DEVELOPMENT AND BIOMECHANICAL ASSESSMENT OF ANKLE-FOOT PROSTHESES FOR ACTIVITIES OF DAILY LIVING

By

Rachel Teater

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Committee:

Karl Zelik, Ph.D.

Gerasimos Bastas, M.D., Ph.D.

Kevin Galloway, Ph.D.

Michael Goldfarb, Ph.D.

Alena Grabowski, Ph.D.

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CHAPTER 1

Introduction

1.1 Background

The incidence of amputation globally is estimated to be 1.2 to 4.4 individuals per 10,000 with estimates of over 40 million amputees in the developing world [1,2]. In America, it is estimated that more than 1.6 million individuals are living with limb loss and this number is expected to increase [3]. Within this group, it is estimated that 65-90% of these people have had a lower limb amputation [2,3]. Living with lower limb loss often causes mobility challenges that can negatively impact an individual's ability to engage in their community and complete activities of daily living. Additionally, this group is at an increased risk of developing secondary musculoskeletal conditions such as low back pain and osteoarthritis in their lower limb joints [4].

Many individuals with below-knee limb loss use a prosthetic ankle-foot device called an Energy Storage and Return (ESR) foot to replace their missing biology and enable mobility [5]. These passive devices are comprised of composite leaf springs often made of carbon fiber or fiberglass and are designed to store energy during the early stance phase of gait as they compress and then return this energy to the user during late stance to assist with the Push-Off phase of gait [5,6]. These devices have led to improvements in overall user performance during walking when compared to previous prosthetic designs such as the SACH (Solid Ankle Cushion Heel) foot [6]. However, functional ability and biomechanical deficits persist for many prosthesis users [6–8]. Many lower limb prosthesis users report difficulties with varying modes of locomotion, such as walking up and down slopes and over uneven terrain [7–10]. A significant percentage of users also struggle with activities of daily living outside of locomotion, such as standing up out of a chair, squatting, or picking up an item off the ground [7,10–12]. These persisting mobility challenges suggest that existing ESR feet do not adequately replace the function of the biological ankle and foot for all daily tasks. There exist key knowledge gaps related to how users compensate or use altered movement patterns to perform certain activities of daily living. Additionally, there are opportunities to investigate if prosthetic interventions can improve task performance.

Altering prosthetic ankle and toe joint dynamics is one way to potentially improve gait or other daily tasks for lower limb prosthesis users. Most commercial prosthetic ankle-foot devices, including ESR feet, have a relatively stiff ankle joint and forefoot [5,6]. During typical human walking, the biological metatarsophalangeal joints undergo extension/flexion, termed as toe joint articulation. Prior studies in the fields of footwear, sports biomechanics, and humanoid robotics provide evidence that toe joint articulation can impact locomotor economy and other performance metrics [13–16]. Incorporating a toe joint into a passive prosthetic foot could impact overall gait mechanics by altering prosthetic-ankle foot dynamics without the added complexity, weight, and cost that come with microprocessor and powered prosthetic devices. A flexible toe joint could potentially benefit users across multiple modes of locomotion by adding an additional degree of freedom to the prosthetic foot to accommodate varying slopes and terrain. However, the impact of adding an articulating toe joint to an ankle-foot prosthesis has not previously been systematically evaluated.

While there exists a large body of work investigating prosthesis user biomechanics during locomotion, less work has investigated user performance during other activities of daily living. Activities such as standing up from a chair, picking up an item off the floor, reaching for an object, and kneeling are everyday movements that are essential for independent living, but are challenging for many lower limb prosthesis users [7,10–12]. There is limited investigation into how transtibial prosthesis users perform these tasks with their current devices and even less investigation into interventions to improve their ability to do these tasks. Some existing work has characterized user biomechanics during sit-to-stand and found individuals with unilateral limb loss typically perform this task asymmetrically by loading their intact limb more than their prosthetic limb [17–19]. This asymmetric movement strategy is concerning as it can result in increased loads in the joints of the intact limb and the low back which may contribute to the development of chronic pain and secondary conditions, such as knee osteoarthritis [4,18,20]. Outside of sit-to-stand, there are few investigations into other functional movements, such as squatting, lifting, and lunging. These movements are also common in daily life and often required for recreation, exercise, and in some occupations. Yet, no existing work has characterized the strategies and biomechanics of lower limb prosthesis users during these tasks. Characterizing how prosthesis users perform these essential daily activities can provide insight into why users have challenges with these movements and elucidate directions for rehabilitation and device interventions.

Novel prosthetic ankle-foot devices may be able to improve the functional ability and limb loading of users performing these tasks, but these largely have not been investigated. Prosthetic knee interventions for transfemoral prosthesis users performing sit-to-stand have shown the potential to increase limb loading symmetry and user performance [21–23]. However, investigations into interventions for transtibial prosthesis users doing sit-to-stand are limited and have not looked at adapting prosthetic ankle-foot behavior [24–26]. Prosthetic ankle interventions that are designed for sit-to-stand could potentially improve the functional ability of users who struggle to complete this task while also enabling higher activity users to complete this task with less effort or in a more symmetrical way, which could reduce intact limb loading. A prosthetic ankle intervention may also be useful for other daily tasks that have a similar motion, such as squatting and lifting.

1.2 Dissertation Contributions

In this dissertation, I address several of the knowledge gaps previously mentioned by altering prosthetic ankle and foot properties and evaluating the biomechanics of lower limb prosthesis users across several daily tasks. I first evaluate the effect of adding an articulating toe joint to a passive foot prosthesis during both level ground and sloped walking (Chapters 2 and 3). Second, I characterize how transtibial prosthesis users complete various activities of daily living, including sit-to-stand, squatting, lifting, and lunging (Chapters 4 and 5). By evaluating user strategies during these tasks, I identify deficits in functional ability, characterize limb loading that is concerning due to osteoarthritis injury potential, and provide insights for future directions for rehabilitation and device interventions. Lastly, I evaluate how altering prosthetic ankle stiffness (and range of motion) impacts the limb loading and preference of transtibial prosthesis users during sit-to-stand (Chapter 6).

1.2.1 Chapter 2 Contributions

The primary contribution of this work is that this is the first study to systematically evaluate the impact of adding a flexible toe joint to a passive prosthesis during <u>level ground</u> walking for individuals with unilateral below-knee limb loss. The biological toe joint is known to play an important role in able-bodied gait, but most commercial prosthetic feet have relatively rigid keels and the effect of adding a toe joint to a prosthetic foot is not well understood. Here I found that adding a flexible toe joint to a passive prosthesis reduced Push-Off work, but had minimal impact on rate of oxygen consumption and the biomechanics at other joints. This work was published as an article titled "Adding a toe joint to a prosthesis: walking biomechanics, energetics, and preference of individuals with unilateral below-knee limb loss" in Scientific Reports in 2021.

1.2.2 Chapter 3 Contributions

The primary contribution of this work is that this is the first study to systematically evaluate the impact of adding a flexible toe joint to a passive prosthesis during <u>incline and decline walking</u> for individuals with unilateral below-knee limb loss. Walking on sloped surfaces is challenging for many lower limb prosthesis users, likely due to the limited ankle range of motion provided by typical prosthetic ankle-foot devices. Adding a toe joint could benefit users by providing an additional degree of flexibility to adapt to sloped surfaces during walking, but this has not been studied. This work found the flexible toe joint reduced prosthesis Push-Off work during incline and decline walking. Preference for the toe joint was mixed among participants and varied between incline and decline walking. In this chapter, I also summarize findings from a larger body of work that includes assessing the impact of a prosthetic toe joint during uneven terrain walking and stair ascent/descent. Collectively, this research found the addition of a toe joint did not substantially or consistently alter lower limb mechanics for active unilateral below-knee prosthesis users. It also highlights that user preference for passive prosthetic technology is often subject-specific and task-specific. This work was published as an article titled "Biomechanical effects of adding an articulating toe joint to a passive foot prosthesis for incline and decline walking" in PLoS ONE in 2024.

1.2.3 Chapter 4 Contributions

The primary contribution of this work is the characterization of the lower limb loading of unilateral transtibial prosthesis users during sit-to-stand, squatting and lifting. This is the first study to investigate the limb loading of a group of lower limb prosthesis users during squatting and lifting, and it confirms prior experiments that measured increased loading of the intact limb during sit-to-stand. Transtibial prosthesis users are at increased risk of musculoskeletal injury, joint degeneration, and pain in their intact limb compared to the general population. Previous work has proposed this may stem from the altered movement strategies that prosthesis users employ to accomplish daily tasks, which result in overloading their intact limb. While the limb loading biomechanics of prosthesis users have been extensively studied during walking, fewer investigations into limb loading during other functional movements exist. In this study, I established that unilateral transtibial prosthesis users load their intact limb more than their prosthetic limb during sit-to-stand, squatting, and lifting. All eight study participants were found to overload their intact limb for all three tasks. This work was published as an article titled "Unilateral transtibial prosthesis users load their intact limb more than their prosthetic limb during sit-to-stand, squatting, and lifting" in Clinical Biomechanics in 2023.

1.2.4 Chapter 5 Contributions

The primary contribution of this work is a characterization of the performance and movement patterns of unilateral transtibial prosthesis users during lunging. This is one of the first investigations into the movement preferences and biomechanics of prosthesis users performing a task that places separate demands on each limb. Lunging and related everyday movements are challenging for many lower limb prosthesis users. Tasks such as kneeling down on the ground, getting up off the floor, and stepping over objects are difficult even for individuals with a high level of functional ability. However, little work has investigated how prosthesis users approach and perform daily tasks that put independent demands on each leg. This work addresses that gap by characterizing the movement patterns of transtibial prosthesis users during lunging and evaluating differences between lunging with their intact limb versus their prosthetic limb leading. Lunging with the intact limb leading was preferred by most participants and all reported feeling more stable lunging this way. Participants put a greater percentage of force in their front limb when it was their intact limb. Additionally, differences in leading limb kinematics were observed between lunges with the intact versus the prosthetic limb leading. This research was submitted as an article titled "Transtibial prosthesis users lunging: a characterization of movement strategies and impact of leading limb" to the Journal of Biomechanics and is currently in review.

1.2.5 Chapter 6 Contributions

The primary contribution of this chapter is the evaluation of how altering prosthetic ankle stiffness (and range of motion) impacts transtibial prosthesis users performing sit-to-stand. This case series is one of the first studies to specifically investigate a prosthetic ankle intervention to improve the sit-to-stand task performance of transtibial prosthesis users. The limited ankle range of motion provided by a typical prosthesis during the sit-to-stand motion may contribute to the challenges and asymmetrical limb loading transtibial prosthesis users experience during this essential daily task. Increasing prosthetic ankle range of motion may help users orient and load their limbs more symmetrically, which could potentially increase ability, reduce effort, or reduce intact limb joint loads, but this has not been investigated. To examine how increasing prosthetic dorsiflexion capabilities impact sit-to-stand, this study used the Vanderbilt Powered Ankle to alter prosthetic ankle stiffness. Reducing prosthetic ankle stiffness increased prosthetic ankle range of motion during sit-to-stand for all participants, but limb loading and preference results were participant-specific. This work provides insight on how ankle stiffness and range of motion affect sit-to-stand, and it highlights the individual nature of prosthesis user responses to technology. The results from this work will be submitted to a peer-reviewed journal.

1.3 Summary of Contribution Deliverables

1.3.1 Journal Papers

K. A. McDonald, R. H. Teater, J. P. Cruz, J. T. Kerr, G. Bastas, and K. E. Zelik, "Adding a toe joint to a prosthesis: walking biomechanics, energetics, and preference of individuals with unilateral below-knee limb loss," *Scientific Reports*, vol. 11, Jan. 2021, doi: 10.1038/s41598-021-81565-1.

R. H. Teater, K. E. Zelik, and K. A. McDonald, "Biomechanical effects of adding an articulating toe joint to a passive foot prosthesis for incline and decline walking," *PLoS ONE*, vol. 19, May 2024, doi: 10.1371/journal.pone.0295465.

R. H. Teater, D. N. Wolf, K. A. McDonald, and K. E. Zelik, "Unilateral transtibial prosthesis users load their intact limb more than their prosthetic limb during sit-to-stand, squatting, and lifting," *Clinical Biomechanics*, vol. 108, Aug. 2023, doi: 10.1016/j.clinbiomech.2023.106041.

R. H. Teater, D. N. Wolf, and K. E. Zelik, "Transtibial prosthesis users lunging: a characterization of movement strategies and impact of leading limb," *Journal of Biomechanics*, In Review.

R. H. Teater, D. N. Wolf, K. M. Rodzak, E. G. Walther, S. Huang, and K. E. Zelik, "The impact of prosthetic ankle stiffness on the sit-to-stand performance of transtibial prosthesis users: A case series," Planned Submission.

1.3.2 Conference Presentations

R. H. Teater, K. A. McDonald, O. S. Cook, G. Bastas, and K. E. Zelik, “Addition of a passive toe joint: considerations for passive and powered ankle-foot prosthesis design,” International Society of Biomechanics, Calgary, Canada, Aug. 2019, Oral Presentation.

K. A. McDonald, R. H. Teater, O. S. Cook, G. Bastas, and K. E. Zelik, “The biomechanical and met-toe-bolic effects of walking on a passive prosthetic foot with an added toe joint,” International Society of Biomechanics, Calgary, Canada, Aug. 2019, Poster Presentation.

R. H. Teater, C. Klapka, K. A. McDonald, G. Bastas, and K. E. Zelik, “asymmetry, instability, & functional deficits in transtibial prosthesis users during squatting, lifting, & sit-to stand,” American Society of Biomechanics (Virtual) Conference, Aug. 2020, Poster Presentation.

R. H. Teater, K. A. McDonald, and K. E. Zelik, “Exploring effects of prosthetic ankle and toe joint range of motion on activities of daily living,” International Society of Biomechanics (Virtual) Conference, July 2021, Poster Presentation.

R. H. Teater, D. N. Wolf, B. A. Ausec, K. A. McDonald, and K. E. Zelik, “Transtibial prosthesis user biomechanics during functional tasks: characterizing strategies and evaluating effects of increased prosthetic ankle and toe range of motion”, 9th World Congress of Biomechanics (Virtual), July 2022, Oral Presentation.

R. H. Teater, D. N. Wolf, K. A. McDonald, and K. E. Zelik, “Characterizing strategies and exploring interventions for transtibial prosthesis users during activities of daily living,” RehabWeek, Rotterdam, The Netherlands, July 2022, Poster Presentation.

R. H. Teater, D. N. Wolf, K. A. McDonald, and K. E. Zelik, “Transtibial prosthesis users overload their intact limb even for tasks perceived as easy”, American Academy of Orthotists & Prosthetists Annual Meeting, Nashville, TN, Mar. 2023, Poster Presentation.

R. H. Teater, D. N. Wolf, and K. E. Zelik, “Transtibial prosthesis users lunging: evaluating functional ability and lower limb loading,” American Society of Biomechanics, Knoxville, TN, Aug. 2023, Poster Presentation.

1.3.3 Additional Academic Contributions not Discussed in Dissertation

K. A. McDonald, R. H. Teater, J. P. Cruz, and K. E. Zelik, “Unilateral below-knee prosthesis users walking on uneven terrain: the effect of adding a toe joint to a passive prosthesis,” *Journal of Biomechanics*, vol. 138, Jun. 2022, doi: 10.1016/j.jbiomech.2022.111115.

S. Huang, R. H. Teater, K. E. Zelik, and K. A. McDonald, “Biomechanical effects of an articulating toe joint during stair navigation for individuals with unilateral, below-knee limb loss,” *Journal of Biomechanics*, vol. 161, Dec. 2023, doi: 10.1016/j.jbiomech.2023.111841

C. A. Nurse, D. N. Wolf, K. M. Rodzak, R. H. Teater, S. J. Fine, Chad. C. Ice, E. C. Holtzman, M. Lee, and K. E. Zelik, “User-centric iterative design of an ankle exosuit to reduce Achilles tendon load during running,” American Society of Biomechanics, Knoxville, TN, Aug. 2023, Poster Presentation.

CHAPTER 2

Adding a Toe Joint to a Prosthesis: Walking Biomechanics, Energetics, and Preference of Individuals with Unilateral Below Knee Limb Loss

2.1 Summary

Toe joints play an important functional role in able-bodied walking; however, for prosthesis users, the effect of adding a toe joint to a passive prosthetic foot remains largely unknown. The current study explores the kinematics, kinetics, rate of oxygen consumption, and user preference of nine individuals with below-knee limb loss. Participants walked on a passive prosthetic foot in two configurations: with a Flexible, articulating toe joint and with a Locked-out toe joint. During level treadmill gait, participants exhibited a decrease in Push-Off work when using the Flexible toe joint prosthesis versus the Locked toe joint prosthesis: 16% less from the prosthesis ($p = 0.004$) and 10% less at the center of mass level ($p = 0.039$). However, between configurations, participants exhibited little change in other gait kinematics or kinetics, and no apparent or consistent difference in the rate of oxygen consumption ($p = 0.097$). None of the traditional biomechanical or metabolic outcomes seemed to explain user preference. However, an unexpected and intriguing observation was that all participants who wore the prosthesis on their dominant limb preferred the Flexible toe joint, and every other participant preferred the Locked configuration. Although perhaps coincidental, such findings may suggest a potential link between user preference and limb dominance, offering an interesting avenue for future research.

2.2 Background

In humans, the metatarsophalangeal (toe) joints extend and flex during walking. This toe joint articulation affects musculoskeletal dynamics within the foot and ankle [27–29], as well as whole-body gait biomechanics [30]. Both theoretical and experimental findings indicate that altering or augmenting toe joint articulation dynamics can impact key variables related to gait economy [31,32] and stability [33,34].

Recent work from our laboratory found that changing toe joint stiffness has a sizeable effect on center of mass Push-Off power during walking, to an extent comparable with changing ankle joint stiffness [30]. Here, the authors utilized adapted walking boots to immobilize the biological ankle joints of participants whilst enabling the attachment of prosthetic feet to each boot base. In the case of prosthetic devices, a toe joint refers to the articulating region that connects the prosthetic keel and the section equivalent to the biological forefoot (e.g., Fig. 2.1). Interestingly, in this study nine of the ten participants reported that they preferred walking on a foot prosthesis with an articulating toe joint versus one without a toe joint. Furthermore, a small sample of prostheses with toe joints have recently entered the commercial market (e.g., Ottobock Meridium, ST&G ToeFlex). Whether this feature is preferable and/or beneficial relative to a fully rigid/stiff keel, and how this may vary according to locomotor task, remains unclear. Together, these prior research findings and contemporary commercial devices motivated us to explore the effects and implications of toe joint dynamics on lower limb prosthesis users, most of whom walk on commercially-available prosthetic feet that do not include an articulating toe joint.

Prosthesis design and prescription related to toe joint articulation could benefit from multi-subject studies, assessing the effect of toe joint dynamics on the biomechanics and energetics of lower limb prosthesis users during walking. Previously, Zhu and colleagues [35] assessed the effect of adding a toe joint to the foot keel of a powered prosthesis during walking, but only with a single prosthesis user. The authors observed improved ground reaction force symmetry, which they attributed to restoring toe joint articulation. Yet it remains unclear whether prosthesis users subjectively prefer to have a toe joint or not during ambulation. It is also noteworthy to add that cosmetic foot shells typically include aesthetic toes (made of rubber or foam) which, in combination with shoes, often extend out beyond the prosthetic foot keel. However, it also remains unknown whether these aesthetic toes behave functionally as a toe joint, or if the stiffness properties of the cosmesis provide auxiliary benefits during walking and other locomotor tasks.

To address these knowledge gaps, the objective of this study was to compare the biomechanics, energetics, and user preference of individuals with unilateral below-knee limb loss walking on a prosthetic foot with and without a toe joint. Based on the findings of Honert and colleagues [30], it was hypothesized that the addition of a toe joint would reduce center of mass Push-Off work.

2.3 Methods

2.3.1 Participants

Healthy, active persons with unilateral below-knee limb loss (N = 9; Medicare Functional Classification Level: K3/K4; age: 41 ± 11 years; body mass: 94 ± 13 kg; height: 1.84 ± 0.05 m; mean ± standard deviation) provided their informed written consent before participating in this study, which was approved by the Institutional Review Board at Vanderbilt University. Sample size calculations were originally computed based on peak center of mass Push-Off power (and work). Early pilot data had suggested differences on the order of 30–45 W, and previous studies on hemiparetic [36,37] and elderly gait [38] had interpreted similar Push-Off differences to be clinically meaningful. Using this mean difference range and standard deviation of 30 W, and assuming alpha = 0.05 and power = 0.8, paired t-test sample size calculations indicated a need for 7–16 participants. Our study on nine participants was on the lower end of this range and does not guarantee that the study was sufficiently powered for all other (non-Push-Off) outcomes.

Participants capable of normal community ambulation were required for this study, given the physical demands of this four-day, multi-task protocol. Three foot prostheses were modified and available to accommodate body masses from 75 to 120 kg and shoe sizes from US men’s 7–12. Individuals were excluded from this study if they did not fit these size requirements. Individual participant demographics are presented in Table 2.1.

Table 2.1 Participant demographics.

Participant ID	Age (years)	Body Mass (kg)	Height (m)	Leg Length (m)	Years Since Limb Loss	K-Level	Cause of Limb Loss	Daily-Use Prosthesis
1	33	119.1	1.92	1.00	3.8	4	Traumatic	Fillauer Formula
2	49	94.4	1.86	0.95	7.5	4	Traumatic	Fillauer AllPro
3	33	97.8	1.88	0.98	9.3	4	Traumatic	Össur Pro-Flex XC
4	55	100.5	1.83	0.94	4.7	3	Vascular	Fillauer AllPro
5	28	81.5	1.90	0.99	8.8	4	Traumatic	Fillauer AllPro
6	41	99.7	1.80	0.93	41.0	4	Congenital	Ottobock Triton
7	47	83.9	1.76	0.97	7.4	4	Traumatic	Fillauer AllPro
8	52	73.4	1.85	0.98	2.5	4	Traumatic	Fillauer Formula
9	28	97.4	1.78	0.94	5.3	4	Traumatic	Fillauer AllPro
Mean ± SD	40.7 ± 10.5	94.1 ± 13.3	1.84 ± 0.05	0.96 ± 0.02	10.0 ± 11.8			

2.3.2 Experimental Prosthesis

We modified three categories of a single commercial prosthesis (Balance Foot J, Össur, Sizes 25, 27, and 28) such that each could function in two configurations: (i) with a Flexible toe joint, which was accomplished by using sheets of spring steel affixed between the foot keel and toe segment, and (ii) with a Locked toe joint which used an aluminum block to prevent flexion and extension, thus effectively creating a solid foot keel without a toe joint (Fig. 2.1). The Flexible toe joint was designed to have a stiffness of 0.34 Nm degree^{-1}, an intermediate stiffness selected based on results of Honert and colleagues [30]. The prosthesis was housed in a modified cosmetic foot shell only (i.e., no shoe was used) to allow foot and toe joint markers to be visible and to avoid confounds due to the bending stiffness of the shoe itself. When communicating with participants during training and testing, we simply referred to these as Foot One and Foot Two, to minimize the risk of biasing participant preferences.

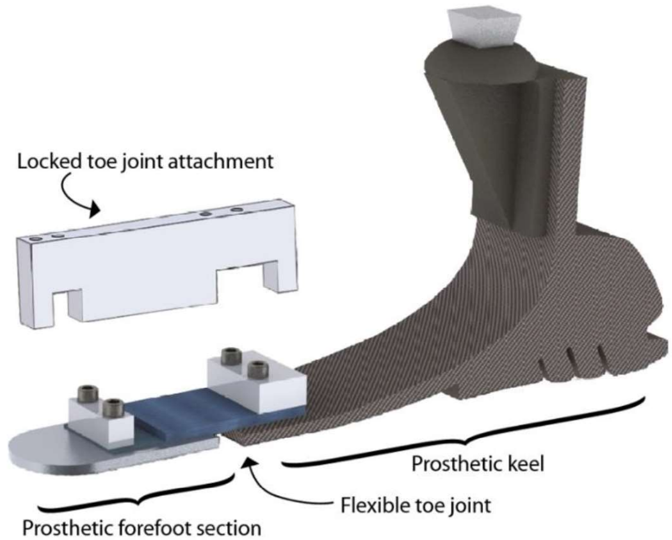


Figure 2.1 A custom-modified Össur Balance Foot J passive prosthesis shown in a Flexible toe joint configuration. The aluminum block attachment (above) can be secured over the joint to create a Locked-out toe joint configuration.

2.3.3 Protocol

The study protocol described below was developed in conjunction with institutional guidelines. It involved four sessions: two training and two testing. Training sessions were separated by at least 24 h and, at most, 11 days. No more than 7 days elapsed from the final training to the first testing session. Testing sessions were separated by 24 h when possible; however, two participants required both testing sessions to be conducted on the same day due to availability constraints. The acclimation protocol described below was chosen based on pilot testing and our experience with prior prosthetics studies [30,39,40].

2.3.4 Training Sessions

At the beginning of the first session, participants wore their prescribed prosthesis and were provided time to familiarize themselves with several locomotor tasks and laboratory equipment. The analysis and results detailed in this manuscript are only on level walking, however this was part of a larger protocol which also included stair ascent/descent, ramp ascent/descent, and walking over uneven terrain.

Next, the experimental prosthesis was fit and aligned by a certified prosthetist. Participants were assigned a fitting and training order for the two conditions, either Locked-then-Flexible or Flexible-then-Locked. These assignments were made on an alternating basis (meaning if one participant was assigned Locked-then-Flexible, the next participant would be assigned Flexible-then-Locked) to avoid introducing a potential bias by fitting all participants in the same configuration. The alignment and fitting process was performed once by the prosthetist, held constant for all training and testing sessions, and kept the same for both foot configurations. After the fitting was complete, each participant was asked “On a scale from 1 to 10, with 10 being maximally satisfied, how satisfied are you with your alignment?” All participants rated their satisfaction with their experimental prosthesis alignment to be between 8 and 10 (mean: 9.4/10). At the end of the first training session, participants walked on the level treadmill in the Locked and Flexible toe joint configurations (for 5–10 min each) to begin acclimating to these feet.

During the second training session, the participants trained on stairs, on level and uneven terrain overground, and on a sloped treadmill. Each task was performed with both the Locked and Flexible configurations, using the assigned order from the first training day. In total, participants spent approximately 20 min walking on and acclimating to each foot configuration. Afterwards, participants were asked if they were satisfied with their training volume on the experimental prostheses. All participants reported scores of 9 or 10 on a 1–10 scale with 10 being fully satisfied.

At the conclusion of the second training session, participants were asked to rank their preferences for Foot One versus Foot Two. The investigator verbally asked the participant: “For level walking, did you prefer Foot One or Foot Two?”, where One and Two refer to the order each participant was assigned to complete the Locked versus Flexible toe joint configurations.

2.3.5 Testing Sessions

All participants were required to fast for the three hours preceding the metabolic data collection that occurred in the third session. They were also asked to refrain from consuming caffeine and from performing strenuous physical activity/exercising on the day of testing. When participants arrived at the laboratory, retro-reflective markers were affixed to their pelvis (4–6), thighs (8), knees (4), and shanks (8). On their intact limb, markers were also applied to the calcaneus (3) and metatarsal heads (2), and on their prosthetic limb, markers were applied to the cosmesis (3) and either side (3) of the prosthetic toe joint (6 total). During all data collection, three-dimensional motion capture (200 Hz; 10-camera system, Vicon, Oxford, UK) and synchronized ground reaction forces (1000 Hz; split-belt instrumented treadmill, Bertec, Columbus, USA) were collected. Level walking trials were a minimum of 5 minutes long, however, only 60 seconds of kinematic and kinetic data (cropped at random) advanced to the data processing stage. The inspired volume of oxygen (VO2) was continuously sampled (breath by breath) for the entire five-minute trial, using a portable metabolic system (COSMED K4b2, Rome, Italy). To aid in interpreting metabolic results, we elected to complete level walking trials using a withdrawal study design (i.e., A-B-A design in a Flexible-Locked-Flexible order). In line with previous studies on similar populations [41,42], participants walked on the treadmill at a constant speed of 1.14 ms^{-1}.

We note that stair ascent and descent data were also collected in this session (after level walking), and uneven terrain and sloped walking were collected in a separate testing session. Specific methods related to these additional tasks are not detailed because only level walking data are presented and discussed in this manuscript.

2.3.6 Data Processing and Analysis

Marker trajectories and ground reaction force data were low-pass filtered at 8 Hz and 15 Hz, respectively, with a fourth order Butterworth filter. Spatiotemporal variables (stride length and time; stance and swing time of each limb) were computed using the ground reaction force and foot/prosthesis marker data. Stride length was then non-dimensionalized by leg length (L) and all time variables were non-dimensionalized by $\sqrt{L/g}$, where g is acceleration due to gravity [43,44]. Sagittal plane joint angles and net moments, net joint powers (six degree-of-freedom) and work, and center of mass dynamics (individual limbs method [45]) were computed in Visual3D (C-motion, Germantown, USA) and further processed using custom-built MATLAB (MathWorks, Natick, USA) functions. Moments and work were non-dimensionalized by MgL where M is body mass. Power was non-dimensionalized by $Mg\sqrt{gL}$ [43,44]. Prosthesis power and work were also calculated in accordance with Takahashi and Stanhope [16] and Zelik and Honert [46]. Center of mass work and prosthesis work were cropped to the Push-Off phase of gait using the positive range of center of mass power near terminal stance. Gross rate of oxygen consumption was estimated by averaging the last minute of raw VO2/min data per toe joint configuration and normalizing by body mass. Where relevant, group results are presented below as mean ± standard deviation. Average non-dimensionalization constants were 0.96 m (length), 0.31 s (time), 889.3 Nm/J (moment/work), and 2839.1 W (power). Some outcomes were re-dimensionalized for reporting purposes using these constants.

Maximum prosthetic toe joint angle was used to confirm the modified device was functioning as intended (i.e., reaching a significantly greater peak flexion angle in the Flexible versus Locked configuration). Spatiotemporal parameters were assessed to determine if any notable adjustments to these basic gait outcomes were present. Consistent with previous literature assessing assistive technology device design, we also compared prosthesis and center of mass Push-Off work, and gross rate of oxygen consumption between the two configurations [30,39,47,48]. Passive prostheses have been noted to contribute substantially less positive power during the Push-Off phase of gait, relative to the intact ankle joint [49]. This loss of power has also been observed at the center of mass level [50]. Restoring positive power during Push-Off may lead to improved metabolic cost [51], ultimately reducing the muscular exertion required to walk using a passive prosthesis.

2.3.7 Statistical Analyses

All data were determined, via one sample Kolmogorov–Smirnov tests, to be non-normally distributed. Therefore, non-parametric repeated measures tests were used to assess differences between the Locked versus Flexible toe joints. Wilcoxon tests were used to investigate differences in all biomechanical variables. For gross rate of oxygen consumption, however, a Friedman test was used to compare the Flexible-Locked-Flexible (A-B-A) trials. Following this, Holm-Bonferroni corrections were applied to account for familywise error rates across the groups of principal kinematic/kinetic and spatiotemporal variables. For maximum toe joint angle, distal segment work, and center of mass work the adjusted alpha levels were 0.025, 0.017, and 0.050, respectively. For intact limb stance time, prosthetic limb stance time, intact limb swing time, prosthetic limb swing time, stride time, and stride length, the adjusted alpha levels were 0.017, 0.025, 0.050, 0.008, 0.010, and 0.013, respectively. For gross rate of oxygen consumption, an alpha level of 0.05 was applied. Statistical tests were conducted in MATLAB (MathWorks, Natick, USA).

2.4 Results

2.4.1 Spatiotemporal

Mean stride lengths were similar for Locked versus Flexible configurations (1.21 versus 1.20 m, respectively; $p = 0.054$; Table 2.2). Mean temporal variables (stride, stance, and swing times) were all within 0.02 s of each other for Locked versus Flexible configurations. These differences did not reach the adjusted threshold for significance when the Holm-Bonferroni method was applied, with the exception of prosthetic limb swing time ($p = 0.008$).

Table 2.2 Re-dimensionalized spaciotemporal variables

	Stride Length (m)	Stride Time (s)	Prosthesis Limb		Biological Limb	
			Stance Time (s)	Swing Time (s)	Stance Time (s)	Swing Time (s)
Flexible (Mean ± SD)	1.21 ± 0.08	1.07 ± 0.07*	0.67 ± 0.05	0.38 ± 0.04*	0.71 ± 0.05	0.34 ± 0.03
Locked (Mean ± SD)	1.20 ± 0.08	1.06 ± 0.07*	0.67 ± 0.05	0.40 ± 0.04*	0.72 ± 0.05	0.35 ± 0.03

*Significant difference between conditions ($p < 0.05$). Note, statistical analyses were performed on dimensionless values.

2.4.2 Joint Kinematics

Intact (non-prosthetic) limb ankle, knee, and hip angles, and prosthetic limb toe, knee, and hip angles are presented in Figs. 2.2 and 2.3, respectively. The average kinematic profiles at each joint were similar between configurations, with the exception of prosthesis toe joint angle. We observed a significant increase in maximum angle from 1.1 ± 1.6° in the Locked configuration, to 20.8 ± 3.0° in the Flexible configuration ($p = 0.008$), thus confirming our experimental design was effective in varying toe joint articulation.

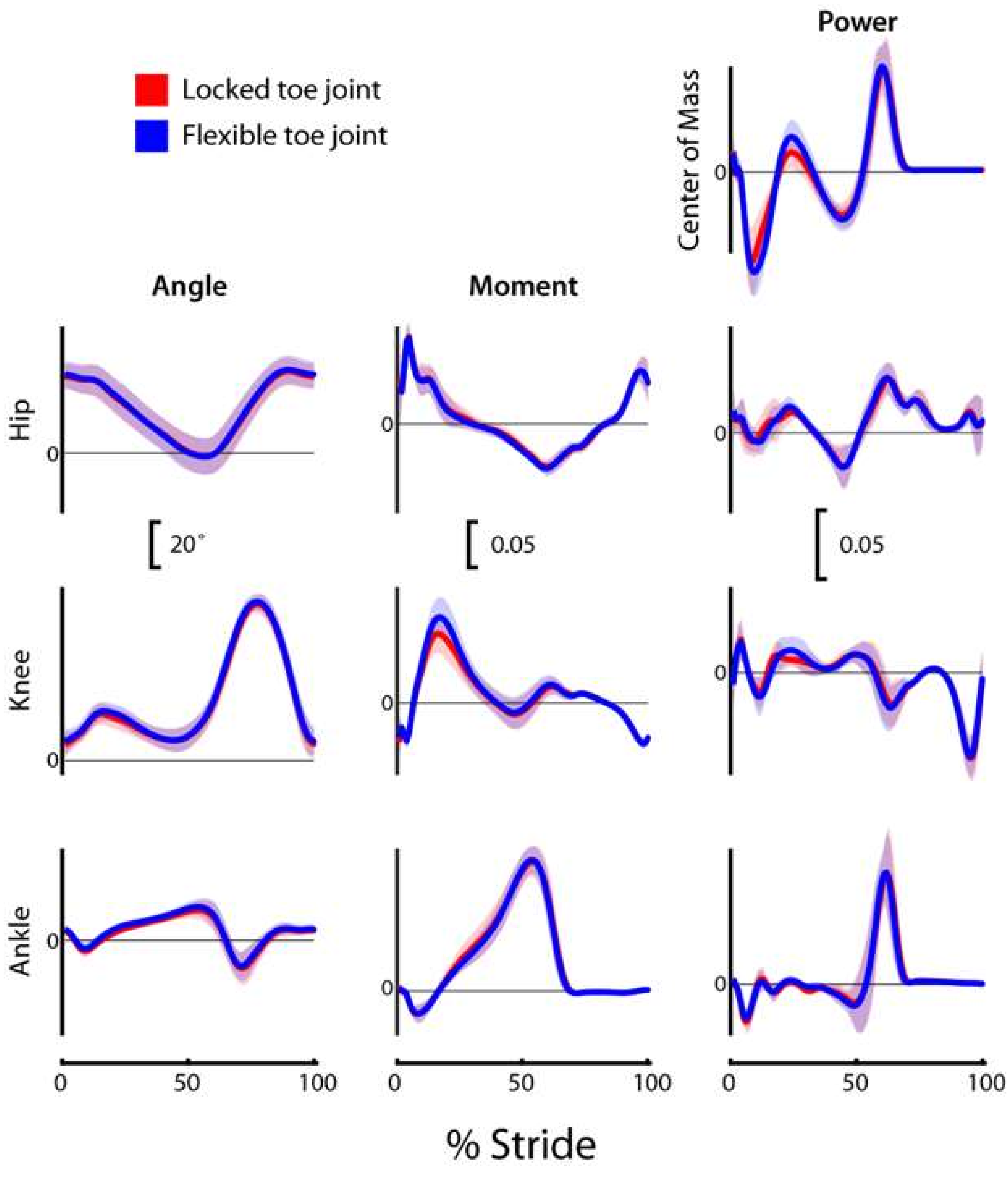


Figure 2.2 Intact (non-prosthetic) limb joint and center of mass dynamics for participants ($N = 9$) walking in a passive prosthesis with (i) a Flexible (dark blue line) and (ii) a Locked (light red line) toe joint configuration. Kinematic (angles) and kinetic (moments, powers) data were cropped into strides using ipsilateral heel strikes of the intact limb. Data presented as mean ± standard deviation (shaded regions). Using group mean re-dimensionalization constants, 0.05 corresponds to 0.47 Nm kg^{-1} for moments, and 1.50 W kg^{-1} for powers

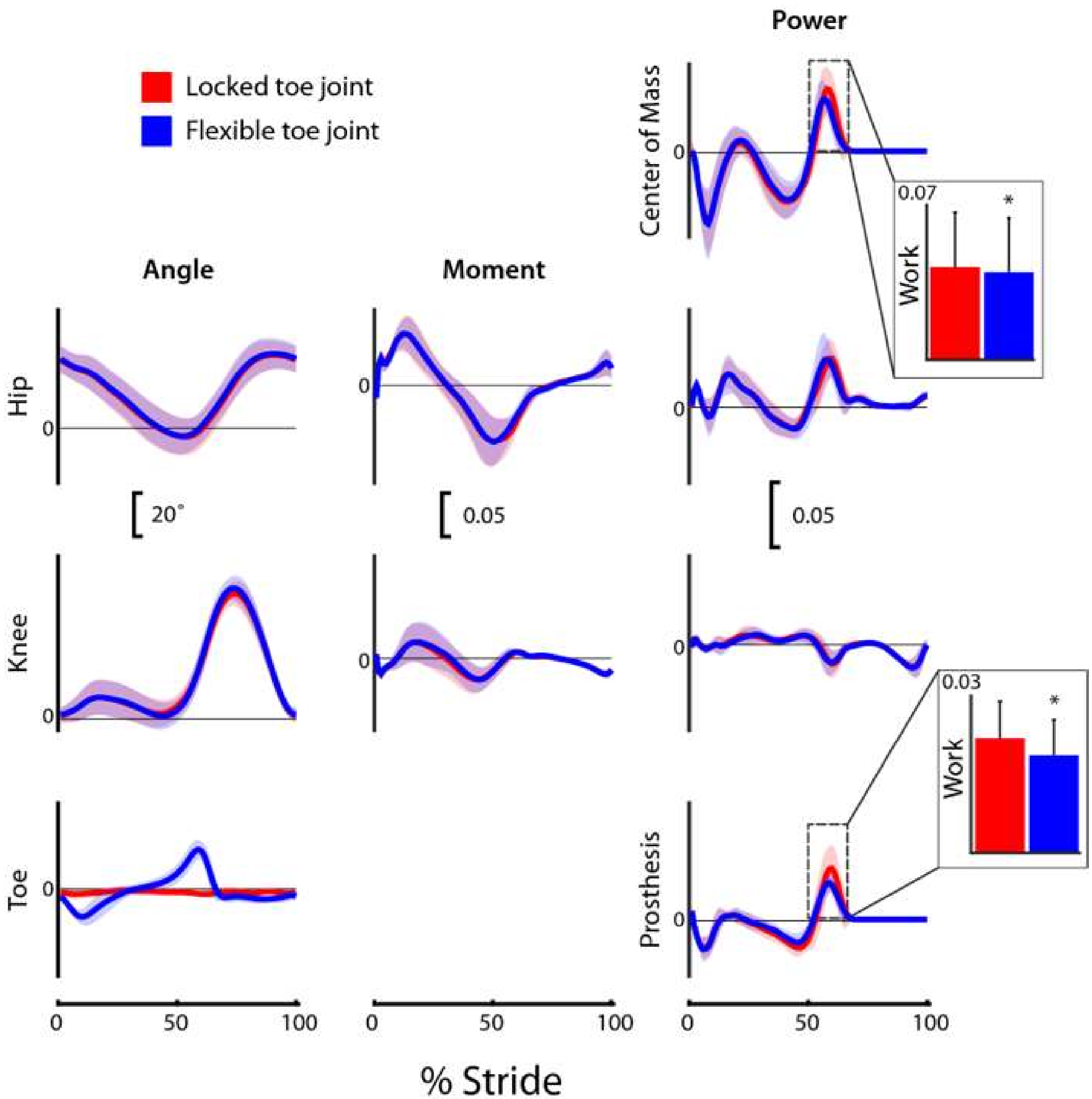


Figure 2.3 Prosthetic limb joint, center of mass, and prosthesis dynamics for participants ($N = 9$) walking in a passive prosthesis with (i) a Flexible (dark blue line) and (ii) a Locked (light red line) toe joint configuration. Kinematic (angles) and kinetic (moments, powers) data were cropped into strides using ipsilateral heel strikes of the prosthetic limb. Positive prosthesis work and center of mass work were computed during Push-Off phase only (defined by center of mass power traces). Data are presented as mean ± standard deviation (shaded regions). Using group mean re-dimensionalization constants, 0.05 corresponds to 0.47 Nm kg^{-1}/J kg^{-1} for moments and work, and 1.50 W kg^{-1} for powers.

2.4.3 Joint Kinetics

Most kinetic profiles were unaltered by the transition between Locked and Flexible toe joint configuration (Figs. 2.2 and 2.3). In fact, for all but the intact limb knee moment, prosthesis power, and center of mass powers, the group mean plots were visually indistinguishable. Positive prosthesis work during Push-Off was reduced in the Flexible configuration (0.018 ± 0.007 dimensionless, or 16.0 J) compared to the Locked configuration (0.021 ± 0.007 dimensionless, or 18.7 J; $p = 0.004$; Fig. 2.3). On average this decrease in prosthesis Push-Off work was 16% but ranged from 3 to 31% across our participant sample. The reduction in Push-Off also appeared in whole-body center of mass power (0.037 ± 0.023 dimensionless in the Flexible configuration versus 0.040 ± 0.023 dimensionless in the Locked configuration; $p = 0.039$; Fig. 2.3).

2.4.4 Gross Rate of Oxygen Consumption

No significant differences in gross rate of oxygen consumption were found between the Flexible-Locked-Flexible trials ($p = 0.097$; Fig. 2.4A). The initial Flexible test incurred 14.8 ± 2.6 ml O2 kg^{-1} min^{-1}, the Locked configuration incurred 14.2 ± 2.4 ml O2 kg^{-1} min^{-1} and the final Flexible test incurred 14.3 ± 1.9 ml O2 kg^{-1} min^{-1}. Subject-specific metabolic results are shown in Figure 2.4B.

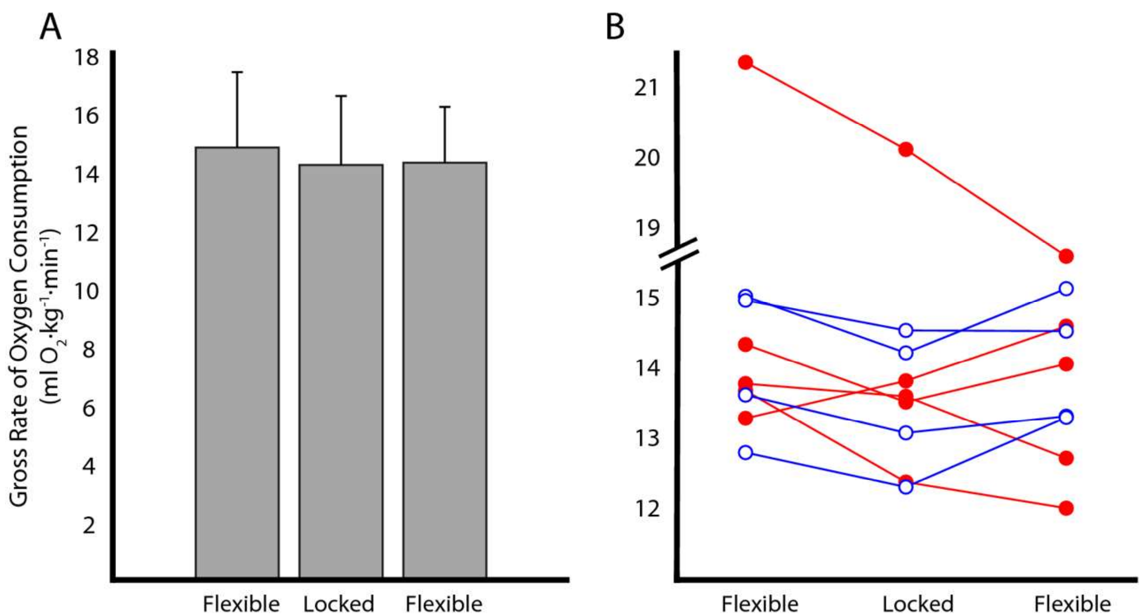


Figure 2.4 Effect of toe joint on gross rate of oxygen consumption. Results shown are from the A-B-A (Flexible-Locked-Flexible) study design. (A) Group means ($N = 9$) with error bars representing standard deviations. (B) Individual participant data points are indicated by variations in marker shape and color. Filled markers (red) indicate the user preferred the Flexible toe joint configuration and empty markers (blue) indicate the user preferred the Locked toe joint configuration.

2.4.5 User Preference

Five users preferred the Locked configuration, while the remaining four preferred the Flexible configuration during level walking (Table 2.3).

Table 2.3 Participant preference, side of limb loss, and self-identified limb dominance before amputation (if applicable).

Participant ID	User Preference	Side of Limb Loss	Was the Amputated Limb Dominant or Non-Dominant?
1	Flexible	R	Dominant
3		R	Dominant
4		R	Dominant
5		R	Dominant
2	Locked	L	Non-Dominant
7		L	Non-Dominant
8		L	Non-Dominant
9		L	N/A (Ambipedal)
6		L	N/A (Congenital)

We also reviewed subject-specific kinematics, kinetics, and metabolic results. We did not observe any signals, features, or differences that seemed to explain or elucidate individual preferences with respect to Locked versus Flexible configurations. For brevity, subject-specific results are not presented here, but data/results are publicly archived.

2.5 Discussion

Lower limb prosthesis users walking with the Flexible toe joint exhibited a decrease in Push-Off work: approximately 16% less from the prosthesis and 10% less at the center of mass level. Participants displayed little change in other joint kinematics or kinetics, and no apparent difference in rate of oxygen consumption versus the Locked toe joint configuration. Preferences were divided; four of the nine participants preferred walking with the Flexible toe joint, while the remaining five preferred the Locked toe joint. None of the traditional biomechanical or metabolic outcomes seemed to explain this observation. Interestingly, every participant who had an amputation on their dominant limb (defined below) preferred the Flexible toe joint, and all other participants preferred the Locked toe joint.

Kinematic and kinetic profiles from all intact and prosthetic limb joints were remarkably similar in the Flexible and Locked toe joint configurations (Figs. 2.2 and 2.3). This finding is consistent with previous results obtained when able-bodied persons walked with and without a toe joint using prosthetic adaptors [30]. Our observation that prosthesis Push-Off work decreased with the addition of the Flexible toe joint is also consistent with Honert et al. [30]. As noted by the authors [30], reduced Push-Off was likely the result of the decreased effective length of the foot segment [52–54].

We observed inconsistent changes in rate of oxygen consumption between the Locked and Flexible toe joint configurations (Fig. 2.4). Three participants appeared to have a monotonically decreasing trend across the A-B-A trials, one participant had a monotonically increasing trend, and four appeared to have a slightly lower oxygen consumption rate in the Locked (B) versus Flexible (A) configuration (Fig. 2.4B). The reason for this variability is unclear to us. No significant differences were detected at the group level. This may be explained by the small sample size or could be, in part, due to measurement limitations. For instance, prior studies report a minimum detectable change threshold of 0.8–1.0 ml O2 kg^{-1} min^{-1} associated with the metabolic equipment used [55,56], and most participants in our study exhibited changes below this threshold. Nevertheless, across the A-B-A trials about half of the participants exhibited clear, reversible trends in oxygen consumption (i.e., a small decrease from A to B, followed a similar magnitude increase from B to A). This return to baseline suggests that the measurement resolution may have been sufficient for these participants, or at least better than the thresholds previously reported in literature; though again it is not clear why this observation held for some participants and not others. The biggest confound to the group level analysis was likely participants who exhibited monotonically increasing or decreasing trends in oxygen consumption over the A-B-A trials. Our study supports the conclusions of Lamers et al. [40] who recently discussed similar challenges in interpreting group level statistical comparisons for a population of transtibial prosthesis users. Taken together, these findings highlight the benefits of using single-subject designs (including A-B-A protocols and subject-specific analysis methods) to gain more reliable insight regarding the effects of prosthetic interventions. Thus, the lack of statistical significance at the group level (particularly in small samples) should not automatically be interpreted to mean that certain individuals did not experience real, meaningful effects from an intervention.

All participants exhibited a higher magnitude of Push-Off work in the Locked configuration, but we cannot infer how this would be expected to have affected participants' rate of oxygen consumption. This is because the relationship between device Push-Off work and metabolic cost is difficult to discern from the existing literature. For example, Caputo and Collins [51] observed a significant reduction in metabolic cost when prosthesis Push-Off work was systematically increased; however, these findings were not replicated in a later study by the same group [57]. The onset of positive prosthesis Push-Off power is also likely to affect metabolic cost [58]. A noteworthy observation of the current study is that the user preference for seven of our nine participants did not correspond to the configuration that returned the lowest rate of oxygen consumption (Fig. 2.4B), with one possible explanation being that metabolic cost minimization was not the highest priority of our participant sample.

An unexpected surprise came as we compiled user demographic tables and noticed that all participants with right side limb loss preferred the Flexible toe joint ($N = 4$), while the remaining participants with left side limb loss preferred the Locked toe configuration ($N = 5$; Table 2.3). Given our relatively small sample size, this observation may be purely coincidental. However, the right versus left split perfectly matched the user preference results leading us to question if this phenomenon could be related to laterality (limb dominance). While there remains some debate about the roles of dominant and non-dominant lower limbs [59], coordinated bilateral movement tasks (e.g., kicking a soccer ball) appear to rely on the dominant limb to execute the more dynamic aspect of the motion, with the non-dominant limb assuming a stabilizing role [59–61]. It therefore seems plausible that adding an additional degree-of-freedom into the foot keel might be preferred on the dominant limb, yet non-preferred on the non-dominant limb.

To explore this possibility, we followed up with each participant in this study to inquire about whether their right or left limb was dominant prior to amputation. One individual had congenital limb loss, which made the concept of limb dominance somewhat ill-defined, and as such we were unsure how to ask or establish which of their limbs was dominant. For the remaining eight non-congenital participants, we asked them to self-identify their dominant limb prior to amputation; specifically, we asked: "Before losing your leg, would you prefer to kick a soccer ball with your right or left leg?" Seven of eight individuals confidently identified as right-limb dominant, and one identified as ambipedal (non-discriminant). We compiled participant responses into Table 2.3, and the results were quite striking: all participants who had dominant limb loss preferred the Flexible toe joint, and all other participants preferred the Locked toe joint. This offers an intriguing avenue for future research to explore whether prosthesis users who have a dominant limb amputation exhibit different functional outcomes or device preferences than those who have a non-dominant limb amputation. If so, these findings could have important implications to prosthetic foot design and clinical prescription. Moving forward, we plan to collect limb dominance information from all prosthesis study participants, along with the other conventional demographic data such as height, weight, prescribed prosthesis, etc. We encourage other researchers in the field to record and report limb dominance as well. It seems likely that trends and insights may emerge organically in the scientific literature if limb dominance is reported alongside standard demographics (e.g., Table 2.1).

The results and interpretation here are based on data from nine K3/K4 level, unilateral below-knee prosthesis users. Based on discussions with clinicians, study participants, other end-users and prosthesis manufacturers, we suspect that the addition of a toe joint may actually be of most benefit and interest to K2 level individuals, for whom replacing lost Push-Off power may not be as important as restoring other aspects of mobility. However, the multi-task protocol we performed in this study was determined to be too strenuous for most K2 level participants. An interesting follow-up study would be to explore the effect of adding a toe joint in a K2 population, during a reduced set of locomotor tasks. We also note that the study participants were not fully blinded to the prosthesis configurations. This was for two reasons: (i) the toe section of the prosthesis was open/visible to allow for motion capture marker tracking, and (ii) our participants were very perceptive and, in general, they quickly felt the difference in toe/keel stiffness between the two configurations. To help mitigate biasing participants based on our language as experimenters, we referred to Locked and Flexible configurations as Foot One and Foot Two throughout data collections, and when asking for user preference.

2.6 Conclusion

In conclusion, the addition of a toe joint to a passive foot prosthesis reduced Push-Off work in all participants by approximately 2.5 J, but appeared to have little effect on joint kinematics, kinetics, or rate of oxygen consumption. Participant preference for the Flexible or Locked toe joint during level walking was divided among our sample. The most intriguing, albeit preliminary, observation was the potential link between user preference and limb dominance—an area requiring further investigation.

CHAPTER 3

Biomechanical Effects of Adding an Articulating Toe Joint to a Passive Foot Prosthesis for Incline and Decline Walking

3.1 Summary

Walking on sloped surfaces is challenging for many lower limb prosthesis users, in part due to the limited ankle range of motion provided by typical prosthetic ankle-foot devices. Adding a toe joint could potentially benefit users by providing an additional degree of flexibility to adapt to sloped surfaces, but this remains untested. The objective of this study was to characterize the effect of a prosthesis with an articulating toe joint on the preferences and gait biomechanics of individuals with unilateral below-knee limb loss walking on slopes. Nine active prosthesis users walked on an instrumented treadmill at a +5° incline and -5° decline while wearing an experimental foot prosthesis with two configurations: a Flexible toe joint and a Locked-out toe joint. Three participants preferred the Flexible toe joint over the Locked-out toe joint for incline and decline walking. Eight of nine participants went on to participate in a biomechanical data collection. The Flexible toe joint decreased prosthesis Push-off work by 2 Joules during both incline ($p = 0.008$; $g = -0.63$) and decline ($p = 0.008$; $g = -0.65$) walking. During incline walking, prosthetic limb knee flexion at toe-off was 3° greater in the Flexible configuration compared to the Locked ($p = 0.008$; $g = 0.42$). Overall, these results indicate that adding a toe joint to a passive foot prosthesis has relatively small effects on joint kinematics and kinetics during sloped walking. This study is part of a larger body of work that also assessed the impact of a prosthetic toe joint for level and uneven terrain walking and stair ascent/descent. Collectively, toe joints do not appear to substantially or consistently alter lower limb mechanics for active unilateral below-knee prosthesis users. Our findings also demonstrate that user preference for passive prosthetic technology may be both subject-specific and task-specific. Future work could investigate the inter-individual preferences and potential benefits of a prosthetic toe joint for lower-mobility individuals.

3.2 Background

Typically-able-bodied individuals adapt to walking on sloped surfaces by altering their gait mechanics. For example, relative to walking on level ground, they exhibit increased magnitudes of ankle dorsiflexion on both inclines and declines [62,63]. For walking uphill, the biological ankle also provides additional positive work to move the center of mass up the slope against gravity. During downhill walking, the lower limbs mostly absorb energy and generate less positive work at the joints as the center of mass is lowered [64–67].

Unlike able-bodied individuals, people with lower limb loss cannot easily alter their prosthetic ankle's flexion or power generation to accommodate a slope [68,69]. As a result, many lower limb prosthesis users (LLPUs) struggle to comfortably navigate sloped terrains. A study that surveyed over 300 LLPUs found that only 52% of users were able to walk on uneven ground such as sloped surfaces without assistance [10]. LLPUs have also been observed to have reduced walking speed and cadence when walking on slopes [68,69] and increased metabolic cost on inclines [70] compared to individuals without limb loss. These challenges associated with sloped walking can have substantial impacts on a person's physical activity level, quality-of-life, and societal participation.

Most LLPUs use a passive ankle-foot prosthesis that has a fixed ankle set-point angle and rigid foot segment [6]. This results in limited ankle range of motion and power generation from the device, which likely contribute to gait compensations observed during sloped walking [40,69,71,72]. For example, individuals with below-knee limb loss often exhibit altered knee mechanics compared to individuals without limb loss when walking on slopes [69,73]. During incline walking, users have reduced knee flexion in early stance accompanied by reduced dorsiflexion provided by the prosthetic ankle [69,73]. During decline walking, the reported increase in prosthetic limb knee flexion during late stance is thought to compensate for the lack of prosthetic ankle range of motion when lowering one's center of mass [69,73,74].

Device interventions that aim to improve the ability of LLPUs to walk on sloped surfaces have often focused on adapting the behavior of the prosthetic ankle joint. Passive, hydraulic, microprocessor, and fully powered devices have all been investigated to determine if they can improve the ability of users to walk on slopes [40,70–78]. Some studies have found a benefit in their approach to modulating ankle behavior to improve incline and decline walking, but most have reported mixed or conflicting results. For example, a study investigating a microprocessor device that adjusts the set-point of the ankle joint during sloped walking reported an increase in ankle range of motion and prosthetic limb knee flexion during incline walking, but for declines the added plantarflexion did not show a measurable benefit and biomechanical results conflicted with participant feedback on the device [73].

An alternative or complementary approach to adjusting device ankle behavior during sloped walking may be to incorporate a passive toe joint into a prosthetic foot. Biological metatarsophalangeal (i.e., toe) joint articulation plays an important role in locomotion and prior experimental and simulation research suggests that altering toe joint dynamics can impact gait mechanics and locomotor economy [27,28,30,31,34,79–81]. Incorporating a toe joint into a prosthetic foot could benefit LLPUs during locomotion in general, or for specific locomotor tasks. We have previously investigated level ground walking with a toe joint added to a passive ankle-foot prosthesis [82]. During this study, we found that a Flexible toe joint decreased the amount of Push-off power provided by the prosthesis compared to a Locked-out toe joint configuration, but observed no significant difference in rate of oxygen consumption or the biomechanics of other lower limb joints. Four of nine participants preferred the Flexible configuration for level ground walking.

For walking on slopes, an articulating toe joint could provide LLPUs with an additional degree of compliance to help compensate for the lack of prosthetic ankle flexion. For walking uphill, a prosthesis with a flexible toe joint may increase the ability of the device to conform to the sloped surface, but potentially has the drawback of providing less Push-off power compared to a prosthetic foot of the same design without a toe joint. For walking downhill, a prosthesis with a toe joint could potentially aid LLPUs by providing flexibility in the device during late stance to support lowering their center of mass. The potential reduction in prosthetic Push-off power may be inconsequential or potentially beneficial when walking downhill as there is less need to generate positive power with the lower limbs and specifically the ankle joint [64–67]. However, the impact of incorporating a flexible toe joint into a prothesis for sloped walking has never been tested. The potential gait adaptations or benefits and preferences of LLPUs are unknown.

Therefore, the objective of this study was to characterize the preferences and gait biomechanics of unilateral below-knee prosthesis users walking on an incline and decline wearing a prosthetic foot in two configurations: a Flexible and a Locked-out toe joint. Specifically, we evaluated user preference, spatiotemporal variables, prosthesis Push-off work, and prosthetic limb knee kinematics to determine the impact of a Flexible toe joint during sloped walking. We expected positive prosthesis Push-off work to be reduced for the Flexible configuration compared to the Locked configuration for both incline and decline walking. We expected LLPUs to prefer the Locked configuration for incline walking due to the increased amount of positive work (from the ankle and at the center of mass level) that is necessary to ascend ramps [64–67]. For decline walking, we expected users to prefer the Flexible configuration as it provides an additional degree of flexibility during late stance to assist LLPUs in lowering their center of mass. We also predicted that early stance kinematics of the prosthetic limb would not be influenced by the addition of a toe joint, but late stance kinematics would be affected. This was evaluated by quantifying prosthetic limb knee angle at initial contact and toe-off.

3.3 Methods

3.3.1 Participants

Nine below-knee prosthesis users (male, age: 40.7 ± 10.5 years, mass: 95.0 ± 12.9 kg, height: 1.84 ± 0.05 m; Table 3.1) participated in a multi-day research protocol, which included incline and decline walking. The overall protocol also included level ground walking, stair ascent and decent, and uneven terrain walking. Results from those activities have been reported in separate manuscripts [82–84]. Participant recruitment for this study started on November 1st, 2018 and concluded on September 15th, 2019. Each participant provided written informed consent, according to Vanderbilt University's Institutional Review Board procedures. Participant 7 was not able to attend the session when incline and decline biomechanical walking data were collected due to scheduling constraints and therefore only eight participants are included in the biomechanical analyses. All participants were a Medicare Functional Classification Level of K4, except one (K3). No participants required the use of a walking aid, and all were at least six months post amputation surgery at the time of data collection.

Table 3.1 Individual and mean (± standard deviation) participant demographics

Participant ID	Age (years)	Body Mass (kg)	Height (m)	Leg Length (m)	Years Since Limb Loss	K-Level	Cause of Limb Loss	Daily-Use Prosthesis
1	33	119.1	1.92	1.00	3.8	4	Traumatic	Fillauer Formula
2	49	96.3	1.86	0.95	7.5	4	Traumatic	Fillauer AllPro
3	33	98.7	1.88	0.98	9.3	4	Traumatic	Össur Pro-Flex XC
4	55	99.9	1.83	0.94	4.7	3	Vascular	Fillauer AllPro
5	28	82.0	1.90	0.99	8.8	4	Traumatic	Fillauer AllPro
6	41	99.8	1.80	0.93	41.0	4	Congenital	Ottobock Triton
7	47	85.1	1.76	0.97	7.4	4	Traumatic	Fillauer AllPro
8	52	75.0	1.85	0.98	2.5	4	Traumatic	Fillauer Formula
9	28	99.0	1.78	0.94	5.3	4	Traumatic	Fillauer AllPro
Mean ± SD	40.7 ± 10.5	95.0 ± 12.9	1.84 ± 0.05	0.96 ± 0.02	10.0 ± 11.8			

3.3.2 Experimental Prosthesis

The experimental device was a commercial prosthetic foot (Balance Foot J, Össur, Reykjavik, Iceland) that was modified to function in two configurations (Fig. 3.1). The first configuration included a Flexible toe joint that was accomplished by attaching a truncated foot keel to a toe segment with sheets of spring steel allowing toe joint flexion during loading (Fig. 3.1A). The stiffness of the toe joint was 0.34 Nm/°. The Locked toe joint configuration was accomplished by connecting the foot and toe segments with a rigid aluminum block that prevented toe joint flexion to effectively create a solid foot keel without a toe joint (Fig. 3.1B). The mass of the experimental prosthesis was similar in both configurations with less than 20 g difference between the Flexible and Locked configurations. Three versions of the commercial foot were modified (length-category: 25-3, 27-3, and 28-4). The version used for each participant was selected based on their shoe size and body mass.

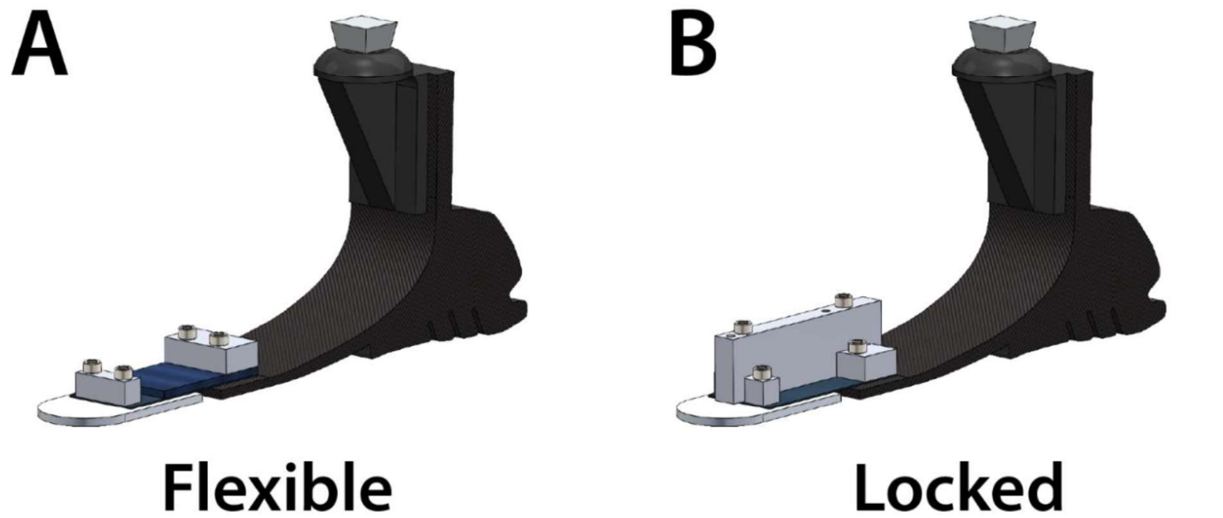


Figure 3.1 Experimental prosthetic foot. A commercial prosthetic foot (Össur Balance Foot J) modified to function in two configurations: (A) a Flexible toe joint configuration made using sheets of spring steel and (B) a Locked toe joint configuration accomplished by securing an aluminum block across the joint to prevent flexion.

3.3.3 Training Protocol

The full research protocol involved four sessions: two training and two testing. During the first training session, participants familiarized themselves with six locomotor tasks (walking over level, incline, decline, and uneven terrain surfaces, and ascending/descending stairs) while wearing their prescribed prosthesis. They were then fitted with the experimental prosthesis in a randomized starting configuration (Flexible or Locked). A certified prosthetist conducted the fitting and alignment of the experimental prosthesis, which was maintained across both configurations for all training and testing sessions. During fitting, training, and data collection, participants wore a cosmesis over the experimental prosthesis, with no shoe. This facilitated motion capture marker tracking and allowed investigators to change between toe joint configurations without removing the device. For the remainder of the first training session and during the second training session, participants acclimated to the six previously mentioned locomotor tasks while wearing the experimental prosthesis in both the Flexible and Locked configurations. In total, participants spent approximately 20 min walking on and acclimating to each foot configuration. Participants were not explicitly told about the purpose of the study and were introduced to the configurations as Foot One and Foot Two, depending on the random order they were assigned to complete all training and testing (i.e., Flexible then Locked or Locked then Flexible), which alternated for consecutive participants. At the end of the second training session, participants ranked their satisfaction with their familiarization on the experimental prosthesis in each configuration for all locomotor tasks on a scale of 1-10. All participants reported a 9 or 10 across tasks and configurations, indicating they felt comfortable and acclimated to walking on the experimental prosthesis. At the conclusion of the second training session, participants were also asked to report their preference for Foot One or Foot Two for each locomotor task.

3.3.4 Testing Protocol and Data Collection

Data collection for incline and decline walking in each toe joint configuration was performed on the fourth day of the protocol (second testing session). Participants had 40-42 reflective markers affixed to their lower limbs and the experimental prosthesis (two markers were added to the iliac crests if pelvis marker occlusion issues arose) [82]. Kinematics were simultaneously collected at 200 Hz (10-camera system, Vicon, Oxford, UK) with ground reaction forces (GRFs) collected at 1,000 Hz while participants walked at 1 m s^{-1} on a dual-belt force-measuring treadmill (Bertec, Columbus, OH, USA) at a +5° and -5° slope. Speed and slopes were chosen based on existing literature examining prosthesis user locomotion [70,76,85]. The duration of the walking trial for both the Flexible and Locked configuration was approximately 90 s, with the middle 60 s of data collected for analysis.

3.3.5 Outcome Metrics

In this study, we provide time-series angle, moment, and power data for all lower limb joints during both incline and decline walking. However, we chose a select number of key outcome metrics to evaluate the impact of incorporating a toe joint into a passive ankle-foot prosthesis. Peak prosthesis toe joint angle was computed to confirm that our experimental prosthesis functioned as intended in both configurations. We computed positive prosthesis Push-off work to evaluate the hypothesized difference in energy provided by the device in the two configurations. We also characterized prosthetic limb knee angle at initial contact and toe-off to determine whether adding a toe joint impacts the altered knee flexion angles typically observed for LLPUs walking on slopes compared to individuals without limb loss [69,73,86].

3.3.6 Data Analysis

Motion capture and GRF data were filtered with a fourth order, low-pass Butterworth filter with a cutoff frequency of 8 and 15 Hz, respectively. Spatiotemporal results (stride length and time; stance and swing time for each limb) were computed using a 20 N threshold for vertical GRF (to identify initial contact and toe-off of each limb) and the position of the posterior calcaneus marker on each limb. Sagittal plane joint angles and net moments, net joint powers (six degree-of-freedom), and center of mass dynamics [45] were computed via inverse dynamics using Visual3D (C-motion, Germantown, MD, USA) and custom MATLAB code (R2018b, MathWorks, Natick, MA, USA). Prosthesis power and work were calculated using the distal segment power method [16,46]. Prosthesis work was computed for the Push-off phase of gait by taking the positive integral of the time-series prosthesis power data during late stance. Data for each participant and condition were further processed in MATLAB and divided into strides then normalized to 100% of the stride cycle. An average of 40 strides per trial were included for analysis with included strides determined by clean force plate contacts. Strides where a foot contacted two force plates at once were detected and omitted using a custom MATLAB script and GRF data.

Outcome metrics were then non-dimensionalized to account for differences in participant size. Stride length was non-dimensionalized by leg length (L). Stride time, stance time, and swing time were non-dimensionalized by $\sqrt{L/g}$, where g is acceleration due to gravity [43,44]. Moments and work were non-dimensionalized by MgL where M is body mass. Power was non-dimensionalized by $Mg\sqrt{gL}$ [43,44]. Average non-dimensionalization constants were 0.96 m (length), 0.31 s (time), 893.5 Nm and J (moment and work), and 2853.6 W (power). Some outcomes were re-dimensionalized using these constants for reporting purposes.

3.3.7 Statistical Analysis

Group results for relevant outcome metrics are reported as mean ± standard deviation. Data were screened for normality via a Shapiro-Wilk test. Following this, a series of paired-samples t-tests (normal distribution) or Wilcoxon signed-rank tests (non-normal distribution) were applied to detect differences in spatiotemporal variables, peak toe joint angle, prosthesis Push-off work, prosthetic limb knee angle at initial contact, and prosthetic limb knee angle at toe-off between the Flexible and Locked configuration trials. Holm-Bonferroni corrections were applied to account for familywise error rates across the groups for spatiotemporal and principal kinematic and kinetic variables. Incline and decline data were considered separate families. Adjusted alpha levels for each variable during incline walking are listed in parentheses: stride length ($p = 0.017$), stride time ($p = 0.010$), prosthetic limb stance time ($p = 0.013$), prosthetic limb swing time ($p = 0.025$), intact limb stance time ($p = 0.008$), intact limb swing time ($p = 0.05$), peak toe joint angle ($p = 0.013$), prosthesis Push-off work ($p = 0.018$), prosthetic limb knee angle at initial contact ($p = 0.050$), and prosthetic limb knee angle at toe-off ($p = 0.025$). Adjusted alpha levels for each variable during decline walking are listed here: stride length ($p = 0.017$), stride time ($p = 0.050$), prosthetic limb stance time ($p = 0.010$), prosthetic limb swing time ($p = 0.013$), intact limb stance time ($p = 0.025$), intact limb swing time ($p = 0.008$), peak toe joint angle ($p = 0.0125$), prosthesis Push-off work ($p = 0.018$), prosthetic limb knee angle at initial contact ($p = 0.05$), and prosthetic limb knee angle at toe-off ($p = 0.025$). To quantify effect sizes, Hedges' g was also calculated. Statistical analyses were conducted in MATLAB and Excel (v2108, Microsoft, Redmond, WA, USA).

3.4 Results

Group-level average curves for lower limb kinematics and kinetics divided by limb and slope are provided in Figs. 3.2-3.5. Most results were normally distributed. Non-normally distributed variables for incline walking included prosthetic limb swing time, intact limb swing time, prosthesis Push-off work, and prosthetic limb knee angle at initial contact. Non-normally distributed variables for decline walking included stride time, intact limb stance time, and prosthesis Push-off work.

3.4.1 User Preference

Participant preference was divided between the Flexible and Locked configuration for both incline and decline walking. For incline walking, three of nine participants (Participants 1, 3, and 4) preferred the Flexible toe joint while the remaining six preferred the Locked toe joint. For decline walking, three of nine again preferred the Flexible configuration while the remaining six preferred the Locked, but it was a slightly different group of three participants (Participants 1, 2, and 3).

3.4.2 Spatiotemporal

Spatiotemporal results are presented in Table 3.2. During incline walking, there was only a significant difference between the Flexible (0.77 s) and Locked (0.79 s) configurations for intact limb stance time ($p = 0.008$; $g = -0.24$). During decline walking there were no significant differences in spatiotemporal variables between configurations ($p > 0.48$).

Table 3.2 Mean (± standard deviation) re-dimensionalized spatiotemporal variables.

		Stride Length (m)	Stride Time (s)	Prosthetic Limb		Intact Limb	
				Stance Time (s)	Swing Time (s)	Stance Time (s)	Swing Time (s)
Incline (+5°)	Flexible	1.13 ± 0.09	1.13 ± 0.09	0.72 ± 0.07	0.41 ± 0.04	0.77 ± 0.06*	0.36 ± 0.04
	Locked	1.15 ± 0.09	1.15 ± 0.09	0.74 ± 0.08	0.41 ± 0.08	0.79 ± 0.06*	0.37 ± 0.03
Decline (-5°)	Flexible	1.03 ± 0.07	1.03 ± 0.07	0.65 ± 0.06	0.38 ± 0.03	0.68 ± 0.05	0.35 ± 0.04
	Locked	1.03 ± 0.07	1.03 ± 0.07	0.64 ± 0.06	0.38 ± 0.03	0.68 ± 0.05	0.35 ± 0.04

*Significant difference detected between the Flexible and Locked configurations.

3.4.3 Toe Joint Angle

During incline walking, the peak toe joint angle for the Flexible configuration (18.0 ± 3.7°) was significantly greater than the Locked configuration (1.7 ± 1.3°; $p < 0.001$; $g = 5.29$; Table 3.3; Fig. 3.2). There was also a significant difference in peak toe joint angle during decline walking between the Flexible configuration (16.7 ± 4.6°) and Locked configuration (1.5 ± 1.5°; $p < 0.001$; $g = 3.93$; Table 3.3; Fig. 3.4).

3.4.4 Prosthesis Push-Off Work

During both incline and decline walking, participants exhibited a decrease in Push-off work when using the Flexible toe joint versus the Locked toe joint (both $p = 0.008$; incline: $g = -0.63$; decline: $g = -0.65$; Table 3.3). This was 25% (~2 J) less prosthesis Push-off work for both incline walking (6.9 vs. 9.2 J, respectively) and decline walking (6.3 vs. 8.3 J, respectively).

3.4.5 Prosthetic Limb Knee Kinematics

For both incline and decline walking, there was no significant difference in prosthetic limb knee angle at initial contact between configurations (incline: $p = 0.59$; decline: $p = 0.32$; Table 3.3). However, during incline walking, participants had ~3° more prosthetic limb knee flexion at toe-off for the Flexible configuration (34.5 ± 5.8°) compared to the Locked (31.3 ± 7.5°; $p = 0.008$; $g = 0.42$). During decline walking, there was no significant difference between configurations for prosthetic limb knee angle at toe-off ($p = 0.14$; Table 3.3).

Table 3.3 Mean (± standard deviation) peak toe joint angle, (re-dimensionalized) prosthesis Push-off work, and prosthetic limb knee angle at initial contact and toe-off.

		Peak toe angle (°)	Prosthesis Push-off work (J)	Prosthetic limb knee angle (°)	
				Initial contact	**Toe off**
Incline (+5°)	**Flexible**	18.01 ± 3.67*	6.88 ± 2.77*	9.13 ± 5.73	34.48 ± 5.78*
	Locked	1.67 ± 1.25*	9.20 ± 3.93*	8.63 ± 5.32	31.31 ± 7.50*
Decline (-5°)	**Flexible**	16.70 ± 4.64*	6.25 ± 2.41*	1.97 ± 4.80	51.79 ± 6.98
	Locked	1.46 ± 1.49*	8.31 ± 3.31*	2.52 ± 4.31	50.81 ± 7.34

*Significant difference detected between the Flexible and Locked configurations.

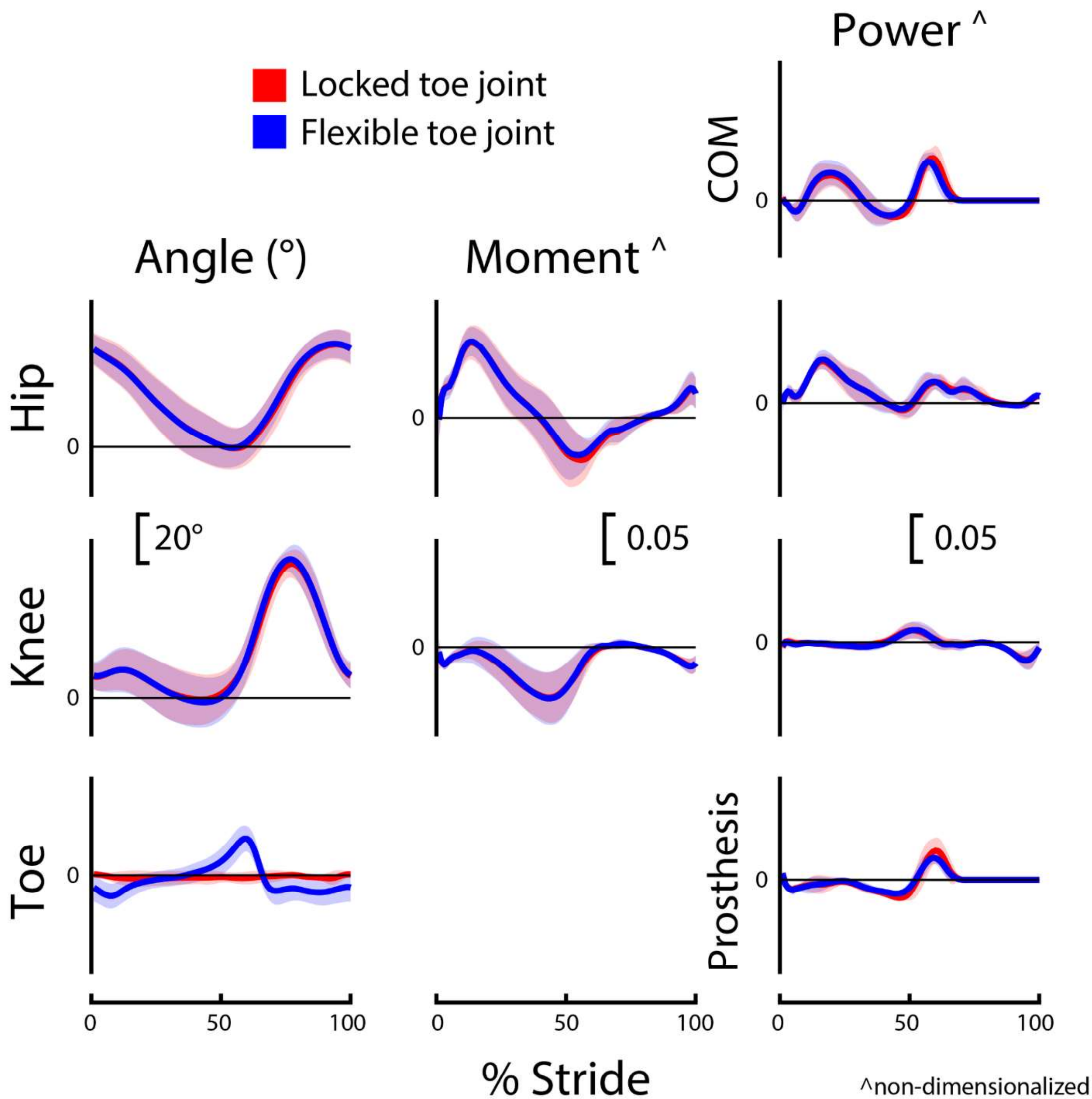


Figure 3.2 Prosthetic limb biomechanics during incline (+5°) walking. Prosthetic limb joint, center of mass (COM), and prosthesis dynamics for participants (N = 8) using a passive prosthetic foot with a Flexible (blue) and Locked (red) toe joint configuration. Data were cropped into strides using prosthetic limb heel strikes. Data are presented as mean ± standard deviation (shaded regions). Moment and power data are presented as dimensionless values. Using group mean re-dimensionalization constants, 0.05 corresponds to 0.47 Nm kg^{-1} for moments and 1.50 W kg^{-1} for powers.

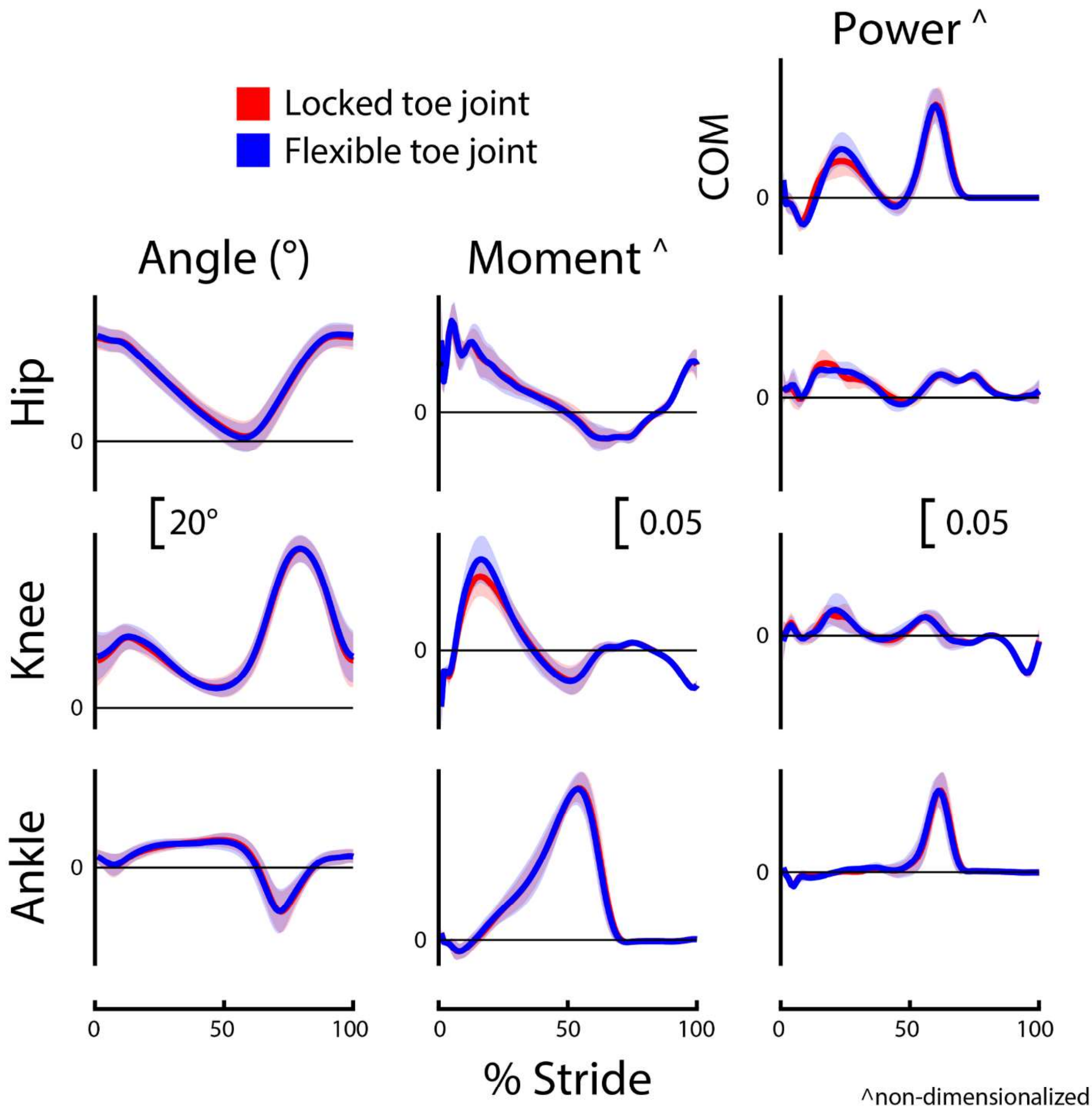


Figure 3.3 Intact limb biomechanics during incline (+5°) walking. Intact (non-prosthetic) limb joint and center of mass (COM) dynamics for participants ($N = 8$) using a passive prosthetic foot with a Flexible (blue) and Locked (red) toe joint configuration. Data were cropped into strides using intact limb heel strikes. Data are presented as mean ± standard deviation (shaded regions). Moment and power data are presented as dimensionless values. Using group mean re-dimensionalization constants, 0.05 corresponds to 0.47 Nm kg^{-1} for moments and 1.50 W kg^{-1} for powers.

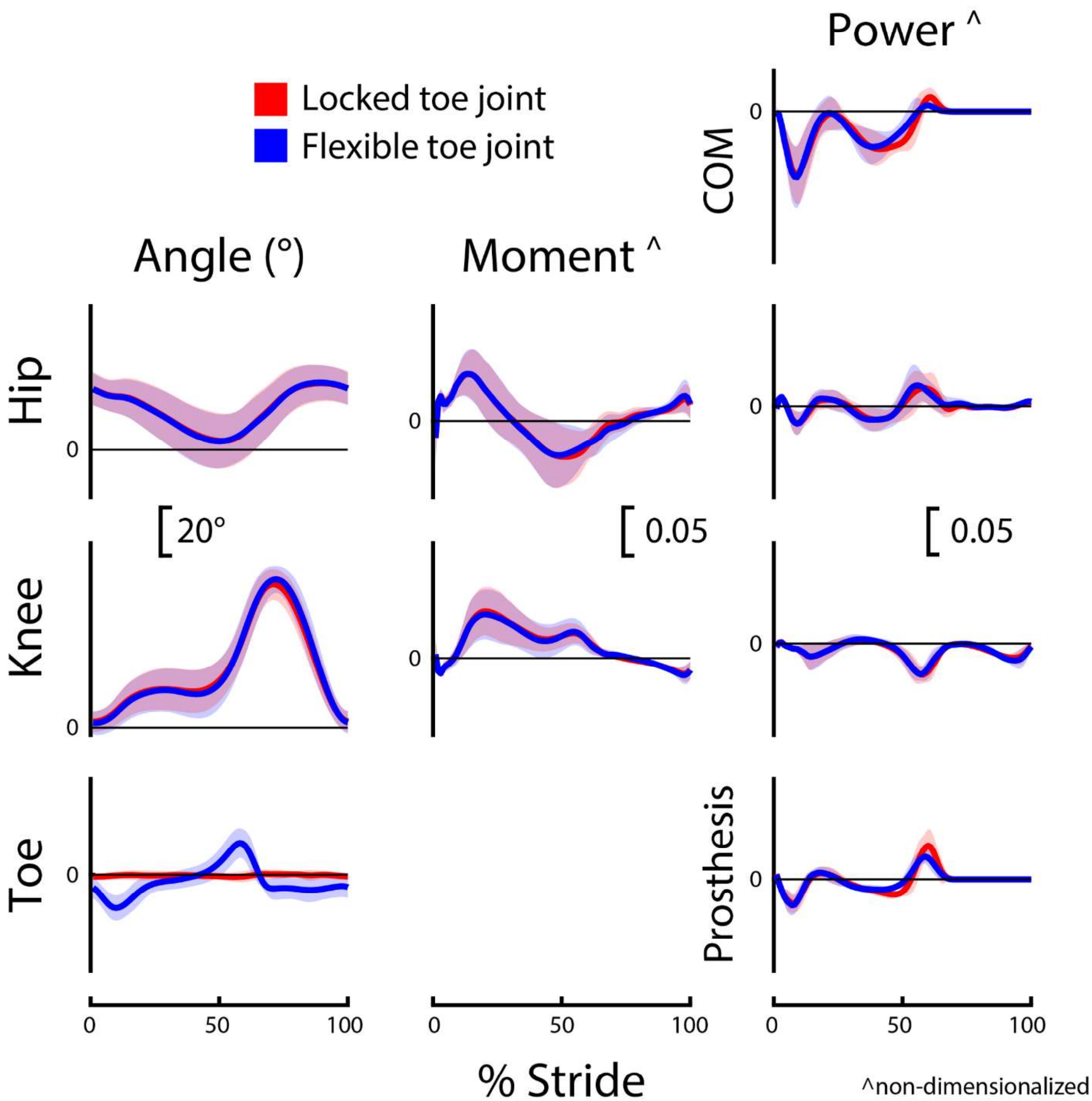


Figure 3.4 Prosthetic limb biomechanics during decline (-5°) walking. Prosthetic limb joint, center of mass (COM), and prosthesis dynamics for participants ($N = 8$) using a passive prosthetic foot with a Flexible (blue) and Locked (red) toe joint configuration. Data were cropped into strides using prosthetic limb heel strikes. Data are presented as mean ± standard deviation (shaded regions). Moment and power data are presented as dimensionless values. Using group mean re-dimensionalization constants, 0.05 corresponds to 0.47 Nm kg^{-1} for moments and 1.50 W kg^{-1} for powers.

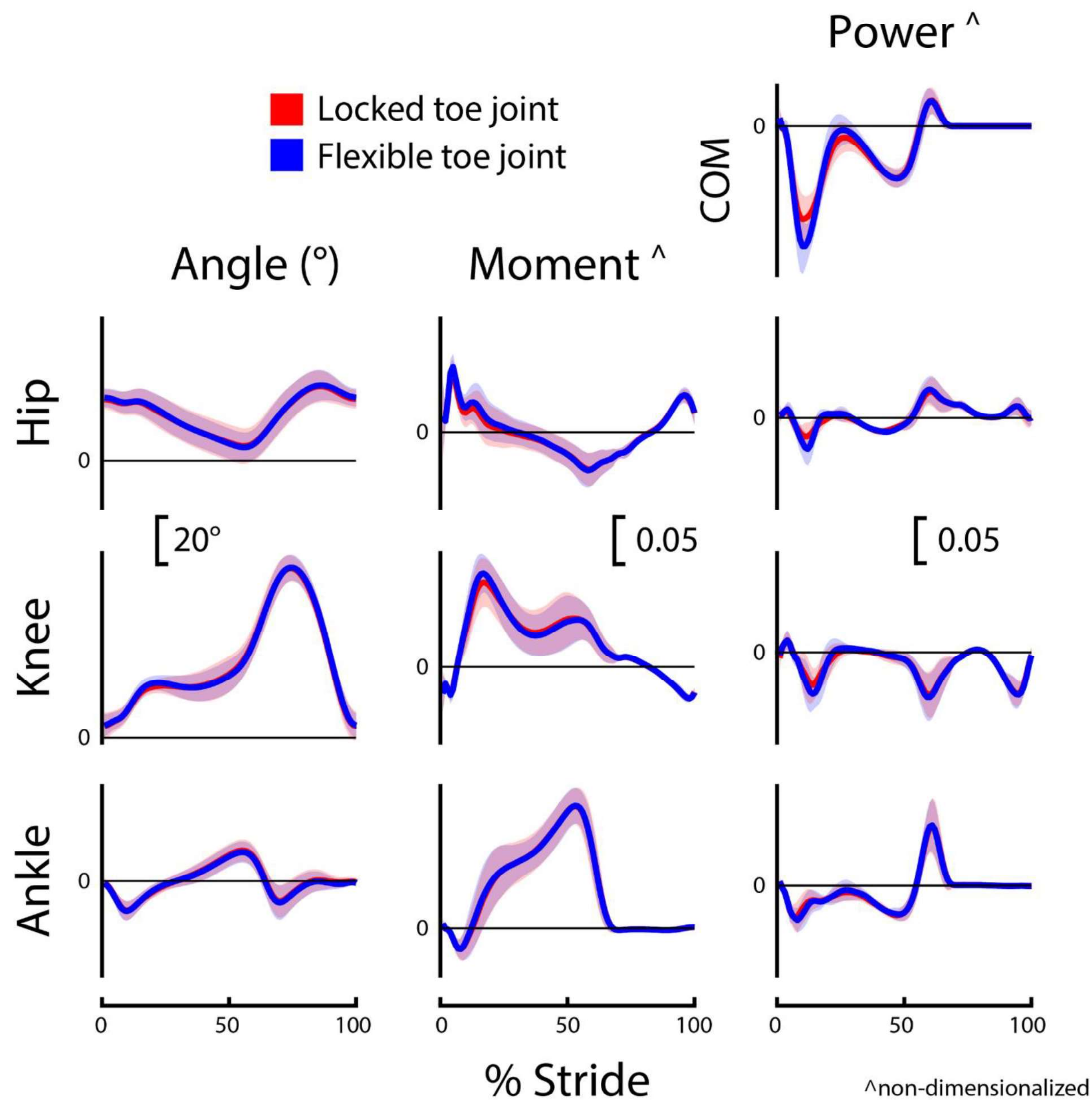


Figure 3.5 Intact limb biomechanics during decline (-5°) walking. Intact (non-prosthetic) limb joint and center of mass (COM) dynamics for participants ($N = 8$) using a passive prosthetic foot with a Flexible (blue) and Locked (red) toe joint configuration. Data were cropped into strides using intact limb heel strikes. Data are presented as mean ± standard deviation (shaded regions). Moment and power data are presented as dimensionless values. Using group mean re-dimensionalization constants, 0.05 corresponds to 0.47 Nm kg^{-1} for moments, and 1.50 W kg^{-1} for powers.

3.5 Discussion

The aim of this study was to characterize the preferences and gait biomechanics of unilateral below-knee prosthesis users walking on an incline and decline wearing a prosthesis in two configurations: a Flexible and Locked-out toe joint. The majority of participants (six of nine) preferred the Locked configuration for incline and decline walking. Participants exhibited less prosthesis Push-off work during both incline and decline walking when walking with a Flexible toe joint. During incline walking, the Flexible configuration resulted in slightly more prosthetic limb knee flexion at toe-off compared to the Locked configuration.

The reduction in positive prosthesis Push-off work observed for the Flexible versus Locked configuration was statistically significant but small (incline: 6.9 vs. 9.2 J respectively; decline: 6.3 vs. 8.3 J, respectively). During incline walking at similar grades and speeds, the biological ankle/foot complex provides more than 25 J of positive work [67]. Thus, the ~2 J difference in prosthesis work between configurations may not be impactful given the 15 J or more deficit in ankle work when compared to biological magnitudes. For decline walking, positive ankle/foot work is estimated to be ~15 J [67]. Therefore, a 2 J difference in prosthesis work may or may not be impactful. However, for decline walking, maximizing prosthesis Push-off work is likely not the most important determinant of a LLPU's locomotive ability. Walking downhill does not require high levels of positive joint or center of mass work (Figs. 3.4 and 3.5), and instead negative ankle/foot work for controlled lowering may be more important [64,67,72].

The kinematic and kinetic profiles of both intact and prosthetic limb joints were similar for the Flexible and Locked toe joint configurations, as depicted in Figs. 3.2-3.5. Decreased prosthetic limb knee angle at initial contact is a common compensation employed by LLPUs to accommodate for the lack of dorsiflexion provided by typical prosthetic ankles [69,73]. Prosthetic interventions that modulate ankle dynamics have had some success in improving this metric by dorsiflexing the ankle joint during swing which emulates how individuals without limb loss adapt to walking uphill [73]. However, we anticipated that toe joint flexion would occur only in mid to late stance, and therefore correctly hypothesized that their knee joint angle at initial contact would be unaltered by the toe joint configuration. During decline walking, increased prosthetic limb knee flexion at toe-off is considered a compensation strategy that possibly stems from the lack of ankle range of motion and stiff foot of typical prostheses [69,73]. As such, we hypothesized the Flexible toe joint would provide users with additional flexibility in their ankle-foot device that could assist in lowering during late stance and therefore reduce knee flexion compared to the Locked configuration. However, we did not see a difference in prosthetic limb knee flexion at toe-off during decline walking between the Flexible and Locked configurations. It is possible that 18° of toe joint flexion at the distal end of a prosthesis does not provide adequate flexibility to compensate for the limited flexion available at the ankle during late stance. During incline walking, we did observe a 3° increase in prosthetic limb knee flexion at toe-off with the Flexible configuration. Because previous work has reported LLPUs have reduced prosthetic limb knee flexion during stance on inclines compared to individuals without limb loss [69,73], this increase may indicate the knee angle results in the Flexible configuration are more similar to typically-able-bodied control data. However, this difference in angle is small (with a small reported effect size of $g = 0.42$) and the plot of average prosthetic limb knee angle throughout the gait cycle is highly similar between configurations (Fig. 3.2).

This is the fourth manuscript in a series of studies evaluating the effects of adding a toe joint to a passive foot prosthesis during different forms of locomotion. Across all studies, we have evaluated level ground walking, sloped walking, stair ascent and decent, and uneven terrain walking with eight or nine unilateral below-knee prosthesis users [82–84]. For several tasks, we observed that the Flexible toe joint reduced prosthesis Push-off work compared to the Locked toe joint. This aligns with observations of able-bodied individuals walking on level ground using a similar device where increasing toe stiffness resulted in greater prosthetic and center of mass Push-off work [30]. Reductions in effective foot length, i.e., the anterior displacement of the center of pressure under the foot expressed as a percentage of total foot length [53], may be responsible. The Locked-out toe joint would enable the center of pressure to extend more anteriorly as it is stiffer at the distal end of the foot. In turn, the prosthetic ankle has the potential to generate larger ankle moments, and subsequently store and return more energy during walking [30,53,54]. Reducing Push-off work could be considered a negative result in some instances as typical passive devices already provide reduced amounts of Push-off power compared to what is provided by the biological ankle [70,87]. However, for certain tasks, maximizing Push-off work is likely not the primary factor limiting the ability of LLPUs. Tasks such as stair decent and decline walking do not require high amounts of positive joint or center of mass work (Figs. 3.4 and 3.5) and instead controlled lowering (negative work) may be more important for LLPUs to feel comfortable and stable during locomotion.

Relatively few differences in the kinematics and kinetics of other lower limb joints were observed at the group level across the tasks tested in the full protocol. When walking on uneven terrain, a consistent reduction in prosthetic limb positive hip joint work was found [84], but most other noteworthy outcomes related to subject-specific observations. When considering the collective results from these studies, they suggest that adding an articulating toe joint likely has minimal impacts on the overall biomechanics of active unilateral LLPUs. A clinician's decision to prescribe a prosthesis with a toe joint may be best guided by individual user preference and considerations outside of the evaluated biomechanical measures (e.g., user stability).

By considering the preference results from our full protocol, the subject-specific and task-specific nature of user preference is highlighted (Table 3.4). User preference was mixed across the six tasks, with three to five users preferring the Flexible toe joint for each task. The Flexible toe joint was only preferred by the majority of participants during one task: walking on uneven terrain. When comparing level, incline, and decline walking, three participants had split preferences between the two configurations. Only four participants had a consistent preference for the Flexible or Locked configuration across all tasks, with the remaining participants preferring the Flexible configuration for some tasks and the Locked for others. Given that preference may be user and task specific, the selection, fitting, and alignment of a prosthetic device may benefit from evaluation across multiple tasks, beyond level ground walking. Additionally, researchers and developers should consider user preference during device design as it can be key for user acceptance [88] and note that preference for a device or behavior likely varies between tasks. Acknowledging our small sample size does not represent the full spectrum of prosthesis users, further investigation into determinants of user preference is warranted—particularly in relation to biomechanical outcomes associated with passive prosthetic devices. Given the complexity of prosthetic gait, future work could also investigate motor control and muscle activation measures in addition to biomechanical outcomes to give a holistic evaluation of potential gait adaptations and determinants of participant preference [89]. Future studies could also consider alterative toe joint-related modifications including changing the relative position of the toe joint along the keel or assessing a broader range of stiffness magnitudes.

Table 3.4 Participant preference for Flexible versus Locked toe joint configuration across tasks tested in full protocol [82,84,90].

Participant ID	Level Walking	Incline Walking	Decline Walking	Stair Ascent	Stair Decent	Uneven Terrain Walking
1	**Flexible**	**Flexible**	**Flexible**	**Flexible**	**Flexible**	**Flexible**
2	Locked	Locked	**Flexible**	Locked	Locked	**Flexible**
3	**Flexible**	**Flexible**	**Flexible**	Locked	**Flexible**	**Flexible**
4	**Flexible**	**Flexible**	Locked	**Flexible**	Locked	**Flexible**
5	**Flexible**	Locked	Locked	**Flexible**	**Flexible**	Locked
6	Locked	Locked	Locked	Locked	Locked	Locked
7	Locked	Locked	Locked	Locked	Locked	Locked
8	Locked	Locked	Locked	Locked	Locked	Locked
9	Locked	Locked	Locked	Locked	Locked	**Flexible**

The nine participants for this series of studies were all active individuals with a high level of functional ability (all K3-K4). From both local clinicians and LLPUs, we received feedback that adding a Flexible toe joint to a prothesis may be more beneficial for lower-activity individuals with unilateral limb loss or individuals with bilateral limb loss. It was proposed that a toe joint may play an important role in user stability and comfort for activities of daily living like picking up an item off the ground, turning corners, or reaching for an object on a shelf. This could be valuable for users who have limited community ambulation and desire a prosthetic ankle-foot device that provides flexibly during daily tasks. Future work could evaluate adding a Flexible toe joint to a prosthesis in a population of lower mobility users and assess tasks outside of locomotion—particularly given the challenges and potentially harmful movement adaptations that have been observed for LLPUs across a number of activities of daily living [7,10,91].

In this study, we adapted the Balance Foot J (a commercial prosthetic foot) to create the experimental device. This prosthesis is often prescribed to individuals with a low activity level and thus, may have felt less familiar to our higher activity cohort. Also, the toe joint stiffness was not normalized to participant body mass, which may have had a minor effect on our results. Additionally, the experimental prosthesis was not realigned in each configuration, although the configuration for fitting and alignment was randomized. This was to minimize the impact alignment changes could have on results, but potentially could have affected user preference and biomechanical outcomes.

3.6 Conclusion

The current study characterizes the effect of adding a Flexible toe joint to a passive foot prosthesis during sloped walking for active individuals with unilateral below-knee limb loss. Three of nine participants preferred the Flexible toe joint over the Locked toe joint for incline and decline walking. We saw statistically significant changes in prosthesis Push-off work during both sloped conditions with the Flexible configuration providing ~2 J less work than the Locked. Overall, results indicated that adding a toe joint to a passive foot prosthesis had a relatively small effect on joint kinematics and kinetics during sloped walking. This work is the fourth manuscript of a multi-part series that assessed the impact of a prosthetic toe joint across six locomotor tasks (walking over level, incline, decline, and uneven terrain surfaces, and ascending/descending stairs). The collective findings from this dataset demonstrate that user preference for passive prosthetic technology may be both highly subject-specific and task-specific. We conclude that toe joints do not appear to substantially or consistently alter lower limb mechanics for highly active (K3-K4) unilateral below-knee prosthesis users. Future work could investigate the preference and potential benefit of a prosthesis with a toe joint with lower-mobility individuals.

CHAPTER 4

Unilateral Transtibial Prosthesis Users Load Their Intact Limb More Than Their Prosthetic Limb During Sit-to-Stand, Squatting, and Lifting

4.1 Summary

Lower limb prosthesis users exhibit high rates of joint pain and disease, such as osteoarthritis, in their intact limb. Overloading of their intact limb during daily activities may be a contributing factor. Limb loading biomechanics have been extensively studied during walking, but fewer investigations into limb loading during other functional movements exist. The purpose of this study was to characterize the lower limb loading of transtibial prosthesis users during three common daily tasks: sit-to-stand, squatting, and lifting. Eight unilateral transtibial prosthesis users performed sit-to-stand (from three chair heights), squatting, and lifting a 10 kg box. Peak vertical ground reaction forces and peak knee flexion moments were computed for each limb (intact and prosthetic) to characterize limb loading and asymmetry. Ranges of motion of the intact and prosthetic ankles were also quantified. Users had greater peak ground reaction forces and knee flexion moments in their intact limb for all tasks ($p < 0.02$). On average, the intact limb had 36–48% greater peak ground reaction forces and 168–343% greater peak knee flexion moments compared to the prosthetic limb. The prosthetic ankle provided <10° of ankle range of motion for all tasks, less than half the range of motion provided by the intact ankle. Prosthesis users overloaded their intact limb during all tasks. This asymmetric loading may lead to an accumulation of damage to the intact limb joints, such as the knee, and may contribute to the development of osteoarthritis. Prosthetic design and rehabilitation interventions that promote more symmetric loading should be investigated for these tasks.

4.2 Background

Lower limb prosthesis users are a diverse population encompassing individuals of all ages, activity levels, and lifestyles and with varying causes of limb loss. However, there are significant impacts of being a prosthesis user that are prevalent throughout the population including challenges to mobility, quality-of-life, and long-term health.

Many unilateral lower limb prosthesis users (LLPUs) develop secondary physical conditions, such as low back pain, osteoarthritis, and osteoporosis [4]. Specifically, they are at greater risk of musculoskeletal injury, joint degeneration, and pain in their intact (non-prosthetic) limb compared to the general population [4]. Previous observational studies have reported unilateral LLPUs are more likely to develop knee and hip osteoarthritis and have a high incidence of pain in the joints of their intact limb. The prevalence of osteoarthritis in LLPUs is broadly estimated to be between 16 and 60% for the knee [92–96] and 14% for the hip [95] compared to 2–11% of the general population experiencing knee or hip osteoarthritis [94,95]. Intact limb joint pain is also a primary concern for long-term prosthesis users, with over half (55%) reporting knee pain and 23% reporting hip pain [97]. These findings of increased joint pain and osteoarthritis among LLPUs remain even when age, gender, and body mass are controlled [93,94].

Previous work has proposed the increased pain and injury to the intact limb potentially comes from LLPUs employing altered movement strategies during daily tasks that overload their intact limb relative to their prosthetic limb [4,19,98]. During walking, LLPUs often exhibit asymmetrical motion (e.g., spatiotemporal parameters, joint kinematics), joint moments, and ground reaction forces, where the intact limb bears more load than the prosthetic limb [99]. LLPUs have increased intact limb stance time indicating they spend more time on their intact limb than prosthetic limb while walking [100,101]. When comparing peak vertical ground reaction forces during walking, the intact limb experiences up to 21% more force than the prosthetic limb depending on the type of prosthesis used [100,102–105]. In contrast, individuals without limb loss display <10% asymmetry in peak force between limbs during walking [100,103,106].

Repeated elevated mechanical loading on the intact limb joints can cause tissue damage to accumulate over time and is concerning as long-term exposure can lead to the degeneration of weight-bearing joints and joint pain [107–109]. While the greater susceptibility of LLPUs to secondary musculoskeletal conditions such as osteoarthritis is multifactorial, the increased loads experienced by the joints of the intact limb over long periods of time is likely a primary contributor.

While there exists considerable investigation into LLPU performance and lower limb loading during walking, less work has investigated user performance during other activities of daily living. Activities such as standing up from a chair, picking up an item off the floor, and squatting down are everyday movements that are essential for independent living, but are challenging tasks for many LLPUs [7,10–12]. Sit-to-stand is an important and biomechanically demanding task that LLPUs and individuals without limb loss do over 50 times per day [110]. While some LLPUs struggle to stand up from a chair independently, those who can have been shown to complete the sit-to-stand motion asymmetrically by having greater ground reaction forces under their intact limb compared to their prosthetic limb [19]. Increased intact limb joint moments and lumbar loads compared to individuals without limb loss have also been observed [17–19,111].

The general motion of squatting down or lifting an object is also common in daily life and often required for recreation, exercise, and in some occupations. Squatting and lifting involve lowering and raising one's center of mass through coordinated flexion and extension of the lower limb joints. A proportion of LLPUs cannot squat, and even those with high levels of functional ability often find it difficult [8,10–12]. Lifting has been studied extensively in individuals without limb loss as jobs that involve strenuous lifting have high rates of musculoskeletal injury. However, there exists little investigation into how LLPUs perform squatting or lifting. The limited existing work focuses on low back muscle activation in occupational lifting tasks [112–114] or presents case studies of one LLPU performing a weighted back squat [115,116]. While lifting and squatting are common daily tasks performed frequently by LLPUs, there exists no characterization of the lower limb loading of this population during these tasks.

The objective of this study was to characterize the lower limb loading of unilateral transtibial prosthesis users during sit-to-stand, squatting, and lifting. We hypothesized LLPUs would load their intact limb more than their prosthetic limb, as indicated by greater peak ground reaction forces and knee flexion moments in the intact limb. We also explore user and prosthesis performance to gain insight into why users have challenges with these movements and elucidate directions for future interventions.

4.3 Methods

We analyzed the lower limb loading of LLPUs completing sit-to-stand, squatting, and lifting while wearing their clinically prescribed prosthesis. Participants completed these tasks as part of a larger data collection that also included reaching and lunging. Through reviewing the scientific literature and interviewing local LLPUs, physicians, and prosthetists, we identified this larger set as common daily tasks that LLPUs often avoid or find challenging. In this study, we focused our analysis on sit-to-stand, squatting, and lifting. These are bilateral movements in which individuals without limb loss typically move and load their lower limbs symmetrically. Lunging and reaching will form the basis of a separate study due to the more asymmetrical nature of these movements.

4.3.1 Participants

A convenience sample of eight unilateral transtibial LLPUs (7 M/1 F, age: 39.4 ± 13.9 years, mass: 85.8 ± 14.1 kg, height: 1.78 ± 0.13 m) was recruited for this study (Table 4.1). Participants were included if they were at least four months post-surgery, could walk without an aid, and had no recent injuries that impacted mobility. All participants provided written informed consent according to Vanderbilt Institutional Review Board approved procedures.

Table 4.1 Individual and mean (± standard deviation) participant demographics for unilateral transtibial prosthesis users

Participant ID	Sex	Age (years)	Body Mass (kg)	Height (m)	Years Since Limb Loss	K-Level	Cause of Limb Loss	Daily-Use Prosthesis
1	M	30	86.9	1.77	7.5	4	Traumatic	Fillauer Formula
2	M	26	76.2	1.74	8.5	4	Traumatic	Fillauer AllPro
3	M	52	102.8	1.87	10.2	4	Traumatic	Fillauer AllPro
4	M	32	88.5	1.86	2.0	4	Traumatic	Blatchford Echelon
5	M	40	69.5	1.76	9.0	4	Traumatic	Össur Vari-Flex
6	F	42	68.6	1.53	4.0	4	Traumatic	Össur Pro-Flex Pivot
7	M	66	107.0	1.78	21.0	4	Traumatic	Blatchford Elan
8	M	27	86.6	1.97	0.5	4	Traumatic	Fillauer AllPro
Mean ± SD		39.4 ± 13.9	85.8 ± 14.1	1.78 ± 0.13	7.8 ± 6.4			

4.3.2 Experimental Protocol

Prosthesis users wore their prescribed prosthesis (Table 4.1) and their preferred footwear during data collection. Ground reaction force (GRF) data were recorded under each foot at 1000 Hz using in-ground force plates (AMTI, Watertown, MA, USA) and lower-body kinematics were recorded at 200 Hz using a 10-camera motion capture system (Vicon, Oxford, UK). Passive reflective markers were affixed to the trunk (6), pelvis (6), thighs (8), knees (4), and shanks (8). On the intact limb, markers were placed on the medial and lateral malleoli (2), calcaneus (3), first and fifth metatarsal base and head (4), and the second toe (1). On the prosthetic limb, the medial and lateral malleoli markers were placed on the prosthesis at the same height as the malleoli markers on the intact limb. The prosthetic foot markers were mirrored from the shoe of the intact limb.

Participants were instructed to complete the tasks in the way that felt most comfortable to them. They were not instructed to complete the tasks at any specific pace or with any specific movement pattern. Foot position was not controlled besides the constraint that each foot had to remain on a separate force plate. If a participant could not complete a task, this was documented before proceeding to the next task. For sit-to-stand, data were collected as the participant stood up from a chair of standard height (48 cm) that had a backrest, no armrests, and no padding [117,118]. Two more variations of the sit-to-stand task were performed at lower chair heights of 38 cm and 28 cm. Standing up from a low chair was included in this protocol because it was specifically mentioned as being difficult by prosthesis users and clinicians during interviews. Participants did not push on the chair with their arms to assist them in standing up. For squatting, participants started from standing with a foot under each shoulder and were instructed to "squat down to a comfortable level" before returning to standing. The lifting task required participants to pick up a 10 kg box (27 × 27 × 40 cm) from the floor in front of them and return to standing. The parameters of this task were chosen to provide a simple and reasonable representation of lifts encountered in daily life. Each task was repeated three times [117] resulting in fifteen total trials. Tasks were completed in the order listed and breaks between tasks were provided as needed.

After each task, participants were asked to verbally rate effort, stability, and comfort on a scale of 0 to 10. For perceived effort, a rating of 0 indicated "the task took no effort" and a rating of 10 indicated "the task took maximum effort." For stability and comfort, a rating of 0 indicated the participant felt "completely unstable" or "completely uncomfortable" and a rating of 10 indicated the participant felt "completely stable" or "completely comfortable" doing the task.

4.3.3 Data Processing and Analysis

We computed two complementary metrics to characterize the lower limb loading of participants: vertical ground reaction forces (GRF) and knee flexion moments. The vertical GRF is the primary direction of the force under the feet during these tasks [117], and it is commonly used as an indicator of the overall loading strategy of LLPUs during activities of daily living [17,21,119]. Large asymmetries in GRF during a bilateral task indicate participants are bearing more weight on one limb over the other, which often contributes to increased moments and contact forces in the joints of the overloaded limb [24,111,120,121]. Knee moments have been used as an indicator of loading of the internal structures of the knee joint [20,122–124]. The sagittal plane knee moment, often reported as the external knee flexion moment, has been shown to correlate to both modeled and direct measurements of forces within the knee [125,126]. Especially for bilateral tasks that require a high degree of knee flexion (e.g., sit-to-stand, squatting), an increase in knee flexion moment is indicative of an increase in knee joint contact forces both in the tibiofemoral and patellofemoral spaces [120,126,127].

We also computed the range of motion (ROM) of the intact and prosthetic ankle during each task. Ankle ROM was computed as a secondary metric to characterize the performance of the prostheses during these tasks. For individuals without limb loss, sit-to-stand, squatting, and lifting typically involve a large amount of ankle flexion [128], which most ankle-foot prostheses lack. Characterizing the prosthesis ROM could help explain user challenges, limb loading asymmetries, and elucidate directions for future prosthetic interventions.

GRF data and marker trajectories were low-pass filtered at 15 Hz and 8 Hz, respectively, before analysis. The start and end of each task repetition was determined using the vertical movement of the marker placed on the C7 vertebrae of participants (with approximately 0.5 cm of increase or decrease in position used as a threshold of movement). For sit-to-stand, only the standing up portion of the movement is included in this analysis. This task started when the participant began moving from seated and ended when they were standing. The squatting task started when the participant began to lower and ended when they returned to standing upright. Similarly, lifting began when the participant started bending down and ended when they returned to standing holding the 10 kg box.

Peak vertical GRF under each limb was computed for each repetition before being averaged across the three repetitions of each task. For a small number of lifting trials, some participants shifted their weight from one foot to the other as they set up to complete the task, which resulted in a brief peak in GRF. In these instances, force data were manually cropped to ensure that peak GRFs were only extracted while the task was actually being completed. GRF data were normalized by participant body weight. We used Visual3D (C-motion, Germantown, MD, USA) to create an eight-segment model (trunk, pelvis, two thighs, two shanks, and two feet). Segment inertial properties were set to the default values built into the software. Inertial properties of the prosthetic limb were assumed to be identical to the intact limb as previous work has observed this has minimal impact on knee moments during stance [129]. We used this model and inverse dynamics to compute the net external knee joint moment in the sagittal plane. We report this as the knee flexion moment with flexion defined as positive. Peak knee flexion moment was computed for each task repetition then averaged across repetitions. Moment data were normalized by participant body weight and height before being averaged across participants.

Ankle angle was computed in Visual3D as the angle between the shank segment and the rearfoot segment in the sagittal plane for each lower limb. The motion of the rearfoot segment was tracked by the movement of three markers on the calcaneus for almost all trials. For a small number of sit-to-stand trials from the lower chairs ($N = 5$), a calcaneus marker was occluded by the chair so the model of the rearfoot was altered to include the markers on the base of the first and fifth metatarsals in addition to the calcaneus markers. A sensitivity analysis revealed the effect of using these alternate markers was negligible (<1° change in results). Ankle ROM for each limb was computed as the difference between the minimum and maximum ankle angle. This was computed for each repetition before averaging across the three repetitions for each task.

Descriptive statistics (mean ± standard deviation) were computed, and the data were screened for normality via a Shapiro-Wilk test. Following this, differences in peak vertical GRF, peak knee flexion moment, and ankle ROM between the intact and prosthetic limb for each task were assessed using a paired t-test (normally distributed) or Wilcoxon signed-rank test (non-normally distributed) with an alpha level of 0.05.

4.3.4 Control Data

Eight individuals without limb loss were recruited as control participants (5 M/3 F, age: 35.9 ± 9.7 years, mass: 78.4 ± 14.6 kg, height: 1.77 ± 0.09 m). They were tested with the same protocol to provide a reference for interpretation of LLPU results (participant details in Sup. Table 4.3). This dataset provides a comparison for the exact tasks performed by the LLPU participants in this study. For control participants, peak GRF, peak knee flexion moment, and ankle ROM were compared between their dominant and non-dominant limb. The dominant limb was defined as the self-reported leg they use to kick a ball [130].

4.4 Results

Our core analysis focuses on sit-to-stand from a standard chair height (48 cm), squatting, and lifting a 10 kg box. All participants were able to complete three repetitions of these three core tasks. A brief analysis comparing sit-to-stand from three chair heights (48 cm, 38 cm, 28 cm) is also included at the end of this section.

4.4.1 Ground Reaction Force and Knee Flexion Moment

Peak GRF and peak knee flexion moment were significantly greater in the intact limb compared to the prosthetic limb during sit-to-stand from a standard chair height, squatting, and lifting a 10 kg box ($p < 0.01$ for all three tasks, Table 4.2). On average, peak vertical GRFs for the intact limb were greater than the prosthetic limb by 36% during sit-to-stand, 39% during squatting, and 39% during lifting (Fig. 4.1, Table 4.2). Peak knee flexion moments in the intact limb were greater than the prosthetic limb by 343% during sit-to-stand, 218% during squatting and, 168% during lifting (Fig. 4.2, Table 4.2). For control participants, peak GRFs between the dominant and non-dominant limb were typically within 5% ($p > 0.1$; Sup. Fig. 4.7, Sup. Table 4.4) and peak knee flexion moments between limbs were within 3% ($p > 0.4$; Sup. Fig. 4.8, Sup. Table 4.4).

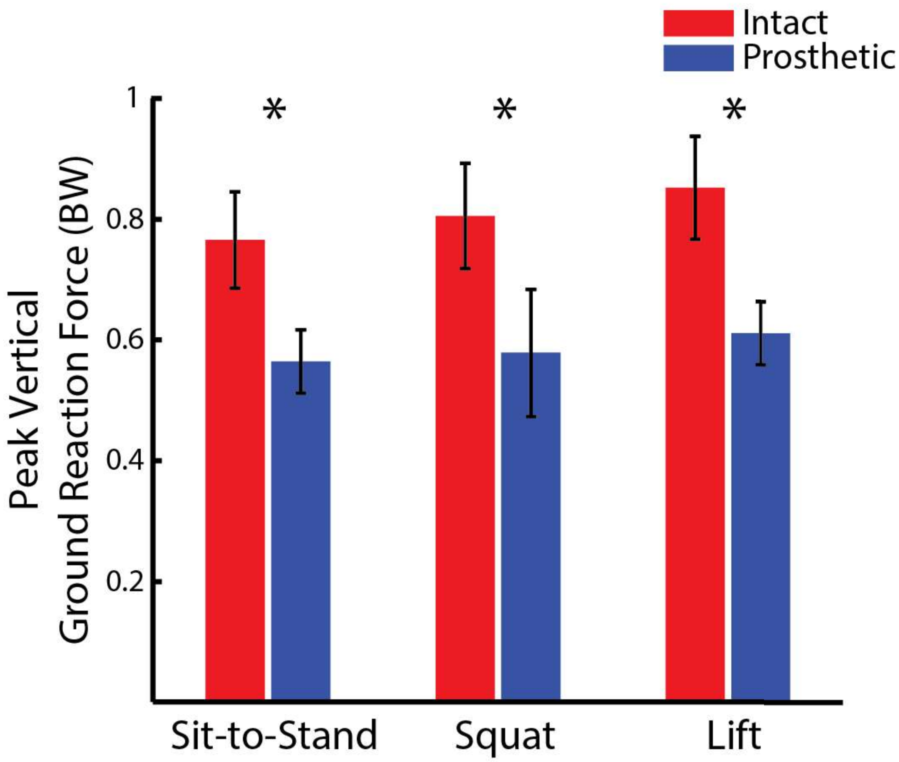


Figure 4.1 Peak vertical ground reaction force under each limb during sit-to-stand (48 cm), squatting, and lifting ($N = 8$). Force is normalized to participant body weight (BW). *A significant difference was detected between the intact limb (red) and the prosthetic limb (blue) for all tasks.

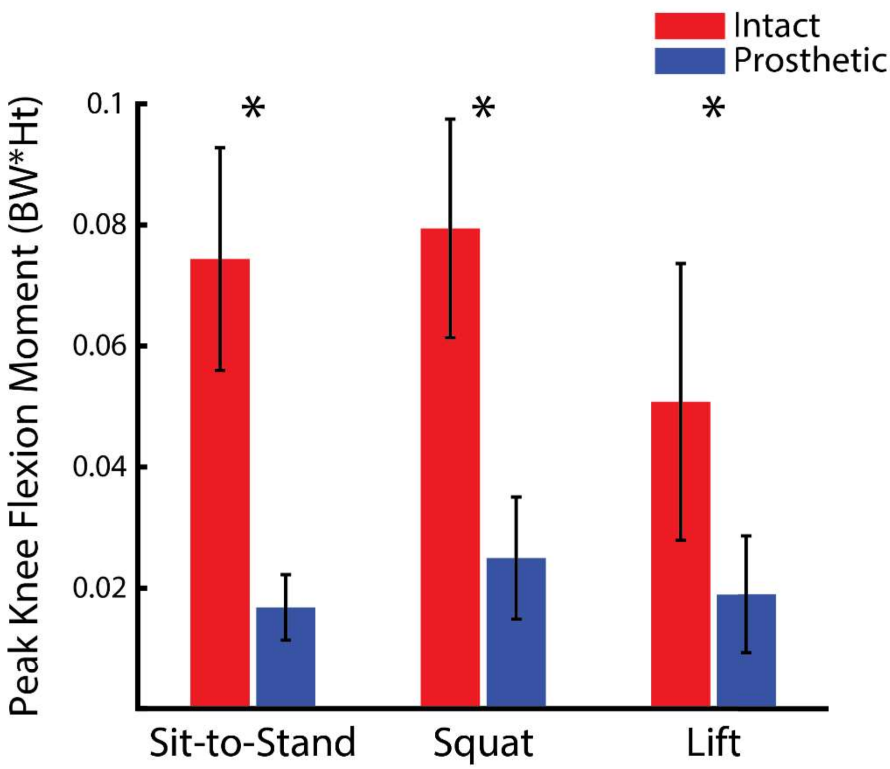


Figure 4.2 Peak knee flexion moments during sit-to-stand (48 cm), squatting, and lifting ($N = 8$). Moment is scaled by participant body weight (BW) and height (Ht). *A significant difference was detected between the intact limb (red) and the prosthetic limb (blue) for all tasks.

Representative time-series plots and individual participant results for peak GRF and peak knee flexion moment can be seen in Figures 4.3 and 4.4, respectively. All participants overloaded their intact limb for all three tasks. Every participant had a greater peak GRF (Fig. 4.3) and peak knee flexion moment (Fig. 4.4) in their intact limb relative to their prosthetic limb. Most participants continually put more force through their intact limb and had an increased knee flexion moment throughout the duration of each task, not just at the instance of peak force or moment. Corresponding time-series and participant-specific plots for control participants are provided in the Supplementary Materials (Sup. Figs. 4.9 and 4.10).

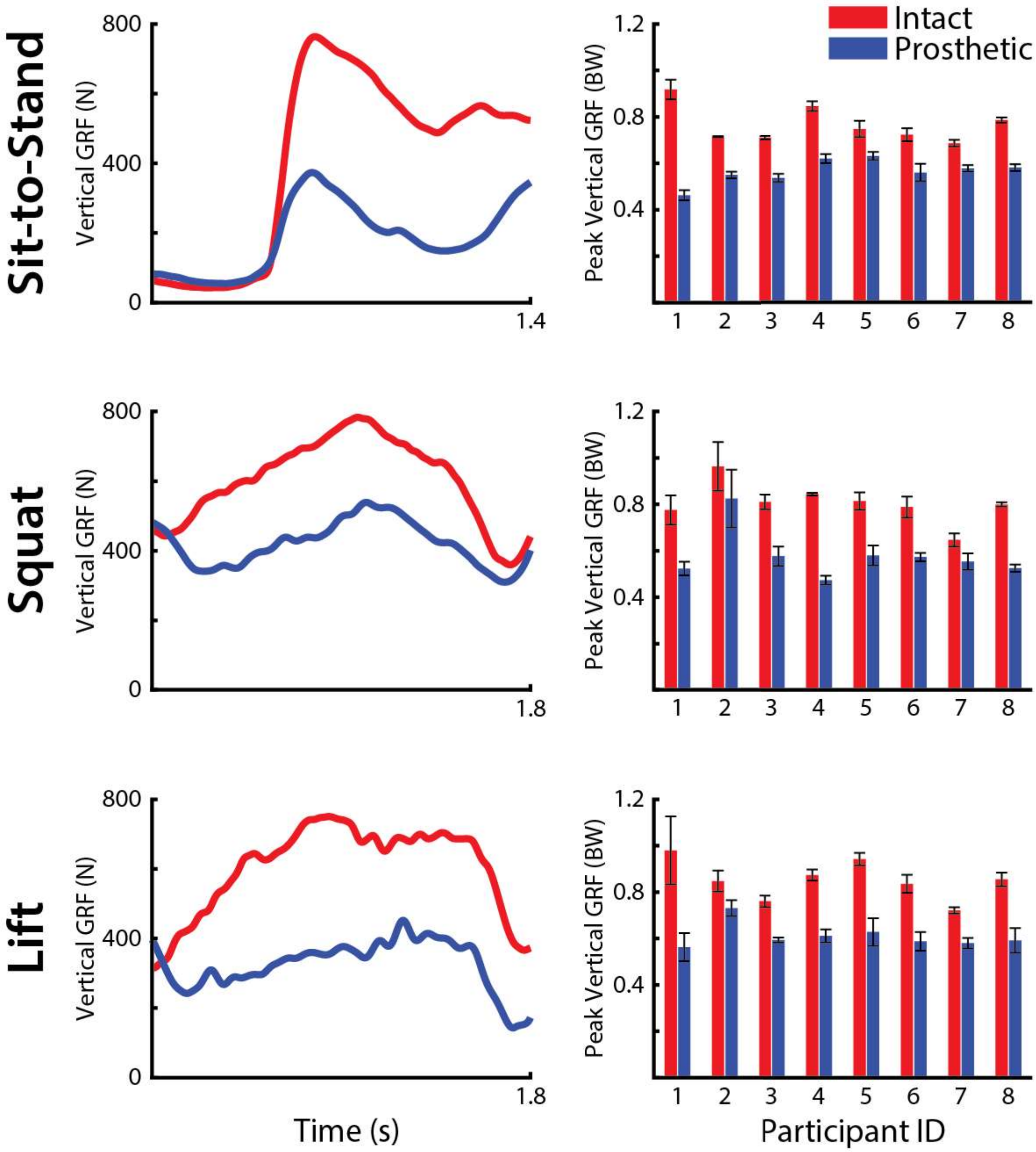


Figure 4.3 Left: Representative time-series data of the vertical ground reaction force (GRF) during sit-to-stand (48 cm), squatting, and lifting. Right: Participant-specific averages of peak vertical ground reaction force during each task. Peak force values were normalized to bodyweight (BW).

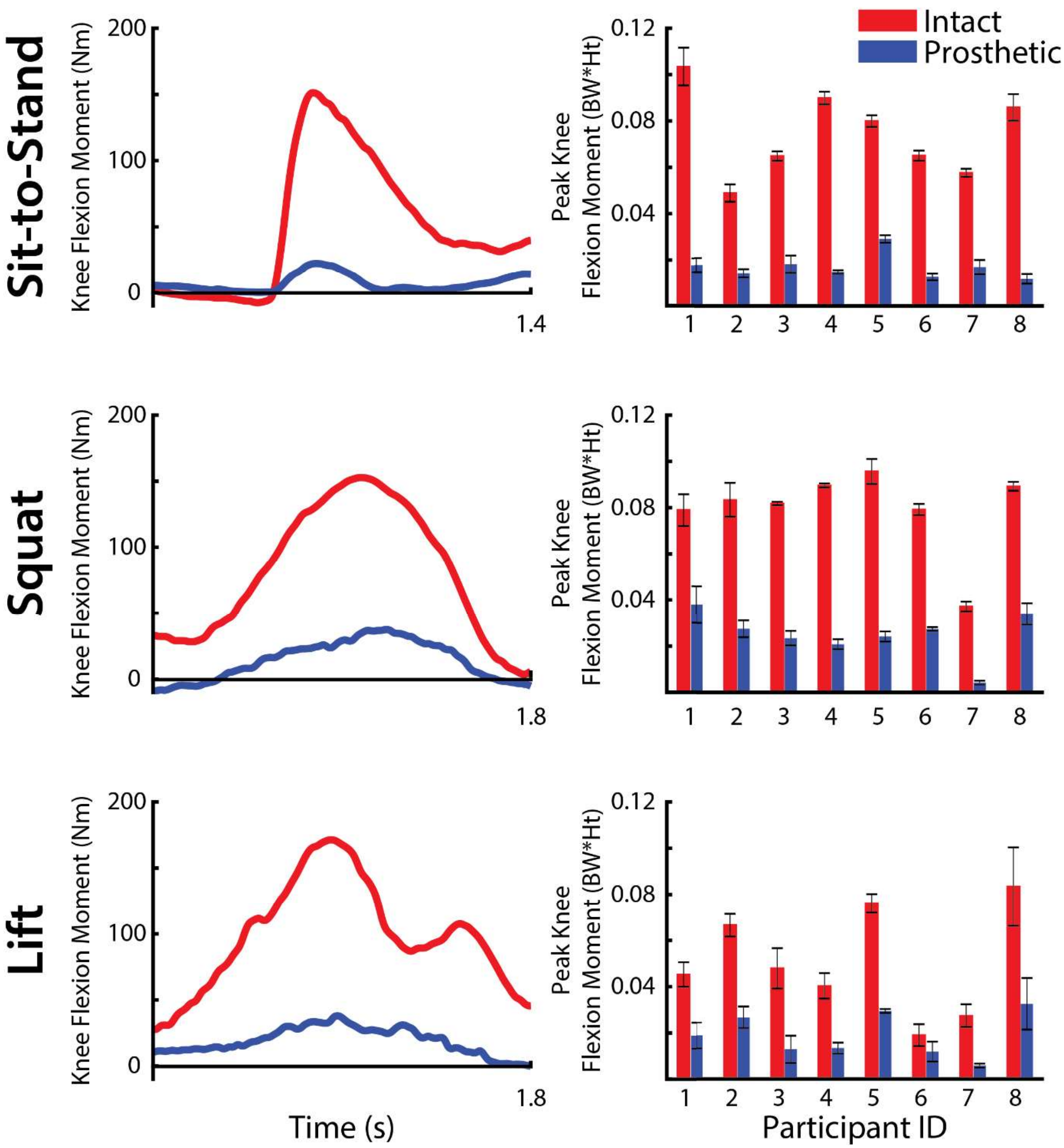


Figure 4.4 Left: Representative time-series data of the knee flexion moment during sit-to-stand (48 cm), squatting, and lifting. Right: Participant-specific averages of peak knee flexion moment during each task. Peak moment values were normalized to bodyweight (BW) and height (Ht).

4.4.2 Ankle Range of Motion

On average, the intact ankle ROM of LLPUs was 13°, 25°, and 21° during sit-to-stand, squatting, and lifting, respectively. This is significantly more ROM than the prosthetic ankle provided which was only 6–8° for these tasks ($p < 0.001$; Fig. 4.5, Table 4.2). There was no significant difference in ankle ROM between the limbs of control participants ($p > 0.08$). Their ankle ROM was approximately 19°, 32°, and 33° during sit-to-stand, squatting, and lifting, respectively (Sup. Fig. 4.11, Sup. Table 4.4).

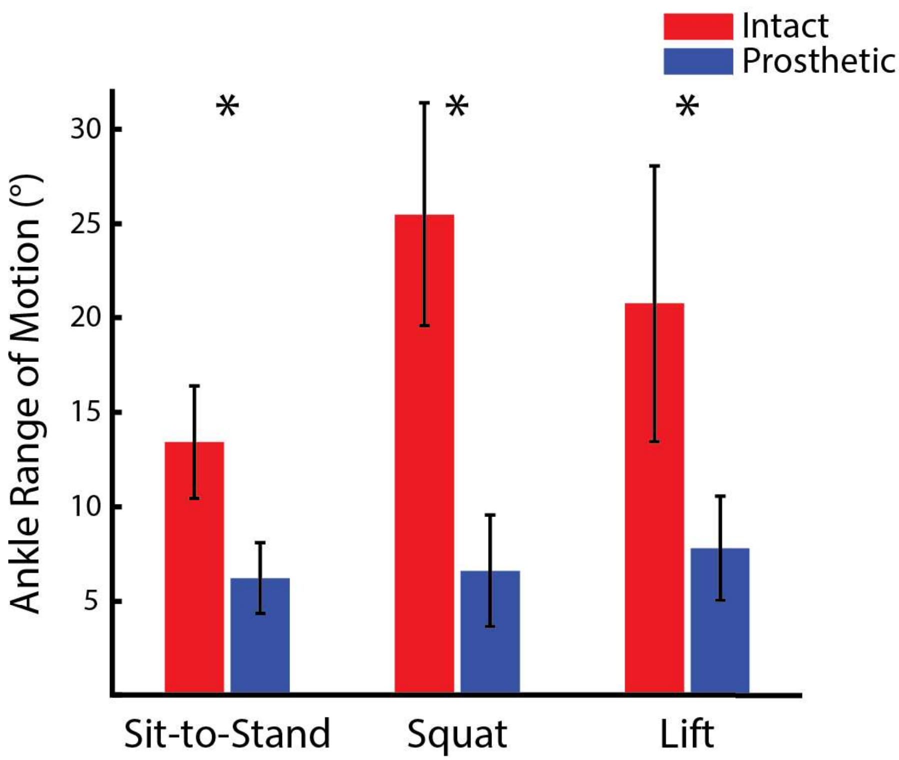


Figure 4.5 Ankle range of motion during sit-to-stand (48 cm), squatting, and lifting ($N = 8$) *A significant difference was detected between the intact limb (red) and the prosthetic limb (blue) for all tasks.

4.4.3 Participant Ratings of Task Difficulty

When rating their perceived effort on a scale of 0 to 10, participants reported sit-to-stand from a standard chair height, squatting, and lifting a 10 kg box required little effort indicated by a maximum rating of 2 (with 0 indicating "the task took no effort"). The exception to this was P7, the oldest participant (66 years old), who gave sit-to-stand from a standard chair height an effort rating of 3 and lifting a rating of 6. Participant ratings of stability and comfort tracked with their ratings of effort indicating they also felt stable and comfortable during these tasks. All stability and comfort ratings were >7 (with 10 indicating they felt "completely stable" or "completely comfortable"). All participants' individual ratings are provided in the Supplementary Material (Sup. Table 4.5).

4.4.4 Sit-to-Stand across Chair Heights

When testing sit-to-stand from the two lower chair heights, all participants were able to complete these tasks except one. Participant 7 was unable to stand up out of the lowest chair (28 cm) so his biomechanics data for that task were not included in analysis. While participants reported standing up from a standard chair height as taking little effort, standing up out of the lowest chair was reported as challenging (Sup. Table 4.5). The majority of LLPUs gave the effort required to stand up from the lowest chair a score of 5 or more on the scale of 0 to 10 (with 10 being "the task took maximum effort"). Participants also reported feeling unstable and uncomfortable while standing up out of the lowest chair.

The significant difference in GRF, knee flexion moment, and ankle ROM observed during sit-to-stand from a standard height chair was also observed for the two lower chairs tested (Fig. 4.6, Table 4.2). For the low chair (38 cm) and the lowest chair (28 cm), LLPUs put 44% and 48% more force through their intact limb ($p < 0.001$). Peak knee flexion moments were 298% and 324% greater in the intact limb for the low and lowest chairs ($p < 0.02$). The average ROM of the intact ankle during these two tasks was 18° and 21° while only 7° of ROM was provided by the prosthetic ankle ($p < 0.01$). Control participants had no significant difference in peak GRF, peak knee flexion moment, or ankle ROM between limbs at any chair height ($p > 0.4$; Sup. Fig. 4.12, Sup. Table 4.4).

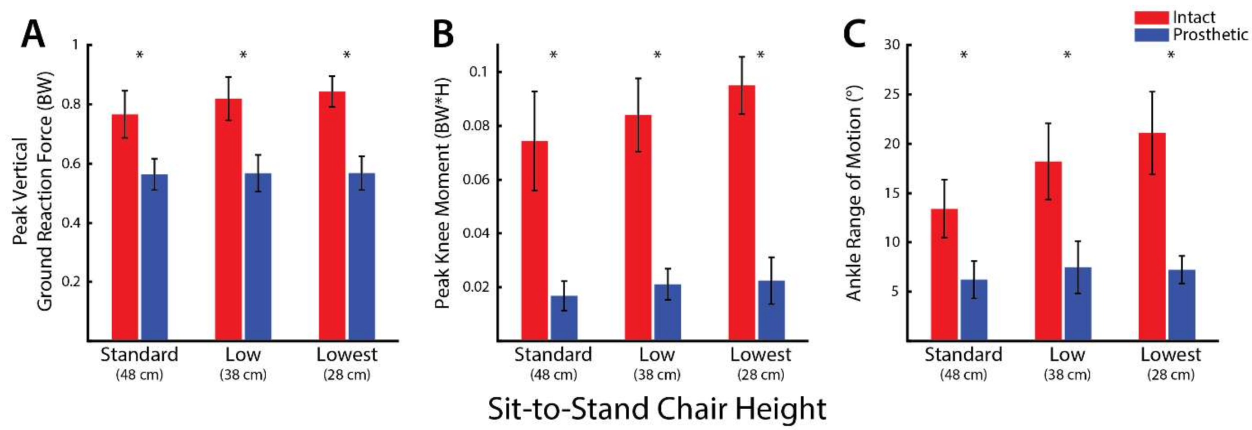


Figure 4.6 (A) Peak vertical ground reaction force, (B) peak knee flexion moment, and (C) ankle range of motion during sit-to-stand from three chair heights: Standard (48 cm), Low (38 cm), and Lowest (28 cm). Intact limb values are in red and prosthetic limb values are in blue. Participant 7 could not complete the Lowest condition, so the data presented for that task is an average from $N = 7$. The Standard and Low tasks are averages from $N = 8$. Force was normalized to body weight (BW) and moment was normalized to body weight and height (Ht). *A significant difference was detected between the intact limb (red) and the prosthetic limb (blue) for all tasks.

Table 4.2 Mean (± standard deviation) peak vertical ground reaction force, peak knee flexion moment, and ankle range of motion for the intact and prosthetic limb of LLPUs. Force was normalized to body weight (BW) and moment was normalized to body weight and height (Ht). A significant difference was detected between limbs for all metrics and all tasks.

	Peak Vertical Ground Reaction Force (BW)			**Peak Knee Flexion Moment (BW*Ht)**			**Ankle Range of Motion (°)**		
	Intact Limb	Prosthetic Limb	P-value	Intact Limb	Prosthetic Limb	P-value	Intact Ankle	Prosthetic Ankle	P-value
Sit-to-Stand (Standard, 48 cm)	0.77 ± 0.08	0.56 ± 0.05	0.001	0.074 ± 0.018	0.017 ± 0.005	0.008	13.4 ± 3.0	6.2 ± 1.9	<0.001
Squat	0.81 ± 0.09	0.58 ± 0.11	0.008	0.079 ± 0.018	0.025 ± 0.010	0.008	25.5 ± 5.9	6.6 ± 3.0	<0.001
Lift	0.85 ± 0.09	0.61 ± 0.05	0.008	0.051 ± 0.023	0.019 ± 0.001	<0.001	20.8 ± 7.3	7.8 ± 2.8	<0.001
Sit-to-Stand (Low, 38 cm)	0.82 ± 0.07	0.57 ± 0.06	<0.001	0.084 ± 0.014	0.021 ± 0.006	0.008	18.2 ± 3.8	7.5 ± 2.7	0.008
Sit-to-Stand (Lowest, 28 cm)	0.84 ± 0.05	0.57 ± 0.06	<0.001	0.095 ± 0.011	0.022 ± 0.009	0.016	21.1 ± 4.2	7.2 ± 1.4	<0.001

4.5 Discussion

Unilateral transtibial LLPUs asymmetrically load their lower limbs during sit-to-stand, squatting, and lifting. Users had greater peak GRFs (Fig. 4.1) and peak knee flexion moments (Fig. 4.2) in their intact limb compared to their prosthetic limb. This overloading of the intact limb was seen for every study participant and across the duration of the tasks tested (Figs. 4.3 and 4.4). During these tasks, the ROM of the prosthetic ankle was significantly less than the intact ankle for LLPUs (Fig. 4.5). The greater peak GRF, peak knee flexion moment, and ankle ROM in the intact limb observed during sit-to-stand from a standard chair height was also observed during sit-to-stand from two lower chairs (Fig. 4.6).

The current study confirms prior experiments that measured increased vertical GRFs and knee flexion moments in the intact limb compared to the prosthetic limb of LLPUs during sit-to-stand [17,24,111,121] and builds upon this prior analysis by showing these loading asymmetries also exist during squatting and lifting. This is the first study, to our knowledge, characterizing the lower limb loading of a group of LLPUs during squatting and lifting which are essential daily tasks. In addition to asymmetrical loading, the intact limb of LLPUs generally exhibited higher peak GRF and knee flexion moments than those experienced by either limb of control participants (Table 4.2 and Sup. Table 4.4). Overloading the intact limb repeatedly during these common daily movements could result in joint damage accumulation and contribute to the development of joint degeneration and pain over time [109].

The increased load LLPUs put on their intact limb and specifically their knee joint during daily tasks may contribute to the high rates of joint degeneration and pain observed in the LLPU population. Previous research in walking and other tasks has shown increases in GRFs and knee moments correlate to increased knee contact forces, loads on the cartilage in the knee, and prevalence of cartilage degeneration [120,123,131,131,132]. Observational studies have suggested that high knee loads are a risk for the initiation and progression of osteoarthritis [107,133,134]. These findings support the association between the mechanical loading of the knee joint and the development of osteoarthritis. Overloading of the intact limb during walking has been proposed to be a contributor to the high rates of joint pain and osteoarthritis observed in LLPUs. This study highlights the overloading of the intact limb during other common daily movements, which could be another contributor to the increased mechanical loading of the intact limb joints and the resulting joint degeneration and pain experienced by many LLPUs.

The results of this study indicate that LLPUs are overloading their intact limb, even during tasks they perceive as easy and comfortable. Thus, they may be accumulating damage to the joints of their intact limb without realizing it. The LLPUs in this study all have a high level of functional ability (all K4) and on average, are relatively young (39.4 ± 13.9 years). All participants were able to complete all tasks included in this analysis (except P7, who was unable to stand up from the lowest chair) with minimal effort (excluding standing up from a low chair). Sit-to-stand, squatting, and lifting are tasks known to be challenging for many LLPUs with a significant number of users unable to stand up from a chair independently or pick up an item off the floor [10]. Even though the users in this study did not find most tasks challenging, on average they had 36–48% greater peak GRFs and 168–343% greater peak knee flexion moments in their intact limb compared to their prosthetic limb. Additionally, because the LLPUs in this study are relatively young, they will likely be prosthesis users for decades. Frequent overloading of the intact limb during daily tasks throughout their lifetime may further increase their risk of intact limb joint pain, knee osteoarthritis, and other musculoskeletal injuries.

Although LLPUs are a heterogenous population, often exhibiting individualized movement strategies [40,84], the present study found that overloading of the intact limb during daily tasks was ubiquitous for all eight participants (Figs. 4.3 and 4.4). These participants had similar functional ability, but used various prescribed prostheses and differed in age, mass, height, and time using a prosthesis (Table 4.1). Despite these differences, all participants relied more on their intact limb than their prosthetic limb when completing sit-to-stand, squatting, and lifting. The ubiquitous overloading of the intact limb observed in this study suggests that interventions to promote more symmetric loading between limbs during these tasks may be broadly applicable for LLPUs.

During all tasks, the prosthetic ankle of LLPUs provided a limited amount of ankle ROM (Figs. 4.5 and 4.6). Sit-to-stand, squatting, and lifting are all tasks known to involve a high degree of biological ankle flexion [128]. Our control participants had 19° of ankle ROM during sit-to-stand and >30° during squatting and lifting (Sup. Figs. 4.11 and 4.12, Sup. Table 4.4). In contrast, the prosthetic ankle provided <10° of ankle ROM for all tasks (Figs. 4.5 and 4.6, Table 4.2). Interestingly, the intact (biological) ankle of prosthesis users seems to also have reduced ROM compared to the ankles of controls. Even so, the intact ankle of LLPUs had more than twice the ROM of their prosthetic ankle. The large difference in ROM between the intact and prosthetic ankle might be a contributing factor to why prosthesis users overload their intact limb. Inadequate dorsiflexion may hinder users from comfortably positioning their prosthetic limb and trusting its ability to handle loading during these tasks. A prosthetic ankle-foot with increased dorsiflexion capabilities might allow LLPUs to position their lower limbs more symmetrically and put more force through their prosthetic limb while standing up or squatting down, but this requires further investigation.

Future work should investigate interventions that promote symmetric loading during sit-to-stand, squatting, and lifting to increase the safety and ability of LLPUs to complete these tasks. Interventions that involve lower limb muscle strengthening or task-specific training should be considered in addition to prosthetic device design approaches. Future work should also investigate lower limb loading during daily tasks in a broader population of LLPUs. One limitation of this study is all participants are highly active, unilateral transtibial LLPUs. Less active prosthesis users who find sit-to-stand, squatting, and lifting challenging or even impossible may exhibit different loading asymmetries and overall movement patterns, although we expect they would still accomplish these tasks by overloading their intact limb. Additionally, we focused on a limited set of biomechanics metrics. We characterized limb loading using peak vertical GRFs and knee flexion moments. We did not characterize frontal plane knee moments, which are often used as an indicator of knee loading and osteoarthritis risk during walking. During bilateral tasks (like the tasks presented in this study), frontal plane knee moments are relatively small due to a less dynamic shift in the center of pressure from side to side [126,127]. Instead, increases in the sagittal plane knee moment have been shown to correlate to increased knee contact forces during these tasks [120,126]. While we assessed lower limb loading and ankle ROM, LLPUs may exhibit other compensation strategies during these tasks, such as altered trunk mechanics. Future research should build on this work to further characterize LLPU biomechanics during daily tasks.

4.6 Conclusion

Unilateral transtibial LLPUs asymmetrically load their lower limbs during sit-to-stand, squatting, and lifting by overloading their intact limb compared to their prosthetic limb. The increased load on the intact limb was evident through significantly greater peak vertical GRFs and knee flexion moments. This asymmetric loading could be a contributing factor to the increased risk of musculoskeletal injury, joint degeneration, and pain in the intact limb of LLPUs. During all tasks, the prosthetic ankle provided significantly less ankle ROM than the intact ankle. Future work should investigate rehabilitation and prosthetic device interventions that promote symmetric loading to determine how this impacts user performance during these tasks.

4.7 Supplementary Material

Supplementary Table 4.3 Individual and mean (± standard deviation) participant demographics for control participants without limb loss.

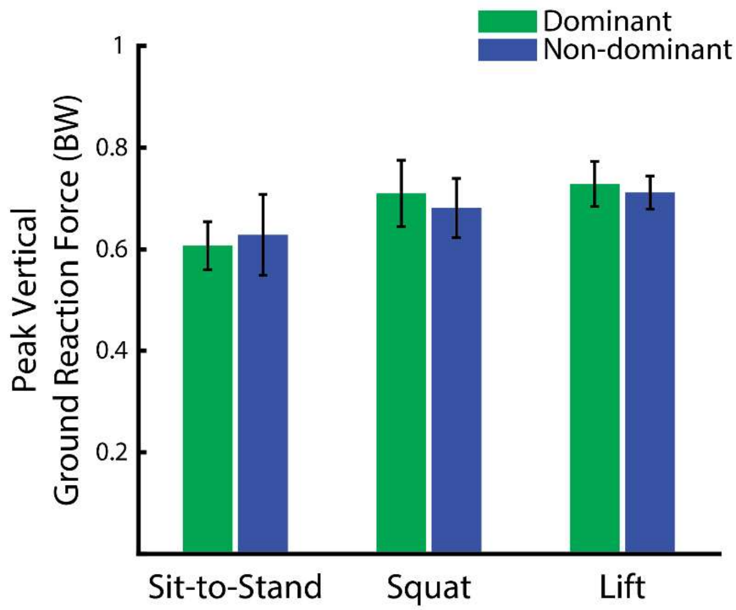
Control Participant ID	Sex	Age (years)	Body Mass (kg)	Height (m)	Dominant Limb
1	M	30	94.4	1.85	Right
2	M	26	75.5	1.75	Right
3	M	34	83.1	1.73	Right
4	M	36	78.0	1.79	Right
5	F	58	66.3	1.62	Right
6	F	34	50.9	1.70	Right
7	F	31	95.4	1.79	Right
8	M	38	83.2	1.90	Right
Mean ± SD		35.9 ± 9.7	78.3 ± 14.6	1.77 ± 0.09	

Supplementary Table 4.4 Mean (± standard deviation) peak vertical ground reaction force, peak knee flexion moment, and ankle range of motion for the dominant and non-dominant limbs of controls. Force was normalized to body weight (BW) and moment was normalized to body weight times height (Ht)

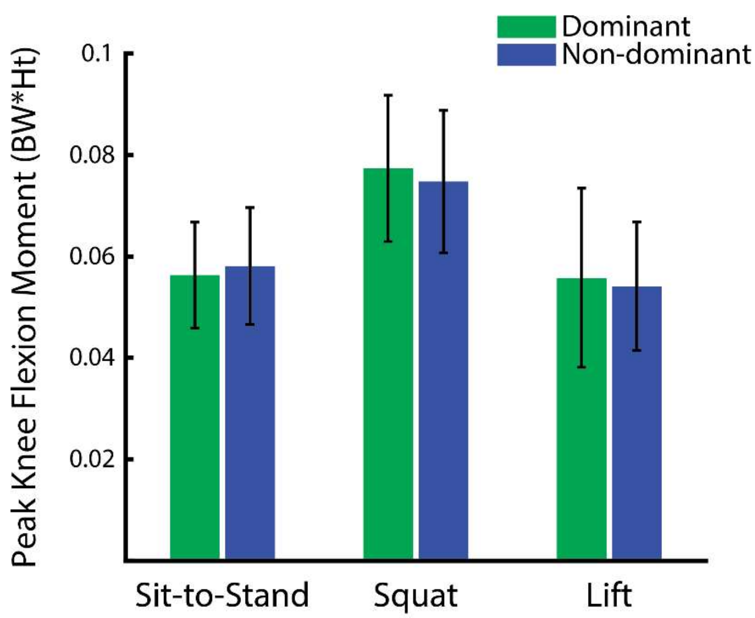
	Peak Vertical Ground Reaction Force (BW)			**Peak Knee Flexion Moment (BW*Ht)**			**Ankle Range of Motion (°)**		
	Dominant Limb	Non-dominant Limb	P-value	Dominant Limb	Non-dominant Limb	P-value	Dominant Ankle	Non-dominant Ankle	P-value
Sit-to-Stand (Standard, 48 cm)	0.61 ± 0.05	0.63 ± 0.08	0.40	0.056 ± 0.010	0.058 ± 0.012	0.58	18.6 ± 5.0	19.1 ± 3.3	0.60
Squat	0.71 ± 0.07	0.68 ± 0.06	0.14	0.077 ± 0.014	0.075 ± 0.014	0.43	32.4 ± 5.4	32.9 ± 4.4	0.64
Lift	0.73 ± 0.04	0.71 ± 0.03	0.29	0.056 ± 0.018	0.054 ± 0.013	0.62	32.5 ± 6.0	34.0 ± 5.4	0.09
Sit-to-Stand (Low, 38 cm)	0.63 ± 0.03	0.64 ± 0.05	0.58	0.067 ± 0.011	0.069 ± 0.012	0.43	24.9 ± 4.8	25.6 ± 2.7	0.56
Sit-to-Stand (Lowest, 28 cm)	0.66 ± 0.04	0.65 ± 0.04	0.47	0.073 ± 0.010	0.073 ± 0.011	0.93	27.3 ± 3.5	27.5 ± 3.3	0.85

Supplementary Table 4.5 Prosthesis user ratings of effort, stability, and comfort on a scale of 0 to 10. For perceived effort, a rating of 0 indicated "the task took no effort" and a rating of 10 indicated "the task took maximum effort". For stability and comfort, a rating of 0 indicated the participant felt "completely unstable" or "completely uncomfortable" and a rating of 10 indicated the participant felt "completely stable" or "completely comfortable" doing the task. *P7 was unable to complete sit-to-stand from the lowest chair without the use of a handrail, but still provided ratings for this task.

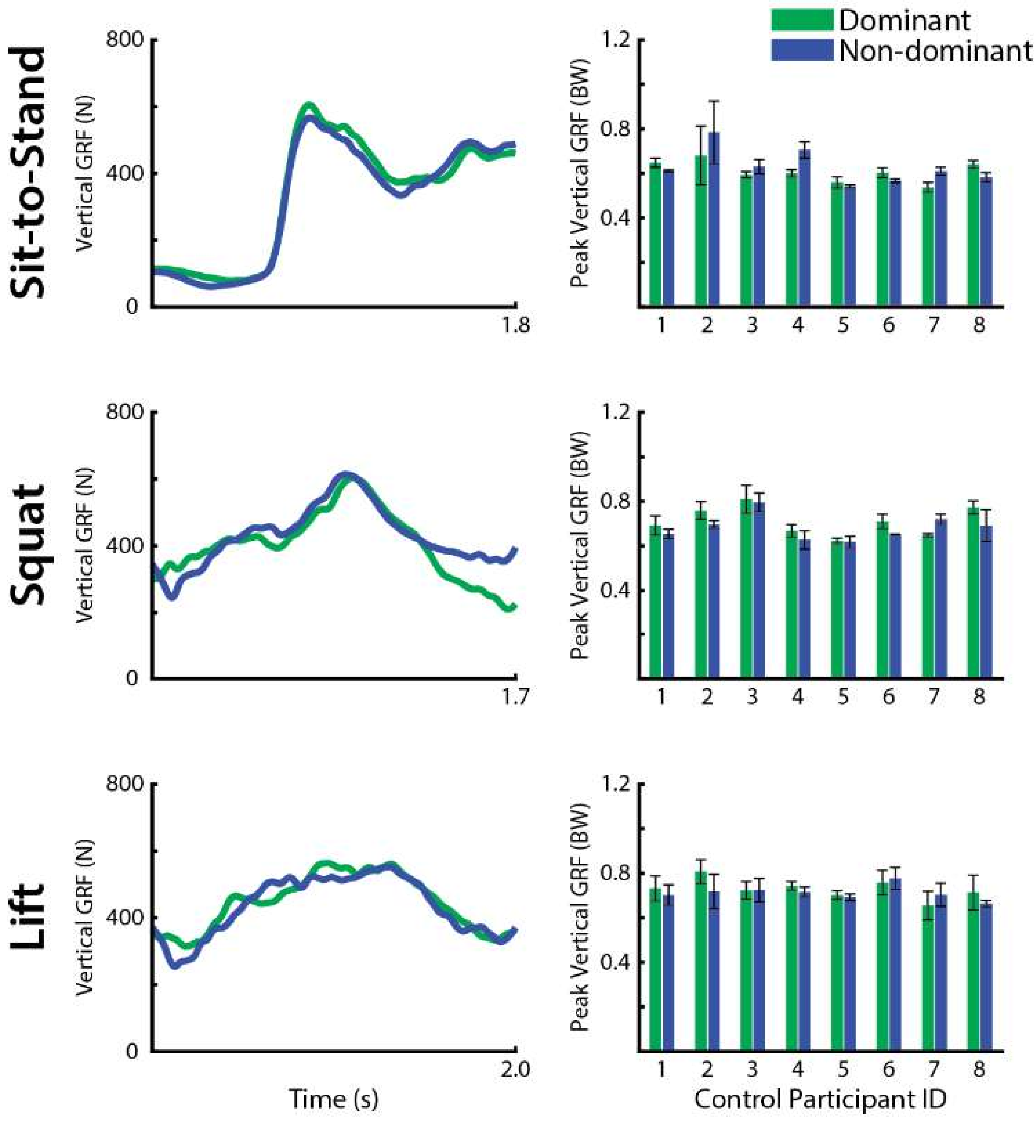
Participant ID	Sit-to-Stand (Standard, 48 cm)			Squat			Lift			Sit-to-Stand (Lowest, 28 cm)		
	Effort	Stability	Comfort	Effort	Stability	Comfort	Effort	Stability	Comfort	Effort	Stability	Comfort
1	0	10	10	0	9	9	0	10	10	3	9	8
2	0	10	10	0	10	10	0	10	9	1	6	6
3	2	7	8	1	10	10	2	10	9	8	1	3
4	2	10	10	0	10	10	0	10	9	5	8	8
5	1	10	10	0	10	10	2	10	10	5	10	6
6	0	10	10	0	10	10	0	10	10	0	10	10
7	3	8	9	1	10	10	6	9	10	8*	2*	4*
8	1	10	10	1	10	8	2	10	10	5	9	8



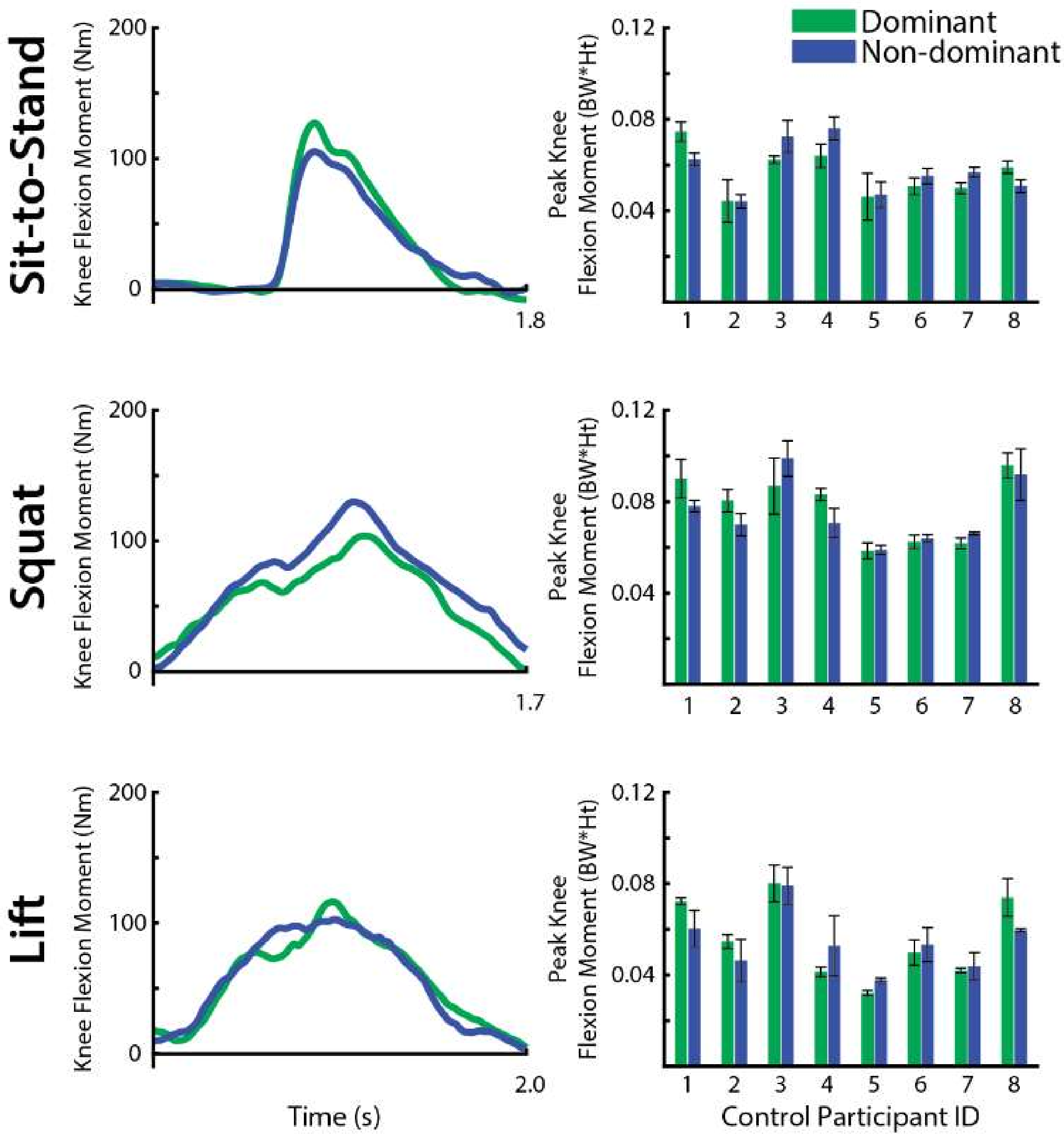
Supplementary Figure 4.7 Peak vertical ground reaction force under each limb during sit-to-stand (48 cm), squatting, and lifting for control participants without limb loss ($N = 8$). Force is normalized to body weight (BW).



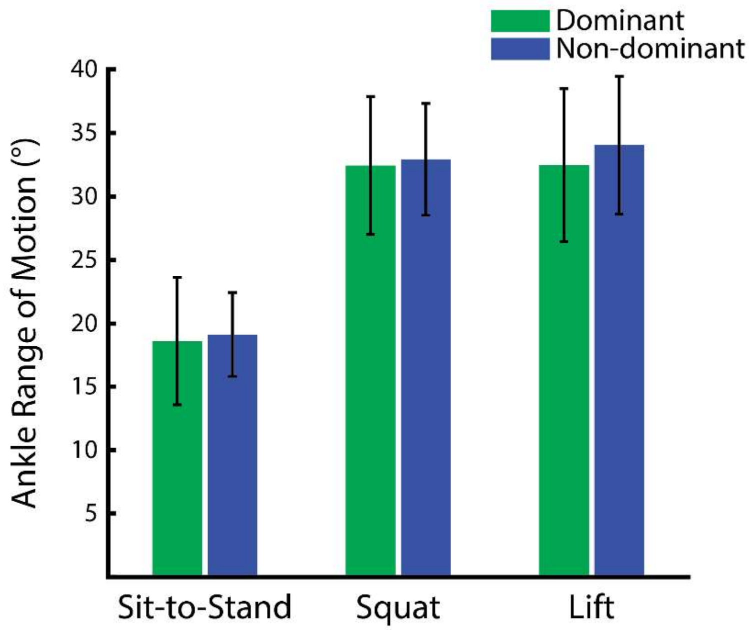
Supplementary Figure 4.8 Peak knee flexion moments during sit-to-stand (48 cm), squatting, and lifting for control participants without limb loss ($N = 8$). Moment is scaled by participant body weight (BW) and height (Ht).



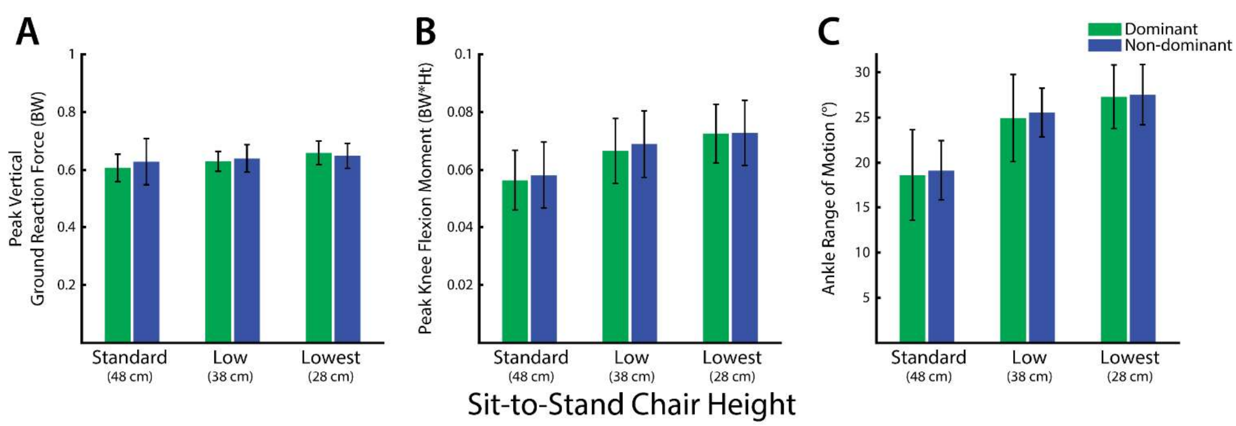
Supplementary Figure 4.9 Left: Representative time-series data of a control participant's vertical ground reaction force (GRF) during sit-to-stand (48 cm), squatting, and lifting. Right: Participant-specific averages of peak vertical ground reaction force for controls (participants without limb loss) during each task. Peak force values were normalized to bodyweight (BW).



Supplementary Figure 4.10 Left: Representative time-series data of a control participant's knee flexion moment during sit-to-stand (48 cm), squatting, and lifting. Right: Participant-specific averages of peak knee flexion moment for controls (participants without limb loss) during each task. Peak moment values were normalized to bodyweight (BW) and height (Ht).



Supplementary Figure 4.11 Ankle range of motion during sit-to-stand (48 cm), squatting, and lifting for control participants without limb loss ($N = 8$).



Supplementary Figure 4.12 (A) Peak vertical ground reaction force, (B) peak knee flexion moment and (C) ankle range of motion for control participants without limb loss ($N = 8$) during sit-to-stand from three chair heights: Standard (48 cm), Low (38 cm), and Lowest (28 cm).

CHAPTER 5

Transtibial Prosthesis Users Lunging: A Characterization of Movement Strategies and Impact of Leading Limb

5.1 Summary

Lunging movements are challenging for many lower limb prosthesis users. However, the movement strategies and biomechanics of prosthesis users during lunging has not been explored. The purpose of this study was to characterize the movement patterns of unilateral transtibial prosthesis users lunging and evaluate differences in biomechanics between lunging with their intact versus their prosthetic limb leading. We collected motion capture and ground reaction force data with eight prosthesis users lunging with each limb leading. We also collected data with a group of eight control participants without limb loss to provide reference results. All eight prosthesis users were able to successfully lunge with their intact limb leading while only five of eight participants were able to complete the lunging task with their prosthetic limb leading. Lunging with the intact limb leading was preferred by most prosthesis users and all reported feeling more stable lunging this way. When lunging with their intact limb leading, participants put 21% more force under their front limb ($p < 0.001$) and had more ankle and knee range of motion in their front limb ($p = 0.002$ and $p = 0.005$) compared to lunging with their prosthetic limb leading. Results from this study provide insight into how individuals with lower limb loss perform daily activities that involve movements similar to lunging, such as kneeling, reaching, or stepping over obstacles. Additionally, these findings can inform future rehabilitation and device interventions that aim to improve the daily task performance of lower limb prosthesis users.

5.2 Background

Lunging and related everyday movements are challenging for many lower limb prosthesis users (LLPUs) [7,8,10]. The lunging motion serves as the basis of many daily tasks, such as kneeling down on the ground, getting up off the floor, stepping over things, and getting out of the back seat of a car [135,136]. These activities are important for independent living and challenging even for LLPUs with a high level of functional ability [7,8,11].

Lunging involves lowering and raising one's center of mass in a split stance with one foot in front and one behind. This requires balance and strength to coordinate the flexion and extension of multiple joints on both legs simultaneously [135]. Researchers have studied lunging variations for exercise and rehabilitation applications for individuals without limb loss [135–138]. During a lunge, the demands on the front leg are different from the demands on the back leg. The front leg bears the majority of the weight and requires a high degree of hip, knee, and ankle flexion

[135,137]. The back leg bears less weight, but still involves flexion at the hip, knee, and ankle in addition to toe flexion [138].

Although lunging is often challenging for LLPUs, it has not been deeply explored, particularly from a biomechanical perspective. A large amount of human movement research with LLPUs has focused on walking [99]. Some research has characterized other daily tasks, such as sit-to-stand and squatting, where individuals without limb loss tend to load their limbs symmetrically. LLPUs with unilateral limb loss typically perform these tasks asymmetrically often loading their intact limb more than their prosthetic limb [19,91,115]. Additional differences in lower limb joint kinematics and kinetics between limbs and altered trunk motion have also been observed [18,111,121]. These asymmetric strategies can result in increased loads in the joints of the intact limb and low back which may contribute to the development of chronic pain and secondary conditions [4,18,20]. It is theorized that these altered movement strategies are likely due to LLPUs using their intact limb to compensate for limitations in their prosthetic limb [4]. However, for tasks such as lunging where each limb is performing a disparate function, LLPUs may be less able to use their intact limb to compensate for strength or mobility deficits in their prosthetic limb.

Investigating how LLPUs lunge and characterizing differences between lunging with their intact limb leading versus their prosthetic limb leading could provide insight into how LLPUs approach a broader range of daily activities. Understanding how LLPUs currently perform this task may also provide foundational information to inform future rehabilitation and device interventions. The objective of this study is to characterize how unilateral transtibial prosthesis users lunge and investigate the differences in users performing a lunge with their intact limb leading versus their prosthetic limb leading. Specifically, we report the ability, preferences, and ratings of task difficulty for LLPUs lunging with each limb leading. We also report ground reaction forces and lower limb joint and trunk kinematics. Additionally, we include data from control participants without limb loss to assist in the interpretation of results.

5.3 Methods

We analyzed the movement strategies of LLPUs and individuals without limb loss lunging with each limb leading. Participants completed these tasks as part of a larger data collection that also included sit-to-stand, squatting, and lifting. Results from those tasks have been reported in a separate manuscript [91].

5.3.1 Participants

A convenience sample of eight unilateral transtibial LLPUs (7M/1F, age: 39.4 ± 13.9 years, mass: 85.8 ± 14.1 kg, height: 1.78 ± 0.13 m) was recruited for this study (Table 5.1). LLPU participants were included if they were at least four months post-surgery, could walk without an aid, and had no recent injuries that impacted mobility. We also collected data with eight individuals without limb loss (5M/3F, age: 35.9 ± 9.7 years, mass: 78.4 ± 14.6 kg, height: 1.77 ± 0.09 m). Individuals without limb loss were included if they had no recent lower extremity injury and were otherwise heathy. All participants provided written informed consent according to Vanderbilt Institutional Review Board approved procedures.

Table 5.1 Individual and mean participant demographics for unilateral transtibial prosthesis users.

Participant ID	Sex	Age (years)	Body Mass (kg)	Height (m)	Years Since Limb Loss	K-Level	Cause of Limb Loss	Daily-Use Prosthesis
1	M	30	86.9	1.77	7.5	4	Traumatic	Fillauer Formula
2	M	26	76.2	1.74	8.5	4	Traumatic	Fillauer AllPro
3	M	52	102.8	1.87	10.2	4	Traumatic	Fillauer AllPro
4	M	32	88.5	1.86	2	4	Traumatic	Blatchford Echelon
5	M	40	69.5	1.76	9	4	Traumatic	Össur Vari-Flex
6	F	42	68.6	1.53	4	4	Traumatic	Össur Pro-Flex Pivot
7	M	66	107.0	1.78	21	4	Traumatic	Blatchford Elan
8	M	27	86.6	1.97	0.5	4	Traumatic	Fillauer AllPro
Mean ± SD		39.4 ± 13.9	85.8 ± 14.1	1.78 ± 0.13	7.8 ± 6.4			

5.3.2 Experimental Protocol

Prosthesis users wore their prescribed prosthesis (Table 5.1) and all participants wore their preferred footwear during data collection. Ground reaction force (GRF) data were recorded under each foot at 1000 Hz using in-ground force plates (AMTI, Watertown, MA, USA) and lower-body kinematics were recorded at 200 Hz using a 10-camera motion capture system (Vicon, Oxford, UK). Passive reflective markers were affixed to the trunk, pelvis, thighs, knees, and shanks, ankles, calcaneus, first and fifth metatarsal bases and heads, and the second toes. For prosthesis users, ankle and foot marker locations for the prosthetic limb were mirrored onto the prosthesis and shoe from the placement on the intact limb.

Participants were instructed to lunge "as deep as they felt comfortable." They started from standing with each foot approximately under each shoulder. LLPU participants then stepped forward with their intact limb and lunged as deep as they could before returning to standing with one foot under each shoulder [135]. Participants were not constrained to a specific lunge length, depth, or time. This was repeated three times. Then the same task was performed with their prosthetic limb leading. If a participant lost their balance requiring them to take a compensatory step while completing the task, this was documented as a failed trial and participants were given the opportunity to repeat the trial. This same protocol was completed with control participants where they first lunged with their dominant limb leading followed by lunging with their non-dominant limb leading. The dominant limb was defined as the self-reported leg they use to kick a ball [130].

After each lunging task, participants were asked to verbally rate effort, stability, and comfort on a scale of 0 to 10. For perceived effort, a rating of 0 indicated "the task took no effort" and a rating of 10 indicated "the task took maximum effort". For stability and comfort, a rating of 0 indicated the participant felt "completely unstable" or "completely uncomfortable" and a rating of 10 indicated the participant felt "completely stable" or "completely comfortable" doing the task. Participants were also asked which leg leading they preferred overall.

5.3.3 Data Processing and Analysis

GRF data and marker trajectories were low-pass filtered at 15 Hz and 8 Hz respectively before analysis. The start and end of each lunge repetition was defined as the time from initial contact of the leading limb with the force platform to the time contact was terminated [137]. We used Visual3D (C-motion, Germantown, MD, USA) to create an eight-segment model (trunk, pelvis, two thighs, two shanks, and two feet). We used this model to compute lower limb joint angles in the sagittal plane. Sagittal plane trunk angle (deviation from vertical) was also computed.

Lunge depth, lunge length, and time to complete each lunge were computed to provide a high-level characterization of lunging performance. Lunge depth was computed as the difference in vertical position between the height of pelvis center of mass (computed by the Visual3D model) when standing and the minimum height of the pelvis center of mass during the lunging motion. The instant in time when the pelvis center of mass was at the minimum height was marked as the bottom of the lunge. Lunge length was computed as the distance between the markers on the second toe of each foot along the direction of movement [139]. Lunge length and depth were normalized by dividing by participant height. The overall average lunge length and depth across participants was re-dimensionalized for reporting purposes using average participant height.

The distribution of force between limbs during lunging was characterized by computing the percent of the total vertical GRF (under both limbs) that was under the leading limb. This was measured at the bottom of the lunge. Ankle, knee, and hip range of motion (ROM) during lunging were computed for each leg as the difference in the minimum and maximum sagittal plane joint angle during each lunge repetition. Trunk ROM was also computed in the sagittal plane.

5.3.4 Statistical Analysis

Outcome metrics were computed for each lunge repetition then averaged across the three repetitions for each participant before being averaged across participant group. Data were screened for normality via a Shapiro-Wilk test. For lower limb joint ROM metrics, comparisons were made between the joints of the intact and prosthetic limb when they were in the front position for lunging, then separately, between the joints of the intact and prosthetic limb when they were the back limb during lunging. For control participants, comparisons were performed the same way except between the joints of the dominant and non-dominant limbs. For depth, length, time, percent GRF, and trunk ROM, statistical comparisons were made between the two variations of the lunge task. Differences were assessed using a paired t-test (normally distributed) or Wilcoxon signed-rank test (non-normally distributed) with an alpha level of 0.05. To account for familywise error rates, Holm-Bonferroni corrections were applied for LLPU kinematic outcomes.

5.4 Results

5.4.1 Ability, Preference, and Subjective Rankings

All eight LLPU participants (100%) were able to successfully complete three repetitions of lunging with their intact limb leading. However, only five of eight participants (62.5%) were able to successfully complete all three repetitions of the lunging task with their prosthetic limb leading. The three participants who were unable to complete the task lost their balance and needed to take a compensatory step during at least one lunge repetition when their prosthetic limb was in front. This difference in ability between lunge variations was reflected in the preference of participants with six of eight participants preferring to lunge with their intact limb leading. All prosthesis users rated lunging with their prosthetic limb in front as being less stable. Participant ratings of effort and comfort were either equal between the two lunging variations or worse for lunging with their prosthetic limb in front.

All eight control participants were able to successfully complete the lunging task with their dominant and non-dominant limb leading. Participant preference for leading limb was varied: two preferred their dominant limb, two preferred their non-dominant limb, and four reported no preference. Ratings of effort, stability, and comfort were either the same or within one point (on the ten-point scale) when comparing lunging with each limb leading for control participants.

5.4.2 Lunge Depth, Length, and Time

There was no significant difference in lunge depth, length, or time for prosthesis users lunging with their intact limb in front compared to their prosthetic limb in front (all $p > 0.16$; Fig. 5.1). However, there was relatively high variation in these metrics between participants. For control participants, there was a significant difference for time between lunging with the dominant limb leading (1.49 ± 0.21 s) and the non-dominant limb leading (1.38 ± 0.20 s; $p = 0.01$; Fig. 5.1). There was no significant difference in lunge depth or length between the two lunging variations for control participants (both $p > 0.8$).

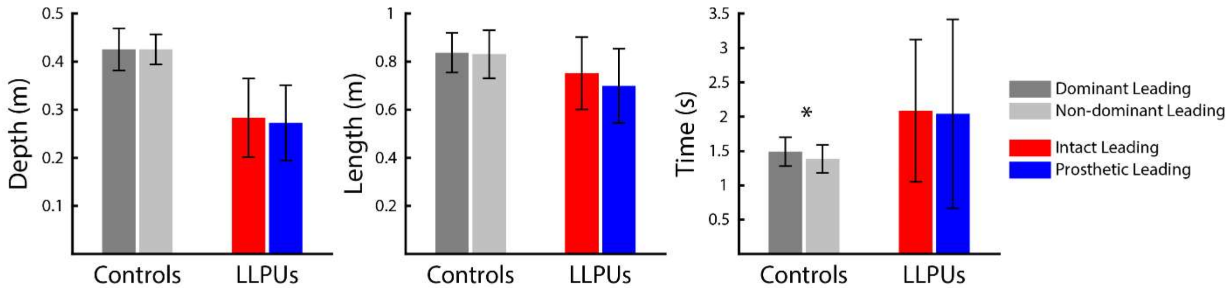


Figure 5.1 Lunge depth, length, and time with each limb leading. Comparisons for control participants ($N = 8$) were made between lunging with their dominant limb leading (dark gray) and lunging with their non-dominant limb leading (light gray). Comparisons for lower limb prosthesis user (LLPU) participants ($N = 8$) were made between lunging with their intact limb leading (red) and lunging with their prosthetic limb leading (blue). *A significant difference was detected in lunge time for the control group.

5.4.3 Ground Reaction Force

Prosthesis users put significantly more force through their front limb when leading with their intact limb ($p < 0.001$; Fig. 5.2). Percent of vertical GRF under the front limb was 21% greater when the intact limb was leading (85.5 ± 8.0%) compared to when the prosthetic limb was leading (64.2 ± 8.8%). Control participants had no difference in percent of vertical GRF under the front limb between lunging with their dominant (74.0 ± 5.6%) and non-dominant limb leading (73.1 ± 5.2%; $p = 0.32$; Fig. 5.2).

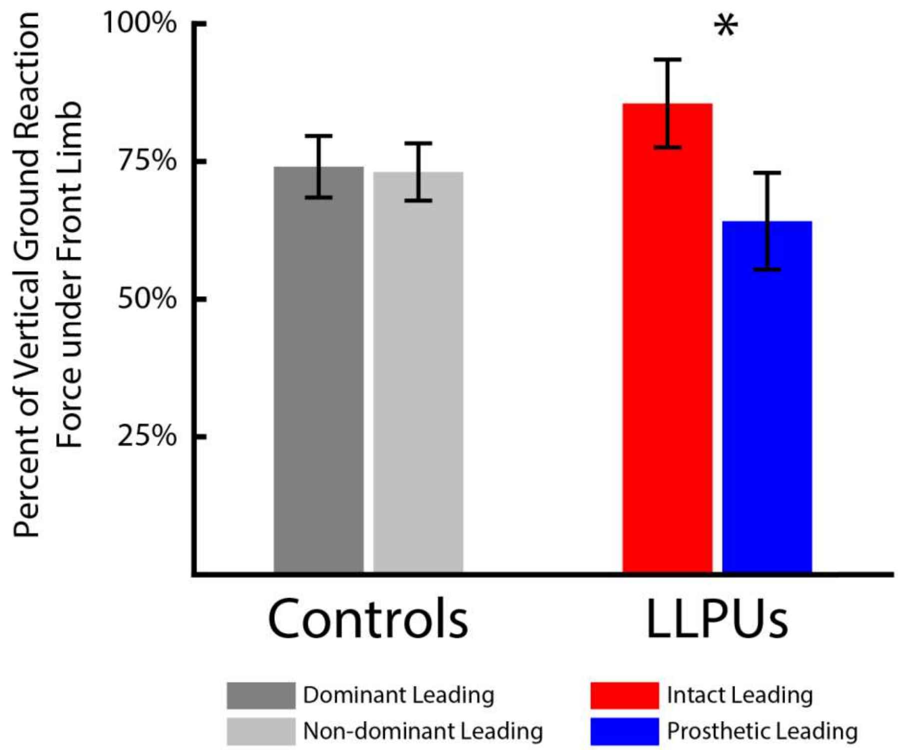


Figure 5.2 Percent of total vertical ground reaction force (front limb + back limb) under the front limb computed at the bottom of the lunge. Comparisons for control participants ($N = 8$) were made between lunging with dominant limb leading (dark gray) and non-dominant limb leading (light gray). Comparisons for lower limb prosthesis user (LLPU) participants ($N = 8$) were made between lunging with intact limb leading (red) and prosthetic limb leading (blue). *A significant difference was detected for the LLPU group.

5.4.4 Range of Motion of Trunk and Lower Limb Joints

All ROM results are presented in Table 5.2 and Figure 5.3. There was no significant difference in trunk ROM for either group between the two lunging variations (both $p > 0.27$). The average ROM between lower limb joints for LLPUs during lunging was only different for the front knee and the front ankle. Prosthesis users flexed their front knee 22% less when it was the prosthetic limb (intact: 81.5 ± 17.8°; prosthetic: 63.9 ± 15.3°; $p = 0.005$). Participants' prostheses provided 16.1 ± 3.6° of ankle ROM when it was the front limb during lunging which was significantly less than the 36.5 ± 10.5° of ROM provided by their intact ankle when it was the front limb ($p = 0.002$). Control participants had no significant difference in lower limb joint ROM when lunging with their dominant or non-dominant limb in front (all $p > 0.35$).

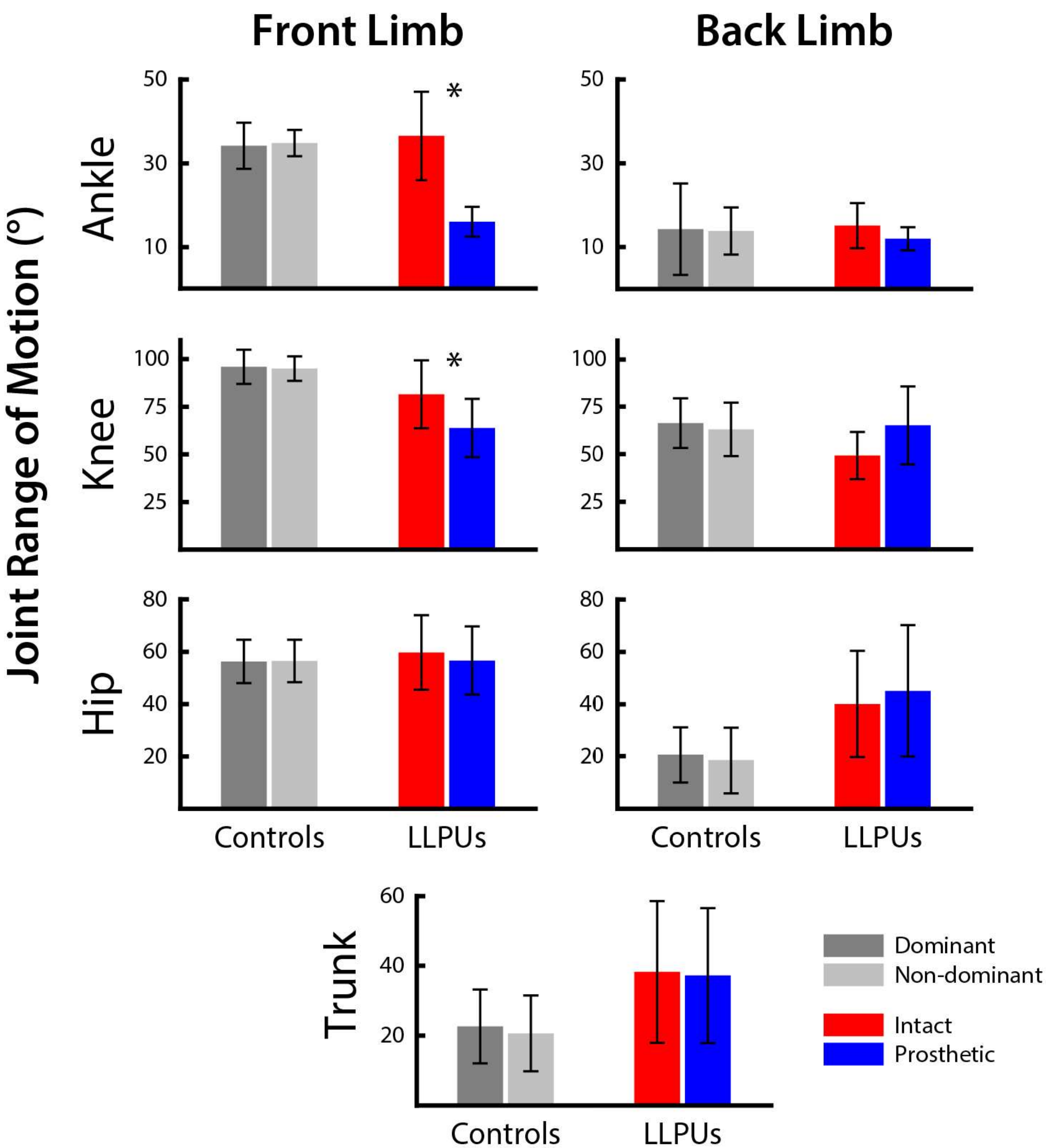


Figure 5.3 Range of motion of the lower limb joints and trunk during lunging. Plots of lower limb joints are grouped by placement of limb during lunging (left column is front limb; right column is back limb). Comparisons for control participants (N = 8) were made between joints on the dominant (dark gray) and non-dominant (light gray) limb within their position as the front or back limb. Comparisons for lower limb prosthesis user (LLPU) participants (N = 8) were made between joints on the intact (red) and prosthetic (blue) limb within their position as the front or back limb. Trunk range of motion was compared between the two lunging variations for each group. *A significant difference was detected in the front knee and ankle range of motion for the prosthesis user group.

5.5 Discussion

This is the first study to investigate how LLPUs approach and execute lunging. For unilateral transtibial LLPUs, there were substantial differences in ability, preference, and reported stability for lunging depending on which limb was in front. All participants were able to complete the lunging task with their intact limb leading, but only 62% of participants were able to successfully complete the task with their prosthetic limb leading. Most users preferred to lunge with their intact limb leading and all reported they felt more stable lunging this way. LLPUs put significantly more force through their front limb when leading with their intact limb. Significant differences in front limb joint kinematics were observed at the ankle and knee. Prosthesis users had significantly less ankle and knee ROM in their front limb when it was their prosthetic limb.

This is also one of the first studies to characterize the biomechanics of the back limb during lunging and examine the impact of leading limb in individuals without limb loss. Overall, we found these individuals lunge with similar biomechanics regardless of leading limb and do not have a strong preference for leading limb. Our results align with one previous study that investigated older adults lunging and found no difference in front limb peak vertical GRF between lunging with their dominant and non-dominant limb leading [140].

We observed that leading with the intact limb is generally the preferred method of lunging for prosthesis users, both from participant-reported outcomes and biomechanically. When the intact limb was in front, all participants could complete the lunging task and reported feeling more stable lunging this way. Additionally, six of eight participants reported lunging with their intact limb leading as their preference. Biomechanically, this preference (of lunging with their intact limb leading) aligns with previous work that indicates LLPUs typically adopt strategies to complete daily tasks that put more force through their intact limb over their prosthetic limb [4,19,91]. During lunging, individuals without limb loss put ~75% of their total vertical GRF through their front limb. It makes sense that prosthesis users would prefer to lunge in a way where their intact limb is bearing more force than their prosthetic limb. Additionally, we observed that when participants lunged with their intact limb in front, they put greater amounts of force through this limb. LLPUs put 85% of their total vertical GRF through their front limb when leading with their intact limb. Conversely, only 64% was put through their front limb when leading with their prosthetic limb. These results establish that, even for tasks with different demands on each leg, prosthesis users may still prefer to adopt a strategy in terms of limb placement or approach that puts more force through their intact limb compared to their prosthetic limb. This broadly observed tendency to load the intact limb more than the prosthetic limb during daily tasks could be due to one or several limiting factors relating to the prosthetic limb, such as lack of proprioception, improper prosthetic fit or alignment, socket discomfort, or reduced strength/loss of muscle volume in the residual limb [4,26]. Additionally, limited ROM and/or power from prosthetic joints likely impacts how LLPUs are able to position and use their limbs to accomplish daily tasks which may encourage putting more force through the intact limb compared to the prosthetic limb [25,91,120].

The joint ROM results further elucidate why LLPUs had greater ability to complete the task and a preference for lunging with their intact limb leading. When the prosthetic limb was leading, LLPUs had less joint ROM in their prosthetic limb knee and prosthetic ankle compared to the ROM in their intact limb knee and ankle when lunging with their intact limb leading. This lack of prosthetic ankle ROM has been observed during other activities of daily living and is likely due to the stiff nature of most commercial prosthetic ankles [69,91]. The reduced amount of prosthetic limb knee ROM observed when lunging with the prosthetic limb leading may be an effect of the reduced prosthetic ankle ROM where the lack of flexion at the more distal joint is preventing users from being able to deeply flex their knee and lower further into the lunge. Also, there is a possibility that socket discomfort, either due to their tibia rotating forward towards the anterior wall of their socket or pinching behind the knee, is the cause of the reduced knee flexion observed in LLPUs when lunging with their prosthetic limb leading.

These results can inform the future design of rehabilitation, task specific training, and prosthetic device interventions. In rehabilitation settings, it may be important to evaluate the ability to do tasks that put different demands on each lower limb and include evaluations of both side variations for these tasks. This could elucidate functional ability deficits or stability challenges that exist for users when performing related motions like reaching for an item or exiting a car on a certain side. Protocols to increase strength, comfort, and stability while lunging with the prosthetic limb leading could help users improve their functional ability and safety when they perform similar tasks in their everyday lives. Additionally, the knowledge that LLPUs are less stable and comfortable when lunging with their prosthetic limb leading may be important to consider when designing and evaluating prosthetic device interventions. Interventions that look to accommodate lunging should be aware that users typically perform this task with their intact limb leading. One approach for future prosthetic design would be to initially develop an intervention for lunging with the intact limb leading because that is the strategy users prefer. In this case, the design of the device would need to accommodate being the back limb during lunging and similar movements. Another approach would be to design a prosthetic behavior that assists users in lunging with their prosthetic limb leading because this is the more prominent functional deficit. An intervention that increases prosthetic ankle ROM for lunging with the prosthetic limb leading could be an approach to investigate further due to the reduced prosthetic ankle ROM observed in this study.

This study has limitations that should be considered when interpreting the findings and provide interesting avenues for further investigation. First, we did not control lunge positioning or timing to observe how LLPUs approach this task with minimal constraints and instructions. Because participants were allowed to lunge to any depth and length over any amount of time, we likely saw larger variances in kinematic outcome measures. Also, we would have potentially seen more pronounced differences in ability to complete the lunging task if we required every user attempt to perform a lunge with strict constraints (e.g., a deep lunge that requires your back knee to touch the ground). Additionally, we assessed one type of lunging task that involved stepping forward into a split stance, lowering into a lunge, and then stepping back to standing. Because of this, ROM values reported in this study will vary from values reported for other types of lunging, such as lunging with participants starting in a split stance or any type of side or backwards lunge. Lastly, this study includes all highly active, unilateral transtibial LLPUs. Transfemoral and bilateral LLPUs in addition to LLPUs who are less mobile may approach lunging in different ways than observed in this study. Users who find lunging more challenging may have even larger deficits in ability and possibly exhibit differences in lunge length and depth between leading limb variations. They may also have additional difference in vertical GRF distribution and lower limb joint/trunk ROM.

5.6 Conclusion

This work evaluated the ability, preferences, and biomechanics of eight LLPUs lunging with each limb leading. Overall, lunging with the intact limb leading was found to be easier and more stable for participants than lunging with the prosthetic limb leading. These differences in ability and preference may be explained by the tendency of LLPUs to put more force through their intact limb during daily tasks and the limited range of motion provided by the prosthetic ankle when it is in front during lunging. The preferences and movement strategies of LLPUs established in this work can help inform the development of rehabilitation and prosthetic device interventions for lunging and similar common daily movements like reaching and kneeling.

CHAPTER 6

The Impact of Prosthetic Ankle Stiffness on the Sit-to-Stand Performance of Transtibial Prosthesis Users: A Case Series

6.1 Summary

The ability to perform sit-to-stand is crucial for functional independence, yet many lower limb prosthesis users find this movement challenging. During sit-to-stand, prosthesis users tend to load their intact limb more than their prosthetic limb which may contribute to their increased risk of intact limb joint degeneration and pain. The limited ankle range of motion provided by typical prosthesis during the sit-to-stand motion may contribute to the challenges and asymmetrical limb loading that unilateral transtibial prosthesis users experience during this essential daily task. Increasing prosthetic ankle range of motion could allow users to orient and load their limbs more symmetrically. The purpose of this study was to evaluate the impact of prosthetic ankle stiffness on the ankle range of motion, limb loading, and preferences of unilateral transtibial prosthesis users performing sit-to-stand. Six unilateral transtibial prosthesis users performed sit-to-stand wearing an experimental prosthesis with three ankle stiffness conditions: STIFF, MEDIUM, and SOFT. Main outcome metrics computed include prosthetic ankle range of motion, ground reaction force symmetry, knee moment symmetry, and participant preference. Reducing prosthetic ankle stiffness increased prosthetic ankle range of motion during sit-to-stand for all participants, but limb loading and preference results were more varied and participant specific. Interestingly, the single K3 participant in this study (all other were K4) had the greatest increase in prosthetic ankle range of motion as stiffness decreased, and he also had the greatest improvement in limb loading symmetry. In addition, he consistently preferred the SOFT ankle over the MEDIUM and STIFF conditions. While decreasing prosthetic ankle stiffness increased ankle range of motion for all participants during sit-to-stand, ankle stiffness had a varied impact on limb loading symmetry and preference across participants. This study highlights the individual biomechanical responses and preferences users can have towards prosthetic device interventions. Considering the results from the K3 participant, future work could further investigate the potential benefits of reducing prosthetic ankle stiffness during sit-to-stand with lower-mobility individuals.

6.2 Background

The ability to rise from sitting to standing (frequently called sit-to-stand) is critical to an individual's quality-of-life, as it is a prerequisite for functional independence. Sit-to-stand is a biomechanically demanding task that individuals perform over 50 times per day [110]. However, a significant percentage of lower limb prosthesis users (LLPUs) struggle or are unable to complete this task on their own [10]. Those who can perform sit-to-stand independently often execute the motion asymmetrically by loading their intact limb more than their prosthetic limb [19]. Previous work has reported greater vertical ground reaction forces and sagittal-plane knee moments in the intact limb compared to the prosthetic limb during this motion [17,24,91,111,121], which may contribute to the higher incidence of knee and hip osteoarthritis observed in the intact limb of unilateral prosthesis users [4,20].

The lack of ankle dorsiflexion provided by commonly prescribed ankle-foot prostheses is likely a contributing factor as to why sit-to-stand is challenging for many LLPUs and why they adopt asymmetrical loading during this task. Previous work from our group has demonstrated that typical prosthetic ankle-foot devices allow a limited amount of ankle range of motion (ROM) during sit-to-stand [91]. We found LLPUs averaged 7° of prosthetic ankle ROM which is less than half the ROM of their intact ankle. This is also significantly less than the 19° of ankle ROM found in non-prosthesis user control participants. This inadequate dorsiflexion may hinder users from comfortably orienting their prosthetic limb and trusting its ability to handle load during this motion.

Existing research has investigated how different prosthetic knee behaviors impact transfemoral prosthesis users during sit-to-stand, but there are no existing investigations into how altering prosthetic ankle behavior impacts transtibial prosthesis users during this task. For transfemoral LLPUs, existing studies have assessed how different commercial devices impact user mechanics during sit-to-stand [119,141]. Several other studies have developed and tested novel prosthetic knee controllers and devices with the aim of specifically improving sit-to-stand outcomes for users. Specifically, powered knee prostheses that provide active extension torques during the transition from sitting to standing have shown the ability to improve symmetry in vertical ground reaction force between the intact and prosthetic limb for transfemoral prosthesis users [21–23].

Investigations into interventions for transtibial prosthesis users during sit-to-stand are limited and have not looked at adapting prosthetic ankle-foot behavior. One group has examined the effect of lower-limb prosthetic alignment on muscle activity, peak ground reaction force, and dynamic balance during sit-to-stand [24,26]. They found that shifting a user's prosthetic alignment laterally may reduce muscle activity during sit-to-stand for unilateral transtibial LLPUs, but otherwise alignment shifts had small to no impacts on ground reaction force and dynamic balance measures. Another study evaluated patient-reported outcomes with 20 transtibial prosthesis users who transitioned from a non-microprocessor foot to a microprocessor foot while maintaining their original socket fit [25]. Patients reported an improvement in their ability to perform sit-to-stand transfers and ability to bend down to retrieve something from the floor. While this study only evaluated patient-reported outcomes, the authors theorized that the microprocessor feet provided increased dorsiflexion which permitted "users to bring their ipsilateral knee and body center-of-mass further anterior over their feet to execute these tasks with easier mechanics." However, no study has measured if microprocessor feet or any other prosthetic device groups increase ankle range of motion during sit-to-stand. At a higher level, no existing work has investigated if increasing prosthetic ankle range of motion is beneficial for transtibial LLPUs during sit-to-stand or quantified what those benefits may be. A prosthetic ankle-foot with increased dorsiflexion capabilities has the potential to allow LLPUs to orient and load their lower limbs more symmetrically while standing up from a chair.

The overarching question we sought to explore was how increasing prosthetic ankle dorsiflexion impacts transtibial prosthesis users' performance during sit-to-stand. We specifically investigated this question via a case series of LLPUs who performed sit-to-stand using the same prosthesis with three different ankle stiffnesses. We measured the prosthetic ankle range of motion in each condition, and we explored related changes in limb loading symmetry and user preference. We expected that decreasing prosthetic ankle stiffness would result in LLPUs increasing their prosthetic ankle range of motion during sit-to-stand. Additionally, we hypothesized that LLPUs would have more symmetrical limb loading, specifically peak ground reaction forces and peak knee flexion moments, with a less stiff prosthetic ankle and that participants would prefer a less stiff prosthetic ankle during sit-to-stand.

6.3 Methods

6.3.1 Participants

A convenience sample of six individuals with unilateral transtibial amputation (5M/1F, age: 45 ± 11 years, mass: 78.8 ± 16.7 kg, height: 1.76 ± 0.05 m) participated in this study (Table 6.1). Individuals were eligible to be participants if they were at least four months post-surgery, had no recent injuries that impacted mobility, and had enough limb clearance to accommodate the experimental prosthesis. All participants provided written informed consent according to Vanderbilt Institutional Review Board approved procedures.

Table 6.1 Participant demographics. All users are unilateral transtibial prosthesis users.

Participant ID	Sex	Age (years)	Body Mass (kg)	Height (m)	Years Since Limb Loss	Prosthetic Side	K-Level	Cause of Limb Loss	Daily-Use Prosthesis
P1	M	28	84.2	1.72	11.6	L	4	Traumatic	Fillauer AllPro
P2	M	54	104.3	1.82	13.0	L	4	Traumatic	Fillauer AllPro
P3	M	60	87.8	1.81	8.7	R	3	Vascular	Fillauer AllPro
P4	M	42	71.0	1.76	10.5	L	4	Traumatic	Össur Vari-Flex
P5	M	42	67.8	1.78	6.8	R	4	Traumatic	Fillauer AllPro
P6	F	46	57.5	1.69	19.0	R	4	Traumatic	Fillauer AllPro
Mean ± SD		45 ± 11	78.8 ± 16.7	1.76 ± 0.05	11.6 ± 4.2				

6.3.2 Experimental Prosthesis

The Vanderbilt Powered Ankle [142] was used as the experimental prosthetic device to test different ankle behaviors during sit-to-stand (Fig. 6.1). This device includes a brushless DC motor with a three-stage belt/chain transmission that can generate peak torques of approximately 100 Nm with a range of motion of 45° of plantarflexion and 25° of dorsiflexion. The prosthesis is powered by an on-board six-cell 24-volt lithium-polymer battery pack. The combined mass of the prosthesis and the battery pack are approximately 3 kg. Onboard sensors measure ankle, shank, and foot angles and velocities. Prosthetic ankle joint torque is controlled using an impedance-based model:

$$\tau = k\left(\theta - \theta_{eq}\right) + b\dot{\theta} \tag{6.1}$$

where θ is the ankle angle and $\dot{\theta}$ is the ankle angular velocity. Impedance parameters—stiffness (k), damping (b), and equilibrium angle (θ_{eq})—were set by the experimenter using a supervisory controller in Simulink Real-Time (MATLAB R2018b, MathWorks, Natick, MA, USA).

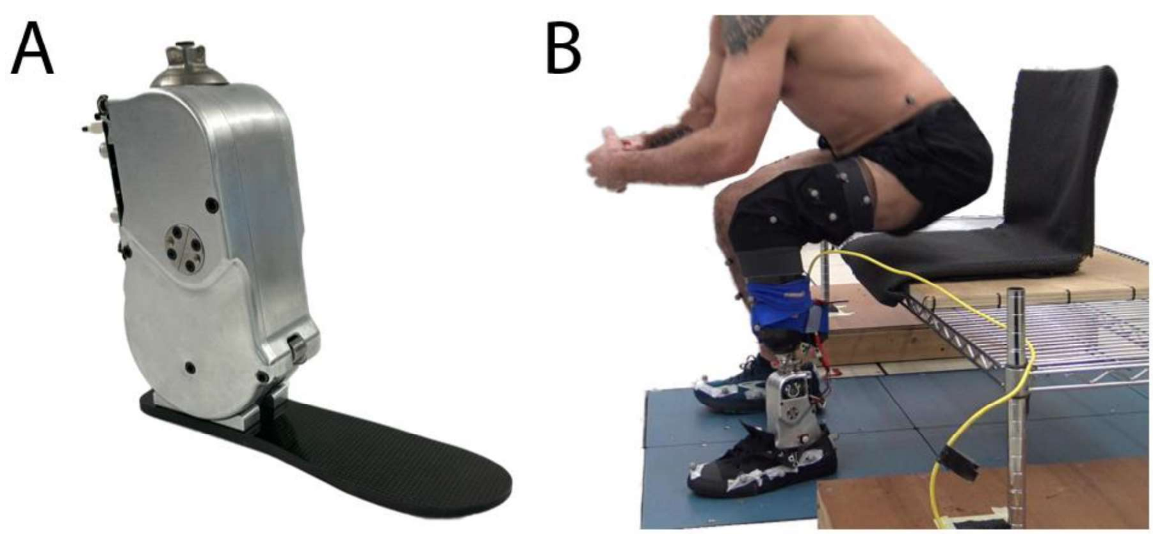


Figure 6.1 Experimental prosthesis and testing setup. (A) The Vanderbilt Powered Ankle [142] was used as the experimental prosthesis to test varying ankle stiffness during sit-to-stand. (B) Sit-to-stand testing setup with participant wearing the experimental prosthesis.

6.3.3 Experimental Conditions

We chose to alter prosthetic ankle behavior for sit-to-stand by modulating the prosthetic ankle stiffness, with the expectation that LLPUs would generate larger prosthetic ankle dorsiflexion on less stiff ankles. Through pilot testing with LLPUs, three ankle stiffness settings were chosen to be the three testing conditions: STIFF, MEDIUM, and SOFT. The same three stiffness values were used for testing with all participants. The stiffest condition, referred to as STIFF, was included to serve as a baseline. This STIFF condition was intended to feel similar to commonly prescribed passive carbon-fiber devices that many LLPUs wear every day. It was expected to provide the least amount of dorsiflexion during the sit-to-stand motion. The MEDIUM and SOFT conditions were half and a quarter of the stiffness of the STIFF condition, respectively. Changing stiffness is not the only way to affect prosthetic ankle angle and range of motion, but served as one convenient way to experimentally and systematically explore the overarching question related to whether more dorsiflexion of a prosthetic ankle impacts performance during sit-to-stand.

For all three conditions, the impedance parameters (Eqn. 1) sent to the prosthesis were constant values during the sit-to-stand motion, so the device emulated a passive rotational spring during the task. For the STIFF, MEDIUM, and SOFT conditions, stiffness k was set to 10 Nm/°, 5 Nm/°, 2.5 Nm/° respectively. During pilot testing, we observed that several participants felt very unstable once standing with stiffness values lower than ~4 Nm/°. Because of this, the controller for the SOFT condition was designed to transition to a higher stiffness state (k = 7 Nm/°) following the sit-to-stand motion. This transition occurred only after the participant was standing, and thus did not affect the dynamic sit-to-stand motion. Damping and equilibrium angle impedance parameters (Eqn. 1) were held consistent across all conditions at b = 0.2 Nms/° and θ_{eq} = 0°.

6.3.4 Experimental Protocol

The experimental protocol involved two sessions: one training and one testing. At the start of the training session, participants were fit with the experimental prosthesis by the experimenter. Throughout training and testing, a zero-drop black sneaker was worn over the experimental prosthesis. Participants wore their preferred footwear on their intact limb (Fig. 6.1B).

The training session was two hours in duration. It was designed to familiarize the participants with the experimental prosthesis and the sit-to-stand task. Participants experienced all three testing conditions and were encouraged to experiment with foot placement and body positioning while performing sit-to-stand. All participants performed more than 50 repetitions of sit-to-stand while wearing the experimental prosthesis during their training session.

Participants returned for their testing session 3 to 23 days after their training session (average: 8.6 days). During this session, ground reaction force (GRF) data were recorded under each foot at 1000 Hz using in-ground force plates (AMTI, Watertown, MA, USA) and lower-body kinematics were recorded at 200 Hz using a 10-camera motion capture system (Vicon, Oxford, UK). At the beginning of the testing session, participants had 52 reflective markers affixed to their trunk and lower limbs. On the intact limb foot and ankle, markers were placed on the medial and lateral malleoli (2), calcaneus (3), first and fifth metatarsal base and head (4), and the second toe (1). On the prosthetic limb, foot markers were mirrored from the shoe of the intact limb. When wearing their passive prescribed prosthesis, medial and lateral malleoli markers were placed on the prosthesis at the same height as the malleoli markers on the intact limb. For testing with the experimental prosthesis, medial and lateral malleoli markers were placed at the known center-of-rotation of the prosthetic ankle.

Each sit-to-stand trial required participants to stand up from a chair five times following cues from the experimenter. The chair had a backrest, no armrests, and no padding. The height of the chair was normalized to approximately 80% of the participant's knee height (Fig. 6.1B).

During the testing session, participants first performed one trial of sit-to-stand wearing their passive prescribed device. These data were collected to provide a reference for how participants perform sit-to-stand in their daily life to aid in interpretation of biomechanical results found when testing with the experimental prosthesis. Participants then switched to the experimental prosthesis and were provided approximately 30 minutes to refamiliarize themselves to the device where they had unstructured time to perform sit-to-stand in all three testing conditions.

Data collection to evaluate the three ankle stiffness conditions occurred using six sets of pair-wise comparisons. Each set was designed to compare one stiffness condition to one other condition by collecting two trials of sit-to-stand (one trial in each condition). Each pair of stiffness conditions (e.g., STIFF vs. MEDIUM, STIFF vs. SOFT, and MEDIUM vs. SOFT) was tested twice with the order of conditions reversed between the two sets. Thus, the six sets were: (1) STIFF vs. MEDIUM, (2) MEDIUM vs. STIFF, (3) STIFF vs. SOFT, (4) SOFT vs. STIFF, (5) MEDIUM vs. SOFT, and (6) SOFT vs. MEDIUM. The order of the six sets was randomized for each participant. Participants were blinded to the conditions, and, during each set, the two conditions were called "Condition 1" and "Condition 2". After each set where participants had performed five sit-to-stand repetitions in each condition, they were asked four questions to assess their subjective preferences. Participants were asked:

1. Which condition did you prefer?
2. Which condition took less effort?
3. Which condition felt more stable?
4. Which condition felt more comfortable?

For all questions, participants provided their response using a five-point Likert Scale with the options of "Condition 1 Strongly", "Condition 1 Slightly", "No Preference or Same", "Condition 2 Slightly", or "Condition 2 Strongly." Participants were provided a few minutes of rest between each set if needed.

6.3.5 Outcome Metrics

In addition to participant-reported preferences, we examined three biomechanical outcome metrics to evaluate the impact of prosthetic ankle stiffness on sit-to-stand: ankle range of motion, vertical ground reaction forces, and sagittal-plane knee moments. Prosthetic ankle range of motion (ROM) is limited during sit-to-stand compared to the intact ankle ROM of LLPUs and compared to the ankle ROM of individuals without limb loss [91]. We evaluated prosthetic ankle ROM to determine if reducing prosthetic ankle stiffness had the expected effect of increasing ROM during sit-to-stand. Vertical ground reaction forces and sagittal-plane knee moments were computed to characterize the limb loading of participants. Vertical ground reaction forces (GRFs) are often used as an indicator of the overall limb loading strategy of individuals during daily tasks [17,21,119]. Asymmetrical GRFs during a bilateral task can contribute to increased moments and contact forces in the joints of the overloaded limb [24,111,120,121]. Knee moments have been used as an indicator of loading of the internal structures of the knee joint [20,122–125]. Especially for bilateral tasks that require a high degree of knee flexion, such as sit-to-stand, an increase in knee flexion moment is indicative of an increase in knee joint contact forces [120,126,127]. During sit-to-stand, LLPUs exhibit asymmetrical vertical GRFs and knee moments, usually loading their intact limb more than their prosthetic limb [91]. This increased loading of the intact limb may contribute to the high rates of joint pain and osteoarthritis observed in the LLPU population [4,20,120]. Therefore, we report the asymmetry in limb loading, specifically peak vertical GRFs and peak knee flexion moments. Overall, these outcome metrics aim to evaluate if reducing prosthetic ankle stiffness increases ankle ROM, which then, in turn, improves limb loading symmetry during sit-to-stand.

6.3.6 Data Processing and Analysis

GRF data and marker trajectories were low-pass filtered at 15 Hz and 8 Hz, respectively, before analysis. Time-series data from each trial were cropped via a custom MATLAB script to isolate the standing up motion. The start and end of each sit-to-stand repetition was determined using the vertical and horizontal movement of the marker placed on the C7 vertebrae of participants with approximately 0.5 cm of increase or decrease in position used as a threshold of movement. Ankle angle was computed in Visual3D (C-motion, Germantown, MD, USA) as the angle between the shank segment and the rearfoot segment in the sagittal plane for each lower limb. Ankle ROM was computed as the difference between the minimum and maximum ankle angle during sit-to-stand. The knee joint moment in the sagittal plane, reported as the knee flexion moment, was computed via inverse dynamics using Visual3D. We computed peak vertical GRF and peak knee moment values during sit-to-stand for each limb. To quantify the asymmetry in limb loading and compare across conditions, we calculated the Degree of Asymmetry (DoA) [21,141,143] between the peak vertical GRFs and peak knee flexion moments of each limb using Equation 6.2.

$$DoA = \frac{Intact\ limb - Prosthetic\ limb}{Intact\ limb + Prosthetic\ limb} \times 100 \tag{6.2}$$

A DoA of zero represents perfect symmetry. A positive DoA indicates asymmetry with a greater load on the intact limb, whereas a negative DoA indicates asymmetry with a greater load on the prosthetic limb.

The six sets of pairwise comparisons (which each included two trials) resulted in 12 total sit-to-stand trials. This yielded four sit-to-stand trials for each stiffness condition and participant, across the entire experiment. For each trial, data from the last three (of five total) sit-to-stand repetitions were averaged. Data were then averaged across the four trials of the same condition for each participant. As this is a case series of six LLPUs, we present results from each participant as well as the average results across participants. Before averaging across participants, peak GRF data were normalized by participant body weight and peak moment data were normalized by participant body weight and height. Additional participant-specific results, including data from the sit-to-stand trial with their prescribed device, can be found in the Supplementary Material.

6.4 Results

6.4.1 Ankle Range of Motion

As the stiffness of the prosthetic ankle decreased (from STIFF to MEDIUM to SOFT), all participants increased their prosthetic ankle ROM during sit-to-stand (Fig. 6.2). For the STIFF condition, participants had between 6.5° and 8.2° of ankle ROM (group average: 7.3 ± 0.6°). In the MEDIUM stiffness condition, LLPUs had a range of 7.3° to 10.2° of prosthetic ankle ROM (group average: 8.3 ± 1.0°). Across participants, the increase in prosthetic ankle ROM from STIFF to MEDIUM was between 0.3° (by P2) and 3.1° (by P3) with an average increase of 1°. In the SOFT condition, participants had a range of 9.1° to 12.1° of ankle ROM (group average: 10.4 ± 1.1°) Comparing the STIFF to the SOFT condition, participants increased their prosthetic ankle ROM between 1.7° (by P4) to 4.8° (by P3) with an average increase of 3.1°. Ankle ROM values for both limbs (intact and prosthetic) for every participant and across all conditions are included in the Supplementary Material.

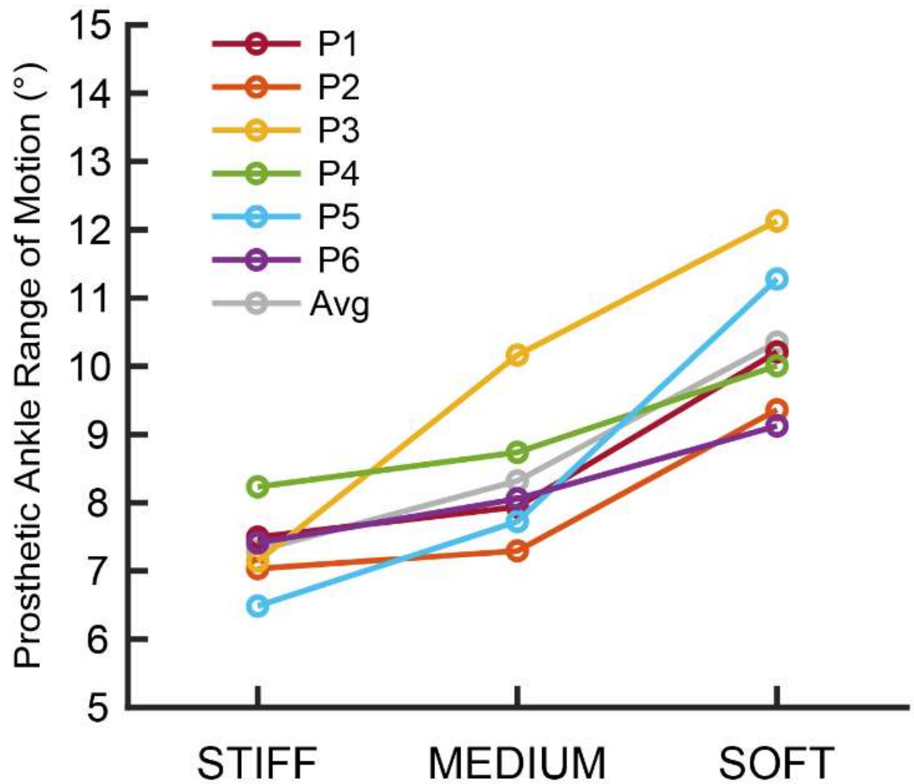


Figure 6.2 Prosthetic ankle range of motion during sit-to-stand. Participant-specific results for each stiffness condition are displayed in addition to the group average (in gray).

6.4.2 Ground Reaction Force

The DoA in peak vertical GRFs for sit-to-stand with the STIFF, MEDIUM, and SOFT prosthetic ankle conditions can be seen in the left panel of Figure 6.3. As indicated by a positive DoA, five of six participants had a greater peak GRF in their intact limb compared to their prosthetic limb during sit-to-stand. This was consistent for all ankle stiffness conditions. One participant (P4) had a negative DoA for all conditions indicating greater peak GRFs in his prosthetic limb than his intact limb. The change in the DoA from the baseline STIFF condition to the MEDIUM and SOFT conditions are shown in the right panel of Figure 6.3. The majority of participants had small changes in peak GRF DoA across conditions indicating relatively small changes in how symmetrically they loaded their limbs during sit-to-stand. A negative change from the STIFF condition to the MEDIUM condition was observed for two participants (range: -1.1 to -4.9 %) indicating they loaded their limbs slightly more symmetrically in the MEDIUM condition compared to the STIFF condition. Four participants had a small positive change in DoA indicating they loaded their limbs slightly less symmetrically in the MEDIUM condition compared to the STIFF (range: 0.5 to 0.9 %). When comparing the SOFT ankle stiffness condition to the STIFF, three participants (P1, P2, P3) loaded their limbs more symmetrically (range: -0.5 to -3.1 %) and three participants (P4, P5, P6) loaded their limbs less symmetrically (range: 0.4 to 1.0 %). Peak GRF values for both limbs (intact and prosthetic) for every participant and across all conditions are included in the Supplementary Material.

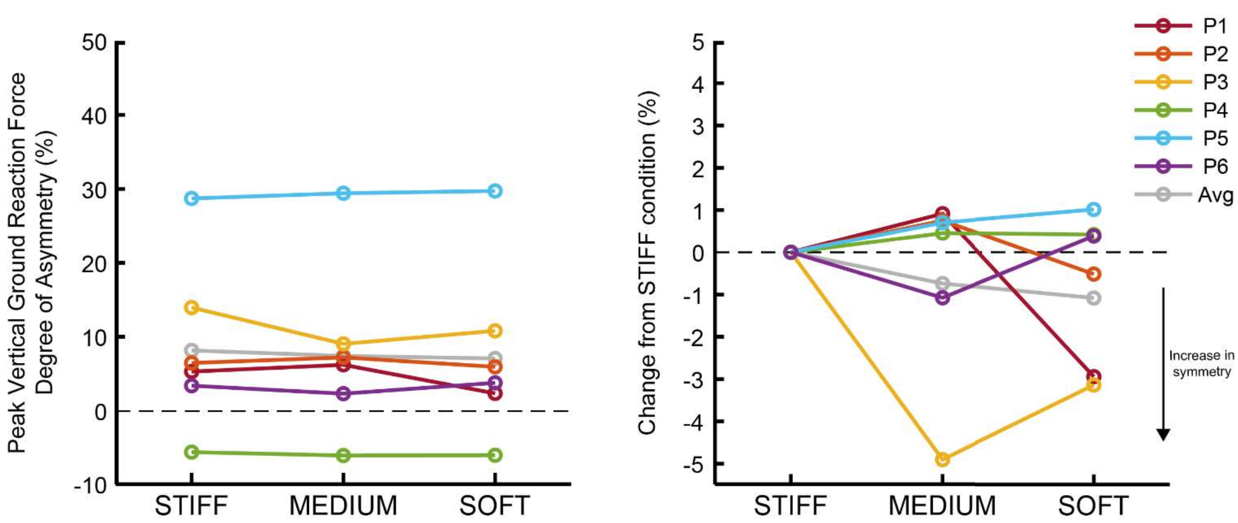


Figure 6.3 Left: Degree of Asymmetry (DoA) in peak vertical ground reaction force between limbs during sit-to-stand. Right: Change in the peak vertical ground reaction force DoA from the STIFF condition. This was computed as a difference in absolute DoA values so that negative values indicate an improvement in symmetry from the STIFF condition (important for P4). Results from each participant are shown in separate colors and the group average (Avg) is displayed in gray.

6.4.3 Knee Flexion Moment

The DoA in peak knee flexion moment during sit-to-stand for all participants can be seen in the left panel of Figure 6.4. All participants had a positive DoA indicating they had greater peak knee moments in their intact limb compared to their prosthetic limb. The right panel of Figure 4 displays the change in DoA from the baseline STIFF condition with negative values indicating a decrease in DoA corresponding to more symmetrical limb loading. Comparing the change in DoA between the MEDIUM and the STIFF condition, three participants (P2, P4, P6) had a similar DoA with a change in asymmetry within 1%, two participants had more symmetrical peak knee moments with the changes in DoA of -1.5% (P1) and -3.8% (P3), and one participant, P5, was less symmetrical with a change in DoA of 2.3%. Comparing the change in symmetry from the STIFF to the SOFT condition, three participants (P1, P3, P6) had more symmetrical knee moments in the SOFT condition shown by a negative change in DoA (range: -2.0 to -17.4%). Two participants had slightly less symmetrical peak knee moments with positive changes in DoA of 1.6% (P2) and 2.4% (P5). P4 had a similar knee moment DoA across all conditions with a change of less than 1%. Peak GRF values for both limbs (intact and prosthetic) for every participant and across all conditions are included in the Supplementary Material.

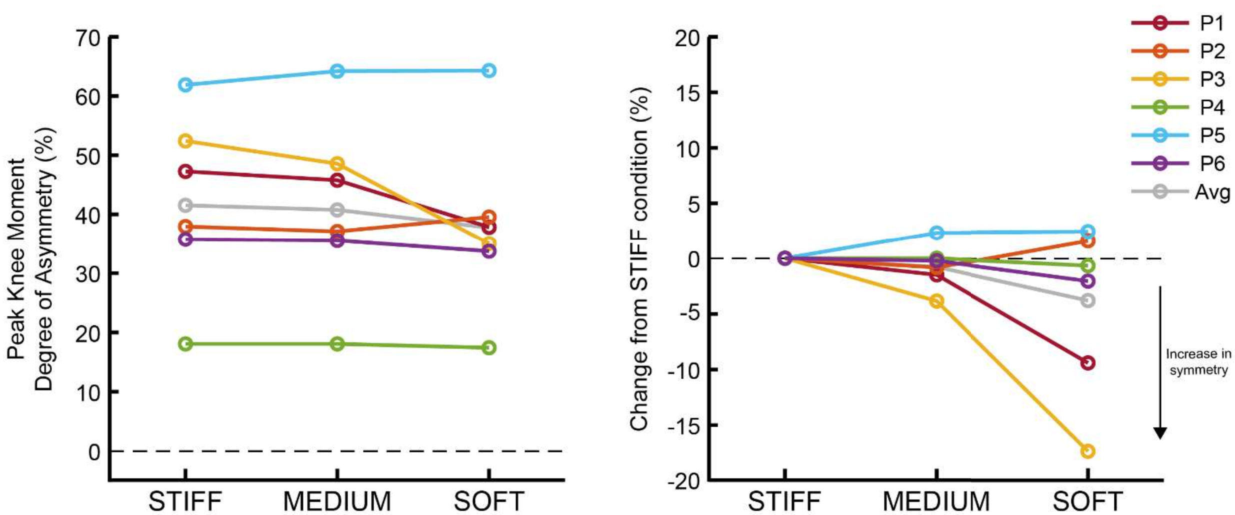


Figure 6.4 Left: Degree of Asymmetry (DoA) in peak knee flexion moment between limbs during sit-to-stand. Right: Change in the peak knee flexion moment DoA from the STIFF condition. Results from each participant are shown in separate colors and the group average (Avg) is displayed in gray.

6.4.4 Participant Preference

Individual participant preference results for the six pairwise comparison sets are shown in Figure 6.5. There was not one stiffness condition that all LLPUs preferred for sit-to-stand. Instead, preference for prosthetic ankle stiffness was varied between participants and not always consistent within a participant. Often, the response participants gave when asked their overall preference for one condition compared to another corresponded to their response when specifically asked which condition required less effort, felt more stable, and felt more comfortable. Three participants (P1, P3, P6) consistently preferred the MEDIUM stiffness ankle over the STIFF ankle. The other three participants (P2, P4, P5) had conflicting preferences between the two sets where MEDIUM and STIFF were compared to each other. For the comparison of STIFF vs. SOFT and MEDIUM vs. SOFT, participants had varying preference results with several instances of individuals giving opposite responses between the two sets comparing the same pair of stiffness conditions.

		STIFF vs. MEDIUM		STIFF vs. SOFT		MEDIUM vs. SOFT	
		Set 1 STIFF vs. MEDIUM	Set 2 MEDIUM vs. STIFF	Set 3 STIFF vs. SOFT	Set 4 SOFT vs. STIFF	Set 5 MEDIUM vs. SOFT	Set 6 SOFT vs. MEDIUM
P1	Randomized set order	1	2	3	4	5	6
	Overall preference	MEDIUM Slightly	MEDIUM Strongly	STIFF Slightly	Same	MEDIUM Strongly	MEDIUM Strongly
	Less effort?	MEDIUM Slightly	MEDIUM Strongly	STIFF Slightly	Same	MEDIUM Slightly	MEDIUM Strongly
	More stable?	MEDIUM Slightly	MEDIUM Strongly	STIFF Strongly	STIFF Slightly	MEDIUM Slightly	MEDIUM Slightly
	More comfortable?	MEDIUM Slightly	MEDIUM Strongly	STIFF Strongly	Same	MEDIUM Strongly	MEDIUM Strongly
P2	Randomized set order	2	3	4	5	1	6
	Overall preference	STIFF Slightly	STIFF Strongly	STIFF Slightly	STIFF Strongly	MEDIUM Strongly	MEDIUM Strongly
	Less effort?	MEDIUM Slightly	STIFF Strongly	STIFF Slightly	STIFF Strongly	MEDIUM Slightly	MEDIUM Strongly
	More stable?	MEDIUM Slightly	STIFF Strongly	STIFF Strongly	STIFF Strongly	MEDIUM Strongly	MEDIUM Strongly
	More comfortable?	STIFF Slightly	STIFF Strongly	STIFF Slightly	STIFF Strongly	Same	MEDIUM Strongly
P3	Randomized set order	6	3	4	1	2	5
	Overall preference	MEDIUM Slightly	MEDIUM Strongly	SOFT Slightly	SOFT Strongly	SOFT Strongly	SOFT Strongly
	Less effort?	MEDIUM Slightly	MEDIUM Strongly	SOFT Slightly	SOFT Strongly	SOFT Strongly	SOFT Slightly
	More stable?	MEDIUM Slightly	MEDIUM Strongly	SOFT Slightly	SOFT Strongly	SOFT Strongly	SOFT Strongly
	More comfortable?	MEDIUM Slightly	MEDIUM Strongly	SOFT Slightly	SOFT Strongly	SOFT Strongly	SOFT Strongly
P4	Randomized set order	3	6	2	1	4	5
	Overall preference	MEDIUM Strongly	STIFF Slightly	SOFT Slightly	STIFF Strongly	Same	MEDIUM Slightly
	Less effort?	MEDIUM Strongly	STIFF Slightly	SOFT Slightly	STIFF Strongly	SOFT Slightly	MEDIUM Slightly
	More stable?	MEDIUM Strongly	Same	SOFT Slightly	STIFF Strongly	Same	Same
	More comfortable?	MEDIUM Strongly	STIFF Slightly	SOFT Slightly	STIFF Strongly	SOFT Slightly	Same
P5	Randomized set order	4	6	5	2	3	1
	Overall preference	STIFF Strongly	Same	STIFF Strongly	STIFF Strongly	MEDIUM Strongly	SOFT Strongly
	Less effort?	STIFF Strongly	Same	STIFF Strongly	STIFF Strongly	MEDIUM Strongly	SOFT Strongly
	More stable?	STIFF Strongly	Same	STIFF Strongly	STIFF Strongly	MEDIUM Strongly	SOFT Strongly
	More comfortable?	STIFF Strongly	Same	STIFF Strongly	STIFF Strongly	MEDIUM Strongly	SOFT Strongly
P6	Randomized set order	5	1	4	2	3	6
	Overall preference	MEDIUM Slightly	MEDIUM Strongly	SOFT Slightly	STIFF Strongly	MEDIUM Strongly	SOFT Strongly
	Less effort?	MEDIUM Slightly	MEDIUM Strongly	SOFT Strongly	STIFF Slightly	MEDIUM Strongly	SOFT Strongly
	More stable?	MEDIUM Slightly	MEDIUM Strongly	SOFT Slightly	STIFF Slightly	MEDIUM Strongly	SOFT Strongly
	More comfortable?	MEDIUM Slightly	MEDIUM Strongly	SOFT Strongly	STIFF Strongly	MEDIUM Slightly	SOFT Strongly

Figure 6.5 Individual preference results for the six sets comparing STIFF, MEDIUM, and SOFT prosthetic ankle stiffness in pairs. Gray indicated the participant had no preference. Red, blue, and purple indicated the participant chose the STIFF, MEDIUM, or SOFT condition, respectively, for that set. Darker shades of each respective color indicate the participant preferred that condition “strongly” while lighter shades indicate they preferred that condition “slightly.”

6.5 Discussion

The purpose of this study was to evaluate the impact of increasing prosthetic ankle dorsiflexion on the biomechanics and preferences of unilateral transtibial prosthesis users during sit-to-stand. To do this, we conducted a case series of six participants wearing an experimental prosthesis with three ankle stiffness conditions. As expected, all six participants increased their prosthetic ankle ROM during sit-to-stand as ankle stiffness decreased (Fig. 6.2). Although, the average increase in ankle ROM was modest. Compared to the STIFF condition, ankle ROM increased 1° with the MEDIUM stiffness ankle and 3.1° with the SOFT. The average prosthetic ankle ROM in the SOFT condition was 10.4° which is still less than the intact ankle ROM for most participants during sit-to-stand, by roughly 5-8° (see Supplementary Material). The impact of decreasing prosthetic ankle stiffness on limb loading symmetry was participant-specific and variable. Most participants only exhibited small changes in peak vertical GRF and peak knee flexion moment symmetry between limbs as prosthetic ankle stiffness decreased (Figs. 6.3 and 6.4). Additionally, participant preference and ratings of effort, stability, and comfort varied between participants and, for some, varied intra-participant between the repeated sets comparing ankle stiffness conditions (Fig. 6.5). Half of the participants (three of six) did consistently prefer the MEDIUM stiffness ankle over the STIFF, suggesting that at least for a subset of LLPUs, prosthetic ankles with lower stiffness or that enable larger ROM during sit-to-stand may be beneficial and preferable. However, the other three participants did not respond with consistent preferences with regards to a MEDIUM vs. STIFF ankle.

6.5.1 Participant-Specific Analysis

Lower limb prosthesis users are a heterogenous population who often employ individualized movement strategies and respond to interventions in different ways [40,84,144]. This heterogeneity, in addition to the small sample sizes common in prosthetics studies, limit the statistical power of experiments and the appropriateness of evaluating the impact of interventions at a group level. Because of this, we designed our study to be a case series where each condition (and condition comparison) was repeated several times in a randomized order to improve our ability to evaluate the impact of the intervention on each participant individually. Below we discuss interesting participant-specific findings and themes by considering the individual demographics, biomechanical results, and preferences of each person.

The results from one participant, P3, fully support our hypothesis that decreasing prosthetic ankle stiffness during sit-to-stand would increase ankle ROM, improve limb loading symmetry, and be preferred by users. P3 had the greatest increase in prosthetic ankle ROM and the largest improvement in limb loading symmetry (decrease in peak GRF DoA and peak knee moment DoA) as the stiffness of the prosthetic ankle decreased from STIFF to MEDIUM to SOFT. Additionally, P3 consistently preferred the less stiff ankle condition when the conditions were compared in pairs (Fig. 6.5). Interestingly, this participant is the oldest participant in this case series and the only participant with a Medicare Functional Classification Level of K3 (all others are K4). Based on this preliminary observation, it is possible that lower-mobility users, who likely find sit-to-stand more challenging, might benefit more from lower prosthetic ankle stiffness and/or increased ankle ROM. If sit-to-stand is near or at the limit of a person's ability, a prosthesis that provides increased ankle dorsiflexion may have a larger impact on their limb loading symmetry, effort, and stability while performing sit-to-stand and similar tasks. Future work might explore the biomechanics and potential benefits of this type of intervention specifically with a population of lower mobility LLPUs.

Apart from P3, the other five LLPUs in this study are K4 level users and are highly active individuals. These participants had more varied biomechanical results and preferences as prosthetic ankle stiffness decreased. For example, Participant 1 preferred the MEDIUM stiffness condition over the STIFF and SOFT (Fig. 6.5). However, it was when performing sit-to-stand with his least preferred condition, SOFT, that he had the most symmetrical limb loading with a 3.5% decrease in GRF DoA and a 9.4% decrease in knee moment DoA compared to the STIFF condition.

P5 had the most asymmetrical limb loading during sit-to-stand (highest GRF and knee moment DoA seen in Fig. 6.3 and Fig. 6.4) of all participants. His limb loading symmetry changed only a small amount with changes in prosthetic ankle stiffness. The DoA for GRFs and knee moments changed only 1-2% when comparing STIFF to MEDIUM and SOFT. P5 generally preferred the STIFF condition and had a split response when directly comparing the MEDIUM and SOFT conditions to each other (Fig. 6.5). Even though his limb loading results contradict our hypothesis, he did have the second largest increase in prosthetic ankle ROM (behind P3) as stiffness decreased (e.g., an 4.8° increase in ROM with the SOFT condition compared to the STIFF).

P2 also generally preferred the STIFF prosthetic ankle condition for sit-to-stand. Based on comments made during training and testing, he seemed to highly prioritize feeling stable once he neared a fully standing posture and he felt that the stiffer ankle condition gave him that support. In examining his intact and prosthetic ankle ROM across all conditions (Sup. Fig. 6.7), it is interesting to note that he had the least ROM in his intact ankle of all participants and that his limb loading asymmetry was similar across ankle stiffness conditions. Intact ankle ROM values for all other participants were 15° or more across every condition (see Supplementary Materials), but P2 had approximately 9-10° of intact ankle ROM both when wearing his prescribed device and the experimental prosthesis. His limb loading tendencies and stability during sit-to-stand may not be improved with a prosthesis that has increased dorsiflexion capabilities considering he uses minimal ankle ROM on his intact side. This also might be the reason that the increased ankle ROM with the less stiff conditions was less preferable for him.

Surprisingly, P4 had greater peak vertical GRFs under his prosthetic limb compared to his intact limb for all three stiffness conditions which can be observed as negative DoA values in Fig. 6.3. He was the only participant who put more force through his prosthetic limb rather than his intact limb. This was in contrast to the GRF data recorded when he performed sit-to-stand wearing his prescribed prosthesis (Sup. Fig. 6.4). When wearing his prescribed prosthesis, he put more force in his intact limb compared to his prosthetic limb with a DoA of 16.1%, but when testing with the experimental prosthesis his GRF DoA was -5.6%, -6.0%, and -6.0% for the STIFF, MEDIUM, and SOFT conditions, respectively (Fig. 6.3). This change in GRF distribution between devices could have been caused by a difference in familiarity with the prosthesis or concentration on the task, but ultimately, we do not know the reason for this change in loading strategy with the experimental prosthesis. Interestingly, P4 still had greater peak knee moments in his intact limb compared to his prosthetic limb even with more force under his prosthetic limb when testing the ankle stiffness conditions. This is likely indicative of differences in limb positioning and the location of the center of pressure under his intact vs. prosthetic foot. Additionally, participant P4 had highly inconsistent preference results giving conflicting responses for all sets comparing the pairs of stiffness conditions (Fig. 6.5).

6.5.2 Limitations and Alternative Approaches

We chose to test the impact of prosthetic ankle stiffness during sit-to-stand using an experimental prosthesis, the Vanderbilt Powered Ankle, with three stiffness conditions. We acknowledge that modulating the ankle stiffness by choosing three stiffness (k) values for the impedance equation (Eqn. 6.1) and emulating a passive rotational spring is only one way to potentially increase dorsiflexion during sit-to-stand and has its limitations. During pilot testing, we found individuals could not perceive a difference in prosthesis behavior once k was greater than 10 Nm/° and prosthetic ankle ROM for these pilot participants was similar between k = 10 Nm/° and other trials where k > 10 Nm/°. Several pilot participants also commented that the powered ankle felt very similar to their prescribed prostheses during sit-to-stand when k was set to 10 Nm/°. Based on this feedback, k = 10 Nm/° was chosen for STIFF condition and used for all participants. We selected the stiffness values of 5 Nm/° for the MEDIUM condition and 2.5 Nm/° for the SOFT condition because they were a logical reduction in the stiffness impedance value (half and a quarter of the STIFF condition), and they felt noticeably different to users during pilot testing. It should be noted that the stiffness values for the STIFF, MEDIUM, and SOFT conditions were the same for all participants. For the reasons stated above, we chose to not normalize stiffness to participant body mass, but acknowledge that could have impacted our biomechanics and participant preference results.

There are several alternative approaches to modulating prosthetic ankle behavior during sit-to-stand that could be explored to potentially improve the ability of LLPUs to do this task. Introducing positive power during the sit-to-stand motion by changing one or more of the impedance parameters is an alternative approach that could be tested using the same experimental device. However, we did not choose this approach because the torque and power generated at the ankle joint during sit-to-stand is relatively small compared to at the knee joint [111]. Additionally, device behaviors that include positive power could only be implemented into a powered prosthetic device which are currently only available to and used by a very small fraction of the prosthesis user population. We tested a simple prosthesis behavior modification, reducing stiffness, as an initial step towards understanding how prosthetic ankle ROM impacts transtibial prosthesis users during sit-to-stand. If this reduction in prosthetic ankle stiffness is further investigated and found to be beneficial for a particular group of users, such as those with a lower mobility level, this modification could be implemented in prostheses available to most individuals (i.e., passive ankle-foot devices). Additionally, this information may be helpful to consider when prescribing prostheses to individuals with limited ambulation. For some individuals, sit-to-stand may be a higher priority movement to enable independent transfers (e.g., in the home), relative to other objectives such as optimizing a foot prosthesis for walking over longer distances (e.g., outside the home).

6.5.3 Other Experimental Considerations

The primary results presented and comparisons made in this study were across experimental conditions that were all tested using the same prosthetic device. Data with participants wearing their prescribed prosthesis was collected at the beginning of the testing session, but only used to aid in interpretation of the primary results. The inclusion of a baseline or control condition (for this protocol, the STIFF condition) with the experimental prosthesis is important as it allows for interpretation of results without the confounding factors that can bias comparisons between a novel or experimental prosthetic device and the prescribed prosthesis that LLPUs wear in their daily lives. In this study, the experimental prosthesis weighed approximately 3 kg, which is significantly heavier than the participants' passive, prescribed devices (often less than 1 kg). In addition to weight and form factor differences, familiarity with a device can impact results and bias the perceived benefits of a novel intervention. The GRF results from participant P4 in this study highlight this fact (Sup. Fig. 6.9). When only comparing the GRF symmetry between sit-to-stand with his prescribed device and the SOFT experimental prosthesis condition, it appears that the experimental prosthesis, and the increased ankle ROM it allowed, caused him to shift a considerable amount of force into his prosthetic limb. This would misconstrue the results as the full data illustrates that the change in GRF distribution between limbs differed between devices, not between prosthetic ankle stiffnesses. Collecting data with users in their prescribed devices is helpful to build out a full picture of an individual's movement strategies, but primary comparisons between the devices LLPUs wear every day and experimental interventions should be carefully interpreted when evaluating the potential benefit to users, particularly in the context of this study's objective.

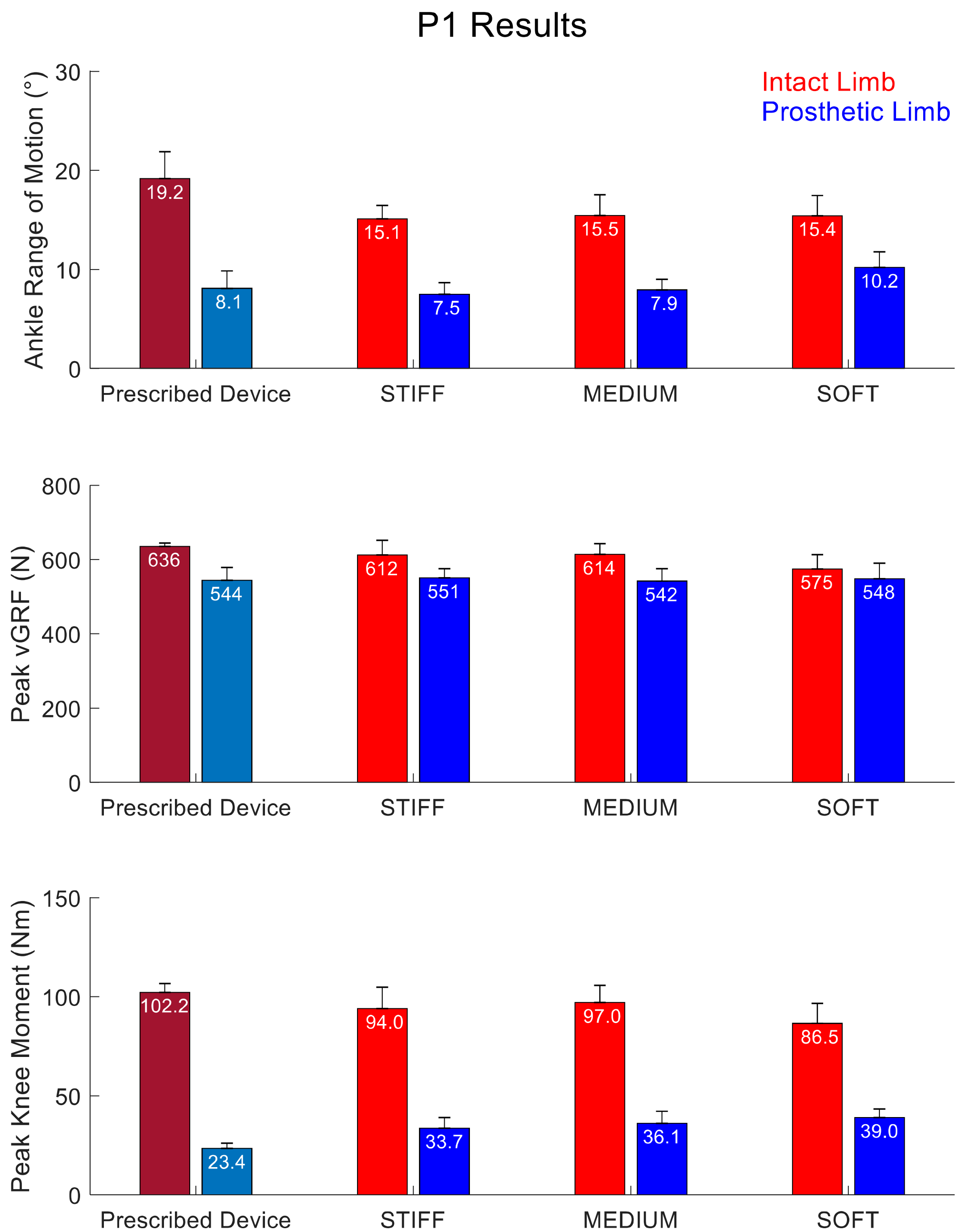
We included a training session in our protocol to improve the familiarity of users with the experimental prosthesis. During this session, participants performed sit-to-stand in all three ankle stiffness conditions many times. After initial familiarization, they were encouraged to explore different starting positions, such as foot placement. During the testing session, foot placement was not constrained. Intact and prosthetic foot placement did vary in the anterior-posterior direction between participants more than between stiffness conditions for each participant. It is possible that a longer acclimation time (or directed training) with each stiffness condition before data collection could have led to alterative foot placement. Foot placement likely has an impact on ankle ROM and limb loading during sit-to-stand [24,145,146] and is an interesting avenue for future research. Future work could combine a prosthetic intervention that enables increased ankle dorsiflexion with a training intervention that encourages/teaches LLPUs to place their prosthetic foot more posterior (closer to under the chair) when preparing to stand up. We expect this could further increase the prosthetic ankle ROM of users if they are using a prosthesis that has the capability to dorsiflex and, with training over a longer period of time, potentially change how users perform sit-to-stand in their daily lives.

6.6 Conclusion

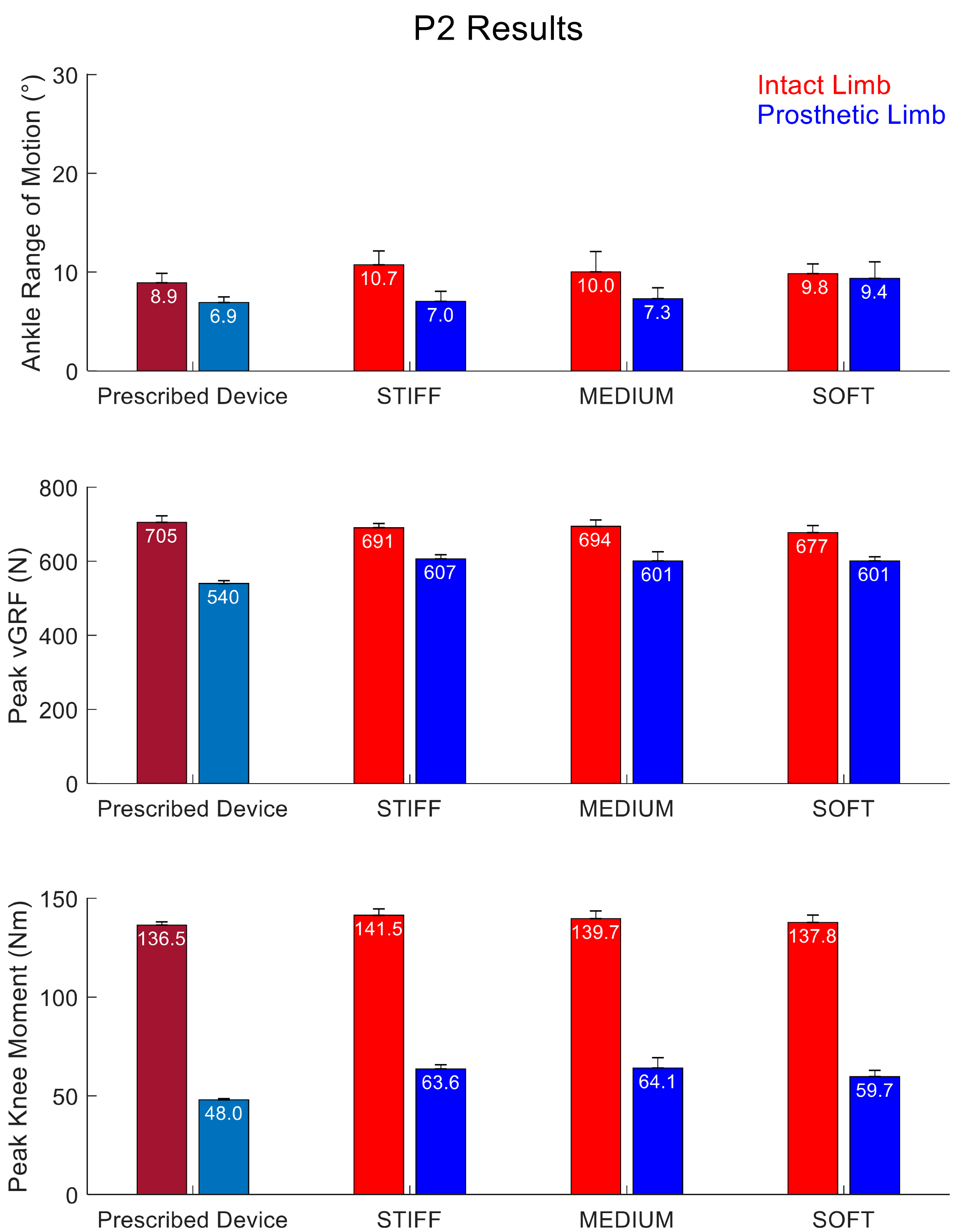
This study aimed to assess the effects of increasing prosthetic ankle dorsiflexion on the performance of LLPUs during sit-to-stand by modulating prosthetic ankle stiffness. In this case series, we found that as prosthetic ankle stiffness decreased, all six participants demonstrated increased prosthetic ankle ROM during sit-to-stand. However, the impact on GRF and knee moment symmetry between limbs was less consistent across participants. Participant-specific analysis highlighted individual variations in biomechanical responses and preferences, underscoring the heterogeneity within the prosthesis user population. Notably, the participant with the largest increase in prosthetic ankle ROM also had the greatest improvement in limb loading symmetry. This participant also consistently preferred the least stiff ankle condition and was the only participant in this case series with a functional level of K3. It may be possible that reducing prosthetic ankle stiffness might be most beneficial for lower-mobility users, but this requires further investigation and future work.

6.7 Supplementary Materials

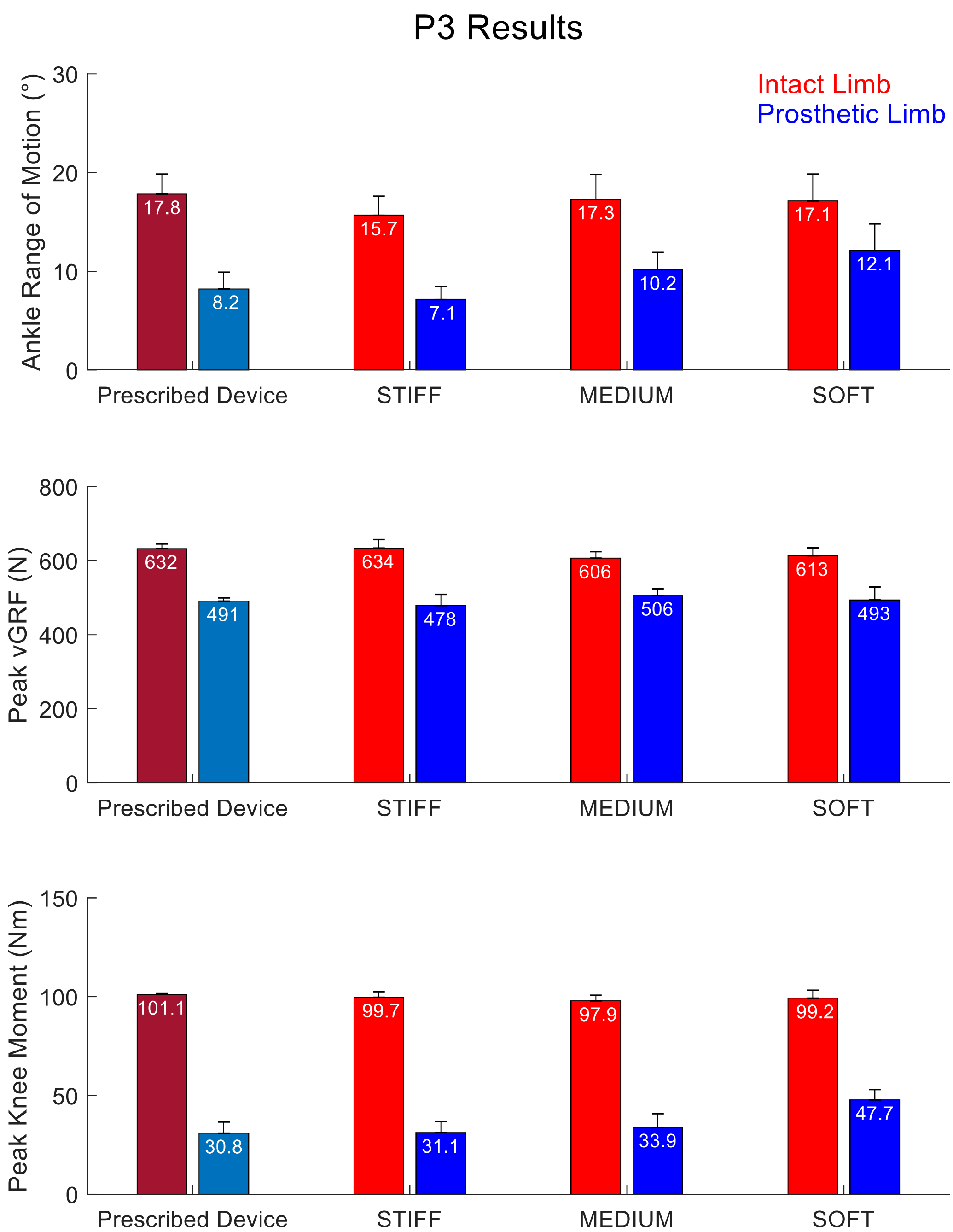
Below are participant-specific results for evaluating sit-to-stand with six unilateral transtibial prosthesis users. Results from testing with their prescribed device and the three experimental ankle stiffness conditions are included.



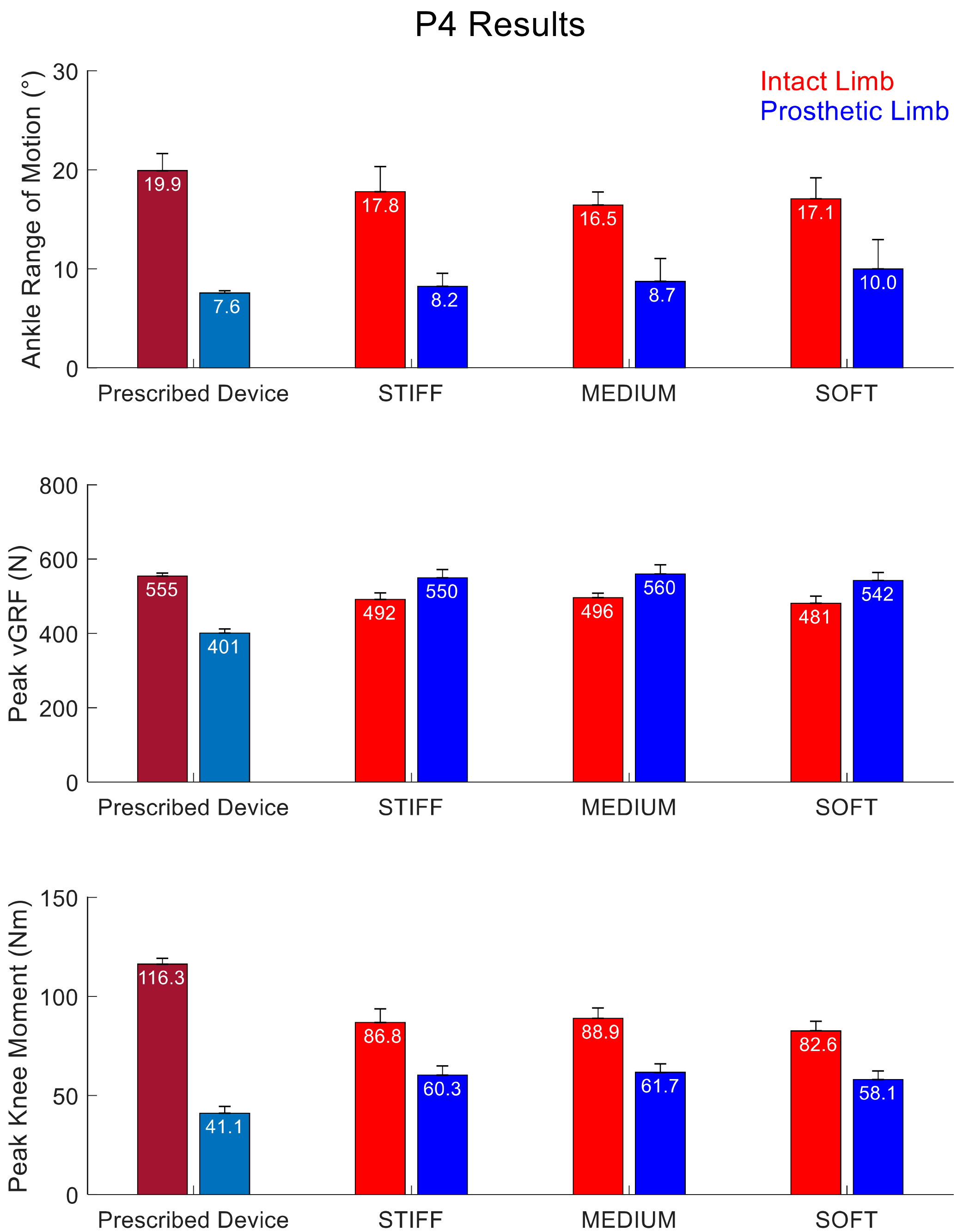
Supplementary Figure 6.6 P1 ankle range of motion and limb loading during sit-to-stand. Intact limb results are shown in red and prosthetic limb results are shown in blue. Results from evaluation with their prescribed device are displayed in the left column in darker colors.



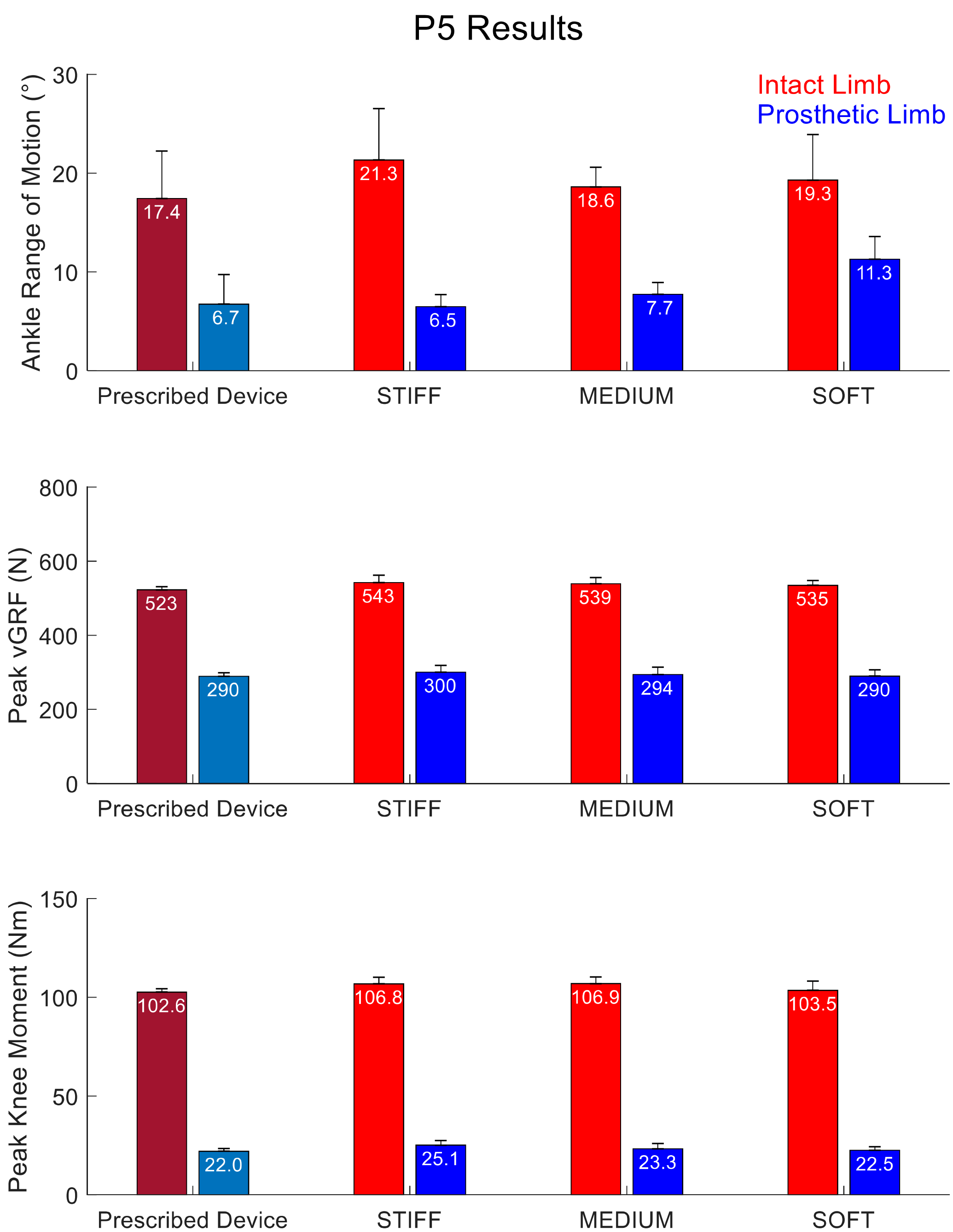
Supplementary Figure 6.7 P2 ankle range of motion and limb loading during sit-to-stand. Intact limb results are shown in red and prosthetic limb results are shown in blue. Results from evaluation with their prescribed device are displayed in the left column in darker colors.



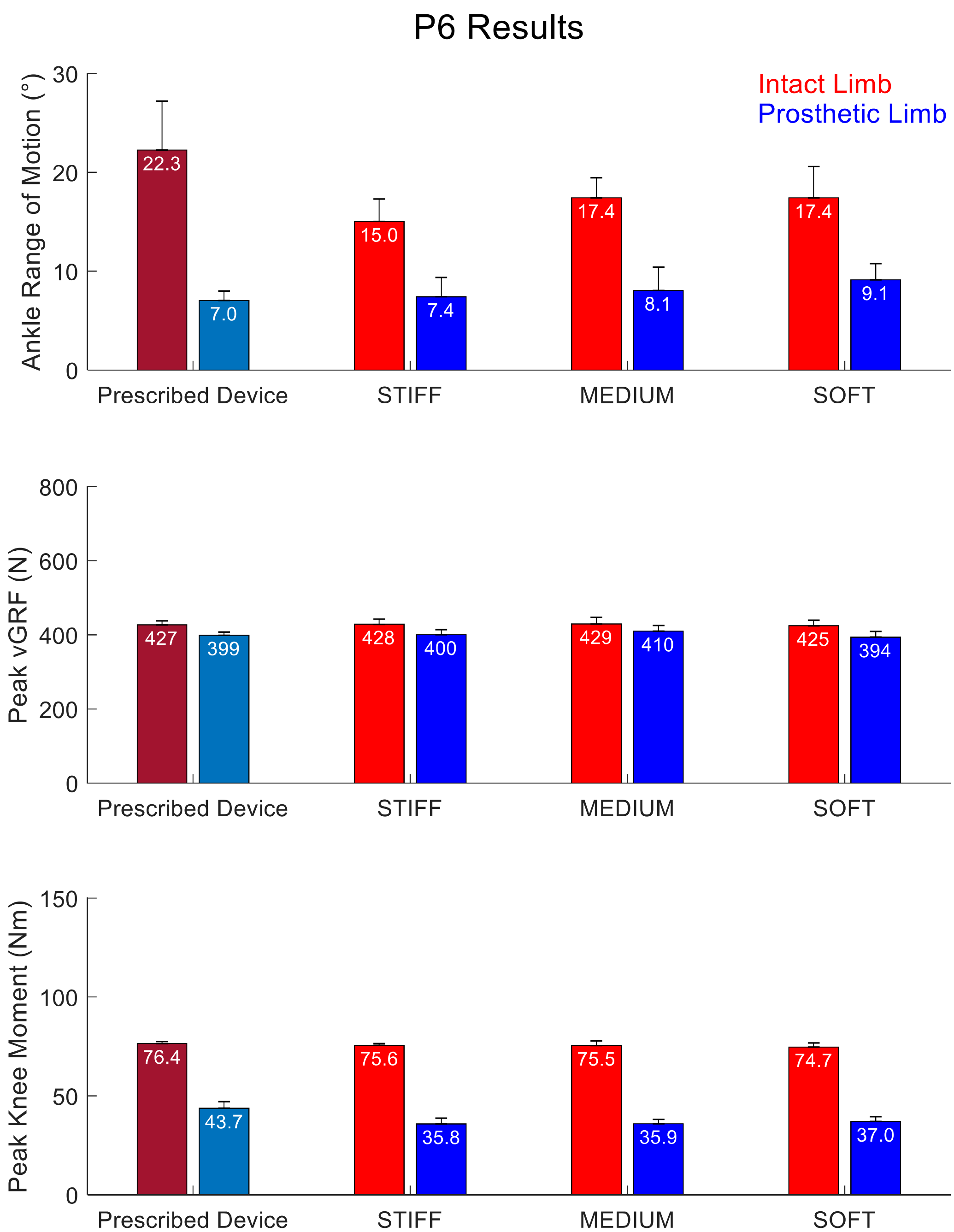
Supplementary Figure 6.8 P3 ankle range of motion and limb loading during sit-to-stand. Intact limb results are shown in red and prosthetic limb results are shown in blue. Results from evaluation with their prescribed device are displayed in the left column in darker colors.



Supplementary Figure 6.9 P4 ankle range of motion and limb loading during sit-to-stand. Intact limb results are shown in red and prosthetic limb results are shown in blue. Results from evaluation with their prescribed device are displayed in the left column in darker colors.



Supplementary Figure 6.10 P5 ankle range of motion and limb loading during sit-to-stand. Intact limb results are shown in red and prosthetic limb results are shown in blue. Results from evaluation with their prescribed device are displayed in the left column in darker colors.



Supplementary Figure 6.11 P6 ankle range of motion and limb loading during sit-to-stand. Intact limb results are shown in red and prosthetic limb results are shown in blue. Results from evaluation with their prescribed device are displayed in the left column in darker colors.

CHAPTER 7

Conclusions and Future Work

7.1 Conclusions

This dissertation includes several research contributions to the field of lower-limb prosthetics and biomechanics. Overall, this work explores the impact of prosthetic ankle-foot dynamics on the preferences and biomechanics of prosthesis users across a number of activities of daily living. It addresses key knowledge gaps in the field by establishing the movement and limb loading patterns of unilateral transtibial prosthesis users for several common daily tasks. Additionally, it investigates the impact prosthetic interventions can have on daily task performance and user preference. Specifically, Chapters 2 and 3 assess how incorporating an articulating toe joint into a passive prosthetic foot impacts the biomechanics of prosthesis users walking on level-ground, inclines, and declines. Chapters 4 and 5 characterize the biomechanics of transtibial prosthesis users during sit-to-stand, squatting, lifting, and lunging. These are common daily tasks that have not previously been extensively explored in this population. By characterizing user strategies and limb loading patterns, this research identifies limb loading asymmetries that could be targeted by interventions to improve functional ability and reduce the risk of secondary musculoskeletal conditions. Lastly, Chapter 6 evaluates the impact of altering prosthetic ankle stiffness during sit-to-stand on prosthesis user preference and biomechanics.

Across the series of studies that comprise this dissertation, changes in prosthetic ankle and foot dynamics impacted biomechanical outcomes at the device level, but often had a minimal impact on the biomechanics of the other biological joints. In Chapters 2 and 3, adding a toe joint to a prosthetic foot impacted prosthetic Push-off work, but did not impact knee, hip, or intact ankle biomechanics during level-ground and sloped walking. In Chapter 6, decreasing prosthetic ankle stiffness increased prosthetic ankle range of motion (ROM) during sit-to-stand, but had minimal impacts on limb loading symmetry for most participants. Additionally, in all three of these Chapters, participant preference for the prosthetic intervention condition was split among participants indicating preference for ankle-foot technology is likely both user-specific and task-specific. Consequently, it may be difficult or impractical to expect to directly relate changes in movement biomechanics to changes in user preference or performance, which suggests that it is often beneficial in prosthesis user experiments to collect these two types of complementary data. Insights gained from this body of work provide valuable guidance for improving prosthetic designs to better serve the diverse needs and preferences of lower limb prosthesis users.

7.2 Future Work

Findings from this dissertation offer exciting opportunities for future innovation and highlight challenging open questions in the field of lower limb prosthetics. The following section details possible directions for future work.

7.2.1 Research and Innovation focused on Lower-Mobility Users

The current prosthetic research landscape primarily focuses on highly active individuals, creating a significant gap in understanding the needs of lower-mobility users. More prosthetics research should prioritize the evaluation of interventions for lower-mobility users, who are often underrepresented in academic research studies despite forming a significant portion of the prosthesis user population. Small sample sizes comprised of mostly (or only) highly mobile users are common in the field of prosthesis research. This can be due to the interest and availability of people willing to volunteer for research studies in addition to the often cumbersome and taxing data collection protocols designed to robustly test novel interventions. In this dissertation, all prosthesis user participants are classified as Medicare Functional Classification Level K3 or K4, reflecting this tendency of studying only highly mobile individuals. While the results from Chapters 2 and 3 indicated minimal biomechanical impacts of adding a toe joint for highly active users, feedback from clinicians and users suggested potential benefits for lower-mobility individuals who may value forefoot compliance for daily tasks. Similarly, Chapters 4-6 evaluated daily task performance, yet the recruited participants, who largely have a very high level of functional ability, demonstrated minimal difficulty with the selected tasks. Notably, in Chapter 6, the single K3 participant exhibited significant improvements in prosthetic ankle ROM, limb loading symmetry, and preferred the least stiff ankle condition. Future work should investigate the movement strategies of lower-mobility users during daily tasks and evaluate the potential benefits of the prosthetic ankle-foot interventions evaluated in this dissertation for that group of users.

Understanding the challenges and movement strategies of this demographic is crucial for developing more effective prosthetic solutions for a larger portion of the prosthesis user population. However, recruiting individuals of different mobility levels is challenging. Intentional recruitment strategies, clinical collaborations, and innovative study designs are likely necessary to effectively conduct research and develop solutions for this population. Future work should consider opportunities to move human movement studies outside of the typical gait lab setting to lower the barrier for participating in prosthetics research. One approach to facilitate recruitment of lower mobility users could be to conduct data collection in clinical settings, such as prosthetists' offices. This approach could streamline participation, allowing data collection before or after appointments, thereby increasing the diversity in participant mobility level. Addressing the needs of lower-mobility users presents significant opportunities for developing innovative prosthetic technology solutions with the potential to have substantial impacts on their ability to navigate their environment and their overall quality-of-life.

7.2.2 Connecting User Preference, Biomechanical Outcomes, and Long-Term Health Outcomes

The complex interplay between user preference, biomechanical outcomes, and real-world functional outcomes in regard to prosthetic technology is an additional exciting area of future research. The work in this dissertation, along with other recent research, has emphasized the individualized responses to prosthetic interventions, but much remains unknown about what drives user preference and how to connect preference to measured movement outcomes. When evaluating preference for prosthetic ankle-foot interventions in Chapters 2, 3, and 6, user preference was split and not clearly explained by the measured biomechanical or metabolic outcomes. When evaluating user preference for level ground walking with or without a toe joint in Chapter 2, the most intriguing preliminary observation was the potential link between user preference and limb dominance. Chapter 6 interestingly showed that the participant who consistently preferred a less stiff prosthetic ankle for sit-to-stand did have the greatest improvement in biomechanical outcome measures (ankle ROM and limb loading symmetry). Researchers and developers should consider user preference during device design as it can be key for user acceptance, but these findings highlight that further investigation into determinants of user preference is needed. It should be noted that in some circumstances, there will be no strong link between user biomechanics and preference. Instead, other factors outside of biomechanical outcomes will determine preference for prosthetic technology. But, in situations where a relationship can be identified, establishing the connection between biomechanical outcomes and user preference could help inform clinical device prescription and prosthetics innovation based on specific user needs or movement patterns.

Another significant opportunity for future work involves understanding how outcomes measured in a lab setting relate to long-term functional ability and health outcomes. In Chapters 4 and 5, I established that users load their intact limb more than their prosthetic limb during common daily tasks. From these results, we theorized that this repetitive increased mechanical loading may contribute to the high rates of intact limb joint pain and osteoarthritis observed in the lower limb prosthesis user population. However, direct measures connecting human movement biomechanics in-lab to long-term health and mobility outcomes are rare. This limits our ability to understand how lab-measured variables truly impact a person’s overall quality-of-life. These potential connections, between in-lab metrics and long-term outcomes, are incredibly challenging to study and quantify. However, new innovations in wearable technology and data science provide opportunities to monitor new variables over longer periods of time and process larger data sets to begin to investigate human movement patterns and health outcomes on a new scale in the real world. Breakthroughs in understanding the relationships between lab-based measurements, user preference, and long-term health and mobility outcomes would significantly impact how prosthetic technology is designed and prescribed, and could translate to improvements in quality-of-life and mobility for individuals with limb loss.

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