Evaluating the Effects of Powered Prostheses on Walking Biomechanics In and Out of the Lab

by

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A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
(Kinesiology and Mechanical Engineering)
in The University of Michigan
2021

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To my family, who taught me to never be afraid of dreaming big.

ACKNOWLEDGEMENTS

I am truly grateful to have met so many wonderful people throughout this journey. My doctoral work would not have been possible without the guidance and support I received from my family, friends, mentors, and colleagues.

First, I would like to acknowledge my primary advisor, Deanna Gates. Thank you for investing in me and giving me the opportunity to learn from you. I have learned so much, not only about what makes a good academic, but also what it means to be a caring and dependable mentor. I would also like to thank the rest of my committee, David Remy, Noel Perkins, Lauro Ojeda, and Brian Umberger, who have offered wonderfully unique perspectives in how to approach open-ended problems and have always given me constructive support. I am so thankful to have a committee that really cares about my growth as a researcher.

I would also like to thank my friends and colleagues. To Fahad Karim, thank you for your friendship and always being a part of that magnetic pull toward anything creative. To Luis Nolasco, I am lucky to have had such an awesome office/lab mate and friend through the PhD journey - thank you. To past and present members of the Rehab Biomechanics Lab: Susannah Engdahl, Deema Totah, Hwan Choi, Kelsey Ebbs, Christina Lee, Jeff Cowley, Michael Gonzalez, Jiyeon Kang, Matt Mulligan, Manan Anjaria, Vibhavari Vempala, Kiichi Ash, and more - thank you for your help and support. This experience was made more rewarding, engaging, and fun because of each of you.

Lastly, thank you to my family. I am the person I am today because of you.

You gave me courage in my pursuits and believed in me even when I didn't. Thank you to my dad, to whom I go to first for unwavering reassurance. Thank you to my mom, who is endlessly eager to help. Thank you to my sister, Jaeah, who can make me laugh harder than anyone. To my wife, Ajin - thank you for being the amazingly warm and genuine person that you are. For you, I aim to be a better person everyday.

PREFACE

Chapters 2 - 6 have been written as separate manuscripts for publication. There may be some repetition of presented material between chapters. Chapter 4 has been published and chapters 2 and 5 are in review.

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LIST OF ABBREVIATIONS

LLA Lower-limb amputation

SACH Solid ankle cushion heel

ESAR Energy storage and return

DR Dynamic response

TTA Transtibial amputation

COM Center of mass

GRF Ground reaction force

ICF International Classification of Functioning, Disability, and Health

GPS Global positioning system

IMU Inertial measurement unit

MTC Minimum toe clearance

BMI Body mass index

EMG Electromyography

GM Gluteus medius

RF Rectus femoris

VL Vastus lateralis

VM Vastus medialis

LH Lateral hamstring

MH Medial hamstring

MG Medial gastrocnemius

LG Lateral gastrocnemius

SOL Soleus

TA Tibialis anterior

MVC Maximum voluntary isometric contraction

COT Cost of transport

iEMG Integrated EMG

CCI Co-contraction index

ROM Range of motion

RPE Rating of perceived exertion

SI Symmetry index

MS Mid-stance

TS Terminal stance

PSw Pre-swing

LR Loading response

ACC Accelerometer

ZUPT Zero velocity updates

CON Control

MCID Minimal clinically important difference

MDC Minimal detectable change

PEQ Prosthetic Evaluation Questionnaire

SF-36 Short Form 36 general health questionnaire

VAS Visual analog scale

RFC Relative foot clearance

CoR Center of rotation

ABSTRACT

Powered ankle prostheses aim to replicate the biological ankle function for individuals with transtibial amputation. The effects of powered prostheses on gait have been experimentally quantified in several studies. The findings are non-universal and potentially dependent on user characteristics. Disparate responses to the powered prosthesis among users point to unanswered questions regarding the fundamental biomechanical effects of the device. Additionally, it is unknown how powered prostheses impact daily function. To address these gaps in knowledge, I investigated various biomechanical and clinical outcomes of the powered prosthesis in the laboratory and in the users' everyday lives. My research can be broken down into two approaches: experimental analyses of *functional capacity* and examinations of *functional performance* in everyday life.

To assess functional capacity in the lab, I first explored users' neuromuscular adaptations to the powered prosthesis (Chapter 2). Specifically, I quantified changes in lower-limb muscle activations and their relationships with changes in metabolic cost. This aim revealed the potential importance of effective residual limb stabilization as a contributor to metabolic reductions. Second, I sought to quantify fatigue-related compensations in walking with the powered prosthesis (Chapter 3). While the powered prosthesis did not improve the user's endurance, there were differences in hip joint compensation strategies when wearing unpowered and powered prostheses.

I then developed methods to bring gait analysis out of the lab, to assess functional performance in daily life. I first explored the use of portable GPS and IMU sensors to quantify functional mobility in everyday walking (Chapter 4). Through this work

I demonstrated the clinical viability of estimating cadence and walking speeds in different real-world environments. I then applied these techniques to assess changes to the volume and characteristics of walking with a powered prosthesis in daily life (Chapter 5). Further, I examined the relationships between capacity in the lab, performance in daily life, and the users' perceptions of mobility. Lastly, I examined potential implications of the powered prosthesis on trips and falls in daily life (Chapter 6). In this study, I applied a novel method for using IMU signals to estimate minimum toe clearance in daily life. Findings from Chapters 5 and 6 suggest there were no universal powered prosthesis-related changes to gait in daily life.

Together, these works add to the existing body of literature and reinforces the notion that the benefits of the powered prosthesis are non-universal and subject-specific. Chapters 4 through 6 specifically represent a meaningful first step toward an evidence-based approach in the prescription, design, and assessment of powered prostheses.

CHAPTER 1

Introduction

Lower-limb amputation (LLA) is a prevalent and ever-growing issue in the United States today. In 2005, close to 1 million people in the United States were living with LLA and this figure is projected to more than double by 2050 [163]. People with LLA are able to regain some level of functional mobility using a prosthesis. In the United States, prostheses are prescribed by first assessing a patients' functional mobility using the Medicare Functional Classification Levels, or K-levels [41]. Based on this designation, they are prescribed devices with appropriate functionalities.

Most commercially available, prosthetic feet are unpowered devices. Solid ankle cushion heel (SACH) feet, which comprise of a soft material molded over a rigid keel, provide little energy storage and return but offer greater stability. Energy storage and return (ESAR), also referred to as dynamic response (DR), feet consist of a carbon fiber spring that stores energy during loading response and releases this energy return during push-off. By nature, unpowered devices cannot perform positive net work and produce less than one eighth of the power compared to the biological plantarflexor muscles [11, 164]. Due, in part, to these deficiencies, individuals with transtibial amputation (TTA) walk with increased metabolic effort [27, 48, 155], increased muscle activation [74, 158], decreased symmetry and stability [133, 5, 46, 72, 74, 81], and at a slower walking speed compared to people without amputation [155, 11]. Individuals with TTA also tend to rely more on their intact limb and are correspondingly at a greater risk for developing osteoarthritis in the intact side knee and hip [141, 93]. These functional deficits represent barriers to healthy amounts of physical activity [19] and contribute to a lower quality of life and greater risk for developing secondary health conditions such as obesity and hypertension [116, 146].

1.1 Powered Push-off at the Prosthetic Ankle Joint

Recent prosthetic research has focused on replicating the biological ankle plantarflexor function by generating power during push-off [6, 24, 21, 66, 58] in hopes of restoring a normal gait pattern. Several powered ankle prostheses have been developed which successfully provide active torque at the ankle comparable to that of the biological ankle during push-off and allow for increased range of motion of the ankle [66, 6, 63, 21]. To date, however, the BiOM (now Empower, Ottobock, Duderstadt, Germany) is the only device that is commercially available.

To evaluate the effectiveness of the powered prosthesis, research efforts have examined several factors that influence functional mobility, including metabolic effort, work done on the body center-of-mass (COM), inter-limb symmetry, stability and fall risk, and self-selected walking speed. I will describe the efforts in each of these areas in the following sections.

1.1.1 Metabolic Effort

Individuals with TTA use greater metabolic effort when walking, compared to people without amputation [26, 155]. Elevated metabolic costs can be attributed to neuromuscular strategies to compensate for the lack of biological plantarflexors and adversely affect functional mobility. The powered prosthesis aims to replicate part of the biological push-off torque, lessen compensations at other joints, and theoretically reduce metabolic costs. Thus, one way to evaluate the efficacy of a powered push-off is to measure metabolic normalization, or how much the prosthesis was able to reduce metabolic effort in users to that of non-amputees [94, 63, 130, 120, 49].

Several studies found that metabolic costs decreased with powered push-off during level walking [7, 63, 94, 130]. However, in cohorts with wider age ranges, metabolic benefits were not observed [49, 102]. This may indicate that the ability to utilize power to reduce metabolic effort depends on individual characteristics. Specifically, Gardinier et al. found a strong association between the participants K-levels and metabolic effort such that more active, higher functioning individuals reduced metabolic costs, while lower functioning individuals increased metabolic costs with the powered prosthesis. It is possible that the benefits of this power may only apply when more power is needed, such as walking at faster speeds [63] or uphill [102]. Overall, the device may be limited due to its uni-articular nature whereas some of the biological ankle plantar flexor muscles are biarticular across the ankle and knee joints. The lack of metabolic benefits may also be due to the loss of mechanical energy transferred from the residual limb to the prosthetic end effector via the limb-socket interface.

During gait, muscle activations are ultimately the primary drivers of metabolic cost [79]. As such, the widely varied metabolic response to the powered push-off may also relate to the participants' neuromuscular control strategy. In general, individuals with TTA walk with increased magnitude and duration of muscle activation at the residual limb quadriceps [158, 144, 118, 124], and gluteus maximus [158, 144], compared to individuals without amputation.

Neuromuscular control strategies are sensitive to the prosthetic device used. Ventura et. al found that with prosthetic ESAR feet, individuals with TTA walked with reduced activity at the residual limb hamstrings but with increased activity at the vastus and rectus femoris muscles [153]. Another study found that as the stiffness of the ESAR decreased, individuals with TTA walked with increased activity at the bilateral vastus muscles and the residual limb gluteus medius [39]. In both studies, the neuromuscular response to different prosthetic characteristics were highly variable across subjects.

The effects of powered prostheses on muscle activity are not clear. Only one previous study has quantified changes in muscle activity with varying levels of push-off power generation [120]. Using an experimental prosthetic emulator, the authors found that with increasing prosthesis work, activity in the residual limb during push-off increased, while activity in the intact limb during early stance decreased. However, it is unclear if these findings will persist when walking with a commercially available powered prosthesis, which is significantly heavier due to the onboard battery and electronics. Additionally, prior work did not measure muscle co-contraction. This is important as co-contraction of agonist and antagonist muscles about a joint is another source of metabolic cost. Individuals with TTA co-contract their residual limb knee muscles to stabilize the residual limb-socket interface during gait [137]. As increased energy storage and return in unpowered prostheses has been shown to require increased stability [39, 153], a powered push-off may similarly yield undesirable increases to residual limb knee co-contraction.

1.1.2 Gait Symmetry

A symmetric gait pattern is a characteristic of unimpaired gait [8, 73]. For people with amputation, a complete symmetry may not always be desired due to the prosthetic limb being inherently different to the intact limb. However, this may have long-term health consequences such as osteoarthritis, as asymmetry in loading is associated with increased risk of knee osteoarthritis in the intact limb [18]. Osteoarthritis and knee pain at the intact limb are prevalent in the TTA population and represent significant barriers to healthy amounts of physical activity [18, 106, 104]. Reducing the overloading on the intact limb, and thereby increasing kinetic symmetry, may mitigate the increased risk of people with TTA developing osteoarthritis in the intact limb [93]. Specifically, increased peak knee external adduction moment is associated with the development of knee osteoarthritis [9, 42]. Prosthetic ankles that produce greater power peaks during push-off have been found to reduce the peak knee external adduction moment at the intact side knee [105]. Thus, powered prostheses could be expected to reduce intact limb knee adduction moments. However, changes to intact limb loading with the powered prosthesis were speed dependent. While the powered prosthesis reduced intact limb GRFs at slow to moderate speeds (0.75 - 1.5 m/s), it reduced adduction moments at the intact side knee only at faster speeds (1.5 and 1.75 m/s) [56].

While we may expect that restoring symmetry to the ankle power may alleviate the overreliance on the intact limb, the effects of the powered prosthesis on gait symmetry remains unclear. The powered prosthesis reduced stance and swing duration asymmetries, which may indicate a decrease in overreliance on the intact limb [38]. However, walking with the powered prosthesis did not reduce interlimb asymmetries of peak knee power absorption. As with metabolic effort, it is possible the benefits of powered prostheses on gait symmetry may only be present when more ankle power is needed. Walking on a loose rock surface is one such activity that may require greater added power but did not affect asymmetries [50]. Walking on an uphill slope, symmetry increased with the powered prosthesis when walking on steep inclines of 6 and 9 degrees [102]. Overall, the effects of powered prostheses on kinetic gait symmetry may be limited by the uni-articular nature of the prosthesis, which lead to compensatory mechanisms in the proximal joints [38]. However, walking tasks that require more push-off torque may yield adaptations to gait symmetry.

Gait symmetry may also change throughout prolonged activity as people adapt to factors such as pain or muscle fatigue. During longer walks, individuals with TTA may experience muscular fatigue and require more push-off power at the prosthetic ankle.

Previous studies primarily assessed gait symmetry during short periods of walking. Therefore, it is unknown if gait symmetry changes over prolonged walking. The effects of lower-limb fatigue on unpowered prosthesis users has only been explored in one study to date [160]. Yeung et al. examined changes to six participants with TTA before, between, and after two 30-minute bouts of continuous treadmill walking and found decreased power absorption and generation in the intact limb ankle, decreased peak propulsion ground reaction force, and increased power generation at the intact limb hip joint. However, authors did not record muscle activity or perceived exertion. Therefore, further work is needed to characterize the effects of fatigue when walking with a powered prosthetic foot.

1.1.3 Evaluating the Prosthetic Use in Daily Life

While instrumented gait analysis has been the standard for evaluating prosthetic interventions by measuring an individual's capacity within a controlled setting, it offers little insight on the potential changes to functional mobility in the everyday, real-world setting [124]. According to the International Classification of Functioning, Disability and Health (ICF), evaluating performance, i.e., what one does in their actual environment is also an important component of characterizing functionality [114]. To this end, an increasing number of studies have utilized portable accelerometry-based sensors to quantify physical activity in daily life. The step count is an informative, robust indicator of overall health and amount of physical activity and has been commonly measured in daily life to characterize individuals with [88, 140, 115, 68, 138] and without lower limb amputation [150, 151, 113, 43]. Activity levels describe the intensity of physical activity in daily life, and are typically reported as durations of light, moderate, or hard activity in a day, based on the vector magnitude of the accelerometer signal [44, 140, 1]. However, the large between-subject variability in daily step counts and activity levels may indicate its limited sensitivity as an outcome measure to evaluate prosthetic interventions.

The ability to vary cadence is one of the criteria for higher functioning levels of mobility as set by the Medicare K-level guidelines [41]. A recent study has explored the viability of quantifying cadence variability in daily life [3, 4]. In this study, cadence was estimated as the step count per minute epoch, and cadence variability was estimated using the distribution of cadence values over 7 days. However, commercial activity monitors will underestimate cadence if walking is not continuous for the entire minute epoch [29], and simple accelerometer-based activity monitors have decreased accuracy at slower walking speeds [43]. These issues may be particularly problematic for individuals with TTA as they tend to walk slowly and in short bouts [88]. Therefore, more advanced signal processing techniques may be required to measure cadence on a stride-by-stride basis.

Walking speed has long been established as a robust indicator of functional mobility. Previous works have used walking speed as an outcome measure to assess mobility [5, 45, 64] and classify individuals' ability for community ambulation [117]. Assessed in the laboratory, the effect of a powered push-off on preferred walking speed is unclear. Younger individuals with TTA increased their preferred walking speed on flat [38] and uneven rock surfaces [50]. With a more diverse cohort, some participants increased their preferred walking speed with a powered push-off [63], while some participants did not [49, 102]. This discrepancy in the findings may be attributed to different methods of measuring preferred walking speed. While Herr et al. [63] incrementally increased and decreased treadmill belt speeds until the participant indicated they were walking at a preferred walking speed, other studies [38, 49, 102] had participants walking over ground at a self-selected speed. No previous study has measured walking speed as performed in daily life.

Another important component of mobility is community-level engagement [41]. Because there is no measurable standard for how well one engages in the community, clinicians typically subjectively assess community engagement through patient self-reports [80]. The emergence and prevalence of global positioning system (GPS) technology in smartphones in the past decade has opened avenues for researchers to explore the feasibility of quantifying community-level ambulation using GPS data in daily life [127, 156, 84, 75, 68, 69]. Community engagement is typically described as the number of steps taken in the community or frequency of visits to community environments. However, this approach may only provide indirect insight into how well people move within community environments. Quantifying mobility using walking speed or cadence variability in different locations and environments may provide more insight into one's ability for community ambulation.

While in-clinic tests such as the 10-meter walk test are capable of measuring steady-state walking speed [45], this may not represent comfortable walking speed in daily life [115]. Recent developments of inertial measurement units (IMU) and inertial navigation algorithms have made it possible to accurately calculate stride-by-stride spatiotemporal gait parameters, by mounting the IMU sensor to the foot. This approach, referred to as "pedestrian dead-reckoning," estimates the position of the foot-mounted sensor by integrating the acceleration signal twice [110]. The gyroscope signal from the IMU is used to detect periods of low movement during foot-flat, assuming no slip between the foot and the ground. In these low-movement foot-flat periods, zero velocity updates are applied to correct for integration error and acceleration signal drift. Though this approach has not yet been applied to the LLA population, experiments successfully calculated travel distance with an error of 1%. With some modifications to stride segmentation, the approach could be applied to calculate stride-by-stride measures of walking speed in daily life. Examining walking speeds in daily life could provide insight on everyday performance with a powered prosthesis, to supplement measures of walking speed capacity as presented in previous studies [63, 38, 50, 49, 102].

1.1.4 Fall Risk

Mitigating fall risk is an important consideration for prosthetic interventions, especially for individuals with TTA, as they are more susceptible to tripping [90, 98]. Surveys regarding fall occurrence showed that more than 50% of individuals with lower-limb amputations had experienced falls in the past year [90, 98]. Falls have been reported to affect the individual's confidence in walking and fear of falling. In addition to the resulting potential physical injuries, fear of falling may affect functional mobility and physical activity in daily life [98]. Individuals with TTA are particularly susceptible to trips due to the inability of the prosthetic foot to actively dorsiflex during swing. This contributes to a low minimum toe clearance (MTC), or the vertical distance between the lowest point of the foot and the ground at the minimum point of swing. Insufficient MTC can lead to trips and subsequently falls [103, 51, 31]. Previous works have found associations between increased fall risk and low MTC and high stride-to-stride MTC variability in healthy non-amputees [99, 136] and people with TTA [78, 128].

The MTC may be affected by the type of prosthesis used. For example, the Proprio Foot (Ossur, Reykjavik, Iceland) is a microprocessor prosthesis, which is the only device to provide active dorsiflexion during swing. Using this foot, people with TTA had increased MTC [129]. While the BiOM powered prosthesis does not actively dorsiflex the foot, it may help initiate swing as it produce comparable step-to-step transition work at the trailing prosthetic limb to that of the intact limb [130]. On a loose rock surface, the BiOM powered prosthesis increased MTC relative to that of the unpowered prosthesis but was still lower than that of the intact limb [50]. Additionally, the differences between powered and unpowered prostheses were small, the powered prosthesis was in a more plantarflexed position, and there were no kinematic differences at the hip or knee joints between prostheses. Thus, authors attributed the increase in MTC to the small changes in intact limb knee flexion during stance.

To better understand the role of MTC in fall risk, it is important to determine how it changes in daily life, when surfaces are varied and speed is modulated. Laboratory findings may also be limited by the size of the motion capture area and the number of walking surfaces that can be simulated in the laboratory. MTC has been found to be sensitive to the walking surface in individuals with [51] and without TTA [135]. Thus, it is important to examine the effects of prosthetic interventions on a variety of real-world environments. Further, measuring MTC variability in walks over straight, level-ground walkways or treadmills may provide useful information on internal sources of movement variability, but limited information on external sources for variability. In contrast individuals experience many external sources for MTC variability in daily life (e.g., turning, changing speed, obstacle navigation, traversing slopes). Measuring MTC variability from a distribution of MTC values derived from everyday walking may provide additional information on the real-world effects of the powered prosthesis on fall risk.

Measuring MTC in daily life is now possible with wearable sensors and can provide a large sample size and describe external, real-world sources for between-stride variability (e.g., turning, changing speed, obstacle navigation, traversing slopes). Several previous studies have explored different methods of measuring MTC using a foot mounted IMU set-up. The aforementioned "pedestrian dead-reckoning" algorithm to foot mounted inertial measurements yields a reliable stride-by-stride estimate of the IMU's position trajectory during walking [110]. Some studies have used the position trajectory to calculate a relative measure of foot clearance, by subtracting the vertical distance between the foot at the lowest point of swing and the foot at foot-flat [12, 87]. However, this approach is not sensitive to the foot's sagittal angle during swing. A more plantarflexed foot during swing would physically reduce the MTC, but the relative foot clearance measure would not be able to detect this variability.

To address this issue, the toe (the point on the foot that is lowest during swing) could be located relative to the IMU. While manually measuring the toe's location relative to the IMU is a potential solution, it would likely lead to precision issues, as sensor placement could be varied by the user during the collection period. The sensor location relative to the toe and heel can also be calculated at every stride [95, 28]. However, this approach requires prior knowledge of the shoe size and the assumption that the heel and toe are at a vertical displacement of 0 at heel strike and toe-off, respectively. These assumptions may not hold true on slopes or uneven surfaces, which are common in real-world walking surfaces. Therefore, quantifying MTC in daily life is an area of research that warrants further improvement.

1.2 Overview of Dissertation

The benefits of powered push-off are not universal nor conclusive. To provide context to the changes to metabolic cost of walking (or lack thereof), examining muscle activation patterns may be a direct approach to explaining the wide variability of metabolic responses between users. Due to previous studies examining short bouts ($<$ 8 minutes) of walking, it is also unclear if the powered push-off's effects on gait symmetry persist over longer walking durations. Further, all previous studies have characterized the capacity for mobility with powered prostheses in controlled laboratory settings. To address these gaps, I quantified the effects of the powered push-off in the laboratory setting using conventional experimental paradigms and in daily life using novel approaches.

The first aim (Chapter 2) was to quantify the effects of powered prostheses on muscle activity during walking. In this work, I used surface electromyography to measure muscle activation and co-contraction in individuals with TTA, and how they related to the metabolic cost of walking. I tested the hypotheses that the powered push-off would alter muscle activity patterns and that changes in muscle activity would be positively related to changes in metabolic cost. This work provided insight into the potential muscular compensations to walking with a heavier prosthesis and identified muscle groups to strengthen to effectively walk with the powered push-off.

The second aim (Chapter 3) was to experimentally quantify the biomechanical effects of powered prostheses on a fatiguing bout of walking. Participants walked with unpowered and powered prostheses, in random order, for as long as possible at a fast speed. I measured participants' endurance with each prosthesis and made pre-/post-fatigue comparisons of joint kinematics and kinetics, ground reaction forces, and muscle activity. This work revealed shortcomings of commercially available powered prosthetic ankles for long-duration walking.

The third aim (Chapter 4) explored the clinical viability of using wearable sensors to quantify functional mobility in daily life. I used accelerometer data from prosthetic foot-mounted portable activity monitors to calculate stride-by-stride measures of cadence, walking speed, and stride length for everyday walking strides over two weeks of unconstrained activity. GPS data from participants' phones were also used to provide location context to walking data. This work demonstrated that pedestrian dead-reckoning algorithms can be used to quantify walking characteristics in the unconstrained, free-living environment.

The fourth aim (Chapter 5) used the methodologies established in Chapter 4 to determine the effects of powered prostheses on everyday walking. Further, I cross-examined changes in everyday walking quantity (step count) and ability (walking speed) to in-lab measures of metabolic cost and user-reported perception of mobility. This work highlighted the need for prosthetic evaluation to consider both perception and objective measures to better inform prosthetic prescription.

The fifth aim (Chapter 6) quantified minimum toe clearance and its between-stride variability for unpowered and powered prostheses in daily life. As part of this aim, I explored a novel method of measuring minimum toe clearance in daily life using inertial measurement units (IMU). With the assumption that the foot mounted IMU rotates about the toe with a constant moment arm during late stance, I approximated the location of the toe using the IMU signals to estimate minimum toe clearance. This aim explored the implications of a powered prosthesis on fall risk in daily life.

In Chapter 7, I discuss the overall findings from the multifaceted approaches described above. I also reflect upon limitations in the work and make several suggestions for future studies. This dissertation makes four unique contributions to the field. First, it explores relationships between activations and co-contractions of lower-limb muscles and metabolic cost of walking. Second, it examines the limiting factors to long-duration walks and how the powered prosthesis alters the effects of fatigue on lower-limb joint mechanics. Third, this dissertation evaluates the powered prosthesis by exploring the interconnected relationships between user perception, functional capacity, and everyday performance. Lastly, this work examines a novel approach to quantifying MTC in daily life. By assessing a variety of factors that constitute functional mobility, these contributions can inform future decisions made by researchers developing advanced prosthetic components as well as the clinicians and prosthetists prescribing the components.

CHAPTER 2

The Effect of Powered Ankle Prostheses on Muscle Activity During Walking

2.1 Introduction

Lower limb prostheses enable individuals with transtibial amputation (TTA) to ambulate independently in daily life. However, current prostheses do not completely replace the function of the biological ankle plantarflexors, which are responsible for support, propulsion, and swing initiation [108]. As a result, people with TTA adopt compensatory strategies characterized by kinematic and kinetic asymmetries [11]. These strategies are associated with increased metabolic energy [70, 145] and altered muscle activity during walking. Specifically, individuals with TTA have greater muscle activity in the residual limb quadriceps [158] and hamstrings [158, 74] and increased co-contraction of residual limb ankle and knee muscles [137] compared to their intact limb or limbs of non-amputees.

To better replicate the function of the intact ankle, researchers have developed motorized ankle prostheses. One such device, the BiOM (now EmPower, Ottobock, Duderstadt, Germany) uses a reflexive controller to provide active torque at the ankle during push-off and increased ankle range of motion [7, 63]. Outcomes with this device have been mixed. In some studies, people preferred to walk faster when wearing the powered ankle compared to unpowered devices [38, 63], while in others there were no differences [49]. Additionally, some studies found that participants used significantly less metabolic energy when walking with powered ankle prostheses [63, 130] while others found no differences [49, 102].

There are several possible explanations for the discrepancies in prior research. First, the current version of the powered ankle prosthesis does not cross the knee and thus acts more like a soleus muscle than the biarticular gastrocnemius muscle. This may limit the transfer of energy from the foot to the body center of mass (COM) during gait. In fact, recent research demonstrated that while the powered prosthesis increased the net work at the prosthetic ankle, it did not increase the individual leg step-to-step transition work when walking on a range of slopes [102]. Another potential explanation is that the prosthesis was not tuned effectively for each participant. For example, the amount of work done by the prosthesis on each stride is currently scaled to match normative data for intact ankle work. Given the losses through interaction with the socket and loss of power transfered across the knee, it is possible that users require more work on the prosthetic side to normalize gait. A recent study found that people used less metabolic energy when the prosthetic ankle produced work that was greater than that of an intact limb [71]. However, even with higher levels of ankle work, metabolic costs may still not be different to costs incurred with an unpowered prosthesis [120].

Another possible explanation for the lack of benefit of powered prostheses is that users may not have been able to adapt their neuromuscular control strategy appropriately to utilize the added power. Prior research suggests that individuals with TTA have some ability to alter their neuromuscular control in response to different prostheses. Ventura et al. found that people with TTA reduced activation of the muscles contributing to propulsion and increased activation in muscles contributing to body support when walking with a passive prosthesis modified to supply greater energy return [153]. The need for increased stability could lead to an increase in co-contraction, potentially incurring additional metabolic costs. In another study, using an experimental prosthetic emulator, Quesada et al. found that with increasing prosthesis work, activity in the residual limb during push-off increased, while activity in the intact limb during early stance decreased [120]. However, neither study specifically explored the relationship between changes in muscle activity or co-contraction and metabolic costs.

The purpose of this study was to determine if people with TTA alter muscle activity when using a commercially available powered ankle prosthesis, relative to an unpowered prosthesis. We also compared these data to that of healthy individuals without amputation to assess if the powered prosthesis normalized muscle activity. A secondary goal was to explore the relationship between changes in muscle activity and changes in metabolic cost when using a powered prosthesis. This approach may reveal muscle groups for training or strengthening, to improve metabolic reductions.

2.2 Methods

2.2.1 Participants

A total of 10 males (46.5 ± 14.9 years old) with unilateral transtibial amputation (TTA) and 10 male, age-matched non-amputee controls participated in this study, previously described in [49]. Inclusion criteria for the group with TTA included: >21.6 cm ground clearance on their prosthetic side, a well-fitting socket, the ability to walk continuously for 20 minutes, and >6 months of prosthetic use. Exclusion criteria for both groups included: self-reported body mass index (BMI) >35, uncorrected vision or balance disturbance, or cardiovascular or neurological comorbidities that prevented the safe completion of the walking protocol. Two participants used the BiOM powered prosthesis as their regular device. Though BiOM owners may be more acclimated to the device and walk differently to non-owners, they were included to maximize recruitment possibilities. All participants provided their written informed consent prior to participating in this institutionally approved study.

2.2.2 Experimental Protocol

All participants came to a research laboratory for a single day of testing. After shaving and cleaning the skin, we applied 16 surface electromyography (EMG) electrodes (Delsys, Inc., Boston, MA, USA) according to [62]. Electrodes were placed bilaterally on the gluteus medius (GM), rectus femoris (RF), vastus lateralis (VL), vastus medialis (VM), lateral hamstrings (LH), medial hamstrings (MH), medial gastrocnemius (MG), lateral gastrocnemius (LG), soleus (SOL), and tibialis anterior (TA). For participants with TTA, electrodes on the MG, LG, SOL, and TA were placed on the intact limb only.

EMG data were collected at 1000 Hz as participants performed a series of maximum voluntary isometric contractions (MVCs) with the prosthesis donned. Knee flexion and extension and ankle plantarflexion and dorsiflexion MVCs were tested using a computerized dynamometer (CSMI, Stoughton, MA, USA), while all other MVCs were tested using manual resistance and a handheld dynamometer (Lafayette Instruments, Lafayette, IN, USA). For each muscle group, participants performed a series of three submaximal contractions, separated by 30 seconds of rest, and a final maximal 5-s volitional contraction for analysis. Knee position was set to 60°and 30°flexion for extension and flexion MVCs, respectively. For the hip abductors, participants performed isometric hip abduction against resistance while lying on their side, with the supporting leg bent for stability. The intact limb shank muscles were tested while the participant lay prone with the knee extended. For the planarflexors, the ankle was secured in neutral position, while for the dorsiflexors, the ankle was in 30°of plantarflexion. To isolate the soleus, participants were positioned on their hands and knees, with the ankle in neutral position. Lower-leg muscles were measured on the intact limb only for participants with TTA and bilaterally for control participants.

Participants with TTA were then randomly selected to be tested first with their unpowered prosthesis or with a powered ankle prosthesis (BiOM T2 Ankle; BionX Medical Technologies Inc., Bedford, MA, USA). A certified prosthetist fit the BiOM to the participants' existing socket and tuned it according to manufacturer guidelines. Details of the fitting and tuning process are provided in [49]. Participants walked on a treadmill at a speed normalized according to a Froude Number of 0.16 to scale speed to each subject's leg length [54]. Energetic costs were measured using a portable metabolic system (Cosmed k4B2, Rome, Italy). All participants walked on the treadmill for an 8-minute accommodation period. Once they achieved steady state energy expenditure, defined as a respiratory exchange ratio <1.0 and a visible plateau in oxygen consumption [30], they continued walking for an additional 3 minutes at steady-state. One participant with TTA was not able to reach steady state energetics and was excluded from all analyses. Twelve reflective markers (18mm diameter, $\sim$1mm base) were affixed on the shoe (2nd and 5th metatarsal, heel, and lateral heel) and pelvis (bilateral anterior and posterior superior iliac spines) using adhesive stickers. Marker positions were tracked at 100 Hz using a 10-camera motion capture system (Vicon, Hauppauge, NY, USA) and electromyography was recorded at 1000 Hz during all trials.

2.2.3 Data Analyses

Metabolic cost of transport (COT) was calculated as the steady state energy expenditure normalized by walking speed and body mass [49]. EMG data were first visually inspected for motion artifacts then band-pass filtered between 20-400 Hz, demeaned, and full wave rectified. A 4th order low-pass Butterworth filter with a cut-off frequency of 6 Hz was used to obtain linear EMG envelopes [22]. We then normalized the linear envelopes to the peak EMG signal obtained during each muscles' MVC [60]. The gluteus medius was normalized to the maximum EMG amplitude across conditions, due to the high variability in the MVCs for this muscle. To segment the data into phases in the gait cycle, heel-strikes and toe-offs were identified using a velocity detection algorithm [162]. Additionally, foot-adjacent instances were identified by detecting sagittal-plane intersections of lateral heel markers during stance.

We calculated integrated EMG (iEMG) as the area under the normalized linear envelope for the full gait cycle and within specific phases: early stance (heel-strike – foot-adjacent), late stance (foot-adjacent – toe-off), and swing (toe-off – heel-strike). For each participant, we analyzed the last 80 strides at steady state energy expenditure. We also measured co-contraction of antagonist muscle groups using a co-contraction index (CCI), calculated as:

$$CCI = \frac{\int EMG_{min}dt}{\int EMG_{ant}dt + \int EMG_{ago}dt} \times 100$$

where $\mathrm{EMG_{ant}}$ denotes the EMG signal of the antagonist muscle, $\mathrm{EMG_{ago}}$ denotes the EMG signal for the agonist muscle, and $\mathrm{EMG_{min}}$ is the lower of the two (agonist/antagonist) signals at each sampling point [100]. CCIs were calculated for the bilateral RF-LH pair for loading response (ipsilateral heel-strike – contralateral toe-off), terminal stance (contralateral heel-strike – ipsilateral toe-off), and late swing (contralateral mid-stance – ipsilateral heel-strike), and for the intact TA-MG pair during loading response only [137].

We excluded signals with excessive noise due to movement artifact, likely due to electrodes loosening due to perspiration. On the intact side, one GM sample was excluded. The excluded samples for the residual side are as follows: RF (n = 2), VL (n = 1), VM (n = 3), and LH (n = 1). The residual side VM was particularly susceptible to motion artifact due to it often being placed under the prosthetic socket liner. This sensor was removed if it caused discomfort or hindered participants' movements.

2.2.4 Statistical Analyses

The dependent measures were iEMG of each muscle and CCI for muscle pairs. We tested for differences between controls and people with TTA using unpowered and powered prostheses using a series of linear mixed models, where controls was the reference condition and subjects was a random effect. As there were no differences between left and right sides for controls (paired t-tests, $p > 0.143$), we used the side corresponding to the intact side of their age-matched participant with TTA. Pairwise group comparisons were made using estimated marginal means within the linear mixed model. To control for Type-I error, these post-hoc comparisons were only made when the linear mixed model had a significant fixed effect. We also calculated the relationships between changes in cost of transport ($\Delta COT = COT_{powered}$ - $COT_{unpowered}$) and changes in muscle activity ($\Delta iEMG = iEMG_{powered}$ - $iEMG_{unpowered}$) and between ΔCOT and changes in CCIs, using a series of Pearson's correlations. Significance was set to $p < 0.05$ for all comparisons.

2.3 Results

2.3.1 iEMG Across the Gait Cycle

There were significant fixed effects for the intact limb GM ($p = 0.001$), VL ($p = 0.007$), and TA ($p = 0.031$), and residual limb RF ($p = 0.013$), VL ($p = 0.$ 010), VM ($p < 0.001$), and LH ($p = 0.004$). Participants using the powered prosthesis had greater iEMG over the gait cycle in the intact limb GM ($p = 0.002$), and residual limb VM ($p = 0.013$; Figure 2.2) compared to that of the unpowered prosthesis. Compared to controls, people with TTA had greater iEMG with both prostheses in the intact limb VL ($p < 0.016$) and TA ($p < 0.015$), and the residual VL ($p < 0.04$), VM ($p <$

0.019), and LH ($p < 0.009$). There was also greater activity in the intact limb GM ($p = 0.028$; Figure 2.2) and the residual limb RF ($p = 0.007$) for the powered prosthesis only.

2.3.2 Muscle Activity during Early Stance

During early stance, there were significant fixed effects for the intact limb GM ($p < 0.001$), VL ($p = 0.004$), and TA ($p = 0.004$), and residual limb GM ($p = 0.048$), RF ($p < 0.001$), VL ($p = 0.005$), VM ($p < 0.001$), and LH ($p = 0.008$). Post-hoc pairwise comparisons revealed that when wearing the powered prosthesis, participants had greater iEMG in the intact limb GM ($p < 0.001$) and residual limb VM ($p = 0.029$) compared to that of the unpowered prosthesis (Figure 2.3). Compared to controls, people with TTA had greater iEMG with both prostheses in the intact limb VL ($p < 0.004$) and TA ($p < 0.003$), and residual limb RF ($p < 0.001$), VL ($p < 0.028$), VM ($p < 0.010$), and LH ($p < 0.005$). There was also greater activity in the intact limb GM ($p = 0.007$) and residual limb GM ($p = 0.024$) with the powered prosthesis only. During the loading response phase specifically, there were no significant fixed effects for co-contraction in any muscle pairs in either limb ($p > 0.067$).

2.3.3 Muscle Activity during Late Stance

During late stance, there were significant fixed effects for the intact limb GM ($p = 0.010$) and residual limb MH ($p = 0.006$) and LH ($p = 0.014$). Compared to the unpowered prosthesis, participants using the powered prosthesis had greater iEMG in the intact limb GM ($p = 0.033$; Figure 2.3). Compared to controls, people with TTA had greater iEMG with both prostheses in the residual limb MH ($p < 0.010$). There was also greater activity in the intact limb GM ($p = 0.022$) and residual limb LH ($p = 0.008$) with the powered prosthesis only. During terminal stance specifically, there were significant fixed effects in the RF-LH co-contraction index in the intact (p

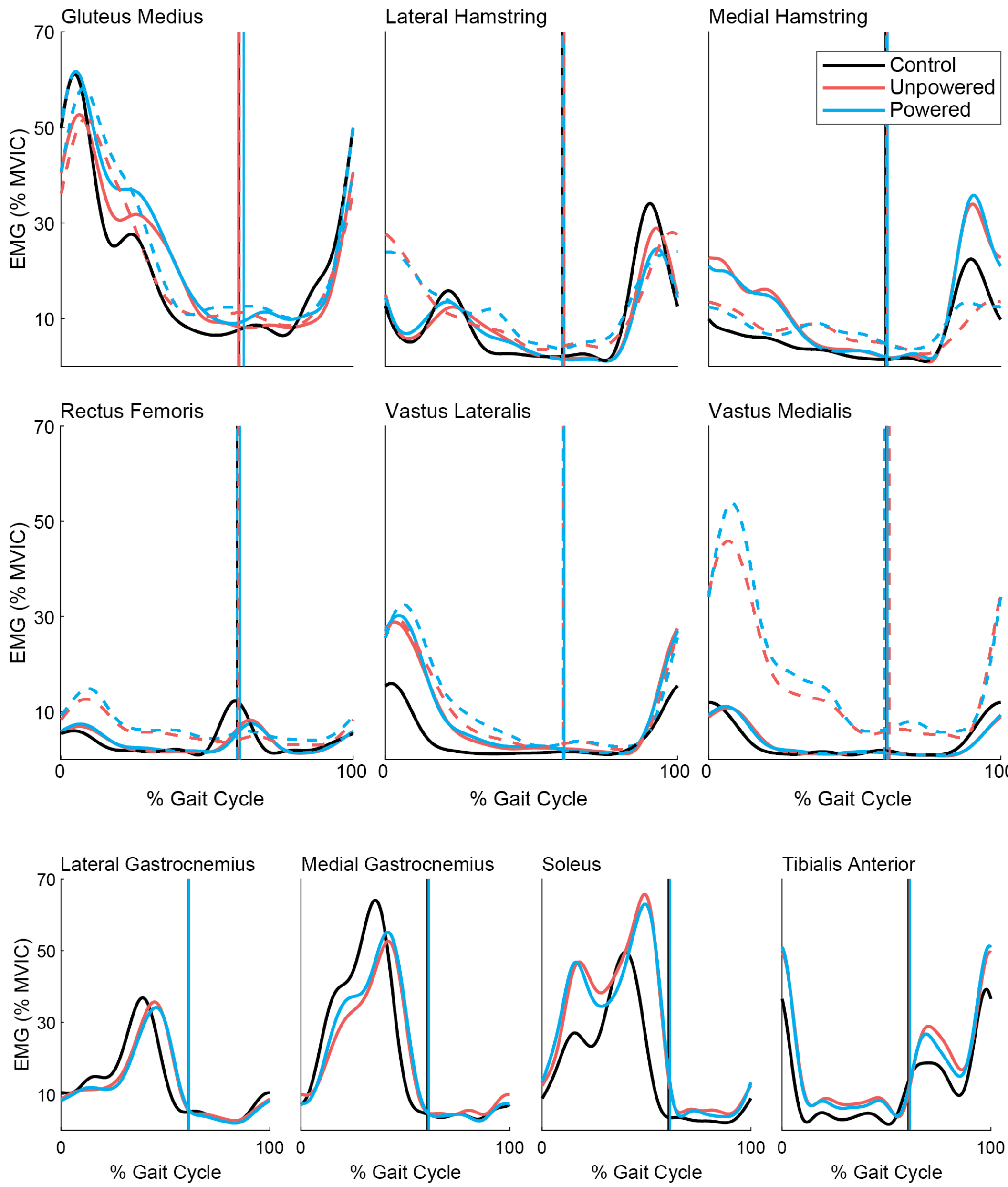

Figure 2.1: Normalized EMG linear envelopes over the gait cycle
EMG linear envelopes averaged over all control participants (black) and participants with TTA using unpowered (red), and powered (blue) prostheses, for intact (solid line) and residual (dashed line) sides. Toe-offs for each condition are plotted as a vertical line.

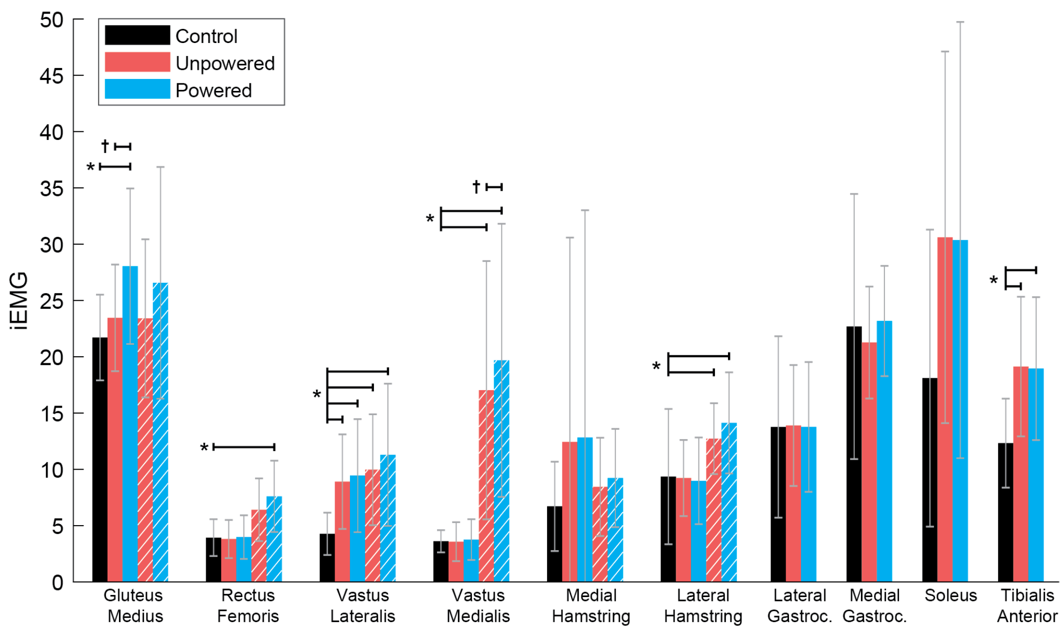

Figure 2.2: Integrated EMG (iEMG) over the entire gait cycle
Average iEMG over gait cycle for control participants (black) and participants with TTA using the unpowered (red) and powered (blue) prostheses for the intact (solid) and residual (striped) limbs. Error bars are the standard deviations across participants. Significant differences from controls (*), between prostheses for the intact limb (†) and residual limb (‡) are indicated.

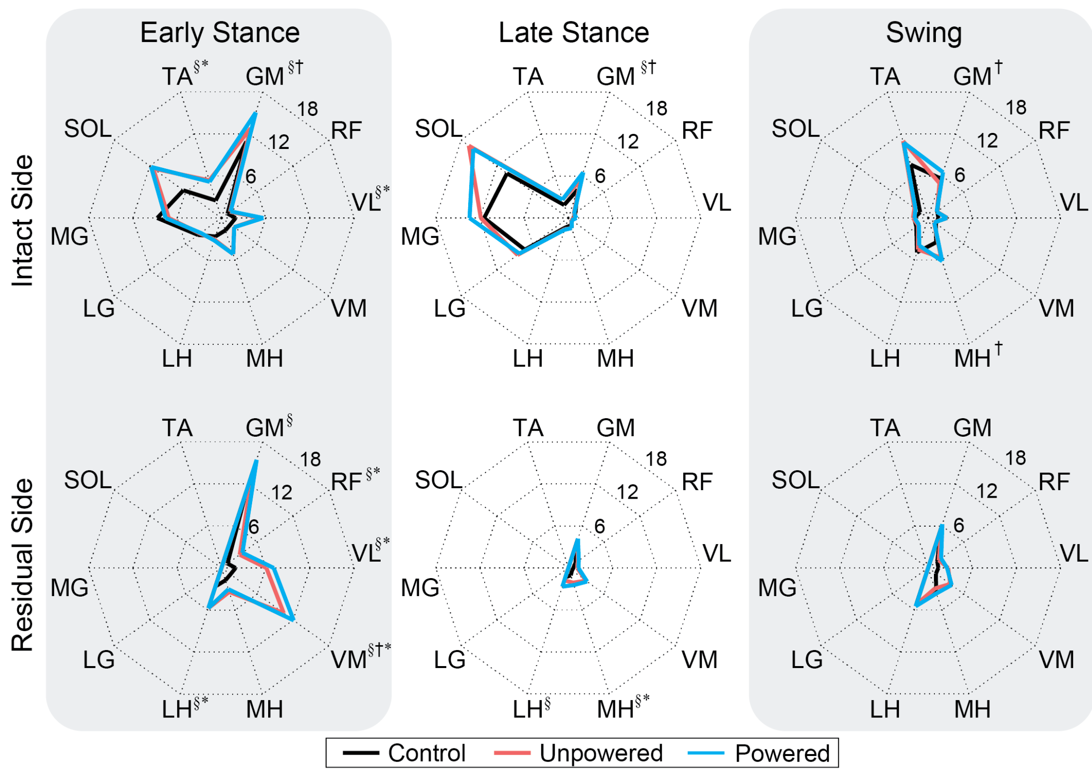

Figure 2.3: Integrated EMG (iEMG) in distinct phases of gait
Radar plots of the iEMG for all muscles during early stance, late stance, and swing phases. Data is shown for control participants (black) and participants with TTA using the unpowered (red) and powered (blue) prostheses. Significant differences between prostheses (†), between unpowered prostheses and controls (*) and powered prostheses and controls (§) are indicated.

= 0.013) and residual ($p < 0.001$) limbs. With the powered prosthesis, participants had greater co-contraction ($p = 0.007$; Figure 2.4A) in the intact thigh compared to the unpowered prosthesis. Compared to controls, people with TTA had greater co-contraction with both prosthesis in the residual limb ($p < 0.001$).

2.3.4 Muscle Activity during Swing

During swing, there were significant fixed effects in the intact limb GM ($p = 0.037$) and LH ($p = 0.037$). Participants using the powered prosthesis had greater iEMG in the intact limb GM ($p = 0.015$) and lower iEMG in the intact limb LH ($p = 0.017$) compared to that of the unpowered prosthesis (Figure 2.3). During the late swing phase specifically, there were no significant fixed effects for co-contraction for any muscle pair in either limb ($p > 0.122$; Figure 2.4A).

2.3.5 Correlations between Muscle Activity and Metabolic Cost

Changes in the intact limb MG-TA co-contraction were moderately correlated with ΔCOT during loading response ($r = -0.464$, $p = 0.208$). Though not significant, there were also moderate and strong correlations between ΔCOT and residual limb RF-LH co-contraction during terminal stance ($r = -0.585$, $p = 0.168$) and late swing ($r = -0.754$, $p = 0.050$; Figure 2.4B), respectively. There were no significant correlations between changes in muscle activity and ΔCOT between prostheses (Figure 2.5). However, there was a strong negative correlation between ΔiEMG of the residual RF and ΔCOT ($r = -0.627$, $p = 0.132$). There were also moderate correlations between ΔiEMG of the residual GM ($r = 0.543$, $p = 0.131$) and MH ($r = -0.537$, $p = 0.136$) and ΔCOT.

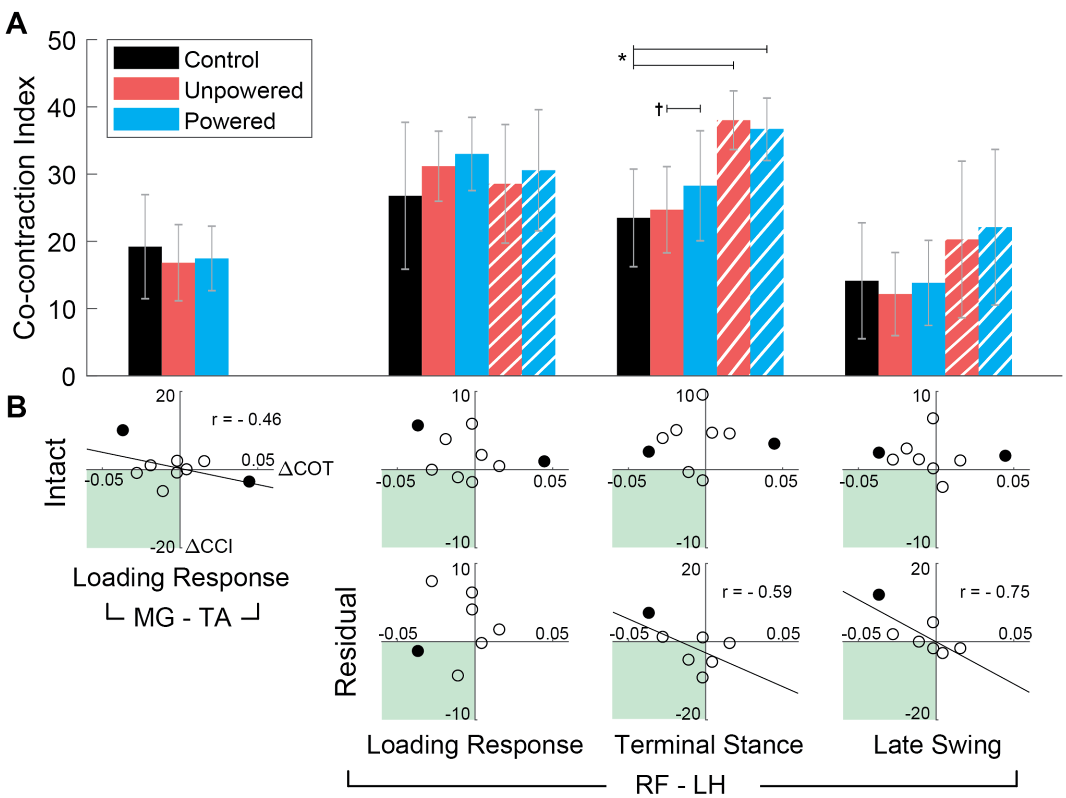

Figure 2.4: Co-contractions and their relationships with metabolic cost
A) Co-contraction indices for the medial gastrocnemius – tibialis anterior (MG – TA) and rectus femoris – lateral hamstring (RF – LH) muscle pairs in different gait phases. Data for control participants (black) and participants with TTA using unpowered (red) and powered (blue) prostheses are shown. The intact side is plotted as solid colors and the residual side is plotted as stripes. Error bars are the standard deviations across subjects. Significant differences from controls (*) and between prostheses (†) are indicated. B) Linear correlations between changes in cost of transport (ΔCOT) and changes in co-contraction indices (ΔCCI). Linear fits are shown for moderate and strong correlations. Data in the third quadrant (highlighted in green) indicate a lower metabolic costs and lower co-contraction with the powered, compared to unpowered prosthesis. Data for the two participants who owned the powered ankle are indicated by closed symbols.

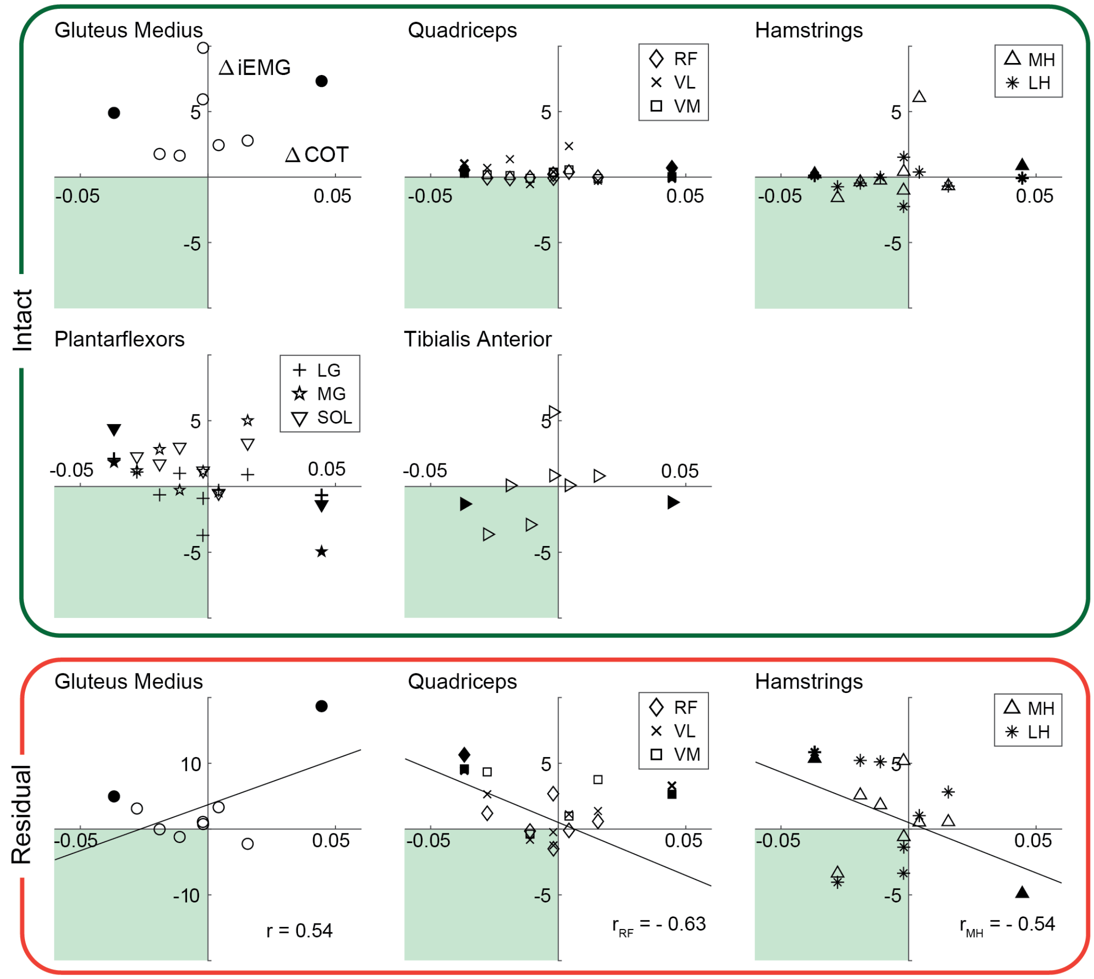

Figure 2.5: Relationships between metabolic cost and muscle activity
Linear correlations between changes in cost of transport (ΔCOT) and changes in integrated EMG (ΔiEMG) for five muscle groups in the intact limb (top two rows) and three muscle groups in the residual limb (bottom row). The quadriceps muscle group included the rectus femoris (RF), vastus lateralis (VL), and vastus medialis (VM). The medial hamstring (MH) and lateral hamstring (LH) muscles made up the hamstrings group. The plantarflexor group consisted of the lateral gastrocnemius (LG), medial gastrocnemius (MG), and soleus (SOL). Changes for each participant are plotted as separate points. Linear fits are shown for moderate and strong correlations. Data in the third quadrant (highlighted in green) indicate lower metabolic costs and lower muscle activity with the powered, compared to unpowered prosthesis. Data for the two participants who owned the powered ankle are indicated by closed/bold symbols.

2.4 Discussion

Participants with TTA had greater muscle activity in the intact limb gluteus medius and residual limb vastus medialis when walking with the powered prosthesis compared to the unpowered prosthesis and controls. While the gluteus medius had increased activation in all phases of the gait cycle (early stance, late stance, swing), the increase in the vastus medialis occurred primarily in early stance (Figure 2.3). One functional role of the gluteus medius is to provide pelvic support during stance [2]. Higher activity in the intact gluteus medius was likely necessary to counteract the increased rotational inertia of the swinging prosthetic limb. Specifically, the powered ankle is heavier, which can create a greater external moment during swing. Additionally, the prosthetic limb's swing trajectory may be altered by the addition and direction of supplied power, which may not be purely directed sagitally as most prostheses are aligned with some degree of toe-out. Increased activity of the residual vastus medialis during early stance could suggest an increased need for stabilization during weight acceptance. This could be attributed to the powered ankle's keel allowing for a smaller range of passive deflection and/or a compensation for decreased comfort relative to unpowered prostheses.

Activity of several residual limb muscles were moderately correlated with changes in metabolic cost. Specifically, decreased metabolic cost was correlated with decreased gluteus medius activity and increased rectus femoris activity. The relationship between residual gluteus medius activity and metabolic cost may reflect that those who were able to reduce their metabolic cost had less need for frontal-plane stabilization using the powered prosthesis. In contrast, the increasing residual limb rectus femoris activity may represent an effective strategy to stiffen the knee such that the person was able to better utilize ankle power. Increased medial hamstring activity was also correlated with decreased metabolic cost. This may be a strategy to resist excessive leg swing, thus decreasing energy loss during the subsequent loading response and consequently decrease metabolic cost [120]. However, it is important to note that the small-sample correlation analysis presented here is exploratory and can be heavily impacted by an individual outlier. In this case, the correlations between metabolic cost and gluteus medius and medial hamstring activity were driven by a single participant with the largest increase in metabolic cost. This individual exhibited a hip-hiking gait, resulting in a hyperactive gluteus medius, which was exacerbated by use of the powered ankle. When this participant was excluded from the correlation, increased gluteus medius activity correlated with decreased metabolic cost ($r = -0.622$, $p = 0.100$) and medial hamstring activity was not correlated with changes in metabolic cost ($r = -0.148$, $p = 0.727$).

There were few differences in muscle co-contraction between the two prostheses. The only significant difference occurred in the intact limb thigh muscles during terminal stance, where co-contraction was greater when walking with the powered compared to unpowered prostheses (Figure 2.4A). This co-contraction may reflect the need for stability when the prosthetic limb was swinging due to the heavier weight and greater inertia of the powered foot. There were two non-significant, correlations between muscle co-contraction and metabolic cost. Increased residual limb thigh muscle co-contraction during terminal stance and late swing correlated with decreased metabolic cost ($r = = -0.585$ and -0.754, respectively). Thigh co-contraction may minimize energy loss in the socket-limb interface and more effectively transfer power to the body's COM during stance [76]. It may also prevent excessive leg swing [120]. It is important to note that the co-contraction indices used here are not unique and other approaches may lead to different findings. However, we chose this specific measure as it is well suited to analysis in specific phases of the gait cycle [83].

2.4.1 Limitations

This study had several limitations. First, participants in this study used their own, clinically prescribed, unpowered prosthesis. The lack of consistent differences in muscle activity between prostheses may be attributed to the variety of prostheses they were prescribed [49]. As there is insufficient research on neuromuscular responses to varying prosthetic characteristics to know how much this may affect study outcomes, we chose to use the device they were comfortable with and acclimated to, rather than have all participants wear the same unpowered foot. Second, while 10 participants completed the study, motion artifact in the EMG reduced the sample size for some muscles to only 6 or 7. Some participants also had difficulty in contracting specific muscles during MVCs, which led to several outliers for peak EMG. These values were not excluded, as the study used a paired, within-subject statistical approach. However, this does contribute to variability in the between-subject averages. Third, the changes in metabolic cost between prostheses in our participants were mostly small, with only three participants falling below the within-day minimal detectable change of 0.022 J/Nm [30]. Thus, it is possible we would observe stronger correlations with a more diverse cohort with more varied responses. While the lack of metabolic changes could be attributed to participants being instructed to walk at a (potentially unnatural) fixed speed rather than their self-selected speed, the two speeds were not significantly different. Further, there was no metabolic difference between prostheses when assessed at the self-selected speed [49]. Lastly, there were differences in acclimation time across participants as two owned and regularly wore the powered ankle prosthesis ($>$ 6 months), while the others were fit with the powered prosthesis and tested on the same day (acclimation $\geq$ 15 minutes). It is possible that changes in neuromuscular control take time and experience to develop. However, even with a prolonged acclimation time, participants who owned the BiOM had disparate metabolic responses to the added ankle power (Figure 2.4 and 2.5). This suggests that acclimation time alone is not what influences metabolic or neuromuscular adaptations and future studies should explore more device-specific acclimation schemes.

2.5 Conclusion

This study explored the effect of powered ankle prostheses on muscle activity during walking. When walking with a powered prosthesis, participants increased activity in muscles that provide support during stance. Thus, exploring training paradigms that strengthen stabilizing muscles may benefit powered prosthesis users' ability to accommodate the heavier powered ankle. Changes in muscle activity between powered and unpowered devices were correlated with changes in metabolic cost. While these correlations were not significant in this small cohort, they provide potential targets for device-specific biofeedback training. Future studies should further explore these relationships in a larger cohort with longer accommodation times.

CHAPTER 3

Determine If the Addition of Prosthetic Ankle Power Delays the Onset of Muscular Fatigue During an Extended Bout of Walking

3.1 Introduction

The primary goal of rehabilitation post-amputation is a return to pre-amputation lifestyles, including the ability to take part in healthy amounts of physical activity [89]. To promote independent bipedal ambulation after a transtibial amputation (TTA), patients are prescribed a prosthesis, as part of the rehabilitation process. However, compared to people without amputation, people with TTA take fewer steps at a time ($<$ 17 steps) and are less physically active overall [88]. A sedentary lifestyle can lead to increased risk of cardiovascular diseases [101] and a lower quality of life [116]. People with TTA rely more on their intact limb and walk with asymmetric step lengths and ground reaction forces [133, 142]. People with TTA also walk with increased muscle activity in the residual limb hamstrings and vasti muscles [118, 74, 134, 40], which contribute to a higher metabolic effort when walking [155]. Further, the overreliance on the intact side ankle subsides only after a prolonged duration of walking, at which point the power generated at the bilateral hip joints increase to compensate for the decreased power generation at the intact side ankle [160]. Therefore, providing active push-off at the prosthetic foot may yield a more symmetric gait, delay the onset of fatigue, and mitigate the barrier to prolonged physical activity in everyday life.

For most people with TTA, they are prescribed either solid ankle cushion heel (SACH) or dynamic response (DR) feet, both of which are passive and do not perform positive net work. Powered prosthetic feet were developed to mimic the ankle by providing assistive push-off power [7]. The powered prosthesis has been shown to increase the prosthetic ankle's range of motion (ROM) and power generation during gait [38]. The powered push-off has contributed to the ability to walk with decreased metabolic effort in some participants [63, 130], though this finding is inconclusive in participant cohorts with greater age ranges [49, 102]. However, all previous studies observed gait for short duration walking (3-5 minutes). Further, changes in metabolic effort between unpowered and powered prostheses were not correlated to changes in everyday step count [Chapter 5], which suggests that the metabolic response to the powered push-off by itself may not explain or predict the potential benefits during prolonged walking bouts. Therefore, to understand whether a powered prosthesis will enable people with TTA to walk for longer, there is a need to explore how a fatiguing bout of walking affects their joint mechanics.

The effects of a powered push-off on mitigating fatigue has not yet been explored. In fact, the effects of lower-limb fatigue on people with TTA has only been reported in one previous study [160]. In this study, people with TTA walked at a self-selected speed with unpowered prostheses for a total of 60 minutes to induce lower-limb muscular fatigue. Authors speculated that fatigue in the intact plantar flexor muscles contributed to the decrease in the power absorbed and generated at the intact side ankle, which was compensated by increased knee moments in loading response to progress the body forward and increased power generated at the hip joint to facilitate forward propulsion. Similar to people with TTA, people with Charcot-Marie-Tooth disease walk with increased reliance on their hip flexors to compensate for their distal limb weakness. In people with Charcot-Marie-Tooth disease, fatigue at the hip flexor muscles were found to limit walking duration [121].

The primary purpose of this study was to quantify the effectiveness of a powered prosthesis on mitigating the onset of fatigue. Our central hypotheses were that with a powered ankle providing assistive push-off, people with TTA would be able to walk for a longer duration and report a lower rating of perceived exertion during the fatiguing walking bout. We will also examine joint mechanics before and after the fatiguing walking bout, to provide insight into how the added push-off power might affect gait mechanics over time. The powered prosthesis contributing to forward propulsion may delay the onset of fatigue at the intact ankle plantar flexors and reduce power compensations at other joints. Thus, we hypothesize that the increase in hip power generation after fatigue will be lower with a powered prosthesis, relative to with an unpowered prosthesis. Exploring changes to joint mechanics before and after a fatiguing walking bout could lend insight into the limiting factors to long duration walking and if those factors persist with a powered push-off.

3.2 Methods

3.2.1 Participants

We recruited twelve individuals with unilateral transtibial amputation from the local community to participate in the study (Table 3.1). Inclusion criteria were age of 21 years or older, unilateral transtibial amputation, and prosthesis use of at least six months. Exclusion criteria were a history of neurological or orthopedic disorders to the intact limb, history of cardiovascular disease, or an inability to walk independently for 10 minutes. Participants provided written informed consent prior to taking part in the study. Two participants did not complete the study due to unrelated personal or health issues.

Table 3.1: Participant demographics

ID	Age (years)	Sex	Mass (kg)	Height (m)	Cause of amputation	Non-Powered Prosthetic Foot	K-Level	Time Since Amputation	Order[1]
S01	57	M	98.4	1.85	Vascular	DR[2]	K3	3 years	UP → P
S02	62	M	118.8	1.82	Trauma	DR	K3	3 years	P → UP
S03	53	M	128.0	1.78	Vascular	DR	K3	8 years	UP → P
S04	65	M	84.1	1.82	Vascular	DR	K3	3 years	P → UP
S05	40	M	123.4	1.78	Trauma	DR	K3	12 years	P → UP
S06	30	M	90.8	1.80	Trauma	Hydraulic	K3	1.2 years	UP → P
S07	65	M	89.1	1.64	Trauma	Hydraulic	K3	9 years	UP → P
S08	55	M	108.0	1.83	Trauma	DR	K3	1.2 years	UP → P
S09	27	M	73.0	1.89	Trauma	DR	K4	5 years	DNC[3]
S10	-	M	71.7	1.72	Trauma	DR	-	-	DNC
S11	54	M	83.0	1.77	Trauma	DR	K4	19 years	P → UP
S12	45	M	98.4	1.85	Trauma	DR	K3	5.5 years	P → UP

[1]Order of testing; UP = unpowered, P = powered. Underline = prescribed prosthesis used everyday

[2]DR = dynamic response foot

[3]DNC = did not complete the study

3.2.2 Protocol

The protocol followed a crossover design in which participants were tested with the two types of prosthetic feet (unpowered and powered). Five individuals were tested with their prescribed, unpowered prosthesis and five individuals were tested with the powered device (BiOM T2, Ottobock, Duderstadt, Germany) first (Table 3.1). Of the ten participants who completed the study, two used the BiOM as their main, everyday prosthesis. After a fitting session with a certified prosthetist, participants wore each prosthesis at home for an acclimation time of at least three weeks. Consequently, data collection for each type of prosthesis occurred on separate days.

First, participants walked over ground along a 7-meter walkway at a fixed speed based on their leg length [54] (PRE). We recorded walking speed using infrared timing gates, spaced approximately 3 meters apart, and trials were included if the walking speed was within 5% of the target speed. One participant (S03) could not walk at the fixed speed, and walked at their slower, self-selected speed. During this phase, participants were given ample time to rest or sit down as needed. To test their endurance, participants then walked on the treadmill at a fixed, faster speed (110% of their fixed speed on a 0% incline for K3 and 5% incline for K4 participants) until they felt they could no longer continue. The faster walking speed was chosen to maximize the potential benefits of the powered prosthesis, as previous studies found metabolic reductions for the powered prosthesis in fast walking speeds but not in slow speeds [7, 63]. Two participants (S04, S07) felt uncomfortable walking at their assigned faster fixed speed and walked at a slightly slower speed, which was held consistent for both prosthesis types. At every minute of the endurance walking bout, we recorded participants' heart rate via a heart rate monitor and rating of perceived exertion (RPE) based on a modified 10-point Borg scale [14]. Heart rate and RPE were also recorded immediately before and after the treadmill walking bout. Following the treadmill walk, the duration of walking was recorded and participants were given a short amount of time (< 2 minutes) to acclimate themselves to over ground walking. Finally, participants once again walked over ground at their fixed speeds (POST).

We recorded kinematic and kinetic data during both phases (PRE and POST) of the protocol at 120 Hz, using a motion capture system (Motion Analysis, Rohnert Park, CA). Reflective markers were placed on participants' C-7 and T-8 vertebrae, sternal notch, xiphoid process, and bilaterally on the acromion, iliac crest, anterior superior iliac spine, posterior superior iliac spine, greater trochanter, medial and lateral femoral condyles, medial and lateral malleoli, heel, lateral heel, 5th and 2nd metatarsals. Additionally, we placed clusters of four markers bilaterally on the lateral side of the thigh and shank segments. We used embedded force plates to collect ground reaction force data and calculate joint kinetics at the hip, knee, and ankle bilaterally.

3.2.3 Data Analysis

Kinematic and kinetic data were low-pass filtered using a 4th order Butterworth filter with a 6 Hz cut-off frequency. We analyzed five fixed-speed trials of walking, where the participant's entire foot landed on the force plate during the stance period. The gait cycle was segmented with heel strikes in Visual 3d (C-Motion, Inc., Germantown, MD). Joint ROMs were assessed over the entire gait cycle. Positive and negative peaks for joint power were addressed over specific phases of the gait cycle (Figure 3.1). Joint kinematics and mechanics in the sagittal plane were averaged across the five trials for each prosthesis type.

3.2.4 Statistical Analysis

Primary dependent measures were the duration of fast-speed treadmill walking and the time at which the participant's RPE exceeded a value of 5 ("Hard"). We tested for differences between the two prostheses (unpowered, powered) using a series of paired t-tests. Secondary dependent measures were sagittal-plane peak power

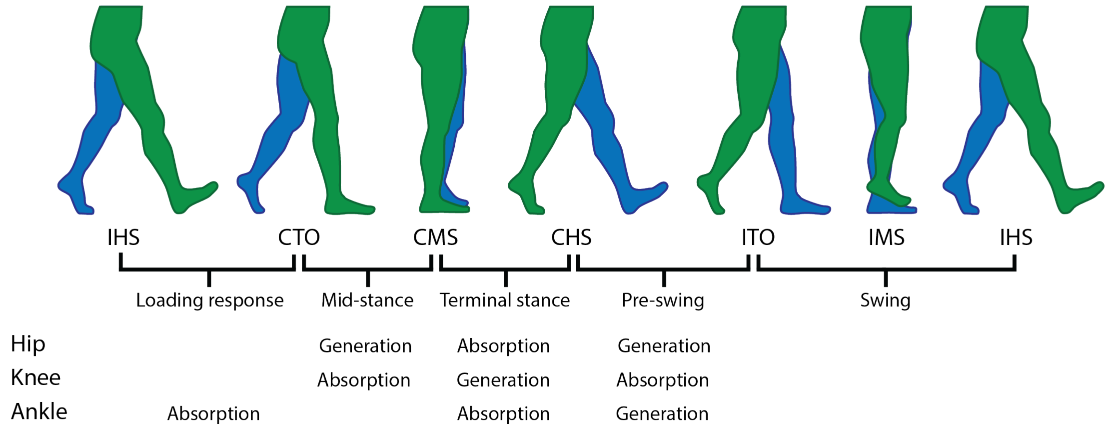

Figure 3.1: Relevant phases of the gait cycle for joint power
Phases of the gait cycle, in which positive (generation) and negative (absorption) power peaks were assessed.

generated and absorbed at the hip, knee, and ankle joints, ground reaction force peaks for each side, sagittal-plane ROM at the hip, knee, and ankle joints, step times and lengths, and symmetry indices for each measure. We calculated symmetry indices (SI) as described by Robinson et al. [126]:

$$SI = \frac{x_{prosthetic} - x_{intact}}{0.5(x_{prosthetic} + x_{intact})} \times 100\%$$

where $x_{prosthetic}$ is the measure at the residual limb and x_{intact} is the measure at the intact limb. A positive SI indicates greater values in the residual limb, a negative SI indicate greater values in the intact side, and a 0% SI indicates perfect symmetry. We tested for fixed effects in the prosthesis (unpowered, powered) and fatigue (PRE, POST) factors and an interaction effect (prosthesis $\times$ fatigue) using a series of linear mixed models, with subjects as a random factor. If there was a significant interaction effect, post-hoc, pair-wise comparisons were made using estimated marginal means within each linear mixed model. We controlled for Type-I error by making these post-hoc comparisons only if the linear mixed model had a significant effect. Because EMG signals for unpowered and powered prostheses were recorded on separate days, we did not compare iEMG and peak EMG between prostheses directly. Instead, we tested for differences between prostheses in the changes in muscle activation pre- and post-fatigue using a series of paired t-tests. Significance was set to $p < 0.05$ for all comparisons. To address the small sample size, we also calculated the effect sizes for all post-hoc pairwise comparisons using Hedge's g:

$$g = \frac{M_{Powered} - M_{Unpowered}}{SD_{pooled}} \times \frac{N-3}{N-2.25} \times \sqrt{\frac{N-2}{N}}$$

$$SD_{pooled} = \sqrt{\frac{(SD^2_{Powered}(n_{Powered}-1)) + (SD^2_{Unpowered}(n_{Unpowered}-1))}{n_{Powered} + n_{Unpowered} - 2}}$$

where M_x is the mean of group x, SD_{pooled} is the pooled standard deviation, N is the sample size, SD_x is the standard deviation within group x, and n_x is the sample size of group x [36]. A small effect is represented by $0.2 \leq g \leq 0.5$, a medium effect by $0.5 \leq g \leq 0.8$, and large effect by $g \geq 0.8$ [23].

3.3 Results

3.3.1 Walking Duration and Perceived Exertion

Participants walked on the treadmill at 110% of their leg length-based walking speed (1.30 $\pm$ 0.09 m/s). There was no difference between unpowered and powered prostheses in how long participants were able to walk on the treadmill ($p = 0.165$, $g = -0.107$; Figure 3.2A). For some participants, lower-limb fatigue was not the primary reason they could no longer keep walking. With the unpowered prosthesis, seven participants reported having to stop walking due to stump pain ($n = 6$), phantom pain ($n = 1$), or hip pain ($n = 1$), rather than due to fatigue ($n = 1$). With the powered prosthesis, three participants stopped due to stump pain, rather than due to fatigue ($n = 6$). Further, we stopped two participants' (S04, S07) treadmill walks

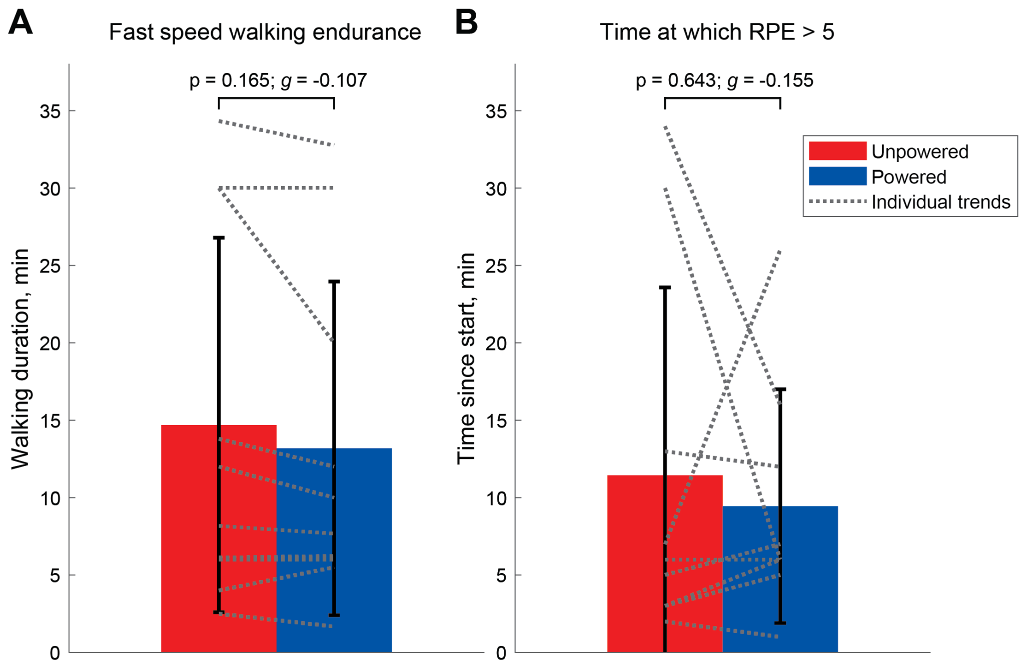

Figure 3.2: Walking endurance and perceived exertion
A. Walking duration and B. Time at which ratings of perceived exertion (RPE) exceeded 5. Individual trends were plotted as grey dotted lines.

at 30 minutes due to concerns about wounds forming at the residual limb. However, excluding those two participants did not change results ($p = 0.168, g = -0.048$). There was also no difference between prostheses in the time at which participants' RPE exceeded a value of 5 ($p = 0.643, g = -0.155$; Figure 3.2B). One participant's RPE never reached 5 and was excluded from analysis.

3.3.2 Spatiotemporal Parameters

Participants' step times on their residual limb was shorter with the powered prosthesis relative to the unpowered prosthesis ($p = 0.012$; Figure 3.3). With the powered prosthesis, participants also took longer steps ($p < 0.001$) and had longer stance times ($p = 0.009$) on their residual limbs. Step lengths were less symmetric ($p = 0.001$), while stance times were more symmetric ($p = 0.003$) with the powered prosthesis. There was no prosthesis × fatigue interaction effect in any spatiotemporal parame-

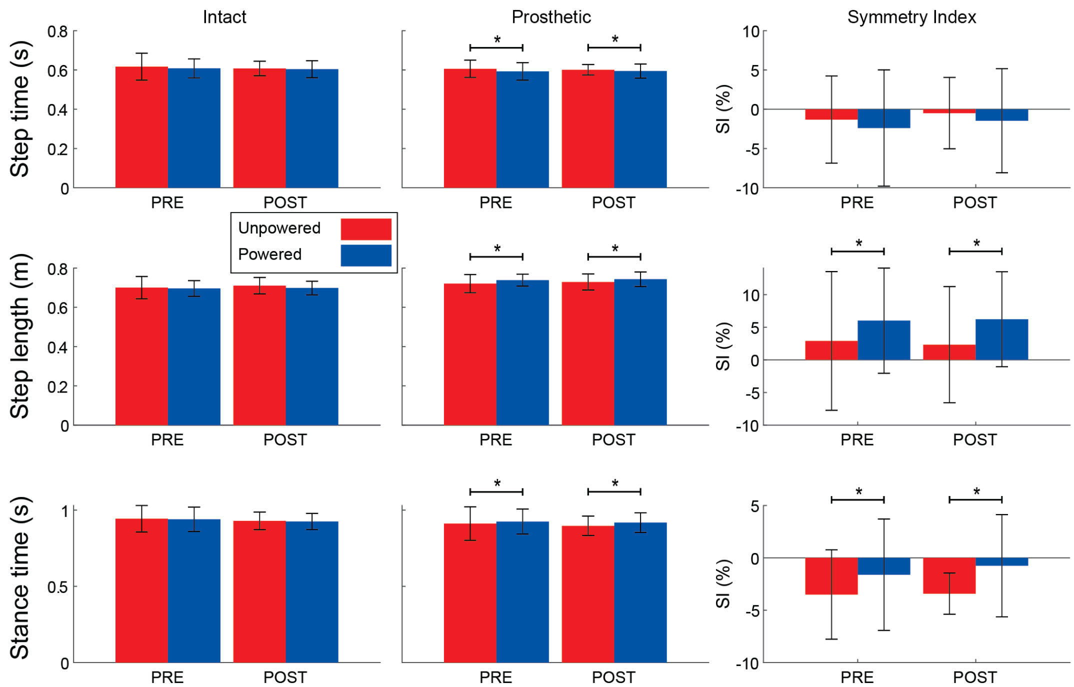

Figure 3.3: Spatiotemporal parameters before and after fatigue
Step lengths, step times, stance times, and symmetry indices (SI) for each parameter. Significant prosthesis effects (*) were denoted.

ters.

3.3.3 Ground Reaction Forces (GRF)

The peak braking force in the anterior-posterior GRF was greater in the residual limb when walking with the powered prosthesis relative to the unpowered prosthesis ($p = 0.044$; Figure 3.4). There was also a significant prosthesis × fatigue effect for the symmetry indices of the peak propulsive GRF ($p = 0.041$). Peak propulsive GRF was less symmetric after fatigue when walking with the unpowered prosthesis ($p = 0.024$;g= -0.225). Further, after fatigue, peak propulsive GRF was more symmetric with the powered prosthesis compared to the unpowered prosthesis ($p = 0.001$;g= 0.333).

In both the intact limb, the first peak of the vertical GRF was greater with the

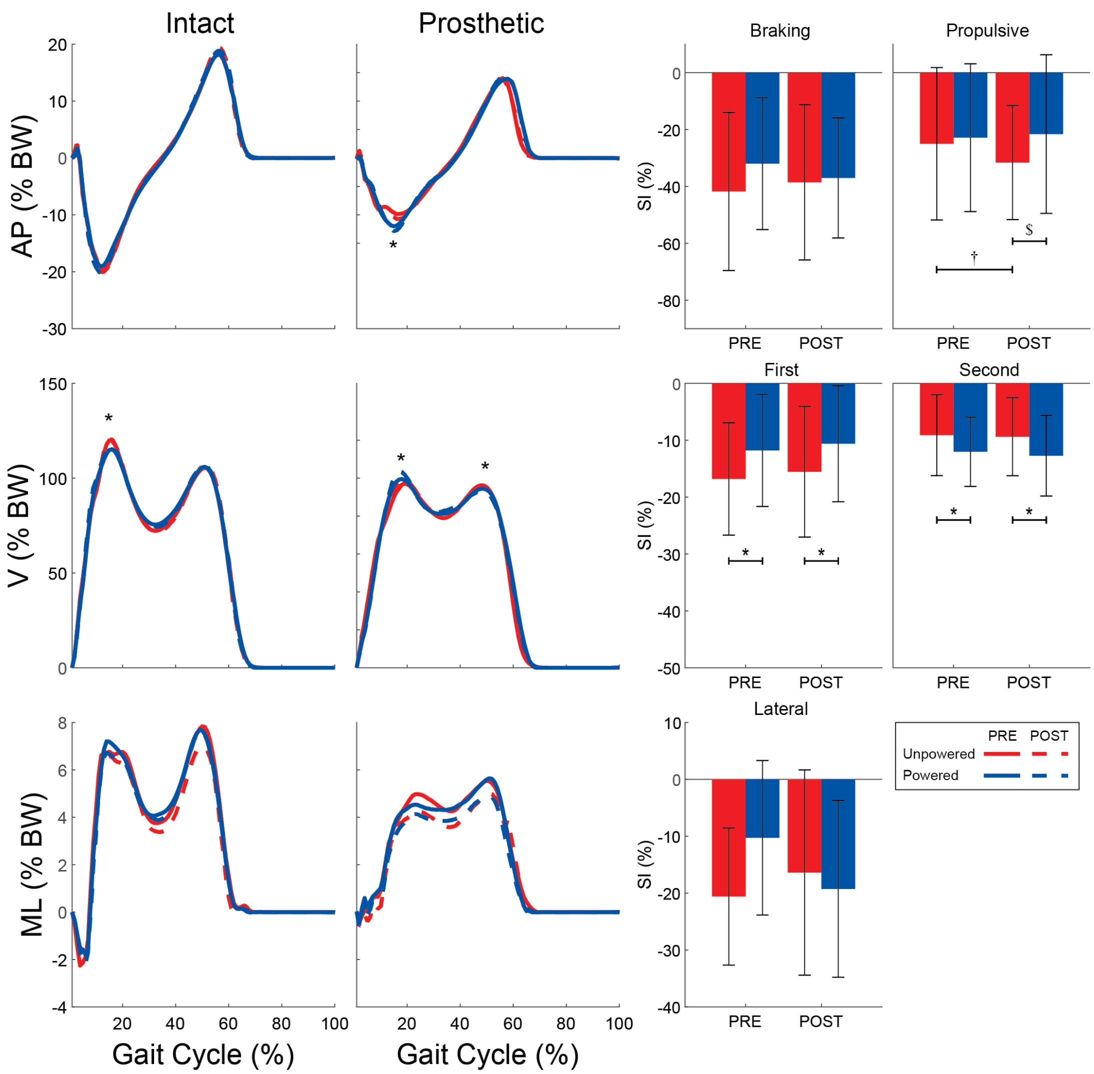

Figure 3.4: Ground reaction forces (GRF) before and after fatigue
GRF and symmetry indices (SI) for peaks in the anterior-posterior (AP), vertical (V), and mediolateral (ML) directions. Significant prosthesis effects (*) were denoted. If the prosthesis × fatigue interaction effect was significant, significant pairwise differences between pre- and post-fatigue with the unpowered prosthesis (†) and significant pairwise differences between prostheses post-fatigue ($) were denoted.

unpowered prosthesis relative to the powered prosthesis ($p = 0.006$), while in the residual limb, this peak was greater with the powered prosthesis ($p < 0.001$; Figure 3.4). The first peak of the vertical GRF was also more symmetric with the powered prosthesis ($p < 0.001$). In the residual limb, the second peak of the vertical GRF was lower with the powered prosthesis ($p < 0.001$). The second peak of the vertical GRF was less symmetric with the powered prosthesis relative to the unpowered prosthesis ($p < 0.001$). There was no prosthesis × fatigue interaction effect in the vertical GRF peaks.

3.3.4 Joint Mechanics

At the residual limb hip, peak power generated during pre-swing was lower when walking with the powered prosthesis relative to the unpowered prosthesis ($p = 0.004$; Figure 3.5). The peak power generated during pre-swing was also less symmetric with the powered prosthesis ($p = 0.006$; Figure 3.6). There was a significant prosthesis × fatigue effect for peak power generated during pre-swing at the residual limb hip ($p = 0.002$). Post-hoc pairwise comparisons revealed that power generated increased after fatigue when walking with the unpowered prosthesis ($p = 0.041$;g= 0.238) but decreased after fatigue when walking with the powered prosthesis ($p = 0.016$;g= -0.238; Figure 3.3). There was also a significant prosthesis × fatigue effect for the symmetry indices of peak power generated during pre-swing ($p = 0.008$). Hip power generated during pre-swing was less symmetric after fatigue when walking with the powered prosthesis ($p = 0.0082$;g= -0.264). Symmetry in hip power generation was not different pre- and post-fatigue with the unpowered prosthesis ($p = 0.262$;g= 0.194).

At the residual limb knee, the peak power generated during terminal stance was lower ($p < 0.001$) and the peak power absorbed during pre-swing was greater ($p < 0.001$) when walking with the powered prosthesis, relative to with the unpowered

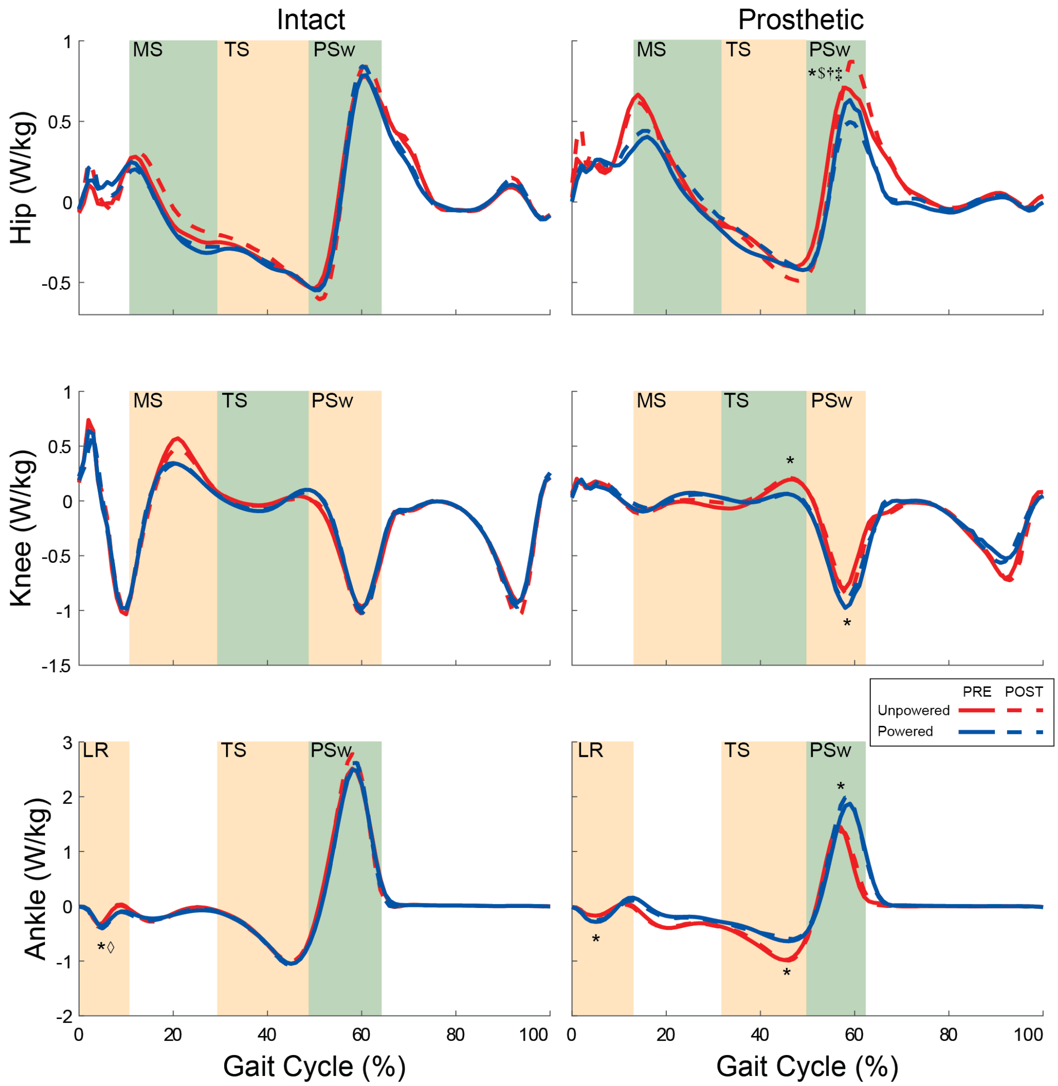

Figure 3.5: Sagittal joint mechanics for the hip, knee, and ankle joints
For the hip and knee, mid-stance (MS), terminal stance (TS), and pre-swing (PSw) phases of gait were highlighted. For the ankle loading response (LR), TS, and PSw phases of gait were highlighted. Significant prosthesis effects (*) and significant fatigue effects (◊) were denoted. If the prosthesis × fatigue interaction effect was significant, significant pairwise differences between pre- and post-fatigue with the unpowered prosthesis (†) and with the powered prosthesis (‡) and significant pairwise differences between prostheses post-fatigue ($) were denoted.

prosthesis (Figure 3.5). The peak power absorbed during pre-swing was also more symmetric when walking with the powered prosthesis ($p = 0.005$; Figure 3.6). There was no prosthesis $\times$ fatigue interaction effect in any of the phases of gait observed.

At the ankle, the peak power absorbed during loading response was greater with the powered prosthesis relative to with the unpowered prosthesis, for both the intact ($p < 0.001$) and residual limbs ($p = 0.002$; Figure 3.5). There was also a significant fatigue effect, as the power absorbed during loading response at the intact limb ankle was greater post-fatigue, relative to pre-fatigue ($p = 0.004$). In the residual limb ankle, the peak power absorbed during terminal stance was lower ($p < 0.001$) and the peak power generated during pre-swing was greater ($p < 0.001$) with the powered prosthesis relative to the unpowered prosthesis. During terminal stance, the power absorbed at the ankle was less symmetric with the powered prosthesis relative to with the unpowered prosthesis ($p < 0.001$; Figure 3.6). During pre-swing, however, the power generated at the ankle was more symmetric with the powered prosthesis ($p < 0.001$). There was no prosthesis $\times$ fatigue interaction effect in any of the phases of gait observed.

3.3.5 Joint Range of Motion (ROM)

Residual side hip joint ROM was lower with the powered prosthesis relative to the unpowered prosthesis ($p < 0.001$; Table 3.2). Hip ROM was also less symmetric with the powered prosthesis ($p = 0.003$). There was a significant prosthesis $\times$ fatigue effect for the residual limb hip ROM ($p = 0.005$). The residual limb hip ROM decreased after fatigue when walking with the powered prosthesis ($p = 0.022; g= -0.197$), while it was unchanged after fatigue when walking with the unpowered prosthesis ($p = 0.085; g= 0.147$). Further, after fatigue, hip ROM was lower with the powered prosthesis relative to the unpowered prosthesis ($p < 0.001; g= -0.480$).

Residual limb knee joint ROM was greater with the powered prosthesis relative to

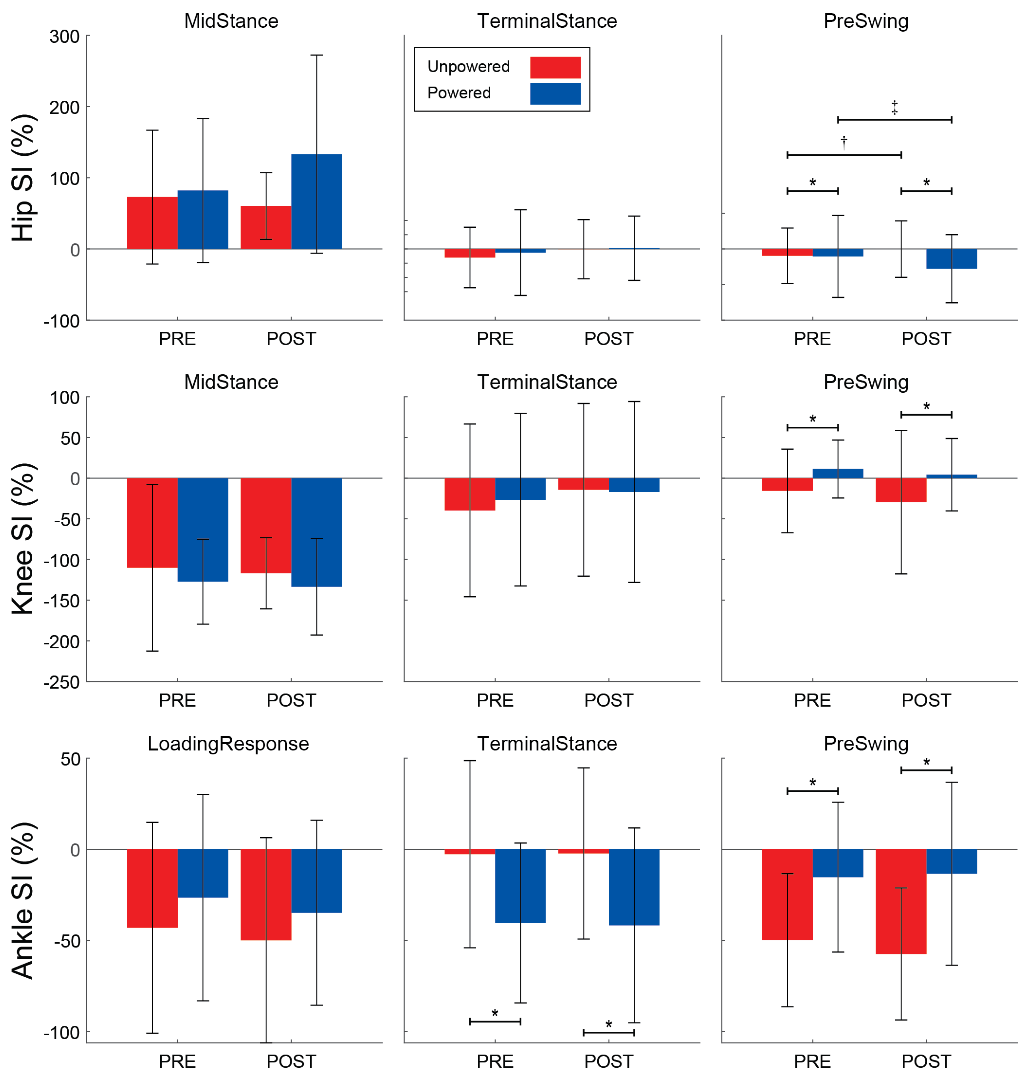

Figure 3.6: Joint mechanics symmetry during specific phases of the gait cycle Significant prosthesis effects (*) were denoted. If the prosthesis × fatigue interaction effect was significant, significant pairwise differences between pre- and post-fatigue with the unpowered prosthesis (†) and with the powered prosthesis (‡) were denoted.

Table 3.2: Joint range of motion (ROM) and symmetry indices (SI)

JOINT ROM

Limb	Intact				Prosthetic			
Device	Unpowered		Powered		Unpowered		Powered	
Fatigue	PRE	POST	PRE	POST	PRE	POST	PRE	POST
Hip	40.6 (4.7)	41.4 (5.8)	40.6 (6.2)	40.2 (5.3)	**41.3 (4.9)***	**42.3 (6.4)***	**40.1 (5.9)***	**38.6 (5.9)***
Knee	64.8 (4.8)	66.0 (5.3)	65.2 (2.8)	65.5 (3.3)	68.3 (9.4)*	68.3 (10.2)*	69.2 (6.4)*	71.1 (8.1)*
Ankle	30.5 (4.2)	30.9 (4.6)	30.2 (5.2)	29.7 (5.0)	20.8 (6.2)*	21.1 (6.4)*	23.1 (2.4)*	23.5 (2.7)*

JOINT ROM SI

Device	Unpowered		Powered	
Fatigue	PRE	POST	PRE	POST
Hip	1.4 (12.7)*	2 (15.4)*	-1.3 (20.7)*	-4.5 (21.4)*
Knee	4.6 (10.6)*	**3 (11.6)***	5.6 (9.9)*	**7.7 (11.1)***
Ankle	-40.5 (22.8)*	-40.6 (25.2)*	-25.5 (23.5)*	-21.9 (25.3)*

*Significant device effect
Significant device × fatigue effect

the unpowered prosthesis ($p = 0.001$; Table 3.2). Knee ROM was also more symmetric with the powered prosthesis ($p = 0.001$). There was a significant prosthesis × fatigue effect for the symmetry indices of ROM at the knee ($p = 0.037$). After fatigue, knee ROM was less symmetric with the powered prosthesis relative to the unpowered prosthesis ($p < 0.001$;$g = 0.337$).

The residual limb ankle ROM was greater with the powered prosthesis relative to the unpowered prosthesis ($p < 0.001$; Table 3.2). Additionally, ankle ROM was more symmetric with the powered prosthesis ($p < 0.001$). There was no prosthesis × fatigue interaction effect in ankle ROM.

3.4 Discussion

3.4.1 Walking Endurance and Perceived Exertion

Our central hypotheses that adding the powered push-off would increase participants' walking endurance and decrease their perceived exertion during walking were not supported. While the intent of the experiment was for participants to walk at a fast speed until they could no longer continue due to muscular fatigue, there were several pain-related reasons that limited participants from walking for longer. With the unpowered prosthesis, only one participant reported having to stop due to fatigue, with others having to stop due to phantom pain, pain at the residual stump, or at the hip. Though the time of walking did not change with the powered prosthesis, more participants were able to walk until they were fatigued, rather than in pain. Though there were no differences in the time at which participants' rating of perceived exertion (RPE) exceeded a 5 ("Hard"), their reasons for stopping may indicate that the powered prosthesis was less painful to walk with, compared to the unpowered prosthesis. This was supported by participants having longer stance times, greater braking ground reaction force (GRF) peaks, and greater vertical GRF peaks on the residual limb with the powered prosthesis. Further, the first vertical GRF peak at the intact limb was lower with the powered prosthesis, suggesting the prosthesis may have mitigated some of the overreliance on the intact limb. Because our study was not designed to specifically evaluate or distinguish the effects of the powered push-off on pain or comfort, this is an area that future research may explore.

3.4.2 Compensatory Mechanisms to Fatigue

Our findings support the secondary hypothesis that the increase in hip power generation after fatigue would be lower with a powered prosthesis compared to an unpowered prosthesis. With the unpowered prosthesis, the peak residual limb hip power generated during pre-swing increased post-fatigue relative to pre-fatigue, which corroborate previous findings [160]. As expected, the intact limb ankle joint absorbed less power during loading response regardless of prosthesis (Figure 3.5). This is consistent with previous findings [160] and is a potential indicator of plantar flexor fatigue, as fatigue associated with long-distance walking has been shown to reduce eccentric contraction at the ankle [161]. With the powered prosthesis, however, peak power generated at the residual limb hip did not increase post-fatigue. This suggests that the powered prosthesis may have reduced the compensatory mechanics at the hip joint, even if the intact limb ankle was eventually fatigued from walking.

The effects of fatigue and the powered push-off on residual limb hip joint mechanics may warrant further investigation, as the residual limb hip in fact generated less power after fatigue. This is an interesting finding, as the residual limb hip flexors are considered a major contributor to forward propulsion [131]. In previous studies quantifying joint power in individuals with TTA under non-fatiguing walking conditions, the increased residual limb hip extensor power has been recognized as a major contribution to forward propulsion [131, 164]. In another study comparing powered and unpowered prostheses, hip power generated at the residual limb was not different between prostheses [38]. In our study, participants' joint mechanics responded differently to a fatiguing bout of walking depending on the prosthesis. With the powered prosthesis, participants had a reduced peak power generation post-fatigue relative to pre-fatigue. Additionally, when making the comparison between prostheses after fatigue, peak hip power was lower with the powered prosthesis. These findings suggest that participants may have adopted a gait strategy that derived greater forward propulsion from the powered push-off after fatigue. However, there were no significant fatigue effects in joint angles at the hip, knee, or ankle that clearly illustrate the adopted gait strategy (Figure 3.7). Thus, while subtle changes at the joints may have propagated to result in changes at the residual limb hip mechanics, it is unclear

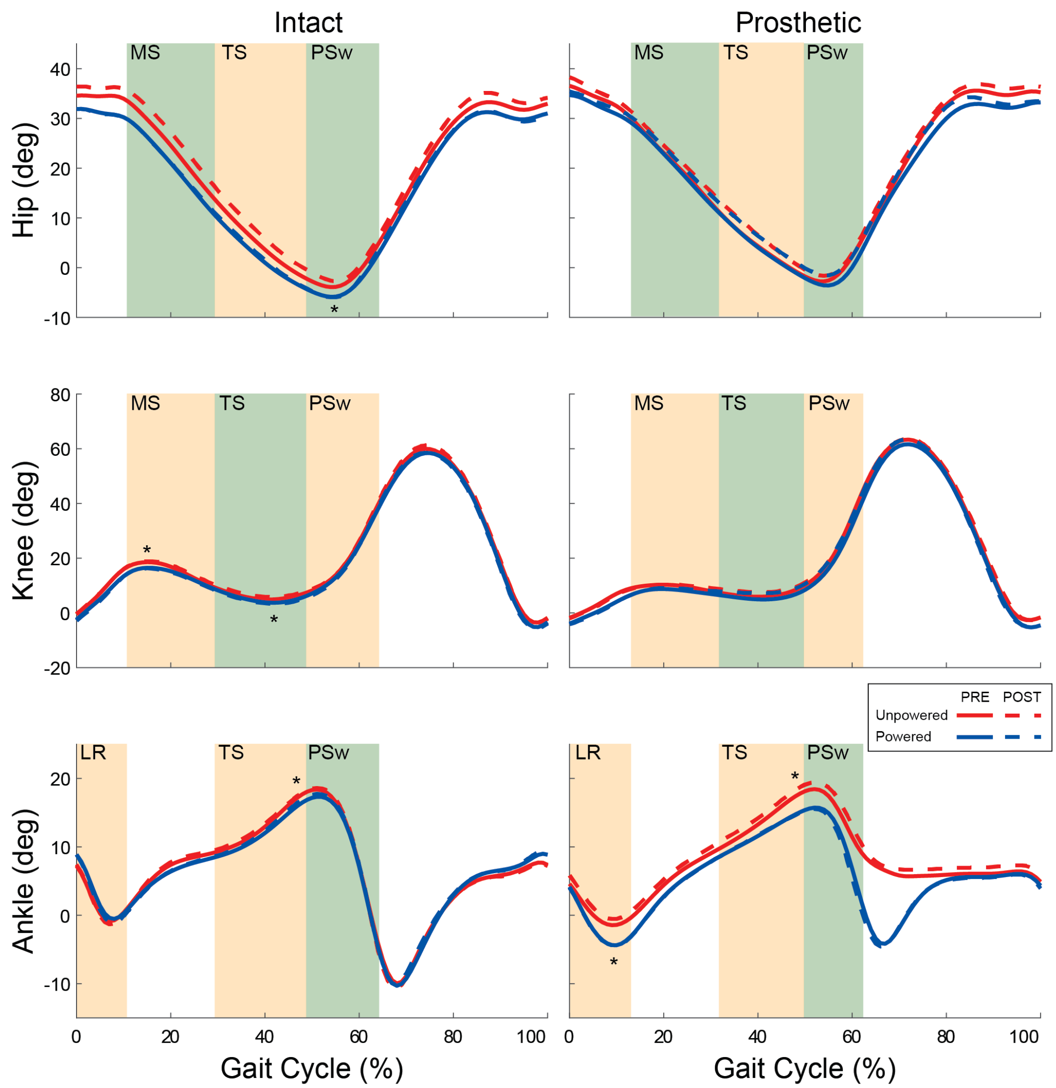

Figure 3.7: Sagittal angles for the hip, knee, and ankle joints
Significant prosthesis effects (*) were denoted.

exactly how the element of fatigue and the powered push-off combined to manifest in this reduction of hip power. It is worth noting that the post-hoc pairwise comparisons of residual limb hip power generation during pre-swing had small effect sizes ($|g| \leq 0.472$; Appendix A.3). Future works with greater sample sizes may utilize EMG measurements of muscle activations to elaborate on this finding.

The fatigue and prosthesis $\times$ fatigue interaction effects were not significant for power generated and absorbed at the knee joint and for GRF peaks. This finding differs from previous work, in which participants reduced their intact limb propulsive GRF peak after fatigue, compensated with an increased residual limb propulsive GRF peak and increases in residual limb knee joint angles and moments in midstance [160]. These differences may be explained through differing protocols and prosthetic types. Our participants walked at a target speed based on their leg length before and after fatigue, whereas no target walking speed is specified in [160]. One reason we observed no differences in propulsive GRF peaks before and after fatigue may be that walking speed was set constant. Further, five of six participants in the previous study walked with solid ankle cushion heel (SACH) feet and only one participant walked with a dynamic response (DR) foot. All ten participants who completed our study walked with a DR foot as their unpowered prosthesis. This discrepancy could explain the absence of fatigue-related changes to knee power, ROM and GRF, as DR feet are more compliant during loading response and provide greater peak push-off power compared to SACH feet [157].

3.4.3 Propulsive GRF

Though the power generated at the prosthetic ankle did not change with fatigue regardless of prosthesis, the symmetry of the propulsive GRF peaks was affected by the prosthesis and fatigue interaction. With the unpowered prosthesis, propulsive GRF was more less symmetric after fatigue, suggesting increased reliance on the intact limb for forward propulsion, whereas this effect was not seen with the powered prosthesis. When making the comparison post-fatigue, propulsive GRF was more symmetric with the powered prosthesis compared to the unpowered prosthesis. This may be an indication that participants were more limited by comfort or pain with the unpowered prosthesis compared to the powered prosthesis.

3.4.4 Ability to Provide Stance Stability

A potential area for improvement could be found by examining the ability of the powered prosthesis to provide stance stability by absorbing power during terminal stance. Power absorption during early to mid-stance serves the purpose of redirecting the center of mass velocity as the contralateral limb generates power by pushing off of the ground [34]. Compared to an unpowered prosthesis, the powered prosthesis has been shown to absorb less power at the prosthetic ankle during terminal stance [38]. Our results were consistent with previous findings in both the pre- and post-fatigue conditions, and was further corroborated by the lower dorsiflexion peak of the powered prosthetic ankle (Figure 3.7). The lack of stance stability with the powered prosthetic ankle may be associated with increases in power absorbed at the intact limb ankle during its loading response and at the residual limb knee during its pre-swing. Further, more power was absorbed at the intact limb ankle post-fatigue relative to pre-fatigue. Therefore, as participants became fatigued, they absorbed more power in the intact limb ankle, potentially as a way to facilitate a smoother step-to-step transition. The reduced power absorption at the prosthetic ankle may incur compensatory increases in eccentric contractions at the intact limb ankle dorsiflexors and residual limb hamstrings. While this finding was limited by a small sample size, the post-hoc comparison had a medium effect size (g = -0.588). Thus, future work should investigate the effects of the reduced power absorption at the prosthetic ankle by quantifying accompanying changes in muscle activity.

3.4.5 Limitations

In our study, participants were instructed to walk on the treadmill at a pre-determined fast speed for as long as they could, and the duration of walking was used as a measure of endurance. The fast target walking speed was used because the powered prosthesis had been shown to reduce metabolic costs in faster speeds but not at slower speeds [7, 63]. To ensure muscular fatigue, we instructed our one K4 participant to walk on a 5% incline, though may have placed larger moments at the hip joint and altered the effects of fatigue . Additionally, the fast-speed walking may have prompted more stoppages due to pain or discomfort, as participants may not have been used to walking at fast speeds. However, fewer participants had issues of pain and discomfort with the powered prosthesis, which may be a finding unique to faster-than-comfortable walking speeds. Further, we were not able to control for or measure the degree of muscular fatigue during the long-duration treadmill walk. The duration of the walk, which would affect the extent to which muscular fatigue was achieved, was dictated by the participant's perceived exertion, and likely affected by pain or discomfort. Future works may record EMG signals during maximal voluntary contractions to control for the degree of fatigue across participants. Additionally, measures of endurance may have been more contextual to walking patterns in daily life if participants walked at their self-selected speed during the fatiguing bout of treadmill walking. Finally, our approach employed a pre- versus post-fatigue paradigm to compare joint mechanics during overground gait. An instrumented treadmill capable of recording ground reaction forces would enable researchers to observe the gradient of changes to joint mechanics throughout the fatiguing bout of walking. Further, recording muscle activity in the lower-limb muscles during the fatiguing bout of walking may provide ways to quantify the onset of muscular fatigue.

3.5 Conclusion

In our study, the powered prosthesis reduced participants' pain and discomfort at the residual limb when walking for long durations. Findings also suggest that when walking with the powered prosthesis, individuals with TTA may adopt a gait strategy that relies more on the prosthetic ankle rather than the residual limb hip joint for forward propulsion. However, participants were not able to walk for longer with the powered prosthesis, suggesting other limiting factors. It is possible that a lack of power absorption at the prosthetic ankle may lead to compensations at the residual limb knee and intact limb ankle. Further work is needed to elucidate the factors that limit the user's endurance when walking with the powered prosthesis.

CHAPTER 4

Wearable Sensors Quantify Mobility in People with Lower Limb Amputation During Daily Life[1]

4.1 Introduction

Rehabilitation after a lower limb amputation (LLA) typically focuses on restoring bipedal ambulation and helping the individual return to their pre-amputation lifestyles [37]. In spite of this goal, people with LLA are less physically active and report decreased quality of life compared to healthy non-amputees [19, 155, 116]. One potential reason for this may be inappropriate prosthetic prescription [1, 89, 115]. To prescribe prosthetic components, clinicians assess patients' current and potential functional capabilities in clinical settings using the Medicare Functional Classification Level (K-level) [47]. The K-level guidelines classify patients into five activity levels, from K0 (least mobile) to K4 (very mobile) [41]. Clinicians typically use patient interviews to gather information about patient history, comorbidities, residual limb health, and motivation to ambulate. This information, along with clinicians' assessment of the K-level guideline descriptors are used to assign patient K-levels [47, 80]. However, these guideline descriptors lack specific criteria or objective standards for

[1] A version of this chapter is published as Kim, J., Colabianchi, N., Wensman, J., & Gates, D. H. (2020). Wearable Sensors Quantify Mobility in People With Lower Limb Amputation During Daily Life. IEEE Transactions on Neural Systems and Rehabilitation Engineering, 28(6), 1282-1291.

the clinicians who evaluate them [25, 80, 112, 46, 32]. Additionally, this system relies on patient self-report, which has been shown to be unreliable [140]. As such, the assignment process is subjective and has no published evidence of reliability [112]. Likely because of these factors, 67.8% of U.S. clinicians reported a lack of confidence in the current system's ability to accurately assign rehabilitation potential [15].

Previous studies have introduced methodologies to aid in prosthetic prescription by moving away from self-report and toward measures of physical performance during daily life [75, 4, 3]. These daily-life measures can be particularly beneficial in quantifying factors such as level of community ambulation or regular physical activity. While these are often assessed through patient interviews, questionnaires, or activity diaries, these self-report methods rely on patient recall, and prior research has found that people tend to overestimate their daily activity [140, 119, 147]. Furthermore, there are likely differences between the individual's capacity, as measured by in-lab or in-clinic assessments, and the individual's performance in daily life [115]. A more holistic view of an individual's functional mobility may include both their capacity and actual daily life activity. As such, a growing number of studies measure functional walking performance during daily life [149, 75, 148, 68, 65].

With the advent of wearable technology, it is now possible to objectively quantify the amount of activity that people do in daily life. Previous works have used step counts as a measure of mobility in people with lower limb loss using inexpensive technology such as accelerometers and pedometers [140, 115, 138]. These studies have found that people with LLA take fewer steps per day than healthy non-amputees or the recommended 10,000 steps per day [88, 140]. While step count is a useful indicator of quantity of physical activity and overall health [150], it lacks information about the quality of the steps taken. Measures such as cadence and walking speed can describe the quality of steps during daily life. Further, these measures paired with the location of where the walking occurs may provide additional insight to clinicians

Table 4.1: Participant demographics and data quantity

LLA										CON					
ID	**Sex**	**Age**	**K-level**	**Level of amp**	**Cause**	**ACC (full days)**	**Total IMU strides[a]**	**IMU strides w/GPS[b]**	**Season**	**Sex**	**Age**	**ACC (full days)**	**Total IMU strides[a]**	**IMU strides w/GPS[b]**	**Season**
01	M	52	3	UTT	trauma	12	25900	3450	Sp	M	29	14	28700	27600	W
02	F	43	2	TT+TF	vasc	12	2650	1830	W	M	26	14	8260	8260	W
03	M	20	3	UTF	cong	11	13700	11400	Sp	F	39	11	26200	25800	W
04	M	71	3	UTT	vasc	14	3200	3200	S	M	24	14	35400	30100	W
05	M	39	3	UTT	trauma	13	12000	11800	S	M	58	17	50100	41800	W
06	M	57	3	UTT	vasc	13	6600	4630	S	M	49	23	82600	36700	Sp
07	M	62	3	UTT	trauma	31	11000	8030	F	M	64	15	16600	15100	Sp
08	M	53	3	UTT	vasc	13	3050	3000	W	M	22	15	23200	19900	Sp
09	M	65	3	UTT	vasc	14	2500	1900	Sp	M	61	19	50400	45100	Sp
10	M	40	3	UTT	trauma	12	2270	2270	F	M	50	22	47700	45600	Sp
11	M	30	3	UTT	trauma	13	1720	1640	F	M	40	14	35400	35300	S
12	M	65	3	UTT	trauma	30	19400	18900	Sp	M	51	9	34700	32600	S
13	M	55	3	UTT	trauma	13	12500	12000	F	M	63	16	39600	32200	S
14	M	27	4	UTT	trauma	3	2220	773	F	M	43	13	29000	28000	S
15	M	54	4	UTT	trauma	19	11200	11100	W						
16	M	45	3	UTT	trauma	10	17600	17600	Sp						
17	F	37	2	UTT	vasc	15	827	752	S						
Mean (SD)		47.9 (14.5)				14.6 (6.75)	8710 (7440)	6720 (5960)			44.2 (14.8)	15.4 (3.84)	36300 (18000)	30300 (10800)	

List of abbreviations: amp: amputation, U: unilateral, TT: transtibial, TF: transfemoral, vasc: dysvascular, cong: congenital, Sp: Spring, S: Summer, F: Fall, W: Winter

[a] Number of straight-line walking strides over the entire two-week collection period

[b] Number of straight-line walking strides over the collection period with successful GPS match

about functional mobility.

The ability or potential to vary cadence is an important part of function per the K-level guidelines [41]. While cadence during daily life can be measured using widely available, inexpensive sensors [88, 149, 112, 4], only one paper quantified the variability of cadence during daily life. Arch et al. proposed a method to calculate cadence variability using the Weibull scale parameter of each participant's cadence distributions [4]. In this method, a smaller scale parameter value indicated that most of the cadence data were lower cadences, describing a person who did not walk at a variety of cadences. They found that their K2 participants had lower scale parameters than their K3 participants and thus walked with less variable cadence. However, such commercial products will underestimate cadence if walking is not continuous for the entire epoch [29]. Moreover, the simple accelerometer-based activity monitors have decreased accuracy at slower walking speeds [43]. These issues are particularly problematic for people with LLA as they tend to walk slowly and in short bouts [88]. Therefore, more advanced sensors or signal processing techniques are required to measure the distribution of cadence.

Another key component of mobility is engagement in the community. Unfortunately, there is no measurable standard for how well one engages in the community. Community ambulation is typically assessed subjectively by the clinician, through patient self-reports [80]. To quantify this criterion, several studies have examined where healthy adults [127], older adults [156, 84], and people with LLA [75, 68, 69] perform physical activity, typically using Global Positioning System (GPS) data in concert with step counts. While this approach measures the number of steps taken in the community, it may only provide indirect insight into how well people move within community environments. A more comprehensive measure may be required in order to assess community ambulation.

Walking speed has long been established as a robust indicator of community ambulation in the stroke population [117] and a key factor in assessing mobility [5, 45, 64]. Examining walking speed across different locations could assist in assessing community ambulation. Recent developments of Inertial Measurement Units (IMU) and inertial navigation algorithms have made it possible to accurately calculate stride-by-stride spatiotemporal parameters (such as cadence and walking speed) using small, wearable sensors. This approach has been applied in the research setting, demonstrating an error of 0.8% for fast walking and 0.3% for slow walking [109]. To our knowledge, however, it has yet to be applied to the amputee population. While in-clinic tests such as the 10-meter walk test can measure walking speed to quantify a patient's walking speed capacity, this likely does not represent their comfortable walking speed in daily life [115].

The purpose of this study was to explore the clinical viability of using a system of IMU and GPS sensors to characterize the functional mobility of people with LLA. We measured cadence, walking speed, characteristics of their distributions, and how they change with location. We used wearable sensors to measure patient walking during their daily lives to provide a better understanding of everyday walking performance,

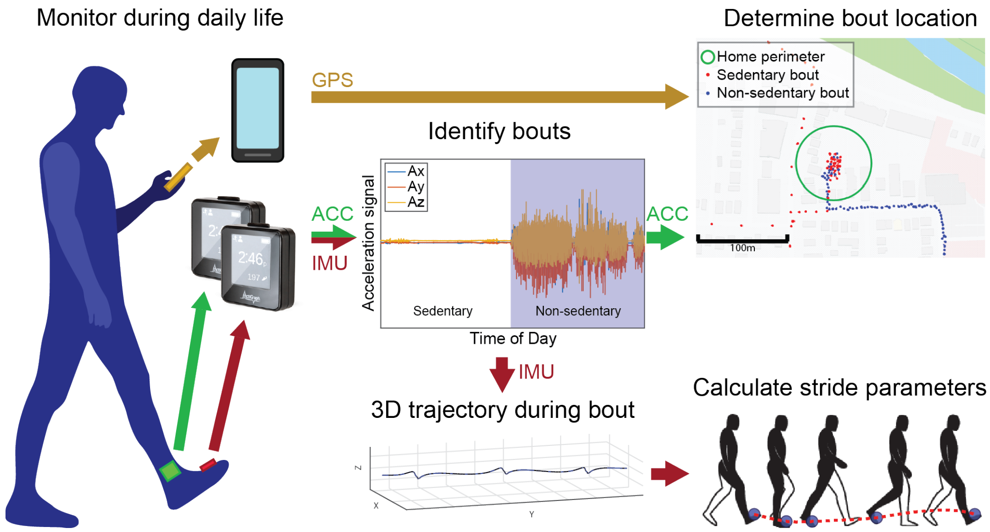

Figure 4.1: Sensor setup and processing
Participants wore an IMU mounted on the prosthetic foot, an accelerometer (ACC) on the prosthetic pylon (non-dominant limb for non-amputees) and carried a GPS-enabled smartphone. We identified periods of non-sedentary activity from the ACC. We then calculated the three-dimensional position of the foot using IMU data during non-sedentary periods. From this, we calculated stride parameters including stride length, cadence and speed. We then determined where this activity occurred using time-synchronized GPS data.

in addition to in-lab capacity measures. Our secondary goal was to examine the potential added value of "everyday performance measures" as compared with in-lab measures of capacity. Because everyday cadence variability and walking speed have yet to be quantified using this method, we also recruited healthy, non-amputee adults to provide a basis for comparison.

4.2 Methods

4.2.1 Subjects

We recruited 17 individuals (15 males; 47.9 ± 14.5 years old) with lower limb amputation from the University of Michigan Orthotics and Prosthetics Center. Potential participants were included if they were over the age of 18, had a lower limb amputation, had been using a prosthesis for at least 6 months, and were able to walk independently. Of these individuals, two were classified as K2, 13 as K3, and two as K4 (Table 4.1). We also recruited 14 healthy, non-amputee controls (13 males; 44.2 $\pm$ 14.8 years old) through an online database (http://umhealthresearch.org). Participants were screened to ensure that they did not have any history of neurological diseases or injuries that would affect their ability to ambulate. All participants provided their informed consent to the experimental protocol, approved by the University of Michigan Institutional Review Board (HUM00096819).

4.2.2 Experimental Protocol

Participants walked at their comfortable speed in a straight line over an 8 m walkway five times at self-selected speed. The average walking speed and cadence across these trials was the in-lab capacity measure. Participants were then given two activity monitors (Actigraph GT9X Link, ActiGraph) and a Global Positioning System (GPS) enabled smartphone (if they did not own one) to carry with them for a two-week period (Fig. 4.1). One activity monitor was attached to the top of the shoe via a small pouch. This monitor collected both accelerometer and gyroscope (IMU) data at 100 Hz. A second monitor attached to the ankle of controls or prosthetic pylon for individuals with amputation collected accelerometer (ACC) data at 30 Hz. Location was monitored using the GPS tracking software Ethica (Ethica Data, Ontario, Canada) or MapMyRun (Under Armour, Baltimore, MD).

4.2.3 Data Analysis

We defined non-sedentary bouts of activity using the ACC signal and ActiLife software (ActiGraph, Pensacola, FL) as any period of activity with greater than 30 counts per minute (cpm) which lasted at least 1 minute [143]. This definition was chosen as it had been previously used in people with lower limb amputation, who are less active than healthy adults. ActiLife software calculated the total number of steps per day from the ACC signal as double the single leg stride count.

We first excluded any GPS data points given a low accuracy rating by Ethica. For each observed bout from the accelerometer, we calculated the midpoint between the bout's start and end times (t_{mid}, Fig. 4.2). The closest GPS time point to t_{mid} was denoted as t_{best}. The difference in time, t_{diff}, between t_{mid} and t_{best} was used to assess whether there was sufficient overlap of the ACC and GPS data (Fig. 4.2A). Participant-specific perimeters established the boundaries of the home. These were based on type of location (urban, suburban, and rural), sensor noise and resolution around the home. From this, we designated bouts as "at home" or "away from home" (Fig. 4.2B). If t_{diff} was less than 5 minutes, we used the GPS point at t_{best} to calculate the distance between their location at that time and their home. If t_{diff} was between 5 minutes and 12 hours (Fig. 4.2C), we then checked if t_{best} was within the range of the bout's start and end times (Fig. 4.2D). If it fell within this bout, we determined t_{adj} as the chronologically adjacent GPS point, such that t_{mid} was between t_{best} and t_{adj} in time. If the distance between these two GPS points was within the acceptable noise based on participant-specific parameters (Fig. 4.2E), the person was assumed to have stayed at the same general location and the GPS point at t_{best} was used to make the at-home/away designation. For bouts that did not sufficiently overlap in time with any GPS data point (i.e. t_{diff} >12 hr), or if the participant's location change between two consecutive GPS points was greater than the acceptable noise, we marked the location as unknown.

Finally, we used IMU data to estimate the position of the prosthetic foot, in order to calculate stride-by-stride cadence and walking speed. For each bout of non-sedentary activity, the position and orientation of the foot were calculated using pedestrian dead reckoning algorithms previously described in [109, 122]. Briefly, we first identified a quiet period preceding the bout of movement using the gyroscope signal. During this period, we oriented the IMU to the global reference frame and normalized the acceleration signal to gravity. We then integrated the acceleration signal twice to calculate the trajectory of the foot. In order to reduce the error due to signal drift, we applied zero velocity updates (ZUPT) at every foot-flat phase. These phases were identified as periods when the gyroscope and gravity-normalized acceleration magnitudes were close to zero (ω <30 °/s; α <1 m/s^2). This process corrected for erroneous velocities observed during each foot-flat phase by assuming no slip between the foot and the ground. Next, we detected heel strikes by identifying peaks in the vertical acceleration signal (minimum peak value of 6 G and a minimum period of 500 ms between each peak). Heel strikes segmented the bouts of movement into walking strides. We then used a rule-based algorithm to identify straight-line walking strides (Fig. 4.3). We identified valid walking strides as those that had horizontal position displacements between 0.5 m and 2 m and lasted less than 3.5 s. We excluded any steps taken on stairs by eliminating any strides where the vertical displacement of the foot between consecutive heel strikes exceeded the standard stair height of 0.178 m [53].

We quantified the distribution of walking speeds and cadences taken during daily life using a probability density function. To quantify cadence variability, we calculated the variance of the cadence distribution. Additionally, we calculated the skew of each distribution according to [77]

$$skew = \frac{\frac{1}{n}\sum_{i=1}^{n}(x_i - \bar{x})^3}{(\frac{1}{n}\sum_{i=1}^{n}(x_i - \bar{x})^2)^{\frac{3}{2}}}$$

where $\bar{x}$ is the sample mean, x_i is each data point, and n is the sample size. Assuming a unimodal distribution, a positive skew represents a distribution with a mode that is lower than the mean, i.e., a long tail of values greater than the mean. Conversely, a negative skew indicates the opposite, with a long tail of values less than the median. A skew magnitude between 0.5 and 1 indicate a moderate skew, while those less than 0.5 indicate an approximately symmetric distribution.

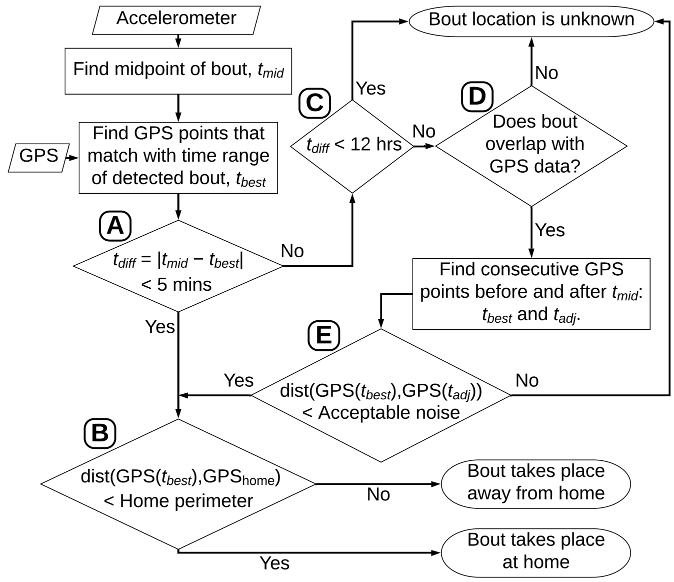

Figure 4.2: Flowchart: syncing steps with location data
Determination of the location of non-sedentary bouts and the associated step counts.

4.2.4 Statistical Analysis

We excluded any day with insufficient wear time (i.e., <6 hours). Because participants had varying amounts of valid sensor data, we bootstrapped each data set before calculating the mean. For a data set with n elements, we sampled n elements with replacement, then took the mean of the resampled set. This process was repeated 10,000 times. The bootstrapped mean was the mean of all 10,000 resampled means [123].

We first compared the steps per day and steps per bout measured by the ACC between groups (LLA/CON) using independent samples t-tests. The bootstrapped mean cadence, walking speed, and stride length during daily life were calculated from IMU data for all straight-line walking strides and compared between groups using t-tests. We then compared the variance and skew of the distributions of cadence and walking speed between groups using t-tests. Differences between average cadence and walking speed measured in the lab and the average of those measured

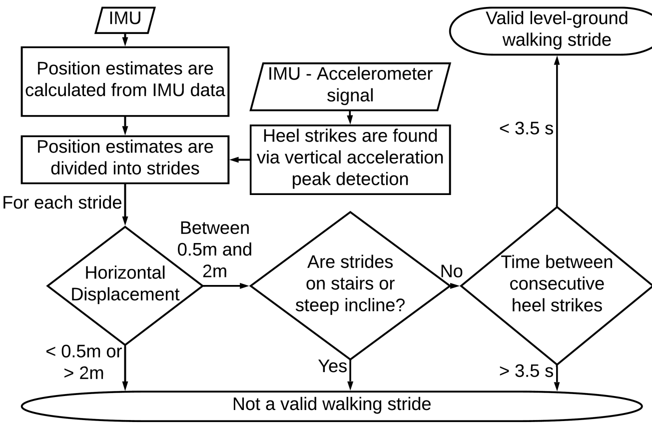

Figure 4.3: Flowchart: valid walking stride criteria
Rule-based algorithm for determination of valid level-ground walking strides. Minimum detectable walking speed is 0.142 m/s, which encompasses common walking speeds by limited and unlimited community ambulators [45]

during daily life were explored using a two-factor mixed measures ANOVA, where group (LLA/CON) was a between subjects factor and setting (in-lab/daily life) was a within subject factor. After excluding activity data without a successful location designation, we compared straight-line walking cadence and walking speed between locations (Home/Away) and groups (LLA/CON) using a series of mixed measures ANOVAs. All statistics were performed in SPSS v24 (IBM, Armonk, NY) with a significance level of 0.05.

4.3 Results

We collected an average of 7.59 days of IMU data, 16.9 days of ACC data, and 13.9 days of GPS data from the LLA group. An average of 2.3 days of ACC data per person were excluded when calculating daily step counts due to insufficient wear time. The LLA group took an average of 4252 $\pm$ 2558 steps per day, with half on the instrumented leg. The IMU data yielded a total of 8710 $\pm$ 7440 straight-line walking strides of the instrumented leg, over the collection period, per person (Table 4.1). Of these, 2670 $\pm$ 2500 strides detected as at home and 4250 $\pm$ 4520 strides away from

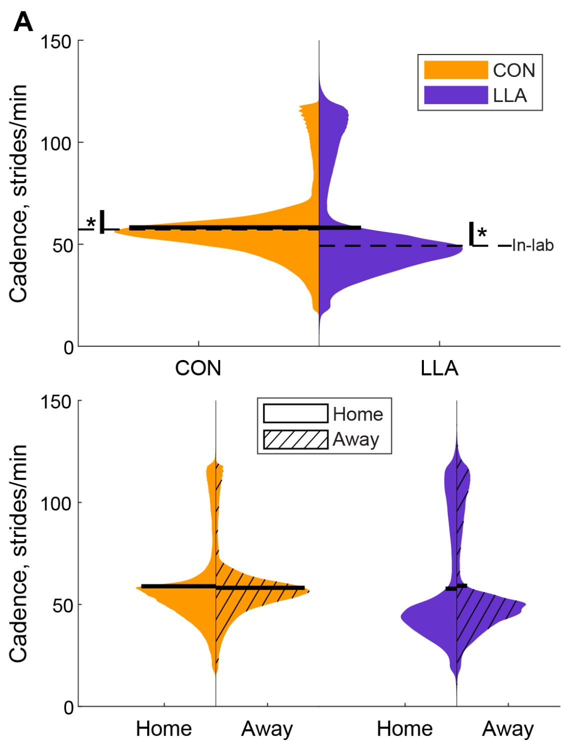

Figure 4.4: Cadence in daily life
A. Split violin plot of the probability density functions of cadence distributions for the group with lower limb amputation (LLA) and control (CON) group (top) and between strides taken at home and away (bottom). Raw distributions were smoothed using a kernel smoothing function (*ksdensity*) in MATLAB for visualization. Shaded regions are averaged distributions, solid horizontal lines are the group means, and dashed horizontal lines are the group means for in-lab measures. B. Variance of cadence distribution for each group (top) and for strides taken at home and away (bottom). C. Skew of the cadence distribution for each group (top) and for strides taken at home and away (bottom). K2 (△), K3 (○), K4 (×). *significant differences ($p < 0.05$) between in-lab and daily life.

Table 4.2: Group comparisons of activity during daily life

	CONTROL	LLA	p_{group}
Steps per day	7774 (1448)	4249 (2142)	**< 0.001**
Steps per bout	149 (46.7)	78.6 (41.1)	**< 0.001**
Cadence, strides/min			
Mean (In-lab)	57.2 (4.02)	49.4 (3.82)	**< 0.001**
Mean (Daily life)*	58.3 (3.30)	58.1 (14.0)	0.964
Variance	318 (136)	494 (328)	0.070
Skew	1.60 (0.50)	1.50 (1.28)	0.796
Walking speed, m/s			
Mean (In-lab)	1.35 (0.133)	1.19 (0.148)	**0.005**
Mean (Daily life)*	1.20 (0.121)	0.99 (0.228)	**0.004**
Variance	0.165 (0.053)	0.167 (0.083)	0.930
Skew	0.059 (0.541)	0.478 (0.582)	**0.048**
Stride length, m	1.24 (0.112)	1.05 (0.225)	**0.007**

*Significant difference between daily life and in-lab measures ($p < 0.05$)

home. 11 participants in the LLA group completed the in-lab portion of the study and were analyzed for the in-lab/daily life comparison. One participant (LLA 01) did not record any IMU walking strides while at home and was therefore excluded from location comparisons for cadence and walking speed ($n_{LLA} = 16$ for location comparisons).

Control participants had an average of 14.0 days of IMU data, 17.3 days of ACC data, and 16.7 days of GPS data. We excluded an average of 1.9 days of ACC data due to insufficient wear time. The control group took 7774 $\pm$ 1448 steps per day, which was significantly greater than that of the LLA group ($p < 0.001$). The control group took a total of 36300 $\pm$ 18000 straight-line walking strides, per person, over the collection period (Table 4.1). Of these, 7210 $\pm$ 8460 strides were taken at home and 23100 $\pm$ 10700 strides were away from home. While we did not match control and LLA participants, there were no differences in age ($p = 0.485$), height ($p = 0.598$), or BMI ($p = 0.061$) between the groups. Data collection occurred through different seasons (Table 4.1).

4.3.1 Cadence

The control and LLA groups both walked at similar cadences during their daily lives, at 58.3 strides/min for controls and 58.1 strides/min for the LLA group (Fig.

4.4A). Both groups walked at a lower cadence (57.2 strides/min for controls and 49.4 strides/min for the LLA group) during the in-lab session ($p = 0.041$, Table 3). While there were no group differences in cadence ($p = 0.070$), the LLA group had a much larger within-group range compared to the control group (Fig. 4.4B). Both groups' cadence distributions were positively skewed, indicating a greater concentration of cadence values below the mean (Fig. 4.4C). There were no significant differences between the groups. While all control participants had a positive skew, four participants in the LLA group either had a negative skew or a symmetric distribution. There were no differences in cadence, cadence variance, or cadence skew between steps taken in and out of the home (Table 4.3).

4.3.2 Walking Speed

During daily life, the control group walked faster than the LLA group by an average of 0.21 m/s ($p = 0.005$; Table 4.2 Fig. 4.5A). Both groups also walked faster during the in-lab session than in daily life ($p < 0.001$). This difference was larger for the LLA group (0.2 m/s vs 0.15 m/s). Walking speed variance was not different between the two groups (Fig. 4.5B). Both groups' walking speed distributions were symmetric, though the LLA speed distribution was significantly more positively skewed than that of the control group. This indicates that a larger number of walking

Table 4.3: Comparison of activity taken in and away from home

	CONTROL		LLA		
	Home	**Away**	**Home**	**Away**	**$p_{location}$**
Total number of straight-line walking strides over the two-week collection period*	7210 (8460)	23100 (10700)	2670 (2500)	4250 (4520)	**p_{CON} = 0.003** p_{LLA} = 0.138
Cadence, strides/min					
Mean (SD)	58.9 (5.89)	58.2 (3.03)	57.7 (15.1)	59.1 (15.0)	0.907
Variance	414 (177)	281 (138)	549 (303)	489 (374)	0.173
Skew	1.41 (0.605)	1.67 (0.540)	1.30 (1.24)	1.57 (1.45)	0.344
Walking speed, m/s					
Mean (SD)	1.12 (0.161)	1.23 (0.120)	0.88 (0.218)	1.04 (0.257)	**0.014**
Variance	0.179 (0.050)	0.160 (0.068)	0.165 (0.088)	0.166 (0.105)	0.673
Skew	0.370 (0.774)	-0.089 (0.552)	0.830 (0.634)	0.356 (0.721)	**0.010**
Stride length, m	1.15 (0.160)	1.27 (0.105)	0.93 (0.156)	1.08 (0.248)	**0.006**

*Significant group × location interaction ($p < 0.001$)

strides were taken at slower speeds for the LLA group ($p = 0.048$; Fig. 4.5C). Two participants in the LLA group had skew values greater than 1, while all other participants either had moderate or symmetric skew values. Both groups walked faster when away from home ($p = 0.014$, Table 4.3). Location had no effect on the variance of walking speeds. Both groups' walking speed distributions were more symmetric when away from home ($p = 0.010$).

4.3.3 Walking Speed vs. Stride Length

Because there were group differences in walking speed but not in cadence, we conjectured there would be differences in stride length. As expected, individuals with LLA had a shorter stride length ($p = 0.007$; Table 4.2). Similarly, as there was a location effect on walking speed but not on cadence, changes in stride length facilitated this change in walking speed, as stride length increased when away from home ($p = 0.006$; Table 4.3).

4.4 Discussion

Recent studies have shown the effectiveness of using wearable sensors to understand ambulation characteristics of individuals with LLA during daily life [88, 68, 75]. The purpose of this study was to fuse IMU with GPS data during daily life and explore its clinical viability of characterizing functional mobility. The findings can be summarized as follows: (1) both healthy controls and individuals with LLA walked slower during their daily lives compared to their in-lab measures (2) cadence variance during daily life was not different between the control and LLA groups, and (3) both groups walked significantly faster outside of the home.

There were no differences in average cadence, cadence variance, or skew between steps taken at home and those away from the home. On the other hand, location had a significant effect on walking speed and walking speed skew. Controls increased

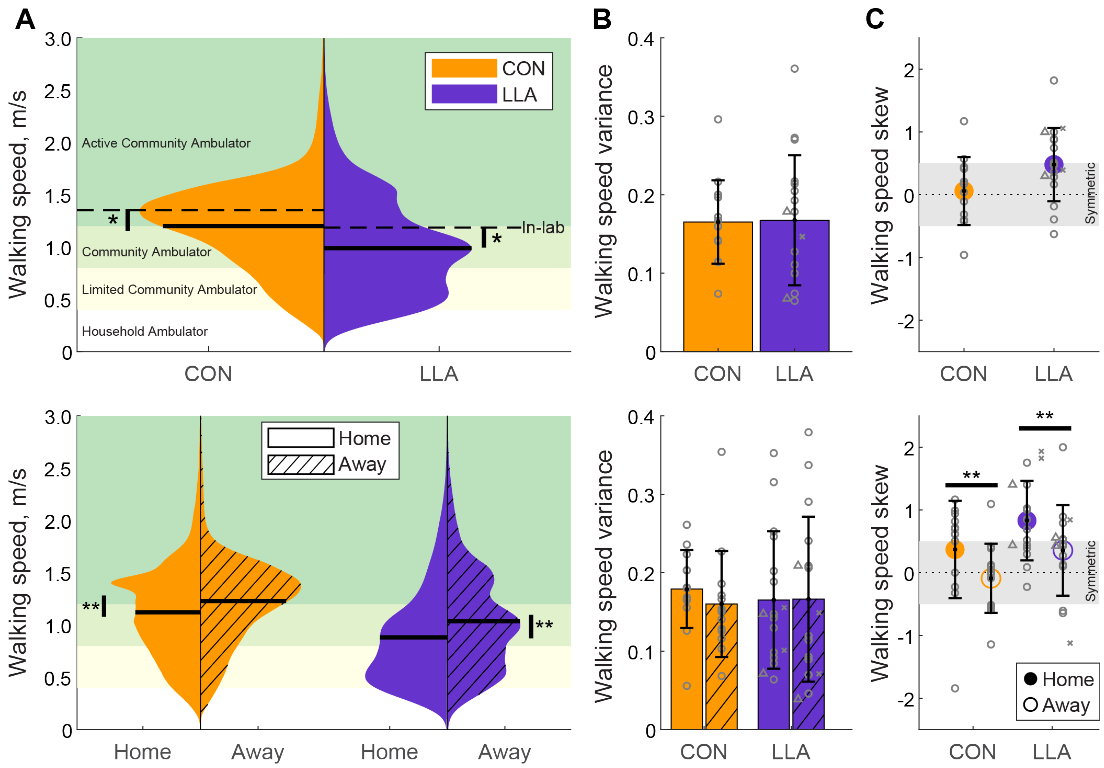

Figure 4.5: Walking speed in daily life

A. Split violin plot of the probability density functions of walking speed distributions for the group with lower limb amputation (LLA) and control (CON) group (top) and between strides taken at home and away (bottom). Raw distributions were smoothed using a kernel smoothing function (*ksdensity*) in MATLAB for visualization. Shaded regions are averaged distributions, solid horizontal lines are the group means, and dashed horizontal lines are the group means for in-lab measures. B. Variance of walking speed distribution for each group (top) and for strides taken at home and away (bottom). C. Skew of the walking speed distribution for each group (top) and for strides taken at home and away (bottom). K2 (△), K3 (○), K4 (×). *significant differences ($p < 0.05$) between in-lab and daily life. **significant differences ($p < 0.05$) between home and away.

the walking speed from 1.12 m/s in the home to 1.23 m/s out of the home, while the LLA group increased from 0.88 to 1.04 m/s. While both groups had increased speeds, the average speed for the LLA group was still less than that required for traversing crosswalks [45, 35]. Lastly, both groups increased their stride lengths (by 0.12 m/s for controls, 0.15 m/s for LLA) when away from home to facilitate the faster walking speeds. We do not know enough about the external factors that brought about these changes in gait to claim the relative importance of cadence, walking speed, or stride length, and the majority of relevant studies have only reported cadence and/or walking speed during daily life [68, 4, 75]. However, measuring the relationship between the three gait parameters and how they change may provide insight on gait adaptability and mobility. To do this, we used pedestrian dead reckoning algorithms to calculate stride-by-stride values of stride length, cadence, and walking speed during daily life.

Both groups had greater cadence and walking speed when measured in-lab compared to their performance measures from daily life (Table 4.2). The differences in walking speed (0.15 m/s for controls and 0.2 m/s for LLA) were greater than the minimal clinically important difference (MCID) or minimal detectable change (MDC) in walking speed (between 0.1 and 0.2 m/s for individuals with impaired mobility [13, 97]. Similarly, Urbanek et al. found that older adults had a 20 step/min greater cadence in the lab compared to daily life [152]. They speculated that participants being alert and focused during the experiment led to them "over performing" in the lab [152]. In daily life, people have many additional things to focus their attention on beyond simply walking. As such, everyday walking speed is more similar to dual-task walking done in-lab compared to normal walking in the lab [65].

Walking speed is an important indicator of health and is strongly associated with community ambulation [117, 45, 132, 35]. Previous studies have established speed cut-offs to classify household (<0.4 m/s), limited community (0.4 — 0.8 m/s), normal community (0.8 — 1.2 m/s), and active community ambulators, or those who can comfortably cross the street (>1.2 m/s) [5, 35]. From a clinical perspective, the distinction between a community- and household ambulator is quite simply dependent on whether the patient walked outside their home. Further, if their average speed exceeded 0.8 m/s away from home (14 of 16 LLAs, all controls), they could safely be classified as a normal community ambulator. Beyond these distinctions, however, it is unclear if we can conclusively classify levels of community ambulation using walking speeds during daily life. Moreover, we cannot comment on the relative validity of the settings in which the walking speed is measured (in-lab vs daily life). It is nonetheless important to recognize that walking speed differed at different settings of measurement and that measurements during daily life can offer a perspective that in-lab measurements do not.

The LLA group walked significantly slower than the control group during daily life. This result agreed with numerous previous studies that have measured preferred walking speeds in laboratory/clinic settings [74, 11, 107, 155] as well as average walking speeds in the everyday environment [68]. We expanded upon prior work by characterizing the distribution of walking speeds for steps taken in daily life. While the LLA and Control groups had similar variance in speeds, the LLA group had a more positively skewed distribution of speeds. This indicates that LLA and control participants had similar ranges of speeds throughout the day, but that the LLA group took more of their steps at slower speeds. There are several possible reasons why the LLA group had a greater concentration of strides at lower speeds compared to controls. First, the LLA group took a greater proportion of their walking strides at home compared to controls (Table 4.3) and walking bouts at home may consist of lower-speed (Fig. 4.5A, bottom) short-distance trips (e.g. bedroom to bathroom). Another potential explanation is that LLAs walk faster only when required (e.g. cross the street, catch the bus), but prefer to walk at slower speeds. However, these possibilities are speculative as activity data can only quantify what the person did in their daily life, not why they chose to do it.

We also quantified cadence variability as it is a K-level descriptor and thought to represent adaptability to different circumstances and environments [59]. The control and LLA groups had similar cadence variance. This is perhaps unsurprising, as a majority of the LLA participants were K3 or higher, and thus should have "the ability or potential for ambulation with variable cadence" [41]. However, there was a great deal of variability within the LLA group. The average cadence variance in strides^2/min^2 was 522 for the K2 group (n = 2), 522 for the K3 group (n = 13) and 285 for the K4 group (n = 2), while the control group averaged 318. While these results seem to indicate that K-levels could not be differentiated based on daily cadence variance alone, the sample sizes are small. In the current Medicare system, the ability for variable cadence is associated with higher functionality. Our results suggest that those with higher function actually walk at a narrower range of cadences throughout daily life. It is important to recognize that while K-levels are aimed at assessing capacity or potential for mobility, our approach measured the actual cadence variability during daily life. During in-clinic assessments, prosthetists may instruct patients to walk at different speeds to visually assess cadence variability. Our approach of examining cadence values from steps taken during daily life utilized a rule-based algorithm (Fig. 4.3) that could have eliminated walking steps where cadence variability was high, such as sharp turns, side steps, or small steps in crowded or tight areas. Ultimately, people may not vary their cadence for a significant portion of straight-line walking during daily life, not because they are unable to, but because they are not required to. Therefore, future work with a larger and more heterogeneous cohort is needed to determine the relationship between everyday cadence variability and functional mobility.

In this study, we were able to specifically explore how characteristics of walking differ in and out of the home. There are several reasons to suspect that these might be different. Walking may be affected by external requirements, environmental barriers (e.g. curbs, slopes, or uneven terrain), space limitations, or other factors that may be different in and out of the home. The control group took a greater number of straight-line walking strides when away from home, whereas the LLA group's number of strides did not change by location (Table 4.3). This may suggest individuals with LLA do not take more steps away from the home due to environmental constraints or lower confidence in their mobility. Important to note, however, is that the IMU sensor was worn on the shoe and many control participants noted that they did not wear their shoes (and IMU) at home. To investigate this issue, we compared the end-of-day doff times (based on wear time analysis) between the IMU and ACC using a t-test. On average, control participants doffed the IMU an hour and a half before they doffed the ACC, while the difference in doff time for the LLA group was approximately 30 minutes, though this was a non-significant trend ($p = 0.07$). Additionally, people do not tend to take many steps at the end of the day, so this issue may not have a large effect on total number of strides at home.

While it may be of interest to know specifically where people perform activities, there are several issues that may limit the feasibility of this approach. These issues mainly stemmed from the use of GPS data taken from smart phones. Most smart phones are not dedicated GPS collection devices, so their GPS sampling rate and accuracy can be highly variable and dependent on factors such as location (i.e. GPS signal tends to be less accurate in buildings as well as more rural areas) and hardware type (i.e. different phones have different signal strengths). Additionally, the phones had to be charged nightly, which participants often forgot to do according to their self-report. This resulted in missing GPS data. Gaps in GPS data were examined through a rule-based algorithm (Fig. 4.2) that found the best GPS match for activity data. Unfortunately, there was still a non-negligible amount of activity data that could not be properly synchronized with location data. This data was excluded from location (home vs away) analysis. Given the sparsity of the GPS data and the fact that many of our participants were either retired or did not have routine schedules, we were unable to distinguish activity location beyond "home" and "away from home." While we attempted to obtain more context on where participants were throughout the day via a self-recorded activity log, these were often returned empty or lacking information regarding type of activity or where it took place. The feasibility of location determination may be improved by emerging technology for dedicated GPS devices, which continues to improve in terms of sampling rate and battery life.

There are several other findings regarding the feasibility of our approach. While we aimed to collect data for a two-week period, the actual number of days was highly variable across participants. Some participants did not charge the IMU at night. When the battery dies on these sensors, they must be re-initialized using the ActiLife software. We made every effort to replace monitors, however, many of these participants ended the collection period with incomplete sets of data. Using activity monitors that do not require re-initialization for collection after a dead battery may improve the completeness of recorded data. Additionally, while the groups had similar age, height, and BMI, there was no way to control for other factors that may have influenced participant behavior. These factors include weather, living environments, social support systems, working environments and associated travel requirements, personality, among others. Weather conditions may influence the amount of physical activity away from home, particularly in the colder Michigan climate. A snowy day with slippery walkways during winter may affect walking speed or stride length away from home differently to a similarly cold winter day with no snow or ice. We collected both groups across a range of seasons such that each group would be similarly affected by these climate conditions. While logistically difficult, future work could initialize activity monitors for patient and control groups on the same day to mitigate weather effects.

Our approach of measuring functional mobility from walking during daily life has shown that it is feasible to measure the daily performance of a person with lower limb amputation in a way that provides useful information to the providers of clinical care. Using wearable sensors, we were able to record a large number of straight-line walking strides, on the order of thousands of strides over a two-week collection period. Approximately 83% of all strides had a location designation (at home or away), which added location context to a large volume of collected data. In addition, we were able to extend on prior work by calculating walking speed for each stride using IMUs. This approach has the potential to aid clinicians during the prescription of prosthetic components by accompanying clinicians' in-clinic assessments of functional capacity with measures of physical performance during daily life. Claims for more advanced components can be stronger if they are substantiated by walking data spanning multiple days of unconstrained observation rather than in-clinic assessments alone. For example, if the amputee exhibits higher walking speeds from a large number of steps away from home, they will likely experience many environmental barriers such as stairs and ramps, which would justify the need for more sophisticated prosthetic componentry. Additionally, this technology could be used post-prescription to evaluate the effectiveness of the prosthetic intervention in the patient's routine environment. Pre-prescription measurements could establish a baseline measurement of activity and establish goals with the patient. Post-prescription measurements could then help assess the achievement of these goals. Improvements toward clinical feasibility would involve further categorizing the data into different contexts for clinical interpretation. The ability to categorize walking strides into different tasks or contexts (e.g. climbing stairs, walking up a curb, navigating ramps or tight spaces) was not demonstrated in this paper, but would give clinicians more specific information on patient mobility during daily life.

4.5 Conclusion

This study presented a novel approach to quantifying performance of functional mobility during everyday life for healthy adults and individuals with LLA. Our results demonstrated the importance in measuring walking speed performance during daily life, in addition to measuring its capacity in clinic or laboratory settings. Additional research is needed to understand the clinical relevance of cadence variation during daily life. The presented approach is a step toward developing objective methods to help inform clinicians about functional mobility in lower-limb prosthesis users. Future studies should expand this approach to more heterogeneous populations across different K-levels.

CHAPTER 5

The Influence of Powered Prostheses on User Perspectives, Metabolics, and Activity: A Randomized Crossover Trial

5.1 Introduction

People with transtibial amputations (TTA) walk with greater asymmetry, using more metabolic energy, and prefer to walk more slowly than people without amputation [155]. These factors may contribute to their decreased physical activity level [92]. In particular, people with TTA have lower daily step counts [140] and walk for shorter durations at a time, compared to people without amputation [88, 113]. This deficit is important to address, as physical inactivity is related to lower quality of life [116] and can lead to secondary comorbidities such as obesity and cardiovascular disease [61].

Powered ankle-foot systems, such as the BiOM (now Ottobock Empower, Duderstadt, Germany) aim to reduce gait asymmetries and metabolic effort by providing active "ankle" power during the push-off phase of gait [7]. Prior studies have found that the powered prosthesis enabled people with TTA to use less metabolic effort to walk over level-ground [63, 130], while others found no differences on level-ground [49] or on slopes [102]. Similarly, while some studies found that participants walked at faster speeds with the powered prosthesis over a loose rock surface [50] and on level surfaces [63, 38], a more recent study found no differences in self-selected walking speed [49]. The participant cohort in the latter study differed from earlier ones as participants were older and potentially less physically active. Further, the study found that people designated as the highest Medicare functional classification level (K4) had reduced metabolic effort with the powered prosthesis, while those at a lower level (K3) did not [49]. This suggests that the benefits of prosthetic ankle power may depend on characteristics of the user, as the Medicare Functional Classification Level, or K-level, is a system that describes the rehabilitation potential of a person with lower-limb amputation [41].

While mixed, prior studies provide some evidence that prosthetic ankle power can be effectively incorporated into the user's biomechanics to reduce their effort. It is unclear, however, whether this translates to changes in physical activity in daily life. Prior work has exclusively characterized measures of *capacity*, or what one is capable of in a standardized or optimal environment. According to the International Classification of Functioning, Disability and Health (ICF), evaluating *performance*, i.e., what one does in their actual environment, is also an important component of characterizing functionality [114]. Because the patient's surroundings can play a large role in the accessibility to physical activity, it is imperative that evaluations of physical activity are made in the patient's everyday environment. As such, a growing number of studies have employed community-based activity monitoring to evaluate prosthetic interventions, to provide clinicians with more comprehensive characterizations of the patient's functional mobility [20]. The ICF also recommends that to properly measure improvements in health, psychological and social aspects of health should also be collected, which may heavily impact everyday performance. Overall, there are numerous factors that can contribute to or limit a patient's performance in everyday life. Evaluating changes to those factors is a necessary step in moving toward a more comprehensive evaluation of powered prostheses.

Examining patient perception is one way to track changes to psychosocial factors that may affect mobility. While metabolic effort undoubtedly represents valuable information, it may not necessarily correlate to the patient's perception of exertion [139]. Further, a previous study found no statistical difference in participants' Prosthetic Evaluation Questionnaire scores between using unpowered and powered prostheses [38], whereas the same cohort reduced their metabolic costs with the powered prosthesis [130]. Given these differences, it is important to explore both perception of effort and measures of effort as is it unclear which relates more to a person's physical activity. For example, if a device is perceived to be easier to walk with, even if it does not objectively reduce metabolic effort, this may alleviate conscious barriers to physical activity and enable an increase in the amount of physical activity.

In this study, we conducted a randomized crossover trial comparing the use of unpowered and powered prostheses in people with TTA, after one week of unsupervised device acclimation. Our primary goal was to quantify differences in metabolic cost, the volume (step count) and characteristics (walking speed) of everyday walking, as well as patient perceptions of their mobility and quality of life when wearing each prosthesis. We hypothesized that there would be differences in metabolic cost, step count, and walking speed when using the powered prosthesis, compared to the unpowered prosthesis. Based on prior work, we also hypothesized that participants would not perceive a change in mobility with the powered prosthesis. A secondary aim of this work was to explore the relationship between patient perceptions and functional outcomes measured in the lab and in daily life.

5.2 Methods

5.2.1 Participant Recruitment

People with unilateral transtibial amputations (TTA) were recruited through clinical referral from the University of Michigan Orthotics and Prosthetics Center and through flyers and postings on https://umhealthresearch.org and https://clinicaltrials.gov (NCT02828982). Inclusion criteria included: aged 21 years or older, unilateral TTA, and prosthetic use for at least six months. Potential participants were excluded if they had a history of cardiovascular disease, or orthopedic or neurological disorders to their intact limb, or were unable to walk independently for 10 minutes at a time. Participants' K-levels were obtained from their physician. We initially recruited older community ambulators (K3) who may be less physically active than in previous works [130, 38], as benefits of the powered prosthesis were less clear for this population [49]. However, due to recruiting difficulties, we later included more active community ambulators (K4). All participants provided their written informed consent prior to participation.

5.2.2 Experimental Protocol

This study utilized a cross-over design where participants were randomly assigned to perform testing first with their prescribed, unpowered prosthesis or with a powered prosthesis. For the powered condition, a certified prosthetist fit participants with a BiOM T2 powered prosthesis (BionX Medical Technologies Inc., Bedford, MA, USA) and tuned the device according to procedures described in Gardinier et al. [49]. They were then given one week to acclimate to the device at home and did not receive any device-specific training. Participants returned to the clinic if they needed any adjustments to their prosthetic settings or alignment. After any change, participants were given another week to acclimate. Only two participants (S03, S06) required readjustments. Participants acclimated freely at home and did not receive any directed training with the powered prosthesis. For the unpowered condition, participants needed to be stable in their prescribed prosthesis (no adjustments) for a period of at least one month prior to collection.

After the acclimation period, participants were given two activity monitors (ActiGraph GT9X Link, ActiGraph, Pensacola, FL, USA) and a global positioning system (GPS) enabled smartphone for a two-week period. One activity monitor was mounted on top of the prosthetic foot and collected accelerometer and gyroscope (IMU) data at 100 Hz, while the other (ACC) was attached to the lateral side of the prosthetic pylon and collected accelerometer data at 30 Hz. The placement for the ACC was chosen for its high test-retest reliability for step counts [16], while the IMU was place on top of the foot to ensure minimum movement during foot-flat [122]. GPS data were collected using either Ethica (Ethica Data, Ontario, Canada) or MapMyRun (Under Armour, Baltimore, MD). Participants were given an activity log to record their activity during the collection.

Following acclimation and activity data collection ($\geq$ 3 weeks), participants came to the lab for metabolic testing and to complete questionnaires assessing their overall health and quality of life. Participants were instructed to fast for at least four hours prior to metabolic testing. We used a portable metabolic system (Cosmed K4b2, Rome, Italy) to measure participants' oxygen consumption and carbon dioxide production. We first measured baseline metabolic costs as participants rested in a seated position for at least 10 minutes. We then measured metabolic costs while participants walked on a treadmill at a controlled speed based on leg length [54]. Participants walked for a minimum of three minutes after they achieved steady-state oxygen consumption, characterized by a visible plateau [30]. Once participants felt rested, we measured their self-selected walking speed by having them walk over a straight 8 m walkway, ten times.

Participants completed the Prosthetic Evaluation Questionnaire (PEQ) and Short Form (SF)-36 after each prosthetic condition and a Prosthetic Preference questionnaire at the end of the study. The PEQ consists of 82 questions that describe the function of a lower-limb prosthesis and assesses prosthesis-related quality of life [91]. The questionnaire is divided into ten functional scales, addressing four major domains: prosthetic function, mobility, psychosocial experience, and well-being. Participant's quality of life was assessed using the Short Form (SF)-36 general health questionnaire, which provides eight component scores and Physical and Mental component scores. The Prosthetic Preference Questionnaire consisted of a single question where participants were asked to indicate which device they preferred on a 100 mm visual analog scale (VAS) from their unpowered device (0) to the powered ankle (100). Finally, using a semi-structured questionnaire, we asked participants for subjective feedback about their likes and dislikes and what if anything felt easier and/or harder with the powered prosthesis. If not mentioned, we then specifically asked about the ease of walking faster, longer, and on different types of terrain (e.g. uneven ground, stairs, slopes).

5.2.3 Data Analysis

We first verified that the last three minutes of breath measurements were at a steady state by confirming a respiratory exchange ratio between 0.7 and 1.0. Using the recorded steady-state oxygen consumption and carbon dioxide production rates, we estimated energy expenditure using the Brockway equation [17]. To generalize energy expenditure across participants, we calculated a dimensionless metabolic cost of transport (COT) by normalizing energy expenditure by participant weight and walking speed [33].

The accelerometer and IMU were programmed to begin data collection on the day following meeting with study personnel at 12 am, to avoid partial day collections. The accelerometer collected data until the battery died, which was typically around 12 days. We excluded data from days in which wear time was < 6 hours [85], which may be due to participants not wearing the prosthesis or leaving the accelerometer on the charger for the day. ActiLife software (ActiGraph, Pensacola, FL, USA) calculated daily step counts as double the single leg stride count from the pylon-mounted accelerometer. Periods of non-sedentary activity were defined as any period of activity greater than 30 counts per minute epoch [143]. Such a low threshold includes small movements and detects even a single strides as 'non-sedentary activity.' We then separated steps that occurred during the active period as 'at home' and 'away from home' using the time matched GPS data [85].

Because the pylon-mounted accelerometer recorded data at a low sampling rate (30 Hz), battery life lasted approximately 12 days, and we did not instruct participants to recharge the accelerometer overnight. IMU battery life was typically only 24 hours, due to the higher sampling rate. As such, participants were instructed to charge the IMU every night. Because we did not derive daily averages from the IMU, we did not exclude data from days with low wear time. To calculate stride-by-stride walking speed, we first calculated the position trajectory of the prosthesis-mounted IMU using a strapdown inertial navigation algorithm [110]. Briefly, the algorithm integrated the acceleration signal twice to calculate a position trajectory and applied zero velocity updates at every foot-flat to reduce drift error [122]. Strides were segmented with heel strikes, detected using the acceleration signal (vertical peak acceleration > 6 G and 500 ms between peaks) and velocity estimates (5 ms-window mean vertical velocity $<$ 0). We then used this data to calculate walking speed according to methods described in Kim et al. [85].

For the PEQ and SF-36, we averaged scores for questions within each domain or sub-scale, omitting any blank entries. Values were only included where participants answered more than 50% of the questions in that domain [91].

5.2.4 Statistical Analysis

To mitigate the effects of varying amounts of accelerometer and IMU data collected by each participant, we calculated the bootstrapped mean for each outcome measure taken during everyday activity (step counts, walking speed). For example, from a data set with size n, we sampled n elements with replacement, took the mean of the resampled set, and repeated this process 1000 times. The mean of all 1000 resampled means is the bootstrapped mean [123], which was used for analysis. Self-selected walking speed in the lab was the average of 10 trials. We tested for differences in COT, daily step count, daily step count away from home, walking speed (in-lab and in daily life), PEQ (by sub-scale), and SF-36 (by sub-scale and physical and mental components) between the two prostheses (unpowered, powered) using a series of paired t-tests. We assessed whether prosthetic preference was significantly different from 50 (no preference) using a one sample t-test. Significance was set to $p < 0.05$ for all comparisons. Given the small sample size, we calculated the effect sizes for all pairwise comparisons using Hedge's g:

$$g = \frac{M_{Powered} - M_{Unpowered}}{SD_{pooled}} \times \frac{N-3}{N-2.25} \times \sqrt{\frac{N-2}{N}}$$

$$SD_{pooled} = \sqrt{\frac{(SD^2_{Powered}(n_{Powered}-1)) + (SD^2_{Unpowered}(n_{Unpowered}-1))}{n_{Powered} + n_{Unpowered} - 2}}$$

where M_x is the mean of group x, SD_{pooled} is the pooled standard deviation, N is the sample size, SD_x is the standard deviation within group x, and n_x is the sample size of group x [36]. Effect sizes are interpreted as being small for $0.2 \leq g \leq 0.5$, medium for $0.5 \leq g \leq 0.8$, and large for $g \geq 0.8$ [23]. We also explored the relationships between COT, activity during daily life, prosthetic preference, and patient perception using Pearson correlations. We noted comparisons with medium effect sizes ($|g| \geq 0.5$) in the results section.

5.3 Results

5.3.1 Participant Details

A total of 31 patients were contacted about the study (Figure 5.1). Eight declined to participate citing the time commitment or their lack of interest in new prostheses, while three others did not respond. Another eight were deemed ineligible. The remaining 12 individuals were randomly allocated to a prosthetic testing order (Table 5.1). S09 dropped out before completing the study due to an unrelated medical condition. S10 was assigned to the powered prosthesis first, acclimated to the device and was provided activity monitors. During this time, he developed a wound on his residual limb and subsequently dropped out of the study. Ten males (52.6 ± 11.3 years old) completed the study. Nine were classified as K3 and one was classified as K4 on the Medicare K-level.

5.3.2 Metabolic Cost

There were no differences between the fixed treadmill speed (1.20 ± 0.07 m/s) and self-selected walking speeds with the unpowered (1.16 ± 0.16 m/s; $p = 0.435$) or powered prostheses (1.21 ± 0.12 m/s; $p = 0.794$). S03 was not able to achieve steady-state energetic expenditure on a treadmill. For the remaining participants, there was no group difference in metabolic cost of transport (COT) between prostheses ($n = 9$; $p = 0.585$, $g = -0.150$), but there was variability across participants. While six participants had lower COT with the powered prosthesis, only two participants had reductions greater than the between-day minimal detectable change of 0.051 J/Nm [30].

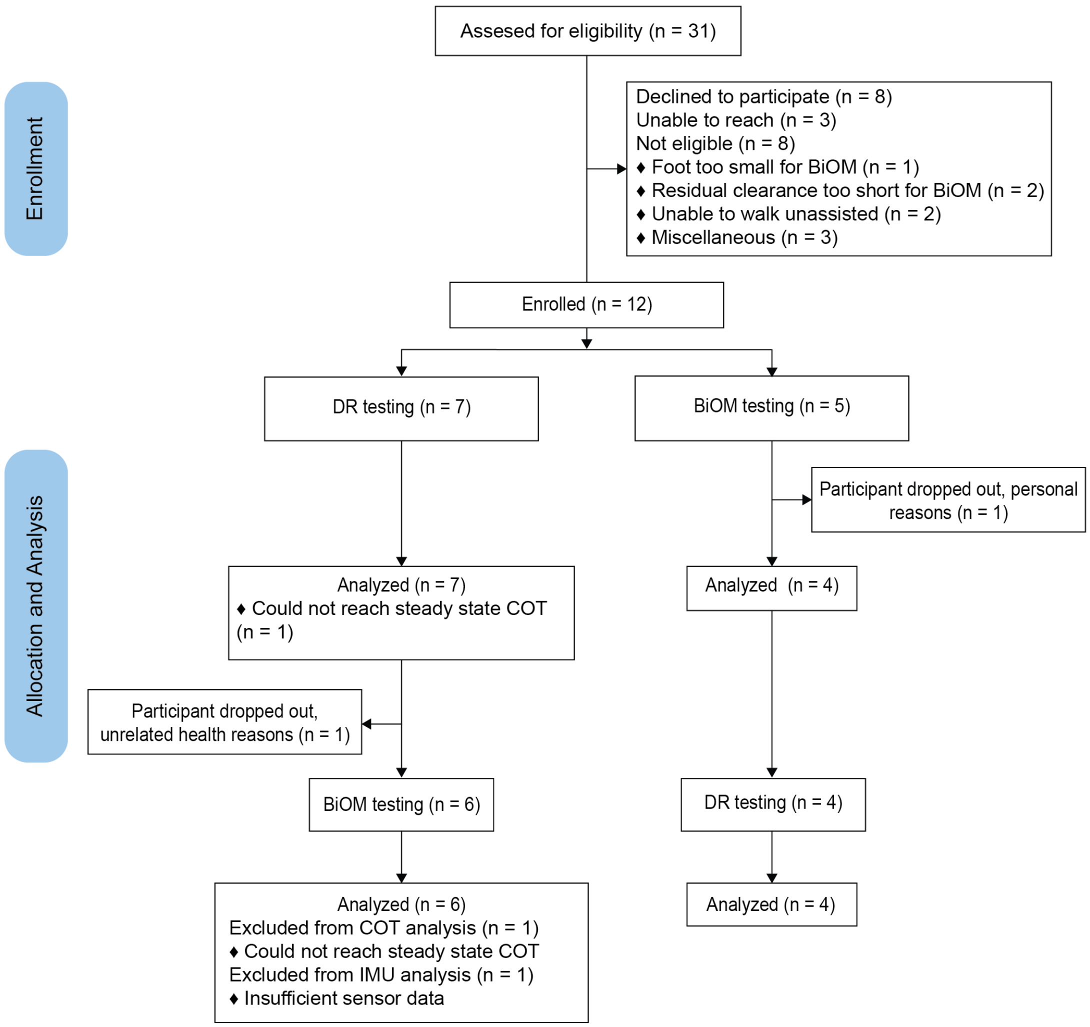

Figure 5.1: Consort flow diagram for recruitment, enrollment, and analysis

Table 5.1: Participant demographics

ID	Age (years)	Sex	Mass (kg)	Height (m)	Cause of amputation	Non-Powered Prosthetic Foot	K-Level	Time Since Amputation	Completed Full Study?
S01	57	M	98.4	1.85	Vascular	DR[1]	K3	3 years	Y
S02	62	M	118.8	1.82	Trauma	DR	K3	3 years	Y
S03	53	M	128.0	1.78	Vascular	DR	K3	8 years	Y
S04	65	M	84.1	1.82	Vascular	DR	K3	3 years	Y
S05	40	M	123.4	1.78	Trauma	DR	K3	12 years	Y
S06	30	M	90.8	1.80	Trauma	Hydraulic	K3	1.2 years	Y
S07	65	M	89.1	1.64	Trauma	Hydraulic	K3	9 years	Y
S08	55	M	108.0	1.83	Trauma	DR	K3	1.2 years	Y
S09	27	M	73.0	1.89	Trauma	DR	K4	5 years	N
S10	-	M	71.7	1.72	Trauma	DR	-	-	N
S11	54	M	83.0	1.77	Trauma	DR	K4	19 years	Y
S12	45	M	98.4	1.85	Trauma	DR	K3	5.5 years	Y

[1]DR is a dynamic response foot

Table 5.2: Step count and walking speed in-lab and in daily life (mean ± SD)

	Unpowered	Powered	p-value	Hedge's *g*
Daily step count	4770 ± 2150	4760 ± 2150	0.995	-0.001
Daily step count away from home	2030 ± 1440	1640 ± 1100	0.452	-0.248
Walking speed, in-lab (m/s)	1.15 ± 0.16	1.18 ± 0.16	0.145	0.310
Walking speed (m/s)	0.76 ± 0.09	0.71 ± 0.13	0.147	-0.574

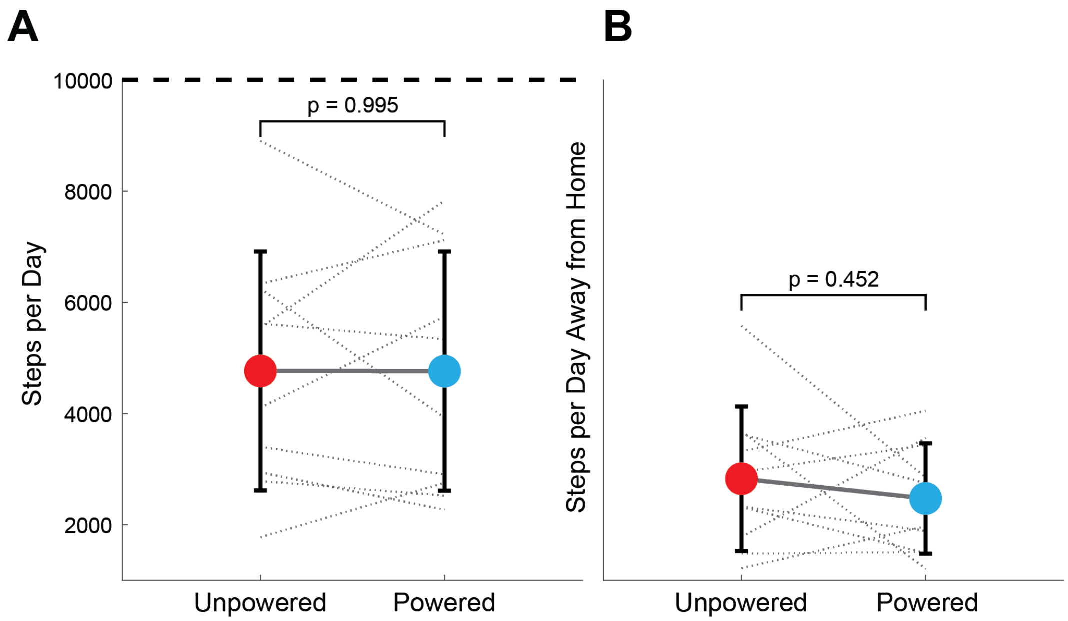

Figure 5.2: Overall step count and step count away from home
A. Daily step count using the unpowered (red) and powered (blue) prostheses. Dashed horizontal line represents the recommended 10,000 steps per day. B. Daily step count away from home using the unpowered (red) and powered (blue) prostheses. Gray x's and lines represent individual participant trends.

5.3.3 Activity Data

There were no differences in the bootstrapped daily step count (p = 0.995, g = -0.001; Figure 5.2A) or daily step count away from home (p = 0.452, g = -0.248; Figure 5.2B) between prostheses (Table 5.2). While step counts varied across participants, none achieved the recommended 10,000 steps per day [150].

There was no difference between prostheses in self-selected walking speeds in the lab (p = 0.145, g = 0.310; Figure 5.3A). Though S05 and S06 completed the study, due to a sensor malfunction, the activity monitor did not record sufficient IMU data with the powered prosthesis. These participants were therefore excluded from all daily-life walking speed comparisons. There was no difference between prostheses in walking speeds during daily life (n = 8; p = 0.226, g = -0.158; Figure 5.3B).

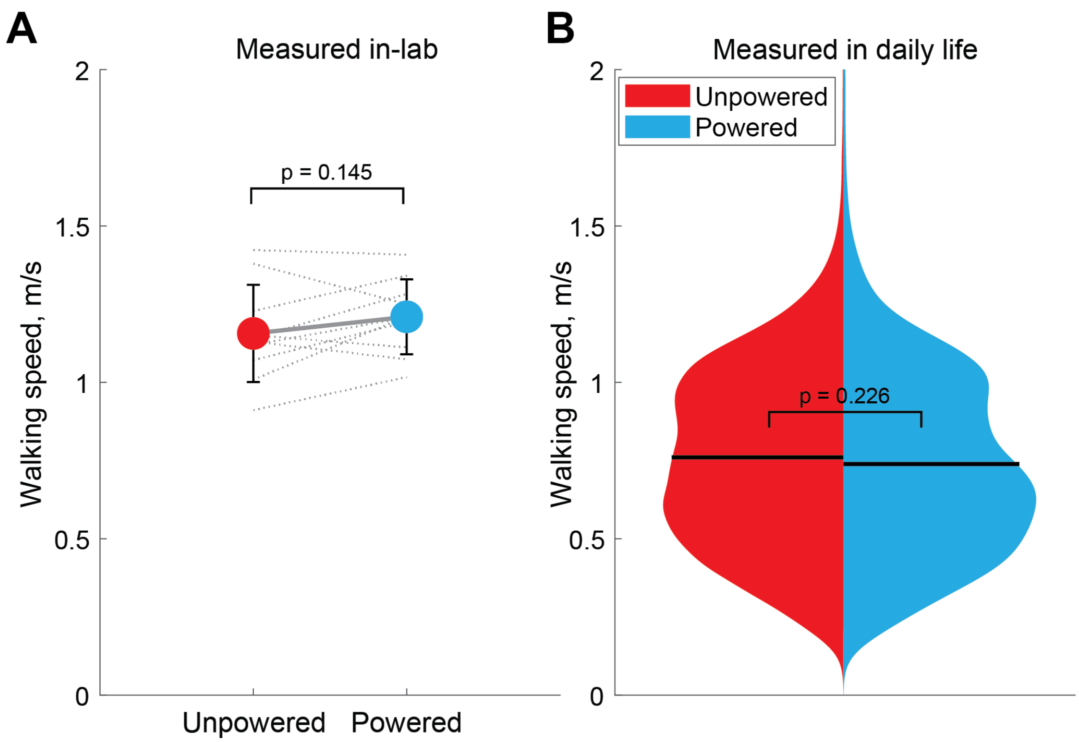

Figure 5.3: Walking speed in-lab and in daily life
A. Self-selected walking speeds measured in the lab for participants using the unpowered (red) and powered (blue) prostheses. Gray x's and lines represent individual participant trends. B. Split violin plot of the probability density functions of walking speed distributions of walking strides taken in daily life. To visualize, raw distributions were smoothed using the *ksdensity* kernel smoothing function in MATLAB. Shared regions are averaged distributions and solid horizontal lines are the group means.

5.3.4 Questionnaires

In the Prosthetic Evaluation Questionnaire (PEQ), participants reported significantly less social burden with the powered prosthesis, compared to that of the unpowered prosthesis ($p = 0.043$, $g = 0.268$; Figure 5.4). There were also non-significant, medium- and large-sized effects in the mobility and frustration sub-scales where participants reported better mobility ($p = 0.058$, $g = 0.682$) and less frustration ($p = 0.052$, $g = 0.506$) with the powered prosthesis. For the Short Form (SF)-36 questionnaire, there were no differences in the physical ($p = 0.480$, $g = -0.143$) or mental component scores ($p = 0.370$, $g = 0.141$), or any of the individual sub-scales ($p \geq 0.080$, $|g| \leq 0.408$). While participants generally preferred the powered prosthesis (prosthetic preference score = 64.1 ± 33.8; $g = 0.598$), this was not significantly different from no preference($p = 0.132$).

5.3.5 User Feedback

The open-ended user feedback was mixed across participants. One participant reported that they *liked* that the BiOM "almost felt like a real ankle" while another participant similarly commented that walking with the BiOM "felt more natural." Six participants *disliked* that the BiOM batteries die too soon, two said it was too bulky, one said it was too noisy, one said it was too heavy, and one described the BiOM as being too controlling and causing more phantom pain. Six participants felt that they could walk *faster* with the BiOM, while four did not. Five participants felt they could walk for *longer* when wearing the BiOM. Five participants found walking to be *easier*: five found it easier to walk on slopes, six found it easier to walk upstairs, and three found it easier to walk downstairs. In contrast, four found level-ground walking *harder*: five found walking down stairs to be more difficult, four found uneven terrain (specifically grass and snow) to be more difficult, two found driving more difficult and one found it more difficult to stand from a chair. The remaining respondents did not

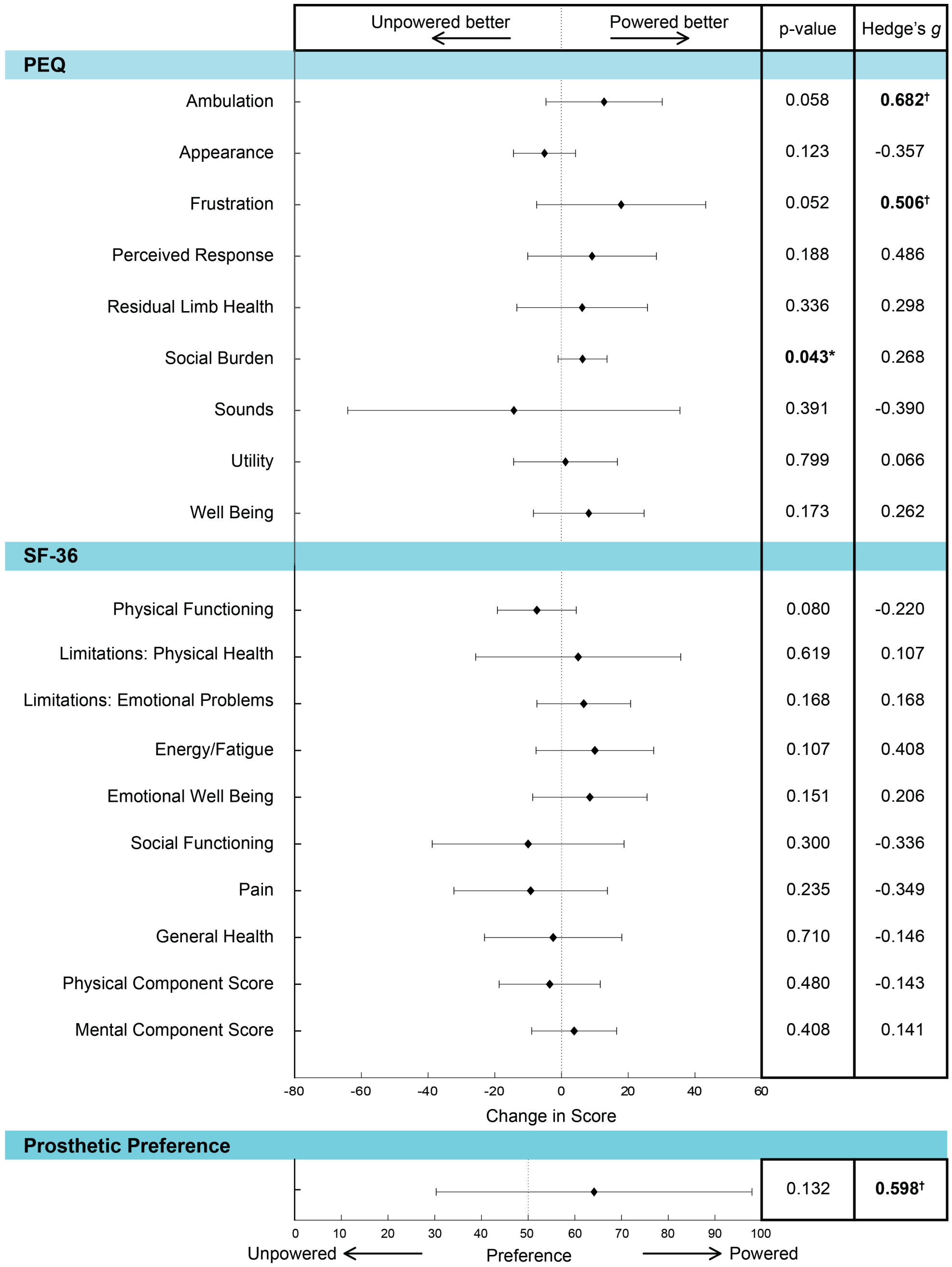

Figure 5.4: Prosthetic comparisons in questionnaires and surveys
Changes in participant responses for the Prosthesis Evaluation Questionnaire, Short Form-36 and Prosthetic Preference, by sub-scale. Significant differences ($p < 0.05$) between prosthesis are indicated and bolded (*). Changes with a medium or large effect size ($g \geq 0.5$) are also indicated and bolded (†).

notice a difference or did not perform that activity.

5.3.6 Correlations

Prosthetic preference was not correlated with changes in COT (r = -0.181, p = 0.667; Figure 5.5A), with changes in walking speed measured in-lab (r = -0.086, p = 0.814; Figure 5.5B), or with changes in walking speed in daily life (r = 0.070, p = 0.869; Figure 5.5C).

Changes in daily step count were not correlated with changes in COT (r = -0.074, p = 0.849; Figure 5.6A), or perception of mobility when assessed with the PEQ ambulation sub-scale (r = 0.324, p = 0.395; Figure 5.6B). There was a moderate correlation between changes in step counts and the SF-36 physical functioning sub-scale (r = 0.505, p = 0.137; Figure 5.6B). There were no relationships between changes in step count away from home and the PEQ social burden sub-scale (r = 0.204, p = 0.628) or the SF-36 social functioning sub-scale (r = 0.120, p = 0.740; Figure 5.6C).

5.4 Discussion

Contrary to our hypothesis, we did not find differences between prostheses in metabolic costs. Differences in metabolic cost between prostheses varied across participants, however. Two participants reduced their metabolic effort by more than the minimum detectable change (MDC) of 0.051 J/Nm, while two others increased their metabolic cost more than this amount [19]. In our study, we measured metabolic costs as participants walked at a fixed, leg length-based, speed. While metabolic results may have been different if participants walked at their self-selected speed, potential differences in our study were likely marginal. There were no differences between fixed (1.20 ± 0.07 m/s) and self-selected walking speeds with the unpowered (1.16 ± 0.16 m/s; p = 0.435) or powered prostheses (1.21 ± 0.12 m/s; p = 0.794). Additionally, in a previous study with a similar participant cohort, there were no metabolic dif-

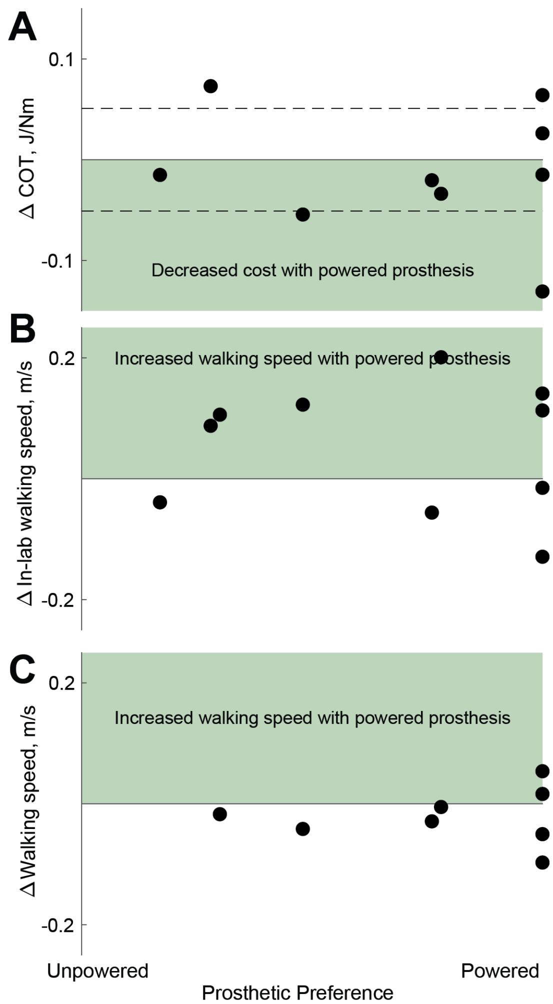

Figure 5.5: Relationships between prosthetic preference and other outcomes
A. Changes in prosthetic preference vs. changes in metabolic cost (ΔCOT). Dashed lines indicate the minimal detectable change in COT. B. Changes in prosthetic preference vs. changes in daily step count. C. Changes in prosthetic preference vs. changes in walking speed in daily life.

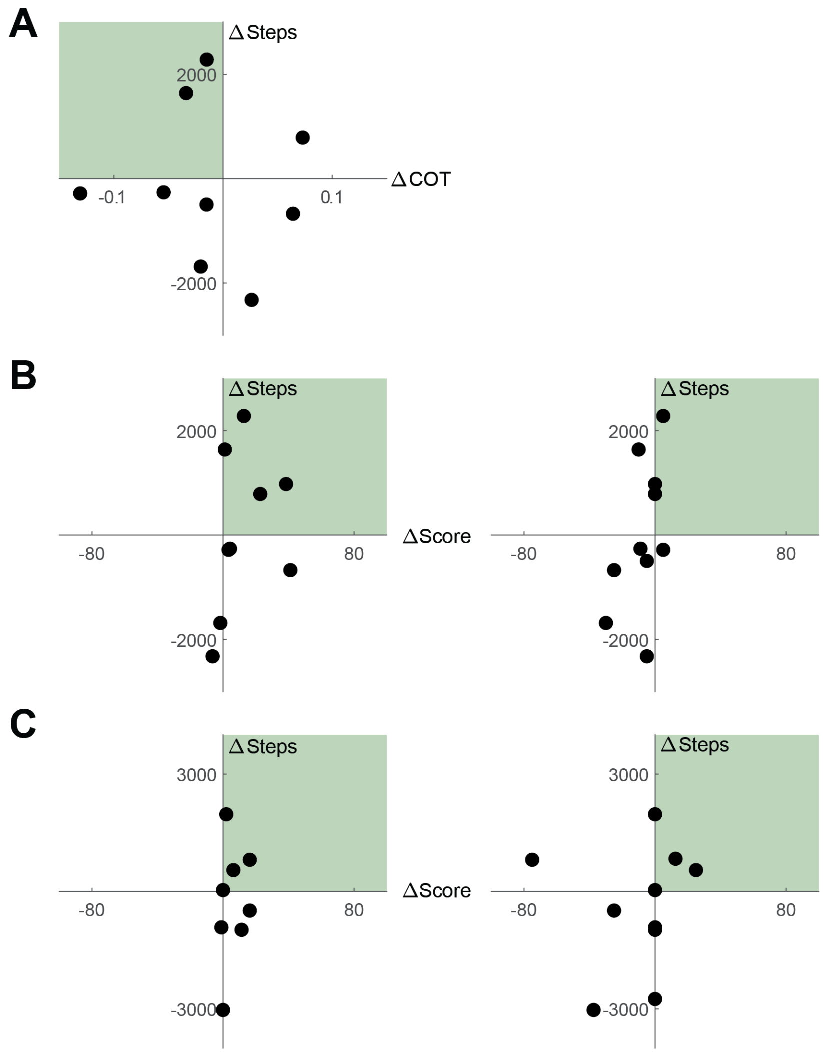

Figure 5.6: Relationships between step counts and other outcomes
A. Changes in metabolic cost (ΔCOT) vs. changes in daily step count. Data in the second quadrant (highlighted in green) indicate lower metabolic cost and greater step count with the powered prosthesis. B. Changes in the PEQ ambulation sub-scale vs. changes in SF-36 physical functioning sub-scale scores (left) and changes in daily step count (right). C. Changes in the PEQ social burden sub-scale vs. changes in SF-36 social functioning sub-scale scores (left) and changes in daily step count away from home (right). Data in the first quadrant (highlighted in green) indicate greater scores and greater step count with the powered prosthesis.

ferences between unpowered and powered prostheses in both fixed and self-selected walking speeds [49]. Overall, these findings agree with one previous study [49], but disagree with two others [63, 130]. There are two notable differences in these prior works. In those studies that found a metabolic benefit, participants were young or physically active and had time to adjust to the powered prosthesis (≥ 2 hours). The study that did not find a benefit tested an older, less active cohort and only provided a short time (~ 15 min) for device accommodation. Here, we also tested a population that was generally less active, but participants had a minimum of three weeks of device use prior to metabolic testing. Further, two participants already owned the BiOM and had been regularly using the device for at least 6 months. The two BiOM owners had contrasting responses to the powered prosthesis in metabolic cost, step count, and walking speed. While this may suggest that the lack of metabolic benefit is more related to patient characteristics than accommodation time, it is also possible that less active individuals require even more accommodation or more focused rehabilitation. Although there is no consensus on the time required to acclimate to a prosthetic intervention [154], the accommodation provided here falls in line with previous studies that found significant metabolic reductions after 1.5 weeks [159] and 21 days [57] of a prosthetic intervention. There is also no set training for adjusting to a new prosthesis. This likely contributes to the variability in participant responses. Our user feedback on learning to use the powered prosthesis also supports this idea as some felt they learned “right away” while others said they “still haven’t figured it out yet” (Appendix B.3). Additionally, while we ensured a minimum time period for acclimation, we could not control for the actual amount of acclimation, as this may depend on how much each participant used the prosthesis in daily life. As seen in daily step counts, this varied widely among participants (Figure 5.2). Thus, we should potentially view accommodation as a function of steps taken, rather than in days of use.

Table 5.3: User feedback and changes in capacity and performance

ID	User feedback regarding the powered prosthesis			Changes in outcome measures (+: increase from unpowered to powered)			
	Is walking easier/harder? (including uneven terrains)	Can walk faster?	Can walk for longer?	Metabolic cost	Daily step count	Walking speed, in-lab	Walking speed, daily life
S01	Easier	Y	Y	**-0.131**[a]	-280	**0.14**[b]	-0.05
S02	Easier	Y	Y	-0.015	2280	-0.02	-0.10
S03	Harder	N/A	N	N/A	980	0.11	-0.02
S04	Easier	N/A	Y	0.026	-2320	**-0.13**[b]	0.05
S05	Harder	N/A	N	**0.073**[a]	790	0.09	-0.25
S06	Harder	Y	N/A	-0.015	-500	-0.04	N/A
S07	Harder	Y	N/A	**-0.054**[a]	-260	**0.12**[b]	-0.04
S08	N/A	N/A	Y	-0.034	1640	**0.20**[b]	-0.01
S11	Easier	Y	Y	**0.064**[a]	-670	**0.11**[b]	0.02
S12	Easier	Y	N	-0.020	-1680	-0.06	-0.03

[a]Changes in metabolic cost greater than between-day minimal detectable change of 0.051 J/Nm

[b]Changes in walking speed greater than minimal detectable change of 0.108 m/s

Given the varied metabolic responses to the powered prosthesis, we also explored if users perceived walking to be easier with the powered prosthesis. Five participants felt that walking with the powered prosthesis was easier while four participants responded that walking with the powered prosthesis was harder. Of the five participants that felt walking with the powered prosthesis was easier, only one had reduced metabolic cost with the powered prosthesis, while another had greater metabolic cost (Table 5.3). Similarly, of the four participants that felt walking with the powered prosthesis was harder, one had increased metabolic cost, while another had decreased metabolic cost with the powered prosthesis. This agrees with prior work that found that the perception of exertion contrasts to the physiological measure of metabolic cost [139].

Further, we explored how everyday physical activity levels might reflect changes in metabolic costs or perceived ease of walking. Among the five participants that felt walking with the powered prosthesis was easier, only one increased their daily step count (Table 5.3). Physical activity in daily life may be more dependent on factors other than the prosthesis, such as the surrounding environment, weather, lifestyle, personality, and occupation. In particular, walking with the powered prosthesis is more destabilizing when walking on icy or otherwise slippery surfaces, which may have influenced participants' walking patterns and confounded our results. Though we could not control the weather conditions, we did collect each participants' activity with both prostheses in a single season, when possible (Appendix B.1). Similar to our findings, a previous study evaluating the effects of a microprocessor knee found no differences in everyday activity [88].

Participants also had varied feelings about the powered prosthesis and how it improved or did not improve their function. Four preferred their prescribed, unpowered prosthesis while six preferred the powered prosthesis. Prosthetic preference was not related to changes in metabolic cost or walking speed. While there was no relationship between prosthetic preference and measures of functional capacity or performance, participants who preferred the powered prosthesis tended to feel that the powered device helped them walk for longer without rest, faster (Appendix B.3), and with more ease (Table 5.3). This user feedback may provide information regarding the factors that determine prosthetic preference and/or acceptance.

There were differences between participants' perception of their function and their performance in daily life. While six participants responded that they felt they could walk faster with the powered prosthesis, only three walked faster in-lab by more than 0.108 m/s (MDC for older adults in 4-meter walk tests) [55], and only one walked faster in daily life, by an amount far less than the in-lab MDC of walking speed (Table 5.3). Furthermore, while five participants responded that they felt they could walk for longer with the powered prosthesis, only two participants increased their daily step count. Comparing qualitative user feedback and measures of step count and walking speed in daily life, there seemed to be a disconnect between what people perceived they were capable of doing and what they did in daily life. This dissonance is supported by the weak correlations between changes in step count and changes in the PEQ ambulation sub-scale and changes in the SF-36 physical functioning sub-scale. This suggests that future research and clinical approaches to prescription should consider both perception and objective measures. This is important as daily prosthetic use is largely dependent on an individual's feelings about their function, while device prescription is predominantly supported by more objective measurable outcomes.

Psycho-social responses to the powered prosthesis may affect physical activity, especially in community settings. Participants perceiving less social burden with the powered prosthesis contrasted with previous findings with a younger cohort [38], which suggests that psycho-social responses may be age-dependent. This may be attributed to the higher likelihood for older individuals to be in co-dependent domestic relationships, as the social burden sub-scale describes one's perception of how the prosthesis affects the relationships with their partner or family members [91]. However, the weak correlations between changes in community engagement and changes in psycho-social sub-scales of the PEQ and SF-36 suggest that other factors may influence community engagement more strongly. A more practical limiting factor for community engagement may be the short battery life, as expressed in user feedback by six participants. Because the heavy weight of the powered prosthesis is more noticeable when the battery dies and makes walking harder, users may choose to engage in the community only when they are equipped with several fully charged batteries. The Ottobock Empower (current version of the BiOM) has a battery life of 8 hours, which may alleviate these issues. However, battery life is dependent on intensity of use and may still be a concern for very active individuals who would require a battery change for all-day use.

This study had several limitations. Walking speed in daily life was calculated from all straight-line over-ground walking strides, which had variable sample sizes as participants did not all log the same number of strides in daily life. We addressed this issue by calculating the bootstrapped mean of walking speeds, thereby minimizing bias caused by varied sample sizes. Further, consistent with previous studies done in the lab [63, 130, 49], we focused only on straight-line strides and thus did not include turning strides or stair-walking. While more work can be done toward specifically identifying and examining non-straight-line walking, this may require additional sensors on the hip or intact foot. We chose to only attach the sensors directly on the prosthetic foot to minimize the day-to-day variability in sensor placement and maximize sensor wear time. Further, data for the powered prosthesis may include steps for which the person did not receive power, either because the battery died or because the participant turned it off (e.g., to traverse uneven terrain). We cannot identify these steps based on the data from our sensors. Based on participant feedback, however, we expect that theses instances represent a very small portion of measured steps. As mentioned above, weather conditions may have also affected everyday performance. While collections for different prostheses were done mostly in the same season, one participant's everyday activity was collected in different seasons due to scheduling conflicts (Appendix B.1). Additionally, some variability in performance may be due to lifestyle or life events (e.g., vacation, hospitalization), rather than the prosthesis. No participants reported such events in their activity logs, though several participants were retired and did not have a regular day-to-day schedule. Lastly, this study was limited by a small sample size due to difficulties in recruitment. To mitigate these difficulties, we amended the study to additionally recruit K4 participants, which further diversified the already heterogeneous cohort of K3 participants. The low sample size increases the likelihood of type II errors. To address this issue, we have provided effect sizes for all comparisons. Future studies should confirm these findings in larger cohorts.

5.5 Conclusion

This study compared participants' metabolic costs, walking speeds in-lab and in daily life, step count, step count away from home, perceived mobility, and preference between powered and unpowered prostheses. There was no statistically significant preference for either prosthesis. Additionally, wearing the powered prosthesis did not significantly decrease metabolic costs, increase physical activity or walking speed, or increase perceived mobility. Though the powered prosthesis was not universally beneficial to the participant cohort, the large variability in responses across participants suggests that different people may benefit in different ways and to varying degrees. Regarding the powered prosthesis, participants reported feeling they could walk faster and with more ease, while battery life and weight were prevalent complaints. There was disparity between participants' perceptions of their mobility and what they perform during daily life when using the powered prosthesis. This suggests that future research should continue to examine both perception and objective measures of mobility to better evaluate prostheses and inform prescriptions of advanced prosthetic components.

CHAPTER 6

Quantifying the Effect of Powered Prostheses on Toe Clearance Using Inertial Measurements

6.1 Introduction

After a transtibial amputation (TTA), people are more prone to trips and falls [90, 98]. This may be due to the inability of the prosthetic foot to actively dorsiflex during swing, which contributes to a low minimum toe clearance (MTC) [31, 52]. MTC is defined as the vertical distance between the lowest point of the foot and the ground at the minimum point of swing. The failure to achieve an adequate MTC during swing leads to stumbles or trips, that may result in falls. To compensate, individuals with TTA may increase their residual limb hip and knee flexion for the foot to clear the ground [103, 52]. Due in part to these compensations, individuals with TTA have greater MTC variability [78], which may contribute to increased risk of falls [10].

Most commercially available prosthetic feet are passive and unpowered, classified as solid ankle cushion heel (SACH) feet that provide stability to the user, or as energy storage and return (ESAR) feet that store energy during loading response and return energy during push-off. Commercially available powered prostheses have been developed to better replicate the active function of the biological ankle. One such device is the Proprio Foot (Ossur, Reykjavik, Iceland), which provides active dorsiflexion during swing and has been shown to increase MTC in individuals with TTA [129]. However, the Proprio Foot does not replicate the active plantarflexion function of the biological ankle. The BiOM T2 (now Ottobock Empower, Duderstadt, Germany) is the only commercially available prosthesis that provides active push-off torque at the prosthetic ankle. The BiOM powered prosthesis has been shown to produce comparable step-to-step transition work at the trailing prosthetic limb to that of the intact limb [130] and may help initiate swing by replicating the push-off function of the biological plantarflexors [108]. However, qualitative user feedback has shown a potential for the heavier BiOM prosthesis to affect stability and fall risk [Chapter 5].

MTC has been primarily measured using motion capture systems. As such, the effects of powered prostheses on MTC have been quantified in well-constrained laboratory environments. The Proprio Foot active dorsiflexor prosthesis has been shown to increase MTC in treadmill walks, though MTC variability was not affected [129]. In the same study, the authors introduced the "likelihood of tripping curve" that represents the likelihood of contacting a hypothetical, unseen obstacle of a specific height at the point of MTC by calculating the cumulative probability distribution from all MTC values measured during the treadmill walk. The active dorsiflexor foot was shown to decrease the likelihood of contacting a hypothetical obstacle with a 5mm height. On a loose rock surface, the BiOM powered prosthesis has also been shown to increase MTC relative to that of unpowered prostheses but not to the level of the intact limb [50]. While participants increased their MTC with the powered prosthesis, mean differences were small, the powered prosthesis was in a more plantarflexed position, and there were no kinematic differences at the hip or knee joints between prostheses. Thus, authors attributed the increase in MTC to the small changes in intact limb knee flexion during stance.

To date, the effects of a powered prosthesis on MTC in daily life have not been quantified. While motion capture systems are capable of measuring MTC and joint kinematics concurrently, findings may be limited by the size of the motion capture area and the number of walking surfaces that can be simulated in the laboratory. MTC has been found to be sensitive to the walking surface in individuals with [52] and without TTA [135]. Thus, it is important to examine the effects of prosthetic interventions on a variety of real-world environments. Further, measuring MTC variability in walks over straight, level-ground walkways or treadmills may provide useful information on internal sources of movement variability, but limited information on external sources for variability. In contrast individuals experience many external sources for MTC variability in daily life (e.g., turning, changing speed, obstacle navigation, traversing slopes). Measuring MTC variability from a distribution of MTC values derived from everyday walking may provide additional information on the real-world effects of the powered prosthesis on fall risk.

The use of foot mounted inertial measurement units (IMU) and inertial navigation algorithms have enabled researchers to estimate the position trajectory of the IMU and calculate stride-by-stride spatiotemporal parameters in a variety of unconstrained environments [110, 122, 85]. Various works have demonstrated the ability to use the position estimates of the IMU to calculate MTC in a research setting [95, 28, 82, 87, 12]. Only one of these works have measured MTC with a clinical purpose, though gait analysis was done along an indoor 20 m walkway [28].

Previous approaches of estimating MTC have shown mean absolute error rates of 10 to 30% when compared to motion capture estimates [12, 87, 95, 82]. However, these approaches require prior knowledge of shoe size [95] or the assumption of a level-ground during foot-flat [95, 12, 87]. These assumptions may present difficulties in analyzing walking data from the free-living environment. Additionally, some studies calculated the vertical position displacement of the IMU between foot-flat and at the low-point of swing [12, 87], which measures the relative clearance of the foot. This approach assumes that the foot's orientation during its lowest point of swing is the same as its orientation at foot-flat and is not sensitive to variations of the foot's pitch angle during swing. Because most prosthetic feet cannot dorsiflex and remain at their neutral angle during swing, users compensate with increased hip and knee flexion, the foot's sagittal angle may vary during swing, suggesting an increased likelihood for error in estimating MTC in individuals with TTA. One previous study presented a method of estimating the location of the IMU relative to the toe and heel points without prior knowledge of shoe size [82]. However, this approach may be difficult to implement to everyday walking data, as it used inertial estimates of position at single time points of estimated toe-off and heel-strike and may be over-reliant on robust detection of these gait events and accurate position estimates.

The purpose of this study was to quantify the effects of the BiOM powered prosthesis on MTC and MTC variability in daily life. We first compared the relative feasibility of a novel method for calculating MTC using inertial signals and a published method for MTC calculation in the lab, tested against motion capture-based estimates (Feasibility study). We then conducted a randomized clinical trial of a powered prosthesis in ten individuals with TTA (Prosthetic comparison study). Our central hypothesis was that MTC would not be lower and MTC variability would not be higher with the powered prosthesis compared to the unpowered prosthesis.

6.2 Methods

6.2.1 Participants

We recruited individuals with transtibial amputation (TTA) through clinical referral from the University of Michigan Orthotics and Prosthetics Center and through postings on https://umhealthresearch.org and https://clinicaltrials.gov. We included participants with unilateral TTA, aged 21 years or older, and having used a prosthesis for at least six months. We excluded potential participants if they had a history of cardiovascular disease, orthopedic or neurological disorders to their intact limb, or were unable to walk independently for 10 minutes at a time. One male with TTA (age: 39 years, height: 1.76 m, weight: 79 kg) participated in the feasibility study. Ten other males with TTA (age: 46.5 $\pm$ 14.9 years, height: 1.79 $\pm$ 0.07 m, weight: 97 $\pm$ 20 kg) participated in the prosthetic comparison study. All participants provided their written informed consent prior to participating in these studies, which were approved by the University of Michigan Institutional Review Board (HUM00080734).

6.2.2 Experimental Protocol

In the feasibility study, the participant came to the laboratory for a single session of testing. The participant walked on a level-ground 7-meter walkway at self-selected preferred speed for 10 trials, after which the mean walking speed was determined. This process was repeated for self-selected slow and fast speeds. The participant then walked on the treadmill at the predetermined slow (0.70 m/s), preferred (1.23 m/s), and fast (1.88 m/s) speeds for at least 2 minutes each, coming to a full stop after each speed. We placed an IMU (Actigraph GT9X Link, Actigraph, Pensacola, FL, USA) on the shoe of the prosthetic limb (Figure 6.1). The IMU collected accelerometer and gyroscope data at 100 Hz. We recorded kinematic data of the treadmill walking protocol at 120 Hz, using a motion capture system (Motion Analysis, Rohnert Park, CA). Reflective markers were placed on the IMU, the medial and lateral malleoli, heel, lateral heel, and 5th and 2nd metatarsals. Reflective tape was placed on the anterior tip of the shoe (TOE; Figure 6.1). Reflective markers were also placed on the treadmill to locate the ground surface.

The prosthetic comparison study used a cross-over design where participants were tested with their prescribed, unpowered prosthesis and the BiOM T2 powered pros-

Figure 6.1: Placement of inertial measurement unit (IMU) and reflective markers.

thesis (BionX Medical Technologies Inc., Bedford, MA, USA) in random order. A certified prosthesis fit the participants with the powered and unpowered prostheses. After a change in prostheses, participants were given one week to acclimate to the device. If needed, participants returned to the clinic for adjustments or changes to alignment, after which they were given another week to acclimate. Participants were then given an IMU to wear on top of their prosthetic shoe for two weeks.

6.2.3 Data Processing and Analysis

We compared motion capture-based estimates of MTC and two methods of calculating MTC using IMU-derived position estimates. First, marker position data from motion capture were low pass filtered using a 4th order Butterworth filter with a 6 Hz cut-off frequency. MTC were calculated from motion capture data by subtracting the vertical position of the ground marker from that of the TOE marker during the TOE marker's local minimum position during swing (MTC_{Mocap}).

The position of the IMU was calculated using pedestrian dead reckoning algorithms described in [110, 122]. These algorithms rely on an assumption that the foot does not slip on the ground during foot-flat. First, during a period of low movement detected using the gyroscope signal, we oriented the IMU to the lab reference frame (Figure 6.2A). We then applied zero velocity updates (ZUPT) to the acceleration signal at every foot-flat, so that the velocity of the IMU (integrated from acceleration) during foot-flat was corrected to be zero, which simultaneously removed the acceleration signal due to gravity. We then integrated the resulting acceleration signal twice to calculate the position trajectory of the IMU. As done with previous studies to estimate MTC, we used the position trajectory of the IMU to calculate relative foot clearance (RFC) as the relative vertical displacement of the IMU between its position during foot-flat and its position during the lowest point of swing [12, 87]. This method of estimating MTC by way of a proxy measure of foot clearance assumes the orientation of the foot during the lowest point of swing is the same as its orientation at foot-flat. Therefore, this estimate would not be sensitive to changes in the foot's sagittal angle, which would in fact alter the actual MTC.

We attempted to address this shortcoming with a novel method that approximated the location of the toe during swing. In addition to the no-slip assumption, this approach relies on a further assumption that between foot-flat and toe-off, the foot rotates about a stationary center of rotation (CoR), which is approximately the toe point, at an equidistant moment arm (Figure 6.3). We detected toe-off as the local maximum of the sensor's pitch angle. The location of the CoR was calculated using the following equation describing the acceleration of a rotating body [96]

$$\overrightarrow{{}_s a_s} = \overrightarrow{{}_s a_c} + \frac{\overrightarrow{d_s \omega_s}}{dt} \times \overrightarrow{{}_s r_c} + \overrightarrow{{}_s \omega_s} \times (\overrightarrow{{}_s \omega_s} \times \overrightarrow{{}_s r_c})$$

where $\overrightarrow{{}_s a_s}$ is the acceleration of the IMU sensor in the sensor frame, $\overrightarrow{{}_s a_c}$ is the acceleration of the CoR in the sensor frame, $\overrightarrow{{}_s \omega_s}$ is the angular velocity of the sensor, and $\overrightarrow{{}_s r_c}$ is the moment arm that describes the location of the CoR in the sensor frame.

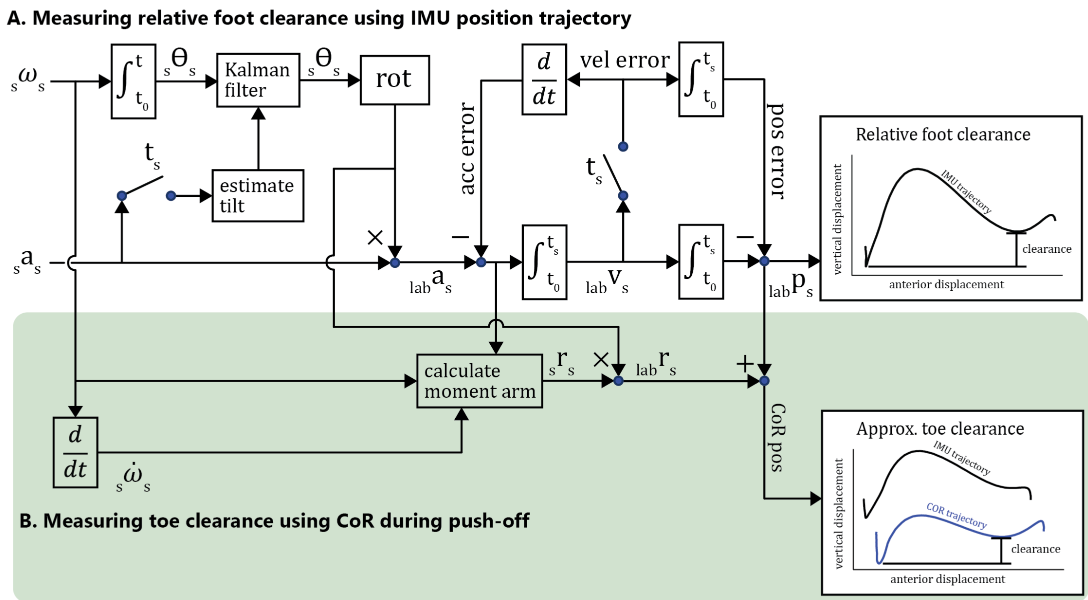

Figure 6.2: Flowchart: algorithm schematics
Algorithm schematics for the IMU-based measures of A. relative foot clearance (RFC) and B. minimum toe clearance using the center of rotation assumption (MTC_{CoR}).

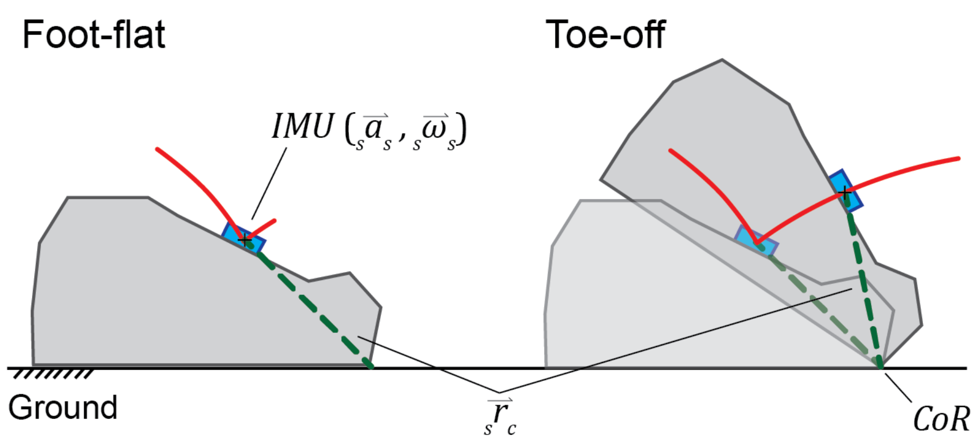

Figure 6.3: Sensor's rotation about the stationary center of rotation (CoR)
The constant moment arm vector ($\overrightarrow{_sr_c}$) between foot-flat and toe-off describes the displacement of the CoR point from the IMU in the IMU reference frame. The moment arm vector can be solved using acceleration ($\overrightarrow{_sa_s}$) and gyroscope ($\overrightarrow{_s\omega_s}$) signals from the IMU.

With the stationary CoR assumption, the equation was simplified as follows.

$$\overrightarrow{{}_s a_s} = 0 + \frac{\overrightarrow{d_s \omega_s}}{dt} \times \overrightarrow{{}_s r_c} + \overrightarrow{{}_s \omega_s} \times (\overrightarrow{{}_s \omega_s} \times \overrightarrow{{}_s r_c})$$

We further simplified the equation with the triple product formula.

$$\overrightarrow{{}_s a_s} = \frac{\overrightarrow{d_s \omega_s}}{dt} \times \overrightarrow{{}_s r_c} + (\overrightarrow{{}_s \omega_s} \cdot \overrightarrow{{}_s r_c})\overrightarrow{{}_s \omega_s} - ||\overrightarrow{{}_s \omega_s}||^2 \overrightarrow{{}_s r_c})$$

Because $\overrightarrow{{}_s \omega_s}$ and $\overrightarrow{{}_s r_c}$ are orthogonal, their dot product is zero.

$$\overrightarrow{{}_s a_s} = \frac{\overrightarrow{d_s \omega_s}}{dt} \times \overrightarrow{{}_s r_c} - ||\overrightarrow{{}_s \omega_s}||^2 \overrightarrow{{}_s r_c})$$

This leaves a linear system of equations

$$\begin{bmatrix} {}_s a_{s,x} \\ {}_s a_{s,y} \\ {}_s a_{s,z} \end{bmatrix} = \begin{bmatrix} 0 & -\dot{\omega}_{s,z} & \dot{\omega_{s,y}} \\ \dot{\omega_{s,z}} & 0 & -\dot{\omega}_{s,x} \\ -\dot{\omega}_{s,y} & \dot{\omega_{s,x}} & 0 \end{bmatrix} \cdot \begin{bmatrix} {}_s r_{c,x} \\ {}_s r_{c,y} \\ {}_s r_{c,z} \end{bmatrix} - ||\overrightarrow{{}_s \omega_s}||^2 \begin{bmatrix} {}_s r_{c,x} \\ {}_s r_{c,y} \\ {}_s r_{c,z} \end{bmatrix}$$

where $\overrightarrow{{}_s a_s}$ and $\overrightarrow{{}_s \omega_s}$ are extracted from the sensor signals. $\overrightarrow{{}_s r_c}$ was calculated at every time point in each stride between foot-flat and toe-off where the sensor's pitch angular velocity was greater than 50% of the local maximum. Signals with low angular velocity were excluded as they were likely to have a low signal to noise ratio. We then calculated a single moment arm estimate as the mean of all calculated moment arm values. The calculated mean moment arm was then rotated to the lab reference frame and subtracted from the IMU position trajectory (Figure 6.2B) to calculate the position trajectory of the approximated toe during swing. MTC was estimated as the vertical displacement of the approximated toe during the lowest point of swing (MTC_{CoR}). We excluded strides if foot-flat could not be detected within the stride.

In daily life, non-sedentary bouts of activity were detected using the IMU signal and ActiLife software (ActiGraph, Pensacola, FL, USA) as any period in which the acceleration vector magnitude exceeded 30 counts per minute and lasted at least 1 minute [143]. Within these bouts, we identified valid straight-line walking strides using a rule-based algorithm as described in [85]. We excluded strides taken on stairs by eliminating strides with a vertical displacement between consecutive foot-flats that exceeded the standard star height of 17.8 cm [53]. Using the above system of equations, we calculated moment arms at every valid stride and took the mean for every bout, as the placement of the IMU is not likely to change during a bout of walking but may change between periods of rest. MTC were calculated on these valid strides using the bout-wide mean moment arm calculations. Within-bout MTC variability was calculated as the standard deviation of MTC values within every bout of walking with 8 or more strides.

6.2.4 Statistical Analysis

In the feasibility study, we tested for fixed effects in the measurement method (MTC_{Mocap}, RFC, MTC_{CoR}) and speed (slow, preferred, fast) factors and an interaction effect (method $\times$ speed) using a linear mixed model. To examine the relative accuracy of MTC estimates, we also reported the mean absolute difference between IMU-based measures (RFC, MTC_{CoR}) and MTC_{Mocap}. In the prosthetic comparison study, participants had varying sample sizes for MTC (N = number of strides) and MTC variability (N = number of bouts) estimates over two weeks. To adjust for the different sample sizes between participants and prostheses, we bootstrapped each set of MTC before calculating the mean. For a set of n values, we sampled n elements with replacement then calculated the mean of the resampled set. This process was repeated 1000 times, and the bootstrapped mean was the mean of all 1000 resampled means [123]. We tested for differences in the bootstrapped means of MTC and MTC variability between prostheses in daily life using paired t-tests. Significance was set to $p < 0.05$ for all comparisons. To address the low number of participants, we also calculated the effect sizes for MTC and MTC variability using Hedge's g:

Table 6.1: Mean absolute differences between methods, mean ± sd in cm

	Between RFC and MTC$_{Mocap}$	**Between MTC$_{CoR}$ and MTC$_{Mocap}$**
Slow	0.59 ± 0.43	0.46 ± 0.31
Preferred	1.01 ± 0.79	0.79 ± 0.56
Fast	4.29 ± 3.79	3.61 ± 3.08

$$g = \frac{M_{Powered} - M_{Unpowered}}{SD_{pooled}} \times \frac{N-3}{N-2.25} \times \sqrt{\frac{N-2}{N}}$$

$$SD_{pooled} = \sqrt{\frac{(SD^2_{Powered}(n_{Powered}-1)) + (SD^2_{Unpowered}(n_{Unpowered}-1))}{n_{Powered}+n_{Unpowered}-2}}$$

where M_x is the mean of group x, SD_{pooled} is the pooled standard deviation, N is the sample size, SD_x is the standard deviation within group x, and n_x is the sample size of group x [36]. An effect size is small if $0.2 \leq g \leq 0.5$, medium if $0.5 \leq g \leq 0.8$, and large if $g \geq 0.8$ [23].

6.3 Results

6.3.1 Feasibility Study

There were significant method ($p < 0.001$), speed ($p < 0.001$), and method × speed ($p < 0.001$) interaction effects in MTC. Post-hoc pairwise comparisons revealed no differences between MTC$_{Mocap}$ and RFC ($p = 0.535$) or between MTC$_{Mocap}$ and MTC$_{CoR}$ ($p = 1.000$) at the slow walking speed (Figure 6.4). At the preferred walking speed, RFC was greater than MTC$_{Mocap}$ ($p < 0.001$) while MTC$_{CoR}$ was not different to MTC$_{Mocap}$ ($p = 1.000$). At the fast speed, both RFC ($p < 0.001$) and MTC$_{CoR}$ ($p < 0.001$) were different to MTC$_{Mocap}$. The mean absolute differences between MTC$_{Mocap}$ and RFC and MTC$_{CoR}$ are reported in Table 6.1.

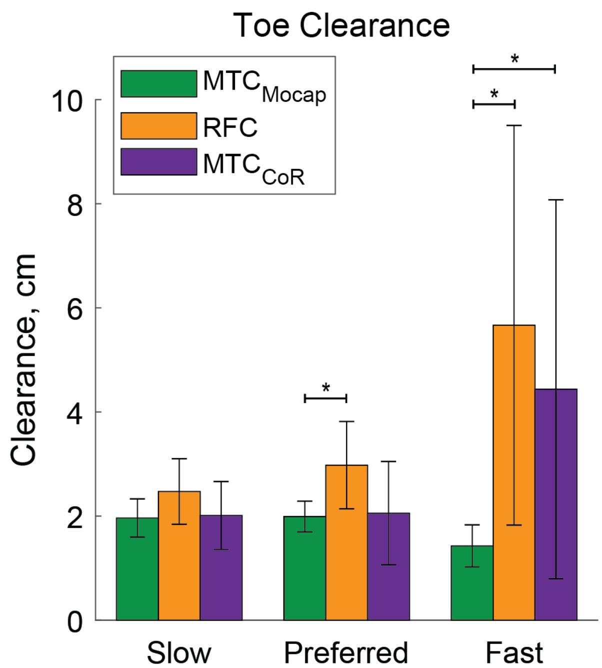

Figure 6.4: Toe clearance estimates from the feasibility study
Toe clearance results plotted for motion capture estimates (MTC_{Mocap}), IMU-based estimates of relative foot clearance (RFC), and IMU-based estimates of toe clearance using approximated location of toe (MTC_{CoR}). Significant pairwise differences between MTC_{Mocap} and RFC or MTC_{CoR} were denoted (*).

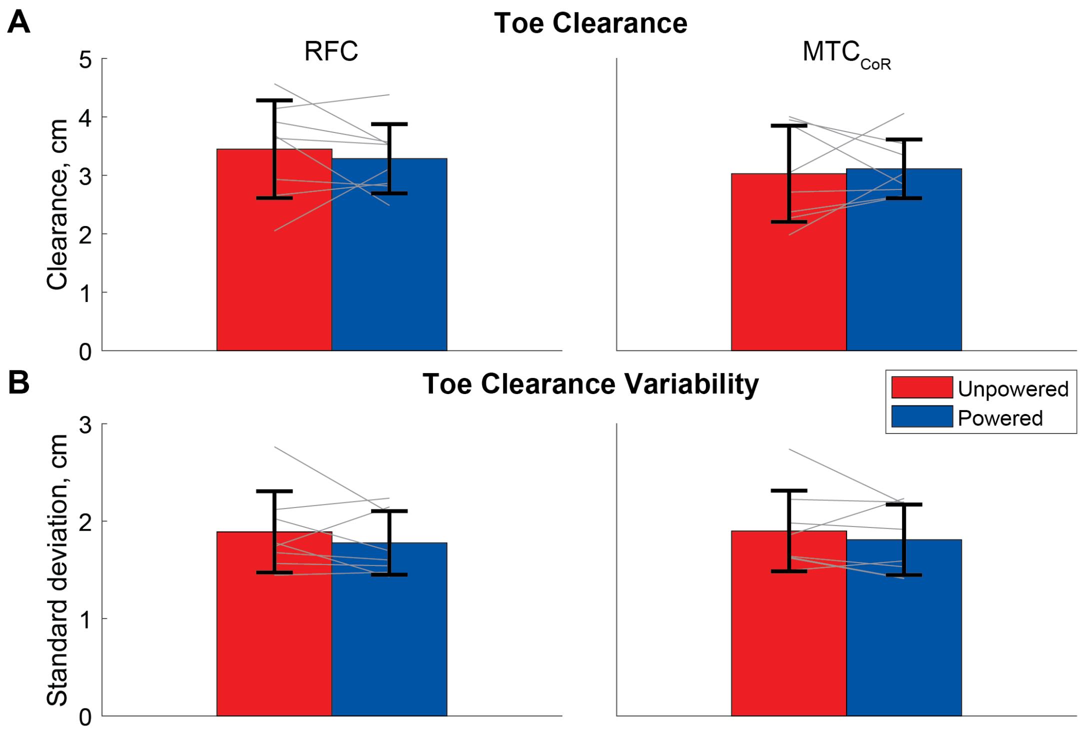

Figure 6.5: Toe clearance and its variability in daily life
Results from the prosthetic comparison study: A. toe clearance estimates and B. within-bout toe clearance variability. Individual trends were plotted as gray lines.

6.3.2 Prosthetic Comparison Study

Two participants' IMU data from daily life did not collect sufficient data due to potential battery malfunctions and were excluded from analysis. From the two-week collection, we estimated MTC values of 7600 $\pm$ 4950 strides from participants wearing the unpowered prosthesis and 9470 $\pm$ 8710 strides from participants wearing the powered prosthesis. We calculated within-bout MTC variability from 181 $\pm$ 135 bouts with the unpowered prosthesis and 214 $\pm$ 211 bouts with the powered prosthesis. There were no differences between prostheses in MTC$_{CoR}$ ($p = 0.792$) or MTC$_{CoR}$ variability ($p = 0.329$) in daily life. There were also no differences between prostheses in RFC ($p = 0.588$) or RFC variability ($p = 0.335$) in daily life (Figure 6.5). The effect sizes for these comparisons were small ($|g| \leq 0.228$; Table 6.2).

Table 6.2: Comparisons of toe clearance and its variability between prostheses

	Mean ± SD, cm		Statistical Results	
	Unpowered	**Powered**	**p**	**Hedge's *g***
MTC				
RFC	3.44 ± 0.85	3.29 ± 0.59	0.588	-0.169
MTC_{CoR}	3.03 ± 0.81	3.10 ± 0.51	0.792	0.0920
MTC variability				
RFC	1.89 ± 0.43	1.76 ± 0.32	0.335	-0.228
MTC_{CoR}	1.89 ± 0.41	1.80 ± 0.37	0.329	-0.174

6.4 Discussion

6.4.1 Evaluating Fall Risk in Daily Life

Our central hypotheses that the powered prosthesis would not decrease participants' minimum toe clearance (MTC) and increase MTC variability in daily life were supported. When estimated using the center of rotation (CoR) assumption (MTC_{CoR}), there were no differences between prostheses in MTC or MTC variability in daily life. This finding was consistent when evaluating relative foot clearance (RFC) and its variability. Therefore, we did not detect an increase in fall risk with the powered prosthesis in daily life.

6.4.2 Feasibility of the Center of Rotation Assumption

Using the motion capture-based estimate of MTC as reference, MTC using the CoR assumption had smaller mean absolute differences compared to that of RFC over the three tested walking speeds (Table 6.1). Assuming the MTC_{Mocap} measure is the most accurate estimate of MTC, MTC_{CoR} and RFC measures did not perform differently at slow and fast speeds. At the preferred speed, however, MTC_{Cor} was a more accurate estimate than RFC. The relative advantage of MTC_{CoR} over RFC can also be realized by examining the effects of speed on MTC. There were no differences between speeds in MTC_{Mocap}, which suggests that walking speed did not affect MTC for this participant. This finding agrees with a previous study in which individuals with TTA did not alter their prosthetic side MTC when walking at different speeds [31]. However, while MTC_{Mocap} and MTC_{CoR} were not different in the slow and preferred speeds, RFC was different to MTC_{Mocap} at the preferred speed but not at the slow speed. An increase in walking speed is associated with increased stride length [86] and thus a decrease in the vertical distance between the hip joint and ground. With the prosthetic ankle fixed at its neutral angle, increased hip and knee flexions may be required to ensure ground clearance [103, 135] and the prosthetic foot's toe may be closer to the ground during swing. This may explain the different trends in how RFC and MTC_{CoR} change between slow and preferred speeds and lend credence to the relative advantage of the MTC_{CoR} estimate in being able to detect variation in toe clearance that may not be detectable by RFC.

At the fast speed, both RFC and MTC_{Mocap} were significantly different to MTC_{Mocap}, with high variability. This could be attributed to the IMU shifting around during stance, as it was loosely mounted using a cloth pouch. The IMU not being properly secured to the shoe would detract from the algorithm's ability to properly apply the zero velocity update during foot-flat and increase noise in the position estimates. However, the fast speed (1.88 m/s) is much faster than the range of speeds that individuals with TTA usually walk at in daily life ($\sim 0.6 - 1.3$ m/s) [85], thus calculation problems at this speed may not be prevalent in everyday walking data. Future work that aim to test faster walking speeds may benefit from applying a tight wrap around the foot-mounted IMU as done in previous studies on running biomechanics [111].

The motion capture-based MTC estimates and its variability (standard deviation) from in-lab treadmill walking were comparable to published values for MTC and within-subject MTC variability as measured in previous in-lab studies on individuals with TTA [31, 78, 129]. At the slow and preferred speeds, IMU-based toe clearance estimates were also similar to published values, though with higher variability.

6.4.3 Prosthetic Comparison in Daily Life

RFC and MTC_{CoR} estimates and their variability in daily life were not different to each other. Both MTC and within-bout MTC variability were higher than published values from in-lab studies [31, 78, 129]. Higher MTC and MTC variability in daily life may be attributed to participants navigating obstacles, stepping onto curbs that are lower than standard stair heights, walking on various terrains, and transitioning between different terrains. The MTC variability measure in daily life may not be able to detect changes in gait due to a prosthetic intervention, as the results from the in-lab feasibility study showed that IMU-based MTC variability may be dominated by variability in the calculation algorithm rather than kinematic variability, which contains more meaningful information regarding fall risk.

While the variability of MTC in daily life may not contain salient information, the distribution of MTC_{CoR} values in daily life provides more information about the effects of the powered prosthesis. With the unpowered prosthesis, the group wide mean MTC_{CoR} distribution has a positive skew, indicating a greater concentration of MTC values below the mean (Figure 6.6). While the MTC_{CoR} distribution with the powered prosthesis also has a positive skew, relative to that of the unpowered prosthesis, MTC values with greater probability density were shifted toward higher toe clearance values. That is, MTC was likely to be higher with the powered prosthesis than with the unpowered prosthesis. Using the RFC estimate for toe clearance, there was no noticeable difference between prostheses in the distribution skew of toe clearance values. This may suggest that in everyday walking strides, the foot's orientation during the low point of swing is such that the toe is pointing more downward with the unpowered prosthesis, compared to the powered prosthesis.

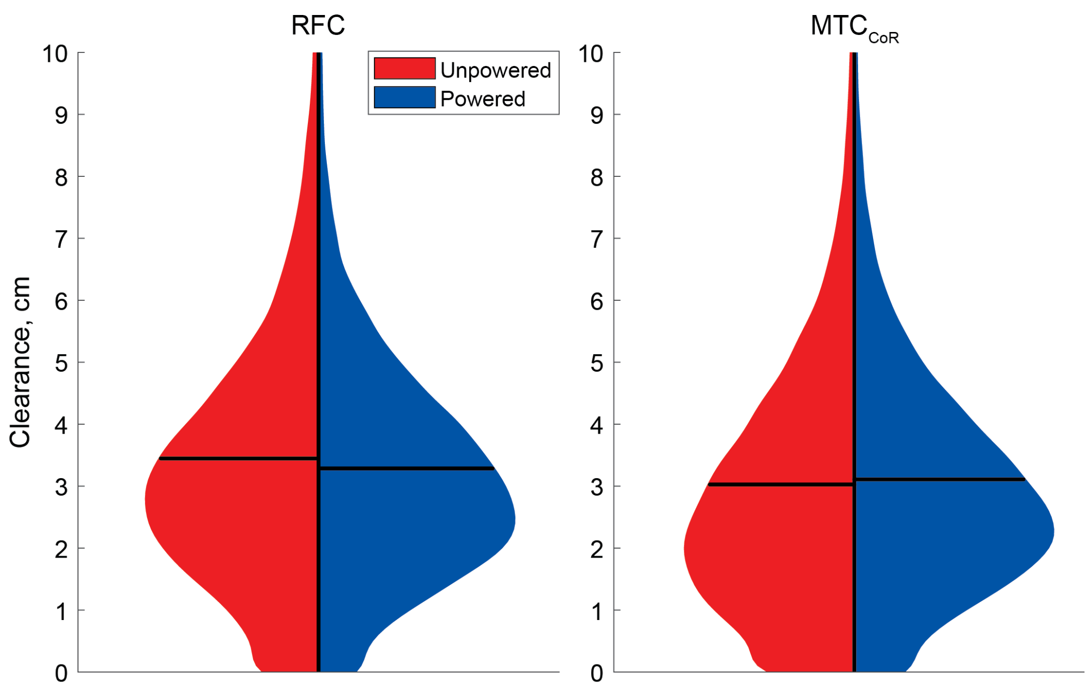

Figure 6.6: Distribution of toe clearance values in daily life
Split violin plot of the probability density functions of distributions of relative foot clearance (RFC) and minimum toe clearance using the center of rotation assumption (MTC$_{CoR}$) in daily life. Raw distributions were smoothed using the MATLAB kernel smoothing function *ksdensity* for visualization. Horizontal bars represent group means.

6.4.4 Limitations

In exploring the feasibility of our approach to estimating MTC, we were only able to collect data from one participant with TTA, due to COVID-19 restrictions. Further validation with greater statistical power is required to support the claims made in the feasibility study. Additionally, our in-lab protocol utilized a treadmill walking activity. While there may not be significant kinematic differences between treadmill and overground walking [125], treadmill walking may constrain kinematic variability [67] and inherently limit some of the variability in MTC. Thus, future studies should validate these results in overground walking. Finally, the theoretical validity of the stationary CoR assumption also relies on the foot being a rigid component. While this assumption may be easily broken in the biological foot and articulating metatarsal joint, the carbon fiber prosthetic keel component is stiff. Thus, we made the assumption that the resulting deflection between the toe point and the IMU would be negligible.

6.5 Conclusion

This study explored a novel method of assessing fall risk in daily life by estimating minimum toe clearance (MTC) using IMU signals. This approach aimed to improve on existing methods by approximating the location of the toe in relation to the foot mounted IMU during swing. We applied this approach to quantify the effects of the powered prosthesis on MTC in all straight-line level steps taken in a two-week period. There were no differences in MTC or MTC variability between powered and unpowered prostheses in daily life. Thus, the powered prosthesis may not affect users' fall risk in daily life.

CHAPTER 7

Conclusion

7.1 Summary and Recommendations for Future Work

There are several gaps in existing literature regarding the effectiveness of powered prosthetic feet. This dissertation addresses these gaps by quantifying how the powered prosthesis impacts the user's neuromuscular strategy and fatigue-related compensations using experimental approaches in the lab. This work further expands the scope of prosthetic evaluation by quantifying gait characteristics in everyday life. To do this, I examined the clinical viability of several novel approaches for characterizing mobility using wearable sensors. My work can therefore be categorized into two areas: *the analysis of functional capacity demonstrated by users in laboratory experiments* (Chapters 2 and 3) and *the examination of walking performance demonstrated by users in their daily lives* (Chapters 4, 5, and 6). Findings from this work can provide important information regarding the implications for prosthetic prescription, design, and evaluation paradigms.

The primary purpose of the prosthesis is to replicate the biological limb to restore pre-amputation levels of mobility. The effects of the powered prosthesis on metabolic cost, endurance, walking speed, and step count are subject-specific and not universal. No single participant improved in all metrics of mobility, and improvements may be accompanied by trade-offs in other metrics. Therefore, in prescribing the powered prosthesis, clinicians may benefit from understanding the patient's specific desired outcomes and adopting realistic expectations for potential shortfalls. Metabolic reductions in powered prosthesis users were shown in earlier studies [7, 63] and used as a common evaluation metric for the device's effectiveness. However, not all users experience metabolic reductions. I revealed a moderate relationship between co-contractions at the residual limb thigh and metabolic cost, which suggests that individuals who are able to effectively stabilize their residual limb during stance may experience metabolic benefits (Chapter 2). Thus, if the clinician's primary goal of prescribing the powered prosthesis is to reduce the patient's metabolic cost, the prescription may be more effective for a select group of individuals that are already able ambulators. However, the ability to effectively stabilize the residual limb may be a subjective and under-defined criterion. Thus, *future work should examine the effects of directed training schemes involving strengthening the residual limb stabilizer muscles.*

Before we invest solely in metabolic reductions as the determining criterion for prosthetic evaluation, we must also consider if metabolic benefits affect the user's mobility. Interestingly, metabolic reductions associated with the powered prosthesis likely do not manifest into improved walking endurance or increased physical activity in daily life (Chapters 3 and 5). The powered prosthesis may, however, cause less pain or discomfort at the socket-limb interface in long-duration walks, compared to unpowered devices. If patients report socket pain or discomfort as a limiting factor for healthy amounts of physical activity, these issues may be alleviated with the powered prosthesis. However, this recommendation requires further work, as the specific factors associated to the powered prosthesis that mitigate socket pain is not yet clear. Therefore, *further work is needed to understand the relationship between the powered push-off and socket pain.*

In addition to the powered prosthesis' potential benefits to mobility, we must also be cognizant of its potential adverse effects on safety and fall risk. After a two-week period of walking with the powered prosthesis in their daily lives, some participants reported feeling unstable particularly when traversing outdoor terrains such as grass or gravel (Chapter 5). In examining the potential for tripping-related falls in daily life, I found that the powered prosthesis did not affect minimum toe clearance (Chapter 6). As such, while the powered prosthesis did not increase the likelihood for tripping due to a low toe clearance, it is unlikely to increase toe clearance. This may serve as an important distinction between the powered prosthesis and active dorsiflexor prostheses (such as the Ossur Proprio Foot), which are more specialized for actively increasing toe clearance. An important consideration here is my approach in examining straight-line walking strides. Walking with the relatively heavier powered prosthesis incurred greater activation at the intact limb gluteus medius, which may be associated with greater frontal plane moments at the hip (Chapter 2). This finding may have implications for compensatory strategies when making turns. Thus, it is unclear if users are more or less susceptible to falls during turning steps with the powered prosthesis, and *future work should characterize balance and fall risk with the powered prosthesis for turning steps.*

The benefits of the powered prosthesis are non-universal and inconclusive, which suggests there may be design considerations that require further attention. Of particular interest is the relatively stiff keel of the powered prosthesis, which may limit its ability to provide a stable loading response and weight acceptance during the residual limb's stance phase. Increased activations at muscles responsible for stabilizing the limb during stance suggest that the powered prosthesis incurs a greater need to stabilize the residual limb (Chapter 2). These increases were large enough to be perceived by several participants who reported stability issues (Chapter 5). This issue may also impact walking endurance. The fatigue- and device-related increases in power absorption at the intact limb ankle during loading response could be attributed to the lack of power absorption at the powered ankle or a misalignment in the timing or magnitude of the powered push-off that becomes apparent after fatigue (Chapter 3). These effects are yet to be fully quantified and *future work should examine ways to alleviate stability issues at the residual limb during stance.*

7.2 Long-term Vision

My unique contribution to the body of work evaluating the powered prosthesis is the use of wearable sensors to characterize gait in daily life. In addition to measuring functional *capacity* in the lab, measuring the *performance* of mobility in daily life takes an important step toward evaluating the real-world impact of prosthetic devices. I anticipate that as the mobility measures examined in Chapters 4 to 6 are refined, standardized, and validated, prosthetic evaluation studies will trend toward taking place in patients' everyday lives. To successfully characterize or evaluate gait in daily life, it is imperative that clinicians and engineers collectively work toward establishing and refining outcomes that can be quantified in daily life. One example is the concept of variable cadence, which has long been a part of the Medicare Functional Classification Level guidelines. There is a large variability in how clinicians assess this trait in the clinic, which contributes to a large variability in functional classification. This can lead to uncertainty in how cadence variability should be quantified in daily life. Thus, the process of implementing clinical outcomes to be measured in daily life may not always be straightforward and may require careful interpretation.

Given the widespread use of wearable sensors, such as the Fitbit (Fitbit, CA, USA) and Apple Watch (Apple, CA, USA), to track our daily activity today, I believe there is an avenue for integrating sensors to microprocessor prosthetic devices. Embedding an IMU sensor within the prosthetic component would not only mitigate sensor noise, but also provide pathways to various clinical and technological applications. Currently, when a patient is first prescribed the powered prosthesis, a certified prosthetist will observe the patient walking in the clinic with the prosthesis, while iteratively tuning the device's stiffness, push-off and timing parameters. Once both the patient and clinician are satisfied, the parameters are set and only changed if patients return for additional tuning. While the manufacturer suggests that users can quickly learn to walk with the device, user feedback from Chapter 5 suggests that this learning process was not always immediate. Given the foundation laid in this work, the data collected during everyday walking could provide useful information to clinicians about the user's learning and acclimation process. Further, data from the embedded sensors could also provide users with feedback on their walking performance. An effective prosthetic intervention does not necessarily occur during a single clinic visit. As such, facilitating a successful adaptation to the device and promoting healthy walking patterns in everyday life is a long-term challenge that may require long-term solutions.

APPENDICES

APPENDIX A

Appendix for Chapter 3

Table A.1: Spatiotemporal parameters (pairwise p value and Hedge's g)

	Unpowered: PRE vs POST		Powered: PRE vs POST		PRE: unpowered vs powered		POST: unpowered vs powered	
	p	g	p	g	p	g	p	g
Step time								
Intact limb	0.250	-0.135	0.705	-0.077	0.244	-0.124	0.700	-0.085
Residual limb	0.256	-0.118	0.736	0.037	0.011	-0.250	0.294	-0.169
Symmetry	0.725	0.123	0.617	0.107	0.504	-0.138	0.611	0.257
Step length								
Intact limb	0.159	0.166	0.941	0.054	0.511	-0.073	0.051	-0.256
Residual limb	0.137	0.152	0.438	0.111	0.003	0.371	0.028	0.297
Symmetry	0.790	-0.054	0.817	0.023	0.027	-0.137	0.009	0.387
Stance time								
Intact limb	0.068	-0.155	0.148	-0.169	0.616	-0.037	0.898	-0.055
Residual limb	0.086	-0.134	0.457	-0.072	0.168	0.109	0.019	0.268
Symmetry	0.958	0.020	0.475	0.136	0.066	0.316	0.016	0.579

Table A.2: Ground reaction force peaks (pairwise p value and Hedge's g)

	Unpowered: PRE vs POST		Powered: PRE vs POST		PRE: unpowered vs powered		POST: unpowered vs powered	
	p	g	p	g	p	g	p	g
Anterior-Posterior								
Braking Intact	0.265	-0.106	0.062	-0.166	0.857	0.015	0.559	-0.059
Braking Residual	0.015	-0.346	0.8559	-0.041	0.010	-0.478	0.785	-0.077
Braking SI	0.329	0.094	0.218	-0.184	0.019	0.309	0.907	0.052
Propulsive Intact	0.032	0.174	0.382	0.085	0.632	0.036	0.429	-0.050
Propulsive Residual	0.472	-0.061	0.113	0.175	0.101	0.228	<0.001	0.481
Propulsive SI*	**0.024**	-0.225	0.552	0.038	0.591	0.066	**0.001**	0.333
Vertical								
First Intact	0.981	<0.001	0.605	0.046	0.025	-0.179	0.093	-0.138
First Residual	0.198	0.175	0.078	0.245	0.018	0.318	0.006	0.294
First SI	0.428	0.944	0.479	0.094	<0.001	0.410	0.001	0.367
Second Intact	0.291	0.084	0.945	0.001	0.123	0.121	0.682	0.048
Second Residual	0.516	0.072	0.216	-0.146	0.010	-0.277	<0.001	-0.505
Second SI	0.759	-0.031	0.393	-0.087	0.003	-0.356	0.001	-0.388
Mediolateral								
Lateral Intact	0.032	-0.288	0.637	-0.052	0.168	-0.176	0.761	0.054
Lateral Residual	0.633	-0.095	0.015	-0.328	0.138	0.204	0.640	-0.047
Lateral SI	0.370	0.222	0.094	-0.499	0.038	0.650	0.609	-0.139

*Significant prosthesis × fatigue interaction effect ($p < 0.05$)

Table A.3: Joint power peaks (pairwise p value and Hedge's g)

	Unpowered: PRE vs POST		**Powered: PRE vs POST**		**PRE: unpowered vs powered**		**POST: unpowered vs powered**	
	p	***g***	**p**	***g***	**p**	***g***	**p**	***g***
Hip								
Gen Intact – MS	0.863	0.048	0.663	-0.032	0.252	-0.122	0.086	-0.240
Gen Residual – MS	0.542	0.044	0.111	0.125	0.055	-0.163	0.368	-0.082
Gen – MS SI	0.669	-0.135	0.101	0.339	0.791	0.076	0.023	0.565
Abs Intact – TS	0.759	0.043	0.587	0.042	0.718	-0.044	0.906	-0.053
Abs Residual – TS	0.058	-0.250	0.998	-0.001	0.130	-0.203	0.678	0.021
Abs – TS SI	0.036	0.222	0.385	0.094	0.359	0.106	0.724	-0.508
Gen Intact – PSw	0.454	-0.091	0.142	0.220	0.187	-0.149	0.366	0.142
Gen Residual – PSw*	**0.041**	0.238	**0.016**	-0.238	0.872	0.017	**<0.001**	-0.472
Gen – PSw SI*	0.262	0.194	**0.008**	-0.264	0.939	-0.016	**<0.001**	0.028
Knee								
Abs Intact – MS	0.877	0.005	0.633	-0.055	0.542	0.054	0.977	-0.010
Abs Residual – MS	0.252	-0.195	0.575	0.016	0.855	-0.012	0.131	0.156
Abs – MS SI	0.509	-0.069	0.476	-0.091	0.121	-0.169	0.122	-0.258
Gen Intact – TS	0.235	-0.284	0.229	-0.240	0.714	-0.069	0.701	-0.096
Gen Residual – TS	0.574	0.030	0.786	-0.050	0.005	-0.353	<0.001	-0.430
Gen – TS SI	0.229	0.193	0.686	0.071	0.565	0.100	0.807	-0.020
Abs Intact – PSw	0.388	0.071	0.882	-0.038	0.141	0.131	0.653	0.047
Abs Residual – PSw	0.551	-0.095	0.347	0.115	<0.001	-0.549	0.009	-0.331
Abs – PSw SI	0.322	-0.157	0.590	-0.139	0.075	0.490	0.029	0.392
Ankle								
Abs Intact – LR	0.161	-0.415	0.008	-0.377	0.020	-0.449	<0.001	-0.588
Abs Residual – LR	0.224	-0.114	0.227	-0.196	0.024	-0.318	0.028	-0.335
Abs – LR SI	0.789	-0.097	0.537	-0.125	0.116	0.234	0.243	0.228
Abs Intact – TS	0.507	0.095	0.871	-0.041	0.994	-0.001	0.410	-0.125
Abs Residual – TS	0.947	0.003	0.707	0.105	<0.001	0.791	<0.001	0.761
Abs – TS SI	0.912	0.007	0.972	-0.021	<0.001	-0.638	<0.001	-0.633
Gen Intact – PSw	0.396	0.071	0.571	0.047	0.519	-0.045	0.364	-0.059
Gen Residual – PSw	0.602	-0.044	0.114	0.161	<0.001	0.630	<0.001	0.806
Gen – PSw SI	0.253	-0.168	0.719	0.033	<0.001	0.719	<0.001	0.812

*Significant prosthesis × fatigue interaction effect ($p < 0.05$)

Table A.4: Joint ranges of motion (pairwise p value and Hedge's g)

	Unpowered: PRE vs POST		Powered: PRE vs POST		PRE: unpowered vs powered		POST: unpowered vs powered	
	p	g	p	g	p	g	p	g
Hip ROM								
Intact	0.119	0.117	0.448	-0.049	0.979	-0.002	0.021	-0.164
Residual*	0.085	0.147	**0.022**	-0.197	0.069	-0.177	**<0.001**	-0.480
Symmetry	0.980	0.030	0.107	-0.122	0.178	-0.128	0.005	-0.278
Knee ROM								
Intact	0.024	0.187	0.817	0.057	0.408	0.088	0.231	-0.096
Residual	0.775	0.003	0.014	0.213	0.194	0.092	0.001	0.247
Symmetry*	0.160	-0.120	0.125	0.165	0.345	0.074	**<0.001**	0.337
Ankle ROM								
Intact	0.319	0.084	0.241	-0.088	0.584	-0.041	0.008	-0.211
Residual	0.521	0.033	0.570	0.130	0.001	0.399	0.002	0.407
Symmetry	0.864	-0.001	0.292	0.118	<0.001	0.525	<0.001	0.597

*Significant prosthesis × fatigue interaction effect ($p < 0.05$)

Table A.5: Peak joint angle, moment, and power at the hip, knee, and ankle

Limb	**Intact**				**Prosthetic**			
Device	**Unpowered**		**Powered**		**Unpowered**		**Powered**	
Fatigue	**PRE**	**POST**	**PRE**	**POST**	**PRE**	**POST**	**PRE**	**POST**
				JOINT ANGLES				
Hip								
ROM	40.6 (4.7)	41.4 (5.8)	40.6 (6.2)	40.2 (5.3)	**41.3 (4.9)***	**42.3 (6.4)***	**40.1 (5.9)***	**38.6 (5.9)***
Flx – LR	35.6 (6.8)*	37.5 (7.6)*	32.6 (8.8)*	32.7 (8.3)*	36.6 (7.5)	38.3 (8.0)	34.9 (10.2)	35.6 (8.2)
Ext – PSw	-4.4 (8.6)*	-3.1 (9.6)*	-6.6 (6.9)*	-6.6 (7.3)*	-3.7 (6.4)	-2.7 (6.3)	-4.2 (11.1)	-2.3 (9.3)
Flx – LSw	34.6 (7.3)	36.3 (7.9)	32.8 (9.1)	32.4 (9.0)	36.8 (7.5)*◊	38.4 (7.1)*◊	34.8 (9.5)*◊	35.7 (8.1)*◊
Knee								
ROM	64.8 (4.8)	66.0 (5.3)	65.2 (2.8)	65.5 (3.3)	68.3 (9.4)*	68.3 (10.2)*	69.2 (6.4)*	71.1 (8.1)*
Ext – IC	-0.6 (7.8)*	-0.4 (5.8)*	-2.4 (5.4)*	-2.8 (5.4)*	-1.8 (8.7)*	-1.9 (8.6)*	-3.9 (10.8)*	-4.2 (10.1)*
Flx – MS	18.8 (6.3)*	19.2 (4.5)*	17.1 (8.4)*	16.7 (7.8)*	11.4 (10.4)	11.8 (12.1)	9.7 (11.8)	10.1 (11.4)
Ext – TS	4.2 (7.9)*	5.0 (6.4)*	3.0 (4.7)*	2.6 (4.7)*	5.2 (11.2)	6.3 (11.3)	4.3 (9.9)	6.6 (9.5)
Flx – LSw	51.7 (9.0)	52.5 (8.0)	51.0 (7.3)	50.6 (8.1)	53.4 (6.3)	53.7 (7.2)	52.3 (10)	53.9 (10.2)
Ankle								
ROM	30.5 (4.2)	30.9 (4.6)	30.2 (5.2)	29.7 (5.0)	20.8 (6.2)*	21.1 (6.4)*	23.1 (2.4)*	23.5 (2.7)*
PF – LR	-1.3 (4.0)	-1.8 (4.0)	-1.2 (3.3)	-1.8 (3.2)	-1.7 (4.5)*	-0.8 (5.3)*	-4.7 (4.5)*	-4.9 (4.5)*
DF – TS	17.7 (4.5)*	17.9 (4.9)*	16.8 (4.3)*	17.1 (4.7)*	17.8 (3.7)*	18.6 (4.4)*	15.3 (3.7)*	15.2 (3.9)*
PF – ESw	-11.1 (4.6)	-11.5 (4.9)	-11.8 (5.6)	-10.9 (4.9)	5.4 (3.2)*	6.3 (3.7)*	-5.4 (3.5)*	-6.0 (3.5)*
				JOINT MOMENTS				
Hip								
Ext – IC	0.1 (0.2)	0.1 (0.1)	0.1 (0.1)	0.1 (0.1)	**0.1 (0.1)**	**0.2 (0.1)**	**0.1 (0.1)**	**0.1 (0.1)**
Flx – TS	-0.7 (0.2)	-0.6 (0.2)	-0.7 (0.3)	-0.7 (0.3)	-0.6 (0.2)*◊	-0.6 (0.1)*◊	-0.7 (0.2)*◊	-0.6 (0.2)*◊
Knee								
Flx – IC	-0.1 (0.1)	-0.1 (0.1)	-0.1 (0.1)	-0.1 (0.1)	**-0.1 (0.1)**	**-0.1 (0.1)**	**-0.1 (0.1)**	**-0.1 (0.1)**
Ext – MS	0.8 (0.2)*	0.8 (0.2)*	0.7 (0.3)*	0.7 (0.2)*	0.1 (0.2)	0.1 (0.2)	0.2 (0.2)	0.2 (0.2)
Flx – TS	-0.1 (0.3)*	-0.1 (0.2)*	-0.2 (0.2)*	-0.2 (0.2)*	-0.2 (0.3)*	-0.2 (0.3)*	-0.1 (0.2)*	-0.1 (0.2)*
Ankle								
DF – LR	-0.2 (0.1)	-0.2 (0.1)	-0.2 (0.1)	-0.2 (0.1)	-0.2 (0.1)*	-0.2 (0.1)*	-0.3 (0.1)*	-0.3 (0.1)*
PF – TS	1.3 (0.3)*	1.4 (0.2)*	1.4 (0.2)*	1.4 (0.2)*	1.4 (0.2)*	1.4 (0.1)*	1.2 (0.1)*	1.2 (0.1)*
				JOINT POWERS`				
Hip								
Gen – MS	0.3 (0.2)	0.4 (0.2)	0.3 (0.4)	0.3 (0.3)	0.7 (0.4)	0.7 (0.3)	0.6 (0.5)	0.7 (0.4)
Abs – TS	-0.6 (0.3)	-0.6 (0.2)	-0.6 (0.3)	-0.6 (0.2)	-0.5 (0.2)	-0.6 (0.2)	-0.6 (0.3)	-0.6 (0.2)
Gen – PSw	1 (0.3)	1 (0.3)	1 (0.2)	1.1 (0.2)	**1 (0.4)***	**1.1 (0.4)***	**1 (0.4)***	**0.9 (0.3)***
Knee								
Abs – MS	-1 (0.5)	-1 (0.5)	-0.9 (0.7)	-1 (0.6)	-0.2 (0.1)	-0.2 (0.1)	-0.2 (0.1)	-0.2 (0.2)
Gen – TS	0.2 (0.1)	0.2 (0.1)	0.2 (0.1)	0.2 (0.1)	0.2 (0.2)*	0.3 (0.2)*	0.2 (0.1)*	0.1 (0.1)*
Abs – PSw	-1.2 (0.6)	-1.2 (0.4)	-1.2 (0.4)	-1.2 (0.3)	-1 (0.4)*	-1.1 (0.5)*	-1.3 (0.5)*	-1.3 (0.4)*
Ankle								
Abs – LR	-0.4 (0.1)*◊	-0.5 (0.1)*◊	-0.5 (0.2)*◊	-0.6 (0.3)*◊	-0.3 (0.2)*	-0.3 (0.2)*	-0.4 (0.2)*	-0.4 (0.2)*
Abs – TS	-1.1 (0.3)	-1.1 (0.3)	-1.1 (0.3)	-1.1 (0.4)	-1.1 (0.6)*	-1.1 (0.7)*	-0.7 (0.2)*	-0.7 (0.2)*
Gen – PSw	2.9 (0.9)	3 (0.8)	2.9 (1.1)	2.9 (1.1)	1.8 (0.8)*	1.7 (0.7)*	2.4 (0.8)*	2.6 (0.9)*

Abbreviations – Flx: flexion, Ext: extension, PF: plantarflexion, DF: dorsiflexion, Gen: generation, Abs: Absorption, IC: initial contact, LR: loading response, MS: midstance, TS: terminal stance, PSw: pre-swing, ESw: early swing, LSw: late swing

*Significant device effect

◊Significant fatigue effect

Significant device × fatigue effect

Table A.6: Symmetry indices for joint angle, moment, and power

Device	Unpowered		Powered	
Fatigue	**PRE**	**POST**	**PRE**	**POST**
		JOINT ANGLES		
Hip				
ROM	1.4 (12.7)*	2 (15.4)*	-1.3 (20.7)*	-4.5 (21.4)*
Flx – LR	2.2 (23.1)	1.5 (14.8)	6.6 (10.7)	8.4 (11)
Ext – PSw	-101 (565)	186.3 (911.3)	14300 (45100)	200 (846)
Flx – LSw	6.1 (25.1)	6 (21.1)	5.8 (14.9)	10.6 (15.3)
Knee				
ROM	4.6 (10.6)*	**3 (11.6)***	5.6 (9.9)*	**7.7 (11.1)***
Ext – IC	116 (485.3)	3190 (9980)	35.9 (78.4)	103 (146)
Flx – MS	-82.7 (129.2)	-89.5 (123.3)	-101 (114)	-108 (148)
Ext – TS	73.8 (607.2)	-59.7 (266)	-1.3 (661.4)	76.9 (154.3)
Flx – LSw	4 (16.3)	2.8 (15.9)	1.7 (13.6)	6.1 (15.7)
Ankle				
ROM	-40.5 (22.8)*	-40.6 (25.2)*	-25.5 (23.5)*	-21.9 (25.3)*
PF – LR	-1972 (4620)	388 (1040)	-176 (765)	-75.9 (476)
DF – TS	2.2 (38.6)*	4.6 (47)*	-7.7 (47)*	-10.1 (54.9)*
PF – ESw	426 (2090)	-864 (1590)	-74.9 (70.5)	-66.9 (72.5)
		JOINT MOMENTS		
Hip				
Ext – IC	101 (376)	745 (5830)	-35 (171)	-1030 (3070)
Flx – TS	-11 (43)	-3.1 (33.7)	-3.8 (43.3)	-5.8 (35.3)
Knee				
Flx – IC	-50.9 (111.2)	160 (367.6)	-798.1 (2464.6)	-27.7 (124.8)
Ext – MS	-167.4 (84.7)	-201.8 (211.9)	-140.2 (85.7)	-155.6 (87.9)
Flx – TS	241 (1040)	150 (1360)	-135 (229)	-39.4 (449.4)
Ankle				
DF – LR	6.6 (47.5)*	-1.4 (53.8)*	51.6 (58.5)*	43.5 (60.7)*
PF – TS	5.1 (20)*	0 (14.3)*	-13.6 (14.3)*	-13.6 (20.4)*
		JOINT POWERS		
Hip				
Gen – MS	72.9 (94.1)	60.5 (46.8)	82.1 (101)	133 (139)
Abs – TS	-11.9 (42.6)	-0.4 (41.5)	-5.1 (60.1)	1.1 (45.1)
Gen – PSw	**-9.5 (39)***	**-0.1 (39.7)***	**-10.5 (57.6)***	**-27.8 (47.9)***
Knee				
Abs – MS	-110 (102)	-116.9 (43.8)	-127.2 (52.3)	-133.5 (59.3)
Gen – TS	-39.7 (106.2)	-14.3 (106.1)	-26.5 (106)	-17 (111.2)
Abs – PSw	-15.6 (51.4)*	-29.6 (88.2)*	11.2 (35.6)*	4.3 (44.5)*
Ankle				
Abs – LR	-43.1 (57.8)	-49.9 (56.3)	-26.5 (56.6)	-34.8 (50.7)
Abs – TS	-2.7 (51.3)*	-2.3 (47)*	-40.4 (43.9)*	-41.7 (53.5)*
Gen – PSw	-49.9 (36.5)*	-57.4 (36.2)*	-15.3 (41.1)*	-13.5 (50.2)*

*Significant device effect
†Significant fatigue effect
Significant device × fatigue effect

APPENDIX B

Appendix for Chapter 5

Table B.1: Accelerometer (ACC) sensor data collection month and quantity

ID	Unpowered			Powered		
	Months	# Days	Wear time / day (hrs)	Months	# Days	Wear time / day (hrs)
S01	Jul – Aug	13	14.6	Aug	13	14.4
S02	Sep – Oct	18	16.1	Oct – Nov	21	17.0
S03	Dec – Jan	13	10.9	Jan – Feb	11	12.3
S04	Mar – Apr	14	16.3	Apr – May	15	15.4
S05	Aug – Sep	11	13.4	Jul – Aug	11	14.4
S06	Sep – Oct	12	7.3	Nov – Dec	10	4.4
S07	Mar – Apr	29	9.3	May	13	9.6
S08	Feb	8	14.1	Aug	9	14.6
S11	Apr – May	27	13.9	Mar – Apr	25	9.9
S12	May – Jun	19	7.0	Apr – May	28	10.6
Mean		16.4	12.3		15.6	12.3
SD		6.9	3.4		6.7	3.7

Table B.2: IMU sensor data collection month and quantity

ID	Unpowered			Powered		
	Months	# Days	Wear time / day (hrs)	Months	# Days	Wear time / day (hrs)
S01	Jul – Aug	5	12.0	Aug	1	8.6
S02	Sep – Oct	8	9.2	Oct – Nov	18	12.5
S03	Dec – Jan	6	10.9	Jan – Feb	1	8.0
S04	Mar – Apr	2	11.1	Apr – May	5	11.3
S05	Aug – Sep	1	12.9	Jul – Aug	1	1.7*
S06	Sep – Oct	4	3.7	Nov – Dec	1	0.0*
S07	Mar – Apr	20	9.1	May	30	9.5
S08	Feb	8	13.9	Aug	6	15.4
S11	Apr – May	14	11.2	Mar – Apr	8	10.6
S12	May – Jun	7	9.2	Apr – May	12	9.1
Mean		7.5	10.3		8.3	8.7
SD		5.7	2.8		9.5	4.7

*IMU data was not sufficient so S05 and S06 were excluded from walking speed analysis in daily life

Table B.3: User feedback and preference

ID	Did the BiOM help you walk/work longer without rest?	Can you walk faster with the BiOM?	How long did it take to learn? Did you ever learn?	Other comments	Preference[a]
S01	Yes	Yes	Leg felt heavy the first few days; Noticed he got more power by extending the knee. Pointed to quads and said "when I contract these muscles, I get more power out of it"	Needed socks because device is heavier & causes more pistoning. Got distal cup to lift residual limb over bursa	100
S02	Yes	Yes	Not answered	Not answered	100
S03	No; back pain	Not answered	3-4 days	Doesn't feel "even." Started having back pain. Didn't like the lift because it caused pain on top of foot	30
S04	Yes	Not answered	Adjusted quickly: "right away"	A little off balance with alignment; got heel caught on back of stair; some stability issues	100
S05	No	No	Took a month to get used to. Felt it gets easier over time. Still has not quite figured it out yet.	Not answered	28
S06	Not answered	Yes (only on flat ground)	Not answered	The BiOM makes you do what it wants you to do instead of doing what you want it to do. BiOM doesn't adapt to terrain well.	17
S07	Not answered	Yes	About an hour but sometimes it surprises him	Not answered	48
S08	Yes	Not answered	Not answered; BiOM owner	Not answered	78
S11	Yes	Yes	Not answered; BiOM owner	Would never walk with unpowered foot unless BiOM was broken	100
S12	No; calf pressure	Yes	Not answered	More calf pressure with BiOM	76

[a] Preference scale: 0 = unpowered, 100 = powered

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