7 ± 1.7 kgm			
	Control					Male: 12.2 ± 2.7 kgm Female: 9.0 ± 1.2 kgm			
Nadollek et al. (2002)[37]	Residual	Isometric	Peak force	5 s	Not reported	22.10 ± 6.55 N	Two trials	Side-lying	Hip: 0° abd
	Intact					22.71 ± 6.44 N			
Lloyd et al. (2010)[49]	Residual	Isometric	Peak torque	5 s	Prosthesis	0.63 ± 0.2 Nm/kg	3–5 trials	Side-lying	Hip: 0° abd
	Intact					0.66 ± 0.2 Nm/kg			
	Control					0.91 ± 0.3 Nm/kg			

SD: standard deviation; s: seconds; kgm: kilogram-meter; °: degrees; abd: abduction; N: newton; Nm/kg: newton-meter per kilogram.

Table 10. Summary of studies investigating hip abductor strength in unilateral transfemoral prosthesis users.

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
James (1973)[41]	Residual	Isometric	Peak torque	3 s	No prosthesis	8.2 ± 0.50 kpm	3 trials	Standing	Hip: 0° abd
	Intact					14.9 ± 0.61 kpm			
	Control					15.2 ± 0.57 kpm			
Ryser et al. (1988)[43]	Residual	Isometric	Peak Torque	2 s	No prosthesis	62 ± 32 Nm[a,b]	3–6 trials	Standing	Hip: 0° abd
	Intact					86 ± 41 Nm			
	Control					85 ± 27 Nm			

SD: standard deviation; s: seconds; kpm: kilopound-meters; °: degrees; abd: abduction; Nm: newton-meter.

[a] Residual limb significantly weaker than intact limb ($p < 0.002$).

Table 11. Summary of studies investigating hip adductor strength in unilateral transfemoral prosthesis users.

Author (year)	Leg	Muscle action	Metric	Contraction time or speed	With or without prosthesis	Result mean ± SD	Number of trials	Posture	Joint angles
James (1973)[41]	Residual	Isometric	Peak torque	3 s	No prosthesis	7.2 ± 0.46 kpm[a]	3 trials	Standing	Hip: 0° abd
	Intact					13.7 ± 0.66 kpm			
	Control					17.0 ± 0.80 kpm			

SD: standard deviation; s: seconds; kpm: kilopound-meters; °: degrees; abd: abduction; Nm: newton-meter

[a] Residual limb significantly weaker than intact limb ($p < 0.001$).

and 3). There is less agreement, however, regarding deficits in knee flexion and extension strength in the intact limb of unilateral transtibial (Tables 2 and 3) and transfemoral prosthesis users (Table 4) compared with controls.

Residual versus intact limb

Seven studies (n=8–32) compared knee flexion and/or extension strength between the residual and intact limb of unilateral transtibial prosthesis users[42,45–49] (Tables 2 and 3). Peak isometric knee extension torque was reported to be between 57% and 70% lower in the residual limb than the intact limb.[42,44,45,49] Three of those studies found this deficit to be statistically significant,[42,44,45] while the fourth did not perform direct statistical comparisons.[49] Three of those same studies[42,44,49] also reported that peak isometric knee flexion torque was significantly lower in the residual versus the intact limb of transtibial prosthesis users (i.e. 42%–68%). In addition to deficits in isometric knee strength, five studies found that across a range of angular velocities (i.e. 30–180°/s), peak concentric isokinetic knee flexion and extension torque were significantly lower in the residual limb than the intact limb of unilateral transtibial prosthesis users (flexion: 33%–60%, extension: 40%–75%).[42,44,46,47] One study found peak eccentric isokinetic knee flexion and extension torque to be 50% and 35% lower, respectively, in the residual limb than the intact limb of unilateral transtibial prosthesis users.[44]

Residual limb versus controls

Three studies (n=8–25) compared residual limb knee flexion and/or extension strength with that of controls (Table 2).[45,47,49] In each study, peak isometric knee flexion and extension torque was lower in the residual limb of unilateral transtibial prosthesis users compared with controls (i.e. flexion: 56% lower; extension: 49%–70% lower).[45,49] Peak concentric isokinetic knee flexion and extension torque in the residual limb of unilateral transtibial prosthesis users was also significantly lower (i.e. flexion: 60%–62% lower; extension: 53%–60% lower) compared with controls (Tables 2 and 3).[47] Eccentric strength of residual limb knee muscles has yet to be assessed or compared with controls.

Intact limb versus controls

Six studies (n=8–38) compared knee flexion and extension strength between the intact limb of people with unilateral lower limb amputation and controls.[40,41,44,45,47,49] While there was a general consensus for strength deficits in the residual limb, findings were more variable when comparing the intact limb with controls. Bäcklund et al.[40] reported no marked difference between the intact limb of unilateral transtibial prosthesis users and controls in peak isometric knee flexion and extension force. The capacity of the intact limb to generate peak isometric knee flexion torque equivalent to that of controls was confirmed by a second study.[49] That same study however,[49] and one other,[45] found peak isometric knee extension torque generated by the intact limb of transtibial prosthesis users to be 26%–64% lower than that of controls.[45,49] Regardless of angular velocity (i.e. 60°/s and 180°/s), peak concentric isokinetic knee flexion and extension torque was reported to be significantly lower in the intact limb of transtibial prosthesis users compared with controls (i.e. 23%-34% lower).[47] Eccentric strength of the intact limb knee muscles has yet to be compared with controls.

Hip strength

There is evidence that across muscle actions (i.e. isometric[37,40,41,43,45,49,50] and isokinetic[48,50]), test postures (i.e. seated,[48] standing,[40,41,43] supine,[45,50] side-lying,[37,49] and prone[51]), hip joint angles (i.e. 0° of abduction,[37,41,43,45,49] 20° and 90° of flexion[45,48]), and angular velocities (i.e. 30–120°/s[48,50]), hip strength of transtibial prosthesis users does not differ significantly between their residual and intact limb, or with respect to control subjects (Tables 5, 6, and 9). In contrast, residual limb hip strength among unilateral transfemoral prosthesis users is significantly lower than in their intact limb (Tables 7, 8, 10, and 11). To date, there is limited data characterizing differences in hip flexion, extension, or adduction strength between transfemoral prosthesis users and controls, or in hip abduction strength among transtibial prosthesis users.

Hip flexion and extension

Residual versus intact limb

Three studies (n=15–22) have compared hip flexion and/or extension strength between the residual and intact limb of transtibial prosthesis users (Tables 5 and 6).[40,45,48] Two studies (n=14 and 38) have done the same among transfemoral prosthesis users (Tables 7 and 8).[41,50] Regardless of muscle action (i.e. isometric or isokinetic), peak hip flexion and extension torque or force were not significantly different between the residual and intact limb of transtibial prosthesis users (i.e. 0%–12% lower) (Tables 5 and 6).[40,48] In contrast, among transfemoral prosthesis users, peak isometric and isokinetic hip flexion and extension torque were substantially lower in the residual versus intact limb.[41,50] Peak residual limb isometric and isokinetic hip extension torque was between 25%–43% and 21%–30% lower than the intact limb, respectively,[41,50] while residual limb peak isometric and isokinetic hip flexion torque was between 22%–47% and 36% lower than the intact limb, respectively.[41,50]

Residual and intact limb versus controls

There is some disagreement as to whether hip extension strength differs between transtibial prosthesis users and controls. Bäcklund et al.[40] reported that neither residual nor intact limb peak isometric hip extension force differed between transtibial prosthesis users and controls (i.e. residual limb: 2% lower; intact limb: 4% higher).[40] In contrast, Powers et al.[45] reported much larger deficits in peak isometric hip extension torque in the residual limb (41%–64% lower) and intact limb (i.e. 39%–58% lower) compared with controls.[45] Differences in hip flexion strength between transtibial prosthesis users and controls have not been assessed. There is also limited data concerning differences in hip flexion and extension strength between transfemoral prosthesis users and controls. In a single study of 38 unilateral transfemoral prosthesis users, peak isometric hip extension and flexion torque were 5% and 20% higher in the intact limb than controls.[41] Residual limb values were 47% and 53% lower than controls.[41]

Hip adduction and abduction

Residual versus intact limb

Three studies ($n=8$–22) have tested hip abduction strength among transtibial prosthesis users (Table 9),[37,45,49] while two ($n=10$–38) have examined hip abduction strength among transfemoral prosthesis users (Table 10).[41,43] Hip adduction strength, however, has only been evaluated in a single study of transfemoral prosthesis users (Table 11).[41] Among unilateral transtibial prosthesis users, peak isometric hip abduction torque was not significantly lower in their residual versus intact limb (i.e. 3%–13% lower).[37,45,49] In contrast, among transfemoral prosthesis users, peak isometric hip abduction torque was significantly lower in their residual versus intact limb (i.e. 33%–46% lower).[41,43] Data to support similar differences in hip adduction strength among lower limb prosthesis users are limited to a single study of transfemoral prosthesis users that found residual limb peak isometric hip adduction torque to be significantly lower than in the intact limb (i.e. 47% lower).[41]

Residual and intact limb versus controls

Regardless of amputation level, and despite sizable differences in magnitude, neither residual nor intact limb hip adduction nor abduction strength differed significantly with respect to controls (Tables 9 to 11). Peak isometric hip abduction torque in the residual and intact limbs of unilateral transtibial prosthesis users were lower (i.e. 31%–60% and 27%–59%, respectively), but not significantly different from controls.[45,49] Similarly, neither residual nor intact limb peak isometric hip abduction torque of transfemoral prosthesis users differed significantly from controls (residual limb: 29% lower, intact limb: 1%–20% lower).[43,45] Peak isometric hip adduction torque in the residual limb of transfemoral prosthesis users is the lone exception, being significantly lower compared with controls (i.e. 68% lower).[41]

Additional strength measures

Beyond peak torque, other measures have been used, albeit sparingly, to characterize strength deficits in lower limb prosthesis users. Pedrinelli et al.[47] reported that among transtibial prosthesis users, the isokinetic work performed by residual limb knee flexors and extensors was substantially lower than that generated by their intact limb (i.e. extensors: 42%–46%, flexors: 25%–34% lower). Similarly, residual and intact limb knee flexion and extension work were lower than that of controls (i.e. residual limb extensors: 61%–63% lower, residual limb flexors: 57%–60% lower; intact limb extensors: 31%–36%, and intact limb flexors: 33%–46% lower). Similar differences were reported for joint power (i.e. the rate of doing work).[47] Moirenfeld et al.[46] used the percentage difference in total work between the last 10 and the first 10 repetitions to evaluate muscular endurance. Among a sample of 11 traumatic transtibial prosthesis users, residual limb knee flexors had significantly greater endurance than intact limb knee flexors (i.e. 23% more fatigue resistant), while knee extensor endurance did not differ between the residual and intact limb.[46] Differences in fatigue resistance between lower limb prosthesis users and controls remain untested.

Discussion

The objective of this scoping review was to synthesize reported strength deficits in lower limb prosthesis users, discuss their potential causes, consequences, and possible solutions, while highlighting gaps and suggesting future research directions. Among transtibial prosthesis users, muscle weakness appears to be the most prominent among residual limb knee flexors and extensors when compared with the intact limb or controls. Muscle weakness among transfemoral prosthesis users is the most prominent in the hip of their residual limb with respect to the intact limb. These between-limb differences exceeded a 10% bilateral deficit cited as the norm for controls,[52] and frequently exceeded a 20% threshold often cited as abnormal in other patient populations.[53] Below, we discuss the potential explanations, interpretations, and consequences of the reported strength deficits, and whether strength deficits in people with lower limb amputation are modifiable.

Amputation-, demographic-, and activity-related factors may contribute to muscle weakness in lower limb prosthesis users

Strength deficits among people with lower limb amputation appear related to several amputation, demographic, and activity-related factors. Among amputation-related factors, a shorter residual limb, dysvascular etiology, and certain aspects of the amputation procedure have been associated with reduced residual limb strength in lower limb prosthesis users. Peak isokinetic torque and maximal average isometric torque are significantly lower in people with transtibial amputation when the residual limb is shorter than 15.1 cm.[54] Similarly, hip strength on the amputated side is positively correlated to the length of the residual limb among transfemoral prosthesis users.[41] Specifically, peak extension and abduction torque weakly correlated to residual limb length ($r=0.41$ and 0.44, respectively), while flexion and adduction torque moderately correlated to limb length ($r=0.50$ and 0.60, respectively).[41] The higher correlations between residual limb length and hip adduction and flexion torque might be expected, as hip flexor and adductor muscles are both transected during transfemoral amputation.

The impact of a shorter residual limb on muscle strength may be offset by properly tensioning the muscles transected during an amputation.[55] Using a musculoskeletal simulation, Ranz et al.[55] found that preserving muscle tension following transfemoral amputation had the single greatest impact on a muscle's force-generating capacity, to the point that femur length had little effect. Other features of transfemoral amputation, including muscle wrap orientation, has less impact on the force-generating capacity of residual hip muscles.[55] Disruption of the insertion of the iliotibial band during transfemoral amputation may also contribute to hip abductor weakness in people with transfemoral amputation.[43] The tensor fascia lata is believed to assist in hip abduction through its insertion in the iliotibial band.[56,57] Thus, if the iliotibial band is not appropriately anchored following transfemoral amputation, the potential contribution of this muscle is reduced.

Time since amputation does not appear to play a substantial role in lower extremity weakness among lower limb prosthesis users. Isakov et al.[44] found no significant difference in isometric or isokinetic knee flexion or extension strength between transtibial prosthesis users less than or greater than 7 years post-amputation. The main effects of amputation on muscle strength may therefore occur in the years immediately following surgery.[44] Similarly, Croisier et al.[58] found that variation in time since amputation did not affect peak isokinetic hip torque among transtibial prosthesis users, and Pedrinelli et al.[47] reported that time since amputation was not a significant factor related to knee strength.

A single study directly compared lower extremity strength of dysvascular and non-dysvascular lower limb prosthesis users. Renström et al.[42] found that isometric and isokinetic strengths in the intact and residual limb were significantly lower in people with transtibial amputation due to peripheral vascular disease and diabetes than traumatic causes. The results of this study suggest that when interpreting strength values among dysvascular lower limb prosthesis users, we are looking at not only the impact of amputation, but also that of the underlying disease. A direct assessment of the impact of amputation alone on strength could be accomplished by limiting study samples to traumatic lower limb prosthesis users, as was done in 3 of the 12 studies.[40,46,48] Alternatively, selecting controls who are also dysvascular would control for the impact of the disease. This was not done, however, in any of the studies that included dysvascular lower limb prosthesis users. The current body of literature may therefore be skewed toward greater strength deficits when the cause of amputation is dysvascular.

Demographic-related factors. Strength in lower limb prosthesis users appears related to age and sex. In people with transtibial amputation, isometric, as well as isokinetic knee flexion and extension strength decreased with increasing age both with and without a prosthesis.[42] Hip abductor strength has also been reported to negatively correlate with age (i.e. $r=-0.539$).[37] In a conflicting result, Pedrinelli et al.[47] found that age was not a significant factor related to isokinetic knee flexion or extension torque among transtibial prosthesis users. However, the subjects in that study were younger than those in the other two studies (see Table 1), with subjects ranging from 12 to 59 years of age with a mean age of 35.9 years.[47]

Powers et al.[45] measured the isometric hip, knee, and ankle strength of female and male transtibial lower limb prosthesis users. Although direct statistical comparisons were not made, female prosthesis users had consistently lower strength than males (Table 2).[45] Women also demonstrated a larger difference between the residual and intact limb than men (i.e. 60% vs 23%).[45] Similarly, Renström et al.[42] found that residual limb isokinetic knee extension strength was lower among female transtibial prosthesis users than males (i.e. 45% lower).

Activity-related factors. Decreased activity prior to and after amputation may also contribute to weakness in the lower limbs. In a study of isometric and isokinetic strength in transfemoral prosthesis users, the etiology of weak residual limb hip abductors was believed to be deconditioning due to decreased use before and following amputation.[43] This disuse may be due to a decrease in ambulation and activity in general. Among transtibial prosthesis users, greater hip abductor strength is positively correlated with greater time spent wearing the prosthesis per day ($r=0.576$).[37]

Strength deficits among lower limb prosthesis users are consequential

There is evidence that lower muscular strength among lower limb prosthesis users contributes to mobility and health impairments. Specifically, changes in gait,[37,40,42,45] reductions in energy efficiency[35] and walking endurance,[59] altered joint loading,[37,50] as well as increased risk of knee osteoarthritis and low-back pain have been linked to deficits in lower extremity strength among lower limb prosthesis users.[49,60]

The strength of residual limb muscles appears critical to several aspects of mobility among lower limb prosthesis users. First, both preferred ($r=0.50$–0.61)[37,45] and fast ($r=0.30$–0.72)[42,45] walking speeds of transtibial prosthesis users are positively correlated to peak isometric hip extension,[45] hip abduction,[37] as well as knee flexion and extension torque in the residual limb.[42] Second, decreases in walking speed associated with a loss of residual limb strength appear to be attributable to shorter step and stride lengths, which in turn decrease with peak residual limb knee flexor ($r=0.46$–0.52)[42] and extensor ($r=0.53$–0.71) torque,[42] as well as hip abductor torque ($r=0.63$).[37] In addition to walking speed, deficits in muscle strength also appear to impact walking endurance among transtibial and transfemoral prosthesis users. Among a host of variables (i.e. demographics, time since amputation, etiology, and level), residual limb hip extensor strength, followed by hip abductor strength, were the greatest predictors of walking endurance (i.e. 6-min-walk test distance) among lower limb prosthesis users (i.e. $r=0.69$, 0.66 respectively).[59] Further, transtibial prosthesis users who were unable to walk 1 km had lower residual limb peak hip extension force than non-amputee controls.[40]

Reductions in walking speed among lower limb prosthesis users have historically been attributed to an increased metabolic cost of locomotion.[61] The extent to which this increase is caused by lower muscular strength is controversial.[47] Recent evidence, however, suggests this may be the case. In a musculoskeletal simulation of walking, when pre-limb loss muscle strength was maintained, metabolic cost did not increase above pre-limb loss cost.[35] In addition, when matched for age and fitness, transtibial prosthesis users tend to walk with a metabolic cost that is equivalent to that of controls.[33,34] Together, these results imply that strength, and specifically residual limb strength, plays a major role in offsetting increases in metabolic cost typically associated with lower limb amputation.

Lower limb prosthesis users are at risk for loading asymmetries between their intact and residual limbs that can introduce secondary disabilities. Increased loading of the intact limb is positively correlated with asymmetries in hip extensor strength among transfemoral prosthesis users,[50] and hip abductor strength among transtibial prosthesis users.[37] Several asymmetric loading patterns observed among transtibial prosthesis users[62] have been linked to degenerative changes in the knee (i.e. knee adduction moment load rate and maximum vertical ground reaction force load rate).[60] Asymmetries in peak isometric knee flexor and extensor torque (i.e. lower residual limb values) are correlated with these load rate variables ($r=0.64$–0.71).[49] The loss of muscular strength among lower limb prosthesis users may therefore not only limit gait performance, but also introduce loading patterns that increase susceptibility to degenerative joint disease.

Strength deficits in lower limb prosthesis users appear to be modifiable

Given their consequences, it is essential to know whether, to what extent, and through what methods, strength deficits in lower limb prosthesis users may be best resolved. A variety of resistance and exercise training programs have shown promise in resolving strength deficits in transtibial[38,51,63–65] and transfemoral prosthesis users.[36,38,51,66] Increases in muscle size, muscle strength, and/or functional performance have been reported across training programs. This suggests that strength deficits, and their consequences, are amenable to modification among lower limb prosthesis users.

A variety of frequencies, intensities, durations, and types of training have been studied. Exercise types have included isometric[64] and isokinetic[65] strength training, as well as general exercise (i.e. cycling, weight lifting circuit, and walking).[36,38,51,66] Training duration has varied between 8 and 12 weeks, frequency from twice a day[64] to two or three times a week,[38,65] while the intensity of training has also fluctuated between studies (e.g. 25 contractions,[64] 2 sets of 10 repetitions,[65] 3 sets of 10 repetition max).[36] Interestingly, four studies implemented training programs that were in part or in whole performed at home,[38,51,64,66] suggesting that barriers to facilities and access to equipment can be overcome. Study samples, while small ($n=4$–17), included both transtibial ($n=21$) and transfemoral prosthesis users ($n=41$), varied amputation etiology (i.e. dysvascular and non-dysvascular), as well as average age (37.5–67.8 years) and time since amputation (2.5–19 years).[36,38,51,63–66] This suggests that a number of key demographic and amputation-related characteristics may not pose as limiting of factors in addressing strength deficits among lower limb prosthesis users. Further research is required to identify barriers and facilitators to exercise among lower limb prosthesis users.

All training programs, regardless of frequency, intensity, time, or type of training were effective in reducing strength deficits and/or their functional consequences. Evidence of changes in muscle structure and size varied. While no changes in fiber composition were reported,[65] the mean cross-sectional area of residual limb knee extensor muscle fibers increased.[65] This, however, did not translate to an overall increase in size (i.e. thigh circumference) or cross-sectional area of the knee extensors.[65] In contrast, Kegel et al.[64] reported an increase in the cross-sectional area of the gastrocnemius muscle of the residual limb among transtibial prosthesis users following isometric strength training. Strength, largely measured via peak torque, increased in both residual and intact limb muscles between 11% and 22%.[36,51,65,66] These strength gains translated to improvements in mobility (i.e. walking speed, Timed Up and Go performance),[36,38] walking endurance (i.e. 2-min-walk test distance, walking distance),[36,65] balance (i.e. reduction in falls, improved balance confidence),[36,38] and gait (i.e. reduced asymmetry and increased propulsion).[38,66] Despite these initial successes addressing strength deficits in lower limb prosthesis users, a number of needs remain. Namely, there are no specific recommendations for strength training of lower limb prosthesis users (i.e. which muscles, which deficits, timing post-amputation),[36] sample sizes were small, and more focused comparisons of specific training regiments are required.

Gaps and directions for future research

There is limited data characterizing differences in hip strength among lower limb prosthesis users and controls. With the importance of hip muscle function in lower limb prosthesis users,[67–69] additional research is warranted.

Functional strength measures and assessments have, to date, been limited in large part to non-fatiguing conditions and measures of maximum voluntary strength. Important functional aspects of strength including the rate of force development, which is essential to balance,[70–72] and muscular endurance, which is crucial to mobility[46,73] have been overlooked. Additional research exploring these and other measures of strength, and their relationship to clinical strength tests (e.g. 5-times Sit to Stand) is necessary to advance our understanding of how amputation affects strength, and to identify or develop quick, simple, inexpensive, and valid clinical tests of strength tailored to lower limb prosthesis users. There was considerable variation in the methods used among the reviewed studies to test muscle strength in lower limb prosthesis users. Such variation makes it difficult to compare between studies. As such, working toward a common set of recommended methods would increase the consistency of reporting and facilitate greater comparisons between studies.

Muscle weakness has been associated with a number of functional challenges among lower limb prosthesis users including gait abnormalities,[74,75] secondary degenerative disorders (e.g. joint degeneration),[76] increased metabolic cost of gait,[35,39] and balance confidence.[36] Causal links, however, between muscle function and balance, mobility, or endurance among lower limb prosthesis users remain poorly understood.[1] Additional research is therefore needed to address this gap and help identify those muscles most closely associated with these functional challenges.

Conclusion

The reviewed studies provide evidence of strength deficits in lower limb prosthesis users. These deficits appear to be consequential, contributing to balance, mobility, and endurance impairments. Fortunately, preliminary studies have found these deficits to be modifiable, responding to an assortment of physical conditioning training programs. Additional research exploring alternative strength metrics, clinical tests, training program parameters, surgical procedures, and causal links to functional impairments is required.

Author contribution

The study concept and design were created by A.H. and A.S., acquisition of data was done by A.H., analysis and interpretation of data was carried out by A.H., S.D., and A.S., drafting of the manuscript was done by A.H., critical revision of the manuscript of important intellectual content was taken care of by S.D. and A.S., and study supervision was conducted by A.S.

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