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13. SUPPLEMENTARY NOTES

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 lower limb prosthesis users. This is to be accomplished by conducting cross-sectional (aim 1) and longitudinal (aim 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 2). To date we have made completed recruitment, enrollment, and data collection for aim 1 (14 transfemoral, 14 transtibial, and 28 age- and sex-matched controls). We have recruited and enrolled 6 of 8 transfemoral prosthesis users for aim 2. Prospective data collection (baseline, follow up 1 and follow up 2) has been completed for 1 participant. Two other participants have completed baseline and follow up 1, with follow up 2 scheduled for Dec 2021. The remaining three participants have completed baseline testing and are scheduled for follow up 1 and 2 prior to the end of the NCE. 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). Two other manuscripts are in preparation. Notable findings from this research to date include: i) the normalization of hip muscle strength by appropriate body parameters alters our understanding of its relationship to balance ability, and reveals between limb differences, and ii) in contrast to popular opinion, residual limb hip muscles are not weaker, but rather stronger than intact hip muscles in unilateral transfemoral prosthesis users.

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

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

<u>Goal 1</u>: Obtain and maintain IRB approvals from UIC, NU, and ORP/HRPO
(*Target date: Y1Q1, Y1Q4, Y2Q4 – 100% Completed*).

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

<u>Goal 3</u>: 28 participants enrolled (*Y2Q4 – 100% Completed*).

<u>Goal 4</u>: Data collection completed (*Y2Q3 – 100% Completed*).

- Aim 1 (100% Completed)
- Aim 2 (100% Completed)

<u>Goal 5</u>: Data entered, processed, and analyzed to address study hypotheses (*Y2Q4 – 80% completed*).

- Aim 1 (100% Completed)
- Aim 2 (80% 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 – 50% completed*).

Accomplishments under these goals: For each of the goals/milestones outlined in the SOW, we have made significant and timely progress despite challenges presented by COVID-19. All goals have been completed, apart from goals 5 and 6, which are 80% and 50% completed, respectively. We anticipate completing all remaining goals/milestones of the project by the end of the no-cost extension period.

Goal 1: Both study sites (UIC and NU) have completed their annual IRB and ORP/HRPO continuing reviews, with approval obtained on and maintained since 07/28/20. No cost extension (NCE) documentation were submitted on 06/15/22, and approved 09/21/22, extending the current project until 09/22/23.

Goal 2: The PI and Co-I of the project continue to maintain all study protocols, equipment, and data collection forms. For example, the motor driven dynamometer has been regularly serviced and maintained by the manufacturer (i.e., Biodex System 4 Pro (Biodex Medical Systems, Inc., Shirley, NY). New research staff were also trained to assist with data collection at the UIC site with graduation of a student.

Goal 3: For aim 1 (i.e., cross-sectional assessment of hip muscle strength) we have completed all planned recruitment and enrollment. Lower limb prosthesis user participant characteristics are presented in Table 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.

Table 1. Amputation, prosthetic, demographic, balance, and mobility-related characteristics of study participants by level of amputation.

	etiology	gender	MFCL	time since amputation (years)	SCS (0-10)	age (years)	ABC scale (0-4)	PLUS-M (T-score)
Transtibial prosthesis users								
LLA-01	dysvascular	male	K2	19	8	63	2.00	49.1
LLA-02	non-dysvascular	male	K3	12	7	32	3.94	61.0
LLA-03	dysvascular	male	K2	20	9	69	2.44	54.4
LLA-04	non-dysvascular	female	K3	17	8	44	2.94	47.7
LLA-05	non-dysvascular	female	K3	9	8	55	3.06	55.3
LLA-06	non-dysvascular	male	K2	5	5	36	3.31	55.3
LLA-07	non-dysvascular	male	K3	55	9	59	3.25	59.6
LLA-08	non-dysvascular	male	K3	6	9	39	3.19	55.3
LLA-09	non-dysvascular	male	K3	34	8	56	3.13	53.6
LLA-10	non-dysvascular	female	K3	5	5	54	2.06	37.1
LLA-11	non-dysvascular	female	K3	24	8	59	3.25	59.6
LLA-12	non-dysvascular	male	K3	46	7	78	2.06	49.8
LLA-13	dysvascular	female	K3	4	10	44	3.69	56.3
frequency	*3 dysvascular* *10 non-dysvascular*	*8 male* *5 female*	*3 K2* *10 K3*					
			mean (95% CI)	*20 (20)*	*7.7 (2)*	*52.9 (16.2)*	*2.95 (0.76)*	*53.4 (7.6)*
			median (IQR)	*17 (23)*	*8 (2)*	*55.0 (19.5)*	*3.13 (1.03)*	*55.3 (7.5)*
Transfemoral prosthesis users								
	etiology	gender	MFCL	time since amputation (years)	SCS (0-10)	age (years)	ABC scale (0-4)	PLUS-M (T-score)
LLA-14	non-dysvascular	female	K3	5	5	25	3.19	54.4
LLA-15	non-dysvascular	female	K3	31	10	53	3.44	54.4
LLA-16	dysvascular	male	K2	6	10	73	3.13	48.4
LLA-17	non-dysvascular	male	K2	5	7	64	2.38	55.3
LLA-18	non-dysvascular	male	K3	7	4	60	2.44	48.2
LLA-19	non-dysvascular	male	K2	17	7	55	2.75	48.5
LLA-20	dysvascular	female	K2	12	7	59	2.80	46.7
LLA-21	non-dysvascular	male	K3	3	7	21	2.56	49.8
LLA-22	non-dysvascular	female	K2	21	5	45	1.88	45.2
LLA-23	non-dysvascular	female	K3	38	9	61	4.00	61.0
LLA-24	non-dysvascular	female	K3	32	10	51	2.63	2.63
LLA-25	dysvascular	female	K3	3	8	29	2.13	2.13
LLA-26	dysvascular	male	K2	6	6	73	2.63	2.63
frequency	*4 dysvascular* *9 non-dysvascular*	*6 male* *7 female*	*6 K2* *7 K3*					
			mean (95% CI)	*14 (15)*	*7.3 (2)*	*51.5 (20.6)*	*2.77 (0.68)*	*50.4 (5.5)*
			median (IQR)	*7 (21)*	*7 (4)*	*55.0 (25.5)*	*2.63 (0.75)*	*48.5 (7.0)*
p-value	1.00[a]	0.43[b]	0.41[a]	0.31[c]	0.60[d]	0.81[d]	0.22[d]	0.06[c]

a: Fisher's Exact Test; b: Pearson Chi-Square Test; c: Mann-Whitney U Test; d: unpaired t-test. MFCL: Medicare Functional Classification Level; SCS: Socket Comfort Score; ABC: Activities-specific Balance Confidence; PLUS-M: Prosthesis Limb User Survey – Mobility; CI: Confidence Interval: IQR: Inter-Quartile Range

For aim 2 (i.e., prospective pilot clinical trial of sub-ischial socket) we have recruited and enrolled 7 transfemoral prosthesis users in the pilot clinical trial. One of the aim 2 participants dropped out due to health issues, while a second had a heart attack between the 8- and 42-week follow up data collections, preventing him from completing the 42-week follow up visit. This brings the total number of participants with full data (i.e., baseline, 8-week and 42-week follow up) to 5 of the originally planned 8 transfemoral prosthesis users, and a 6th with baseline and 8-week follow up data.

Owing to the interruptions and challenges associated with recruiting transfemoral prosthesis users for a 42-week prospective study during the pandemic, we have elected to cap the pilot clinical trial (Aim 2) sample size at the currently enrolled 7 participants. We expect that having a full dataset on 5 participants and a partial data set on 1 participant will provide the data required to address the research questions of the pilot clinical trial (i.e., does TF socket design influence hip muscle strength, and if so how (altered recruitment, or increased physical activity). These important data will be sufficient to serve as pilot data to determine whether a larger, full clinical trial is justified. The demographic, amputation, health, balance, and mobility characteristics of the 6 enrolled participants are presented in table 2.

Table 2. Aim 2 participant demographic, amputation, and prosthetic-related characteristics

							Amputation			**Prosthesis**						
ID	**Age**	**Sex**	**Weight (kg)**	**Height (cm)**	**Race**	**Ethnicity**	**Level**	**Time (yrs)**	**Cause**	**Socket**	**SCS**	**Liner**	**Suspension**	**Knee**	**Pylon**	**Foot**
1	59	M	85.1	178.5	W	Not Hispanic or Latino	TF	7	Cancer	IC	4	Seal in X5	Suction	C-leg 4	Torsion	Maverick Comfort AT
2	20	M	63.5	170.2	W	Hispanic or Latino	TF	3.5	Trauma	IC	8	Seal in X5	Suction	C-leg	Standard	Triton VS
3	44	F	72.6	157.5	AA	Not Hispanic or Latino	TF	6	Trauma	IC	6	Seal in conical	Suction	C-leg	Standard	Otto Bock Meridium
4	51	F	53.5	167.0	W	Not Hispanic or Latino	TF	32	Trauma	IC	7	Seal in standard	Suction	C-leg 4	Torsion	Proflex Align
5	29	F	76.3	167.3	AA	Not Hispanic or Latino	TF	2.5	Other	IC	6	Seal in conical	Suction	C-leg 4	Standard	Fillauer Aeris
6	73	M	86.5	180.1	AA	Not Hispanic or Latino	TF	6	Other	IC	5	Seal in conical	Suction	C-leg 4	Torsion	Otto Bock Trias

M: male; F: female; W: white; AA: African American; TF: transfemoral; L: left; R: right; IC: ischial containment;

<u>Goal 4</u>: Over the past year we completed data collection for aims 1 and 2. For aim 1 this included isometric hip muscle strength data, as well as clinical walking and balance test data (e.g., 2-minute walk test, four square step test). For aim 2 data collection included isometric hip strength data, hip muscle electromyographic data, clinical walking, and balance test data, as well as step count data, each at baseline, 8-week follow up and 42-week follow up visits. We have also completed the 42-week follow-up testing after sub-ischial socket fitting (i.e., hip muscle strength, electromyography, and walking and balance performance) on 5 of the 7 enrolled transfemoral prosthesis users. Due to a heart attack data collection was stopped after the 8-week follow up for 1 additional transfemoral prosthesis user. Data collection for aim 2 has been closed out at 6 participants.

<u>Goal 5</u>: We recently completed our analysis investigating the need for, and influence of normalization on hip strength in unilateral lower limb prosthesis users. We found that normalization of hip muscle strength to body size (i.e., the product of body mass x thigh length) was required to and effective in creating body size independent measures of hip muscle function. Additionally, the normalization of

hip muscle strength altered the interpretation of between limb differences. The resulting manuscript was published in Clinical Biomechanics in June of 2022 (see Appendix 1). We also completed our analysis investigating differences in hip muscle function between lower limb prosthesis users (transtibial and transfemoral) and age- and gender-matched controls. We found that in contrast to popular opinion, and previous research, the residual limb of transtibial and transfemoral prosthesis users was significantly stronger than their intact limb, not weaker. Further, residual limb hip muscles were also as strong as those of age- and sex-matched controls. This stands in stark contrast to previous research suggesting that residual limb hip muscles in transfemoral prosthesis users were weaker than their intact muscles. No differences in hip strength were observed between transtibial and transfemoral prosthesis users. The resulting manuscript has been submitted to the Journal of NeuroEngineering and Rehabilitation for peer-review (see Appendix 2). We have also recently completed the final planned analyses for aim 1, investigating the contributions of isometric hip muscle function to walking and balance performance among unilateral transtibial and transfemoral prosthesis users. Using multiple linear regression modeling, we found that a unique combination of residual and intact limb hip muscle functions (both muscle strength and steadiness) were required to explain significant amounts of the variability in walking speed, walking endurance, and walking balance performance among unilateral LLP users. For example, nearly 90% of the variance in walking speed among unilateral transtibial prosthesis users was explained by a combination of residual limb maximum hip extension torque, residual limb hip abduction torque steadiness, and intact limb hip flexion instantaneous rate of torque development (see Appendix 3). In contrast, 41% of the variance in walking speed among unilateral transfemoral prosthesis users was explained by a single hip muscle function alone, intact hip abduction torque impulse. The full regression models, as well as their development, for walking speed, endurance, and balance performance are presented in Appendix 3.

Goal 6: We authored a conference abstract based on the strength normalization data analysis. This abstract will be presented at the World Congress of the International Society for Prosthetics and Orthotics. We submitted a separate abstract to the 2023 American Academy of Orthotists and Prosthetists Annual Meeting based on our between limb strength differences among lower limb prosthesis users and age- and sex-matched controls. We plan to submit an additional abstract to the American Society of Biomechanics Annual Conference detailing the contributions of hip muscle function to walking and balance performance in unilateral lower limb prosthesis users. In addition to the publication of our normalization manuscript (Appendix 1), we submitted an additional manuscript detailing between limb differences in hip muscle strength to the Journal of NeuroEngineering and Rehabilitation (Appendix 2). Several other manuscripts are currently in preparation. These include: i) contributions of hip muscle function to walking and balance performance in unilateral lower limb prosthesis users (Appendix 3), and ii) the effect of sub-ischial socket design on hip muscle strength and coordination.

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 no-cost extension we intend to: i) complete data analysis for Aim 2; ii) conduct hypothesis testing for Aim 2; iii) prepare and submit the final manuscript related to Aim 1 (hip muscle contributions to walking and balance in LLP users), iv) prepare and submit the planned manuscript related to Aim 2 (effect of sub-ischial sockets on residual limb hip muscle function); and v) present study results to local prosthetists in the Chicago and Seattle, the AAOP Annual Meeting, and the American Society of Biomechanics Annual Conference.

IMPACT: Nothing to report.

CHANGES/PROBLEMS

Nothing to report.

PRODUCTS

Journal publications (in this reporting period)

Sawers A, Fatone S. Normalization alters the interpretation of hip strength in established unilateral lower limb prosthesis users. Clin Biomech (Bristol, Avon). 2022 Jul;97:105702. doi: 10.1016/j.clinbiomech.2022.105702. Epub 2022 Jun 4. PMID: 35714413.

Sawers A, Fatone S. Hip strength of the residual limb exceeds that of the intact limb among unilateral lower limb prosthesis users. JNER, 2022 (in review).

Conference presentations (in this reporting period)

Dent SR, Fatone S, Sawers A. Normalization alters the interpretation of between limb differences in peak isometric hip extension torque among lower limb prosthesis users. *International Society of Prosthetics and Orthotics World Congress*. Nov 1-4, 2021 (*Poster*).

Sawers A, Fatone S. Normalization alters the interpretation of hip strength in established unilateral lower limb prosthesis users. *Movement Rehabilitation Sciences (MRS) Training Day*. Aug 19, 2022 (*Poster*).

Sawers A, Fatone S. Rethinking hip strength in lower limb prosthesis users. *American Academy of Orthotists and Prosthetists 49th Academy Annual Meeting and Scientific Symposium. March 1-4, 2023 (Podium)*.

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

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Project Role:	Co-Investigator (UW)
Researcher Identifier:	
Nearest person month worked:	<1
Contribution to Project:	Dr. Fatone has been responsible for assisting with data analysis and dissemination efforts.
Funding Support:	N/A

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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: Normalization manuscript
Appendix 2: Hip muscle strength LLP users vs. age- and gender matched controls manuscript
Appendix 3: Contributions of hip muscle function to walking and balance (data analysis)
Appendix 4: ISPO & MRS Training Day Poster
Appendix 5: American Academy of Orthotists and Prosthetists Annual Meeting abstract
Appendix 6: Quad Chart

Appendix 1

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Normalization alters the interpretation of hip strength in established unilateral lower limb prosthesis users

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ABSTRACT

Background: Valid comparisons of muscle strength between individuals or legs that differ in size requires normalization, often by simple anthropometric variables. Few studies of muscle strength in lower-limb prosthesis users have normalized strength data by any anthropometric variable, potentially confounding our understanding of strength deficits in lower-limb prosthesis users. The objective of this pilot study was to determine the need for as well as effectiveness and impact of normalizing hip strength in lower-limb prosthesis users.
Methods: Peak isometric hip extension and abduction torques were collected from 28 lower-limb prosthesis users. Allometric scaling was used to determine if hip torque values were significantly associated with, and therefore needed to be adjusted for, body mass, thigh length, or body mass x thigh length, and whether normalization was effective in reducing any associations. Between limb differences in peak hip torque, and correlations with balance ability, were inspected pre- and post-normalization.
Findings: Hip torques were consistently and significantly associated with body-mass x thigh length. Associations between peak hip torque and body-mass x thigh length were reduced by normalization. After normalization by body-mass x thigh length, between limb differences in hip extension torque, as well as the correlation between hip abduction torque and balance ability, changed from non-significant to significant.
Interpretation: In the absence of normalization, hip strength (i.e., peak torque) in lower-limb prosthesis users remains dependent on basic anthropometric variables, masking relationships between hip strength and balance ability, as well as between limb differences.

1. Introduction

Normalization of muscle function data is uncommon in lower-limb prosthesis (LLP) user research (Hewson et al., 2020), potentially causing the field to misinterpret patterns of muscle weakness, and overlook important relationships between the varied aspects of muscle function (i.e., muscle strength, power, or endurance) (Beaudart et al., 2019), and walking or balance ability. Valid comparisons of muscle function between individuals or legs that differ in size requires normalization (Bazett-Jones et al., 2011; Folland et al., 2008; Hurd et al., 2011). Normalization can be achieved by scaling measures of muscle function to one or a combination of simple anthropometric variables like body mass, height, or segment length, which serve as proxy measures for factors known to positively influence the generation of muscle force or torque (e.g., muscle mass, muscle moment arm length) (Hurd et al., 2011; Jaric, 2002; Jaric, 2003). A recent review of muscle function in LLP users (Hewson et al., 2020) however, found that less than a third of published studies normalized muscle strength data (i.e., peak torque) by any anthropometric variable. As a result, reported differences in strength, or the lack thereof, between individuals and/or legs may be confounded by differences in body size. Studies that did normalize peak torque, did so using body mass alone (Crozara et al., 2019; Heitzmann et al., 2020; Kowal and Rutkowska-Kucharska, 2014; Lloyd et al., 2010; Rutkowska-Kucharska et al., 2018; Sibley et al., 2021; Slater et al., 2021), a choice likely attributable to the popular view that larger individuals possess more muscle mass and are therefore stronger than smaller individuals (Jaric, 2002). Increases in body mass however, are not universally associated with increases in muscle mass and the

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ability to generate greater muscle force or torque (Folland et al., 2008). Further, there is no evidence to suggest that the normalization of muscle function data in LLP users by body mass, or any other anthropometric variable, is required or effective in establishing anthropometric-independent measures of muscle function that are suitable for comparison between individuals or legs that differ in size. The limited application of normalization to muscle function data in LLP user research, coupled with the lack of evidence to guide the selection of effective normalization procedures, limits the analysis and understanding of impairments in muscle function, as well as their impact on LLP users' physical function.

The objective of this pilot study was therefore to address three questions. First, is normalization of muscle strength data (i.e., peak torque) required in LLP users (i.e., is muscle strength significantly associated with common anthropometric variables)? Second, is normalization effective (i.e., does it return strength measures that are independent of anthropometric variables)? And third, does normalization alter the interpretation of strength data in LLP users? Answers to these questions were sought by analyzing peak torque data from two muscle groups central to LLP users' physical function, the hip abductors and extensors.

2. Methods

2.1. Study design

A cross-sectional pilot study was conducted to determine the need for, as well as effectiveness and impact of, normalizing maximum voluntary isometric hip peak torque by conventional anthropometric variables in established unilateral LLP users. Study protocols were reviewed and approved by an institutional review board at the University of Illinois at Chicago. All individuals gave written informed consent before participating.

2.2. Participant recruitment

Individuals with a unilateral transtibial or transfemoral amputation due to trauma, dysvascular complications, cancer, or infection were recruited from prosthetic clinics in Chicago using convenience sampling. To participate, individuals were required to be 18 years of age or older; have a history of wearing a prosthesis for at least two years post amputation; be able to walk 10 m without the use of a cane or walker; and be able to read, write, and speak English. Participants were excluded if they had a second amputation, contralateral complications, or a neuromusculoskeletal or cardiopulmonary condition (e.g., Chronic Obstructive Pulmonary Disease) that would preclude them from completing testing procedures.

2.3. Data collection

2.3.1. Participant characterization

Participant age and sex were collected via self-report, while amputation characteristics (e.g., etiology) Medicare Functional Classification Level (MFCL), or K-level (Palmento Government Benefits Administrators, 1994), and hours of prosthesis use per day were determined via interview by a certified prosthetist. Perceived mobility was assessed with the Prosthetic Limb Users Survey – Mobility (PLUS-M) (Hafner et al., 2017), while balance ability and number of co-morbidities were characterized by distance walked on the Narrowing Beam Walking Test (NBWT) (Sawers and Hafner, 2018a), and the Charlson Comorbidity Index (CCI) (Chaudhry et al., 2005), respectively. The NBWT was chosen for its challenge to lateral balance control (Sawers and Hafner, 2018a; Sawers and Ting, 2015), the ensuing demand placed on hip abductor muscle function (Curtze et al., 2010; Sawers et al., 2015), and its psychometric properties among unilateral LLP users (Sawers et al., 2020; Sawers and Hafner, 2018b).

Three anthropometric variables recognized for their potential influence on muscle strength were tested for their association with peak isometric hip extension and abduction torque: body mass (BM), thigh length (TL), and the product of body mass and thigh length (BM x TL) (Jaric, 2002; Jaric et al., 2005). Transfemoral amputation disrupts the relationship between height and muscle moment arm length in the residual limb because the length of the residual limb (i.e., thigh) is no longer proportional to body height. Thigh length (or residual limb length) was therefore selected in lieu of height as a proxy for muscle moment arm length. Residual limb thigh length in transfemoral prosthesis users was measured as the distance from the ischium to the distal end of the residuum.

2.3.2. Hip torque data collection

Maximum voluntary isometric hip extension and abduction torques were measured using a motor-driven dynamometer (Biodex System 4 Pro, Biodex Medical Systems, Inc., Shirley, NY) (Drouin et al., 2004). When testing hip extension or abduction, participants were positioned in a supine position (Meyer et al., 2013; Rutkowska-Kucharska et al., 2018) with the hip flexed to 20 degrees (Powers et al., 1996), or a side-lying position (Lloyd et al., 2010; Meyer et al., 2013; Nadollek et al., 2002; Widler et al., 2009), with the hip abducted to 10 degrees (Meyer et al., 2013; Powers et al., 1996), respectively. A supine rather than prone position was chosen for the assessment of hip extension for participant comfort, and for consistency with previous research (Hewson et al., 2020). The order of testing (i.e., leg and muscle group) was randomized, and the prosthesis was removed when testing the residual limb (Rutkowska-Kucharska et al., 2018; Ryser et al., 1988). After three-submaximal practice trials (Broekmans et al., 2013), participants completed 15 five-second maximum voluntary effort trials with 10 s rest between each trial. Participants were instructed to generate their maximum isometric force as quickly as they could, and to hold that maximum force until told to relax. The analog signal from the dynamometer was sampled at 1000 Hz, starting just before the verbal "go" command was given. Verbal encouragement was provided throughout the 5-s contraction. Five-minute rest periods were enforced between testing positions.

2.4. Data processing and analysis

2.4.1. Hip torque data processing

The maximum voluntary isometric torque for each muscle group and leg was derived from the digitized analog signal (NI USB-6341, National Instruments, Austin, TX), adjusted for the effects of gravity, and smoothed using a low-pass Svetsky-Golay filter. Peak torque was computed as the maximum torque recorded between signal onset and offset across all 15 trials. All processing and analysis steps were performed using custom MATLAB (MathWorks, Natick, MA) routines.

2.4.2. Normalization procedure

Allometric scaling (Jaric, 2002; Nevill et al., 2005; Owings et al., 2002; Vanderburgh et al., 1995) was used to determine *if* maximum voluntary isometric hip torque needed to be adjusted for the influence of anthropometric variables, and whether any needed adjustments were *effective* in returning a measure of hip torque that was independent of anthropometric variables in unilateral LLP users. Non-normalized hip torque (i.e., muscle strength) (S) was modeled as a function of a confounding anthropometric scaling variable (X), by the power function:

$$S = S_n(X)^{\beta} \quad (1)$$

where (S_n) is normalized hip strength (i.e., peak torque), and (β) is the scaling exponent (Jaric, 2002; Kleiber, 1950; Nevill et al., 1992; Nevill et al., 2005). *Re*-writing Eq. (1), normalized hip strength (S_n) can be represented as:

$$S_n = S \Big/ (X)^{\beta} \tag{2}$$

To determine the appropriate value for the scaling exponent (β) the power function (Eq. (1)) is linearized with a log-transformation, yielding:

$$log\ (S) = log\ (S_n) + \beta\ (log\ X) \tag{3}$$

As the equation of a straight line, the scaling exponent (β) represents the slope of that line. The value of the slope can be estimated by performing a standard linear regression with log (S) as the dependent variable, and log (X) as the independent variable. To determine whether the slope of the log-transformed regression is significantly greater than zero, and hip strength is significantly associated with the anthropometric variable in question, the 95% confidence interval (CI) of the slope is inspected to determine whether it includes the values zero or 1. Table 1 describes how to interpret the 95% CI of the slope for significance and if normalization is needed (i.e., if an association exists), as well as how normalization should be applied (Owings et al., 2002).

2.4.3. Statistical analysis

Departures from normality among continuous variables were evaluated with Shapiro-Wilk tests (Shapiro and Wilk, 1965). Outliers were detected and removed if they exceeded a threshold of ±3.0 median absolute deviations (MAD) beyond the median (Leys et al., 2013). Measures of central tendency and dispersion, as well as frequency and proportion, were computed to describe the continuous and categorical characteristics of the study sample, respectively. As an initial assessment of whether normalization alters the interpretation of hip strength in unilateral LLP users, Spearman's rho coefficients were computed between peak hip abduction torque and NBWT performance prior to and following normalization. Wilcoxon signed rank tests were also run to test for differences in peak hip extension torque between the residual and intact limbs before and after normalization. The level of significance for all tests was set to $\alpha \leq 0.05$. Normalization procedures and statistical analyses were performed using SPSS v.28 (Chicago, IL).

3. Results

Twenty-eight unilateral lower limb prosthesis (LLP) users participated in the study. Age, body mass index (BMI), and NBWT scores were normally distributed ($W \geq 0.952$, $p \geq .256$). The remaining amputation, health, and mobility-related continuous variables were non-normally distributed ($W \leq 0.899$, $p \leq .015$). Body mass (BM) (mean ± 95% CI) (83.8 kg ±16.4), height (1.73 m ±0.07), and intact thigh length (TL) (0.42 m ±0.02) were normally distributed ($W \geq 0.949$, $p \geq .216$), while residual limb thigh length (median ± MAD) (0.36 m ±0.13) was non-normally distributed ($W = 0.905$, $p = .021$).

Prior to log-transformation, and regardless of leg, non-normalized peak isometric hip extension and abduction torque values were non-normally distributed ($W \leq 0.770$, $p \leq .001$). Following their log-transformation non-normalized torque values were normally distributed ($W \geq 0.913$, $p \geq .112$). Torque values from two participants, one transtibial and one transfemoral, were found to exceed the outlier threshold of median ± 2.5 median absolute deviations (Leys et al., 2013) and were therefore excluded from subsequent analyses. Hence, 26 participants remained in the final analysis (Tables 2 and 3).

Within the residual limb, the slope coefficients (i.e., scaling exponent (β)) of linearized regression equations between non-normalized peak isometric hip torques and body mass (BM), as well as thigh length (TL), were not significantly greater than zero (Table 4). In contrast, slopes of the linearized regression equations between residual limb hip torques and BM x TL were significantly greater than zero (Table 4). Within the intact limb, slope coefficients of linearized regression equations between non-normalized peak isometric hip torques and all anthropometric variables (i.e., BM, TL, and BM x TL) were significantly greater than zero (Table 4).

After normalizing residual and intact limb peak hip extension and abduction torques by BM x TL, the slopes of the respective linearized regression equations were no longer significantly greater than zero (i.e., confidence intervals included 0 but not 1, no significant association) (Table 5). Similarly, after normalizing intact limb peak torques by body mass, the slopes of the linearized regression equations were no longer significantly greater than zero. In contrast, when intact hip extension and abduction torques were normalized by thigh length, the slopes of the linearized regression equations were indeterminant (i.e., confidence intervals included 0 and 1) (Table 5).

Prior to normalization the correlation between intact limb hip abduction torque and balance performance (i.e., NBWT distance walked) was small and not statistically significant ($r_s = 0.316$, $p = .109$). Once normalized by BM x TL intact limb hip abduction torque was moderately and significantly correlated with NBWT performance ($r_s = 0.513$, $p = .006$). Differences in hip extension torque between the intact and residual limb were also affected by normalization. Initially, no significant difference was found between intact and residual limb hip extension torques (intact: 71.4 Nm, residual: 72.9 Nm; $Z = -0.102$, $p = .918$). However, once normalized by BM x TL the same between limb difference was statistically significant (intact: 8.39 (% BM X TL), residual: 24.5 (% BM X TL); $Z = -4.60$, $p < .001$).

4. Discussion

The objective of this pilot study was to determine the need for as well as effectiveness and impact of normalizing hip extension and abduction muscle strength, as estimated by peak isometric torque, in LLP users. Results suggest that hip extension and abduction strength are significantly and consistently associated with body mass x thigh length in unilateral LLP users, which when adjusted for, alters the interpretation of between limb differences in hip extension strength, as well as the relationship between hip abduction strength and balance ability. Except for amputation etiology and sex, participant characteristics (e.g., age, amputation level, PLUS-M T-scores,) were largely consistent with those reported in large national studies of LLP users (i.e., $n = 146$–1568) (Ehde et al., 2000; Hafner et al., 2016; Pezzin et al., 2000; Wurdeman et al., 2018; Ziegler-Graham et al., 2008). The results of this pilot study may therefore generalize to the broader population of established unilateral non-dysvascular LLP users.

Table 1
Interpretation of the 95% confidence intervals (CI) accompanying the slope (β) of log-log regressions.

95% CI	Slope of log-log regression	Association between strength and anthropometric variable	Normalization
includes zero, not 1	slope *not* significantly > zero	*no* significant association	not indicated
includes 1, not zero	slope significantly > zero	significant *linear* association	indicated; $Sn = S/(X)^1$
between zero and 1	slope significantly > zero	significant *non-linear* association	indicated; $Sn = S/(X)^{\beta}$
includes zero and 1	slope indeterminant	association is indeterminant	N/A

Table 2
Participant demographic, health, amputation, mobility, and balance-related characteristics.

Demographics		Health		Amputation			Balance and Mobility			
Age	Sex	CCI	BMI	Level	Etiology	Time Since Amputation (*years*)	MFCL	PLUS-M (*T-score*)	Prosthetic Use (*hrs/day*)	NBWT (*/1.0*)
Mean (95% CI)	Subjects (/26)	Median (MAD)	Mean (95% CI)	Subjects (/26)	Subjects (/26)	Median (MAD)	Subjects (/26)	Mean (95% CI)	Median (MAD)	Mean (95% CI)
53.7 (47.7, 59.7)	Male (n = 13) Female (*n* = 13)	1.0 (1.5)	27.9 (25.3, 30.5)	Transtibial (n = 13) Transfemoral (n = 13)	Non-dysvascular (*n* = 19) Dysvascular (*n* = 7)	12.0 (13.3)	K2 (*n* = 12) K3 (n = 14)	51.1 (48.0, 54.2)	14.0 (2.97)	0.44 (0.35, 0.53)

BMI: Body Mass Index; CCI: Charlson Co-morbidity Index; CI: Confidence Interval; MAD: Median Absolute Deviation; MFCL: Medicare Functional Classification Level (K-level); NBWT: Narrowing Beam Walking Test; PLUS-M: Prosthetic Limb Users Survey-Mobility.

Table 3
Non-normalized residual and intact limb peak isometric hip extension and abduction torques.

	Hip extensors		Hip abductors	
	Residual limb	Intact limb	Residual limb	Intact limb
	Median (MAD)	Median (MAD)	Median (MAD)	Median (MAD)
Non-normalized peak torque (Nm)	72.9 (17.8)	71.4 (12.2)	81.4 (12.0)	74.3 (17.6)

MAD: Median Absolute Deviation.

Table 4
The slopes (β-values) and accompanying 95% confidence intervals (CI) of linear regressions performed on the logarithm of *non-normalized* hip extensor and abductor maximum voluntary isometric peak torque and the logarithm of body mass (BM), thigh length (TL), or body mass x thigh length (BM x TL).

	Hip extensors		Hip abductors	
	Residual limb	Intact limb	Residual limb	Intact limb
	β (95% CI [LB, UB])	β (95% CI [LB, UB])	β (95% CI [LB, UB])	β (95% CI [LB, UB])
Body mass (BM)	0.44 (−0.08, 0.95)[a]	0.60 (0.22, 1.1)[b]	0.44 (−0.10, 0.98)[a]	0.80 (0.29, 1.3)[b]
Thigh length (TL)	0.31 (−0.16, 0.77)[a]	2.9 (0.73 5.0)[b]	0.38 (−0.10, 0.85)[a]	2.9 (0.38, 5.3)[b]
BM x TL	0.33 (0.01, 0.64)[c]	0.61 (0.24, 0.97)[c]	0.35 (0.036, 0.67)[c]	0.73 (0.29, 1.2)[b]

β: slope coefficient; BM: body mass; CI: confidence interval; LB: lower bound; TL: thigh length; UB: upper bound.
a: no significant association between peak torque and anthropometric variable (CI includes 0 and not 1, $p \geq .05$).
b: significant linear association between peak torque and anthropometric variable (CI includes 1 or greater but not 0, $p < .05$).
c: significant non-linear association between peak torque and anthropometric variable (CI between 0 and 1, $p < .05$).

Table 5
The slopes (β-values) and accompanying 95% confidence intervals (CI) of linear regressions performed on the logarithm of *normalized* hip extensor and abductor maximum voluntary isometric peak torque and the logarithm of body mass (BM), thigh length (TL), or body mass x thigh length (BM x TL).

	Hip extensors		Hip abductions	
	Residual limb	Intact limb	Residual limb	Intact limb
	β (90% CI [LB, UB])	β (90% CI [LB, UB])	β (90% CI [LB, UB])	β (90% CI [LB, UB])
Body mass (BM)	–	−0.36 (−0.78, 0.10)[a]	–	−0.20 (−0.71, 0.32)[a]
Thigh length (TL)	–	1.9 (−0.27, 4.0)[c]	–	1.9 (−0.63, 4.3)[c]
BM x TL	0.00 (−0.32, 0.32)[a]	0.00 (−0.37, 0.37)[a]	0.00 (−0.32, 0.32)[a]	−0.27 (−0.71, 0.17)[a]

β: slope coefficient; BM: body mass; CI: confidence interval; TL: thigh length LB: lower bound; TL: thigh length; UB: upper bound.
a: no significant association between peak torque and anthropometric variable (CI includes 0 and not 1, $p \geq .05$).
b: significant linear association between peak torque and anthropometric variable (CI includes 1 or greater but not 0, $p < .05$).
c: association between peak torque and anthropometric variable is indeterminant (CI includes both 0 and 1).

4.1. Is hip strength, as estimated by peak isometric torque, significantly associated with anthropometric variables in unilateral LLP users and therefore in need of normalization?

Non-normalized peak isometric hip extension and abduction torques in the residual limb of unilateral LLP users were found to be significantly associated with body mass x thigh length (BM x TL), but not body mass (BM) or thigh length (TL) alone. In contrast, non-normalized peak isometric hip extension and abduction torques in the intact limb were significantly associated with all three anthropometric variables. Across residual and intact limbs, BM x TL was the only anthropometric variable that both hip extension and abduction strength were consistently dependent on, and for which adjustment was needed. The lack of a significant association between non-normalized hip torques and BM or TL in the residual limb may be due to amputation-related changes. Increases in BM may not be accompanied by expected increases in fat-free muscle mass within the residual limb. While strength has been correlated with muscle physiological cross-sectional area (Maughan et al., 1983), increased BM does not necessarily lead to increased fat-free muscle mass and force generating capacity (Folland et al., 2008). Similarly, amputation may alter muscle moment arm length in the residual limb. To date, BM has been the only anthropometric variable with which dynamometer-driven measures of hip torque in LLP users have been normalized (Crozara et al., 2019; Heitzmann et al., 2020; Kowal and Rutkowska-Kucharska, 2014; Lloyd et al., 2010; Rutkowska-Kucharska et al., 2018; Sibley et al., 2021; Slater et al., 2021). Our understanding of hip muscle strength in unilateral LLP users, and its relationship to physical function, is therefore currently limited to measures of hip torque that remain dependent on anthropometric variables.

4.2. Is normalization effective, and does it alter the interpretation of hip extension and abduction strength in unilateral LLP users?

Normalization of residual and intact limb peak isometric hip extension and abduction torques by BM x TL was found to reduce significant associations and return measures of hip strength that were independent of the tested anthropometric variables. Among LLP users, adjusting for the influence of BM x TL on hip extension and abduction torques yields strength indices that are suitable for comparison between individuals and legs that differ in size. Importantly, normalization by BM x TL was found to alter the interpretation of hip strength in this pilot study. Specifically, normalization of intact limb hip abduction torque by BM x TL led to the identification of a larger and significant correlation between hip abduction peak torque (i.e., muscle strength) and balance ability, as estimated by NBWT performance, that would otherwise have been overlooked in the absence of normalization. While several other factors may contribute to balance ability (e.g., socket fit, proprioception), these results suggest that a potentially important relationship between a modifiable factor, intact limb hip abduction strength, and fall risk as estimated by the NBWT (Sawers et al., 2020; Sawers and Hafner, 2018b), would go unnoticed and untreated. Additionally, previous research, which either did not normalize hip torques or did so using body mass alone, has suggested that hip extension strength in unilateral LLP users is either lower in the residual versus intact limb (James, 1973; Rutkowska-Kucharska et al., 2018), or not significantly different (Bäcklund et al., 1968; Powers et al., 1996). In contrast, the current results suggest that hip extension strength, once normalized to BM x TL, is significantly greater in the residual than the intact limb of unilateral LLP users. While limited to two specific examples, these data serve to initially illustrate how a failure to normalize hip strength data in LLP users to appropriate anthropometric variables may confound results, alter their interpretation, and ultimately influence the treatments and research questions clinicians and scientists pursue.

4.3. Future research and limitations

Future research with a larger sample is needed to confirm the current results, conduct important sub-analyses (e.g., level of amputation, etiology) (Bazett-Jones et al., 2011; Powers et al., 1996), and compare theoretical and empirical scaling exponents for LLP users (Wren and Engsberg, 2007). A comprehensive evaluation of additional aspects of muscle function (e.g., power and endurance), muscle groups (e.g., knee extensors), and muscle actions (e.g., eccentric) is required to determine whether the current results apply to the broader construct of muscle function in LLP users. Consideration for alternative normalization models that do not presume geometric similarity (e.g., a gamma function model) (Nevill et al., 2004; Nevill and Holder, 1999) and additional anthropometric scaling variables (e.g., fat free muscle mass, muscle thickness, hip girth) (Jaric, 2002) are necessary to identify and adopt the most physiologically-relevant and effective normalization procedure(s). While motor-driven dynamometers are regularly used to evaluate muscle strength in LLP users (Hewson et al., 2020), and have been shown to possess degrees of validity and reliability in other clinical populations (Drouin et al., 2004; Jørgensen et al., 2017; Kristensen et al., 2017; Lienhard et al., 2013), their psychometric properties in LLP users remain to be confirmed. Establishing key psychometric indices for motor-driven dynamometers, as well as other means of evaluating muscle function in LLP users is necessary to develop a gold-standard against which clinically-feasible assessments can be compared, and changes over time evaluated.

5. Conclusion

In this pilot study we demonstrate that hip extension and abduction strength in unilateral LLP users, as estimated by maximum voluntary isometric peak torque, are significantly and consistently associated with BM x TL. The dependence on BM x TL can be minimized via normalization to create measures of hip strength amenable to comparisons between individuals and legs that differ in size. In the absence of such procedures, important relationships between hip strength and balance ability, as well as critical between limb differences may go unnoticed. This pilot study suggests that until further research is conducted to confirm and expand upon the present findings, researchers should consider the potential confounding effects of anthropometric variables on strength data among unilateral LLP users and adjust for any significant associations accordingly. The findings of this pilot study suggest that non-normalized peak torque strength data in LLP users should be interpreted cautiously, and that the application of validated normalization procedures may challenge long-held beliefs regarding patterns of muscle weakness and their association with walking or balance ability in LLP users.

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Declaration of conflicting interest

The authors declare that there is no conflict of interest.

Institutional review

All study procedures were reviewed and approved by a University of Illinois at Chicago institutional review board.

Clinical trial registration

N/A.

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Appendix 2

Title: Hip strength of the residual limb exceeds that of the intact limb among unilateral lower limb prosthesis users.

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Abstract

Background: Hip muscles play a prominent role in compensating for the loss of ankle and/or knee muscle function after lower limb amputation. Despite contributions to walking and balance, there is no consensus regarding hip strength deficits in lower limb prosthesis (LLP) users. The purpose of this study was to test whether hip strength, estimated by maximum voluntary isometric peak torque, differed between the residual and intact limbs of LLP users, and age- and gender-matched controls.

Methods: 28 LLP users (14 transtibial, 7 dysvascular, 13.5 years since amputation), and 28 age- and gender-matched controls participated in a cross-sectional study. Maximum voluntary isometric hip extension, flexion, and abd/adduction torque were measured with a motorized dynamometer. Participants completed 15 five-second trials with 10-seconds rest between trials. Peak isometric hip torque was normalized to body mass x thigh length. A 2-way mixed-ANOVA with a between-subject factor of leg (intact, residual, control) and a within-subject factor of muscle group (extensors, flexors, abd/adductors) tested for differences in strength among combinations of leg and muscle group ($\alpha=0.05$). Multiple comparisons were adjusted using Tukey's Honest-Difference.

Results: A significant 2-way interaction between leg and muscle group indicated normalized peak torque differed among combinations of muscle group and leg ($p<.001$). A significant simple main effect of leg ($p=.001$) indicated peak torque differed between two or more legs per muscle group. Post-hoc comparisons revealed hip extensor, flexor, and abductor peak torque was not significantly different between the residual and control legs ($p\geq.067$), but both were significantly greater than in the intact leg ($p<.001$). Peak hip abductor torque was significantly greater in the control and residual legs than the intact leg ($p<.001$), and significantly greater in the residual than control leg ($p<.001$).

Conclusions: Our results suggest that it is the intact, rather than the residual limb, that is weaker. These findings may be due to methodological choices (e.g., normalization), or biomechanical demands placed on residual limb hip muscles. Further research is warranted to both confirm, expand upon, and elucidate possible mechanisms for the present findings; and clarify contributions of intact and residual limb hip muscles to walking and balance in LLP users.

Clinical Trial Registration: N/A

Key Words: amputation, amputee, muscle strength, rehabilitation

1.0 Background

Hip muscles play a prominent role in the biomechanical adaptation to unilateral lower limb amputation (1, 2). Unilateral lower limb prosthesis (LLP) users compensate for the loss of ankle and/or knee muscle function by recruiting ipsilateral hip muscles to produce propulsive, stabilizing, and body weight supporting forces during locomotor activities (1-5). Hip muscles in transfemoral prosthesis users may also serve to stabilize their residual limb within the socket (6, 7) and provide a degree of control over the prosthesis (3). Given their expansive set of responsibilities, it is perhaps not suprising that residual and intact limb hip muscle weakness (8-13) has been associated with a host of gait impairments including reduced walking speed (5, 8, 10, 11, 14), increased metabolic cost (15-17), decreased balance confidence (18), abnormal joint loading (8, 14), as well as reduced mobility (19) and walking endurance (20, 21). Hip strength may therefore prove to be an appealing target for interventions that seek to improve walking and balance performance in LLP users.

There is currently no consensus regarding the extent of hip strength deficits in unilateral LLP users (22). In the absence of agreement, suitable targets for rehabilitation cannot be clearly identified. To date, many (5, 12, 14, 21, 23), but not all (10, 11) studies involving transtibial prosthesis users report *no* significant difference in hip strength between the residual and intact limbs, regardless of hip muscle group. Studies of transfemoral prosthesis users typically report residual limb hip muscles as significantly weaker than their intact limb counterparts, but the specifics (i.e., which muscles) varies from study to study (8, 9, 13, 24). To advance our understanding of hip strength deficits in unilateral LLP users several historically overlooked factors must be addressed (22). First, hip strength must be interpreted in the absence of the confounding effects of age, gender, and body size (25, 26). Age and gender-matched controls can be recruited to address the former (9, 12, 27), while the biological influence of body size (i.e., muscle mass) on muscle strength can be addressed by normalizing strength data to appropriate anthropometric variable(s) (28), ensuring unbiased comparisons between people and legs that differ in size (26, 29, 30). Second, documentation of hip strength across all four major hip muscle groups, in both the residual and intact limb, is required to characterize within and between limb patterns of hip strength among unilateral LLP users(11, 13, 19, 31). Finally, nearly half of the evidence concerning hip strength in unilateral LLP users is based on data collected almost 20 years ago (22). Changes in amputation technique and immediate post-operative care, a decline in the provision of rehabilitation services, an aging and increasingly co-morbid population, as well as advances in prosthetic socket design may affect hip strength in LLP users and our understanding of it, necessitating the collection of further data.

The purpose of this study was to test whether hip extension, flexion, abd- and adduction muscle strength, estimated by maximum voluntary isometric peak torque, and normalized to body mass x thigh length, differed between the residual and intact limbs of unilateral LLP users, as well as age- and gender-matched controls. We hypothesized that the residual limb would be the weakest of the three legs, regardless of hip muscle group. We also hypothesized that hip strength would be significantly lower in transfemoral versus transtibial prosthesis users.

2.0 Methods

2.1 Study Design

A cross-sectional study was conducted to determine the effect of amputation level (i.e., transfemoral and transtibial), leg (i.e., residual, intact, and control), as well as muscle group (i.e., extensors, flexors, abductors, and adductors) on hip strength, as estimated by maximum voluntary isometric peak torque, in established unilateral lower limb prosthesis (LLP) users, as well as age- and sex-matched controls. Study protocols were reviewed and approved by an institutional review board at XXXX. All individuals provided written informed consent prior to participation.

2.2 Participant Recruitment

Individuals with a unilateral transtibial and transfemoral amputation due to trauma, dysvascular complications, cancer, or infection were recruited from prosthetic clinics in XXXX using convenience sampling. To participate, LLP users were required to be 18 years of age or older; have a history of wearing a prosthesis for at least two years post amputation; be able to walk short distances (e.g., 10 meters); and be able to read, write, and speak English. LLP users were excluded if they had a congenital amputation, a second amputation, contralateral complications, or a neuromusculoskeletal or cardiopulmonary condition that would preclude them from completing testing procedures. Able-bodied persons were recruited from the community as controls using convenience sampling. Controls were matched to individual LLP users based on gender and age ±5 years (27).

2.3 Data Collection

2.3.1 Participant characterization

Participant age, gender, and amputation characteristics (e.g., etiology, time since amputation) were collected via self-report, while the Medicare Functional Classification Level (MFCL) (i.e., K-level)(32) of LLP user participants was determined via interview by a certified prosthetist. The perceived physical function and fatigue of LLP users and controls were assessed by administering the PROMIS-29 Physical Function and Fatigue scales (33, 34), respectively. Perceived physical function specific to LLP users was documented by administering the Prosthetic Limb Users Survey of Mobility (PLUS-M) (35). The number of co-morbidities was characterized by administering the Charlson Comorbidity Index (CCI) (36). Body mass, height, and thigh length (ASIS to medial condyle or distal end of residual limb) were also recorded to aid in the normalization of peak hip torque.

2.3.2 Hip torque data collection

Maximum voluntary isometric hip extension, flexion, abduction, and adduction torques were measured using a motor-driven dynamometer (Biodex System 4 Pro, Biodex Medical Systems, Inc., Shirley, NY)(37). When testing hip extension or flexion, participants were placed in a supine position(8, 38) with the hip flexed to 20 degrees (5). To test abduction or adduction, participants assumed a side-lying position(12, 14, 38, 39), with the hip abducted 10 degrees (5, 10, 38). Testing order (i.e., leg and muscle group) was randomized, and the prosthesis was removed when testing the residual limb (8, 9). Following three-submaximal practice trials (40), participants performed 15 five-second maximum voluntary effort isometric trials with 10 seconds of rest between trials. Instructions to participants were to generate maximum voluntary isometric force as quickly as possible, and to hold that maximum effort until told to relax. The analog signal from the dynamometer was sampled at 1000 Hz, beginning just prior to the verbal “go” command. Verbal encouragement was provided during the 5-second contraction. Five-minute rest periods were implemented between the testing of each muscle group.

2.4 Data Processing and Analysis

2.4.1 Hip torque data processing

The maximum voluntary isometric peak torque for each muscle group in each leg was derived from the digitized analog signal (NI USB-6341, National Instruments, Austin, TX) after adjusting for the effects of gravity, and smoothed using a low-pass Svetsky-Golay filter. Peak torque was calculated as the maximum torque recorded between signal onset and offset across all 15 trials. Data processing steps were run using custom MATLAB (MathWorks, Natick, MA) routines. Mathematically adjusting for the biological influence of body size on muscle strength is necessary to create measures of hip torque that are independent of confounding anthropometric variables, and suitable for comparison between people and legs that differ in size (26, 29, 30). Based on prior research (28), peak hip torque was normalized to body mass x thigh length (BM x TL) using allometric scaling (25, 26, 41-43). Non-normalized hip torque (S) was modeled as a power function $S = S_n (BM \times TL)^{\beta}$, where ($S_n$) is normalized hip torque, and (β) is the scaling exponent (25, 26, 44, 45). To determine appropriate values for the scaling exponent of each muscle group and leg combination, the power function was log transformed, and standard linear regression was used to calculate the slope of the resulting linearized equation, $\log(S) = \log(S_n) + \beta (\log BM \times TL)$ (41). Peak torque values for each muscle group and leg combination were then scaled to BM x TL by inserting the corresponding β-value into the re-written power function, $S_n = (S) / (BM \times TL)^{\beta}$. Normalization of peak torque values was conducted using SPSS v.28 (Chicago, IL).

2.4.2 Statistical analysis

Departures from normality among continuous variables were evaluated with Shapiro-Wilk tests (46). Peak hip torque values, normalized to body mass x thigh length were identified as outliers and removed if they exceeded a threshold of ±2.5 median absolute deviations (MAD) above or below the median (47). Measures of central tendency and dispersion, or frequency and proportion, were calculated to describe continuous and categorical characteristics of the study sample, respectively. Independent-samples t-tests, or Mann-Whitney U tests, were run to test for differences in characteristics (e.g., age, perceived physical function) between LLP users and matched controls.

Using only the data of LLP users, a three-way mixed ANOVA with one between-subject factor of amputation level and two-within-subject factors of leg and muscle group was run to determine whether the effects of leg and muscle group on maximum voluntary isometric peak torque were dependent on amputation level. The absence of a significant 3-way interaction between amputation level, leg, and muscle group would indicate that the effects of leg and muscle group on peak hip torque were *not* dependent on amputation level. Similarly, the absence of significant 2-way interactions between muscle group and amputation level, or leg and amputation level, would indicate that peak torque values did not differ according to combinations of muscle group and amputation level, or leg and amputation level, respectively. Transtibial and transfemoral prosthesis users could subsequently be combined into a single group of LLP users for analysis with respect to matched controls.

A two-way mixed ANOVA with a between-subject factor of leg (3-levels: intact, residual, control), and a within-subject factor of muscle group (4 levels: extensors, flexors, abductors, adductors), was run to test for differences in peak isometric hip torque among combinations of leg and muscle group. Assumptions of homogeneity of variances and covariances, as well as sphericity in the dependent variable (i.e., normalized peak torque) were evaluated with Levene's test of homogeneity, Box's test of equality, and Mauchly's test of sphericity, respectively. The level of significance for all tests was set to $\alpha \leq .05$. Multiple comparisons during post-hoc tests were adjusted using Tukey's Honest Significant Difference (HSD) test. All statistical analyses were performed with SPSS v.28 (Chicago, IL).

3.0 Results

3.1 Participant characteristics

Twenty-eight unilateral lower limb prosthesis (LLP) users, 14 transfemoral and 14 transtibial, as well as 28 age- and gender-matched controls were recruited and participated in the study (Table 1). The cause of amputation was non-dysvascular in 21 (75%) of the LLP users, and dysvascular in seven (25%). Fifty percent had a K3 Medicare Functional Classification Level (K2: n=14, K3: n=14,), and the median time since amputation, which was non-normally distributed ($W = .857$, $p = .001$) was 12 years with an interquartile range of 17 years. LLP users' PLUS-M T-scores (median: 51.7, IQR: 7.47) were non-normally distributed ($W = .879$, $p = .004$). The number of co-morbidities, PROMIS-29 Physical Function T-scores, and PROMIS-29 Fatigue T-scores were non-normally distributed (LLP users: $W \leq .889$, $p \leq .009$; controls: $W \leq .835$, $p < .001$), while age, body mass, and height were normally distributed (LLP: $W \geq .950$, $p \geq .231$; controls: $W \geq .928$, $p \geq .068$). Mann-Whitney U tests revealed no statistically significant differences between LLP users and matched controls in age, body mass, or height, ($U \geq 250.5$, $z \geq -1.60$, $p \geq .109$) (Table 1). Perceived physical function (i.e., PROMIS-29 Physical Function T-scores) was significantly lower in LLP users than matched controls ($U = 544$, $z = 4.07$, $p \leq .001$) (Table 1), while the number of co-morbidities and perceived fatigue (i.e., PROMIS-29 Fatigue T-scores) were significantly greater in LLP users than matched controls ($U \leq 232$, $z \leq -2.21$, $p \leq .027$) (Table 1). Median thigh length was non-normally distributed ($W \leq .917$, $p \leq .03$) and not significantly different ($U=250$, $z = -1.60$, $p=.109$) between the intact leg of LLP users (0.43m) and that of controls (0.42m).

Median residual limb thigh length among transfemoral prosthesis users (0.26m) was normally distributed (W=.921, p=.260) and significantly shorter than that of transtibial prosthesis users (0.42m) (U=0.12, z = -4.52, p<.001).

3.2 Peak hip extension, flexion, abduction, and adduction torque

3.2.1 Analysis of statistical assumptions for mixed ANOVA

In all four hip muscle groups, across all three limbs, peak isometric torque was significantly associated with body mass x thigh length (BM x TL), indicating that normalization was required for valid and fair comparisons between people and legs that differ in size. Associations between peak torque and BM x TL were *non-linear* in the residual and control limbs, as well as the hip extensors of the intact limb. In the remaining intact limb hip muscle groups, peak torque had a *linear* association with BM x TL (Supplemental Material 1). Normalization successfully removed the association between peak torque and BM x TL in all four muscle groups, across all three limbs, producing body size independent measures of hip torque suitable for comparison between participants and legs that differed in size (Supplemental Material 1).

Peak torque values normalized to BM x TL exceeded the outlier threshold of ±2.5 median absolute deviations (47) in one transfemoral and one transtibial prosthesis user. Both LLP users, and his/her matched control, were therefore excluded from further analyses. Normalized peak torque (Table 2) was then log-transformed so that values approximated a normal distribution for any combination of amputation level, leg, and hip muscle group ($W \geq .868$, $p \geq .050$). Homogeneity of variance and covariance of the normalized and log-transformed peak hip torque values were confirmed by Levene's test of equality of variance, $p \geq .298$, and Box's test of equality of covariance, p = .116, respectively. Mauchly's test of sphericity revealed that the assumption of sphericity was violated for the three-way interaction between amputation level, leg, and muscle group, $X^2(5) = 14.40$, p = .013. Greenhouse-Geisser corrections were therefore applied to the interpretation of the mixed-ANOVA output.

3.2.2 The effect of amputation level on hip muscle strength: 3-way mixed ANOVA

After applying a Greenhouse-Geisser correction for the violation of sphericity, the three-way interaction between amputation level, leg, and muscle group on normalized and log-transformed peak torque in LLP users was not statistically significant, $F(1.44, 34.6) = 1.29$, p = .279. The absence of a significant three-way interaction indicates that the interpretation of any two-way interaction between amputation level, leg, or muscle group (e.g., leg x muscle group) on normalized and log-transformed peak torque was not dependent on the third remaining factor (e.g., level of amputation). Similarly, 2-way interactions between muscle group and amputation level $F(1.40, 33.7) = .059$, $p=.885$), as well as leg and amputation level $F(1, 24) = .001$, $p=.885$) were not statistically significant. The absence of significant two-way interactions indicates that normalized and log-transformed peak torque values did not differ according to combinations of muscle group and amputation level, or leg and amputation level. These results indicate that the effects of leg and muscle group on normalized maximum voluntary isometric peak torque were *not* dependent on amputation level. Transtibial and transfemoral prosthesis users were therefore combined into a single group of LLP users in all subsequent analyses.

3.2.3 The effect of leg and muscle group on hip strength: 2-way mixed ANOVA

There was a statistically significant two-way interaction between leg and muscle group on normalized and log-transformed peak torque values, $F(5.17, 194) = 78.8$, $p < .001$. The significant two-way interaction between leg and muscle group indicates that normalized and log-transformed peak torque values differed according to combinations of muscle group (e.g., hip extensors, abductors) and leg (i.e., residual, intact, or control leg). Consequently, simple main effects of leg on each muscle group (i.e., between leg differences), and muscle group on each leg (i.e., within leg differences) were tested and interpreted using univariate and repeated measures ANOVA procedures, respectively. Pairwise comparisons were performed for all significant simple main effects.

3.2.4 Between leg comparisons: Simple main effects of leg on hip muscle group and accompanying pairwise comparisons

All torque data are reported as mean % BM x TL ± 95% CI. Simple main effects of leg on hip muscle group were considered statistically significant at a Bonferroni-adjusted alpha level of .0125 (i.e., 4 simple main effects, one per muscle group). There was a statistically significant simple main effect of leg on peak torque for each hip muscle group, $F(2, 75) \geq 130.6$, $p < .001$, indicating that normalized and log-transformed peak torque differed between two or more legs for each hip muscle group. Post-hoc pairwise comparisons, examined with a Tukey HSD adjusted p-value of .0167, (i.e., comparisons between three legs), revealed that normalized and log-transformed peak torque values for the hip extensor, flexor, and abductor muscle groups were not significantly different between the residual and control legs ($p \geq .067$) (Table 3; Figure 1). However, values from the residual and controls legs were significantly greater than those in the intact leg ($p < .001$) (Table 3; Figure 1). Peak hip adduction torque was also significantly greater in the control and residual legs compared to the intact leg ($p < .001$) (Figure 1; Table 3), yet unlike the other hip muscle groups, peak hip adduction torque was significantly greater in the residual than the control leg ($p < .001$) (Table 3; Figure 1).

3.2.5 Within leg comparisons: Simple main effects of hip muscle group within each leg and accompanying pairwise comparisons

All torque data are reported as mean % BM x TL ± 95% CI. Simple main effects of hip muscle group were considered statistically significant at a Bonferroni-adjusted alpha level of .0167 (i.e., 3 simple main effects, one per leg). There was a significant simple main effect of muscle group on normalized and log-transformed peak torque within the residual leg, $F(2.14, 53.6) = 69.3$, $p < .001$, intact leg, $F(2.51, 62.8) = 247.1$, $p < .001$, and control leg, $F(2.60, 64.9) = 189.6$, $p < .001$, indicating that normalized and log-transformed peak torque differed between two or more hip muscle groups within each leg. Post-hoc pairwise comparisons, examined with Bonferroni adjusted p-values (i.e., .0083, six comparisons between four muscle groups), revealed that within the residual limb, normalized and log-transformed peak torque was not significantly different between the hip extensors and abductors ($p = .98$), but both were significantly greater than the flexors or adductors ($p < .001$) (Table 3, Figure 1). Normalized peak hip flexion torque was also significantly greater than peak hip adductor torque ($p = .007$) (Table 3, Figure 1). Within the intact leg, normalized and log-transformed peak torque was significantly greater in the hip extensors than the flexors, abductors, and adductors ($p < .001$) (Table 3, Figure 1). Peak torque was not significantly different however, between the flexors, abductors, or adductors ($p \geq .018$) (Table 3, Figure 1). Within the control leg, normalized and log-transformed peak torque was not significantly different between the hip extensors, flexors, and abductors ($p \geq .041$), but all three were significantly greater than peak torque in the adductors ($p \leq .001$) (Table 3, Figure 1).

4.0 Discussion

The objective of this study was to test whether hip muscle strength, estimated by maximum voluntary isometric peak torque, and normalized to BM x TL, differed between the residual and intact limbs of unilateral LLP users, as well as age- and gender-matched controls. In contrast to previous research, and our own hypothesis, the results suggest that it is the intact, rather than the residual limb, that is the weakest of the three legs. Direct comparisons across the literature are however fraught with methodological differences between studies. Notable variations in data collection and analysis throughout the literature include testing posture (e.g., supine, sitting, or standing) and joint angle (5, 21, 23), testing equipment (i.e., computerized versus handheld dynamometer) (11-13, 19, 20), mode of muscle action (i.e., isometric versus isokinetic) (5, 8, 11, 13, 23), whether the prosthesis is worn (10-12, 21, 23) or removed (5, 8, 9, 13, 19, 24, 28, 31) while testing the residual limb, gravity compensation, familiarization (i.e., number of trials) (48), and normalization for confounding anthropometric variables (22). Given our findings that residual limb hip muscles may not be weaker than intact limb hip muscles, below we describe how the elevated and prolonged activation of residual limb hip muscles during ambulatory activities may act to preserve or restore residual limb hip muscle strength in the face of reduced physical activity. Next, we explain how normalization, a key methodological choice, may reveal otherwise obscured between limb differences in hip strength among unilateral LLP users. Finally, we highlight clinical implications of the results, and proposed future research needs.

4.1 Elevated and prolonged activation of residual limb hip muscles while walking may offset reduced physical activity, preserving, or restoring residual limb hip strength in unilateral lower limb prosthesis users.

Physical activity among LLP users is characterized by limited volume (49-52), duration (49, 51), and intensity (50, 53). For example, LLP users take between 1,540 and 4,000 steps per day (50-57), well below physical activity guidelines for the general population (i.e., 10,000 steps per day) (58, 59) or adults with a disability or chronic illness (i.e., 5,500 to 6,500 steps per day) (60). While lower body muscle strength would be expected to decrease with reduced physical activity and the accompanying disuse of lower limb muscles (9), residual limb hip muscles may be less susceptible to the adverse effects of inactivity than their intact counterparts. Specifically, residual limb hip muscles are constantly active during ambulatory activities (3, 4, 6, 61-63), while those in the intact limb retain burst-like activity that is consistent with age- and gender-matched controls (6, 63, 64). Whether meant to compensate for the loss of ipsilateral ankle and/or knee muscle function (1-4, 65-67), stabilize the residual limb within the socket (6, 7), or provide some control over the prosthesis (3), the elevated and prolonged activation of residual limb hip muscles during each step (3, 4, 6, 61-63) may have the unintended benefit of offering a degree of protection against the weakening effects of reduced physical activity that drives intact limb hip muscles weakness. The "always-on" pattern of residual limb hip muscle activity may therefore preserve, or with time, restore residual limb hip muscle strength in unilateral LLP users by increasing their "use" per step. Additional research is required to investigate associations between physical (in)activity, hip muscle activation, and hip muscle strength in unilateral LLP users.

4.2 Detection of between limb differences in hip strength among unilateral LLP users may depend on identifying and adjusting for confounding anthropometric variables.

While historically considered to be weaker (8, 9, 24), hip muscles in the residual limb of unilateral LLP users were found to be as strong or stronger than those in the intact limb, or those of age- and gender-matched controls (Figure 1, Table 3). Unlike much of the research conducted to quantify hip strength in LLP users to date (22), here, peak torque was scaled (i.e., normalized) to BM x TL, with the aim of mathematically adjusting for the biological influence of body size on muscle strength (28). Allometric scaling, and in particular the values of the scaling exponents (i.e., β) used to adjust for the *linear* and *non-linear* associations observed between non-normalized peak torque and BM x TL, may have revealed otherwise obscured between limb differences in hip strength. Among controls and the residual limb of LLP users, non-normalized peak torque (S) had a *non-linear* association with BM x TL (Supplemental Material 1). The resulting scaling exponents therefore assume smaller values (i.e., between zero and 1.0) (41) than those used to adjust for the *linear* associations between non-normalized peak torque and BM x TL in the intact limb of LLP users (i.e., β=1) (41) (Supplemental Material 1). When applied to the re-written power function, $S_n = (S) / (BM \times TL)^{\beta}$, the smaller *non-linear* scaling exponents (β) have the effect of reducing the size of the denominator and, in turn, increasing the magnitude of normalized peak torque values (S_n) relative to those of the intact limb in LLP users (Table 2). Identifying and adjusting for linear and non-linear associations between peak torque and confounding anthropometric variables appear therefore to have a considerable influence on the interpretation of hip strength data among unilateral LLP users. Consequently, between limb differences in hip muscle strength among LLP users may be revealed only when appropriately scaled to body size. Given the apparent importance of normalization to the interpretation of hip muscle function in unilateral LLP users, additional research is required to identify and establish biomechanically-sound, clinically feasible, and standardized approaches to the normalization of muscle function in unilateral LLP users (28).

4.3 Several important considerations for the assessment and rehabilitation of unilateral LLP users emerge from the observed within and between limb hip strength differences.

Gait deviations (10, 12, 13), reduced walking speed and endurance (5, 11, 14, 20, 21, 68, 69), as well as increased metabolic cost (16) have historically been associated with weakness in the *residual limb* of unilateral LLP users. Several recent studies have however reported that *intact limb* muscle function may also play a substantial role in determining walking endurance (70) and physical activity levels (19) among unilateral LLP users. The results of these latter studies, and our discovery that once scaled to body size, the intact not residual limb hip muscles appear weaker, injects uncertainty into whether walking and balance performance in unilateral LLP users is limited primarily by intact or residual limb muscle function. Additional research using body size independent measures of muscle function is required to clarify the contributions of intact and residual limb hip muscles to walking and balance performance in unilateral LLP users (22, 71). Rehabilitation protocols that focus on strengthening intact limb muscles as much or more than those in the residual limb may also be warranted.

The strength of the residual limb hip muscles in the current study suggests that determining how residual limb hip muscle torques can be most efficiently transferred through the prosthesis to the ground may have important implications for walking and balance performance. Controlled experimental conditions were used to isolate and quantify the torque generating capacity of residual and intact limb hip muscles. Whether this torque generating capacity generalizes to functional activities, whereby the “strongest” LLP users also possess the ability to generate the greatest hip torques while walking with their prosthesis, and do so in an efficient manner, remains unknown. Similarly, factors that mediate the efficiency with which residual limb hip muscle torques contribute to propulsive, braking, stabilizing, and body-weight supporting forces while walking remains unknown. Prosthetic-specific factors including socket designs, interfaces, and alignment; biomechanical factors such as co-contraction; rehabilitative factors like gait training; and physiological factors such as pain, may all contribute to the efficiency with which unilateral LLP users are able to generalize residual limb hip strength to walking and balance performance. Identifying modifiable factors that maximize the efficiency of force transmission from the residual limb through the prosthesis may enhance walking and balance performance in unilateral LLP users.

Existing clinical tests of lower body muscle function would be unable to identify either the between or within limb strength deficits described in the current study. Contemporary, standardized, and routinely administered clinical tests of lower body muscle function are largely based on variations of timed sit-to-stand tasks (72-75). Compared to computerized dynamometers, these clinical tests engage multiple muscle groups across and within the intact and residual limb of unilateral LLP users (73, 76), often in unique, varied, and asymmetric patterns (77, 78). Such compensations, coupled with the inability to evaluate individual muscle groups, may mask important muscle- and limb-specific strength deficits, limiting the ability of clinicians to provide personalized treatment. Consequently, while existing clinical tests of lower body muscle function may provide a generic assessment of how strong or weak a LLP user is, they cannot specify where weakness resides, limiting the ability of clinicians to intervene. Existing clinical tests of lower body muscle function should therefore be interpreted cautiously if administered to unilateral LLP users. Future research to develop and assess the validity of clinically feasible methods for quantifying within and between limb strength deficits among unilateral LLP users is required.

4.4 Several limitations should be considered when interpreting the results of the current study. Beyond amputation etiology, characteristics of the LLP user sample (e.g., age, amputation level, and perceived mobility) were largely consistent with those reported in large national studies of LLP users (i.e., n=146-1568)(79-83). While the results of this study may therefore generalize to the broader population of established unilateral non-dysvascular LLP users, they are limited to the characterization of *isometric* hip muscle function by *peak torque* at a single joint angle. Whether similar between limb differences are observed at different joint angles (84), during isokinetic muscle actions (85), and when other descriptors of muscle function (86) including rate of torque development (87), steadiness (88), and fatigue (89) are used to characterize hip muscle function remains to be determined. Data collection in the current study was lengthy and demanding. Multiple trials were performed to assess four hip muscle groups across the intact and residual limbs. The burden placed on study participants may have induced varying degrees of mental and/or physical fatigue, which may have affected study results. Mandatory rest periods and randomization of test conditions were implemented to minimize the systematic effect of participant fatigue and/or concentration. Aspects of sample heterogeneity may have influenced study results. While several sources of sample heterogeneity were managed through normalization (i.e., body size), statistical analysis (i.e., amputation level), and inclusion or matching criteria (i.e., age and gender), other sources of heterogeneity (i.e., cause of amputation, time since amputation, and amputation technique) were not. The potential for cause of and time since amputation to confound study results is limited, as most LLP user participants (i.e., 75%) had amputations of non-dysvascular etiology, and time since amputation does not appear to be related to muscle strength in LLP users (31, 90, 91). Nonetheless, future research examining the influence of these amputation-related factors on muscle function, and specifically amputation technique (92), is warranted. As with all research that examines muscle function, the results of the current study are subject to the chosen data collection and analysis methods. The variation in methods throughout the literature (22) limits comparisons between studies. Consequently, the extent to which the results and conclusion presented herein diverge from or confirm prior findings is difficult to ascertain. Further, the lack of consistent methodologies across studies presents a challenge to the aggregation of key findings, and the formation of a consensus regarding muscle function in LLP users. The development and dissemination of standardized methods for the collection, analysis, and reporting of strength-related outcomes in LLP users is needed.

5.0 Conclusion

In this study we found residual limb hip strength of unilateral LLP users, as estimated by maximum voluntary isometric peak torque, and normalized to BM x TL, to be significantly greater than that of their intact limb, and equivalent to that of age- and gender-matched controls. We propose that the observed pattern of between limb differences in hip muscle strength may be attributed to the elevated and prolonged activation of residual limb hip muscles during ambulatory activities, and only detected after having identified and adjusted for confounding anthropometric variables through appropriate scaling techniques. The findings of this study challenge long-held beliefs regarding patterns of hip strength among unilateral LLP users. Further research is warranted to confirm, expand upon, and elucidate possible mechanisms for the present findings. Specifically, when seeking to describe and explain between and within limb patterns of hip muscle function among unilateral LLP users, researchers should consider additional measures of muscle function (e.g., rate of torque development and steadiness), isokinetic muscle actions, as well as the concurrent collection of electromyographic, imaging, physical activity, and gait data.

List of Abbreviations

BM: Body mass

INT: Intact

LLP: Lower limb prosthesis

RL: Residual limb

S: non-normalized strength

S_n: normalized strength

TL: Thigh length

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Declaration of Conflicting Interest

The authors declare that there is no conflict of interest.

Availability of data and materials'

The dataset(s) supporting the conclusions of this article is(are) included within the article (and its additional file(s)).

Figure Captions

Figure 1. Within and between limb differences in log transformed, peak torque values (mean ±95% CI) normalized to body mass x thigh length for the hip extensor, flexor, abductor, and adductor muscle groups in the residual (filled black, solid line) and intact (filled grey, solid line) limbs of unilateral lower

limb prosthesis users, as well as age- and gender-matched controls (filled white, dashed line). Hip strength was significantly lower among all four hip muscle groups in the intact limb when compared to the residual and control limbs.

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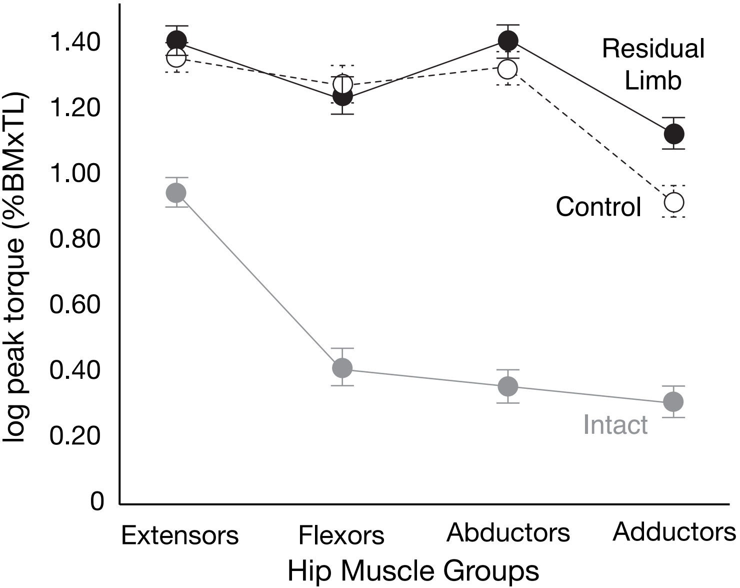

log peak torque (%BMxTL)
1.40
1.20
1.00
0.80
0.60
0.40
0.20
0
Residual Limb
Control
Intact
Extensors
Flexors
Abductors
Adductors
Hip Muscle Groups

Table 1. Demographic, health, and mobility-related characteristics common to lower limb prosthesis (LLP) users as well as age- and gender-matched controls (CONT).

	Group	Median (Q1, Q3)	p-value
Age (years)	LLP	55.0 (44.0, 60.8)	.993
	CONT	55.0 (39.5, 62.8)	
Body mass (kg)	LLP	82.2 (68.7, 100.2)	.641
	CONT	78.3 (64.3, 96.1)	
Height (m)	LLP	1.74 (1.68, 1.82)	.133
	CONT	1.71 (1.65, 1.78)	
PROMIS-29 Physical Function	LLP	41.8 (37.9, 48.3)	<.001
	CONT	57.0 (57.0, 57.0)	
PROMIS-29 Fatigue	LLP	48.6 (46.0, 55.1)	.003
	CONT	43.1 (33.7, 48.6)	
CCI	LLP	1 (0, 2)	.027
	CONT	0 (0,1)	

CCI: Charlson Co-morbidity Index; PLUS-M: Prosthetic Limb Users Survey of Mobility; Q1: first quartile; Q3: third quartile

Table 2. Normalized peak isometric torque (% BM x TL) for residual and intact limb hip muscle groups in unilateral lower limb prosthesis users, as well as age- and gender-matched controls. Data are presented as median ± median absolute deviation (MAD).

Peak isometric hip extension torque		
Residual limb	Intact limb	Control limb
25.7±7.35	8.52 ± 2.03	22.4 ± 5.14
Peak isometric hip flexion torque		
Residual limb	Intact limb	Control limb
17.3 ± 5.81	2.44 ± 0.882	18.1 ± 6.04
Peak isometric hip abduction torque		
Residual limb	Intact limb	Control limb
26.5 ± 7.71	2.15 ± 0.667	21.9 ± 5.48
Peak isometric hip adduction torque		
Residual limb	Intact limb	Control limb
13.5 ± 4.75	2.06 ± 0.638	8.40 ± 1.59

BM: body mass; MAD: median absolute deviation; TL: thigh length

Table 3. Log-transformed peak isometric hip torque normalized to body mass x thigh length in the residual and intact limbs of unilateral lower limb prosthesis users as well as age- and gender-matched controls. Data are presented as mean ± 95% confidence interval.

	Hip extensors (HE)	Hip flexors (HF)	Hip abductors (ABD)	Hip adductors (ADD)	Simple main effects of muscle group
Residual limb (RL)	1.40 ± 0.10	1.23 ± 0.14	1.40 ± 0.12	1.12 ± 0.11	(HE = ABD) > (HF > ADD)[b]
Intact limb (INT)	0.927 ± 0.11	0.401 ± 0.12	0.350 ± 0.10	0.303 ± 0.11	HE > (ABD = HF = ADD)][b]
Control (CONT)	1.35 ± 0.07	1.27 ± 0.08	1.32 ± 0.09	0.916 ± 0.07	(HE = ABD = HF) > ADD[b]
Simple main effects of leg	(RL = CONT) > INT[a]	(RL = CONT) > INT[a]	(RL = CONT) > INT[a]	(RL > CONT)> INT[a]	

a: pairwise between leg comparisons, $p \leq .0167$; b: pairwise within leg comparisons, $p \leq .0083$

Appendix 3

Table 3. Contributions of isometric hip muscle function to walking and balance performance in unilateral transtibial (n=13) and transfemoral (n=13) prosthesis users.					
Transtibial 10mWT model: $F(3,9) = 23.95$, $p < .001$, $R^2 = .889$, SEE = .100					
Independent variable(s)	B (95% CI)	β	t-statistic (p-value)	Durbin-Watson	VIF
Constant (B_0)	.716 (.412, 1.02)		5.32 (<.001)	2.59	1.02
RL hip extension average torque	.027 (.018, .037)	.769	6.82 (<.001)		
INT hip flexion iRTD	.015 (.008, .023)	.546	4.80 (< .001)		
RL hip abduction steadiness	-.030 (-.057, -.003)	-.285	-2.54 (.032)		
Transfemoral 10mWT model: $F(1,11) = 5.36$, $p = .041$, $R^2 = .327$, SEE = .153					
Independent variable(s)	B (95% CI)	β	t-statistic (p-value)	Durbin-Watson	VIF
Constant (B_0)	.857 (.490, 1.22)		5.14 (<.001)	2.25	1.00
INT hip abduction impulse	.009 (.000, .017)	.572	2.314 (.041)		
Transtibial 2minWT model: $F(2,10) = 7.46$, $p = .010$, $R^2 = .559$, SEE = 33.9					
Independent variable(s)	B (95% CI)	β	t-statistic (p-value)	Durbin-Watson	VIF
Constant (B_0)	101.5 (13.5, 189.5)		2.57 (.028)	1.62	1.01
RL hip extension average torque	3.93 (.927, 6.93)	.584	2.92 (.015)		
RL hip abduction steadiness	-9.76 (-18.7, -.846)	-.489	-2.44 (.035)		
Transfemoral 2minWT model: $F(1,11) = 9.51$, $p = .010$, $R^2 = .464$, SEE = 24.4					
Independent variable(s)	B (95% CI)	β	t-statistic (p-value)	Durbin-Watson	VIF
Constant (B_0)	41.6 (-16.5, 99.8)		1.58 (.144)	2.52	1.00
INT hip abduction impulse	1.82 (.520, 3.11)	.681	3.08 (.010)		
Transtibial FSST model: $F(1,11) = 24.31$, $p < .001$, $R^2 = .688$, SEE = 3.96					
Independent variable(s)	B (95% CI)	β	t-statistic (p-value)	Durbin-Watson	VIF
Constant (B_0)	2.31 (-2.42, 7.05)		1.07 (.305)	2.84	1.01
RL hip abduction steadiness	1.43 (.791, 2.07)	.830	4.93 (<.001)		
Transfemoral FSST model: $F(1,11) = 5.43$, $p = .042$, $R^2 = .352$, SEE = 3.74					
Independent variable(s)	B (95% CI)	β	t-statistic (p-value)	Durbin-Watson	VIF
Constant (B_0)	24.5 (13.5, 35.5)		4.98 (<.001)	1.21	1.00
INT hip abduction impulse	-.248 (-.486, -.011)	-.593	-2.33 (.042)		
Transtibial NBWT model: $F(2,10) = 10.74$, $p = .003$, $R^2 = .682$, SEE = 3.25					
Independent variable(s)	B (95% CI)	β	t-statistic (p-value)	Durbin-Watson	VIF
Constant (B_0)	12.8 (6.06, 19.6)		4.22 (.002)	1.85	1.01
RL hip abduction steadiness	-1.54 (-2.39, -.689)	-.718	-4.03 (.002)		
INT hip flexion average torque	2.12 (.085, 4.16)	.414	2.32 (.043)		
Transfemoral NBWT model: $F(1,11) = 10.27$, $p = .008$, $R^2 = .483$, SEE = 2.98					
Independent variable(s)	B (95% CI)	β	t-statistic (p-value)	Durbin-Watson	VIF
Constant (B_0)	-1.89 (-8.99, 5.21)		-.587 (.569)	2.08	1.00
INT hip abduction impulse	.231 (.072, .389)	.695	3.21 (.008)		

10mWT: 10-meter walk test; 2minWT: 2-minute walk test; B: unstandardized beta coefficient; β: standardized beta coefficient; FSST: Four Square Step Test; INT: intact limb; iRTD: instantaneous rate of torque development; NBWT: Narrowing Beam Walking Test; RL: residual limb; SEE: standard error of the estimate; VIF: variance inflation factor.

<table>
<tr><td colspan="5">Supplementary Table 1. Forward model development. Independent variables added to each model, and the respective increments of change in R^2.</td></tr>
<tr><td colspan="5">Transtibial 10mWT model: $F(3,9) = 23.95$, $p < .001$, $R^2 = .889$, SEE = .100</td></tr>
<tr><td>Independent variable(s)</td><td>R^2 change (p-value)</td><td>F change</td><td>Significance of F change</td><td>VIF</td></tr>
<tr><td>RL hip extension average torque</td><td>.476 (.009)</td><td>10.01</td><td>.009</td><td>1.00</td></tr>
<tr><td>INT hip flexion iRTD</td><td>.333 (.002)</td><td>17.43</td><td>.002</td><td>1.03</td></tr>
<tr><td>RL hip abduction steadiness</td><td>.080 (.032)</td><td>6.43</td><td>.032</td><td>1.05</td></tr>
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<tr><td colspan="5">Transfemoral 10mWT model: $F(1,11) = 5.36$, $p = .041$, $R^2 = .327$, SEE = .153</td></tr>
<tr><td>Independent variable(s)</td><td>R^2 change (p-value)</td><td>F change</td><td>Significance of F change</td><td>VIF</td></tr>
<tr><td>INT hip abduction impulse</td><td>.327 (.041)</td><td></td><td>.041</td><td>1.00</td></tr>
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<tr><td colspan="5">Transtibial 2minWT model: $F(2,10) = 7.46$, $p = .010$, $R^2 = .559$, SEE = 33.9</td></tr>
<tr><td>Independent variable(s)</td><td>R^2 change (p-value)</td><td>F change</td><td>Significance of F change</td><td>VIF</td></tr>
<tr><td>RL hip extension average torque</td><td>.360 (.030)</td><td>.015</td><td rowspan="2">1.62</td><td>1.00</td></tr>
<tr><td>RL hip abduction steadiness</td><td>.239 (.035)</td><td>.035</td><td>1.01</td></tr>
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<tr><td colspan="5">Transfemoral 2minWT model: $F(1,11) = 9.51$, $p = .010$, $R^2 = .464$, SEE = 24.4</td></tr>
<tr><td>Independent variable(s)</td><td>R^2 change (p-value)</td><td>F change</td><td>Significance of F change</td><td>VIF</td></tr>
<tr><td>INT hip abduction impulse</td><td>.464 (.010)</td><td>.010</td><td>2.52</td><td>1.00</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Transtibial FSST model: $F(1,11) = 24.31$, $p < .001$, $R^2 = .688$, SEE = 3.96</td></tr>
<tr><td>Independent variable(s)</td><td>R^2 change (p-value)</td><td>F change</td><td>Significance of F change</td><td>VIF</td></tr>
<tr><td>RL hip abduction steadiness</td><td>.688 (<.001)</td><td>< .001</td><td>2.84</td><td>1.01</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Transfemoral FSST model: $F(1,11) = 5.43$, $p = .042$, $R^2 = .352$, SEE = 3.74</td></tr>
<tr><td>Independent variable(s)</td><td>R^2 change (p-value)</td><td>F change</td><td>Significance of F change</td><td>VIF</td></tr>
<tr><td>INT hip abduction impulse</td><td>.352 (.042)</td><td>.042</td><td>1.21</td><td>1.00</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Transtibial NBWT model: $F(2,10) = 10.74$, $p = .003$, $R^2 = .682$, SEE = 3.25</td></tr>
<tr><td>Independent variable(s)</td><td>R^2 change (p-value)</td><td>F change</td><td>Significance of F change</td><td>VIF</td></tr>
<tr><td>RL hip abduction steadiness</td><td>.511 (.006)</td><td>.002</td><td rowspan="2">1.85</td><td rowspan="2">1.01</td></tr>
<tr><td>INT hip flexion average torque</td><td>.171 (.043)</td><td>.043</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Transfemoral NBWT model: $F(1,11) = 10.27$, $p = .008$, $R^2 = .483$, SEE = 2.98</td></tr>
<tr><td>Independent variable(s)</td><td>R^2 change (p-value)</td><td>coefficient p-value</td><td>Significance of F change</td><td>VIF</td></tr>
<tr><td>INT hip abduction impulse</td><td>.483 (.008)</td><td>.008</td><td>2.08</td><td>1.00</td></tr>
</table>

10mWT: 10-meter walk test; 2minWT: 2-minute walk test; FSST: Four Square Step Test; INT: intact limb; iRTD: instantaneous rate of torque development; NBWT: Narrowing Beam Walking Test; RL: residual limb; R^2: coefficient of determination; VIF: variance inflation factor.

Normalization alters the interpretation of hip strength in established unilateral lower limb prosthesis users

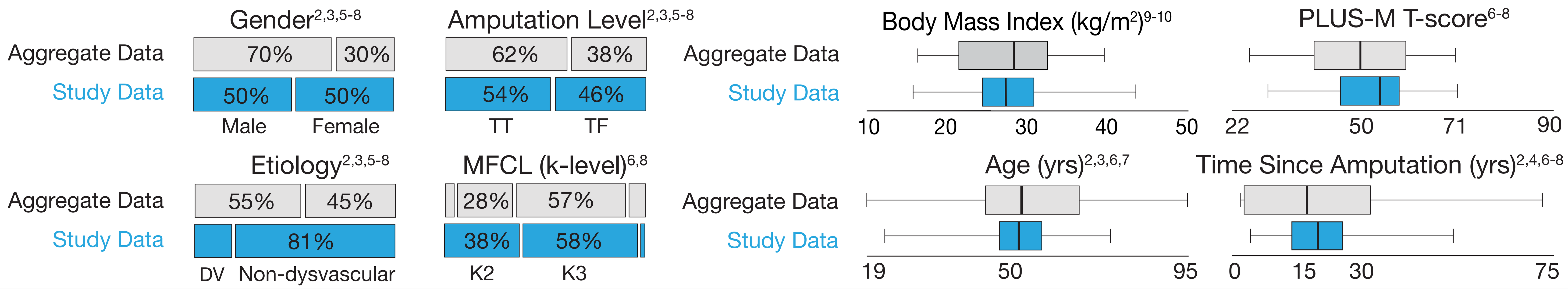
Shaquitta Dent[1], Stefania Fatone[2], Andrew Sawers[1]
(1) University of Illinios-Chicago, (2) Northwestern University

UIC — Northwestern Medicine

Motivation: Normalization of strength data is uncommon in lower limb prosthesis (LLP) user researcher, potentially causing us to overlook important relationships between strength and walking or balance ability, as well as critical between limb differences.

- A recent review of muscle strength in LLP users[1] noted that only a quarter of the studies normalized strength data by key body parameters (e.g., body mass, height, segment length). Normalization by body parameters is important because it allows for fair comparisons between people and legs that differ in size and shape. Failure to normalize strength data may confound or alter the interpretation of important results.
- The **objective** of this pilot study was to address this gap by answering 3 questions: i) is normalization of strength data required in LLP users, ii) does normalization "work" (ie., reduce influence of body parameters), and iii) what are the consequences of failing to normalize strength data?

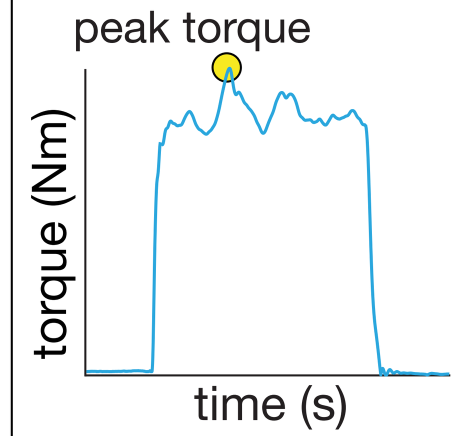
Result 1: Sample characteristics (n=26) were largely consistent with those from larger studies of lower limb prosthesis (LLP) users



Approach: Maximum vountary isometric hip extension (HEXT) and abduction (HABD) torques were recorded from 26 LLP users.

1. Data Collection (motor-driven dynamometer)

Positioning	Testing
HABD: side-lying, 10°	Three practice trials
HEXT: supine, 20°	Fifteen 5s trials, 10s rest
Prosthesis removed	Muscle & leg randomized



2. Data Acquisition and Processing

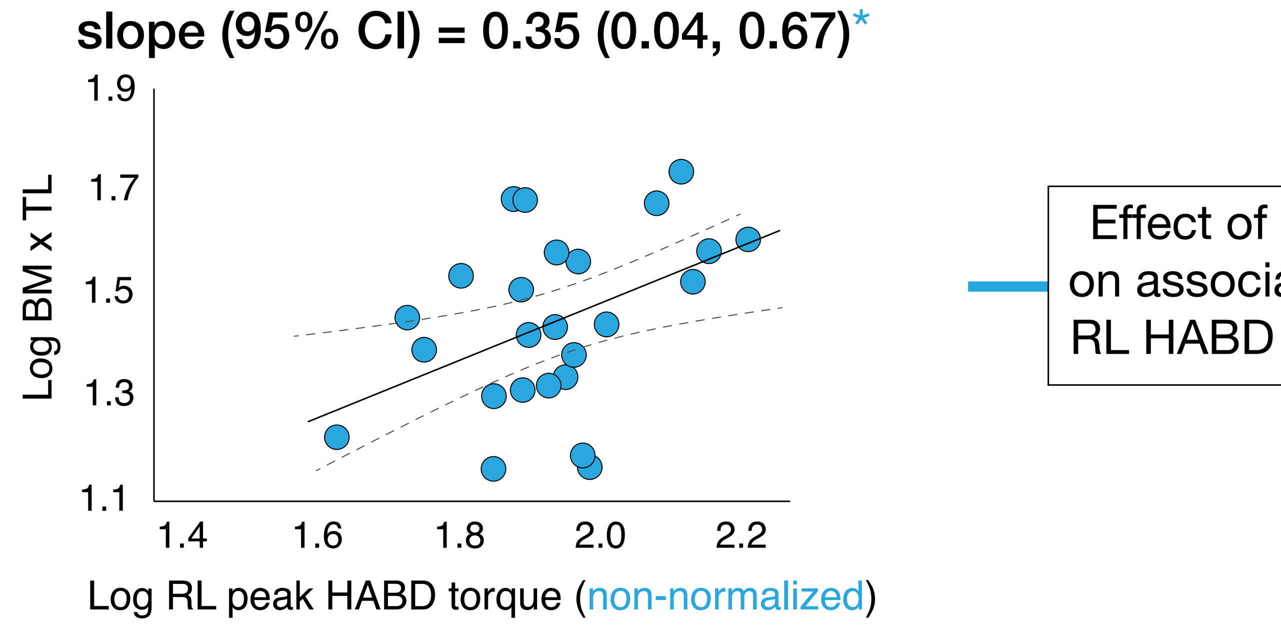
- Dynamometer analog signal sampled at 1000Hz
- Torque signal converted from volts to Nm, corrected for gravity, and low-pass filtered (Svetsky-Golay)
- Peak torque detected between signal onset / offset

3. Normalization Procedure

Power function: $Y = AX^{\beta}$ $\xrightarrow[\text{log}]{\text{linearize}}$ $\log Y = \log A + \beta(\log X)$ $\rightarrow$ $A = YX^{-\beta}$

Y = non-normalized torque *X = body parameter*
A = normalized torque *β = scaling constant (slope)*

Result 2: Is hip strength, estimated by peak torque, significantly associated with (dependent on) body parameters in LLP users?



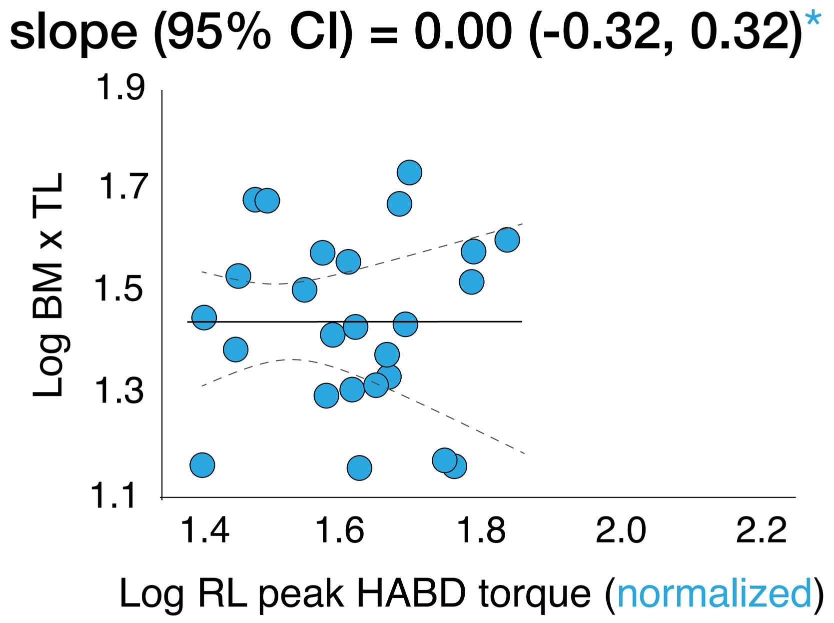
Effect of normalization on association between RL HABD and body size

body parameters	Hip extensors residual limb ß (95% CI)	Hip extensors intact limb ß (95% CI)	Hip abductors residual limb ß (95% CI)	Hip abductors intact limb ß (95% CI)
Body mass	.44 (-.10, .95)	.60 (.22, 1.1)*	.44 (-.10, .98)	.80 (.29, 1.3)*
Thigh length	.31 (-.18, .77)	2.9 (.73, 5.0)*	.38 (-.10, .85)	2.9 (.38, 5.3)*
Body size	.33 (.01, .64)*	.61 (.24, .97)*	.35 (.04, .67)*	.73 (.29, 1.2)*

*Confidence intervals around the slope of log regressions relating non-normalized torque to confounding body parameters did not include 0

Yes, residual and intact limb peak hip torques were significantly and consistently associated with (dependent on) body size

Result 3: Does normalization reduce the association between peak hip torques and body size in LLP users?

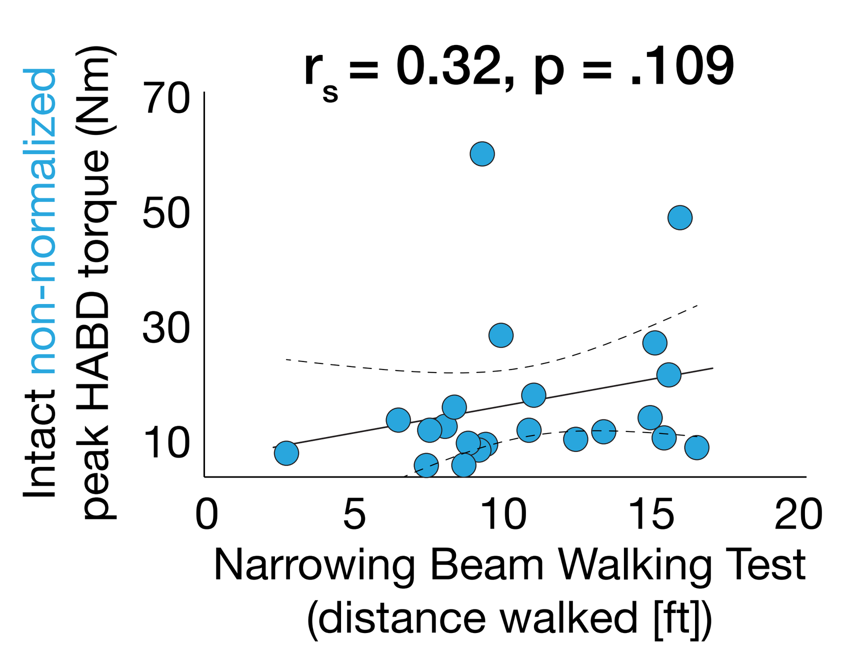


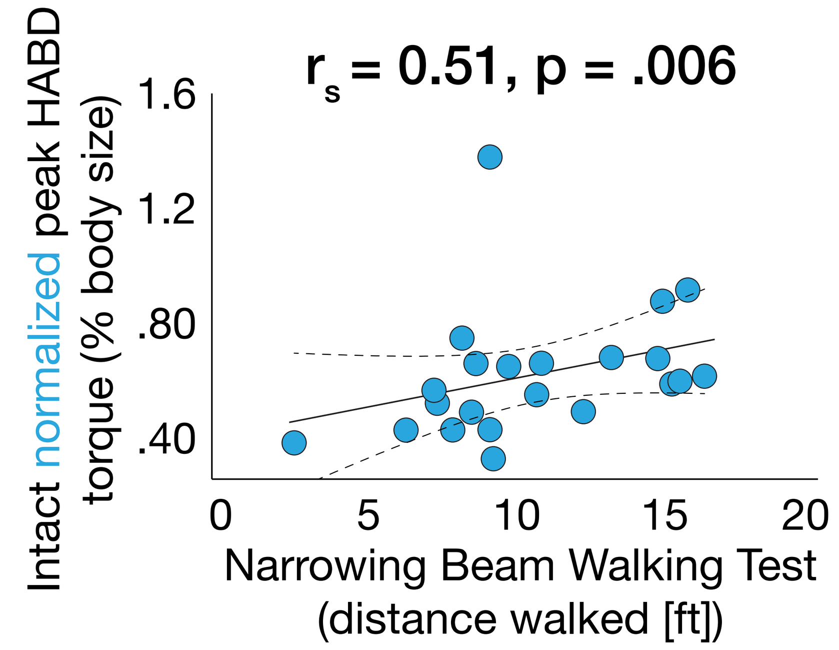
body parameters	Hip extensors residual limb ß (95% CI)	Hip extensors intact limb ß (95% CI)	Hip abductors residual limb ß (95% CI)	Hip abductors intact limb ß (95% CI)
Body mass	--	-.36 (-.78, .10)	--	-.20 (-.71, .32)*
Thigh length	--	1.9 (-.27, 4.0)	--	1.9 (-.63, 4.3)
Body size	0.0 (-.32, .32)*	0.0 (-.37, .37)*	0.0 (-.32, .32)*	-.27 (-.71, .17)*

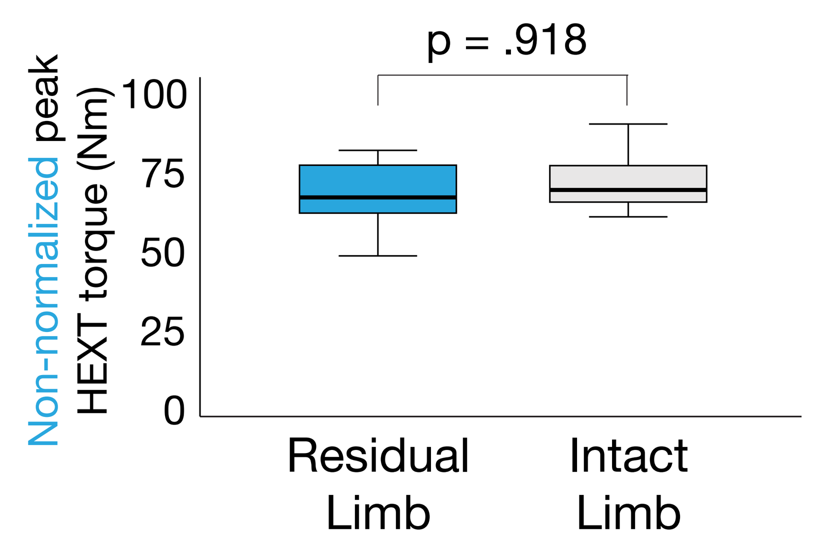
*Confidence intervals around the slope of the log regressions between normalized torque and body size consistently included 0, but not 1

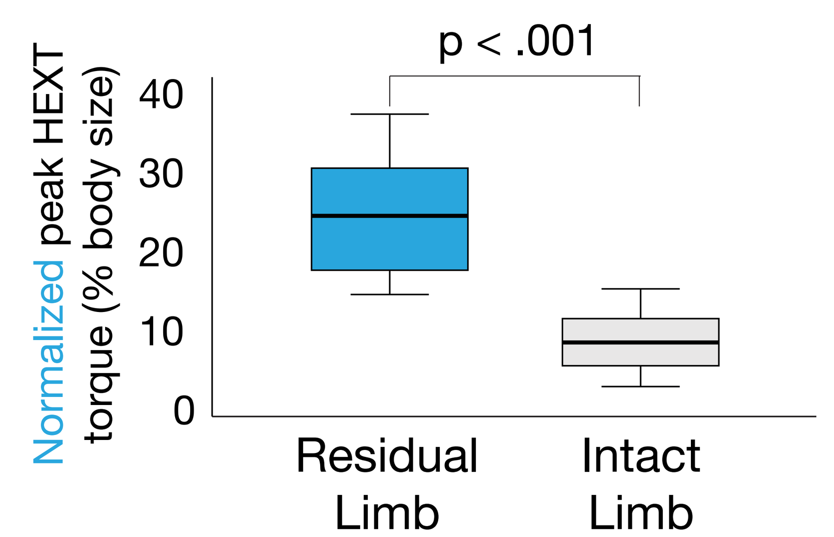
Yes, normalizing peak hip torques by body size consistently and significantly reduced associations, enabling comparisons

Result 4: Does normalization alter the interpretation of hip strength (i.e., peak hip torque) in unilateral LLP users?









Yes, normalization of hip abduction torque by body size alters its relationship to balance ability & reveals between limb differences

Peak hip abduction and extension torques in unilateral LLP users should be normalized to body size (body mass x thigh length)

- Failure to normalize strength data (i.e., peak torque) in LLP users may confound results, alter their interpretation, and influence the treatments and questions clinicians and scientists pursue.
- Further research with a larger sample, additional strength measures, alternative normalization procedures, and other muscle groups is required.

References and Funding Sources

1) Hewson et al., 2020 POI; 2) Ehde et al., 2000 Arch Phys Med Rehabil; 3) Pezzin et al., 2004 Arch Phys Med Rehabil; 4) Ephraim et al., 2005 Arch Phys Med Rehabil; 5) Ziegler-Graham et al., 2008 Arch Phys Med Rehabil; 6) Hafner et al.,2016 J Rehabil Res Dev; 7) Wurdeman et al., 2018 Am J Phys Med Rehabil; 8) ABC Practice Analysis, 2015; 9) Frost et al., POI 2017; 10) Wong et al., 2019 Am J Phys Med Rehabil.

Funding for this study was provided by the US Department of Defence under award number W81XWH1910507

Appendix 5

RETHINKING HIP STRENGTH IN LOWER LIMB PROSTHESIS USERS

Sawers A[1], Fatone S[2], Caldwell R[3]

University of Illinois at Chicago[1], University of Washington[2], and Northwestern University[3]

INTRODUCTION

Strength deficits may play a key role in the severity of balance and mobility impairments in lower limb prosthesis (LLP) users. A recent review of muscle strength in LLP users noted that strength deficits are consequential, yet there was considerable variation in methods used to assess muscle strength (Hewson et al. 2020). Only a quarter of studies normalized strength data to basic anthropometric variables (e.g., body mass), limiting the validity of comparisons between people or legs that vary in size (Hewson et al. 2020). We recently demonstrated that hip strength in LLP users is dependent on body-mass (BM) x thigh length (TL) (Sawers & Fatone, 2022), and failure to adjust for this association masks between limb differences in hip strength and their relationship to balance ability. The objective of this study was to test if hip strength, estimated by peak isometric torque normalized to BMxTL, differed between residual and intact limbs of LLP users, as well as age and sex-matched controls.

METHOD

Cross-sectional study approved by an institutional review board. All subjects provided informed consent.

Participants: 28 unilateral LLP users (mean age: 55 years, mean body mass: 82.2 kg, mean height: 1.75 m, 14 male, 14 transtibial, 7 dysvascular, 10 K2/17 K3/1 K4, median: 13.5 years since amputation). 28 age- and gender-matched control subjects.

Apparatus: Maximum voluntary isometric hip flexion, extension, and abd/adduction torques were measured with a motorized dynamometer (Biodex 4 Pro, NY).

Procedures: The order of testing leg and muscle group was randomized, and the prosthesis removed when testing the residual limb. After 3 submaximal practice trials, participants completed 15 five-second maximum voluntary effort trials with 10 s rest between trials.

Data Analysis: Peak isometric hip torques were normalized to BMxTL. Initial assessment of a 3-way interaction between amputation level, leg, and muscle group indicated that the effects of leg and muscle group on peak torque were not dependent on amputation level. Similarly, 2-way interactions between amputation level and muscle group, as well as amputation level and leg were not significant. LLP users were therefore combined into one group for comparison to controls. A 2-way mixed ANOVA with a between-subject factor of leg (3-levels: intact, residual, control) and a within-subject factor of muscle group (4-levels: extensors, flexors, abd/adductors) was run to test for differences in hip strength among combinations of leg and muscle group. Significance for all tests was set at $\alpha=0.05$. Multiple comparisons during post-hoc tests were adjusted using Tukey's Honest Difference (SPSS; IBM).

RESULTS

Normalized peak torques were log-transformed so that values approximated a normal distribution for any combination of amputation level, leg, and muscle group. A significant 2-way interaction between leg and muscle group indicated that normalized peak torque differed according to combinations of muscle group and leg. Here we focus on the between-leg results. A significant simple main effect of leg ($p=.001$) indicated that peak torque differed between two or more legs for each muscle group. Post-hoc comparisons revealed that for hip extensors, flexors and abductors, peak torques were not significantly different between the residual and control legs ($p \geqslant .067$), but both were significantly greater than the intact leg ($p<.001$) (Fig 1). For hip adductors, peak torque was significantly greater in the control and residual legs compared to the intact leg ($p<.001$), yet unlike other hip muscles, peak adduction torque was significantly greater in the residual than control leg ($p<.001$).

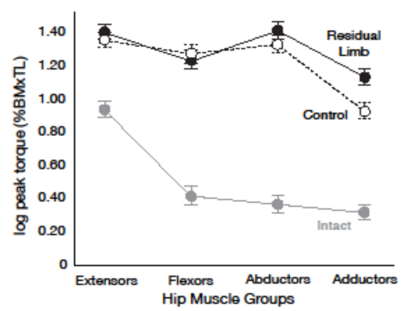


Fig 1. Peak hip torque across muscle group for each limb.

DISCUSSION & CONCLUSION

In contrast to prior research, our results suggest that hip strength does not differ as a function of amputation level, and that it is the intact, rather than the residual limb, that is weaker. These novel findings may be due to methodological choices (e.g., normalization, age- and gender-matching), or biomechanical demands placed on residual limb hip muscles. Specifically, intact limb hip strength may be reduced due to lower overall activity (i.e., fewer steps), while residual limb hip muscles do not suffer the same fate as they are "always on", performing more work per step to compensate for lost ankle and knee muscles. Further research to test these hypotheses is required.

CLINICAL APPLICATIONS

Historical patterns of hip muscle weakness and their implications in LLP users should be reconsidered.

REFERENCES

Hewson et al. Prosthet Orthot Int, 2020; 44(5):323-340.
Sawers & Fatone. Clin Biomech, 2022.105702.

Funded by Department of Defense under Award No. W81XWH1910507.

American Academy of Orthotists & Prosthetists

49th Academy Annual Meeting

& Scientific Symposium

March 1-4, 2023

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).

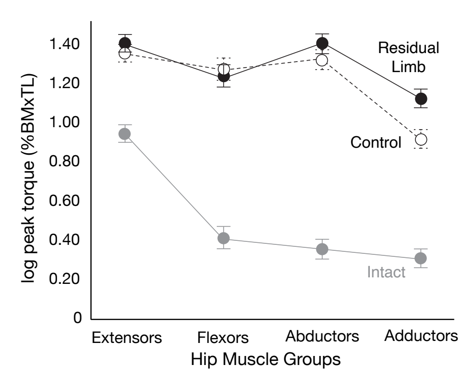


Figure. Within and between limb differences in log transformed, peak torque values (mean ±95% CI) normalized to body mass x thigh length for the hip extensor, flexor, abductor, and adductor muscle groups in the residual (filled black, solid line) and intact (filled grey, solid line) limbs of unilateral lower limb prosthesis users, as well as age- and gender-matched controls (filled white, dashed line). Hip strength was significantly lower among all four hip muscle groups in the intact limb when compared to the residual and control limbs.

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: (11/01/2022)

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

☑ Recruit 8 participants 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

$330,164 (including F&A)