Evaluating use of a robotic prosthetic foot emulator to test-drive prosthetic feet in people with lower limb amputation: mechanical validation and qualitative interviews

Elizabeth G. Halsne

A dissertation

submitted in partial fulfillment of the

requirements for the degree of

Doctor of Philosophy

University of Washington

2021

Reading Committee:

David Morgenroth, Chair

Brian Hafner

Heather Feldner

Program Authorized to Offer Degree:

Rehabilitation Medicine

© Copyright 2021

Elizabeth G. Halsne

University of Washington

Abstract

Evaluating use of a robotic prosthetic foot emulator to test-drive prosthetic feet in people with lower limb amputation: mechanical validation and qualitative interviews

Elizabeth G. Halsne

Chair of the Supervisory Committee:

David Morgenroth

Department of Rehabilitation Medicine

Selection of a prosthetic foot is an important decision for lower limb prosthesis prescription. Without objective evidence to guide foot prescription, clinicians (i.e., physicians and prosthetists) rely on their expertise to best match a foot to a patient's functional goals. However, persons with lower limb amputation typically cannot usually try different prosthetic feet before one is ultimately selected. The robotic prosthetic foot emulator (PFE) is a technological advancement that could facilitate a test-driving approach to foot selection, in which the prosthesis user quickly trials several prosthetic feet and then contributes their experiential input to the decision-making process. This dissertation used quantitative and qualitative approaches to assess use of the PFE for test-driving prosthetic feet. First, quantitative procedures to emulate the angular stiffness of commercial feet used in the PFE were developed and validated. Mechanical

testing procedures were used to collect angular stiffness data for a variety of commercial prosthetic forefeet. PFE foot profiles were created from these data and mechanical testing was repeated with the emulated feet to evaluate the accuracy of the emulation. Angular stiffness of emulated feet was significantly correlated with that of respective commercial feet. Mean differences in angular stiffness between emulated and commercial feet were less than 1%, and were independent of prosthetic foot type and example foot sizes or intended user body weights. Participants with lower limb amputation (LLA) then used both the PFE and commercial feet to complete a test-driving protocol, before completing qualitative, semi-structured interviews with an investigator. The purpose of the interviews was to develop a grounded theory of the experience of prosthetic foot prescription from the perspective of prosthesis users. The core category was the relationship between knowledge about prosthetic feet and decision-making power. Participants described prosthetic foot prescription as an educational journey. Relationships with clinicians and peers with LLA were recognized as highly valued and capable of influencing the quality of the foot prescription experience. Participants also noted the importance of their individuality and preferences for the extent of being engaged in decision-making. Test-driving accelerated users' education about feet options and facilitated discussion with clinicians. Therefore, complementary findings from these two studies support the potential for future use of the PFE for test-driving. Further research may be warranted to evaluate the use of the PFE and test-driving to augment prosthetic foot prescription processes.

This research was conducted with the approval of the VA Central Institutional Review Board.

Application Numbers: IRB# 00949 (Principal Investigator-Study Chair application) and

IRB# 01628 (Local Site Investigator application)

Date of Approval: May 28, 2020

Plain Language Summary

Prosthetic feet are an important part of an artificial leg. Different types of prosthetic feet are available for people with leg amputations. Usually, a doctor or prosthetist uses their best judgment to choose a foot for an amputee based on the person's goals and activities. However, amputees rarely get a chance to try out multiple styles of prosthetic feet to determine which feet they might like best.

We first studied how test-driving could be used for people with leg amputations to decide between prosthetic feet, much like a driver can decide between cars they might like to buy. In this study, we used a robotic foot to mimic the properties of commercially-available prosthetic feet. We tested numerous feet to measure how they responded to applied body weight loads and then programmed the robotic foot to simulate each one. Then, we tested the robotic versions of the feet and compared how well each mimicked the actual, commercial version.

We learned the following from testing the prosthetic feet:

> Simulated versions of prosthetic feet accurately mimicked commercial versions of prosthetic feet, when tested in the same way.

In a separate ongoing study, both robotic and commercial feet are being used by people with leg amputations to quickly trial three different kinds of prosthetic feet. In that study, people with amputations use each foot back-to-back to do things like walking at slow and fast speeds, walking up a hill, or climbing stairs. After test-driving the different feet, participants are asked questions about which feet they liked best.

We subsequently conducted a second study to interview people who had tried test-driving prosthetic feet as part of the ongoing study. We recorded the interviews to learn about their

experiences having a prosthetic foot chosen for them by their doctor or prosthetist. We also wanted to find out if test-driving different types of prosthetic feet could be useful to give them a chance to try feet for themselves.

We learned the following from interviews with prosthetic foot users:

- People with amputations rarely have a chance to try out different kinds of prosthetic feet before one is chosen for their artificial leg.
- The experience of getting a prosthetic foot is a journey of learning about feet from the doctor, prosthetist, or other people with amputations. Prosthesis users learn more over time and like knowing about their options for feet.
- The quality of relationship and communication between a prosthesis user and their prosthetist can affect the experience of prosthetic foot decision-making.
- Not all prosthesis users want to be an equal partner in decision-making for a prosthetic foot with their doctor or prosthetist, but they all appreciated being able to test-drive different feet.
- Test-driving taught participants about differences between prosthetic feet and made them feel like their opinions were a valued part of the decision-making process.

We developed a model based on information collected in the interviews to explain how people with leg amputations experience getting a prosthetic foot. Results of this study also showed us that letting prosthesis users use the robotic foot to test-drive different styles of feet might be helpful. Finally, results of this study suggested that prosthesis users might benefit from doctors and prosthetists teaching them about their options for prosthetic feet, and asking them about their preferences during the decision-making process.

Acknowledgments

This research is a project of the Seattle Institute for Biomedical and Clinical Research supported by the Office of the Assistant Secretary of Defense for Health Affairs, through the Orthotics and Prosthetics Outcomes Research Program under Award No. W81XWH-16-1-0569. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense. The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. This material is the result of work supported with resources and the use of facilities at the VA Puget Sound Health Care System, Seattle, Washington. The contents do not represent the views of the United States Department of Veterans Affairs or the United States Government.

I would like to acknowledge the extensive list of mentors and collaborators who have contributed to the research concerning test-drive strategies for prosthetic foot prescription. This list begins with my advisor and the Principal Investigator for this research, David Morgenroth, M.D. Without Dr. Morgenroth, none of this dissertation work would have been possible, and I am grateful for his wisdom, mentorship, and friendship. I have also benefitted greatly from the professional and personal support of Brian Hafner, Ph.D., who is a Co-Investigator in this research. Dr. Hafner first inspired me to become involved in research in Prosthetics & Orthotics when I was completing my clinical education over a decade ago. The dedication that Dr. Hafner shows his team members and mentees led me to return to the University of Washington for graduate school so that I could continue growing as a scientist with his direction.

I wish to acknowledge the invaluable support of my remaining committee members, Sara Morgan, CPO, Ph.D., Heather Feldner, PT, Ph.D., and Kat Steele, Ph.D. I admire these three women as academic and personal role models, and I feel privileged to benefit from their guidance.

Other important collaborators include Joshua Caputo, Ph.D., Carl Curran, MS and the engineers at Humotech, Inc. In addition, I appreciate the members of the multi-site research team who are helping conduct the ongoing test-driving protocol study, including Andrew Hansen, Ph.D. and his team at the Minneapolis VA Health Care System and W. Lee Childers, Ph.D. at the Center for the Intrepid at the Brooke Army Medical Center.

I would like to thank Anne Turner and Talia Ruxin for their assistance in collecting, analyzing, and interpreting data related to my dissertation. I would also like to thank Olivia Reynolds and Talia Ruxin for their assistance reviewing and editing the manuscripts.

I would like to thank Jane Shofer, M.S., of the University of Washington for her assistance with the statistical data analyses presented within this dissertation and for her patience with my incessant statistical questions.

I would like to acknowledge my friends and my cohort in the Rehabilitation Science Ph.D. program at the University of Washington for supporting me throughout this journey.

I would like to acknowledge the multidisciplinary staff and personnel in the VA RRD Center for Limb Loss and MoBility (CLiMB) at the VA Puget Sound Health Care System who have helped me and have provided me with a wonderful research community.

I would like to acknowledge Taylor Chandler from Purdue University for his assistance in the design and illustrations that accompany these research papers.

Finally, I especially appreciate and acknowledge the Veterans and non-Service Members who volunteered their time and shared their personal experiences during the interviews, and without whom this work possible would not be possible.

Dedication

I dedicate this dissertation to my family, friends, and loved ones. A doctoral dissertation is a process, not a product; I am grateful to the countless individuals who have contributed to the process and supported my journey along the way.

Foremost, I dedicate this to my husband, Matthew, who has been tenacious in his devotion to supporting me throughout my graduate studies. Thank you for celebrating my successes and for propping me up in my weaker moments. I appreciate how you were always ready to make another cup of tea or bowl of ice cream and keep my spirits up with your sense of humor;

to my son, Miles, who is my sweetest joy and whom I consider my first great work;

to my sister, Olivia, who inspires me as a writer and as a human being;

finally, to my parents, Chris and Michelle, who have always believed in me and my dreams. Thank you for the continued sacrifices you made to support me during the last year of my doctoral program, which coincided with a pandemic. I cannot adequately describe the depth of respect and admiration I have for the values of love, commitment, and hard work that you instilled in me, all of which have seen me through this achievement.

"I am a part of all that I have met…

And this grey spirit yearning in desire

To follow knowledge like a sinking star,

Beyond the utmost bound of human thought…

Made weak by time and fate, but strong in will

To strive, to seek, to find, and not to yield."

– *Ulysses*, Alfred, Lord Tennyson

Table of Contents

CHAPTER 1 .... **1**

INTRODUCTION **1**

Prescription of Prosthetic Feet for People with Lower Limb Amputation 1

Studying a Novel Test-Drive Strategy for Prosthetic Foot Prescription 5

Inspiration for this Dissertation 7

The Origins of Chapter Two – A Mechanical Testing Study of Prosthetic Feet 9

The Origins of Chapter Three – A Qualitative Study of Prosthetic Foot Prescription Experiences 14

Linked-Papers Organization 16

CHAPTER 2 .... **26**

INTRODUCTION **27**

Prosthetic Foot Prescription 27

Alternative Approach to Prosthetic Foot Prescription 29

Commercial Prosthetic Foot Stiffness Properties 30

METHODS **31**

Prosthetic Foot Emulator 32

Commercial Prosthetic Feet 33

Mechanical Testing of Commercial Prosthetic Feet 34

Determining Angular Stiffness Properties of Commercial Prosthetic Feet 37

Parameterizing Angular Stiffness Properties as Emulated Prosthetic Feet for Input to PFE 38

Validation Using Mechanical Testing of Emulated Prosthetic Feet 41

Statistical Analyses 42

Quantifying the Quality of the Bezier Curve Fit to Commercial Ankle Torque-Angle Data .47

RESULTS **48**

MECHANICAL TESTING OF COMMERCIAL PROSTHETIC FEET 48

PARAMETERIZATION OF COMMERCIAL PROSTHETIC FEET 48

CORRELATION BETWEEN EMULATED AND COMMERCIAL ANGULAR STIFFNESS PROPERTIES 49

ASSESSING AGREEMENT BETWEEN EMULATED AND COMMERCIAL ANKLE TORQUE MEASUREMENTS 51

ASSESSING EFFECTS OF FACTORS ON DIFFERENCE BETWEEN EMULATED AND COMMERCIAL ANKLE TORQUE 51

QUANTIFYING THE QUALITY OF THE BEZIER CURVE FIT TO COMMERCIAL ANKLE TORQUE-ANGLE DATA . 53

DISCUSSION **54**

AGREEMENT BETWEEN EMULATED AND COMMERCIAL FOOT ANKLE TORQUE MEASUREMENTS 55

EFFECTS OF FACTORS ON DIFFERENCE BETWEEN EMULATED AND COMMERCIAL ANKLE TORQUE 57

QUALITY OF THE BEZIER CURVE FIT TO COMMERCIAL ANKLE TORQUE-ANGLE DATA 58

LIMITATIONS AND FUTURE DIRECTIONS 59

CONCLUSIONS **65**

TABLES AND FIGURES **71**

CHAPTER 3 .... **94**

INTRODUCTION **95**

METHODS **99**

OVERARCHING STUDY: TEST-DRIVING PROSTHETIC FEET 100

SAMPLING STRATEGIES 101

DATA COLLECTION 103

DATA ANALYSIS 105

RESEARCHER POSITIONALITY 106

RESULTS **108**

Theme 1 – Gaining knowledge about prosthetic feet through experience 108

Theme 2 – My external relationships (with clinicians and peers) 114

Theme 3 – My identity and individuality 122

Theme 4 – Different feet for different folks (and activities!) 125

Theme 5 – Test-driving prosthetic feet was a meaningful experience 131

Decision-making preferences questionnaire 142

DISCUSSION 144

A metaphor for the experience of prosthetic foot prescription from the patient's perspective 144

A grounded theoretical framework for prosthetic foot prescription experiences 147

Study limitations and future directions 156

CONCLUSIONS 161

TABLES AND FIGURES 168

CHAPTER 4 180

CONCLUSION 180

Conclusions from Chapter Two – Emulating Commercial Forefoot Properties using the PFE 180

Using the PFE to Accomplish the Aims of the TeD Study 187

Conclusions from Chapter Three – The Value of Test-Driving Prosthetic Feet 187

A Vision for the Future of Prosthetic Foot Prescription Practices 191

List of Tables

Chapter 2

Table 2.1. Manufacturer-specified stiffness categories for all tested feet (i.e., five commercial prosthetic foot models, across four foot sizes) with mean and maximum body weight listed for a medium impact user between 125-250 lbs (exact weight range varies by manufacturer).

Table 2.2. Mean and standard deviation Bezier curve fit by prosthetic foot type, across foot sizes and stiffness categories. R-squared values based on least-squares optimization to parameterize the commercial prosthetic forefoot angular stiffness data from mechanical testing, for input to the prosthetic foot emulator.

Table 2.3. Mean and standard deviation differences in measured ankle torque between commercial and emulated prosthetic feet across ankle angles during loading by prosthetic foot type, across foot sizes, and stiffness categories. A negative difference indicates the commercial prosthetic foot torque had a smaller magnitude than the respective emulated foot at that ankle angle position. Percent differences based on the total magnitude of ankle torque.

Table 2.4. Zero-order disaggregated correlations for variables used in analysis for model 1 with emulator ankle torque defined as outcome.

Table 2.5. Results for multilevel linear regression model 1 on emulated ankle torque.

Table 2.6. Zero-order disaggregated correlations for variables used in analysis for model 3 with difference in ankle torque (commercial-emulated) defined as outcome.

Table 2.7. Results for multilevel linear regression model 3 on difference in ankle torque between commercial and emulated feet.

Table 2.8. Mean and standard deviation differences in quality of Bezier curve fit compared to commercial prosthetic foot angular stiffness data and compared to respective emulated prosthetic foot data by prosthetic foot type, across foot sizes and stiffness categories. Difference calculated using trapezoidal integration and percent calculated relative to commercial foot area.

Table 2.9. Mean and standard deviation differences in nonlinear curve features by prosthetic foot type, across foot sizes and stiffness categories. Peak bend calculated to represent relative degree of nonlinearity based on perpendicular distance from line segment and normalized such that a value of 100% would indicate a circle. Offset of the peak bend location calculated as a percent distance translated from midpoint such that a value of 0% would represent a foot with maximum bend located along the midpoint between the P_0 and P_2 Bezier control points (i.e., data could be perfectly represented by the current Bezier curve technique).

Chapter 3

Table 3.1. Summary of participant demographics.

Table 3.2. Individual participant characteristics.

Table 3.3. Five themes with descriptions on the relationship between knowledge and decision-making power with respect to prosthetic feet, from the perspective of the person with LLA.

List of Figures

Chapter 1

Figure 1.1. PFE end effector attached to a user's prosthetic socket.

Chapter 2

Figure 2.1. a) Photo illustrating a user with transtibial amputation with the PFE end effector attached to their socket and tethered, offboard actuator unit and control hardware depicted behind the user; b) photo of PFE end effector attached to socket of participant with transtibial amputation.

Figure 2.2. Prosthetic foot mechanical testing apparatus with example prosthetic foot set-up: a) aerial view of commercial prosthetic foot set up for testing the forefoot at 20° pylon progression angle, in-line load cell and reflective markers shown; b) same commercial foot depicted under maximum target load; c) repeated testing with PFE end effector setup; d) front view of R2000 robot assembly and frame with a vertically-mounted loading platform shown.

Figure 2.3. Illustration of quadratic Bezier curve control points and the shape parameter used to define the polygon: P0 (i.e., minimum) was optimized to improve overall curve fit, P2 (i.e., maximum) was defined at peak load and peak dorsiflexion angle, and P1 (i.e., where shape parameter is applied) was defined along a line bisecting the linear projection from P0 to P2 and with an axis perpendicular to its slope.

Figure 2.4. Illustration of area difference calculation (shaded grey area) between example commercial prosthetic foot angular stiffness data and the corresponding Bezier curve.

Figure 2.5. Illustration of the nonlinear features that were quantified for each commercial foot from the respective angular stiffness data: a) magnitude of peak bend (in green) and offset of peak bend from point between P0 and P2 (in red); b) peak bend calculated as the relative degree of nonlinearity based on maximum perpendicular distance from the line segment between P0 and P2, normalized to the length of the segment such that a value of 100% indicates a semi-circle; c) offset of the peak bend location calculated as a the relative skew based on distance translated from midpoint, normalized such that a value of 0% indicates peak bend at the midpoint (i.e., data could be perfectly represented by the current Bezier curve fitting technique) and 50% is halfway between P0 and midpoint.

Figure 2.6. Example forefoot ankle torque vs ankle angle data for a given foot size (i.e., 26 cm) and user body weight (i.e., 200 lbs) across all five tested commercial prosthetic foot models. All curves exhibit nonlinear behavior and a range of angular stiffness is demonstrated across foot types. A steeper slope (i.e., less angular displacement under the same amount of ankle torque) demonstrates higher stiffness.

Figure 2.7. Example Bezier curves defined using least-squares optimization to fit control points P0 (minimum), P2 (maximum), P1 (located along axis perpendicular to segment at the midpoint), and shape parameter. Angular stiffness data from two types of commercial prosthetic feet shown from two different stiffness categories (e.g., user body weights) for illustration.

Figure 2.8. Example pairs of emulated and commercial foot angular stiffness data across a range of types of prosthetic feet, sizes of feet, and for differing user body weights. Commercial foot data (black) is displayed along with the corresponding Bezier curves (red, dashed) and emulated foot data (blue).

Figure 2.9. Interaction effect for ankle angle position and commercial prosthetic foot torque tested in model 1. The correlation between the commercial foot torque and the estimated emulated ankle torque shown across a range of ankle angle positions (based on standard deviation from mean ankle angle). Results show disordinal effect with equal and opposite differences in commercial-emulated foot torque values depending on the ankle angle position.

Figure 2.10. Results from Bland-Altman assessment of the limits of agreement (LoA) for one example prosthetic foot (i.e., All-Pro, 27cm) with corresponding pairs of commercial and emulated ankle torque measurements, calculated using model 2: a) simple correlation plot to assess extent of proportional agreement between measurements with the LoA (dashed black lines) displayed; b) Bland-Altman plot with differences between corresponding measurements plotted on the vertical axis and the mean of the corresponding measurements plotted on the horizontal axis. The solid black line represents the mean difference (i.e., bias) between corresponding measurements. The dashed black lines represent the lower and upper LoA between which 95% of differences between device condition measurements are expected.

Figure 2.11. Example of total difference in area (shaded in gray) between the commercial prosthetic foot angular stiffness data and the respective Bezier curve, across a range of prosthetic foot types, sizes, and user body weights.

Figure 2.12. Examples of nonlinear features (i.e., peak bend, offset) for commercial prosthetic feet of differing types, with least-squares optimized Bezier curve shown.

Chapter 3

Figure 3.1. Schematic of the test-driving protocol participants had completed prior to participating in semi-structured interviews.

Figure 3.2. Sample questions from the semi-structured interview guide used to conduct interviews.

Figure 3.3. Bar chart showing results (n=11) for questionnaire items on preferences for decision-making in general (left) and decisions related to the prosthesis (right). Proportion of total participant responses for each item, ranging from Strongly Disagree to Strongly Agree, are displayed.

Figure 3.4. Metaphor for the experience of prosthetic feet prescription from the patient's perspective as a journey in acquiring knowledge and experience over time. As the driver (i.e., prosthesis user) has more mileage (i.e., knowledge) and experience driving their own car, they may wish to negotiate for greater control from the front passenger (i.e., prosthetist) who has dual controls over the car. The rear passengers (i.e., physician and peers with LLA) provide directions, like a navigation system, to direct the driver(s) and orient the car towards the improvements in health-related outcomes and participation in life goals. The tires of the car (i.e., prosthetic foot) should be suited to each car and the types of functional goals and activities that the driver wishes to accomplish. While the car has forward momentum such that it will gain more

mileage over time regardless of what the driver(s) are doing, test-driving acts as the gas pedal to accelerate the pace of learning.

Figure 3.5. A theoretical framework for the relationship between acquisition of knowledge about prosthetic feet and the balance of decision-making power between clinicians and the individual with LLA: a) In the early stages, the decision-making for the foot centers on the clinician and their judgment; b) As time progresses, the prosthesis user will gain knowledge through experience with a foot, but may not have direct experience comparing different types of feet. This shift in relative knowledge may influence the individual's relationship dynamic with their clinicians related to decision-making; c) Through test-driving prosthetic feet, the prostheses user accelerates their experiential knowledge about differences between feet. The experience also invites them to take an active role in providing feedback on the prosthetic foot decision which may further affect the relationship dynamic with their clinicians; d) Ultimately, with time or because of test-driving, the individual with LLA may seek to achieve an equilibrium in their desired role for prosthetic foot decision-making. Given the extent of desired involvement varies across individuals, the balance in decision-making illustrated here indicates fulfillment of the individual's desired participation, rather than implying that equal participation in decisions is a universal goal.

Chapter 1

Introduction

This introductory chapter of my dissertation will review the background and rationale for this research, describe the evolution of my dissertation and how it relates to ongoing work that I have participated in during my graduate studies, and outline the dissertation chapters' organization that follows.

Prescription of Prosthetic Feet for People with Lower Limb Amputation

Undergoing a major lower limb amputation (LLA) can be an experience marked by tremendous uncertainty. On average, more than 350 people per day in the United States will undergo an LLA (Control & Prevention, 2020). LLA typically leads to mobility and participation limitations (Adamczyk & Kuo, 2015; Agrawal, Gailey, Gaunaurd, Gailey, & O'Toole, 2011; Boonstra, Fidler, & Eisma, 1993; Lin, Winston, Mitchell, Girlinghouse, & Crochet, 2014), as well as having negative consequences on body image and identity (Jefferies, Gallagher, & Philbin, 2018a; MacKay et al., 2020; Murray, 2009; Murray & Forshaw, 2013; Murray & Fox, 2002; Williamson, Schulz, Bridges, & Behan, 1994). Therefore, rehabilitation following LLA requires a multidisciplinary team approach to coordinate care and maximize health-related outcomes across a variety of domains (Dyer, Bouman, Davey, & Ismond, 2008; Ennion & Rhoda, 2016; MacKay et al., 2020; Ostler, Ellis-Hill, & Donovan-Hall, 2014; Potter & Scoville, 2006; Sanders, Wadey, Day, & Winter, 2021). Prescription of a prosthesis is often an essential aspect of limb loss rehabilitation because a prosthetic limb can help mitigate LLA-related impairments (Schaffalitzky, Gallagher, Maclachlan, & Ryall, 2011; Schaffalitzky, Gallagher,

MacLachlan, & Wegener, 2012; Van der Linde, Hofstad, Geertzen, Postema, & Van Limbeek, 2007).

The prosthetic foot is an integral component of a lower limb prosthesis because it transmits forces from the ground to the user's limb (Kistenberg, 2014; Stevens, Rheinstein, & Wurdeman, 2018). Optimizing the selection of a foot is important due to the functional trade-offs associated with different prosthetic foot designs. For instance, feet with greater forefoot stiffness may offer increased stability at the expense of reducing ankle range of motion and energy release during walking (Adamczyk, Roland, & Hahn, 2017; Balk et al., 2018; De Asha, Barnett, Struchkov, & Buckley, 2017; Versluys et al., 2009). Additionally, prosthetic feet with less ankle push-off work have been associated with increased frontal plane peak knee moments on the intact limb (Morgenroth et al., 2011; Underwood, Tokuno, & Eng, 2004) that are associated with knee osteoarthritis (Farrokhi, Mazzone, Yoder, Grant, & Wyatt, 2016; Morgenroth, Gellhorn, & Suri, 2012), compared to prosthetic feet with greater push-off work. Irrespective of functional trade-offs between feet, all commercial prosthetic feet are still insufficient replacements for the complex function of the biological ankle-foot.

Despite modern advancements in composite materials and microprocessor technology that attempt to approximate biological function, prosthetic feet remain inadequate. For example, commonly prescribed energy storage and release (ESR) prosthetic feet leverage material properties and design geometries to store energy during compression (i.e., stance phase of walking) and release that energy during unloading (i.e., "push-off" phase of walking). However, ESR feet cannot restore the positive power typically generated by the gastrocnemius and soleus muscles (Au, Herr, Weber, & Martinez-Villalpando, 2007; Endo, Swart, & Herr, 2009; Zelik & Adamczyk, 2016). For most commercial prosthetic feet, including ESR feet, the positive ankle

power is compromised due to the absence of ankle plantarflexor musculature. Thus, the user must compensate by generating power at more proximal joints (e.g., knee and hip) on their amputated side as well as on the contralateral leg (Hansen, Childress, Miff, Gard, & Mesplay, 2004; Russell Esposito, Aldridge Whitehead, & Wilken, 2016; Zelik & Adamczyk, 2016). While motorized prosthetic ankles achieve positive ankle power, motorized feet are limited by the heavy battery packs that need regular charging. Furthermore, reliance on sensitive electronics that may not withstand daily use is also limiting (e.g., they are affected by dirt or water in their environment). These examples of prosthetic foot technology trade-offs and limitations highlight the importance of matching the appropriate technology with the priorities, goals, and abilities of each individual with LLA to maximize their functional outcomes (De Asha et al., 2017; Klute, Kallfelz, & Czerniecki, 2001; Schaffalitzky et al., 2011; Van der Linde et al., 2007). The hundreds of commercial foot models on the market, with a range of features and associated costs, make this decision complex (Hofstad, Linde, Limbeek, & Postema, 2004; Raschke et al., 2015; Stark, 2005; Van Der Linde, Geertzen, Hofstad, Van Limbeek, & Postema, 2003, 2004).

While options for prosthetic feet have improved in recent decades (Highsmith et al., 2016; Hofstad et al., 2004; Versluys et al., 2009), the process of choosing a foot – largely on behalf of the person with LLA – has not. Prosthetic foot prescription relies almost solely on the clinician, especially in the early stages following LLA when the patient does not yet have their own experiences with a prosthesis to inform decision-making (Gallagher & MacLachlan, 2001; Ostler et al., 2014; Sansam, O'Connor, Neumann, & Bhakta, 2014). Unfortunately, scientific evidence is insufficient to establish comprehensive prosthetic foot prescription criteria for people with LLA (B.J. Hafner, 2005; Hofstad et al., 2004; van der Linde, Hofstad, et al., 2004). Furthermore, there is little published objective data about prosthetic foot mechanical properties; thus,

clinicians must rely on manufacturers' claims and learned experience about the performance of select feet. Therefore, when selecting an optimal prosthetic foot for any given patient, the onus is on the prescribing physician and prosthetist to draw on their knowledge of biomechanical principles, manufacturer-supplied prosthetic foot properties, and their own familiarity with particular foot models. Clinicians must synthesize this expertise with information from the patient's physical examination and in-depth conversations with the patient about their desired activities to best match a foot to a patient with LLA (Czerniecki, 2005; Hofstad et al., 2004; Raschke et al., 2015; Stark, 2005; Stevens et al., 2018).

When selecting a prosthetic foot, clinicians might discuss the relative benefits and shortcomings of different prosthetic feet with the patient. However, it is rare for the patient to have an opportunity to experience walking with different prosthetic feet and provide experiential input into the decision-making process. Consequently, while there is evidence to suggest that patients experience improved satisfaction or better functional outcomes when they are included in medical decision-making (Barry & Edgman-Levitan, 2012; Coulter & Collins, 2011; Joosten et al., 2008; Légaré et al., 2014; Rose, Rosewilliam, & Soundy, 2017; Truglio-Londrigan, Slyer, Singleton, & Worral, 2012), people with LLA receiving a prosthetic foot seldom have the ability to participate in this aspect of their care (Fogelberg, Allyn, Smersh, & Maitland, 2016; Murray & Forshaw, 2013; Sansam et al., 2014; Stevens et al., 2018). The current paradigm for prosthetic foot prescription can be compared to a scenario of shopping for a new car: the dealership chooses a car on the client's behalf based on their experience and best judgment of the person, without allowing the client to test-drive different vehicles for themselves. Prosthetic feet can be similar in cost to a car (on the order of thousands to tens of thousands of dollars), and people with LLA are typically only eligible for new prosthetic feet every few years, with medical justification. Thus,

the stakes for selecting a well-matched prosthetic foot are high. Notably, third-party payer guidelines often restrict eligibility across classes of prosthetic feet, depending on the healthcare and insurance system. For example, in the United States, the Center for Medicare and Medicaid Services has defined Local Coverage Determination L33787 for Lower Limb Prostheses which limits eligibility for certain prosthetic foot types and features (e.g., ESR) based on the descriptions of individual functional abilities outlined in Medicare Functional Classification Levels (i.e., K-levels) (Medicare & Services, 2016). While clinicians must adhere to the appropriate third-party payer determinations for each patient where applicable, there remain dozens of manufacturers and foot models to select from within each class of prosthetic foot devices. Furthermore, within health care systems that are not subject to these external insurance restrictions on prosthetic foot eligibility, such as the Veterans Health Administration, the range of feet to select from is even broader. Thus, an individual user's experience and input on differences they perceive between candidate feet of the same class could aid selection between foot models.

Studying a Novel Test-Drive Strategy for Prosthetic Foot Prescription

Due to the limitations of the current paradigm for prosthetic foot prescription described above, coupled with the potential to improve outcomes when patients provide input to medical decision-making, my advisor, David Morgenroth, MD, and his collaborators conceived of studying a novel test-drive strategy for prosthetic foot prescription. Dr. Morgenroth's experience as a researcher and as a physician leading multidisciplinary limb loss rehabilitation clinics (including regularly prescribing prosthetic feet) informed this ongoing line of research which was first funded in 2016.

Because prosthetic feet are one of the modular, off-the-shelf (i.e., not custom) components of a lower limb prosthesis, they could be well-suited to test-driving. One potential test-drive strategy would be for a clinical team to provide a patient with several types of commercial feet to use during a trial period – either within the clinic or at home and in the community – to determine their relative foot preferences. However, this strategy would require ordering multiple feet in the appropriate foot size and manufacturer-determined stiffness and adjusting the height and prosthetic alignment of the person's socket on each of the feet. Indeed, this process could be arduous and time-consuming for both the prosthetist and the person with LLA. Additionally, prosthetic components, including feet, that a person with LLA uses cannot be provided to another person because of the risk of performance deterioration from wear-and-tear. Thus, prosthetic feet intended for trial use would have to be designated as such and could not be sold for use in a definitive prosthesis.

An alternative approach for test-driving feet is to use a robotic prosthetic foot emulator configured to mimic the mechanical performance of different commercial prosthetic foot models. The Caplex prosthetic foot emulator (PFE) system (Humotech, Inc.; Pittsburgh, PA) is a recent technological advancement that may be capable of facilitating such a test-driving approach (Caputo, Adamczyk, & Collins, 2015; Caputo & Collins, 2014a, 2014b; Quesada, Caputo, & Collins, 2016). The PFE is a robotic foot-ankle prosthesis that offers flexible software programming for controlling the mechanical properties of the prosthetic foot end effector (Figure 1.1). Thus, the PFE could permit quick trials of multiple feet with relatively simple software and foot hardware adjustments, avoiding time-consuming and nuanced prosthetic adjustments between feet (e.g., adjusting the height and alignment) (Beck, Taboga, & Grabowski, 2016; Jonkergouw, Prins, Buis, & van der Wurff, 2016; Tafti et al., 2018). The PFE has been used

successfully to test experimental ankle push-off foot conditions in people with LLA (Caputo et al., 2015; Caputo & Collins, 2014b; Kim, Chen, Chen, & Collins, 2018; Malcolm, Quesada, Caputo, & Collins, 2015; Quesada et al., 2016). However, emulating the properties of commercial prosthetic foot models was a novel undertaking when Dr. Morgenroth proposed this approach for test-driving prosthetic feet.

Dr. Morgenroth, along with collaborators from diverse backgrounds (e.g., across academic institutions, engineering and health disciplines, and from industry), designed a study (which I will hereafter refer to as "TeD" for "Test-Drive") to evaluate test-drive strategies. Two parallel test-drive strategies for prosthetic foot prescription were studied: using commercial feet and using the PFE to emulate commercial feet. The TeD study aimed to determine whether prosthetic foot preference from in-laboratory test-driving of multiple prosthetic feet could predict longer-term foot preference after wearing each foot in the community for approximately two weeks. Participants with LLA used both the PFE and corresponding actual (i.e., commercial) prosthetic feet on different days and in a randomized order to test-drive multiple types of feet in the laboratory before wearing the actual prosthetic feet at home and in the community. Furthermore, the TeD study sought to assess whether users' preferred prosthetic feet were associated with improvements in mobility performance tests and patient-reported outcomes.

Inspiration for this Dissertation

When the TeD study was funded in 2016 through the Department of Defense (DoD) Orthotics and Prosthetics Outcomes Research Program (Award No. W81XWH-16-1-0569), Dr. Morgenroth hired me as a research assistant (RA) and became my advisor. My role as an RA was to work as the research prosthetist and lead research coordinator for the TeD study. The TeD

study suited my background researching robotic upper and lower limb prostheses, my interest in pursuing a concurrent degree in Mechanical Engineering, and my previous experience working with people with LLA both clinically and as part of human subjects research. I was interested in Dr. Morgenroth's research on test-drive strategies for prosthetic foot prescription because I value multidisciplinary problem-solving. Also, given my training in needs-based design principles, I believe that seeking the perspectives of various stakeholders is an important aspect of designing an intervention to improve health and healthcare. For instance, the TeD study leverages partnership between clinicians and engineers, addresses a needs-based clinical problem, in part with an engineering-based solution, and recognizes people with the lived experience of LLA as key informants to improving prosthetic prescription practices. With my degrees in Prosthetics and Orthotics and Mechanical Engineering, I have one foot in clinical rehabilitation and the other in engineering; one of my skills is acting as a translator between the different languages spoken in these two worlds. In my experience as an RA for the TeD study over the past four years, I have used my strengths in interdisciplinary translation and many other skills that I developed in my doctoral program. For example, I have worked alongside academic and industry collaborators to develop techniques to conduct mechanical testing of prosthetic feet, analyze the characteristics of foot mechanical properties, and design and test PFE hardware and software used in the TeD study. As part of the TeD study, I have been involved in studying the effects of test-driving prosthetic feet on a range of performance-based and patient-reported outcomes for people with LLA. My work in the TeD study allowed me to develop lines of inquiry related to, but distinct from, the ongoing test-drive strategy for prosthetic foot prescription research.

The Origins of Chapter Two – A Mechanical Testing Study of Prosthetic Feet

An important aspect of accomplishing the TeD study aims was to program the PFE to mimic the mechanical properties of commercial prosthetic foot models. I was integrally involved in developing the techniques used to collect, analyze, and export the mechanical properties of commercial prosthetic feet for use with the robotic PFE. Thus, Chapter Two of this dissertation describes the methodology of data collection and emulation of the mechanical properties of commercial prosthetic feet. In addition, Chapter Two contains the validation testing that I proposed and conducted for the PFE to assess the emulation accuracy.

Commercial Prosthetic Foot Mechanical Properties

One challenge to emulating prosthetic feet is the lack of consensus regarding the most important properties for characterizing the mechanical performance of prosthetic feet. Previous studies have attempted to correlate user perceptions with measured mechanical characteristics of commercial prosthetic feet (B. J. Hafner, 2005; Hafner, Sanders, Czerniecki, & Fergason, 2002; Halsne, Czerniecki, Shofer, & Morgenroth, 2020; Major, Twiste, Kenney, & Howard, 2011; Raschke et al., 2015; Shepherd, Azocar, Major, & Rouse, 2018). These studies demonstrate that people with LLA can detect differences in mechanical properties between prosthetic feet, but it remains unclear which properties are most relevant to the user or how variations in these properties affect clinically relevant outcomes (Adamczyk et al., 2017; Halsne et al., 2020). Regardless, evidence suggests that prosthetic foot stiffness has demonstrable effects on gait and may be important to users. For example, studies that systematically varied the stiffness of experimental feet provide valuable insight into associations between the force-displacement response of feet under load and relative benefits for gait mechanics, prosthetic foot preference,

perceived stability, and energy efficiency in people with LLA (Adamczyk et al., 2017; Fey, Klute, & Neptune, 2011, 2012, 2013; Klodd, Hansen, Fatone, & Edwards, 2010a, 2010b; Major, Twiste, Kenney, & Howard, 2014, 2016). There is also evidence to suggest consequences associated with prosthetic foot stiffness that is overly compliant or overly stiff. For example, excessively soft prosthetic forefoot stiffness has been correlated with detrimental effects on the intact limb, such as increased loading (Adamczyk et al., 2017; Fey et al., 2012; Klodd et al., 2010a) and demand on the ankle musculature (Fey et al., 2011). In contrast, excessively stiff prosthetic heel stiffness can induce knee flexion instability in the loading response period during walking, while overly forefoot stiffness can result in an excessive knee extension moment in late stance phase (Bowker & Michael, 1992).

The stiffness of the human ankle-foot can be modulated dynamically and almost instantaneously via the recruitment of muscles and modification of joint position using intricate neuromuscular feedback and feedforward control (Shumway-Cook & Woollacott, 2007). These adjustments in foot-ankle stiffness enable the performance of a great variety of actions such as maintaining balance on a moving platform and running on a compliant surface (Hof, 1998; Winter, Patla, Prince, Ishac, & Gielo-Perczak, 1998; Winters & Stark, 1988). In contrast, the vast majority of commercial prosthetic feet are passive and unable to alter stiffness (i.e., each prosthetic foot model has a foot-ankle stiffness profile determined by design geometry and material properties). The investigators in the TeD study elected to emulate foot stiffness using the PFE due to the importance of prosthetic foot stiffness as a property of interest and the range of stiffness properties observed across commercial feet.

Since commercial prosthetic feet feature a wide range of materials and designs to achieve different forefoot and heel stiffnesses (Beck et al., 2016; Beck, Taboga, & Grabowski, 2017;

Gard, Su, Lipschutz, & Hansen, 2011; Geil, 2001; Hansen, Childress, & Knox, 2004; Klute & Berge, 2004; Koehler-McNicholas et al., 2018; Versluys et al., 2009; Womac, Neptune, & Klute, 2019), it is important to match the stiffness of a prosthetic foot to best suit a given user's needs, activities and goals (e.g., body weight, activity-level, terrains frequently encountered). In addition to the wide variety of prosthetic foot models, prosthetic foot manufacturers designate a range of "stiffness categories" based on expected user body weight and activity level within individual foot models (e.g., greater stiffness to support higher body weights or activity) (Geil, 2001; Halsne et al., 2020; Womac et al., 2019). However, manufacturers do not publish objective prosthetic foot stiffness data or other mechanical property information, obscuring comparisons both within and between foot models. In the absence of these data, commercial prosthetic foot mechanical properties must be determined experimentally.

Measuring Commercial Prosthetic Foot Mechanical Properties

In order to program the prosthetic foot emulator, multiple techniques to measure commercial foot stiffness could be used. Some techniques for characterizing the behavior of prosthetic feet rely on empirical methods that include the user, while others do not, and these methods have relative strengths and weaknesses. In the TeD study, mechanical testing was used to collect user-independent commercial prosthetic foot stiffness. This decision was made because it permitted standardized data collection across different types of prosthetic feet.

An alternative approach to studying the stance phase properties of prosthetic feet is to use motion analysis to collect kinematic and kinetic data of a person walking (Caputo et al., 2015; Shamaei, Sawicki, & Dollar, 2013; Singer, Ishai, & Kimmel, 1995). This strategy offers physiological loading of each prosthetic foot for a user, which may or may not generalize to

other users (Adamczyk, Roland, & Hahn, 2013; Hansen, 2005; Hansen & Childress, 2010; Hansen & Starker, 2018). However, there are logistical and scientific barriers to deriving prosthetic foot stiffness properties from human subjects data during walking. For example, one might need a person corresponding to every foot size and body weight combination to characterize the properties of each commercial foot model across different users, which is neither pragmatic nor cost-effective. Furthermore, there are scientific considerations for this approach since gait variations observed across individuals would confound differences in prosthetic foot properties (Major, Scham, & Orendurff, 2018; Major et al., 2011). Gait variations (e.g., asymmetrical differences in step length, step time, and fluctuations in limb loading) are often exhibited by people with LLA due to the compensation strategies used to overcome the functional limitations imposed by LLA and prosthesis use. Additionally, there are recognized limitations with using inverse dynamics to evaluate prosthesis performance because segmental assumptions do not hold with respect to mass distribution and rigid bodies (Adamczyk et al., 2017; Ferris, Smith, Heise, Hinrichs, & Martin, 2017; Rusaw & Ramstrand, 2010; Sawers & Hahn, 2011). Motion analysis data collection also requires positioning reflective markers at approximate joint centers of rotation on the person's prosthesis. Markers are often placed to match the height of the malleoli on the contralateral ankle, despite the reality that most prosthetic feet exhibit instantaneous centers of rotation which move during walking and are not well-represented by assumptions of alignment with a physiological ankle (Adamczyk et al., 2017; Rusaw & Ramstrand, 2010; Sawers & Hahn, 2011). In contrast, mechanical testing procedures offer an attractive alternative for collecting data on prosthetic foot properties in a user-independent manner (details described in Chapter Two).

Once the PFE was programmed with respective stiffness data from mechanical testing of commercial prosthetic feet and the human subjects data collection began for the TeD study, we collected subjective feedback from people walking on the PFE. Feedback from participants with LLA seemed to suggest that they could distinguish between foot models (i.e., some could correctly match the emulated foot modes to the corresponding actual prosthetic feet) while walking with them, despite the fact they were blinded to foot condition and that the feet were presented in a randomized order. This feedback was encouraging since it suggested that the PFE emulated the experience of walking with the commercial prosthetic feet. However, up to this point, we had not assessed quantitatively how accurately the PFE was achieving emulation of commercial prosthetic forefoot mechanical properties.

Knowledge about the accuracy of the PFE's commercial prosthetic foot emulation could inform the interpretation of findings from the ongoing TeD study. For example, suppose the PFE mimicked the mechanical behavior of particular commercial foot models more accurately than others. In that case, the predictive validity results from TeD may be skewed by the foot model. Furthermore, assessing the accuracy of the procedures used to emulate feet in the TeD study could illuminate how to expand and improve future methods for testing and emulating commercial prosthetic feet. Therefore, Chapter Two is a mechanical testing study in which I evaluated the mechanical properties of emulated foot conditions compared to the corresponding commercial feet. This mechanical testing study permitted a user-independent assessment of the mechanical properties of the PFE and its accuracy for emulating sagittal-plane angular stiffness of commercial forefeet using the procedures described therein.

The Origins of Chapter Three – A Qualitative Study of Prosthetic Foot Prescription Experiences

While the comparison between emulated and commercial feet mechanical testing described above is important to assessing emulation accuracy quantitatively, ultimately, this line of research aims to improve the experience and outcomes of individuals with LLA. Thus, we felt it was vital to assess participants' experiences in the study to understand their perceptions of test-driving different prosthetic feet.

Another aspect of the TeD study was collecting data using patient-reported outcome measures (PROMs) to evaluate health-related outcomes (e.g., mobility, balance) and prosthetic foot preferences, in addition to performance-based outcomes. The TeD study protocol consisted of each participant attending six study visits for a total of 12-15 hours of in-person participation in study activities over several months. Consequently, I spent an extended period of time learning about each participant's experiences with prosthetic feet in my capacity as an RA conducting the study visits at the VA Puget Sound Health Care System study site. During these study visits, I began to hear unsolicited feedback from participants with LLA. They reflected on previous experiences being prescribed prosthetic feet in the clinic and compared it to the experience of test-driving prosthetic feet as part of the TeD study. Participants in TeD shared how the opportunity to test-drive different prosthetic feet felt revolutionary because many had not been able to try multiple types of feet previously. Participants also consistently commented about how their participation in the TeD study made a difference in their expectations of clinical care beyond the study because it helped them realize they wanted to be a more active part of decision-making for the choice of prosthesis components.

Deciding on behalf of the patient may lead to selecting a foot that does not optimally match their goals and preferences, which can result in dissatisfaction with the prosthesis and poor

functional outcomes (Schaffalitzky et al., 2012; Suckow et al., 2015). Satisfaction and quality of care questionnaires developed for orthotic and prosthetic populations acknowledge the importance of including the patient in the decision-making process related to equipment selection (Heinemann, Bode, & O'Reilly, 2003; Jarl, Heinemann, & Norling Hermansson, 2012; Van der Linde et al., 2007). For example, in the Orthotic and Prosthetic Users' Survey (OPUS), items in the Client Satisfaction with Services module include "Clinic staff fully informed me about equipment choices" and "I was a partner in decision-making with clinic staff regarding my care and equipment" (Heinemann et al., 2003; Jarl et al., 2012; Murray, 2013). Similarly, both patients and clinicians agree that patient input is important to the success of a prosthetic prescription, since patient satisfaction is a key determinant of success (Baars, Schrier, Dijkstra, & Geertzen, 2018; Geertzen, Gankema, Groothoff, & Dijkstra, 2002; Kark & Simmons, 2011; Schaffalitzky et al., 2011; Scherer, Sax, Vanbiervliet, Cushman, & Scherer, 2005; Van Der Linde, Geertzen, et al., 2004).

Qualitative research methods are increasingly advocated as a way to solicit prosthesis users' opinions, including the benefits and limitations to novel interventions to prosthetic care and experiences of LLA (Fogelberg et al., 2016; Gallagher, O'Donovan, Doyle, & Desmond, 2011; Littman, Bouldin, & Haselkorn, 2017; Murray, 2005; Schaffalitzky et al., 2011; Suckow et al., 2015). Qualitative research has previously examined the experiences of people with LLA regarding amputation (Murray & Forshaw, 2013), prosthesis use (Jefferies et al., 2018a; Jefferies, Gallagher, & Philbin, 2018b; Murray, 2005, 2009; Murray & Fox, 2002; Schaffalitzky et al., 2011), and communication between clinicians and patients with LLA (Messinger, Bozorghadad, & Pasquina, 2018; Murray, 2013). However, only a select number of studies have employed qualitative research methods to explore the experiences of people with LLA related to

component use, such as using prosthetic feet (Fogelberg et al., 2016; McDonald, Cheever, Morgan, & Hafner, 2019). While we were collecting data with PROMs for specific health-related constructs as part of the TeD study protocol, we did not have a way to document participants' perceptions about their experiences with prosthetic foot decision-making processes. Thus, I used qualitative research methods to explore the lived experience of prosthetic foot prescription from the perspective of people with LLA to understand how test-drive strategies compare to current prescription practices. Chapter Three is a qualitative study in which I conducted individual, semi-structured interviews with participants who had completed the in-lab portion of the TeD study protocol. This qualitative study enabled us to understand the experience of prosthetic foot prescription processes from the viewpoint of the prosthesis user. The findings complemented the quantitative data collected as part of the ongoing TeD study.

Linked-Papers Organization

I used a linked-papers organization for this dissertation. Chapters Two and Three function as standalone manuscripts due to the distinct methodologies (i.e., quantitative vs. qualitative) and the potential for somewhat different scientific audiences between the papers. In addition, the studies described within this dissertation were conducted at different times in relation to the TeD study and, thus, are organized temporally. For example, the mechanical testing described in Chapter Two was completed before initiating human subjects testing since the human subjects testing protocol for the TeD study necessitated the use of emulated commercial prosthetic foot properties using the PFE. In contrast, the qualitative research evaluating prosthetic foot prescription practices was borne out of feedback from participants during TeD human subjects

study visits. Consequently, the qualitative study was conducted more than a year after human subjects testing began for the TeD study.

The methodologies of the studies are quite different (i.e., quantitative vs. qualitative). Yet, the specific research questions and findings both serve to inform an overarching research thrust focused on using test-drive strategies for prosthetic foot prescription to improve the experience and outcomes of people with LLA. As clinicians and as scientists, we have the opportunity to use different methodologies as tools to offer complementary information from differing viewpoints and attempt to answer clinically important questions to improve outcomes for our patients. Given this overlap in introductory ideas underpinning both the quantitative (Chapter Two) and qualitative (Chapter Three) studies, there is redundancy in the discussion of background literature, motivations for studying prosthetic foot prescription practices, and description of TeD study protocols and equipment across chapters.

Between Chapters Two and Three, we conducted an entire multi-year human subjects trial across three data collection sites with approximately n=60 participants finished thus far (i.e., the TeD study). In Chapter Four, I will therefore incorporate certain summary findings from the TeD study as a means of demonstrating how the results from my dissertation relate to the overall ongoing investigation of test-drive strategies to improve prosthetic foot prescription.

References

Adamczyk, P. G., & Kuo, A. D. (2015). Mechanisms of gait asymmetry due to push-off deficiency in unilateral amputees. *IEEE Trans Neural Syst Rehabil Eng, 23*(5), 776-85.

Adamczyk, P. G., Roland, M., & Hahn, M. E. (2013). Novel method to evaluate angular stiffness of prosthetic feet from linear compression tests. *J Biomech Eng, 135*(10), 104502-5.

Adamczyk, P. G., Roland, M., & Hahn, M. E. (2017). Sensitivity of biomechanical outcomes to independent variations of hindfoot and forefoot stiffness in foot prostheses. *Hum Mov Sci, 54*, 154-71.

Agrawal, V., Gailey, R., Gaunaurd, I., Gailey, R., 3rd, & O'Toole, C. (2011). Weight distribution symmetry during the sit-to-stand movement of unilateral transtibial amputees. *Ergonomics, 54(7)*(7), 656-64.

Au, S. K., Herr, H., Weber, J., & Martinez-Villalpando, E. C. (2007). *Powered ankle-foot prosthesis for the improvement of amputee ambulation.* Paper presented at the 2007 29th Annual International Conference of the IEEE Engineering in Medicine and Biology Society.

Baars, E. C., Schrier, E., Dijkstra, P. U., & Geertzen, J. H. B. (2018). Prosthesis satisfaction in lower limb amputees: A systematic review of associated factors and questionnaires. *Medicine (Baltimore), 97*(39), e12296.

Balk, E. M., Gazula, A., Markozannes, G., Kimmel, H. J., Saldanha, I. J., Resnik, L. J., & Trikalinos, T. A. (2018). Ahrq comparative effectiveness reviews. In *Lower limb prostheses: Measurement instruments, comparison of component effects by subgroups, and long-term outcomes*. Rockville, MD: Agency for Healthcare Research and Quality (US).

Barry, M. J., & Edgman-Levitan, S. (2012). Shared decision making—the pinnacle patient-centered care.

Beck, O. N., Taboga, P., & Grabowski, A. M. (2016). Characterizing the mechanical properties of running-specific prostheses. *PLoS One, 11*(12), e0168298.

Beck, O. N., Taboga, P., & Grabowski, A. M. (2017). Reduced prosthetic stiffness lowers the metabolic cost of running for athletes with bilateral transtibial amputations. *J Appl Physiol 122(4)*, 976-84.

Boonstra, A., Fidler, V., & Eisma, W. (1993). Walking speed of normal subjects and amputees: Aspects of validity of gait analysis. *Prosthet Orthot Int, 17(2)*(2), 78-82.

Bowker, J. H., & Michael, J. W. (1992). *Atlas of limb prosthetics: Surgical prosthetic, and rehabilitation principles. 2nd ed.* St. Louis, MI: Mosby Year Book.

Caputo, J. M., Adamczyk, P. G., & Collins, S. H. (2015). Informing ankle-foot prosthesis prescription through haptic emulation of candidate devices. *IEEE Int Conf Robot Autom, 2015*, 6445-50.

Caputo, J. M., & Collins, S. H. (2014a). Prosthetic ankle push-off work reduces metabolic rate but not collision work in non-amputee walking. *Sci Rep, 4*, 7213.

Caputo, J. M., & Collins, S. H. (2014b). A universal ankle-foot prosthesis emulator for human locomotion experiments. *J Biomech Eng, 136*(3), 035002.

Control, C. f. D., & Prevention. (2020). National diabetes statistics report, 2020. *Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services*, 12-5.

Coulter, A., & Collins, A. (2011). Making shared decision-making a reality. *London: King's Fund*.

Czerniecki, J. M. (2005). Research and clinical selection of foot-ankle systems. *JPO, 17*(4), S35-S7.

De Asha, A. R., Barnett, C. T., Struchkov, V., & Buckley, J. G. (2017). Which prosthetic foot to prescribe?: Biomechanical differences found during a single-session comparison of different foot types hold true 1 year later. *JPO, 29*(1), 39-43.

Dyer, D., Bouman, B., Davey, M., & Ismond, K. P. (2008). An intervention program to reduce falls for adult in-patients following major lower limb amputation. *Healthc Q, 11*(3 Spec No.), 117-21.

Endo, K., Swart, E., & Herr, H. (2009). An artificial gastrocnemius for a transtibial prosthesis. *Conf Proc IEEE Eng Med Biol Soc, 2009*, 5034-7.

Ennion, L., & Rhoda, A. (2016). Roles and challenges of the multidisciplinary team involved in prosthetic rehabilitation, in a rural district in south africa. *Journal of multidisciplinary healthcare, 9*, 565.

Farrokhi, S., Mazzone, B., Yoder, A., Grant, K., & Wyatt, M. (2016). A narrative review of the prevalence and risk factors associated with development of knee osteoarthritis after traumatic unilateral lower limb amputation. *Mil Med, 181*(S4), 38-44.

Ferris, A. E., Smith, J. D., Heise, G. D., Hinrichs, R. N., & Martin, P. E. (2017). A general model for estimating lower extremity inertial properties of individuals with transtibial amputation. *J Biomech, 54*, 44-8.

Fey, N. P., Klute, G. K., & Neptune, R. R. (2011). The influence of energy storage and return foot stiffness on walking mechanics and muscle activity in below-knee amputees. *Clin Biomech, 26*(10), 1025-32.

Fey, N. P., Klute, G. K., & Neptune, R. R. (2012). Optimization of prosthetic foot stiffness to reduce metabolic cost and intact knee loading during below-knee amputee walking: A theoretical study. *J Biomech Eng, 134*(11), 111005.

Fey, N. P., Klute, G. K., & Neptune, R. R. (2013). Altering prosthetic foot stiffness influences foot and muscle function during below-knee amputee walking: A modeling and simulation analysis. *J Biomech, 46*(4), 637-44.

Fogelberg, D. J., Allyn, K. J., Smersh, M., & Maitland, M. E. (2016). What people want in a prosthetic foot: A focus group study. *JPO, 28*(4), 145-51.

Gallagher, P., & MacLachlan, M. (2001). Adjustment to an artificial limb: A qualitative perspective. *J Health Psychol, 6*(1), 85-100.

Gallagher, P., O'Donovan, M. A., Doyle, A., & Desmond, D. (2011). Environmental barriers, activity limitations and participation restrictions experienced by people with major limb amputation. *Prosthet Orthot Int, 35*(3), 278-84.

Gard, S. A., Su, P. F., Lipschutz, R. D., & Hansen, A. H. (2011). Effect of prosthetic ankle units on roll-over shape characteristics during walking in persons with bilateral transtibial amputations. *J Rehabil Res Dev, 48*(9), 1037-48.

Geertzen, J. H., Gankema, H. G., Groothoff, J. W., & Dijkstra, P. U. (2002). Consumer satisfaction in prosthetics and orthotics facilities. *Prosthet Orthot Int, 26*(1), 64-71.

Geil, M. D. (2001). Energy loss and stiffness properties of dynamic elastic response prosthetic feet. *JPO, 13*(3), 70-3.

Hafner, B. J. (2005). Clinical prescription and use of prosthetic foot and ankle mechanisms: A review of the literature. *JPO, 17*(4), S5-S11.

Hafner, B. J. (2005). Perceptive evaluation of prosthetic foot and ankle systems. *JPO, 17*(4), S42-6.

Hafner, B. J., Sanders, J. E., Czerniecki, J., & Fergason, J. (2002). Energy storage and return prostheses: Does patient perception correlate with biomechanical analysis? *Clin Biomech 17(5)*(5), 325-44.

Halsne, E. G., Czerniecki, J. M., Shofer, J. B., & Morgenroth, D. C. (2020). The effect of prosthetic foot stiffness on foot ankle biomechanics and relative foot stiffness perception in people with transtibial amputation. *Clin Biomech, 80*, 105141.

Hansen, A. H. (2005). Scientific methods to determine functional performance of prosthetic ankle-foot systems. *JPO, 17*(4), S23-9.

Hansen, A. H., & Childress, D. S. (2010). Investigations of roll-over shape: Implications for design, alignment, and evaluation of ankle-foot prostheses and orthoses. *Disabil Rehabil, 32*(26), 2201-9.

Hansen, A. H., Childress, D. S., & Knox, E. H. (2004). Roll-over shapes of human locomotor systems: Effects of walking speed. *Clin Biomech, 19*(4), 407-14.

Hansen, A. H., Childress, D. S., Miff, S. C., Gard, S. A., & Mesplay, K. P. (2004). The human ankle during walking: Implications for design of biomimetic ankle prostheses. *J Biomech, 37*(10), 1467-74.

Hansen, A. H., & Starker, F. (2018). Prosthetic foot principles and their influence on gait. In *Handbook of human motion* (pp. 1343-57). Cham: Springer International Publishing.

Heinemann, A. W., Bode, R. K., & O'Reilly, C. (2003). Development and measurement properties of the orthotics and prosthetics users' survey (opus): A comprehensive set of clinical outcome instruments. *Prosthet Orthot Int, 27*(3), 191-206.

Highsmith, M. J., Kahle, J. T., Miro, R. M., Orendurff, M. S., Lewandowski, A. L., Orriola, J. J., . . . Ertl, J. P. (2016). Prosthetic interventions for people with transtibial amputation: Systematic review and meta-analysis of high-quality prospective literature and systematic reviews. *J Rehabil Res Dev, 53*(2), 157-83.

Hof, A. L. (1998). In vivo measurement of the series elasticity release curve of human triceps surae muscle. *J Biomech, 31*(9), 793-800.

Hofstad, C., Linde, H., Limbeek, J., & Postema, K. (2004). Prescription of prosthetic ankle-foot mechanisms after lower limb amputation. *Cochrane Database Syst Rev*(1), Cd003978.

Jarl, G. M., Heinemann, A. W., & Norling Hermansson, L. M. (2012). Validity evidence for a modified version of the orthotics and prosthetics users' survey. *Disability and Rehabilitation: Assistive Technology, 7*(6), 469-78.

Jefferies, P., Gallagher, P., & Philbin, M. (2018a). Being "just normal": A grounded theory of prosthesis use. *Disabil Rehabil, 40*(15), 1754-63.

Jefferies, P., Gallagher, P., & Philbin, M. (2018b). Staying "just normal": Preservation strategies in prosthesis use. *Disability and Rehabilitation: Assistive Technology*.

Jonkergouw, N., Prins, M. R., Buis, A. W., & van der Wurff, P. (2016). The effect of alignment changes on unilateral transtibial amputee's gait: A systematic review. *PLoS One, 11*(12), e0167466.

Joosten, E., DeFuentes-Merillas, L., De Weert, G. H., Sensky, T., Van Der Staak, C. P. F., & de Jong, C. (2008). Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. *Psychotherapy and psychosomatics, 77*(4), 219-26.

Kark, L., & Simmons, A. (2011). Patient satisfaction following lower-limb amputation: The role of gait deviation. *Prosthet Orthot Int, 35*(2), 225-33.

Kim, M., Chen, T., Chen, T., & Collins, S. H. (2018). An ankle-foot prosthesis emulator with control of plantarflexion and inversion-eversion torque. *IEEE Transactions on robotics, 99*, 1-12.

Kistenberg, R. S. (2014). Prosthetic choices for people with leg and arm amputations. *Phys Med Rehabil Clin N Am, 25*(1), 93-115.

Klodd, E., Hansen, A., Fatone, S., & Edwards, M. (2010a). Effects of prosthetic foot forefoot flexibility on gait of unilateral transtibial prosthesis users. *J Rehabil Res Dev, 47*(9), 899-910.

Klodd, E., Hansen, A., Fatone, S., & Edwards, M. (2010b). Effects of prosthetic foot forefoot flexibility on oxygen cost and subjective preference rankings of unilateral transtibial prosthesis users. *J Rehabil Res Dev, 47*(6), 543-52.

Klute, G. K., & Berge, J. S. (2004). Modelling the effect of prosthetic feet and shoes on the heel-ground contact force in amputee gait. *Proc Inst Mech Eng H, 218*(3), 173-82.

Klute, G. K., Kallfelz, C. F., & Czerniecki, J. M. (2001). Mechanical properties of prosthetic limbs: Adapting to the patient. *J Rehabil Res Dev, 38*(3), 299-307.

Koehler-McNicholas, S. R., Nickel, E. A., Barrons, K., Blaharski, K. E., Dellamano, C. A., Ray, S. F., . . . Hansen, A. H. (2018). Mechanical and dynamic characterization of prosthetic feet for high activity users during weighted and unweighted walking. *PLoS One, 13*(9), e0202884.

Légaré, F., Stacey, D., Turcotte, S., Cossi, M., Kryworuchko, J., Graham, I. D., . . . Elwyn, G. (2014). Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database Syst Rev*(9).

Lin, S. J., Winston, K. D., Mitchell, J., Girlinghouse, J., & Crochet, K. (2014). Physical activity, functional capacity, and step variability during walking in people with lower-limb amputation. *Gait Posture, 40(1)*(1), 140-4.

Littman, A. J., Bouldin, E. D., & Haselkorn, J. K. (2017). This is your new normal: A qualitative study of barriers and facilitators to physical activity in veterans with lower extremity loss. *Disabil Health J, 10*(4), 600-6.

MacKay, C., Cimino, S. R., Guilcher, S. J. T., Mayo, A. L., Devlin, M., Dilkas, S., . . . Hitzig, S. L. (2020). A qualitative study exploring individuals' experiences living with dysvascular lower limb amputation. *Disabil Rehabil*, 1-9.

Major, M. J., Scham, J., & Orendurff, M. (2018). The effects of common footwear on stance-phase mechanical properties of the prosthetic foot-shoe system. *Prosthet Orthot Int, 42*(2), 198-207.

Major, M. J., Twiste, M., Kenney, L. P., & Howard, D. (2011). Amputee independent prosthesis properties--a new model for description and measurement. *J Biomech, 44*(14), 2572-5.

Major, M. J., Twiste, M., Kenney, L. P., & Howard, D. (2014). The effects of prosthetic ankle stiffness on ankle and knee kinematics, prosthetic limb loading, and net metabolic cost of trans-tibial amputee gait. *Clin Biomech, 29*(1), 98-104.

Major, M. J., Twiste, M., Kenney, L. P., & Howard, D. (2016). The effects of prosthetic ankle stiffness on stability of gait in people with transtibial amputation. *J Rehabil Res Dev, 53*(6), 839-52.

Malcolm, P., Quesada, R. E., Caputo, J. M., & Collins, S. H. (2015). The influence of push-off timing in a robotic ankle-foot prosthesis on the energetics and mechanics of walking. *J Neuroeng Rehabil, 12*, 21.

McDonald, C. L., Cheever, S. M., Morgan, S. J., & Hafner, B. J. (2019). Prosthetic limb user experiences with crossover feet: A pilot focus group study to explore outcomes that matter. *JPO, 31*(2), 121-32.

Medicare, C. f., & Services, M. (2016). Local coverage determination: Lower limb prostheses (l33787). *Baltimore, MD: Centers for Medicare & Medicaid Services*.

Messinger, S. D., Bozorghadad, S., & Pasquina, P. F. (2018). Social relationships in rehabilitation and their impact on positive outcomes among amputees with lower limb loss at walter reed national military medical center. *J Rehabil Med, 50*(1), 86-93.

Morgenroth, D. C., Gellhorn, A. C., & Suri, P. (2012). Osteoarthritis in the disabled population: A mechanical perspective. *PM&R, 4*(5 Suppl), S20-7.

Morgenroth, D. C., Segal, A. D., Zelik, K. E., Czerniecki, J. M., Klute, G. K., Adamczyk, P. G., . . . Kuo, A. D. (2011). The effect of prosthetic foot push-off on mechanical loading associated with knee osteoarthritis in lower extremity amputees. *Gait Posture, 34*(4), 502-7.

Murray, C. D. (2005). The social meanings of prosthesis use. *J Health Psychol, 10*(3), 425-41.

Murray, C. D. (2009). Being like everybody else: The personal meanings of being a prosthesis user. *Disabil Rehabil, 31*(7), 573-81.

Murray, C. D. (2013). 'Don't you talk to your prosthetist?'communicational problems in the prescription of artificial limbs. *Disabil Rehabil, 35*(6), 513-21.

Murray, C. D., & Forshaw, M. J. (2013). The experience of amputation and prosthesis use for adults: A metasynthesis. *Disabil Rehabil, 35*(14), 1133-42.

Murray, C. D., & Fox, J. (2002). Body image and prosthesis satisfaction in the lower limb amputee. *Disabil Rehabil, 24*(17), 925-31.

Ostler, C., Ellis-Hill, C., & Donovan-Hall, M. (2014). Expectations of rehabilitation following lower limb amputation: A qualitative study. *Disabil Rehabil, 36*(14), 1169-75.

Potter, B. K., & Scoville, C. R. (2006). Amputation is not isolated: An overview of the us army amputee patient care program and associated amputee injuries. *JAAOS, 14*(10), S188-S90.

Quesada, R. E., Caputo, J. M., & Collins, S. H. (2016). Increasing ankle push-off work with a powered prosthesis does not necessarily reduce metabolic rate for transtibial amputees. *J Biomech, 49*(14), 3452-9.

Raschke, S. U., Orendurff, M. S., Mattie, J. L., Kenyon, D. E., Jones, O. Y., Moe, D., . . . Kobayashi, T. (2015). Biomechanical characteristics, patient preference and activity level with different prosthetic feet: A randomized double blind trial with laboratory and community testing. *J Biomech, 48*(1), 146-52.

Rose, A., Rosewilliam, S., & Soundy, A. (2017). Shared decision making within goal setting in rehabilitation settings: A systematic review. *Patient Educ Couns, 100*(1), 65-75.

Rusaw, D., & Ramstrand, N. (2010). Sagittal plane position of the functional joint centre of prosthetic foot/ankle mechanisms. *Clin Biomech, 25*(7), 713-20.

Russell Esposito, E., Aldridge Whitehead, J. M., & Wilken, J. M. (2016). Step-to-step transition work during level and inclined walking using passive and powered ankle-foot prostheses. *Prosthet Orthot Int, 40*(3), 311-9.

Sanders, P., Wadey, R., Day, M., & Winter, S. (2021). Prosthetic rehabilitation in practice: An exploration of experiential knowledge in the multidisciplinary team. *Qual Health Res, 31*(2), 309-22.

Sansam, K., O'Connor, R. J., Neumann, V., & Bhakta, B. (2014). Clinicians' perspectives on decision making in lower limb amputee rehabilitation. *J Rehabil Med, 46*(5), 447-53.

Sawers, A., & Hahn, M. E. (2011). Trajectory of the center of rotation in non-articulated energy storage and return prosthetic feet. *J Biomech, 44*(9), 1673-7.

Schaffalitzky, E., Gallagher, P., Maclachlan, M., & Ryall, N. (2011). Understanding the benefits of prosthetic prescription: Exploring the experiences of practitioners and lower limb prosthetic users. *Disabil Rehabil, 33*(15-16), 1314-23.

Schaffalitzky, E., Gallagher, P., MacLachlan, M., & Wegener, S. (2012). Developing consensus on important factors associated with lower limb prosthetic prescription and use. *Disabil Rehabil, 34*(24), 2085-94.

Scherer, M. J., Sax, C., Vanbiervliet, A., Cushman, L. A., & Scherer, J. V. (2005). Predictors of assistive technology use: The importance of personal and psychosocial factors. *Disabil Rehabil, 27*(21), 1321-31.

Shamaei, K., Sawicki, G. S., & Dollar, A. M. (2013). Estimation of quasi-stiffness and propulsive work of the human ankle in the stance phase of walking. *PLoS One, 8*(3), e59935.

Shepherd, M. K., Azocar, A. F., Major, M. J., & Rouse, E. J. (2018). Amputee perception of prosthetic ankle stiffness during locomotion. *J Neuroeng Rehabil, 15*(1), 99.

Shumway-Cook, A., & Woollacott, M. H. (2007). *Motor control: Translating research into clinical practice*: Lippincott Williams & Wilkins.

Singer, E., Ishai, G., & Kimmel, E. (1995). Parameter estimation for a prosthetic ankle. *Ann Biomed Eng, 23*(5), 691-6.

Stark, G. (2005). Perspectives on how and why feet are prescribed. *JPO, 17*(Supplement), S18-S22.

Stevens, P. M., Rheinstein, J., & Wurdeman, S. R. (2018). Prosthetic foot selection for individuals with lower-limb amputation: A clinical practice guideline. *JPO, 30*(4), 175-80.

Suckow, B. D., Goodney, P. P., Nolan, B. W., Veeraswamy, R. K., Gallagher, P., Cronenwett, J. L., & Kraiss, L. W. (2015). Domains that determine quality of life in vascular amputees. *Ann Vasc Surg, 29*(4), 722-30.

Tafti, N., Hemmati, F., Safari, R., Karimi, M. T., Farmani, F., Khalaf, A., & Mardani, M. A. (2018). A systematic review of variables used to assess clinically acceptable alignment of unilateral transtibial amputees in the literature. *Proc Inst Mech Eng H, 232*(8), 826-40.

Truglio-Londrigan, M., Slyer, J. T., Singleton, J. K., & Worral, P. (2012). A qualitative systematic review of internal and external influences on shared decision-making in all health care settings. *JBI Libr Syst Rev, 10*(58), 4633-46.

Underwood, H. A., Tokuno, C. D., & Eng, J. J. (2004). A comparison of two prosthetic feet on the multi-joint and multi-plane kinetic gait compensations in individuals with a unilateral trans-tibial amputation. *Clin Biomech, 19*(6), 609-16.

Van Der Linde, H., Geertzen, J. H., Hofstad, C. J., Van Limbeek, J., & Postema, K. (2003). Prosthetic prescription in the netherlands: An observational study. *Prosthet Orthot Int, 27*(3), 170-8.

Van Der Linde, H., Geertzen, J. H., Hofstad, C. J., Van Limbeek, J., & Postema, K. (2004). Prosthetic prescription in the netherlands: An interview with clinical experts. *Prosthet Orthot Int, 28*(2), 98-104.

Van der Linde, H., Hofstad, C. J., Geertzen, J. H., Postema, K., & Van Limbeek, J. (2007). From satisfaction to expectation: The patient's perspective in lower limb prosthetic care. *Disabil Rehabil, 29*(13), 1049-55.

van der Linde, H., Hofstad, C. J., Geurts, A. C., Postema, K., Geertzen, J. H., & van Limbeek, J. (2004). A systematic literature review of the effect of different prosthetic components on human functioning with a lower-limb prosthesis. *J Rehabil Res Dev, 41*(4), 555-70.

Versluys, R., Beyl, P., Van Damme, M., Desomer, A., Van Ham, R., & Lefeber, D. (2009). Prosthetic feet: State-of-the-art review and the importance of mimicking human ankle-foot biomechanics. *Disabil Rehabil Assist Technol, 4*(2), 65-75.

Williamson, G. M., Schulz, R., Bridges, M. W., & Behan, A. M. (1994). Social and psychological factors in adjustment to limb amputation. *Journal of Social Behavior and Personality, 9*(5), 249.

Winter, D. A., Patla, A. E., Prince, F., Ishac, M., & Gielo-Perczak, K. (1998). Stiffness control of balance in quiet standing. *Journal of neurophysiology, 80*(3), 1211-21.

Winters, J. M., & Stark, L. (1988). Estimated mechanical properties of synergistic muscles involved in movements of a variety of human joints. *J Biomech, 21*(12), 1027-41.

Womac, N. D., Neptune, R. R., & Klute, G. K. (2019). Stiffness and energy storage characteristics of energy storage and return prosthetic feet. *Prosthet Orthot Int, 43*(3), 266-75.

Zelik, K. E., & Adamczyk, P. G. (2016). A unified perspective on ankle push-off in human walking. *J Exp Biol, 219*(Pt 23), 3676-83.

Tables and Figures

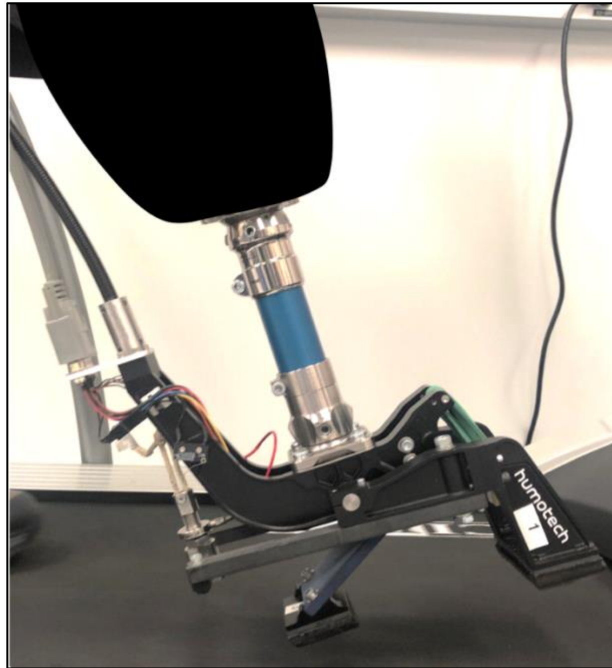

Figure 1.1. PFE end effector attached to a user's prosthetic socket.

Chapter 2

Emulating angular stiffness of commercial prosthetic forefeet using a robotic prosthetic foot emulator: a methods and validation study

Abstract

Background: Prosthetic foot selection for a person with lower limb amputation relies primarily on clinician judgment. The prosthesis user rarely has an opportunity to provide experiential input into the decision by trying different feet. The prosthetic foot emulator (PFE) is a robotic prosthetic foot capable of facilitating test-driving of prosthetic feet, which could enable prosthesis users to trial different types of feet. **Objective:** The purpose of this study was to develop and validate a procedure by which a robotic PFE could be configured to emulate the angular stiffness of a range of commercial prosthetic forefeet in a user-independent manner. Validation testing aimed to assess the agreement between the emulated foot and respective commercial foot angular stiffness. **Methods**: Mechanical testing was used to collect data on five types of commercial prosthetic forefeet across a range of foot sizes and intended user body weights. A Bezier curve was fit to ankle torque-angle data from each commercial foot to create emulated foot profiles for input to the PFE. Subsequently, the PFE was configured to mimic a subset of the tested commercial prosthetic feet, and mechanical testing was repeated with the PFE to assess the accuracy of the emulation. Linear mixed-effects regression and Bland-Altman Limits of Agreement analyses were used to compare emulated and commercial foot angular stiffness. **Results:** Angular stiffness of the emulated prosthetic forefeet were significantly associated with the corresponding commercial prosthetic forefeet ($p < .001$). Furthermore,

differences between emulated and commercial angular stiffness were independent of prosthetic foot type, foot size, or user body weight. On average, the emulated feet overestimated commercial ankle torque by less than 1%, and the Limits of Agreement were between -3.12 to +3.67 Nm (< 5% error). **Conclusions:** Configuring the PFE to mimic a subset of corresponding commercial prosthetic forefeet and replicating the mechanical testing procedures revealed close agreement in angular stiffness between the emulated and commercial forefeet under repeated mechanical testing procedures. These findings suggest the PFE is a promising tool for emulating commercial prosthetic feet to allow a foot test-driving protocol for prosthesis users.

Introduction

Prosthetic Foot Prescription

When prosthetists and prescribing physicians select a prosthetic foot for an individual with a lower limb amputation (LLA), they must integrate a variety of information to choose one that will best suit the person's abilities and functional goals. For example, clinicians use findings from the physical examination of the individual, knowledge of prosthetic foot properties and biomechanics, and familiarity with particular prosthetic feet (Czerniecki, 2005; Hofstad, Linde, Limbeek, & Postema, 2004; Raschke et al., 2015; Stark, 2005; Stevens, Rheinstein, & Wurdeman, 2018). The hundreds of commercial foot models with varying geometries, material properties, features, and costs make foot selection complex (Hofstad et al., 2004; Raschke et al., 2015; Stark, 2005; Van Der Linde, Geertzen, Hofstad, Van Limbeek, & Postema, 2003, 2004). Furthermore, while there is an abundance of comparative studies aimed at evaluating individual prosthetic foot models, reviews on the topic have determined that existing scientific evidence is

insufficient for establishing criteria to guide the prescription of prosthetic feet (Hafner, 2005; Hofstad et al., 2004; van der Linde, Hofstad, et al., 2004).

Optimizing the selection of a foot is an important aspect of prescribing a prosthesis due to the functional trade-offs associated with the mechanical performance of prosthetic feet. For instance, increased forefoot stiffness may improve stance phase stability at the expense of reduced energy return (Adamczyk, Roland, & Hahn, 2017; Balk et al., 2018; De Asha, Barnett, Struchkov, & Buckley, 2017; Versluys et al., 2009). Furthermore, given the functional trade-offs associated with mechanical properties, commercial prosthetic feet are often designed for a specific purpose (e.g., maximizing energy storage or maximizing stability). Therefore, a prosthetic foot should match the priorities, goals, and abilities of each individual with LLA to maximize the individual's participation in their desired activities (De Asha et al., 2017; Klute, Kallfelz, & Czerniecki, 2001; Schaffalitzky, Gallagher, Maclachlan, & Ryall, 2011; Van der Linde, Hofstad, Geertzen, Postema, & Van Limbeek, 2007).

Current decision-making processes for selecting an optimal prosthetic foot rely primarily on clinician judgment (Czerniecki, 2005). Consequently, persons with LLA who receive a foot may seldom be aware of potential options or understand they can participate in this aspect of their prosthetic care (Fogelberg, Allyn, Smersh, & Maitland, 2016; Murray & Forshaw, 2013; Stevens et al., 2018). In addition, there are often limited opportunities for them to provide experiential input into the decision by testing out different types of prosthetic feet. Ideally, people with LLA should play a more prominent role in determining which prosthetic foot is optimally suited to their use based on the relative impact of foot performance on outcomes that are meaningful to them (McDonald, Cheever, Morgan, & Hafner, 2019; Van der Linde et al., 2007).

Alternative Approach to Prosthetic Foot Prescription

A potential approach for involving the patient is to adopt a "test-drive" strategy for prosthetic feet. Using a test-driving strategy, patients would have an opportunity to try multiple feet before determining which one is ultimately used in their prosthesis. This approach could be accomplished using a robotic prosthetic foot emulator configured to mimic the mechanical performance of different commercial prosthetic foot models. The Caplex prosthetic foot emulator (PFE) system (Humotech, Inc.; Pittsburgh, PA) is a recent technological advancement that may be capable of facilitating test-driving (Caputo, Adamczyk, & Collins, 2015; Caputo & Collins, 2014a, 2014b; Quesada, Caputo, & Collins, 2016). The PFE is a robotic foot-ankle prosthesis that offers flexible software programming for controlling the mechanical properties of the end effector (i.e., robotic prosthetic foot). Thus, the PFE could permit quick trials of multiple feet with relatively simple software and foot hardware adjustments while avoiding more time-consuming and nuanced prosthetic adjustments between commercial prosthetic feet (e.g., adjusting the prosthesis build height and alignment) (Beck, Taboga, & Grabowski, 2016; Jonkergouw, Prins, Buis, & van der Wurff, 2016; Tafti et al., 2018). The PFE has been used previously to test experimental ankle push-off foot conditions in people with LLA (Caputo et al., 2015; Caputo & Collins, 2014b; Kim, Chen, Chen, & Collins, 2018; Malcolm, Quesada, Caputo, & Collins, 2015; Quesada et al., 2016). However, emulation of commercial feet is a novel undertaking, requiring first that the properties of prosthetic feet be measured and then used as input for the PFE to mimic the stance phase behavior of the feet during walking.

Commercial Prosthetic Foot Stiffness Properties

Although various mechanical properties describe prosthetic foot behavior, foot stiffness properties have been associated with changes in gait mechanics, prosthetic foot preference, and energy efficiency in people with LLA (Adamczyk et al., 2017; Fey, Klute, & Neptune, 2011, 2012, 2013; Klodd, Hansen, Fatone, & Edwards, 2010a, 2010b; Major, Twiste, Kenney, & Howard, 2014, 2016). In contrast to the biological ankle-foot, each commercial prosthetic foot has static stiffness properties determined by its material composition and shape. Across types of prosthetic feet, a wide range of stiffnesses have been observed (Beck et al., 2016; Beck, Taboga, & Grabowski, 2017; Gard, Su, Lipschutz, & Hansen, 2011; Geil, 2001; Hansen, Childress, & Knox, 2004; Klute & Berge, 2004; Koehler-McNicholas et al., 2018; Versluys et al., 2009; Womac, Neptune, & Klute, 2019). Given the importance of prosthetic forefoot stiffness for walking in people with LLA, we elected to emulate the stance phase stiffness of commercial prosthetic feet using the PFE (Caputo et al., 2015).

Commercial prosthetic foot stiffness properties can be measured by collecting kinematic and kinetic data of a person walking with a foot (Caputo et al., 2015; Shamaei, Sawicki, & Dollar, 2013; Singer, Ishai, & Kimmel, 1995). However, asymmetrical gait deviations and user-specific gait compensations are commonly observed in people with LLA, which could confound the measurement of foot stiffness properties (Major, Scham, & Orendurff, 2018; Major, Twiste, Kenney, & Howard, 2011). In contrast, mechanical testing procedures offer an attractive alternative for collecting data on prosthetic foot properties independent of the user.

The purpose of this study was to develop a novel procedure by which a robotic PFE could be configured to emulate the angular stiffness of commercial prosthetic forefeet in a user-

independent manner. The secondary aim of this study was to assess the accuracy of these commercial prosthetic foot emulation methods by answering the following questions:

1. Is emulated forefoot angular stiffness strongly correlated with the respective commercial prosthetic forefoot angular stiffness? (e.g., accuracy and precision)
2. Does the strength of the correlation observed between commercial and emulated prosthetic ankle torque depend on factors such as the type of prosthetic foot, the foot size, the expected user body weight, or the ankle angle position during loading?

We hypothesized that the angular stiffness of emulated prosthetic forefeet would be significantly associated with the angular stiffness of corresponding commercial prosthetic forefeet. Furthermore, we hypothesized that the magnitude of difference between emulated and commercial forefoot angular stiffness would be independent of factors such as type of prosthetic foot, foot size, or expected user body weight (e.g., load).

Methods

The equipment, mechanical testing procedures, and validation methods are described below under each subheading. First, an overview of the PFE and commercial prosthetic foot hardware is presented. Then, the mechanical testing methods used to measure commercial prosthetic foot stiffness properties are outlined. Next, a novel procedure for characterizing these foot stiffness properties and parameterizing them for input into the robotic PFE is described. Finally, validation methods repeating mechanical testing protocol with the PFE are detailed, along with an analysis of the resultant stiffness properties compared to the commercial prosthetic foot properties.

Prosthetic Foot Emulator

The PFE comprises a single-axis (1-degree of freedom [DOF]) robotic prosthetic foot with an actuated keel to control forefoot stance behavior in the sagittal plane (Figure 2.1). The heel component of the PFE is a passive fiberglass composite strut which is similar to commercial prosthetic feet. The sensors include a single-axis load cell (i.e., measuring ankle torque) and an ankle angle encoder (i.e., measuring ankle angle position). Actuation is accomplished using an off-board actuator unit located behind the user. Accordingly, the PFE is restricted to in-laboratory use on a treadmill or similar equipment. The flexible tether consists of sensor transmission lines and a Bowden cable conduit that houses a three-millimeter synthetic rope. The actuator unit includes a 3-phase electric AC servomotor powered by a variable-frequency drive. The control unit reads data from the sensors integrated within the foot and sends motor velocity commands to the actuator unit, permitting ankle torque control.

The PFE foot uses a standard prosthetic 4-hole male pyramid adapter on its proximal surface, allowing it to connect to a user's existing socket using typical endoskeletal prosthetic components. The build height of the PFE is comparable to low-profile commercial feet at 11.3 cm (4.4 in). The PFE end effector is designed to be used without a shoe because the tethered Bowden cable necessitates access to the foot without interference from footwear. The PFE contains several interchangeable hardware components, including the forefoot module length, which has four possible configurations in 1 cm increments (e.g., 26 - 29cm). Prosthetic feet have differing roll-over characteristics (i.e., effective foot lengths), which can be described by the dynamic progression of the center of pressure (COP) during stance phase (Hansen & Childress, 2010; Hansen, Sam, & Childress, 2004). Thus, the length of the PFE forefoot module for each emulated foot matches the effective foot length of the corresponding commercial feet.

Prosthetic ankle torque (τ_{ank}) of the PFE is controlled as a function of ankle angle (θ) (i.e., angular stiffness) (Caputo et al., 2015; Caputo & Collins, 2014b), which describes the dependence of ankle torque on the angular progression of the pylon as the foot undergoes loading. This characterization of ankle behavior is commonly used to reproduce the stance phase mechanical performance of commercial feet (Adamczyk, Roland, & Hahn, 2013; Hansen, Childress, Miff, Gard, & Mesplay, 2004). The desired ankle torque ($\tau_{ank,des}$) is calculated based on the ankle angle position. Ankle motor command velocities are then sent from the motor driver using proportional control of forefoot torque (Caputo et al., 2015). This input allows the PFE to be responsive to user loading and walking behavior while continuously emulating the ankle torque of a commercial foot depending on the user's ankle angle position. Adjustments made in the control software interface are responsible for altering the desired ankle torque properties for an emulated forefoot, using reference data for the respective commercial prosthetic forefoot during stance phase (Caputo et al., 2015). A finite state-machine control architecture is used to determine PFE behavior, including discrete transitions between stance and swing phases of gait. The learned torque behavior on step *n* is a function of the torque error observed on previous steps ($\tau_{ank,err}$) (Caputo et al., 2015).

Commercial Prosthetic Feet

To facilitate an inclusive test-driving strategy for users with a wide range of walking abilities, we emulated various commercial prosthetic feet intended for lower- and higher-level mobility users. Five commonly-prescribed commercial foot models were selected to represent prosthetic feet appropriate for a variety of user mobility levels: Walk-tek (Freedom Innovations; Irvine, CA), Seattle Lightfoot2 (Trulife USA; Jackson, MI), Vari-flex (Össur; Reykjavik,

Iceland), Rush HiPro (Proteor USA; Tempe, AZ), and All-Pro 8-inch (Fillauer, Inc.; Chattanooga, TN).

Several common foot sizes (i.e., 26-29 cm) for each prosthetic foot model were included to accommodate different users. In addition, all manufacturer-determined stiffness categories intended for user body weights between 58-115 kg (125-250 lbs) were tested (Table 2.1) for each combination of foot model and size. Therefore, a total of 88 prosthetic feet were mechanically tested to build a library of reference data to use as emulated foot profiles for the PFE.

Mechanical Testing of Commercial Prosthetic Feet

Reference data were collected from the commercial prosthetic feet using mechanical testing procedures. Trajectory-based displacement control was used to apply quasi-static loads to each prosthetic foot using a 6-DOF R2000 Rotopod parallel robot (Mikrolar, Inc.; Hampton, NH) with a vertically-mounted loading plate on its top surface (Figure 2.2). The prosthetic feet were attached to the steel frame of the R2000 and remained stationary throughout testing. Custom software architecture was used to control the trajectory of the R2000 to load and unload the forefoot, using the force plate surface as the loading platform. Each foot was shod with its corresponding foot shell (including a Spectra sock, if applicable) and a standardized, heel-height appropriate shoe in the respective size (Model MW577; New Balance; Boston, MA) to mimic clinical use. Thus, shoe stiffness properties were incorporated in a standard way across feet to enable the PFE to emulate the commercial foot and shoe (since the PFE cannot be used with a shoe) (Major et al., 2018). The plantar surface of the shoe was covered in a low-friction film interface to mitigate the effects of tangential shear forces and prevent over-constraining the system during testing (i.e., Shear-ban, Tamarack Habilitation Technologies; St. Paul, MN).

The R2000 is a component of the Robotic Gait Simulator (RGS) which has instrumentation capable of collecting force and moment data (Aubin, Cowley, & Ledoux, 2008; Whittaker, Aubin, & Ledoux, 2011). However, pilot data collection and testing revealed that the load measurements collected with the RGS (i.e., the center of pressure [COP] calculation derived from the vertical force plate) were subject to inertial effects during loading that could not be corrected. These effects are likely due to a lack of gravitational compensation within the integrated load cells of the force plate to account for its atypical vertical orientation. Previous data collection using this equipment to estimate angular stiffness of prosthetic feet used much slower loading rates (i.e., five mm/s, or one-quarter of the loading rate used here) and therefore likely did not encounter this particular issue (Adamczyk et al., 2013). Thus, a 6-axis load cell (MC3A, AMTI; Watertown, MA) was mounted in-line with the prosthetic foot to collect force and moment data (i.e., using a 32mm double-ended female pyramid prosthetic adapter). No pylon was used to avoid bending moments in the pylon during loading, inducing variation in the shear and normal forces.

An 8-camera motion capture system (Vicon Motion Systems Ltd.; Centennial, CO) surrounding the R2000's frame was used to track the motion of the foot and R2000 during testing, with respect to the load cell sensor origin local coordinate system. Reflective markers were placed on the loading platform, the prosthetic foot and shoe, and the load cell. A voltage trigger synced the motion capture system and load cell data collection.

Testing was performed at a discrete pylon progression angle by orienting the R2000 loading platform relative to the foot (i.e., +20° to simulate forefoot unloading) (Figure 2.2). The +20° pylon progression orientation was determined to be the minimum angle that isolated the heel's forefoot properties under full simulated body weight loading conditions. The platform was

displaced along a single axis in the direction of the pylon toward the mounted foot at a fixed rate of 20 mm/s (i.e., the fastest possible system loading rate). Each forefoot was loaded to a threshold representative of the maximum expected user body weight per manufacturer specifications for the foot model to simulate the typical ground reaction force (GRF) experienced in late stance during walking (Table 2.1) (Webber & Kaufman, 2017; Womac et al., 2019). After pilot data collection, it was discovered that users walking with the PFE achieved GRF, which exceeded the maximum loads used to characterize the forefeet during mechanical testing due to increased walking speeds relative to the rate of mechanical testing (Webber & Kaufman, 2017; Womac et al., 2019). Consequently, the PFE controller would estimate a linear extrapolation once the ankle torque surpassed the ankle torque-angle data curve, which may or may not represent the actual behavior of the respective commercial foot in this loading range. Thus, the methods were revised to increase the target load threshold during forefoot testing to 1.2 times the maximum user weight, extending the range of the torque-angle data curve. Each forefoot was loaded and entirely unloaded for six consecutive cycles. Given the viscoelastic nature of composite materials used in commercial prosthetic feet, the first three loading cycles were treated as preconditioning and discarded (Major et al., 2018). During testing, marker position data were collected at 200 Hz and smoothed using a fourth-order Butterworth filter with a cut-off frequency of 50 Hz. Load cell force and moment data were collected at 1000 Hz and resampled at 200 Hz, and no filtering was applied to these data. Finally, ankle torque-angle data from the final three loading cycles were averaged.

Determining Angular Stiffness Properties of Commercial Prosthetic Feet

The variety of commercial foot designs makes calculating forefoot angular stiffness challenging. Complex deformation of the prosthetic foot structural components occurs during loading, resulting in geometric changes and instantaneous centers of rotation that can vary across commercial feet (Adamczyk et al., 2017; Rusaw & Ramstrand, 2010; Sawers & Hahn, 2011). These qualities make it unrealistic to define a fixed ankle axis about which ankle moment can be calculated for the majority of commercial prosthetic feet. However, the PFE has a single, fixed axis of rotation; thus, a reference ankle joint location was defined with respect to the PFE axis to simplify this calculation to emulate the ankle torque behavior using the PFE. This virtual ankle joint was applied consistently across commercial feet and served as the reference for ankle torque and ankle angle calculations (i.e., the coordinates of the PFE ankle axis relative to the male pyramid adapter of each commercial prosthetic foot).

To generate the commercial foot ankle torque vs. ankle angle data, a set of equations was defined to solve for COP using inputs based on 1) load cell data (i.e., normal forces, shear forces, and moment signals), and 2) motion capture data (i.e., position of the platform and the prosthetic foot relative to the load cell origin). COP was calculated using motion capture markers to define the coordinate system for the loading platform (i.e., to constrain the calculation for COP to the surface of the platform) and prosthetic foot with respect to the load cell sensor origin. Model segments (i.e., loading platform, commercial foot, load cell) were used to compute rotational matrices to transform the GRF vector into this local coordinate system. The radius between the GRF point of application and the load cell sensor origin (r_{COP}) was determined and used to calculate the COP position required to impose those moments and forces on the load cell.

Using the COP trajectory during mechanical testing permitted calculating ankle torque and ankle angle relative to the emulator axis of rotation. Desired PFE ankle torque was computed as the cross product of the vector from the virtual PFE ankle joint axis to the COP (r_{COP}) with the GRF vector (F_{total}), or $\tau_{ank,des} = r_{COP} \times F_{total}$. Similar methods have been previously established in the literature to transform linear compression tests of prosthetic feet into angular stiffness properties based on the path of the COP during loading (Adamczyk et al., 2013).

Similarly, ankle angle was calculated by evaluating the trajectory of the COP during forefoot loading and unloading relative to the virtual ankle axis of the PFE. Ankle angle was computed using the COP, combined with the known difference in build height between the commercial prosthetic foot being tested and the PFE, to create a vector originating at the PFE virtual ankle axis terminating at the COP. Ankle angle (θ_{ank}) was defined as the angular change in this vector's trajectory due to the COP motion relative to the PFE axis, using the initial ankle position at initial forefoot contact as the reference point to define $\theta = 0°$. Nonlinear angular stiffness reference data were determined for each commercial prosthetic forefoot to represent the forefoot's unique loading and unloading behavior at a +20° pylon progression angle.

Parameterizing Angular Stiffness Properties as Emulated Prosthetic Feet for Input to PFE

A quadratic Bezier curve was fit to the data for each foot to convert experimentally derived ankle torque-angle data into a continuous function representing a "foot profile" for each commercial foot (i.e., model, size, stiffness category). A Bezier curve is a multi-valued, parametric function that follows the shape of a defining polygon. The direction of the endpoint tangent vector is the same as that of the vector determined by the first and last segments. The convex hull property for a Bezier curve ensures that the polynomial smoothly follows the control

points of the polygon, making Bezier curves well-suited for smoothing trajectories and planning paths in nonlinear robotic control systems (Choi, Curry, & Elkaim, 2008; Elhoseny, Tharwat, & Hassanien, 2018; Simba, Uchiyama, & Sano, 2016; Tharwat, Elhoseny, Hassanien, Gabel, & Kumar, 2019; Yang & Choi, 2013). In this study, the Bezier curve parameters permitted a continuous function of ankle torque-angle data capable of conforming to nonlinear data and smoothing the trajectory for robotic control.

A quadratic Bezier curve relies on three control points (i.e., P_0, P_1, and P_2) to define its polygon. The DOF were restricted to simplify the optimization of the Bezier curve fit for each commercial foot data. Specifically, the central control point (P_1) was dependent on the other two control points. P_1 was defined along a line bisecting the linear projection from P_0 to P_2 and perpendicular to its slope (Figure 2.3). The control points were determined according to the following constraints:

P_2 – defined at peak load and peak dorsiflexion angle

P_0 – optimized to improve overall Bezier curve fit, approximated minimum load, and neutral angle

P_1 – determines the concavity of the Bezier function, location dependent on the bisection of P_0 and P_2, and perpendicular distance from linear projection adjusted to match the radius of curvature (via shape parameter)

The maximum control point (P_2) was anchored at the peak of the ankle torque-angle data for each commercial prosthetic foot (i.e., maximum torque and maximum dorsiflexion angle based on COP, which occurred under peak load during mechanical testing). The third control point, P_1, was dependent on the midline between the minimum and maximum control points. Thus, the minimum control point (P_0) was allowed to shift within a constrained range to align the bisected

line with the peak concave feature of the commercial foot data and, thus, improve the overall fit of the Bezier curve. The range for P_0 was 0-10 degrees (in 0.25-degree increments) in the x-axis and 0-10 Nm (in 0.25-Nm increments) in the y-axis. We assumed that some misalignment between P_0 and the minimum point of the commercial foot data would be relatively imperceptible to the user, given it occurs at loads near zero. This misalignment was deemed acceptable to improve the representation of the Bezier curve to the commercial foot behavior during periods of weight-bearing. It was important to shift the curve to improve overall fit since prosthetic feet exhibit differing degrees of nonlinearity in the angular stiffness data, and the inflection point in the angular stiffness data curve may not align with the midpoint. The concavity shape parameter was allowed to vary in increments of 0.1 between -1 and 1 (i.e., with a shape = 1 matching a concave semicircle, and -1 a convex semicircle). By increasing the shape parameter, P_1 was perpendicularly shifted further from the linear projection between P_0 to P_2. Increasing the shape parameter expanded the width of the polygon and, therefore, the concavity of the Bezier curve.

Least-squares optimization was used to iteratively adjust the position of P_0 and the shape parameter of the Bezier curve. The optimization procedure minimized root mean square error (RMSE) between the estimated Bezier ankle torque and the commercial foot ankle torque, according to the function:

$$RMSE = \sqrt{\frac{\sum_{\theta_i=1}^{\theta_N}(\tau_{\text{comm}(\theta_i)}-\tau_{\text{Bezier}(\theta_i)})^2}{\theta_N}},$$

where θ_N = total number of measurements of commercial foot ankle torque-angle data, θ_i= each ankle angle position observed during loading with a measured ankle torque ($\tau_{\text{comm}(\theta_i)}$), and $\tau_{\text{Bezier}(\theta_i)}$ = estimated Bezier function ankle torque at the corresponding ankle angle position.

The set of control point parameters that provided the best fit to the commercial data of each foot were kept.

The pylon progression angle used during testing (i.e., +20°) corresponds to an orientation near terminal stance when the prosthetic foot is typically being unloaded to facilitate the step-to-step transition onto the contralateral limb. Hence, only the unloading portion of the ankle torque-angle data was fit with a Bezier curve and used to create the commercial foot reference data. The Bezier curve functions were then applied within the finite state-machine controller to determine the ankle torque behavior of the PFE during loading (Caputo et al., 2015).

Validation Using Mechanical Testing of Emulated Prosthetic Feet

The mechanical testing procedures described above were repeated using the PFE programmed to emulate the individual commercial feet to determine the correlation between emulated feet and the respective commercial prosthetic feet. A subset of 20 out of the 88 total emulated prosthetic feet were selected for testing; this subset included all five types of commercial feet across two sizes (i.e., 26 and 27cm). Additionally, within each foot type and size combination, two stiffness categories were selected based on different example user body weights (i.e., 175 and 200lbs). These feet and stiffness categories were chosen to assess a range of PFE hardware and software configurations and evaluate the effect of possible sources of error (e.g., the magnitude of nonlinearity, foot size) on the accuracy of the emulations.

The PFE was attached in line with the load cell with the same prosthetic adapter and aligned neutrally in all planes using the same techniques as the commercial feet. The PFE is designed to be used without footwear and therefore was tested without any. As described above, the emulation for commercial feet incorporated the properties of the standardized footwear and foot

shells used for data collection. In addition, the same low-friction film used in testing commercial feet was attached to the plantar surface of the PFE to mitigate shear forces imposed between the force plate and the tread of the PFE to avoid over-constraining the system. In preparation for each emulated foot test, the PFE was configured with the appropriate forefoot length. The respective Bezier curve reference data was then selected within the software, and the PFE motors were enabled with the controller.

The same testing equipment (i.e., R2000, 8-camera Vicon motion capture system, MC3A load cell) used during commercial foot testing were used for emulated foot testing. Reflective markers were placed in the same locations on the loading platform and the load cell. The locations of reflective markers on the PFE were intended to be similar to the commercial feet, though they differed slightly based on the absence of a shoe. The testing procedures used during commercial foot testing were replicated for emulated foot testing. Testing was performed at the same +20° pylon progression angle by orienting the R2000 loading platform relative to the PFE (Figure 2.2c). In addition to the same data collection and processing steps used for testing commercial feet, data from the PFE on-board torque sensor and ankle angle encoder were read and recorded simultaneously at 1000Hz during mechanical testing using the PFE control software.

Statistical Analyses

Correlation between emulated and commercial ankle torque

Linear multilevel models were used to test the research questions and control for non-independence in the data due to repeated measurements of prosthetic feet. A series of models were specified with pairs of emulated and commercial prosthetic feet, beginning with intercept-

only models to evaluate the intraclass correlations. Evaluations of the histograms, skewness, and kurtosis were used to check the normality of the residuals and supported the use of linear models for all outcomes defined below. Approximate effect sizes were computed for each coefficient by dividing the coefficient by the product of the standard error and square root of the total sample size.

For each foot model, the measured ankle torque (Nm) of the emulated foot and the respective commercial foot were evaluated at matched ankle angle positions (i.e., at increments of 0.01° ankle angle) across the range of unloading to assess forefoot angular stiffness properties. Linear mixed-effects regression was used to assess the association between emulated foot ankle torque (the dependent variable) and commercial foot ankle torque (the independent fixed effect) at a given ankle angle position (Davis, 2002). Prosthetic foot ID (i.e., the combination of foot type, size, and stiffness category) was modeled as a random effect given the paired, repeated measures nature of the data. Ankle torque is dependent on ankle angle position; thus, a commercial ankle torque by ankle angle (degrees) interaction term was used to account for this relationship. Likelihood ratio tests were carried out to assess the mean correlation between emulated and commercial feet ankle torque. Effect modification due to ankle angle was examined by testing the significance of the interaction term. Results were summarized as the slope of change across ± standard error (SE), 95% confidence intervals (CI), and marginal R-squares (R^2). Thus, the linear mixed model 1 was of the form:

$$\text{AnkleTorque_Emulated}_{ij} = \gamma_{00} + \gamma_{10}*\text{AnkleTorque_Commercial}_{ij} + \gamma_{20}*\text{ZAnkleAngle}_{ij} + +\gamma_{30}*\text{AnkleTorque_Commercial}_{ij}*\text{ZAnkleAngle}_{ij} + U_{0j} + r_{ij} \quad \textbf{(1)}$$

In model 1 above, the ith measurement of emulated foot ankle torque within the jth prosthetic foot ID is equal to the sum of the conditional mean (γ_{00}), the unique effects of the corresponding

commercial foot ankle torque and ankle angle position, ($\gamma_{10} - \gamma_{20}$), their two-way interaction (γ_{30}), and the residual error between prosthetic feet (U_{0j}) and within feet (r_{ij}). Approximate R^2 values were computed as the fitted variance divided by the sum of the fitted variance, prosthetic foot variance, and residual variance. All analyses were carried out using R 4.0.2 (Team, 2018) and packages lme4, lmerTest, and emmeans.

Assessing agreement between emulated and commercial ankle torque measurements

There are several methods for assessing agreement between clinical device measurements, including the Bland-Altman analysis method, which allows for direct comparison of the agreement between devices in terms of the original units. Bland and Altman proposed the limits of agreement (LoA) method in their 1986 paper (Bland & Altman, 1986) as an alternative to correlation-based methods, which they posited do not accurately characterize agreement (Bland & Altman, 1990, 1999). Instead, the limits of agreement quantify the dispersion among the paired differences. The wider the LoA, the more dissimilar the measurements between the emulated and commercial device conditions are expected to be, suggesting a lack of agreement (Bland & Altman, 1986; Parker, Scott, Inácio, & Stevens, 2020). For the limits of agreement method, the linear mixed-effects model is fitted to "paired differences" denoting the between-device condition differences measured at the same ankle angle in each foot.

Letting D_{ij} be the difference between commercial-emulated ankle torque for foot i at ankle angle j (i.e., $D_{ij} = Y_{ij2} - Y_{ij1}$), these paired differences were modeled through the following linear mixed-effects model 2:

$$D_{ij} = \mu^* + \alpha_i^* + \gamma_j^* + \varepsilon_{ij}^*, \qquad \textbf{(2)}$$

where μ^* is the overall mean of the between-condition differences (i.e., mean bias between devices), $\alpha_i^* \sim N(0, \sigma_{\alpha^*}^2)$ is the random effect of the ith prosthetic foot ID, $\gamma_j^* \sim N(0, \sigma_{\gamma^*}^2)$ is the random effect of the jth ankle angle position, and $\varepsilon_{ij0}^* \sim N(0, \sigma_{\varepsilon^*}^2)$ is the residual error. The asterisks distinguish the quantities in Eq 2 from their counterparts in Eq 1, which are defined in terms of device measurements (as opposed to differences between devices). The benefit of using Eq 2 is that the normality assumption is less likely to be violated if it is based on the differences in outcomes (Parker et al., 2020). Specifically, residuals associated with the differences in the measurements can be represented by a normal distribution even if the residuals associated with the raw torque measurements cannot. The LoA were then calculated as

$$LoA = \mu^* \pm\ 1.96 * \sqrt{\sigma_{\alpha^*}^2 + \sigma_{\gamma^*}^2 + \sigma_{\varepsilon^*}^2}$$

with the square root of the total variance providing an estimate of the standard deviation for the Bland-Altman LoA formula, with consideration for repeated measurements within each prosthetic foot (Bland & Altman, 1986, 2007). LoA can be interpreted relative to thresholds of minimal detectable change for the outcome. Bland-Altman plots were created to visualize the extent of agreement between emulated and commercial foot measured torque further. The differences between corresponding pairs of measurements were plotted on the y-axis, and the mean of corresponding pairs of measurements plotted on the x-axis. All analyses were carried out using R 4.0.2 (Team, 2018), and packages redres, lme4, and BlandAltmanLeh.

<u>Assessing the effects of factors on differences between emulated and commercial ankle torque</u>

A third linear mixed-effects regression model was used to assess the difference between emulated and commercial feet and to evaluate further what factors predicted the magnitude of the difference between emulated and commercial feet. Ankle torque difference (Nm, dependent

variable) between the commercial forefeet and respective emulated foot was calculated across the loading range. Ankle angle position was treated as a fixed effect (in 0.01-degree increments, independent variable) in the model to determine whether the agreement between emulated and commercial foot angular stiffness differed based on the region of the ankle torque-angle curve. Prosthetic foot ID was modeled as a random effect. Foot type (i.e., five levels), foot size (i.e., two levels), and intended user body weight (i.e., two levels) were fixed-effect covariates, modeled as categorical and effect coded. Foot type resulted in four dummy variables with Walk-tek used as the reference levels for effect-coded terms. Interaction terms for foot type, foot size, and intended user body weight were included to test for effect modification. Likelihood ratio tests were carried out to assess if the mean difference in ankle torque between emulated and commercial feet differed from zero and to test for variability in slopes across foot types, sizes, or intended user body weight. Results were summarized as the slope of change across ± standard error (SE), 95% CI, and marginal *R*-squares (R^2). The resulting model 3 used to evaluate the effects of factors on the difference between commercial-emulated ankle torque measurements was as follows:

$$\text{(Commercial-Emulated) AnkleTorque}_{ij} = \gamma_{00} + \gamma_{10}\text{*ZAnkleAngle}_{ij} + \gamma_{01}\text{*SeaLightftEff}_j + \gamma_{02}\text{*VariflexEff}_j + \gamma_{03}\text{*RushEff}_j + \gamma_{04}\text{*AllProEff}_j + \gamma_{05}\text{*FtSizeEff}_j + \gamma_{06}\text{*BodyWtEff}_j + U_{0j} + r_{ij} \quad \textbf{(3)}$$

In model 3 above, the ith measurement of ankle torque within the jth prosthetic foot ID is equal to the sum of the conditional mean difference (γ_{00}), the unique effects of ankle angle position, prosthetic foot type, foot size, and body weight ($\gamma_{10} - \gamma_{06}$), and the residual error between prosthetic feet (U_{0j}) and within feet (r_{ij}). Approximate R^2 values were computed as the fitted variance divided by the sum of the fitted variance, prosthetic foot variance, and residual

variance. All analyses were carried out using R 4.0.2 (Team, 2018), and packages lme4, lmerTest, and emmeans.

Quantifying the Quality of the Bezier Curve Fit to Commercial Ankle Torque-Angle Data

The difference in area between the torque-angle curve of the commercial foot data and the respective Bezier curve was calculated to quantify the relative error in the Bezier curve fit. Trapezoidal integration was used to calculate the area under the ankle torque-angle curves. The absolute difference between curve areas was calculated as a percent difference in the Bezier curve compared to the respective commercial foot data (i.e., regardless of the Bezier curve angular stiffness being greater or lesser than the commercial foot properties) (Figure 2.4).

To further investigate the source of differences in the quality of Bezier curve fit across commercial feet, features of the nonlinear experimental data were defined and quantified. "Peak bend" was calculated to represent the relative degree of nonlinearity by assessing the maximum perpendicular distance between the commercial forefoot curve and the linear projection from P_0 to P_2, which defined the Bezier curve (Figure 2.5a). This distance was normalized to the length of the segment (i.e., from P_0 and P_2) such that a value of 100% would indicate a peak bend magnitude equal to half the length (i.e., radius) of the segment. In other words, the nonlinearity of the commercial forefoot data could be perfectly represented by a semicircle (Figure 2.5b). Additionally, the peak bend location "offset" was calculated relative to the midpoint between P_0 and P_2 (Figure 2.5a). This offset was calculated as the distance translated from the midpoint of the segment to the peak bend in the commercial foot data curve. This offset distance was normalized to the length of the segment such that a value of 0% offset would indicate a foot with peak bend located at the midpoint between P_0 and P_2 (i.e., no offset, thus the data could be

perfectly represented by the current Bezier curve fitting technique). In comparison, a value of 50% offset would represent a foot with peak bend located halfway between P_0 and the midpoint (Figure 2.5c).

Results

Mechanical Testing of Commercial Prosthetic Feet

All 88 commercial prosthetic feet exhibited nonlinear angular stiffness behavior during forefoot loading and unloading. A range of angular stiffness was observed across the different commercial forefeet by foot type (Figure 2.6). For example, some commercial feet had substantially lower overall angular stiffness than other types (as demonstrated by more displacement under similar loads or less steep slopes). There was a general increase in angular stiffness with increasing manufacturer stiffness category within each foot type (i.e., higher stiffness category feet exhibited stiffer forefoot properties).

Parameterization of Commercial Prosthetic Feet

Least-squares optimization of the Bezier curve control points to minimize the root mean square error (RMSE) in the parameterization resulted in all Bezier curves having R^2 values greater than 0.99 (Figure 2.7, Table 2.2). On average, the R^2 of the Bezier curves compared to the plotted commercial foot stiffness data were 0.998 ± 0.001 across all foot types, foot sizes, and user body weights.

Correlation between Emulated and Commercial Angular Stiffness Properties

The mean difference in measured ankle torque between emulated and commercial prosthetic feet was -0.76 ± 1.73 Nm (-1.0 ± 2.5%) across all ankle angle positions for all foot types, foot sizes, and stiffness categories (Figure 2.8, Table 2.3). Across types of prosthetic feet, the range of differences in forefoot ankle torque was -1.75 ± 2.07 Nm (i.e., for the Walk-tek) to +0.32 ± 1.39 Nm (i.e., for the All-Pro). A negative difference indicated the commercial prosthetic foot torque had a smaller magnitude than the respective emulated foot at a given ankle angle position (i.e., commercial-emulated).

For model 1 (i.e., assessing correlations between commercial and emulated foot ankle torques), the means, standard deviations, and zero-order correlations among all variables are given in Table 2.4. All correlations were significant. Both predictors (i.e., commercial prosthetic foot ankle torque in Nm, ankle angle position in degrees) were significantly correlated with the outcome (i.e., emulated prosthetic foot ankle torque in Nm) but were also correlated with each other and thus may not uniquely predict simulated foot ankle torque. The intercept-only (or "empty") model was specified to evaluate the intraclass correlations (ICCs). The ICC for ankle torque measurements within each pair of prosthetic feet (i.e., corresponding emulated and commercial feet) was 0.046. This ICC indicates that only 4.6% of emulated ankle torque variance can be explained by the specific foot it was emulating (i.e., within-cluster effect).

Next, predictors were added to the model. As shown in Table 2.5 (model 1a, first set of columns), only the paired commercial foot ankle torque predictor was added to the model first. This predictor was added to the model to assess the correlations between commercial and emulated ankle torques before controlling for other factors beyond repeated measurements. The mean estimate of emulated foot ankle torque when commercial ankle torque was zero was 0.76

Nm (i.e., intercept). The slope coefficient indicates that for each 1 Nm increase in commercial foot ankle torque, there was an estimated increase of 1 Nm in emulated foot ankle torque. The approximate variance explained by this predictor was 99.2%, which is 94.6% more than the intercept-only model.

Next, the ankle angle position for the ankle torque measurements was added to the model. As shown in Table 2.5 (model 1b, second set of columns), both commercial foot ankle torque and ankle angle position were significant ($p < .001$). The approximate variance explained with this set of predictors was 99.5%, which is 0.3% more than the previous model. The likelihood ratio test (LRT) comparing this model to the previous was significant and favored the more complex model. The BIC value also decreased by 6733 points, indicating that the model with the additional predictor improved model-data fit. The interaction between commercial ankle torque and ankle angle position was also significant ($p < .001$). Given the quite small remaining unexplained variance (<0.5%), additional models which added prosthetic foot-level predictors (i.e., foot type, foot size, user body weight) did not improve model fit, and these more complex models were not favored based on LRT or BIC values.

In examining the coefficients for the final model 1b, commercial foot ankle torque and ankle angle position had significant correlations with emulated foot ankle torque ($p < .001$). For each 1 Nm increase in commercial foot ankle torque, there was an estimated increase of 0.96 Nm in emulated foot ankle torque, holding all else constant. Similarly, for each SD increase in ankle angle position (with higher values representing greater dorsiflexion), there was an increase of 3.04 Nm emulated foot ankle torque, holding all else constant, demonstrating greater ankle torque measurements under greater forefoot deflection. Furthermore, the two-way interaction was significant, indicating that the relationship between commercial and emulated feet depends

on the ankle angle position during loading. To understand the nature of this interaction, model-implied values were computed for five levels of ankle angle position (-2 *SD,* -1 *SD*, mean, +1 *SD*, and +2 *SD*) across a range of commercial ankle torque values (0-120 Nm). As shown in Figure 2.9, the interaction was disordinal, with the least amount of difference between emulated and commercial ankle torque near the mid-range of ankle torque (approximately 60Nm, on average). Larger magnitude differences were observed near the extreme ends of ankle torque (near zero and peak torque) but in equal and opposite directions depending on the ankle angle position.

Assessing Agreement between Emulated and Commercial Ankle Torque Measurements

Bland-Altman analysis was conducted to quantify the agreement between the emulated and commercial forefeet angular stiffnesses. Repeated measures were taken into account using the linear mixed-effects regression model 2 (i.e., Bland-Altman Limits of Agreement analysis). Diagnostic plots were evaluated for violation of normality assumptions. A mean bias of 0.76 Nm in ankle torque between the commercial and emulated device conditions was observed. The 95% CI for estimated LoA was -3.12 to +3.67 Nm. Bland-Altman plots were created for each prosthetic foot to complement the numerical results, displaying the between-device differences in ankle torque against the mean ankle torque to visualize the spread between emulated and commercial foot properties (Figure 2.10).

Assessing Effects of Factors on Difference between Emulated and Commercial Ankle Torque

To evaluate the factors associated with the magnitude of the differences between emulated and commercial feet, differences in ankle torque between emulated and commercial prosthetic

forefeet were evaluated (commercial-emulated) in model 3. The means, standard deviations, and zero-order correlations among all variables are given in Table 2.6. Many correlations were significant. All predictors were significantly correlated with the outcome (i.e., differences in ankle torque in Nm) but were also correlated with each other and thus may not uniquely predict the difference in ankle torque. As above, the intercept-only (or "empty") model was specified to evaluate the ICCs. The ICC for differences in ankle torque measurements within each pair of prosthetic feet was 0.280. This ICC indicates that 28.0% of differences in ankle torque variance can be explained by the specific prosthetic foot it was emulating (i.e., within-cluster effect).

Next, predictors were added to the model, as shown in Table 2.7 (model 3a, first set of columns). The ankle angle position predictor was added to the model first to assess the effects of measurement-level (level 1) predictors. Similar to the previous estimate, the mean estimate of differences in foot ankle torque was -0.76 Nm (i.e., intercept). The approximate variance explained by this predictor was 24.0%.

Next, prosthetic foot-level predictors (i.e., level 2: foot type, foot size, example user body weight) were added to the model. As shown in Table 2.7 (model 3b, second set of columns), ankle angle position was significantly correlated with differences in ankle torque measurements between devices ($p < .001$). The slope coefficient indicates that for each SD increase in ankle angle position (i.e., more dorsiflexed), there was an estimated increase of 0.38 Nm difference in ankle torque, holding all else constant. In contrast, none of the prosthetic foot-level predictors were significantly associated with differences between emulated and commercial angular stiffnesses. The approximate variance explained with this set of predictors was 32.0%, which is 8% more than the previous model. The likelihood ratio test (LRT) comparing this model to the

last was significant and favored the more complex model. The BIC value also decreased by 46 points, indicating that the model with the additional predictors improved model-data fit.

Quantifying the Quality of the Bezier Curve Fit to Commercial Ankle Torque-Angle Data

Beyond the statistical analyses, plotting the commercial and emulated forefoot data along with the Bezier curve provides another layer of interpretation regarding the quality of agreement in the data. Upon visual inspection, it is apparent that not all Bezier curves fit the experimental commercial forefoot data equally well (Figures 2.7, 2.11), despite similar R^2 values. For example, in Figure 2.7d, there is more distance between the Bezier curve and the commercial foot data than is observed in Figure 2.7a. The larger difference in area between the curves by foot model can also be observed in Figures 2.11c and 2.11d compared to Figure 2.11b. The mean difference in total area between the commercial foot data and the Bezier curve was 4.4 ± 2.0%, and the differences varied by prosthetic foot type (range: 2.3 - 6.1%) (Table 2.8). In contrast, the mean area difference between the emulated foot condition and the Bezier curve (which was used as the PFE control input) was 1.1 ± 0.5%. Consequently, the resulting mean difference in area between the commercial and emulated feet was 4.1 ± 1.4% since the emulated forefoot properties are determined by the Bezier curve (range: 2.9 - 5.9%).

Examining the nonlinear features among commercial prosthetic forefoot data also revealed differences by prosthetic foot type (Figure 2.12, Table 2.9). As can be observed in Figure 2.12a compared to 2.12b, some types of prosthetic feet demonstrated larger peak bend (in blue) or greater offset from the midpoint (in red), which impacted the quality of the resultant Bezier curve fit. The mean magnitude of peak bend in the commercial foot curves was 7.8 ± 0.9% (range: 5.9 – 12.9%), with larger values representing more nonlinear behavior. The mean offset from the

midpoint axis of the Bezier curve control point was 32.1 ± 11.8% (range: 16.0 – 45.9%), with larger values representing more skewed behavior.

Discussion

The purpose of this study was to develop a procedure by which a robotic PFE could be configured to mimic the angular stiffness properties of commercial prosthetic forefeet in a user-independent manner. Furthermore, the procedures were validated by comparing commercial prosthetic forefoot properties to the corresponding emulated forefoot properties across a range of foot types, foot sizes, and example user body weights. Overall, the methods presented in this study provided an accurate (within <5%) estimation of commercial prosthetic forefoot angular stiffness properties using the PFE at a pylon progression angle representative of late stance phase (i.e., +20°).

Mechanical testing procedures were used to collect angular stiffness data for five types of commercial prosthetic forefeet across a range of foot sizes and user body weights. The advantages of mechanical testing were the uniformity and reproducibility in data collection instead of the variability associated with collecting data while a user walks in a motion analysis laboratory (Major et al., 2018; Major et al., 2011). Feasible solutions for characterizing and emulating the behavior of prosthetic feet relied upon testing each foot in a controlled environment and measuring how the foot responds under load. Such precise control over confounding individual variables was facilitated by standardized mechanical property data collection across commercial prosthetic feet, regardless of foot type, size, or intended user body weight (Hansen & Starker, 2018; Major et al., 2011).

Similar mechanical testing procedures have frequently been used to estimate and quantify the stiffness properties of commercial and experimental prototype prosthetic feet (Adamczyk et al., 2013; Beck et al., 2016; Klute, Berge, & Segal, 2004; Koehler-McNicholas et al., 2018; Major et al., 2018; Major et al., 2011; Mason, Pearlman, Cooper, & Laferrier, 2011; Webber & Kaufman, 2017; Womac et al., 2019). The methods described in the current study used a single pylon progression angle to perform quasi-static testing in a manner that isolated the properties of the forefoot, which is a common approach (Major et al., 2018; Webber & Kaufman, 2017).

Bezier curves were fit to the data to transform the mechanical testing data from commercial prosthetic feet into a continuous function for input to the PFE. These curves provided an effective method for parameterizing the experimental data, with R^2 values exceeding 0.99 for all tested commercial prosthetic feet. Previous studies estimating angular stiffness of prosthetic feet with a linear representative model have established RMSE values of less than 5% between the estimated ankle stiffness and observed data (Adamczyk et al., 2013, 2017; Rouse, Hargrove, Perreault, Peshkin, & Kuiken, 2013). Therefore, the nonlinear Bezier curves used to fit the data in this study improved the representation of commercial foot angular stiffness properties, reducing the RMSE to approximately 0.2%.

Agreement between Emulated and Commercial Foot Ankle Torque Measurements

This study revealed close agreement in forefoot angular stiffness properties between the emulated feet and the respective commercial prosthetic feet. Measured ankle torque of emulated feet was significantly correlated with measured ankle torque of commercial feet ($p < .001$). On average, the emulated feet overestimated ankle torque compared to the commercial feet by less than 1 Nm (i.e., 0.76 Nm) at a given ankle angle position during loading. This difference

corresponded to a mean difference of 1% in angular stiffness, which is substantially smaller in magnitude and percentage than values previously observed for differences in estimating ankle angular stiffness (Adamczyk et al., 2013; Rouse et al., 2013).

A mean bias of 0.76 Nm in ankle torque was observed between the commercial and emulated conditions (i.e., same as the intercept established using linear mixed-effects regression above). The associated LoA were -3.12 to +3.67 Nm, within 95% confidence. These limits are centered around zero and substantially smaller than the total range of observed ankle torque values (e.g., 0-100 Nm). These findings support the accuracy of the emulated torque values across the ankle torque range. It is important to note that the calculated LoA are estimates; thus, different samples from the overall population of commercial prosthetic feet may produce other limits. In addition to mean bias, calculation of confidence intervals is recommended to improve the interpretation of agreement (Hamilton & Stamey, 2007; Parker et al., 2020). Furthermore, the LoA must be compared with respect to clinically relevant differences in the outcome. While meaningful differences in prosthetic foot angular stiffness properties have not been established, there is evidence that the threshold for detecting a change in angular stiffness properties is 7.7 ± 1.3% (with 75% accuracy) for people with LLA walking with an experimental prosthetic foot (Shepherd, Azocar, Major, & Rouse, 2018). Therefore, it can be reasonably assumed that a difference of 1% between the emulated and commercial forefoot would not be perceptible to the user. Importantly, the slight offset in angular stiffness properties between emulated and commercial feet appeared consistent across types and sizes of feet, on average, regardless of foot model. Together, these findings support the accuracy of the emulated forefeet angular stiffness relative to commercial feet.

Effects of Factors on Difference between Emulated and Commercial Ankle Torque

Results demonstrated a close match between emulated and commercial foot angular stiffness. Commercial foot torque alone accounted for more than 99% of the variance in emulated foot torque before controlling for other variables. However, the interaction between commercial foot ankle torque and ankle angle position was also significant, suggesting that the correlations between emulated and commercial feet varied depending on how dorsiflexed the foot was under load. Similarly, ankle angle position was significantly associated with the differences in torque between emulated and commercial feet, and ankle angle alone was responsible for 24% of the variance in the differences. Examining this disordinal interaction revealed that differences in torque did not uniformly increase or decrease with ankle angle position but had a more nuanced relationship (Figure 2.9). The largest differences were exhibited, in opposite directions, at both extremes in ankle angle position, while differences near the middle of the angle and torque ranges were smallest. Examinations of the Bland-Altman plots were consistent with this interaction observation, with larger mean differences observed at ankle torque extremes for all prosthetic feet. Given that the emulated feet are based on Bezier curves fit using least-squares optimization, the nature of the curve fitting process (i.e., minimizing total RMSE, rather than differences in the area between curves) explains this unusual pattern of discrepancies. For instance, least-squares methods permit larger RMSE near the curve ends as long as the overall difference is balanced in the opposite direction across the range of ankle torque and ankle angle.

Beyond the noted effects of ankle angle, none of the correlations between commercial and emulated feet were affected by foot type. These findings suggest that emulation accuracy is not dependent on the particular type of prosthetic foot, size of foot, or user body weight (i.e., prosthetic foot stiffness category).

Quality of the Bezier Curve Fit to Commercial Ankle Torque-Angle Data

While all commercial feet had similar R^2 values for the fit of the Bezier curve, an inspection of the Bezier curves compared to the respective commercial foot data revealed differences across prosthetic feet. The use of least-squares optimization to minimize the RMSE permitted Bezier curves to deviate from the commercial foot data so long as the differences were balanced on either side of the curve. Thus, the R^2 value may not adequately capture relative differences in the quality of fit across prosthetic feet since it relies on RMSE rather than other metrics that can be used to understand discrepancies in curve fitting (e.g., the difference in total area between curves).

Differences in the quality of the Bezier curve fit varied by foot type when evaluated in terms of the area difference between the commercial foot data and the Bezier curve. For example, the Seattle Lightfoot2 had differences in the total area that were twice as large as the Vari-flex and Rush HiPro, on average. These findings illustrate the limitations of least-squares optimization for determining the control points and shape parameters of the Bezier curves. Thus, the nonlinear behavior of these angular stiffness data may be better suited to an alternative curve-fitting optimization strategy, such as minimizing the total difference in area between curves.

To examine the underlying cause of the differences in quality of Bezier fit by prosthetic foot type, features related to the extent of nonlinearity of the commercial foot data were quantified, such as the maximum degree of bend (i.e., peak) in the data and the location of this peak bend with respect to the midpoint of the Bezier curve (i.e., offset). The quadratic Bezier curve was restricted in its definition to a single shape parameter applied at the midpoint (P_1) between the minimum (P_0) and maximum (P_2); thus, a greater offset in the peak bend location in combination

with a larger magnitude of peak bend could compromise the quality of the Bezier curve representation. Evaluating the relationship between nonlinear features and the quality of the Bezier curve revealed differences by foot type, normalized to the length of each respective commercial foot data (i.e., prosthetic feet with shorter lines and less displacement were not penalized). For example, feet like the Seattle Lightfoot2 and Walk-tek had higher values for offset from midpoint (i.e., 45.9% and 41.4%, respectively) and showed more skewed commercial foot data than feet with lower offset values, such as the Rush HiPro (i.e., 16.0%). In these cases, the Bezier curve fit was limited by the alignment between the P_1 point, where the shape parameter was applied, and the commercial data peak. Consequently, the differences in the total area observed between the curves were greater. In contrast, the All-Pro did not have as large offset values (i.e., 28.5%) but had larger magnitude peak bends, on average (12.9% compared to 6.3% Rush HiPro). Therefore, the total difference in the area was larger than the Rush HiPro or Vari-flex.

It is important to note that the overall correlations between emulated and commercial foot angular stiffness data were significant. Differences in angular stiffness were less than 1% and did not vary by prosthetic foot type, despite these relative differences in quality of Bezier curve fit across prosthetic feet. The differences between curves were still small compared to the total angular stiffness values.

Limitations and Future Directions

As with any study, there are limitations to the methods and results presented in this study. Future research should address these limitations and systematically evaluate their implications on

using the PFE to emulate the forefoot angular stiffness of commercial prosthetic feet. Specific limitations and suggested areas for future work are discussed in detail below.

<u>Mechanical testing of commercial prosthetic feet: limitations and future directions</u>

Quasi-static testing in this study was limited to a single pylon progression angle to collect angular stiffness data on commercial prosthetic feet. This pylon orientation was selected to isolate the forefoot properties of commercial prosthetic feet because the PFE is restricted to actuating the forefoot section. Therefore, 20° corresponds to a period late in stance phase when the prosthetic foot is being unloaded. There are limitations associated with this decision because prosthetic feet are not loaded vertically, nor are they loaded at a fixed orientation during typical use. Instead, the user's foot stiffness during walking depends on dynamic properties such as walking speed, foot orientation relative to the ground, and loading rate (Adamczyk et al., 2017). While these aspects are not captured with quasi-static mechanical testing procedures like those used in this study, we feel that the strengths of mechanical testing outweighed the limitations. Compared to data collection with human subjects walking with prosthetic feet, standardized mechanical testing protocols ensure consistency across prosthetic foot models and permit direct comparison between feet irrespective of individual gait deviations.

Given the limitations of the mechanical testing used for this study, the angular stiffness measured in this study may not generalize to other loading rates (e.g., differences in loading rates and patterns across users). A constant rate of 20 mm/s was used during testing in this study. This loading rate was two to four times faster than rates previously used to collect mechanical testing data on prosthetic feet (Adamczyk et al., 2013, 2017; AOPA, 2010; Beck et al., 2016; Major et al., 2018; Major et al., 2011, 2014; Womac et al., 2019), and is thus a closer approximation of

loading rates generated during walking. However, it is still slower than physiological loading based on visual observation. Furthermore, people with LLA will exhibit a range of loading rates during walking that vary from the rate used for mechanical testing data collection. It is unknown how well the PFE will represent the corresponding commercial feet when subjected to different loading rates. Commercial prosthetic feet exhibit viscoelastic behavior due to their material composition, which was not captured by constant rate mechanical testing procedures used to define emulated feet. Future research should systematically examine the effect of loading rate on measured stiffness of commercial prosthetic feet.

In addition, the commercial foot angular stiffness from this study may not represent stiffness at other stance phase pylon progression angles (e.g., stiffness of the hindfoot during early stance). The measured angular stiffness at this 20° orientation likely underestimated the stiffness of the prosthetic feet at other pylon progression angles. For example, at progression angles nearer midstance, the COP does not have such a large radius to impart deflection of the forefoot under load since both the heel and forefoot are undergoing loading. In contrast, later in stance phase, the forefoot is isolated and deflects more under load, which results in decreased measured stiffness. These fluctuations in angular stiffness across stance phase (i.e., stiffer behavior in midstance compared to late stance) have been observed in previous mechanical testing studies of commercial prosthetic feet (Major et al., 2018; Womac et al., 2019).

The alignment of the prosthetic feet was neutralized in all planes during testing to promote consistency across prosthetic foot models, similar to previous mechanical testing studies (Adamczyk et al., 2013; Beck et al., 2016; Major, Kenney, Twiste, & Howard, 2012; Major et al., 2018; Major et al., 2011; Webber & Kaufman, 2017; Womac et al., 2019). However, alignment adjustments used to optimize each foot per manufacturer recommendations could

impact the measured stiffness of commercial prosthetic feet. Concerning alignment, we opted to maintain consistency across feet (methodological consistency) at the potential expense of clinical validity.

Additionally, the prosthetic feet in this study were tested with their respective cosmetic foot shell. While shod with standardized heel-height appropriate athletic shoes, the mechanical properties measured in this study include the interaction with the footwear. This decision was purposeful to mimic intended clinical use (i.e., feet are designed for use inside a shoe) since the PFE is not used with a shoe. The same shoe was used within feet of the same foot size, while the same model shoe was used across foot sizes. Thus, the relative offset between measured stiffness of commercial prosthetic feet was considered similar across foot models for a given user since they were collected with the same shoe. However, the properties used to program the PFE may not generalize to different types of shoes that a person with LLA might prefer to use with their prosthetic foot in practice (e.g., shoes with less heel height or more rigid soles) (Major et al., 2018). Therefore, future research should evaluate the effects of alignment and type of footwear on the quality of mechanical property emulation for use with the PFE.

Additionally, the testing performed in this study was limited to the sagittal plane since the PFE is, at present, a single-axis device with no adaptation in the coronal plane. However, coronal plane stiffness is known to vary across prosthetic foot models based on their features and design (e.g., presence of a split-keel) (Womac et al., 2019). Future research should collect prosthetic foot properties in multiple planes (i.e., coronal and transverse, in addition to sagittal).

Finally, while the results of this study only generalize to populations of commercial prosthetic feet similar to those used in the present study, the tested feet were selected to represent a range of commonly used prosthetic foot technology (e.g., flexible feel, energy-storage and

release, extended keel). Additional types of prosthetic feet should be tested in the future to expand the library of commercial feet available for emulation, including those feet with properties designed to vary across stance phase using hydraulic or microprocessor technology.

Parameterization of commercial foot mechanical properties: limitations and future directions

The use of least-squares optimization to fit the Bezier curve functions to commercial foot data minimized the RMSE to improve curve fit, similar to methods used in previous studies of ankle stiffness (Adamczyk et al., 2013; Fey et al., 2011; Rouse et al., 2013; South, Fey, Bosker, & Neptune, 2010). However, when applied to nonlinear angular stiffness data, this technique permitted differences in the data across the loading range so long as they were counterbalanced. Alternative methods for calculating differences between the Bezier curves and the respective commercial foot data, such as differences in the area between curves, revealed systematic differences in the quality of the Bezier curves across prosthetic foot models. These differences were not large enough to detect an effect of commercial foot model in the overall agreement between emulated and commercial foot angular stiffness in this study. Regardless, future techniques for optimizing continuous functions to nonlinear data should consider using strategies to minimize the difference in area between curves rather than minimizing RMSE.

Additionally, the Bezier curve functions defined in this study were quadratic, which resulted in constrained DOF for optimizing each curve. Specifically, the location of P_1 (i.e., where the shape parameter is applied) was dependent on the location of the other two points since it was restricted to the midpoint between P_0 and P_2. In this study, the position of P_0 was allowed to vary within a constrained range to improve the alignment between P_1 and the peak bend of the commercial foot data. It was expected that slight differences between the minimum point of the

Bezier curve and the true zero ankle torque would likely be imperceptible to the user because it occurs at loads near zero. However, this range for incrementally adjusting P_0 was not sufficient to align P_1 based on the amount of skew (i.e., offset of peak bend from midline) that some of the commercial feet exhibited. This decision may have resulted in systematic, albeit small, differences in the accuracy of the Bezier curve across prosthetic foot models, with feet that demonstrated more skew being less well represented by the respective Bezier curve. Future parameterization efforts could benefit from defining additional DOF (e.g., use more points to define a Bezier polygon) to better incorporate the nonlinear features (i.e., amount of offset in peak bend from midline) observed in commercial foot properties without compromising the fit of P_0.

Agreement between emulated and commercial forefeet: limitations and future directions

The methods used to compare the forefoot angular stiffness of emulated and commercial feet relied on replicating the original testing set-up as a means of validation. However, given the limitations of the mechanical testing procedures described above, the agreement evaluated in this study is restricted to a comparison made under the same testing conditions (e.g., single pylon progression angle, fixed loading rate, sagittal plane), which do not reflect clinical use of prosthetic feet. Although we demonstrated high accuracy of emulation under test conditions, it is unclear whether emulation accuracy would remain consistent across clinical use scenarios (e.g., throughout the gait cycle while a person with LLA is walking). Therefore, additional testing is needed to assess the correlation between emulated and commercial feet when users are walking with the PFE (e.g., under typical use, including variable loading positions, loading rates, and individual gait variations). Furthermore, capturing the user's perceptions of the experience

walking with emulated feet compared to commercial feet, in a blinded fashion, would inform aspects of emulation and the feasibility of using the PFE to test-drive prosthetic foot models for people with LLA.

Conclusions

We developed a novel procedure by which a robotic PFE was configured to mimic the angular stiffness of commercial prosthetic forefeet in a user-independent manner. We used mechanical testing procedures to collect data on five types of commercial prosthetic forefeet across a range of foot sizes and user body weights. The Bezier curve functions we defined provided an effective method for parameterizing the respective experimental commercial foot data and enabled input to the PFE. Configuring the PFE to mimic a subset of corresponding commercial prosthetic forefeet and replicating the mechanical testing procedures revealed close agreement in angular stiffness between the emulated and commercial forefeet under replicated testing procedures. While future research is indicated to expand mechanical testing and to assess user-based comparisons of emulated and commercial prosthetic feet (e.g., under dynamic conditions, including self-reported and performance-based measures), these findings suggest that the PFE holds promise as a strategy to enable people with LLA to test-drive different types of prosthetic feet.

References

Adamczyk, P. G., Roland, M., & Hahn, M. E. (2013). Novel method to evaluate angular stiffness of prosthetic feet from linear compression tests. *J Biomech Eng, 135*(10), 104502-5.

Adamczyk, P. G., Roland, M., & Hahn, M. E. (2017). Sensitivity of biomechanical outcomes to independent variations of hindfoot and forefoot stiffness in foot prostheses. *Hum Mov Sci, 54*, 154-71.

AOPA. (2010). Prosthetic foot project.

Aubin, P. M., Cowley, M. S., & Ledoux, W. R. (2008). Gait simulation via a 6-dof parallel robot with iterative learning control. *IEEE Trans Biomed Eng, 55*(3), 1237-40.

Balk, E. M., Gazula, A., Markozannes, G., Kimmel, H. J., Saldanha, I. J., Resnik, L. J., & Trikalinos, T. A. (2018). Ahrq comparative effectiveness reviews. In *Lower limb prostheses: Measurement instruments, comparison of component effects by subgroups, and long-term outcomes*. Rockville, MD: Agency for Healthcare Research and Quality (US).

Beck, O. N., Taboga, P., & Grabowski, A. M. (2016). Characterizing the mechanical properties of running-specific prostheses. *PLoS One, 11*(12), e0168298.

Beck, O. N., Taboga, P., & Grabowski, A. M. (2017). Reduced prosthetic stiffness lowers the metabolic cost of running for athletes with bilateral transtibial amputations. *J Appl Physiol 122(4)*, 976-84.

Bland, J. M., & Altman, D. G. (1986). Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet, 1*(8476), 307-10.

Bland, J. M., & Altman, D. G. (1990). A note on the use of the intraclass correlation coefficient in the evaluation of agreement between two methods of measurement. *Comput Biol Med, 20*(5), 337-40.

Bland, J. M., & Altman, D. G. (1999). Measuring agreement in method comparison studies. *Stat Methods Med Res, 8*(2), 135-60.

Bland, J. M., & Altman, D. G. (2007). Agreement between methods of measurement with multiple observations per individual. *Journal of biopharmaceutical statistics, 17*(4), 571-82.

Caputo, J. M., Adamczyk, P. G., & Collins, S. H. (2015). Informing ankle-foot prosthesis prescription through haptic emulation of candidate devices. *IEEE Int Conf Robot Autom, 2015*, 6445-50.

Caputo, J. M., & Collins, S. H. (2014a). Prosthetic ankle push-off work reduces metabolic rate but not collision work in non-amputee walking. *Sci Rep, 4*, 7213.

Caputo, J. M., & Collins, S. H. (2014b). A universal ankle-foot prosthesis emulator for human locomotion experiments. *J Biomech Eng, 136*(3), 035002.

Choi, J., Curry, R., & Elkaim, G. (2008). *Path planning based on bézier curve for autonomous ground vehicles.* Paper presented at the Advances in Electrical and Electronics Engineering-IAENG Special Edition of the World Congress on Engineering and Computer Science 2008.

Czerniecki, J. M. (2005). Research and clinical selection of foot-ankle systems. *JPO, 17*(4), S35-S7.

Davis, C. S. (2002). *Statistical methods for the analysis of repeated measurements*: Springer Science & Business Media.

De Asha, A. R., Barnett, C. T., Struchkov, V., & Buckley, J. G. (2017). Which prosthetic foot to prescribe?: Biomechanical differences found during a single-session comparison of different foot types hold true 1 year later. *JPO, 29*(1), 39-43.

Elhoseny, M., Tharwat, A., & Hassanien, A. E. (2018). Bezier curve based path planning in a dynamic field using modified genetic algorithm. *Journal of Computational Science, 25*, 339-50.

Fey, N. P., Klute, G. K., & Neptune, R. R. (2011). The influence of energy storage and return foot stiffness on walking mechanics and muscle activity in below-knee amputees. *Clin Biomech, 26*(10), 1025-32.

Fey, N. P., Klute, G. K., & Neptune, R. R. (2012). Optimization of prosthetic foot stiffness to reduce metabolic cost and intact knee loading during below-knee amputee walking: A theoretical study. *J Biomech Eng, 134*(11), 111005.

Fey, N. P., Klute, G. K., & Neptune, R. R. (2013). Altering prosthetic foot stiffness influences foot and muscle function during below-knee amputee walking: A modeling and simulation analysis. *J Biomech, 46*(4), 637-44.

Fogelberg, D. J., Allyn, K. J., Smersh, M., & Maitland, M. E. (2016). What people want in a prosthetic foot: A focus group study. *JPO, 28*(4), 145-51.

Gard, S. A., Su, P. F., Lipschutz, R. D., & Hansen, A. H. (2011). Effect of prosthetic ankle units on roll-over shape characteristics during walking in persons with bilateral transtibial amputations. *J Rehabil Res Dev, 48*(9), 1037-48.

Geil, M. D. (2001). Energy loss and stiffness properties of dynamic elastic response prosthetic feet. *JPO, 13*(3), 70-3.

Hafner, B. J. (2005). Clinical prescription and use of prosthetic foot and ankle mechanisms: A review of the literature. *JPO, 17*(4), S5-S11.

Hamilton, C., & Stamey, J. (2007). Using bland− altman to assess agreement between two medical devices–don't forget the confidence intervals! *Journal of clinical monitoring and computing, 21*(6), 331-3.

Hansen, A. H., & Childress, D. S. (2010). Investigations of roll-over shape: Implications for design, alignment, and evaluation of ankle-foot prostheses and orthoses. *Disabil Rehabil, 32*(26), 2201-9.

Hansen, A. H., Childress, D. S., & Knox, E. H. (2004). Roll-over shapes of human locomotor systems: Effects of walking speed. *Clin Biomech, 19*(4), 407-14.

Hansen, A. H., Childress, D. S., Miff, S. C., Gard, S. A., & Mesplay, K. P. (2004). The human ankle during walking: Implications for design of biomimetic ankle prostheses. *J Biomech, 37*(10), 1467-74.

Hansen, A. H., Sam, M., & Childress, D. S. (2004). The effective foot length ratio: A potential tool for characterization and evaluation of prosthetic feet. *JPO, 16*(2), 41-5.

Hansen, A. H., & Starker, F. (2018). Prosthetic foot principles and their influence on gait. In *Handbook of human motion* (pp. 1343-57). Cham: Springer International Publishing.

Hofstad, C., Linde, H., Limbeek, J., & Postema, K. (2004). Prescription of prosthetic ankle-foot mechanisms after lower limb amputation. *Cochrane Database Syst Rev*(1), Cd003978.

Jonkergouw, N., Prins, M. R., Buis, A. W., & van der Wurff, P. (2016). The effect of alignment changes on unilateral transtibial amputee's gait: A systematic review. *PLoS One, 11*(12), e0167466.

Kim, M., Chen, T., Chen, T., & Collins, S. H. (2018). An ankle-foot prosthesis emulator with control of plantarflexion and inversion-eversion torque. *IEEE Transactions on robotics, 99*, 1-12.

Klodd, E., Hansen, A., Fatone, S., & Edwards, M. (2010a). Effects of prosthetic foot forefoot flexibility on gait of unilateral transtibial prosthesis users. *J Rehabil Res Dev, 47*(9), 899-910.

Klodd, E., Hansen, A., Fatone, S., & Edwards, M. (2010b). Effects of prosthetic foot forefoot flexibility on oxygen cost and subjective preference rankings of unilateral transtibial prosthesis users. *J Rehabil Res Dev, 47*(6), 543-52.

Klute, G. K., & Berge, J. S. (2004). Modelling the effect of prosthetic feet and shoes on the heel-ground contact force in amputee gait. *Proc Inst Mech Eng H, 218*(3), 173-82.

Klute, G. K., Berge, J. S., & Segal, A. D. (2004). Heel-region properties of prosthetic feet and shoes. *J Rehabil Res Dev, 41*(4), 535-46.

Klute, G. K., Kallfelz, C. F., & Czerniecki, J. M. (2001). Mechanical properties of prosthetic limbs: Adapting to the patient. *J Rehabil Res Dev, 38*(3), 299-307.

Koehler-McNicholas, S. R., Nickel, E. A., Barrons, K., Blaharski, K. E., Dellamano, C. A., Ray, S. F., . . . Hansen, A. H. (2018). Mechanical and dynamic characterization of prosthetic feet for high activity users during weighted and unweighted walking. *PLoS One, 13*(9), e0202884.

Major, M. J., Kenney, L. P., Twiste, M., & Howard, D. (2012). Stance phase mechanical characterization of transtibial prostheses distal to the socket: A review. *J Rehabil Res Dev, 49*(6), 815-29.

Major, M. J., Scham, J., & Orendurff, M. (2018). The effects of common footwear on stance-phase mechanical properties of the prosthetic foot-shoe system. *Prosthet Orthot Int, 42*(2), 198-207.

Major, M. J., Twiste, M., Kenney, L. P., & Howard, D. (2011). Amputee independent prosthesis properties--a new model for description and measurement. *J Biomech, 44*(14), 2572-5.

Major, M. J., Twiste, M., Kenney, L. P., & Howard, D. (2014). The effects of prosthetic ankle stiffness on ankle and knee kinematics, prosthetic limb loading, and net metabolic cost of trans-tibial amputee gait. *Clin Biomech, 29*(1), 98-104.

Major, M. J., Twiste, M., Kenney, L. P., & Howard, D. (2016). The effects of prosthetic ankle stiffness on stability of gait in people with transtibial amputation. *J Rehabil Res Dev, 53*(6), 839-52.

Malcolm, P., Quesada, R. E., Caputo, J. M., & Collins, S. H. (2015). The influence of push-off timing in a robotic ankle-foot prosthesis on the energetics and mechanics of walking. *J Neuroeng Rehabil, 12*, 21.

Mason, Z. D., Pearlman, J., Cooper, R. A., & Laferrier, J. Z. (2011). Comparison of prosthetic feet prescribed to active individuals using iso standards. *Prosthet Orthot Int, 35*(4), 418-24.

McDonald, C. L., Cheever, S. M., Morgan, S. J., & Hafner, B. J. (2019). Prosthetic limb user experiences with crossover feet: A pilot focus group study to explore outcomes that matter. *JPO, 31*(2), 121-32.

Murray, C. D., & Forshaw, M. J. (2013). The experience of amputation and prosthesis use for adults: A metasynthesis. *Disabil Rehabil, 35*(14), 1133-42.

Parker, R. A., Scott, C., Inácio, V., & Stevens, N. T. (2020). Using multiple agreement methods for continuous repeated measures data: A tutorial for practitioners. *BMC Med Res Methodol, 20*(1), 154.
Quesada, R. E., Caputo, J. M., & Collins, S. H. (2016). Increasing ankle push-off work with a powered prosthesis does not necessarily reduce metabolic rate for transtibial amputees. *J Biomech, 49*(14), 3452-9.
Raschke, S. U., Orendurff, M. S., Mattie, J. L., Kenyon, D. E., Jones, O. Y., Moe, D., . . . Kobayashi, T. (2015). Biomechanical characteristics, patient preference and activity level with different prosthetic feet: A randomized double blind trial with laboratory and community testing. *J Biomech, 48*(1), 146-52.
Rouse, E. J., Hargrove, L. J., Perreault, E. J., Peshkin, M. A., & Kuiken, T. A. (2013). Development of a mechatronic platform and validation of methods for estimating ankle stiffness during the stance phase of walking. *J Biomech Eng, 135*(8), 81009.
Rusaw, D., & Ramstrand, N. (2010). Sagittal plane position of the functional joint centre of prosthetic foot/ankle mechanisms. *Clin Biomech, 25*(7), 713-20.
Sawers, A., & Hahn, M. E. (2011). Trajectory of the center of rotation in non-articulated energy storage and return prosthetic feet. *J Biomech, 44*(9), 1673-7.
Schaffalitzky, E., Gallagher, P., Maclachlan, M., & Ryall, N. (2011). Understanding the benefits of prosthetic prescription: Exploring the experiences of practitioners and lower limb prosthetic users. *Disabil Rehabil, 33*(15-16), 1314-23.
Shamaei, K., Sawicki, G. S., & Dollar, A. M. (2013). Estimation of quasi-stiffness and propulsive work of the human ankle in the stance phase of walking. *PLoS One, 8*(3), e59935.
Shepherd, M. K., Azocar, A. F., Major, M. J., & Rouse, E. J. (2018). Amputee perception of prosthetic ankle stiffness during locomotion. *J Neuroeng Rehabil, 15*(1), 99.
Simba, K. R., Uchiyama, N., & Sano, S. (2016). Real-time smooth trajectory generation for nonholonomic mobile robots using bézier curves. *Robotics and Computer-Integrated Manufacturing, 41*, 31-42.
Singer, E., Ishai, G., & Kimmel, E. (1995). Parameter estimation for a prosthetic ankle. *Ann Biomed Eng, 23*(5), 691-6.
South, B. J., Fey, N. P., Bosker, G., & Neptune, R. R. (2010). Manufacture of energy storage and return prosthetic feet using selective laser sintering. *J Biomech Eng, 132*(1), 6.
Stark, G. (2005). Perspectives on how and why feet are prescribed. *JPO, 17*(Supplement), S18-S22.
Stevens, P. M., Rheinstein, J., & Wurdeman, S. R. (2018). Prosthetic foot selection for individuals with lower-limb amputation: A clinical practice guideline. *JPO, 30*(4), 175-80.
Tafti, N., Hemmati, F., Safari, R., Karimi, M. T., Farmani, F., Khalaf, A., & Mardani, M. A. (2018). A systematic review of variables used to assess clinically acceptable alignment of unilateral transtibial amputees in the literature. *Proc Inst Mech Eng H, 232*(8), 826-40.
Team, R. C. (2018). R: A language and environment for statistical computing. Vienna, Austria. Retrieved from https://www.R-project.org/.
Tharwat, A., Elhoseny, M., Hassanien, A. E., Gabel, T., & Kumar, A. (2019). Intelligent bézier curve-based path planning model using chaotic particle swarm optimization algorithm. *Cluster Computing, 22*(2), 4745-66.

Van Der Linde, H., Geertzen, J. H., Hofstad, C. J., Van Limbeek, J., & Postema, K. (2003). Prosthetic prescription in the netherlands: An observational study. *Prosthet Orthot Int, 27*(3), 170-8.

Van Der Linde, H., Geertzen, J. H., Hofstad, C. J., Van Limbeek, J., & Postema, K. (2004). Prosthetic prescription in the netherlands: An interview with clinical experts. *Prosthet Orthot Int, 28*(2), 98-104.

Van der Linde, H., Hofstad, C. J., Geertzen, J. H., Postema, K., & Van Limbeek, J. (2007). From satisfaction to expectation: The patient's perspective in lower limb prosthetic care. *Disabil Rehabil, 29*(13), 1049-55.

van der Linde, H., Hofstad, C. J., Geurts, A. C., Postema, K., Geertzen, J. H., & van Limbeek, J. (2004). A systematic literature review of the effect of different prosthetic components on human functioning with a lower-limb prosthesis. *J Rehabil Res Dev, 41*(4), 555-70.

Versluys, R., Beyl, P., Van Damme, M., Desomer, A., Van Ham, R., & Lefeber, D. (2009). Prosthetic feet: State-of-the-art review and the importance of mimicking human ankle-foot biomechanics. *Disabil Rehabil Assist Technol, 4*(2), 65-75.

Webber, C. M., & Kaufman, K. (2017). Instantaneous stiffness and hysteresis of dynamic elastic response prosthetic feet. *Prosthet Orthot Int, 41*(5), 463-8.

Whittaker, E. C., Aubin, P. M., & Ledoux, W. R. (2011). Foot bone kinematics as measured in a cadaveric robotic gait simulator. *Gait Posture, 33*(4), 645-50.

Womac, N. D., Neptune, R. R., & Klute, G. K. (2019). Stiffness and energy storage characteristics of energy storage and return prosthetic feet. *Prosthet Orthot Int, 43*(3), 266-75.

Yang, G. J., & Choi, B. W. (2013). Smooth trajectory planning along bezier curve for mobile robots with velocity constraints. *International Journal of Control and Automation, 6*(2), 225-34.

Tables and Figures

Table 2.1. Manufacturer-specified stiffness categories for all tested prosthetic feet (i.e., five commercial foot models, across four foot sizes) with mean and maximum body weight listed for a medium impact user between 125-250 lbs (exact weight range varies by manufacturer).

Prosthetic Foot Model	Manufacturer	Sizes (cm)	Stiffness Category	Average Medium Impact User Body Weight* (lb)	Maximum Allowable User Body Weight** (lb)
Walk-tek	Freedom Innovations; Irvine, CA	26-29	1	115	130
			2	156	180
			3	211	240
			4	271	300
Seattle Lightfoot2	Trulife USA; Jackson, MI	26-29	6	126	165
			7	176	190
			8	226	255
Vari-flex	Össur; Reykjavik, Iceland	26-29	3	141	170
			4	161	194
			5	183	221
			6	208	256
			7	239	287
			8	272	287
Rush HiPro	Proteor USA; Tempe, AZ	26-29	2	132	146
			3	164	180
			4	200	218
			5	240	261
			6	286	310
All-Pro 8-inch	Fillauer, Inc.; Chattanooga, TN	26	B4	130	159
			C5	180	199
			D6	225	249
		27-28	C6	150	179
			D7	202	224
			E8	250	275
		29	D7	170	199
			E8	225	249

Note: *Averaged from the manufacturer-provided user body weight range for the stiffness category, **Maximum allowable user body weight for the category was used to calculate the target load threshold for mechanical testing

Table 2.2. Mean and standard deviation Bezier curve fit by prosthetic foot type, across foot sizes and stiffness categories. R-squared values based on least-squares optimization to parameterize the commercial prosthetic forefoot angular stiffness data from mechanical testing, for input to the prosthetic foot emulator.

Prosthetic Foot Type	**Bezier Curve Fit (R^2)**
Walk-tek	0.997 ± 0.003
Seattle Lightfoot2	0.999 ± 0.000
Vari-flex	0.997 ± 0.002
Rush HiPro	0.990 ± 0.000
All-Pro	0.998 ± 0.002
Mean	0.998 ± 0.001

Table 2.3. Mean and standard deviation differences in measured ankle torque between commercial and emulated prosthetic feet across ankle angles during loading by prosthetic foot type, across foot sizes, and stiffness categories. A negative difference indicates the commercial prosthetic foot torque had a smaller magnitude than the respective emulated foot at that ankle angle position. Percent differences based on the total magnitude of ankle torque.

Prosthetic Foot Type	**Difference in Ankle Torque** (Nm)	(%)
Walk-tek	-1.75 ± 2.07	-2.0 ± 3.3%
Seattle Lightfoot2	-0.60 ± 3.10	-1.7 ± 2.9%
Vari-flex	-0.75 ± 1.11	-1.9 ± 2.2%
Rush HiPro	-0.26 ± 0.99	-0.1 ± 1.4%
All-Pro	+0.32 ± 1.39	+0.9 ± 2.9%
Mean	-0.76 ± 1.73	-1.0 ± 2.5%

Table 2.4. Zero-order disaggregated correlations for variables used in analysis for model 1 with emulator ankle torque defined as outcome.

Measure	***M***	***(SD)***	**1.**	**2.**	**3.**
Outcome					
1. Emulated Foot Ankle Torque (Nm)	*41.22*	*(22.09)*	--		
Predictors					
2. Commercial Foot Ankle Torque (Nm)	*40.50*	*(22.07)*	1.00 ***	--	
3. Ankle Angle Position (deg)	*5.47*	*(5.17)*	.91 ***	.89 ***	--

Note. N = 40 simulated and commercial foot versions within 20 prosthetic feet. Pearson's r reported.
$^{*}\ p < .05$, $^{**}\ p < .01$, $^{***}\ p < .001$.

Table 2.5. Results for multilevel linear regression model 1 on emulated ankle torque.

	Model 1a						Model 1b					
Fixed Effects	*Coeff*	*SE*	*t*	*df*		*ES*	*Coeff*	*SE*	*t*	*df*		*ES*
Intercept	0.76	0.25	3.06	20	**	0.48	3.30	0.25	13.45	22	***	2.13
1. Commercial Ankle Torque (Nm)	1.00	0.00	1247.63	9784	***	197.29	0.96	0.00	567.31	9794	***	89.71
2. Ankle Angle Position (Z-scored)							3.04	0.03	94.59	9787	***	14.96
Interactions												
1*2							-0.05	0.01	-6.06	9789	***	-0.96
Random Effects	*Var*						*Var*					
Intercept (Foot)	1.13						1.07					
Residual (Measurement)	2.91						1.46					
Model Fit												
Approximate R^2	99.2%						99.5%					
BIC	38416						31683					
Deviance (-2LL)	38379						31628					
Residual *df*	9794						9792					
LRT Chi-square test	--						*					

Note. N = 40 simulated and commercial foot versions within 20 prosthetic feet; metrical predictors are standardized in Z-scores as noted. ES = effect size, calculated as the coefficient divided by the product of the standard error and square root of N. Approximate R2 calculated as the fitted variance divided by the sum of the fitted, prosthetic foot, and residual variances.

$^{*}p < .05$, $^{**}p < .01$, $^{***}p < .001$.

Table 2.6. Zero-order disaggregated correlations for variables used in analysis for model 3 with difference in ankle torque (commercial-emulated) defined as outcome.

Measure	***M***	***(SD)***	**1.**	**2.**	**3.**	**4.**	**5.**	**6.**	**7.**	**8.**
Outcome										
1. Difference in Commercial-Emulated Foot Ankle Torque (Nm)	*-0.76*	*(2.00)*	--							
Predictors										
2. Ankle Angle Position (deg)	*5.47*	*(5.17)*	-.19 ***	--						
3. Foot Type: Seattle Lightfoot2	*0.19*	-	.17 ***	.00	--					
4. Foot Type: Vari-flex	*0.22*	-	.15 ***	.00	.50 ***	--				
5. Foot Type: Rush HiPro	*0.17*	-	.22 ***	.00	.53 ***	.52 ***	--			
6. Foot Type: All-Pro	*0.20*	-	.22 ***	.00	.51 ***	.50 ***	.53 ***	--		
7. Prosthetic Foot Size (27cm)	*0.48*	-	.06 ***	.00	-.01	.00	-.02	-.11 *	--	
8. User Body Weight (200 lb)	*0.47*	-	-.21 ***	.00	-.02	-.01	.02	-.12 *	-.07 ***	--

Note. N = 40 simulated and commercial foot versions within 20 prosthetic feet; categorical variables are dummy coded. Pearson's r reported.
$^{*}p < .05$, $^{**}p < .01$, $^{***}p < .001$.

Table 2.7. Results for multilevel linear regression model 3 on difference in ankle torque between commercial and emulated feet.

	Model 3a						Model 3b					
Fixed Effects	***Coeff***	***SE***	***t***	***df***		***ES***	***Coeff***	***SE***	***t***	***df***		***ES***
Intercept (Mean)	-0.76	0.25	-3.03	19	**	-0.49	-0.76	0.19	-3.92	19	**	-0.62
1. Ankle Angle Position (Z-scored)	-0.38	0.02	-22.69	9779	***	-3.59	-0.38	0.02	-22.69	9779	***	-3.59
2. Foot Type: Seattle Lightfoot2							0.07	0.38	0.19	19		0.03
3. Foot Type: Vari-flex							0.00	0.38	-0.01	19		0.00
4. Foot Type: Rush HiPro							0.19	0.38	0.50	19		0.08
5. Foot Type: All-Pro							0.13	0.43	0.31	19		0.05
6. Prosthetic Foot Size (27cm)							0.12	0.19	0.61	19		0.10
7. User Body Weight (200 lb)							-0.22	0.19	-1.13	19		-0.18
Random Effects	*Var*						*Var*					
Intercept (Foot)	1.14						0.69					
Residual (Measurement)	2.77						2.77					
Model Fit												
Approximate R^2	24.0%						32.0%					
BIC	37960						37914					
Deviance (-2LL)	37878						37868					
Residual *df*	9794						9788					
LRT Chi-square test	--						*					

Note. N = 40 simulated and commercial foot versions within 20 prosthetic feet; metrical predictors are standardized in *z*-scores and categorical predictors are effect coded. Prosthetic foot type (5 levels) was effect coded into four dummy variables with Walk-tek treated as the reference level for all. *ES* = effect size, calculated as the coefficient divided by the product of the standard error and square root of *N*. Approximate R^2 calculated as the fitted variance divided by the sum of the fitted, prosthetic foot, and residual variances.

$^{*}p < .05$, $^{**}p < .01$, $^{***}p < .001$.

Table 2.8. Mean and standard deviation differences in quality of Bezier curve fit compared to commercial prosthetic foot angular stiffness data and compared to respective emulated prosthetic foot data by prosthetic foot type, across foot sizes and stiffness categories. Difference calculated using trapezoidal integration and percent calculated relative to commercial foot area.

	Area Difference (%)		
Prosthetic Foot Type	Bezier-Commercial	Bezier-Emulated	Emulated-Commercial
Walk-tek	5.5 ± 2.3%	1.3 ± 0.6%	5.1 ± 2.5%
Seattle Lightfoot2	6.1 ± 2.8%	1.2 ± 0.8%	5.9 ± 2.6%
Vari-flex	2.3 ± 0.5%	1.5 ± 0.4%	2.9 ± 0.9%
Rush HiPro	3.2 ± 1.4%	0.9 ± 0.6%	3.6 ± 0.8%
All-Pro	4.7 ± 3.1%	0.8 ± 0.5%	3.0 ± 0.0%
Mean	4.4 ± 2.0%	1.1 ± 0.5%	4.1 ± 1.4%

Table 2.9. Mean and standard deviation differences in nonlinear curve features by prosthetic foot type, across foot sizes and stiffness categories. Peak bend calculated to represent relative degree of nonlinearity based on perpendicular distance from line segment and normalized such that a value of 100% would indicate a circle. Offset of the peak bend location calculated as a percent distance translated from midpoint such that a value of 0% would represent a foot with maximum bend located along the midpoint between the P_0 and P_2 Bezier control points (i.e., data could be perfectly represented by the current Bezier curve technique).

Prosthetic Foot Type	**Peak Bend Magnitude (%)**	**Offset from Midpoint (%)**
Walk-tek	7.0 ± 1.7%	41.4 ± 4.7%
Seattle Lightfoot2	5.9 ± 0.3%	45.9 ± 4.9%
Vari-flex	6.6 ± 0.6%	28.6 ± 5.3%
Rush HiPro	6.3 ± 0.9%	16.0 ± 1.6%
All-Pro	12.9 ± 1.2%	28.5 ± 5.2%
Mean	7.8 ± 0.9%	32.1 ± 11.8%

Figure 2.1. a) Photo illustrating a user with transtibial amputation with the PFE end effector attached to their socket and tethered, offboard actuator unit and control hardware depicted behind the user; b) photo of PFE end effector attached to socket of participant with transtibial amputation.

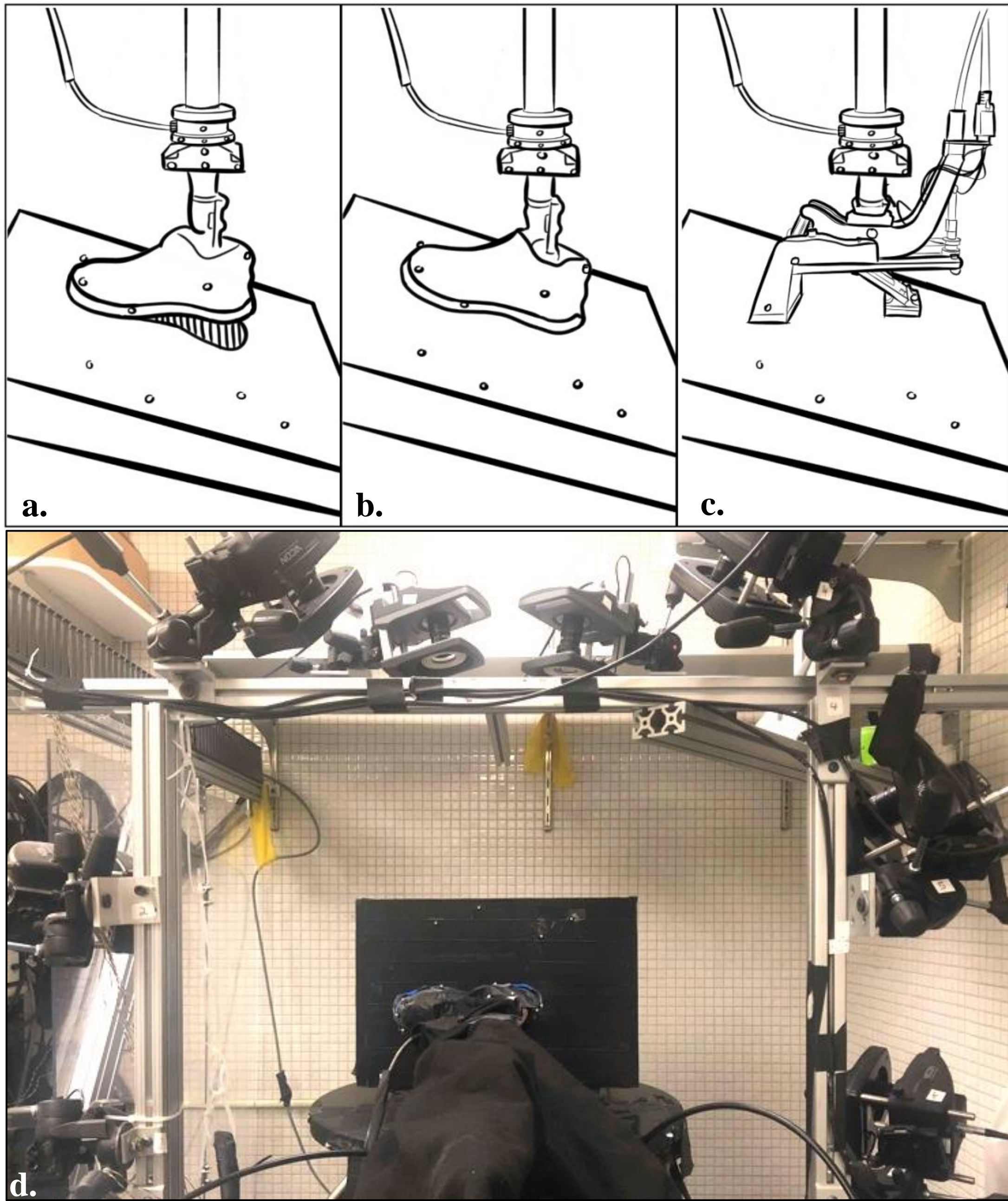

Figure 2.2. Prosthetic foot mechanical testing apparatus with example prosthetic foot set-up: a) aerial view of commercial prosthetic foot set up for testing the forefoot at 20° pylon progression angle, in-line load cell and reflective markers shown; b) same commercial foot depicted under maximum target load; c) repeated testing with PFE end effector setup; d) front view of R2000 robot assembly and frame with a vertically-mounted loading platform shown.

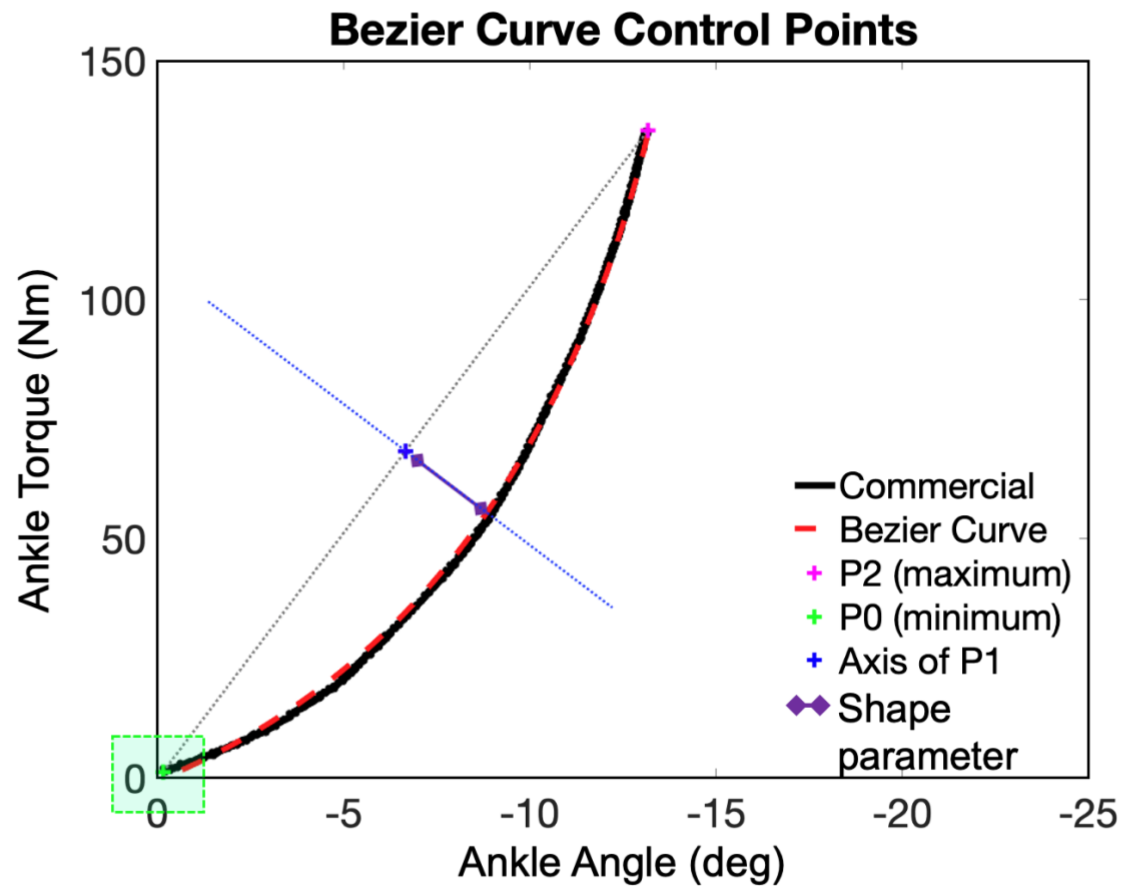

Figure 2.3. Illustration of quadratic Bezier curve control points and the shape parameter used to define the polygon: P0 (i.e., minimum) was optimized to improve overall curve fit within the green bounded region, P2 (i.e., maximum) was defined at peak load and peak dorsiflexion angle, and P1 (i.e., where shape parameter is applied) was defined along a line bisecting the linear projection from P0 to P2 and with an axis perpendicular to its slope.

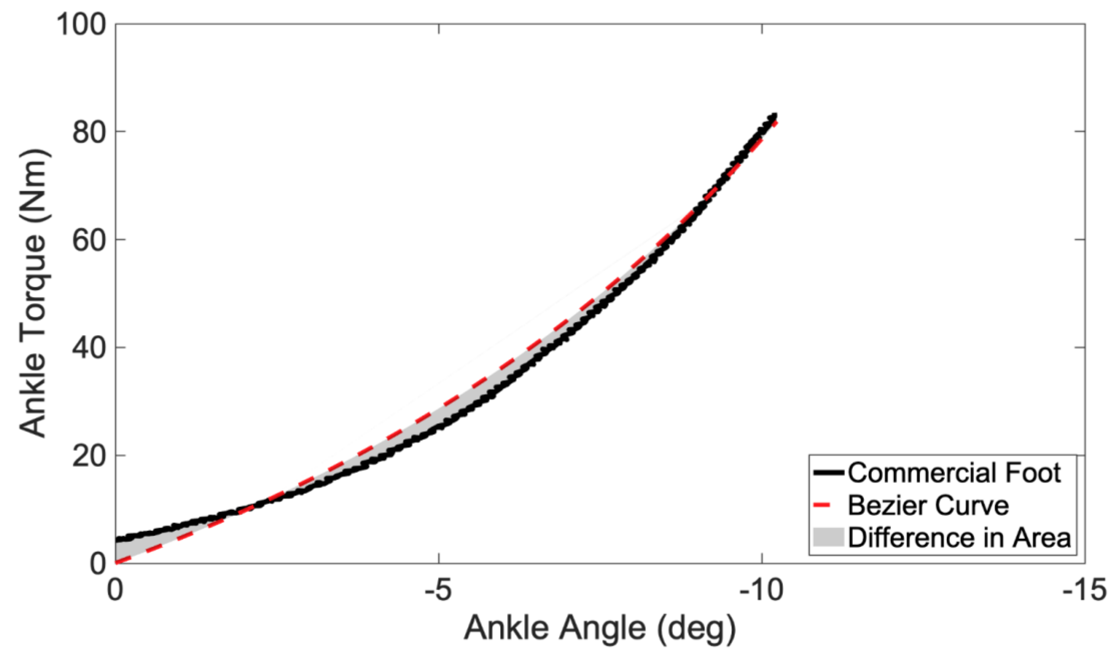

Figure 2.4. Illustration of area difference calculation (shaded grey area) between example commercial prosthetic foot angular stiffness data and the corresponding Bezier curve.

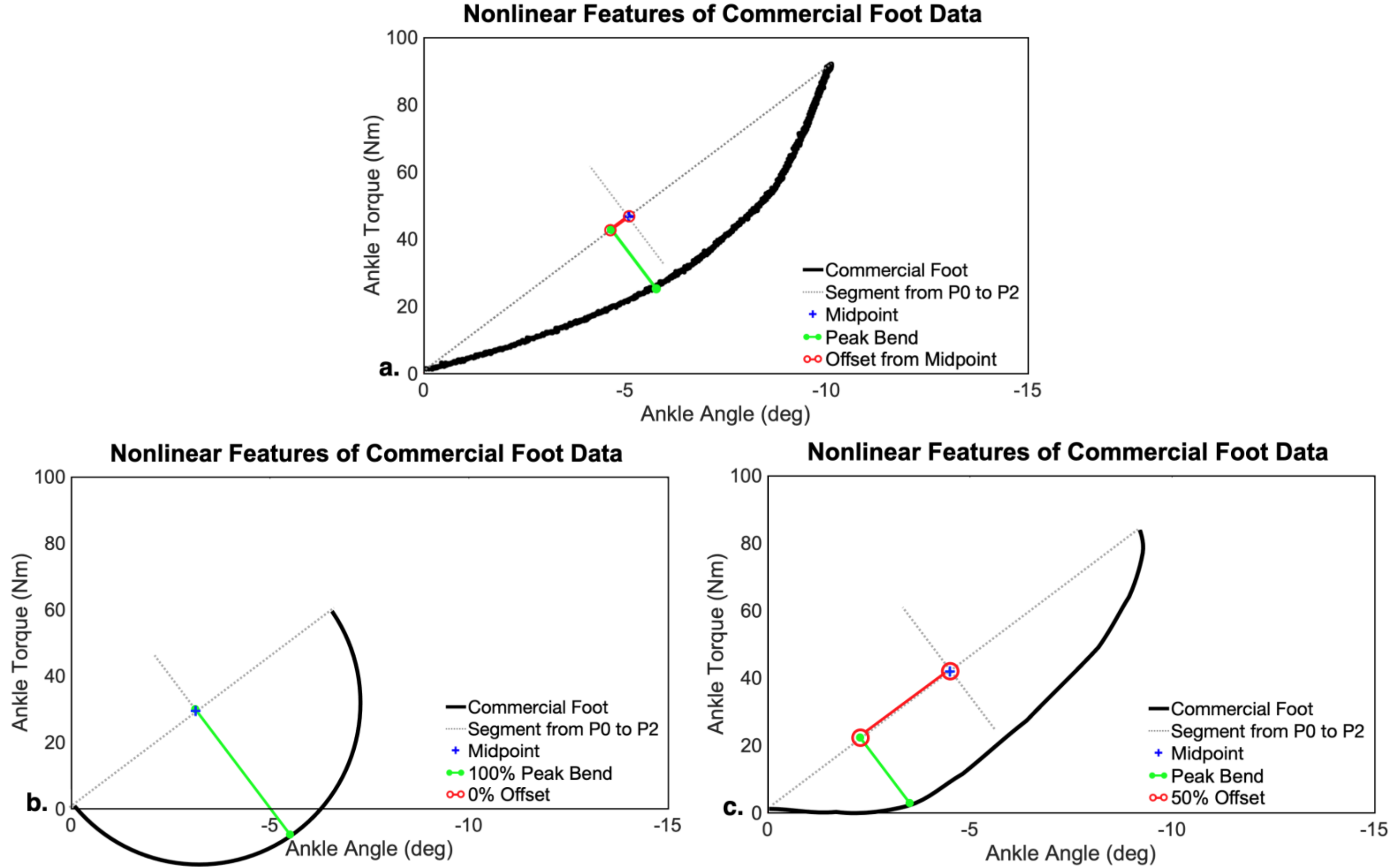

Figure 2.5. Illustration of the nonlinear features that were quantified for each commercial foot from the respective angular stiffness data: a) magnitude of peak bend (in green) and offset of peak bend from point between P0 and P2 (in red); b) peak bend calculated as the relative degree of nonlinearity based on maximum perpendicular distance from the line segment between P0 and P2, normalized to the length of the segment such that a value of 100% indicates a semi-circle; c) offset of the peak bend location calculated as a the

relative skew based on distance translated from midpoint, normalized such that a value of 0% indicates peak bend at the midpoint (i.e., data could be perfectly represented by the current Bezier curve fitting technique) and 50% is halfway between P0 and midpoint.

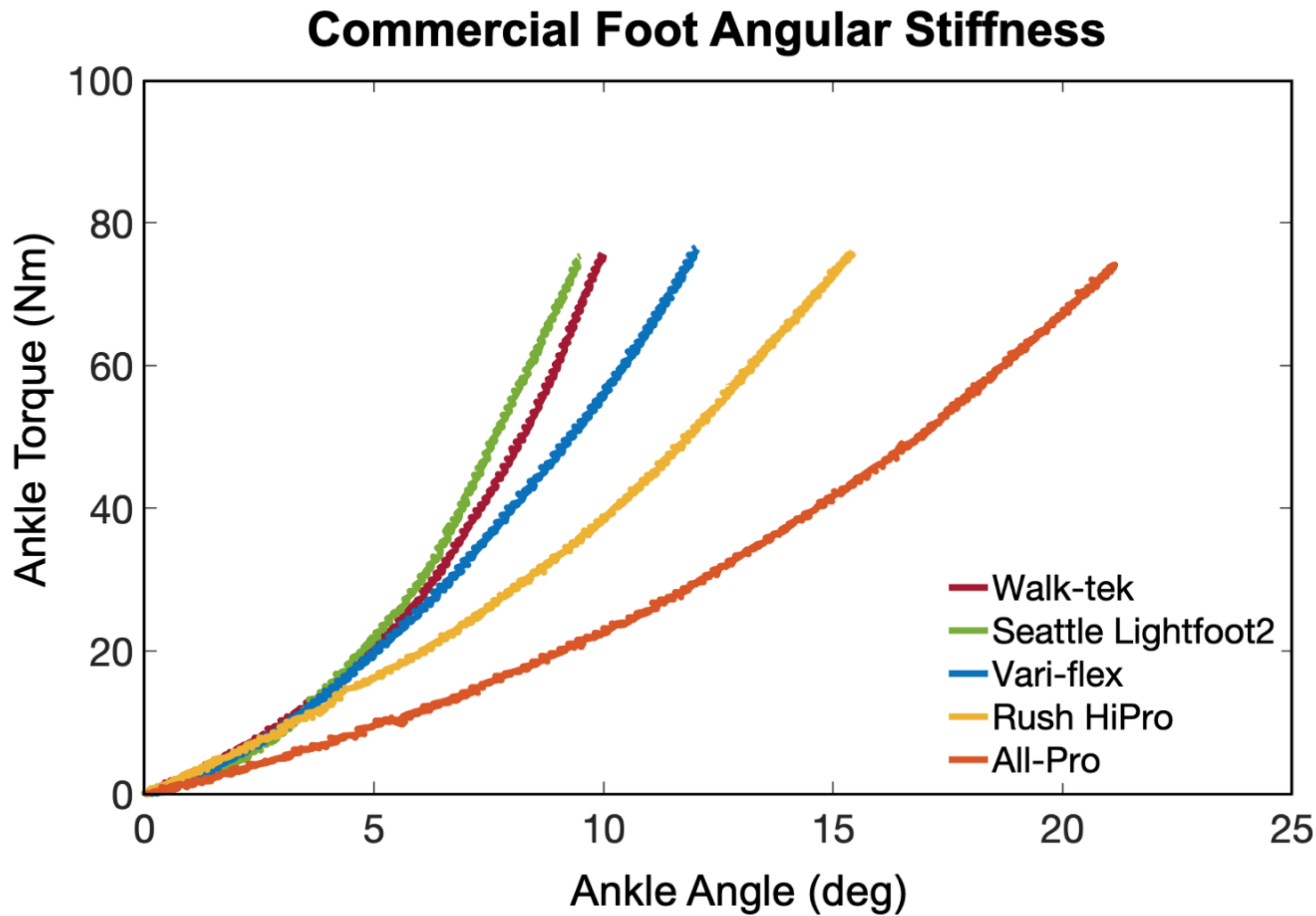

Figure 2.6. Example forefoot ankle torque vs ankle angle data for a given foot size (i.e., 26 cm) and user body weight (i.e., 200 lb) across all five tested commercial prosthetic foot models. All curves exhibit nonlinear behavior and a range of angular stiffness is demonstrated across foot types. A steeper slope (i.e., less angular displacement under the same amount of ankle torque) demonstrates higher stiffness.

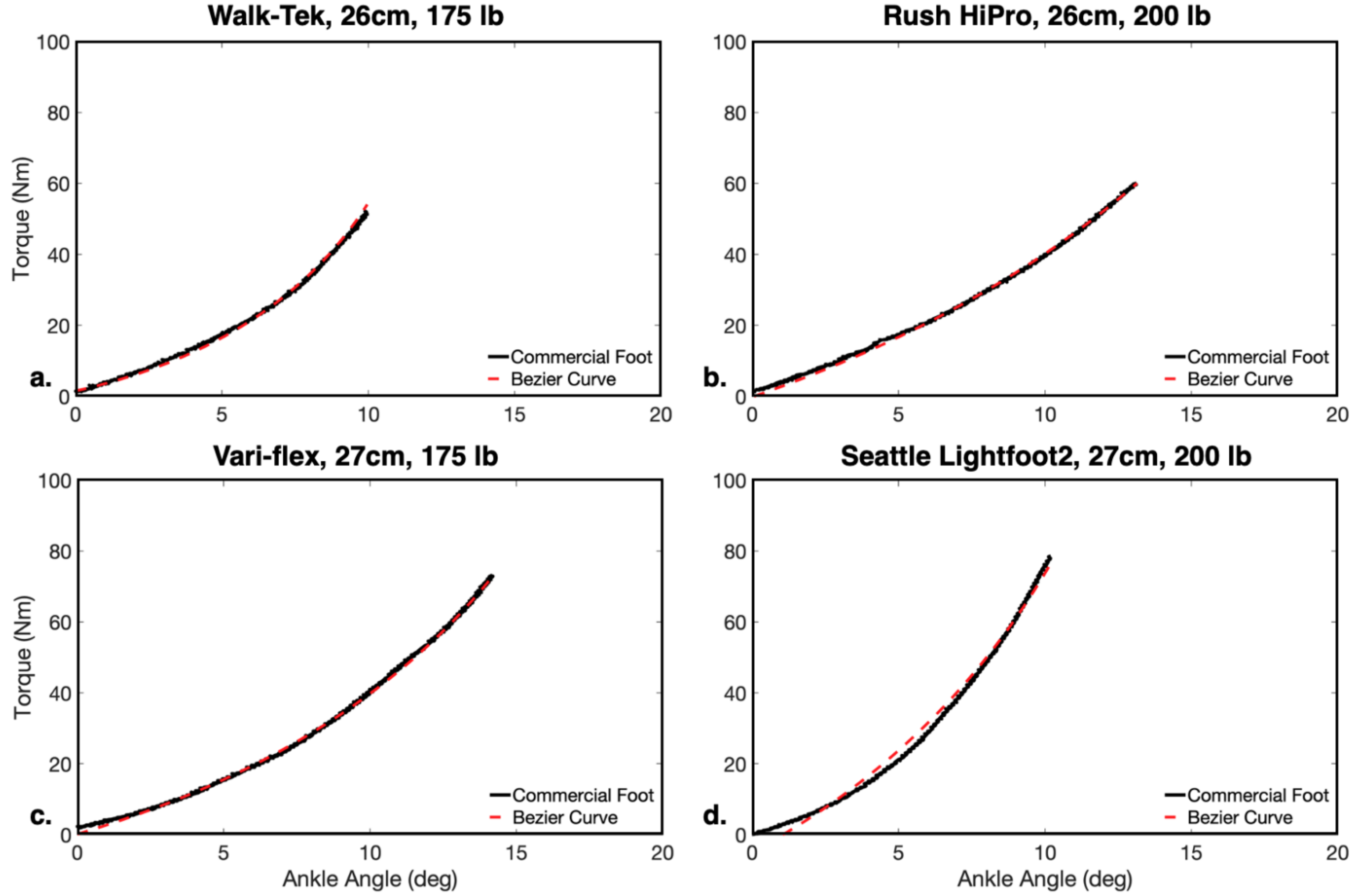

Figure 2.7. Example Bezier curves defined using least-squares optimization to fit control points P0 (minimum), P2 (maximum), P1 (located along axis perpendicular to segment at the midpoint), and shape parameter. Angular stiffness data from two types of commercial prosthetic feet shown from two different stiffness categories (e.g., user body weights) for illustration.

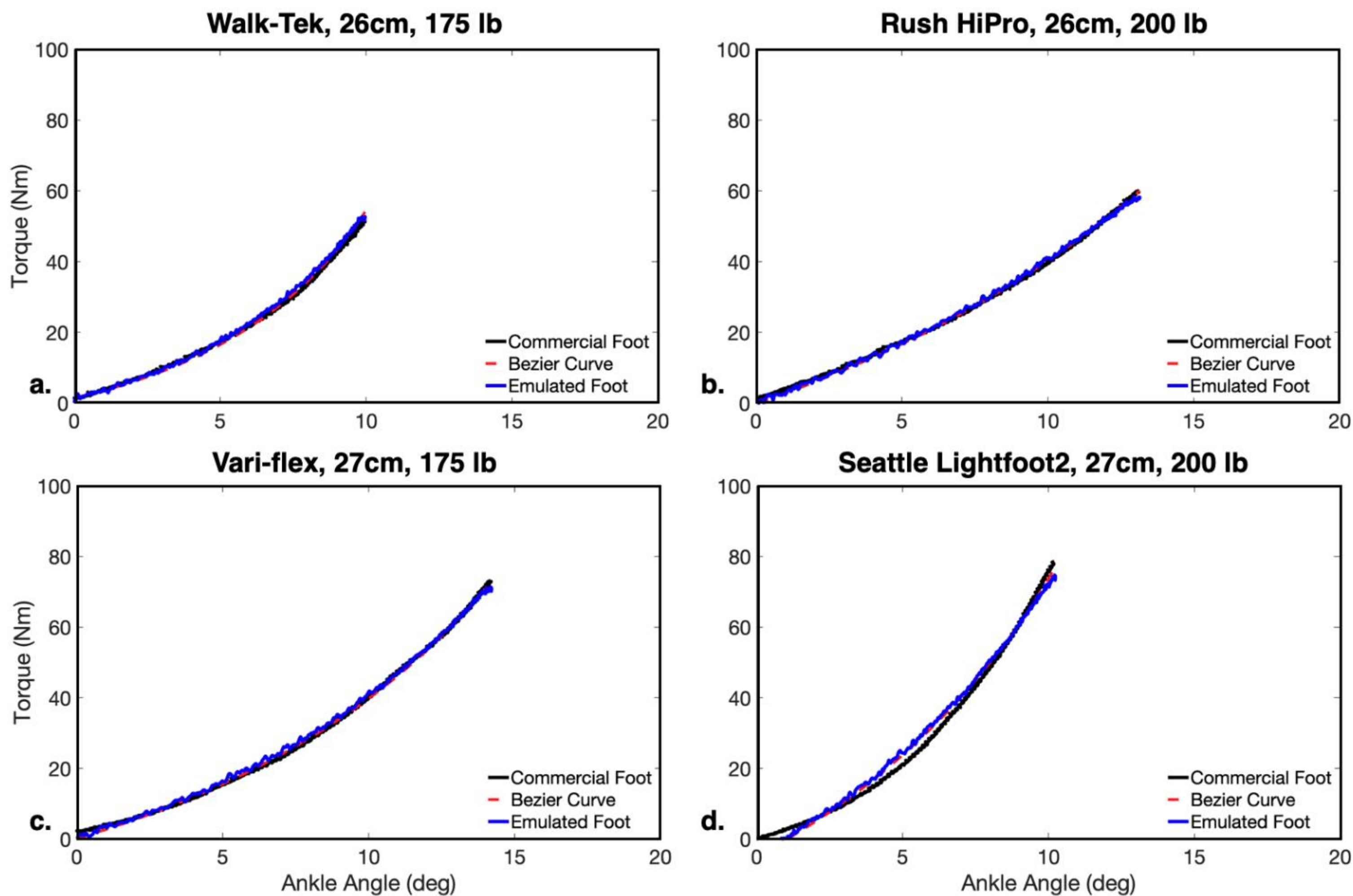

Figure 2.8. Example pairs of emulated and commercial foot angular stiffness data across a range of types of prosthetic feet, sizes of feet, and for differing user body weights. Commercial foot data (black) is displayed along with the corresponding Bezier curves (red, dashed) and emulated foot data (blue).

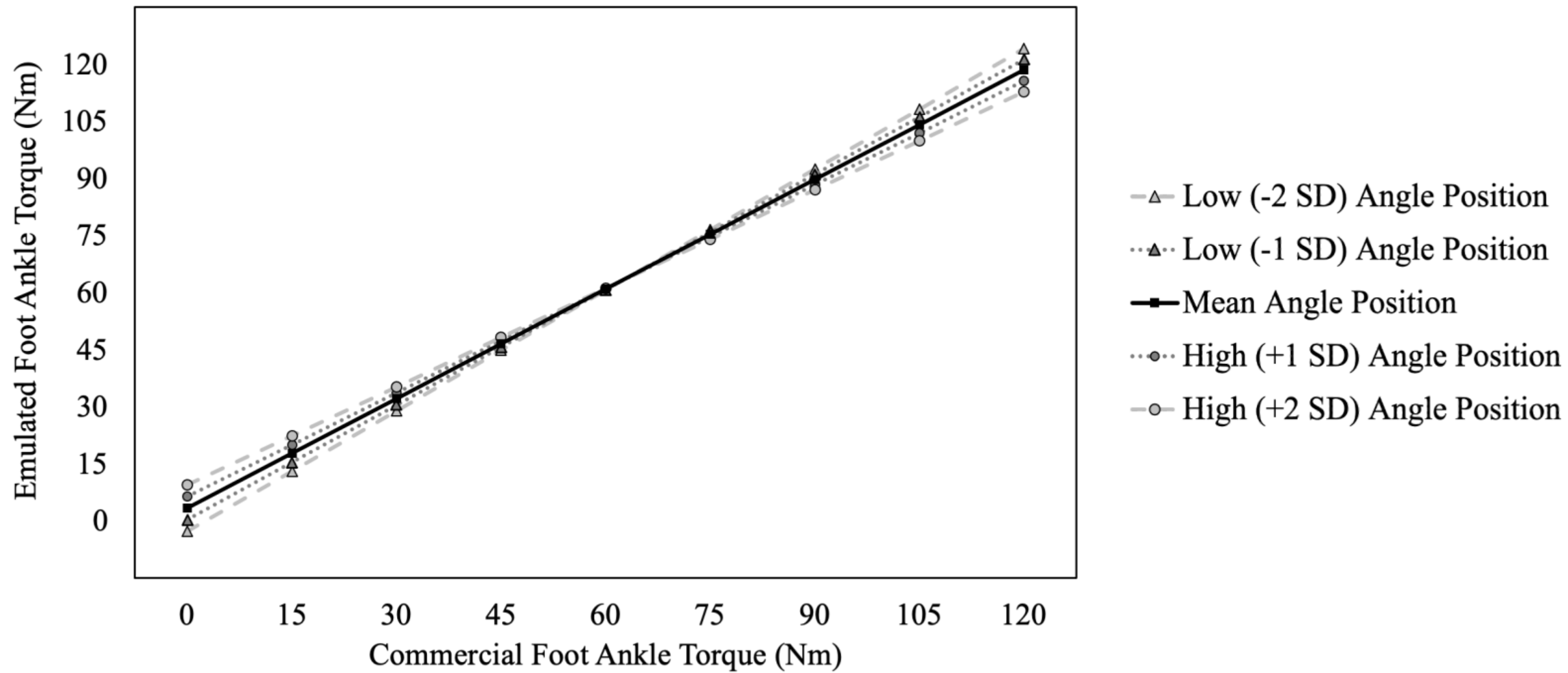

Figure 2.9. Interaction effect for ankle angle position and commercial prosthetic foot torque tested in model 1. The correlation between the commercial foot torque and the estimated emulated ankle torque shown across a range of ankle angle positions (based on standard deviation from mean ankle angle). Results show disordinal effect with equal and opposite differences in commercial-emulated foot torque values depending on the ankle angle position.

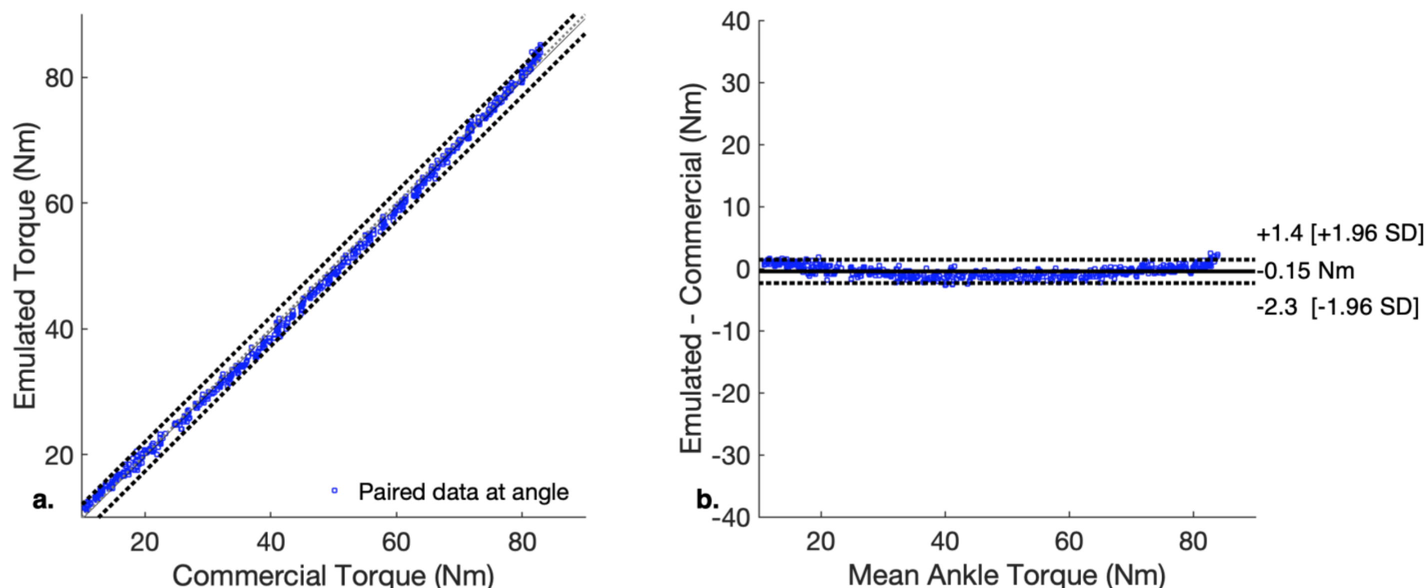

Figure 2.10. Results from Bland-Altman assessment of the limits of agreement (LoA) for one example prosthetic foot (i.e., All-Pro, 27cm) with corresponding pairs of commercial and emulated ankle torque measurements, calculated using model 2: a) simple correlation plot to assess extent of proportional agreement between measurements with the LoA (dashed black lines) displayed; b) Bland-Altman plot with differences between corresponding measurements plotted on the vertical axis and the mean of the corresponding measurements plotted on the horizontal axis. The solid black line represents the mean difference (i.e., bias) between corresponding measurements. The dashed black lines represent the lower and upper LoA between which 95% of differences between device condition measurements are expected.

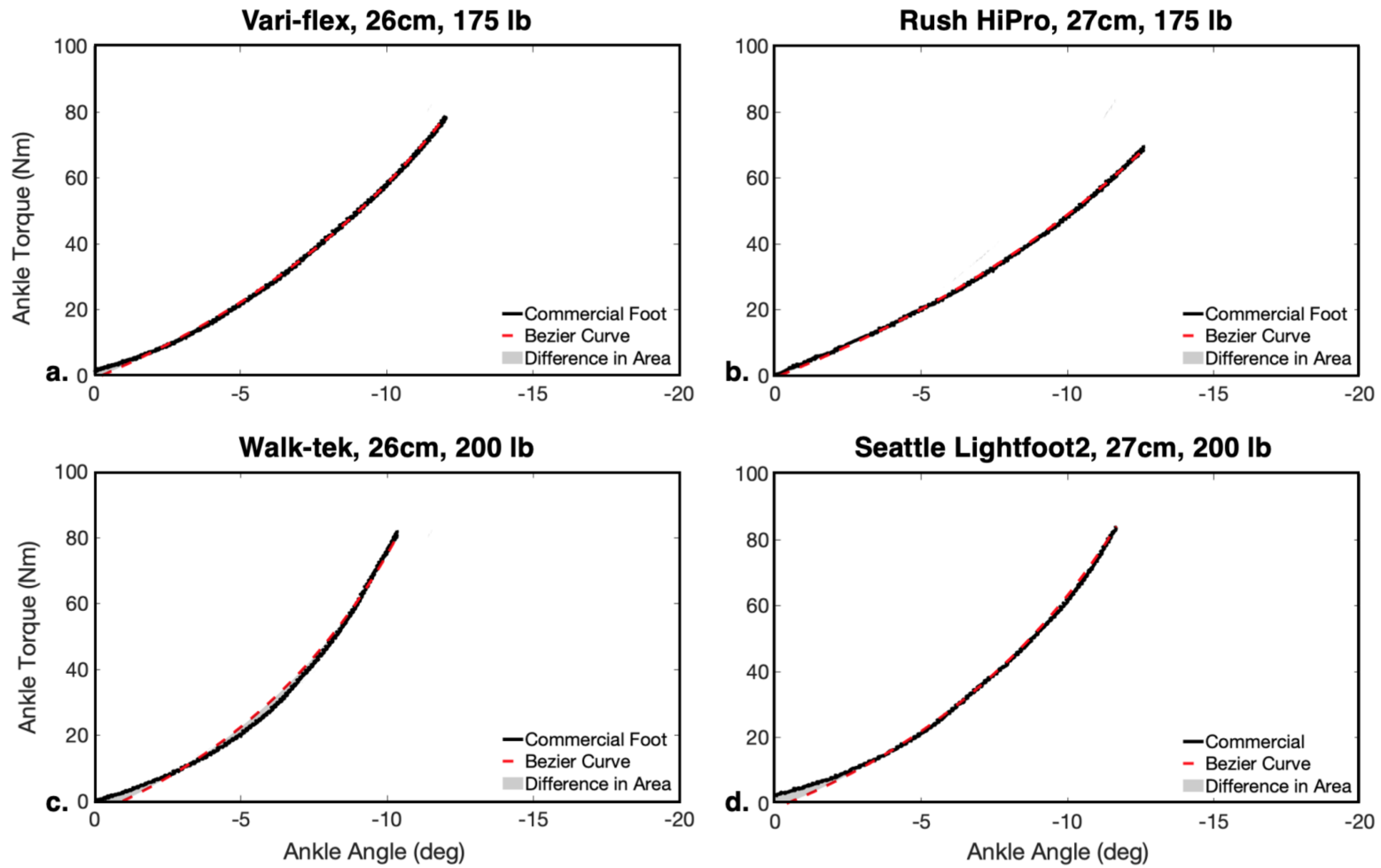

Figure 2.11. Example of total difference in area (shaded in gray) between the commercial prosthetic foot angular stiffness data and the respective Bezier curve, across a range of prosthetic foot types, sizes, and user body weights.

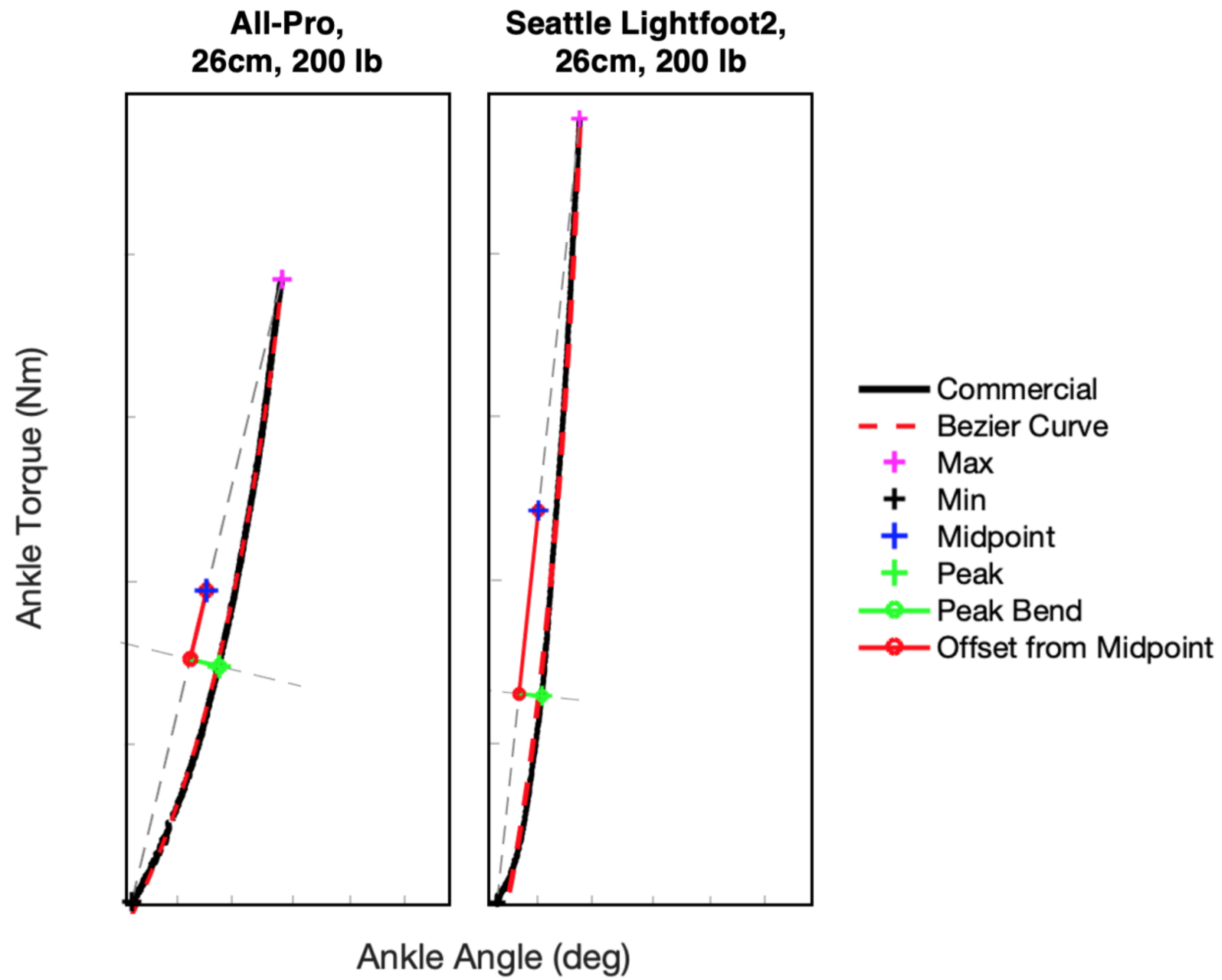

Figure 2.12. Examples of nonlinear features (i.e., peak bend, offset) for commercial prosthetic feet of differing types, with least-squares optimized Bezier curve shown.

Chapter 3

Accelerating education and empowering patients: perceptions of transtibial prosthesis users regarding the use of test-drive strategies for prosthetic foot prescription

Abstract

Purpose: The process for selecting a prosthetic foot relies on clinicians' expertise to match a foot to each patient's functional goals. However, persons with lower limb amputation rarely have the opportunity to provide experiential input to the foot prescription process. A test-driving approach could enhance prescription by offering prosthesis users an opportunity to use multiple feet before a final foot is selected. The purpose of this study was to develop an understanding of prosthesis users' experiences test-driving feet compared to being prescribed a prosthetic foot as part of standard clinical care. **Materials and Methods:** A qualitative, grounded theory study was conducted using individual, semi-structured interviews with transtibial prosthesis users who had completed a test-driving protocol for prosthetic feet. Purposive and theoretical sampling were used to achieve maximum variation. **Results:** Eleven participants with transtibial amputation were interviewed. The core category was the relationship between patients' prosthetic foot knowledge and their decision-making power. Five major themes were identified. First, participants described prosthetic foot prescription as an educational journey where decision-making power dynamics between themselves and their clinicians changed over time. Secondly, relationships with clinicians and peers were recognized as key to the foot prescription decision-making process. The third theme was related to individuality. While all participants endorsed being informed about prosthetic foot options, individual factors were noted to influence

experiences with foot prescription, such as one's preferences for the extent of their involvement in decision-making. The fourth theme described the importance of matching a prosthetic foot to each individual's goals and priorities. Finally, test-driving was perceived to accelerate their education about prosthetic feet and facilitate discussion with their clinicians. **Conclusions:** This study presented the experience of prosthetic foot prescription from the perspective of prosthesis users. Gaining knowledge about prosthetic feet empowered prosthesis users to become more actively involved in decision-making processes with their clinicians. Additionally, the opportunity to test-drive different prosthetic feet may help educate users about feet and facilitate collaborative discussions about foot decision-making. Themes from this study may inform prosthetic foot prescription processes and the use of test-driving as part of foot selection in clinical practice.

Introduction

More than 800,000 individuals in the United States currently live with major lower limb amputation (LLA). An additional 350 people, on average, undergo amputation surgery every day (Control & Prevention, 2020; Ziegler-Graham, MacKenzie, Ephraim, Travison, & Brookmeyer, 2008). Relative to people without amputation, people with unilateral amputation often exhibit mobility limitations, such as walking more asymmetrically, more slowly, and taking fewer daily steps (Adamczyk & Kuo, 2015; Agrawal, Gailey, Gaunaurd, Gailey, & O'Toole, 2011; Boonstra, Fidler, & Eisma, 1993; Lin, Winston, Mitchell, Girlinghouse, & Crochet, 2014). While activity limitations have commonly been studied, people with unilateral LLA also exhibit a range of restrictions in community participation (Resnik, Borgia, & Silver, 2017). Use of a lower limb prosthesis can help attenuate some of the impairments imposed by LLA (E. Schaffalitzky,

Gallagher, Maclachlan, & Ryall, 2011; E. Schaffalitzky, Gallagher, MacLachlan, & Wegener, 2012; Van der Linde, Hofstad, Geertzen, Postema, & Van Limbeek, 2007). For example, prosthesis use has been associated with improvements in psychosocial outcomes, such as self-esteem (Jefferies, Gallagher, & Philbin, 2018a; MacKay et al., 2020; Sarroca et al., 2021), sense of independence (Murray & Forshaw, 2013; E. Schaffalitzky et al., 2011; E. Schaffalitzky et al., 2012), and self-image and social identity as a prosthesis user (Jefferies et al., 2018a; Jefferies, Gallagher, & Philbin, 2018b; MacKay et al., 2020; Murray & Forshaw, 2013; Murray & Fox, 2002; E. Schaffalitzky et al., 2012).

The prosthetic foot is an important modular (i.e., non-custom) component used in the assembly of a transtibial prosthesis, and it has the vital role of transmitting forces from the ground to the user's limb (Kistenberg, 2014; Stevens, Rheinstein, & Wurdeman, 2018). The decision of which prosthetic foot may be optimal for an individual with LLA is complex, given the myriad options available and the variety of shapes, features, and costs associated with them, in addition to third-party payer considerations (Hofstad, Linde, Limbeek, & Postema, 2004; Raschke et al., 2015; Stark, 2005; Van Der Linde, Geertzen, Hofstad, Van Limbeek, & Postema, 2003, 2004). While numerous studies have compared the effectiveness of commercial prosthetic foot models, they are often limited to relatively few types of feet and small study sample sizes and use outcomes of unclear clinical relevance. Consequently, empirical evidence to inform clinical prescription of prosthetic feet is scarce (Hofstad et al., 2004; Stevens et al., 2018). In lieu of sufficient objective evidence to inform prosthetic foot prescription, the process for selecting a foot instead relies on the expertise of the prosthetist and prescribing clinicians to match the perceived function of the foot to the functional goals of the individual patient (Czerniecki, 2005; Stark, 2005; Stevens et al., 2018). The clinical team may also rely on their familiarity with foot

models, the patient's prior experience with particular feet, or marketing materials from prosthetic foot manufacturers (Klute, Kallfelz, & Czerniecki, 2001; Raschke et al., 2015). Although expert recommendations are important, a critical element that is often missing from the process is the ability for the patient to trial different kinds of prosthetic feet and provide experiential input (Sansam, O'Connor, Neumann, & Bhakta, 2014).

Furthermore, a chasm persists for replacing the performance of the biological ankle-foot, even with the advent of modern composite materials and other advanced technology used in prosthetic feet. Despite leg prostheses being presented in the media as high-performance blades or bionic ("Amputees merge with their bionic leg," 2019; Choi, 2020; Pogash, 2008; Sansam et al., 2014), commercial prosthetic feet are typically passive devices that fall short of replicating the muscular control and sensation provided by biological feet. In addition, there are functional trade-offs associated with different commercial prosthetic feet (e.g., more ankle range of motion could reduce stability for someone with compromised balance). Thus, it is crucial to match the properties of individual feet to the needs of individual patients. However, laboratory-based quantitative approaches to assess prosthetic feet have rarely detected differences among commercial models (Hofstad et al., 2004), possibly due to the relative insensitivity of biomechanical and performance outcomes for assessing nuanced differences between feet.

In contrast, participants in these studies have consistently perceived meaningful qualitative differences between prosthetic foot models and, consequently, patient-reported outcomes have demonstrated differences among feet (Hafner, Sanders, Czerniecki, & Fergason, 2002; Houdijk, Wezenberg, Hak, & Cutti, 2018; McDonald et al., 2018; Morgan et al., 2018; Raschke et al., 2015). This apparent discrepancy between perceived differences not being detected quantitively may result from underpowered study sample sizes or outcomes that do not capture the

differences between feet. However, the discrepancy may also suggest that people with LLA experience nuanced differences among commercial prosthetic feet and may have individual preferences for different feet. While clinicians can provide guidance on feet based on their expertise, this guidance is limited by their own experience and judgment of particular prosthetic feet. Thus, the varied priorities and preferences across individuals living with LLA may not be accounted for (Sansam et al., 2014; Van der Linde et al., 2007). Additionally, lower limb prosthesis users have expressed a desire to be more directly involved in the choice of prosthetic components with their clinicians (S. D. Messinger, 2010; Murray, 2013; Nielsen, 1991). Previous research has further demonstrated that engaging the prosthesis user in choosing components of their device improves satisfaction and continued use (Murray, 2013; Postema, Van der Donk, Van Limbeek, Rijken, & Poelma, 1999; E. Schaffalitzky et al., 2009; Van der Linde et al., 2007).

The current paradigm for prosthetic foot selection is analogous to a driver investing in a new car based on the recommendation of the car dealer without being able to test-drive different options for themselves. An alternative "test-drive" approach has been proposed to enhance prosthetic foot prescription by offering people with LLA an opportunity to experience walking with multiple feet to determine their relative foot preference ("A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations," Department of Defense Orthotics and Prosthetics Outcomes Research Program (OPORP) Award No. W81XWH-16-1-0569). However, it is currently unknown whether people with LLA would desire or benefit from such an approach to selecting prosthetic feet. Qualitative research methods are increasingly advocated as a way to explore prosthesis users' experiences and perspectives (Fogelberg, Allyn, Smersh, & Maitland, 2016; Gallagher & MacLachlan, 2001;

Jefferies et al., 2018a; Littman, Bouldin, & Haselkorn, 2017; Murray, 2005; E. Schaffalitzky et al., 2011; Suckow et al., 2015). Qualitative research has previously examined the experiences of people with LLA regarding amputation (Littman et al., 2017; Murray & Forshaw, 2013), prosthesis use (Jefferies et al., 2018a, 2018b; Murray, 2005, 2009; Murray & Fox, 2002; E. Schaffalitzky et al., 2011), and communication between clinicians and patients with LLA (S. D. Messinger, Bozorghadad, & Pasquina, 2018; Murray, 2013). However, very few qualitative studies have examined the experiences of people with LLA related to component use, such as using prosthetic feet (Fogelberg et al., 2016; McDonald, Cheever, Morgan, & Hafner, 2019). Information from prosthesis users about their experiences regarding prosthetic foot selection would be helpful to complement the quantitative data being collected as part of the ongoing study on test-drive approaches for foot prescription to inform practice and further scholarly inquiry (Brousseau et al., 2020; Turner et al., 2020).

Therefore, the purpose of this study was to solicit the perceptions of participants with transtibial amputation (TTA) who had experienced test-driving different types of prosthetic feet. The objective was to develop an integrative understanding of the experience of test-driving compared to previous experiences being prescribed a prosthetic foot as part of routine clinical care.

Methods

A qualitative, grounded theory study was conducted to understand the lived experience of being prescribed a prosthetic foot for people with TTA. This approach allowed for the systematic generation of theory regarding processes and shared experiences related to prosthetic foot selection practices. Theory generation was achieved through adherence to established data

collection and analytical procedures, including open, focused, theoretical coding, and theoretical sampling and memoing (Charmaz, 2014; Corbin & Strauss, 2015). The product of a grounded theory study is a rich, relevant, and inductive theory that addresses how participants in a substantive area process or relate to a primary concern and captures and accounts for variation in their responses and lived experiences (Charmaz, 2014; Corbin & Strauss, 2015).

In accordance with the grounded theory tradition, I adopted elements of both postpositivist (Corbin & Strauss, 2015) and constructivist (Charmaz, 2014) interpretive frameworks. Postpositivist grounded theory frameworks favor methodological rigor to promote objectivity in knowledge creation (Corbin & Strauss, 2015). In contrast, constructivist interpretative frameworks regard knowledge as a co-creation, in which subjective meaning is socially negotiated. Further, constructivists view reciprocity and engagement between the researchers and participants as necessary for the meaningful interpretation of data (Charmaz, 2014). However, these frameworks share fundamental philosophical assumptions and ontological orientations, including accepting that multiple realities exist as seen from differing perspectives (Creswell & Poth, 2018). All study procedures were reviewed and approved by the VA Central Institutional Review Board (IRB) and the Department of Defense (DoD) Human Research Protections Office (HRPO), and all participants provided informed consent. Pseudonyms were used to maintain confidentiality. E.H. (certified prosthetist-orthotist with qualitative research training) led all research activities.

Overarching study: Test-driving prosthetic feet

Participants who had completed the test-drive study (TeD) protocol to trial several prosthetic feet were eligible for recruitment (Figure 3.1). In the TeD protocol, participants were sorted into

low-mobility and high-mobility groups (i.e., based on a two-minute walk test distance cut-off of 375 feet) (Reid, Thomson, Besemann, & Dudek, 2015). Each group was assigned three types of commercial feet that were considered clinically appropriate for the participants' respective activity levels, with one foot type shared across groups. Participants trialed each of three types of prosthetic feet in a laboratory environment and were blinded to the make and model of the foot by a black sock tied around the foot to obscure visual characteristics. Then, using each foot in a randomized order, participants completed a range of walking activities (e.g., range of self-selected speeds, inclines, stairs) and reported their relative foot preferences. On a separate day, participants also used simulated versions of the three feet using a robotic Prosthetic Foot Emulator (PFE) (Humotech, Inc.; Pittsburgh, PA) to complete the same walking activities in the laboratory. After the two in-laboratory test-driving experiences, participants wore each commercial foot at home for consecutive two-week periods, in a randomized order, before completing a range of patient-reported and performance-based outcome measures with each foot (Behrens et al., 2020; Brousseau et al., 2020; Turner et al., 2020). It is because of unsolicited participant responses to the TeD study procedures that this qualitative study was undertaken.

Sampling strategies

For the current study, I intended to recruit up to 15 individuals from the pool of 53 participants who had completed the test-driving protocol across two study sites (i.e., VA Puget Sound Health Care System and Minneapolis VA Health Care System). The inclusion criteria for the test-driving protocol were: 1) adults (18+ years) with unilateral TTA, 2) prosthesis users for 6+ months with a well-fitting prosthetic socket, 3) able to walk for at least two minutes, with an assistive device or breaks, as needed, 4) able to complete study procedures (e.g., proficiency

communicating in English), and 5) body weight <250 lbs (i.e., due to prosthetic feet and PFE weight limits). The original sample was recruited as a convenience sample at each study site. For the semi-structured interviews, participants who had recently finished the test-driving protocol (i.e., within 0-12 months of the participant's interview) at either data collection site were eligible for recruitment to limit compromising recall of test-driving prosthetic feet.

Qualitative research methods often dictate that investigators intentionally recruit participants with a range of characteristics found within the target population to explore multiple dimensions of the experiences (Agan, Koch, & Rumrill, 2008; Krueger, 2014; Morse & Field, 1995). Accordingly, I identified specific participant characteristics observed in the TeD study sample that may be considered essential to gain a rich understanding of the benefits and limitations of test-drive strategies and prosthetic foot prescription. Then, I analyzed the observed range of these characteristics to guide purposive sampling for maximum variation. To achieve maximum variation, I set recruitment targets to sample individuals from across the range of values observed within each participant characteristic. For example, upper and lower quartiles were defined for metric traits (e.g., age, time since amputation), and histograms were generated for categorical traits (e.g., race, ethnicity, military status, education level) (Creswell & Poth, 2018; Miles, Huberman, & Saldaña, 2014). This information was used to guide purposive sampling and recruit individuals from the original sample with a range of traits (e.g., older, younger, differing levels of education, differing racial or ethnic backgrounds) that might be important to inform the research question (Creswell & Poth, 2018; Hennink, Kaiser, & Marconi, 2017).

I used an iterative approach for recruitment as semi-structured interviews were conducted. I used theoretical sampling for ongoing recruitment to invite unique perspectives on concepts derived during data analysis and elaborate on themes and relationships. Research team (i.e., E.H.,

S.M., and H.F.) consensus determined when to suspend interviews based on conceptual saturation, whereby no other distinct properties or dimensions in the concepts were encountered (Corbin & Strauss, 2015).

Data collection

Semi-structured interviews

Using a grounded theory approach to describe and interpret participants' experiences with prosthetic foot prescription, I conducted individual semi-structured interviews to obtain primary source experiences, thoughts, and opinions. Individual interviews offered in-depth conversation to probe participant's personal experiences with being prescribed prosthetic feet, their beliefs about the nature of the decision-making processes in prosthetic foot prescription, and their opinions about test-driving different types of feet (Tolley, Ulin, Mack, Robinson, & Succop, 2016).

I used a semi-structured interview guide to conduct the interviews (Figure 3.2). The interview guide was developed, reviewed, and edited for question content and order by the research team. Open-ended guiding prompts were designed to facilitate discussion about participants' previous experiences with prosthetic foot prescription in routine clinical care and the test-drive strategy they experienced as part of the study. The interview guide was revised with expert feedback from a VA qualitative research consultation group (i.e., VA Health Services Research & Development Center of Innovation for Veteran-Centered and Value-Driven Care (COIN): Seattle, WA, and Denver, CO qualitative research consultation group). I also tested the guide in pilot interviews with clinician stakeholders and one volunteer with TTA, who was not enrolled in the study, to inform further modification and ensure clarity. Participants

received a copy of the interview guide questions before the interview. By providing the guide, participants had the opportunity to understand the interview goals, familiarize themselves with the topics, and reflect on their experiences related to the questions.

All interviews were conducted by the same investigator (E.H.). These interviews were conducted via telephone between August 2020 - January 2021. Telephone interviews permitted participation by individuals from different study sites (i.e., cross-country). Iterative interviewing techniques were used, including modifying the interview guide to elicit more useful information, rearranging the order of questioning, clarifying questions to improve participant understanding, or highlighting new information that warranted the development of additional questions (Galletta & Cross, 2013; Harrell, Bradley, National Defense Research Institute . Intelligence Policy, & Rand, 2009). Each interview lasted between 45-70 minutes. Audio from the interviews was recorded using Skype for Business (Microsoft; Redmond, WA). Transcripts of the first several interviews were reviewed, and revisions were made to the interview guide regarding questions that worked and those that needed to be adjusted for future interviews, based on research team consensus (E.H., T.R., and H.F.). Field notes were taken during and following each interview. Audio from each semi-structured interview was transcribed verbatim and de-identified in Microsoft Word by one of two investigators (E.H. and T.R.) and then checked for accuracy. Anonymized transcripts were analyzed using qualitative analysis software (Atlas.ti; Berlin, Germany) to identify, code, and annotate findings.

Decision-making preferences questionnaire

Following each interview, I also administered an ad hoc questionnaire to collect information about participants' opinions and preferences regarding decision-making and to investigate

whether experiences related to prosthetic foot prescription were influenced by these opinions. Six items on this questionnaire asked about preferences or opinions for decision-making, in general. Another five items were asked about decision-making concerning the prosthesis. Each item was ranked on a 5-point scale ranging from "Strongly Disagree" to "Strongly Agree." This information was collected after participants had concluded their interviews to reduce the chance that these questions influenced interview responses.

Data analysis

Data analysis was inductive, grounded in participants' lived experiences, and responsive to the research aims. Constant comparison and iterative inductive and deductive approaches were used incrementally throughout data collection (Corbin & Strauss, 2015). Open coding was performed line-by-line by two raters independently (E.H. and T.R.), and greater than 95% agreement was observed. Differences in coding were reconciled through research team discussion until consensus was reached. Iterative analysis and inductive reasoning from ongoing findings were used to guide further theoretical sampling. Triangulation of results across multiple sources and an audit trail (e.g., detailed memos and diagrams) were utilized during iterative analysis to support the trustworthiness of the data (Charmaz, 2014; Corbin & Strauss, 2015).

Following focused coding by the first investigator (E.H.), additional investigators conducted thematic analysis (H.F., T.R.). Final inferences, themes, and processes were identified and developed with all investigators (E.H., H.F., S.M., T.R.) to explore alternative coding interpretations. Research team consensus was ultimately used to agree on core categories and themes. Participants were invited to engage in member checking, reviewing portions of their transcripts and the overall study findings to ensure accuracy and avoid misrepresentation. A rich

description of participant experiences supported directly by quotations permits credibility determination of the data analysis to be reader-driven (Corbin & Strauss, 2015).

Data from the questionnaire were recorded in a spreadsheet and assessed for descriptive trends across items and participants. However, total scores were not calculated, and no statistical analysis was performed on these data. The questionnaire data were also imported into Atlas.ti for comparison with qualitative analysis findings to explore relationships between individual preferences for decision-making and qualitative perceptions of lived experience regarding prosthetic foot prescription processes.

Researcher positionality

I acknowledge that the researcher is inextricable from the qualitative research process (Charmaz, 2014). Thus, I engaged passionately in interpretation and embedded myself as part of the co-constructed knowledge from this study regarding the phenomenon of prosthetic foot prescription. To achieve this co-constructed knowledge, I drew on my experience as a certified prosthetist-orthotist and a lead researcher for the TeD protocol (Charmaz, 2014). I am aware of changing context and competing perspectives of reality, but I also posit that my knowledge and experience can aid theory development and nuanced understanding of the data. I attempted to mitigate my influence by using procedures to maximize objectivity in data collection and analysis, as described in detail below.

My status as a researcher, a clinician with ten years of experience, and a person without TTA may have affected participants' responses since I was conducting the interviews. The effect that I had on responses during the interviews may have varied across participants since I had a preexisting relationship with some participants as the researcher for the TeD protocol (i.e., those

from the Seattle data collection site) but not others (i.e., those from the Minneapolis site). I was aware of the potential for acquiescence response bias or social desirability bias due to my role as the interviewer. However, I tried to lessen any adverse consequences of my presence by explicitly positioning the participants as experts on their own experiences and opinions. Interviews were conducted by telephone, affording distance that reduced my physical presence while participants responded to the prompts. I tried to avoid leading prompts or binary questions by developing my interview guide with feedback from qualitative experts and people with TTA who were not a part of the study sample. During the interviews, I also aimed to practice unconditional positive regard in my demeanor to encourage participants to express their views openly. Additionally, I engaged in reflexivity by routinely writing memos and keeping a diary of my reflections throughout conducting this research to maintain a record of how I achieved meaning-making from the data (Finlay, 2002). This practice enables scrutiny of the research by demonstrating a methodological log of my decisions and personal reactions throughout the research stages.

Data analysis was conducted in partnership with other members of the research team. The second independent rater (T.R.) is not a clinician and is not a content area expert or stakeholder in prosthetic foot prescription. Thus, including coding from a second, substantially different perspective ensured that participants own voices were highlighted, that the data were interrogated and scrutinized for alternative interpretations, and that my own experiences did not exclusively inform meaning-making from the data.

Results

Eleven participants with unilateral TTA across two study sites (i.e., Seattle and Minneapolis) completed the semi-structured interviews (Table 3.1). All participants were male since the original study sample who had experienced test-drive strategies were male. Mean age was 59.4 ± 11.8 years (range: 40-74), mean time since amputation was 6.7 ± 5.6 years (range: 1-17), and mean amount of time between finishing the TeD protocol and completing the interview was 3.8 ± 4.1 months (range: 0-12 months). Three participants had been assigned to the low-mobility test-drive group, while eight had been assigned to the high-mobility group.

A range of individual experiences and characteristics were represented in this sample of participants (Table 3.2). Most participants had amputations due to diabetes-related dysvascular disease or trauma. Two participants within the traumatic etiology group had opted for elective amputation surgeries following unsuccessful limb salvage procedures as Active Duty Servicemembers.

The core category identified in this study was the relationship between knowledge and decision-making power concerning prosthetic feet. Related to this core category, five major themes were identified from the perspective of the person with LLA (Table 3.3).

Theme 1 – Gaining knowledge about prosthetic feet through experience

All participants spoke about experiencing a lack of knowledge about prosthetic feet at some point in their history of prosthesis use. Despite the interview guide not including any questions related to the amputation or the first time being prescribed a prosthesis, every participant reflected on their initial experience using a prosthetic foot following amputation. Participants noted the profound impact of prosthesis use on their daily lives and a sense of reliance on the

prosthesis, about which they knew very little initially. One participant who had an amputation over five years earlier shared:

> "I am thinking back to when it all happened, it was so surreal. For a first time foot owner, very surreal. Because you don't know anything and it's something that you are going to use every moment of the day until you take it off at night and go to sleep. It is profound. It is scary and exciting. It's unknown." – Sam (47-year-old, traumatic amputation five years earlier, Veteran)

This strong temporal component was present across responses that started with the unknown, "surreal" experience of amputation. Participants then marked time by the amount of knowledge or experience they gained in relation to a decision about their prosthetic foot. All participants commented on how the early stages of their experiences following amputation were associated with an absence of knowledge about prosthetic feet and the process for selecting one. Two participants with differing histories described this lack of knowledge about prosthetic feet similarly, and both used the generalized pronouns "you" as if to indicate a universal experience people being prescribed a prosthetic foot for the first time, sharing:

> "I knew nothing about it cause I never had one before. You're clueless. I didn't know there were options I just needed a foot. As far as I knew they were all the same. I trusted the people knew what they were doing picking it." – Larry (63-year-old, traumatic amputation two years earlier, Veteran)

> "At first, you don't know anything. One of the amputees I know was just saying, 'They gave me this foot, and I don't know if it was the right one or not. I have no idea, but I can walk.' And it's kind of the excitement too, when you get your first foot, you're just excited that you can walk. You have the freedom in that you just went through a change

of life that was very traumatic, so you're willing to accept a lot just because you get to walk." – Wayne (70-year-old, dysvascular amputation four years earlier, non-Veteran)

This absence of knowledge about feet was associated with a sense that the clinicians (i.e., prosthetists and prescribing physicians) were gatekeepers of that knowledge. Some participants, such as Larry, quoted above, described trust in their clinician to select the prosthetic foot based on clinical wisdom, given their own lack of knowledge on the topic. Other participants described having to rely on clinicians as an undesired consequence of not having their own experiences with prosthetic feet to offer input into the decision-making process.

"I just kind of went with the recommendations of the prosthetist. And we discussed different options, but I wasn't able to try them out really, so I just accepted their word, and it is what it is." – William (63-year-old, dysvascular amputation five years earlier, Veteran)

"I never got to try out any feet. Not to my knowledge. I mean, maybe? But I didn't know that I was trying out different feet. If [the prosthetist] did, he never really made it clear." – Tom (74-year-old, sepsis-related amputation four years earlier, non-Veteran)

"Being a new amputee, that was kind of hard to figure out because until you've actually worn a prosthetic, you don't know much. That's why I had to take my prosthetist's input as to what was the better foot. But now that I have experience with eight different styles of feet, when I talk to my prosthetist, I can talk in a more educated or more informed way." – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

Similar to Frank in the quotation above, many participants described the process of becoming a more experienced prosthetic foot user as an educational journey. Participants viewed

opportunities to use prosthetic feet as a tangible way to become more educated. However, several participants also cited discussions with people they considered experts as a means of learning. Three participants identified discussions with expert clinicians or peers with LLA as increasing their awareness of prosthetic foot options. However, not all participants recalled having a discussion with their clinicians to learn about options. Seven participants reported that they did not learn about any prosthetic foot options from their clinicians before a foot was selected. These participants reflected on the lack of education from clinicians when their first prosthesis was prescribed.

> "It's just more of an educational process to let people even know that there's different options…because, hell, I didn't know when I first lost my leg. They could have gave me a wooden peg leg and said, 'Here you go! Get out of here!' (laughs)"– William (63-year-old, dysvascular amputation five years earlier, Veteran)

> "So the first one, it was just, 'Here's your foot.' I didn't even know it was a separate thing from the socket. The second one was the same. The third foot, I did research on my own and told my prosthetist the foot I wanted." – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

Depending on the participant, some of these seven individuals seemed to blame themselves (or, indirectly, the individual being fit with the prosthesis) versus the clinicians for not teaching them about options for prosthetic feet. For instance, one participant stated:

> "It was as much or more my fault that I stayed uneducated. Like I said, I was in a fog, and whatever foot was presented to me was it. I didn't care to be educated, I guess. I wish that I would have gotten more educated as to what was really going on and as to what my

options were for [the foot].” – Tom (74-year-old, sepsis-related amputation four years earlier, non-Veteran)

A younger, more active participant with traumatic amputation made a similar observation about personal responsibility for becoming knowledgeable as Tom, but about other people with LLA, rather than speaking from personal experience:

> “But if you don’t know anything and you don’t want to, and you’re just like, ‘Just get me a foot so I can walk out of here,’ you know? I mean, that’s on the person.” – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

In contrast to Tom and Eduardo, who identified a personal responsibility to demonstrate an interest in being educated, some participants identified the clinicians as responsible for imparting knowledge about prosthetic feet. Regardless of the source of education, as participants gained more experience using prosthetic feet and interacted with their clinical team (i.e., physicians and prosthetists) over time, all participants noted an increased sense of embodied knowledge. Furthermore, most participants described a direct impact of having more knowledge about prosthetic feet on involvement in decision-making. Participants with more experience with prosthetic feet or elapsed time since amputation discussed this shift in the decision-making dynamic, noting:

> “I try to go in there with more information now. As far as, ‘I researched this foot because I feel that it’s going to work better for me and you know 80% of what I do,’ type of situation.” – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

In contrast, participants with more recent amputations (or less experience with different prosthetic feet) described a newfound knowledge after test-driving feet during research that they

believed would impact their approach to their clinical decision-making in the future. For example:

> "If we knew about [foot] options, it would be very beneficial. Depending on how much we know, then we can ask about it. It would have been very helpful. Now I am curious, what else is out there that I am not aware of? I am happy, my lifestyle is good, things are working fine. But I would be curious to know what else is out there. Now that I know what to do, next time, I am going to ask, 'What are my choices?' Because the more education I get about a foot, I might be able to help them pick the correct device for my use." – Martin (73-year-old, dysvascular amputation two years earlier, Veteran)

From the participants' perspectives, increasing their prosthetic foot knowledge seemed to influence the decision-making dynamic by reducing the discrepancy in the amount of knowledge relative to their clinicians. Further, some participants acknowledged that the type of knowledge that patients contribute to the decision-making process is distinct from clinicians' knowledge. For instance, they recognized that clinicians might consider technical aspects or familiarity with third-party payer guidelines for reimbursement of particular prosthetic feet, which patients would not be expected to know.

> "I know a lot of it is also the prosthetists' knowledge because they have to be like, 'You don't have any room under there for that, or you don't have a long enough limb.' But at the same time, like, if they don't tell me what's out there, how the hell do I know what to ask for?" – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

Conversely, participants valued aspects of their own knowledge, which they perceived as unique to them and which clinicians did not have access to.

“I think the more informed the amputee can be, the better input they can give their prosthetist in the style or in the type of foot that’s going to work better for their day-to-day life.” – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

“It’s cool, [the prosthetists] are trying. But at the same time, I know what I want and what I don’t want now. I’m the expert on what’s best for me.” – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

Overall, knowledge about prosthetic feet was associated with decision-making power. In contrast, other themes identified in the transcripts related to who had access to this knowledge, how it could be transferred, and the corresponding relationship dynamics among stakeholders.

Theme 2 – My external relationships (with clinicians and peers)

All participants discussed the influence of their relationships with other people, including their clinical team and peers with LLA, on selecting their prosthetic foot. In particular, participants described the quality of the relationship with their clinical team as a defining component of previous clinical experiences receiving a prosthetic foot, whether positive or negative. Eight out of eleven participants commented on how their relationship with clinicians evolved as they became experienced prosthesis users. Nearly all participants described being a passive recipient in their earlier prosthetic foot prescription experience rather than being actively involved in the decision-making. These early experiences were often associated with perceptions of being on the outside of the decision-making process related to their prosthetic foot:

“At first, I would just take anything they gave me.” – Larry (63-year-old, traumatic amputation less than two years earlier, Veteran)

> "When it comes to the process of choosing [a foot], we didn't go into that. I just accepted what [the clinical team] gave me. Honestly, the concept of the foot would not enter into my comments because we never had that kind of discussion. I don't believe we ever had a discussion that there might even be a choice. I had no role other than to wear it." – Martin (73-year-old, dysvascular amputation less than two years earlier, Veteran)

> "Basically I said, 'Look, I'm going to trust you because I have no idea. Give me what you think is going to be the better option for me to start with, and I'll go from there.'" – Frank (58-year-old, traumatic amputation more than two years earlier, Veteran)

> "I went in for the leg that second time and I got a different foot…I didn't even know that I got a different foot. So [the prosthetist] just did it. I thought they were just doing the leg portion, but they put a different foot on along with it." – William (63-year-old, dysvascular amputation five years earlier, Veteran)

Despite these feelings of being a passive recipient of their prosthesis, many participants also spoke highly of the overall experience and acknowledged the expertise and care of the clinical team. Many, but not all, participants were treated by multidisciplinary rehabilitation teams (i.e., physicians, prosthetists, physical therapists, and other rehabilitation providers) specializing in the care of people with LLA, and noted this team approach as a benefit:

> "There's a saying in [the Army] that no one person knows as much as two people. So when I go to the amputee clinic, if the ortho guy says something, then I'm gonna listen to them too, you know? He's not a prosthetist, but who knows…when it's all together, the whole team, everybody talking to each other and to me. I think that works out the best; you seem to get the best results." – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

"It's me and five or six other people in a room. I had a great team of people, and that team of people got me standing again and walking. I am eternally grateful. There's not a day that goes by that I don't think about how fortunate I am. They listened to everything that I said, and they discussed and came up with the suggestion that they did…I think I had a really good team of people." – Sam (47-year-old, traumatic amputation five years earlier, Veteran)

However, some participants indicated that the number of people involved in decision-making contributed to their feeling of isolation or exclusion from the discussion. For instance:

"It felt like my opinion wasn't all that important." – Chris (68-year-old, dysvascular amputation 17 years earlier, Veteran)

"There was no one person making the decision. It was a group. They discussed different types of feet with each other." – Larry (63-year-old, traumatic amputation two years earlier, Veteran)

"It was a different process when I started going to the [multidisciplinary amputation care clinic]. They discussed things more. But you got a whole team of people. That was just overwhelming to me, when you walk in and you've got eight people in the room." – William (63-year-old, dysvascular amputation five years earlier, Veteran)

Nine out of eleven participants explicitly described the importance of the relationship with their prosthetist, above and beyond other clinicians. For many individuals, they attributed positive experiences with clinical care to the nature of the communication with their prosthetist:

"I'm pretty sure this is the same with any prosthetist fitting a leg. It's this kind of relationship that you build. They know my personality by now 'cause we've done enough together.

It's the same thing where I go to [prosthetist name], I've been going there for years and I go there often, so we become friends…which is good and you build a relationship with that, but along with that, they start knowing the fit, how your characteristics are. Sometimes you don't see something, but they see it. I think that's important." – Wayne (70-year-old, dysvascular amputation four years earlier, non-Veteran)

"The prosthetists are very crucial in helping guide the patients. They shouldn't direct them, the patient ultimately knows how they feel. But my prosthetist did the best he thought. And I think he did a good job." – Sam (47-year-old, traumatic amputation five years earlier, Veteran)

"I would say you have to get chemistry with your prosthetist and you got to get trust with what they're offering… I think the whole key, as with anything, is to have that relationship with that person that is working on you, giving you advice, recommending what you should try or use. That's very important." – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

Nearly all participants expressed respect for the expertise of the prosthetist. Many also acknowledged that the prosthetist discussed desired activities and functional goals to understand the patient's individual needs.

"I think [the prosthetist] did a really good job. They are really knowledgeable and they take into consideration my body build and what she thought would work best for me. We- she discussed it with me at length." – Larry (63-year-old, traumatic amputation two years earlier, Veteran)

"Initially, if you're a brand new amputee, you should tell them about your hopes, expectations, and wish list, but I think it is the prosthetist that is the expert. They are pointing you- or getting you the foot that you want." – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

However, if participants did not feel that prosthetists adequately discussed and understood their needs, a good rapport was not enough to satisfy the participant.

"I went to a couple different prosthetists, and they're all very friendly and helpful, but when it came to choosing a foot, there wasn't enough questioning as to what the activities were that you were going to do or plan on getting into. So there was no foresight into future use. It was mainly, 'What are you doing now? That's the kind of foot we are going to get for you.'" – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

"[The prosthetist and I], we're friendly and everything, but my problem with him, if I can say this, is there were so many people he was seeing. He was one person. I hate to say this, but it was just lost in translation, so whatever I would say was always lost in translation because he wasn't listening. It was never right. There was always a little thing that was off. And [prosthetist name] didn't take the time with me to discuss and know what I needed." – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

There was a difference between developing trust in the prosthetist's expertise versus feeling a lack of agency and relying on them in the foot selection process. An absence of discussion caused several participants to express frustration about the lack of clarity around considerations for selecting a foot the amount of perceived power the prosthetist wielded.

"I didn't have a role. The prosthetist picked it, and I think it was probably just what they had on the shelf." – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

"I think the conversation I remember was that we talked about my activity level and things I want to do or like to do. It came to down to that [the prosthetist] thought this would be the best foot for me. I don't remember ever discussing other feet." – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

Most participants ultimately described a desire to participate in decision-making. Several participants identified themselves as the decision-maker with guidance from clinicians.

"I will take my prosthetist's- I want them to make a decision based on my input…I don't put all my faith in just letting them make all the decisions for me. Not anymore." – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

"If I had more say so in what I would like to have…that plays a big part with me. If I can just tell [the clinicians] what I want and they try to accommodate me." – Chris (68-year-old, dysvascular amputation 17 years earlier, Veteran)

"I think it should be a committee where [the clinicians and I] have open discussion with each other" – Wayne (70-year-old, dysvascular amputation four years earlier, non-Veteran)

"I'd like more questions from them asking about my lifestyle and goals. I don't think they had an accurate- well I'd like the clinicians to just have me more involved and discuss with them and to have more options available, to teach me." – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

Participants described the importance of advocating for oneself to achieve this type of in-depth discussion and shared decision-making capacities with clinicians. Self-advocacy included taking responsibility for learning to ask clinicians the right questions to benefit from their knowledge and be able to assimilate that knowledge with their own expertise about their bodies and functional goals. For example:

“You’ve got to get to a point where you’re a patient who is knowledgeable enough to at least ask questions and not necessarily accept everything at face value. So it’s a process of educating the patient. Next time I’ll inquire about a little bit more about what it is that they think might be work best for me. I don’t think I will be a challenging patient. I don’t need to try out some of the fancy ones, but I wonder if I could do a little bit more.” – Martin (73-year-old, dysvascular amputation two years earlier, Veteran)

“I think that I am the one wearing [the foot], I need to be definitely involved with [selecting] it. And I need to have an opinion…but I need to communicate that. I think that’s where I made the mistake in the past few years. I didn’t know the right questions to ask.” – Wayne (70-year-old, dysvascular amputation four years earlier, non-Veteran)

“I’d never had an amputation or a prosthesis. I didn’t know anything to ask! All I was concerned about was being able to learn how to walk.” – Tom (74-year-old, sepsis-related amputation four years earlier, non-Veteran)

“It’s important for amputees to know that it’s going to be a continuous process, it’s not a one-all-be all. You’re not going to find your foot the first time, plus you’re going to evolve, you’re going to strengthen, or gain weight, things change. It’s constant change. Amputees need to know: don’t be afraid to try out other things and ask questions, be informed.” – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

“I’m gonna be more adamant to say, ‘Listen, I’d like to look at this one, or that one, or that one.’ I’d want at least two or three feet, and I’d make a decision between two of them. Not that I don’t trust anymore, but I got to a point where I am pretty active, but I have limitations. I want to see what I can do about getting rid of some of these limitations.” – Sam (47-year-old, traumatic amputation five years earlier, Veteran)

In addition to communication and relationship-building with clinicians, several participants described the significance of connecting with peers who had undergone LLA through amputee support groups, peer visitors, online forums, or via encounters in a clinical environment. Those participants who had experience with a community of people with LLA described benefits to their education and expectations about prosthetic feet.

> "Well you see I belong to a very exclusive club that no one wants to be in. We always talk. About what happened, how long ago…what kind of foot you're walking on, how it works for you, how much it weighs, how much it moves. We compare them." – Larry (63-year-old, traumatic amputation two years earlier, Veteran)

> "I talk to amputees all the time, fellow amputees I know. I talk about what foot they've tried, what techniques they try. That's how I wound up with the [foot model]…I heard about it from a buddy of mine. It's just the grapevine of fellow amputees and prosthetists, I guess." – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

> "I don't really do research online because all that is really technical stuff. That personal relationship with your prosthetist or with other amputees is what's really important…You know, like, 'You should do this, this one works better.' Little tricks of the trade." – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

Regardless of who was giving advice, some participants noted the limitations of relying on the recommendations of others, again hinting at the need for self-advocating:

> "Basically, you talk to your prosthetist and you go off of advice that your prosthetist gives and maybe other amputees, if you happen to know some or talk to some on a forum. And then, with the info your prosthetist gives back, you choose a foot. You really just get one

based on someone else's opinion. And opinions are always clouded by a person's perception." – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

Relationships with clinicians and their roles in decision-making relative to the patient with LLA were noted to be an essential part of the foot prescription experience. In particular, communication and rapport with the prosthetist were emphasized. Participants secondarily described relationships with peers with LLA as indispensable when available. While participants indeed acknowledged that the nature of relationships with others contributed to the prosthetic foot prescription experience, participants also described the influence their own identity had on decision-making processes.

Theme 3 – My identity and individuality

In addition to acknowledging that they belonged to a larger community of people living with LLA, participants expressed a sense of individuality which made them distinct from their peers with LLA. Some participants described their identity pre-amputation, which impacted their priorities for the foot and their preferences for being involved in decision-making processes.

"I think I'm not like some amputees. I base it primarily on my sedentary lifestyle, see? So I am not challenged to do things." – Martin (73-year-old, dysvascular amputation two years earlier, Veteran)

"Before I had [an amputation], I thought it'd be cool to get one that looked like a real leg. But it doesn't matter to me anymore, I am just a freak show everywhere I go (laughs). But, hey, we're all different." – Larry (63-year-old, traumatic amputation two years earlier, Veteran)

> “I’m really active, I do a lot of climbing ladders, whatever I want to do. Most people can’t tell that I have one until they know. Which is good, that’s what I want. I don’t want people to look at me differently.” – Sam (47-year-old, traumatic amputation five years earlier, Veteran)

Participants described harmonizing their prostheses with their individuality as a critical component of optimizing outcomes with a prosthetic foot. Most participants mentioned individuality related to their experience test-driving prosthetic feet. For example:

> “So [test-driving feet] gives you that ability to make a better decision on what actually functions for the individual. What functions for me. Because I am different from another person.” – Martin (73-year-old, dysvascular amputation two years earlier, Veteran)

> “This process [test-driving feet] would empower people to pick and choose what works for the individual. And we are all individuals. So we need to maintain that individuality.” – William (63-year-old, dysvascular amputation five years earlier, Veteran)

> “Everyone is different and everybody has a different way of walking. So I think trying it before you actually own it is super beneficial. Because think of the possibilities people would have, you know? You make them feel happy and then their confidence is boosted. And then they’re out there doing good things.” – Sam (47-year-old, traumatic amputation five years earlier, Veteran)

Participants reiterated that their perspective impacted their involvement with prosthetic foot selection. For instance, participants contrasted the knowledge they gleaned from using different prosthetic feet to the clinicians’ expectations:

"I think [the patient] definitely should be involved with that because [the clinician doesn't] know my activities or what I want to do. I can tell them what I want to do, but what is it like for me to walk up the hill with this, or walk downstairs with that, how am I balancing walking across rooms. They don't know that." – Wayne (70-year-old, dysvascular amputation four years earlier, non-Veteran)

Several participants felt that personality impacts a patient's involvement in decision-making. For instance, participants highlighted the importance of personality and communication style with other stakeholders as determining one's involvement in decision-making conversations.

"A lot of it has to do with our own personality. It's all dependent on the personality, so if the prosthetist took into consideration that there are those differences- it's like learning styles. There are many different learning styles. I believe there are many styles to being a patient. And the prosthetist needs to evaluate what kind of patient they have." – Martin (73-year-old, dysvascular amputation two years earlier, Veteran)

"There's some people who go to a doctor and never say anything. And then there's some people who spend three hours telling them about every ache and pain. If you're just going to pass it all off on your prosthetist like, 'I'll take whatever you give me.' Then, what do you expect? You're the only one who knows what you like best." – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

"Yeah for sure I'm the kind of guy who does [want to be involved in discussions with clinicians]. Just talking to the prosthetists, asking them why they were doing this or that, or why the foot was this way or that way. Most of [the prosthetists] were really cool about it. They had no problem explaining it to me. And I'm just a curious dude anyways,

so I was always asking questions." – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

"I think we [the patients] should be totally involved with [selecting prosthetic feet]. However, totality can mean a lot of different things to different people." – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

While a communal identity as people living with LLA was noted, individuality and personal differences also influenced the decision-making process. Participants reported the relationships between themselves and clinicians, the relative amounts of knowledge shared between these two groups, and an awareness that there are differences between prosthetic feet as being key to achieving optimal health outcomes.

Theme 4 – Different feet for different folks (and activities!)

The fourth theme to emerge from participant's experiences was that the decision-making process for prosthetic feet is complex because the prosthetic foot itself affects health outcomes, participation in desired activities, and satisfaction with the prosthesis.

"Well there's so many considerations for the foot that it's infinitesimal. It's a complicated decision." – Sam (47-year-old, traumatic amputation five years earlier, Veteran)

Participants noted that the foot selection process is key because they experienced satisfactory outcomes with the "right" foot and, conversely, poor outcomes with the "wrong" foot.

"When your prosthetic foot isn't right, it feels like your foot is asleep or hurt in some way, you know what I mean? It's like it's not doing the thing I want, it's not me. That's why it's really important to get the right foot, so you can be doing stuff." – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

"I talked to a couple people from an amputee group and my prosthetist. But there's not a best [foot] for everybody. I mean, maybe there's even more feet that I don't know about out there, I'm sure there is. But the one that I want worked really well for me and what I do." – William (63-year-old, dysvascular amputation five years earlier, Veteran)

Many participants also emphasized that having a well-matched prosthetic foot influences their identity, self-image, and embodiment of the prosthesis:

"It would be awesome if [test-driving prosthetic feet] works, because there'd be a lot of civilians who don't get a chance. They don't even realize how close they could get back to who they were before if they had the right foot and the right socket." – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

"Everybody is made different, different feet work better for different people. But, you got to use it for a bit and then it becomes part of you." – Larry (63-year-old, traumatic amputation two years earlier, Veteran)

While four participants had tried multiple feet back-to-back either as part of clinical care or through participation in prosthetic foot studies, most had not had this opportunity before the TeD protocol. Two of these individuals described the experience of trying new prosthetic feet for the first time as a process of discovery and of resetting expectations for how foot selection impacts overall prosthesis use:

"I did not know that options for feet were available and what the function might be. They did give me a second foot for my water leg, but I didn't put two and two together. Today, as I think back on it, it was a lot more stiff than my regular everyday prosthetic and more uncomfortable to walk with. So I knew there were different prosthetic devices, but that

the actual foot could make such a difference, I wasn't aware until I did the test-driving."– Martin (73-year-old, dysvascular amputation two years earlier, Veteran)

"I found out just how different the feet really made the walking. And again I thought for sure this was gonna be my savior as far as phantom pain and sciatica. But no, I just walked more correctly and I did more." – Tom (74-year-old, sepsis-related amputation four years earlier, non-Veteran)

However, participants frequently described how the prosthetic foot was only noticeable after other elements of their prosthetic care were in place. Specifically, once their limb was healed and their socket fit was sufficient, seeking a well-matched prosthetic foot was appropriate.

"I didn't get to try out different feet. I don't know, I wasn't thinking about it at the time. I just wanted any foot so I could walk." – Larry (63-year-old, traumatic amputation two years earlier, Veteran)

"My problems was I was going through sockets like crazy. I was wearing all these socks and I was like, 'I need a new socket.' So that was more my issue in the beginning than the leg or the foot itself." – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

"I never really understood that I had an actual removable foot. I just always assumed that I got a foot with my leg. I wasn't aware that I could test drive or ask for different feet. The main thing for me is how well [the socket] fit and not how the foot walked. That's why maybe I never questioned anything. I just I was ignorant, I didn't know anything. Like that I could have tried out different feet." – Tom (74-year-old, sepsis-related amputation four years earlier, non-Veteran)

On the other hand, several participants shared that the prosthetic foot can impact the socket, so the interplay between socket fit and the prosthetic foot becomes important.

> "I know a big part of it is the socket too. If the socket doesn't fit right, it doesn't matter what the foot is doing. But mostly I'd say [the foot] just changes how I walk and it can actually affect my socket too. So, like, if a foot is too stiff, then I have to slow down and I gotta be more cautious because it's uncomfortable." – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

Many active participants commented on the value of having access to prosthetic feet to facilitate activities like sports, hiking, hunting, or swimming.

> "Being a Veteran, I was lucky to always have them. These feet were all just given to me, so I was like ok whatever. They were recommended, whatever was given to me, I kind of went with. So I had this back-up spare. So I had two. And at the same time, I also had a diving foot and a running one, so I had four or five." – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

> "I talked to civilian amputees and I feel really bad for them. Because every six years they get a foot. This is their one, their only one, you know. And if you get the wrong one, you're shit out of luck. I'm really active and I don't know what I'd do without my legs to hike and bike and stuff." – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

Participants who considered themselves low activity also benefited from getting a prosthetic foot that matched their daily needs. For instance:

"Again with my sedentary lifestyle, it's still real important to make sure that I have the proper foot. One that could help me and encourage me to wear it longer." – Martin (73-year-old, dysvascular amputation two years earlier, Veteran)

While participants felt that the process of matching a prosthetic foot to their individual needs and their activities was necessary, many also spoke about the limitations of available prosthetic foot technology. Participants described prosthetic feet as inadequate replacements for the versatility of their biological ankle-foot:

"Your foot, it does a lot for you and you lose that flexibility 'cause your toes and stuff, they're flexible. When you don't have that, you're missing that flexibility. Because there's nothing like having them being natural…you gotta get used to it, your flexibility's not there. And it holds you back." – Chris (68-year-old, dysvascular amputation 17 years earlier, Veteran)

"So I'm a pretty active person, I have always been pretty active. And so my initial thoughts were, 'I want to be able to run, I want to be able to go out and do everything I did before. I don't see any limitations that will affect me…I don't see what would be holding me back except for you know the foot itself.' I want to do whatever I want to be able to do, whenever I want. If I have to carry a bag of cement or if I want to relax. The first thing that was brought up was, 'You can't do both. It's either one or the other.'" – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

Most participants mentioned having to compromise in function of the prosthetic foot, reporting that certain feet (or properties of feet) are better suited to particular activities, but not all activities that the user encounters.

"It's easier to go up and down hills [with this foot], the disadvantage is…this one is pretty heavy, with the socket it's almost ten pounds. And I have to charge it every night. And it can't get soaked, so no puddle jumping." – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

"I liked the one that's got the spring to it. When I go up the steps, it pushes me up the step, you know, springs me up. But it's got more movement in the foot, so other times it's harder to balance. But moving up the steps is a whole lot better, easier for me." – Chris (68-year-old, dysvascular amputation 17 years earlier, Veteran)

"Some of the feet worked better than others. [That foot] might not be as reactive, but if it's not as reactive, it's going to be a little bit more stable, a bit more safe, if you will. But the more reactive of a foot, the more you are able to do inclines and declines and kickoff and run." – Sam (47-year-old, traumatic amputation five years earlier)

Furthermore, several participants talked about how they must use multiple prosthetic feet to accomplish the variety of their desired activities. For instance:

"My goal is to be as close to what I was before I lost my leg, in terms of getting things done on a daily basis, what I want to do. And I think the prosthetist's goal is to make me satisfied with my leg. I have three legs that I really use, three or four of them. I got the hiking leg, biking leg, and then this running leg. And occasionally, I have a [foot model] for when I'm at the beach or in water all day…so I got four legs that are in my main rotation." – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

"I think it depends on what I am doing. I am not one to carry around a bunch of legs. So some [patients] have a leg for lounging around or going out. I want one leg, I want it to

be as simple as possible." – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

Given the significance of matching a prosthetic foot, or multiple feet, to an individual patient's functional goals and priorities, participants viewed test-driving strategies as a way for them to judge the differences between feet and aid in the selection process.

Theme 5 – Test-driving prosthetic feet was a meaningful experience

All participants described test-driving prosthetic feet as an impactful experience. In fact, during the interviews, the research team learned that nearly half of the participants (n=5) had returned to their prosthetist after completing the TeD protocol to request one of the three prosthetic feet that they had trialed during the study. For example, one participant shared:

> "Yeah and the one that I really liked, I went back and gave the info to my prosthetist. That is the one I have on now." – Wayne (70-year-old, dysvascular amputation four years earlier, non-Veteran)

This finding represented a demonstrable transition from passive recipients of prosthetic feet to active participants in the clinical decision-making process for all five individuals.

For most participants in this study, the TeD protocol was their first opportunity to compare different types of prosthetic feet. However, several participants reported having previous experience trialing multiple prosthetic feet (i.e., by participating in previous prosthetic foot studies). Two participants were active duty Servicemembers and thus had an opportunity to try out different prosthetic feet while being treated at a Department of Defense hospital (i.e., Center for the Intrepid at the Brooke Army Medical Center, Joint Base San Antonio Ft. Sam Houston)

(Gajewski & Granville, 2006; Pasquina, 2004). This unique treatment environment allowed for Servicemembers with LLA to have access to many different prosthetic device options as part of the resources available within the system of care (Seth D Messinger, 2009; S. D. Messinger, 2010). Regardless of whether they had experience test-driving feet before the study, all participants described similar benefits associated with the opportunity to test-drive several types of prosthetic feet.

> "I think they should just let me try a bunch of different feet on. 'Til I find the best one that they have that I can wear." – Chris (no previous experience test-driving, 68-year-old, dysvascular amputation 17 years earlier, Veteran)

> "I feel very lucky I found [prosthetist name] because he takes what he's doing very seriously…but even if you are a super researcher and you come up with all these spec's for a foot and the prosthetist is on board, you don't know until you have a chance to put it on yourself." – Ray (previous experience test-driving, 50-year-old, elective amputation 15 years earlier, Veteran)

> "I think that test-driving is a very valuable thing. I didn't know that I could do that before I did this study, so it made a difference in my real life that it helped me start asking the right questions because I didn't know the questions to ask. It helped me understand the process of getting a good fit, so I can get to do the activities that I want to do with my life…to give better direction so that [the prosthetist] knows what I am doing and I know what I am doing. And so [test-driving] was really helpful for all that." – Wayne (no previous experience test-driving, 70-year-old, dysvascular amputation four years earlier, non-Veteran)

"Anytime you're trying to fit a new foot on the end of your leg, I think you probably should have the ability to try before you buy. And even if it is given to you by the VA, or a charitable organization, you should still be able to try it." – Sam (no previous experience test-driving, 47-year-old, traumatic amputation five years earlier)

Several participants articulated the benefit of test-driving on their lives and its benefit on others with LLA. For instance:

"It's really important that amputees get a chance to be able to try out different feet. But I know for a fact that they don't." – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

"It would great if this whole thing [test-driving prosthetic feet] works, it would make a big difference for people like that. Or me." – Wayne (70-year-old, dysvascular amputation four years earlier, non-Veteran)

"When you get a foot, you wear that foot all the time. Like when you go try on a pair of shoes and you can try on a pair and then you're switching it with other pairs of shoes. Some are a little more comfortable than others, but you only wear them for maybe a little bit of time. But when you get a foot, you're wearing it every day for three or four years. So it would be nice to be able to actually try them out because you're not going to change it." – William (63-year-old, dysvascular amputation five years earlier, Veteran)

Participants consistently described test-driving prosthetic feet as a means of accelerating their education and embodied knowledge. Test-driving seemed to be a process through which they quickly learned about the availability of foot options and the differences between how feet worked for themselves.

"I got a pretty good feel for how each foot was. How it works better, the goods and bads of each one." – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

"I really liked test-driving. It gave me an idea of what kind of foot I liked. And it was enough time to let me know if I liked a foot without too much time with the feet that weren't a good match for me." – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

This acquisition of knowledge via test-driving prosthetic feet seemed to translate into a greater sense of empowerment in the decision-making process. Many participants directly tied the test-driving experience to education and the power of self-determination in the decision-making process.

"It made a difference for me because I got to walk on different types of feet, and I liked doing it because it gave me feedback to get a new one that works better for me. So now I requested a specific one that I know works well for me." – Larry (63-year-old, traumatic amputation two years earlier, Veteran)

"It would be nice if I could just pick which one I prefer using, you know? It gives me a choice of which one I'd prefer to have." – Chris (68-year-old, dysvascular amputation 17 years earlier, Veteran)

After test-driving, even participants who did not request a different prosthetic foot from their prosthetist after the TeD protocol felt empowered. For instance:

"I like it because it gives me a chance to try out all these different styles and types of feet. So it gives me a better idea of what type of features to ask my prosthetist to get the next time I need a replacement. So I like having all the additional knowledge." – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

In addition to the sense of empowerment in the prosthetic foot selection process, some participants described the test-driving experience as a way to improve discussion and communication with their prosthetists. Several participants viewed test-driving as a method for the prosthetist to teach their patients and elicit feedback about differences in the prosthesis, making them feel like their contribution to decision-making was valued. For instance:

> "But it starts with teaching. Maybe the prosthetist has taken the position that they become a teacher…and test-driving is a method and a tool to help them do that. And so like it could be, 'I've got three different choices here for you and we will talk about each of them and when you're walking, this is what I want you to look for with each of these legs, so you have something to compare to it with, and then you can decide which one might be the best for you or for your activities.' That's kind of my sense. But it's the teaching in the process, so that I know what questions to ask and I need help doing that from the prosthetist." – Wayne (70-year-old, dysvascular amputation four years earlier, non-Veteran)

When reflecting on aspects of the test-driving experience that seemed especially useful to them, nearly all participants reported completing various activities in the laboratory helped elucidate differences among prosthetic feet. For example, walking at self-selected speeds over even ground (or treadmill) was insufficient to illuminate differences between feet. Instead, participants suggested that walking at a range of speeds, on the inclined treadmill, and on stairs were essential components of test-driving.

> "I had a pretty good idea from [test-driving prosthetic feet] as to how [the foot] was going to react to things at home. We put all three feet through the paces in the clinic, before I

actually got to wear them home. So I already had a decent idea of how I was gonna like each one just based on wearing it in the lab there." – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

"I can see coming in into the clinic and then [the prosthetist] takes your socket and they install a different foot and you put it on. And then they have you walk on the treadmill, on a hill, on the stair stepper, and as many variety of terrains as possible, so that you get a better idea of how that foot's going to react in real life." – Ray (50-year-old, elective amputation 15 years earlier, Veteran)

"[The researchers] put me through a stress test. I got a chance to get on the treadmill and go on an incline... all those initial things that we did in the lab allowed me to be able to take that foot home and use it, right away, you know...It was good, it was a great way to do it." – Sam (47-year-old, traumatic amputation five years earlier)

Another essential aspect of test-driving prosthetic feet seemed to be the ability to try walking with them back-to-back, rather than rotating prosthetic feet out over some time. For example, one participant who had previous experience test-driving in a clinical scenario made the following comparison:

"It was a different experience than taking home one leg. Because even when I would take a leg home for the weekend, it's like, 'Here's a new foot again. Try it out for the week, or for the next three days.' The farther you get away from wearing the other foot, the more you forget exactly how it feels. The ability to just change it right now and try them back-to-back, that was the starkest [test-drive experience] I've ever had. I could really be like, 'I know exactly what the differences between the feet are.' I could really feel it. Usually

> you're trying to match words to a feeling that happened three days ago or whatever." – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

A participant who had not previously been able to test-drive feet made similar comments:

> "Putting on one right after the other, you feel the difference right away. Like, if you put it on and felt it, but then it was two weeks before you put on another one…But if you could do them all on the same day and try them, that's the idea, isn't it? That would be better, make it easier." – William (63-year-old, dysvascular amputation five years earlier, Veteran)

One curious discrepancy across participants was the notion of for whom test-driving strategies might be the most useful. Some participants did not focus on specific types of people with LLA who would stand to benefit more from test-driving than others, but instead spoke more generally. For instance:

> "I think anybody who needs to pick a foot [could benefit from test-driving]. You can go to a shoe store, pick a pair of shoes. But, ultimately, you're picking the shoes out. You're putting them on your feet, you're walking around in the store a little bit. 'Oh, this one feels tight. This one feels too loose. The arch is too high.' Just think about that with the prosthetic, you know, which is everything." – Sam (47-year-old, traumatic amputation five years earlier, Veteran)

In contrast with the quotation above from Sam, several other participants advised that test-driving would be more helpful for particular groups of people. However, participants had differing ideas about whether test-driving would be more or less valuable in the early stages of prosthesis use following amputation. Specifically, more active or experienced prosthesis users

believed that those with recent amputations could be overwhelmed by test-driving. These individuals suggested that test-driving would be more useful after people acclimate to prosthesis use and stabilize their rehabilitation progress for a few years. For example:

> "I see it being used to help you figure out what kind of foot you want, but like especially early on in your initial amputation, it wouldn't make sense to do it. You should be a year or two away from your amputation before you try it. That first amputation, when you first have your BK (below-knee) or whatever it is, your residual limb's all swollen and weird…and man, that would just be overwhelming, especially if you're new to your amputation and being an amputee. I don't know if you'd really be able get a good idea of what you were getting or what you really wanted. Early on, you don't know what the fuck you want!" – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

In contrast, several other participants, who were themselves less experienced prosthesis users, described test-driving as the most helpful as an educational experience for people who had recent amputations compared to people with more time since amputation. For example:

> "I think [test-driving] would be most beneficial for new amputees. I think that people who have been dealing with this for a while probably have a better understanding of their body and how it reacts to different foot systems." – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

> "New amputees should definitely be able to test-drive. If as a brand-new amputee – once I got my initial socket and they've got all those different issues out of the way – If they had a clinic setup where I could go in there and then they could say, 'Okay, look, these are the different feet that we recommend for new amputees and we want you to go walk

around on these different feet and see what you think.' It would help a brand-new amputee understand the different styles of feet." – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

"Seems like [test-driving] would be more advantageous for someone who's new at it, so they could learn to feel the difference in the foot." – William (63-year-old, dysvascular amputation five years earlier, Veteran)

When asked about the disadvantages of test-driving different prosthetic feet, participants often acknowledged the increased amount of time that test-driving multiple feet requires compared to receiving a single prosthetic foot.

"The process of getting the right fit and the right length and doing that every time takes time. There's no way around that. That's probably the part that I didn't like about [test-driving feet]…when you're having to switch it out, but there's no way around it, I understand that." – Wayne (70-year-old, dysvascular amputation four years earlier, non-Veteran)

"The downside [of test-driving feet] would be the amount of time you end up spending in the clinic. I mean, because you have to keep switching them out and going back, you know. It takes time to get it right, but it's important, okay?" – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

However, like in the quotation from Frank above, this disadvantage was weighed against the potential value of realizing a better matched prosthetic foot and how the extra time spent felt "worth it" to participants.

"There's the patience part. It takes time. But it all takes time: to get a good fit, get a good socket, and a good foot. I feel like that's the biggest part for these amputees – my fellow

amputees – to understand. Like, take the time, get the right foot and it helps you in the long run, rather than going fast and getting a bad foot." – Eduardo (40-year-old, elective amputation 12 years earlier, Veteran)

"It seems like it would be a lot more time-consuming for everybody to try out different feet because of all the adjustments they got to do on it. But I suppose if you're spending three years on a foot, a whole day of trying them out isn't really that much time." – William (63-year-old, dysvascular amputation five years earlier, Veteran)

Another potential disadvantage associated with test-driving prosthetic feet, which came up for two individuals, was the anxiety of trying something new. These two participants spoke to overcome the uncertainty of trying new feet, knowing that some feet would feel better than others:

"There was some anxiety [with test-driving] because I had been walking on my current foot for so many years. It was my second foot, but it was the exact same kind as my first one. There was nothing like the study to figure out what was the better foot for me, so I just went with what was familiar because I was already used to it. I saw no reason to change it up for fear of if I ended up with less than what I had before, I stuck with it. So I had a little anxiety once I put the new [feet] on. But I don't think the anxiety was a bad thing. There is good stress and bad stress." – Sam (47-year-old, traumatic amputation five years earlier, Veteran)

"I didn't say it out loud, but it goes through your mind, like you don't really want to try something new. Partly making sure, 'Is this [foot] going to be a good fit or not? Am I going to be able to walk with this [foot]?' You know, before I actually walked with it. There is some insecurity there, you do have flashes of a little bit of insecurity. But there's

a little bit of fear, I guess that you have to overcome trying out a new one." – Wayne (70-year-old, dysvascular amputation four years earlier, non-Veteran)

One participant also described feasibility concerns from the clinician's point of view when considering disadvantages of test-driving feet:

"The decision-making process is very antiquated and limited. I'd say there's a lot more options [for feet] that are out there that are not given to amputees. But I don't know what the solution is because having a prosthetist keep every foot on the shelf, it just doesn't seem feasible. Especially because people have different-sized feet. Plus, clinics don't have space for all the activities that you'd want to do to test out feet. Like, there's no treadmill." – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

Ultimately, despite some disadvantages noted with test-driving, these participants imagined how test-drive strategies might translate into clinical practice, given the aforementioned value that the experience offered for them. Both individuals proposed the same approach in which test-driving could educate the patient with LLA and narrow down the options by quickly using multiple feet in the clinic before wearing a select few for a more extended trial period:

"In the ideal scenario, if money was no object, the prosthetist could analyze the lifestyle of the person that needs the foot and discuss with them their goals and ambitions of where they want to go after receiving the foot. And then come up with five or six options for them to try out in the office, and then narrow that down to three to try two weeks a piece at home." – Jeff (47-year-old, dysvascular amputation four years earlier, non-Veteran)

"Test-driving in the lab gave me an idea, but I don't think it is enough time to figure out which foot is the right foot. I think it gave a baseline to work from to then venture out and

take more time with the feet that felt better, as opposed to just throwing a bunch of options out every two weeks. I think it makes more sense to do a whole variety for a short time in the clinic and then reduce your choices to a few and then try a few for two weeks a piece." – Sam (47-year-old, traumatic amputation five years earlier, Veteran)

Finally, many participants alluded to analogous scenarios when people can try different options for themselves before purchasing. For example, one participant compared it to being fit for eyeglasses, while several other participants mentioned shoe shopping. However, the most popular scenario given by participants was the comparison to shopping for a vehicle. For instance:

"It's like going out car shopping. You go out and you test drive four or five different cars, right? You don't just go out and get one vehicle and say, 'Okay, that's it. Well, this is how all cars are going to be like.' Because they're not! So, for me, it's kind of the same thing. Being able to try different feet is like being able to go out and drive different cars. It gives you a chance to see what's out there and then to know what are the important things to you." – Frank (58-year-old, traumatic amputation two years earlier, Veteran)

Inspired by this quotation from Frank and others, I proposed a metaphor for the experience of prosthetic foot prescription, including test-driving feet, from the perspective of the prosthesis user that illustrates the relationships between the five themes identified from this study (see Discussion).

Decision-making preferences questionnaire

Results from the decision-making preferences questionnaire were used to inform theme development, triangulate interview findings, and contrast individual cases. Items from the two

subsections of the questionnaire (i.e., preferences for decisions in general and decisions related to the prosthesis) were also compared to examine differences.

Participants reported preferences both for being made aware of their options when making a decision and for being involved in the decision (Figure 3.3). Only one participant (i.e., Tom) responded neutrally across these two items. These preferences were consistently endorsed for decisions in general and prosthesis-specific decisions, with participants rating preferences more strongly for prosthesis-specific ones. A wider range of answers was observed for preferences regarding reliance on the recommendations of others for decision-making in general (Figure 3.3). One participant (i.e., Chris) disagreed with relying on recommendations from other people, and two others (i.e., Martin and Jeff) were neutral, while the remaining participants agreed with relying on recommendations, in general.

In contrast, there was a narrower range of responses for prosthesis-specific decisions, in which every participant agreed with relying on others' recommendations. Several participants (e.g., Wayne and Ray) strongly agreed with relying on people for recommendations regarding their prostheses. In their interviews, they also spoke about the importance of finding the right prosthetist who could be trusted to make good recommendations. In contrast, participants mostly disagreed with preferring others to decide on their behalf (Figure 3.3). Only two participants (i.e., Ray and Tom) preferred that other people make decisions for them. Another questionnaire item with a range of responses was preference for limiting the amount of time spent at a clinical appointment for their prosthesis (Figure 3.3). Still, most participants disagreed or were neutral, with several participants explaining that they did not mind spending time in their prosthetist's office if they felt like the additional time spent resulted in improved outcomes.

Across all preference items, several groups of participants reported similar scores on the questionnaire items to one another—some participants whose responses to items clustered together seemed to align with their characteristics and histories. For example, the two participants (i.e., Ray and Eduardo) who had elective surgeries following limb salvage procedures as Active Duty Service Members and were subsequently treated at a Department of Defense hospital reported similar preferences for decision-making. Other groups of participants with similar preferences had less in common. For example, several pairs of participants (e.g., Martin and Sam) were of differing mobility groups and personal backgrounds but shared preferences for decision-making processes. Overall, results from the questionnaire, when compared to participants' experiences described in interviews, indicate that a range of personal preferences for being involved in prosthesis decision-making may exist, irrespective of other factors.

Discussion

A metaphor for the experience of prosthetic foot prescription from the patient's perspective

Based on participants' descriptions above, I offer a metaphor to represent the core category of knowledge and power in decision-making about prosthetic feet (Figure 3.4) and to relate the five themes in detail: participants with LLA described the experience of being prescribed a prosthetic foot (or having a foot selected for them) as akin to driving in a car at the start of a long journey. On this road, the mileage covered by the driver represents the knowledge and experience that a prosthesis user acquires over time. The road represents knowledge acquisition (Theme 1). An individual has no knowledge at the beginning of the journey, but there is also no fixed destination that one can reach in which all knowledge has been acquired. The car has

inertia, such that it will progress down this road, acquiring knowledge. However, the car's rate of travel and the quality of the ride may depend on other factors.

The car itself represents an individual's identity and personal factors (Theme 3). People with LLA begin this journey in different vehicle types (e.g., a sports car or an SUV). These differing features could represent the socket fit or other aspects of the prosthesis (e.g., suspension, interface). In addition, the engines of some cars may have been maintained better than others or subject to different conditions that influence how the car functions (e.g., health status and comorbidities). The person with LLA is in the driver's seat of their car, but they start with no experience as a prosthesis user. Therefore, they do not know how to drive down the road at the beginning of this journey. Therefore, there are other people in the car with them. The person in the car's front passenger seat is the prosthetist (Theme 2). One unique aspect of their seat is that, much like a driver's education arrangement, the prosthetist is armed with their set of own controls for the car: a steering wheel and pedals. Thus, the prosthetist functions as the primary guide and educator for the person with LLA, especially at the beginning of the journey when they have little driving experience. Notably, the prosthetist has direct control over the car's trajectory and rate of progress down the road (i.e., with access to the gas pedal and the brake). Depending on the driver's readiness and relationship with the prosthetist co-pilot, more control can be relinquished to the driver over time.

From the prosthesis user's perspective, there are also other passengers in this car advising the driver and the prosthetist (Theme 2). These passengers include the physician, who acts as the car's navigation system, providing specific directions to the prosthetist (e.g., prescription for the prosthesis) and orienting the car on its journey (i.e., towards improved health outcomes and

achieving functional goals). Additionally, other passengers who may act as backseat drivers are peers with LLA or other vital relationships who advise the driver as they navigate the car.

In this metaphor, the tires on the car represent the prosthetic foot itself (Theme 4). The set of tires should be matched to a person's type of car, the activities they wish to perform with their car, and other considerations such as budget. It is important to note that there is no optimal type of tire for all cars or even for a given car, depending on the situation (e.g., all-season tires for most of the year but snow tires might be necessary for certain activities). The process of matching the right set of tires to each car at the appropriate time can impact the quality of the experience. For instance, a set of race tires on an SUV may allow the vehicle to move, but not as optimally as possible with tires meant for daily driving needs. Furthermore, the tires are not solely responsible for how well the journey goes or how the driver feels about the experience. Specifically, the tires are irrelevant if the engine is not functioning or the person does not know how to use the car.

Finally, the experience of test-driving acts as an accelerator, quickening the pace of knowledge acquisition (e.g., quickly gaining more mileage as a driver of the car on this road) (Theme 5). This acceleration does not necessarily translate to increased control over the vehicle. However, if the driver feels prepared (or is adequately supported by their prosthetist instructor), the accumulated mileage can benefit the driver because they are more knowledgeable about their prosthesis. While experienced drivers thought that more novice drivers might feel overwhelmed by "the acceleration," the novice drivers themselves believed that it was helpful to see the range of what was possible on their journey.

The person with LLA may never arrive at a destination on this journey towards attaining their health-related goals, their goals may shift, or certain times on this road may be more

uncertain than others. However, the ultimate objective is to have a well-matched set of tires (i.e., prosthetic foot) to their car and their activities and seek to achieve their desired functional goals with guidance from valued relationships (e.g., with clinicians and peers with LLA).

A grounded theoretical framework for prosthetic foot prescription experiences

Overall, the core category identified in this research was the relationship between patients' knowledge about prosthetic feet and their perceived power to contribute to decision-making processes. Figure 3.5 presents a theoretical framework for the relative amount of knowledge among stakeholders (i.e., clinicians and people with LLA) and the power to choose the extent of one's involvement in selecting a prosthetic foot.

Participants described the decision to select an optimal prosthetic foot as complex. Their relationship to decision-making changed over time as they became more knowledgeable and experienced prosthesis users. Clinicians were perceived to be the primary decision-makers for prosthetic feet in participants' previous clinical experiences. Yet, participants explained that their relative contributions to the decision-making process increased over time. In Figure 3.5a, the initial post-amputation experience of being prescribed a prosthetic foot depicts a process that is centered around the clinicians (i.e., prescribing physicians and prosthetists). In the beginning, participants indicated their lack of knowledge led to feelings of dependence on clinicians for decision-making. All participants alluded to this early lack of knowledge as a hallmark of their experience of prosthetic foot prescription, despite there being no questions in the interview guide asking about initial experiences or how they had changed over time. The temporal undercurrent of the data is reflected in Figure 3.5a-d as a gradual shift in relative access to knowledge and ability to participate in decision-making regarding prosthetic feet over time. As time passes, the

individual with LLA can become more knowledgeable may wish to participate more actively in decision-making (Murray, 2013; Nielsen, 1991).

For people with LLA, the experience of having a prosthetic foot selected for them was described foremost as an educational journey. Gaining additional awareness about prosthetic foot options impacted the relationship dynamic that people with LLA described having with their clinicians, which mirrors previous findings from previous qualitative studies describing communication and knowledge shared between prosthetists and patients (Murray, 2013; Murray & Forshaw, 2013). Knowledge acquisition about prosthetic feet occurred through clinicians discussing foot options directly with patients or in front of them. Several previous studies have recognized the value of clinicians educating patients and leading discussions for choices regarding prosthetic components and other assistive technology (Johnston, Currie, Drynan, Stainton, & Jongbloed, 2014; Murray & Forshaw, 2013; Ostler, Ellis-Hill, & Donovan-Hall, 2014; Sansam et al., 2014). Participants expressed a desire to learn from clinicians in the early period following amputation, similar to findings reported in interviews with patients who had recently undergone lower limb amputation (Ostler et al., 2014). While all participants acknowledged that they learned more over time (Figure 3.5b), they had differing views on who was responsible for a patient acquiring knowledge about prosthetic feet. For instance, some individuals expected the clinicians to be accountable for teaching their patients and engaging them in discussing options. In contrast, others felt that the onus was on the patient to indicate an interest in being educated.

The nature and quality of relationships formed between patients with LLA and their clinicians were identified as important to the experience of prosthetic foot prescription. This finding regarding the importance of quality communication and rapport also agrees with previous

research describing clinicians' perspectives on the process of decision-making for prosthetic devices (Sansam et al., 2014). Communication with the prosthetist, in particular, was perceived as a determining factor in the quality of participant's experiences with foot selection and could contribute to either a positive or negative perceived outcome. In one previous study of people with recently-acquired amputations, prosthetists were absent from participants' descriptions of clinicians they expected to be involved in their rehabilitation care, demonstrating the lack of awareness that patients initially have about prosthetic fitting processes immediately following LLA (Ostler et al., 2014). In contrast, several studies of prosthesis user perspectives identified the clinical relationship with one's prosthetist as being of utmost importance (Mackenzie, Morris, Murphy, & Hodge, 2018; Murray, 2013; Nielsen, 1991). The quality of the relationships between people with LLA and their clinical care team has been linked to the attainment of their functional goals and prosthesis satisfaction (Baumann, Frank, Kulla, & Stieglitz, 2020; S. D. Messinger et al., 2018; Murray, 2013; Murray & Forshaw, 2013). All participants in this study described a transition from relating to their care as passive recipients to being actively engaged in collaborative decision-making with their clinicians regarding their prosthetic care (Figure 3.5). In the metaphor described above, this transition is akin to the patient gaining more mileage as they learn to drive the car and taking more control over the car's trajectory from the prosthetist. Murray (2013) similarly detailed the passivity that prosthesis users described the feeling in their early experiences with prosthesis prescription and how this behavior changed as they became more experienced users with known preferences and priorities (Murray, 2013).

One previous study found that clinicians offer more direct patient involvement for decisions about cosmesis rather than technical components of a prosthetic leg, likely due to the ease of explanation using non-technical jargon (Sansam et al., 2014). This issue of technical language is

a barrier to quality communication between people with LLA and prosthetists has been recognized for decades (Nielsen, 1991) and continues to be an area identified for professional growth among prosthetists (Baumann et al., 2020; Mackenzie et al., 2018; Sherwood, Brinkmann, & Fatone, 2018). A recent qualitative study agreed that prosthetists should provide more information and invite more opportunities for people with LLA to participate in making decisions about their devices (Murray, 2013). Participants' experiences in this study agree with these previous findings on the lack of patient involvement in technical decisions about the prosthesis or foot. Similar to findings in the study by Murray (2013), participants in this study explained the importance of advocating for oneself and learning to ask the right questions of the clinicians to elicit the information about relative differences or trade-offs in function between feet (Murray, 2013). In addition to the clinical team, participants identified relationships with peers with LLA as being key to their learning about prosthetic feet. Access to peers with LLA has been widely acknowledged as helpful based on qualitative studies of people after experiencing amputation (Gallagher & MacLachlan, 2001). This finding demonstrates these relationships continue to be valued sources of information even when patients are experienced users (Baumann et al., 2020; Murray & Forshaw, 2013; Ostler et al., 2014). Throughout the interviews, participants relayed to me, as a person without LLA, the experience of identifying as an amputee and their cherished sense of camaraderie with peers with amputations.

While sharing common experiences with the larger community of people living with LLA was recognized, participants also acknowledged differences in their own identity or individuality compared to other people with LLA, which impacted their involvement in decision-making. For instance, some participants identified themselves as particularly active or sedentary, which motivated them to participate in decision-making related to their priorities and saw themselves as

similar or different to “other” people with LLA. Participants frequently mentioned individual personalities and preferences concerning decision-making processes. The results from the questionnaire indicated that participants mostly endorsed seeking recommendations from others and being involved in decision-making for their prosthetic foot. However, there were differing responses across individuals in their willingness to consider recommendations compared to their preference for others to decide on their behalf. The questionnaire results further demonstrated clusters of participants with dissimilar personal backgrounds, based on demographic information, but who shared similar traits or preferences for being involved in the decision-making. This finding reflects the importance of clinicians evaluating the “type of patient” they are working with, as Martin described in his interview, to help patients achieve their optimal engagement in the decision process (Chewning et al., 2012).

Additionally, participants identified that part of acquiring knowledge as a patient is determining one’s interest in being involved in decision-making processes with their clinicians. Thus the balance in relationships to decision-making among stakeholders depicted in Figure 3.5d indicates the patient’s personal preferences being realized. The degree of desired relative power in decision-making will likely vary across individual patients with LLA and throughout an individual patient’s journey as a prosthesis user. Regardless of personality or reported preferences for engaging in decision-making, many participants discussed their empowerment in having sufficient knowledge about prosthetic feet and their desires for decision-making. Participants used this empowerment to advocate for and enact their vision for collaborative prosthetic foot decision-making with their clinicians.

Many participants ascribed different types of knowledge to themselves versus to their clinicians. For instance, participants generally acknowledged and trusted the expertise of their

prosthetist and physician regarding the technical aspects of the feet and their experience treating numerous people with LLA. These sentiments agree with participants with LLA in other qualitative studies who have expressed trust in the advice they receive from their prosthetist and physiatrist regarding their prosthesis equipment (Murray, 2013; E. Schaffalitzky et al., 2012). For example, in a study by Murray on communication between prosthetists and people with LLA, participants with LLA described respect for prosthetists' expertise and technical knowledge (Murray, 2013). However, participants in the Murray (2013) study also acknowledged that their prosthetists and physicians rarely had personal experiences using a prosthesis and thus cannot contribute certain aspects of knowledge to the equipment decision-making that the prosthesis user may be able to. Similarly, participants in this study reflected on their unique perceptions and priorities for prosthetic feet, which they did not feel that knowledge from their clinicians, or peers with LLA, could substitute. Thus, participants in this study acquired knowledge about prosthetic feet through discussion and education from their clinicians and supplemented this with direct experience using different prosthetic feet. In this way, test-driving was a tangible contribution to patients' embodied knowledge about prosthetic feet, which enabled them to provide experiential input to the foot selection and empowered them to be as involved as they wished to be in foot selection.

The selection of a well-chosen prosthetic foot was of great importance to study participants. Prosthesis users should have a prosthetic foot that meets their physical needs and social needs (E. Schaffalitzky et al., 2011; E. Schaffalitzky et al., 2012; E. Schaffalitzky et al., 2009). Participants in this study agreed that there was no single best foot option for an individual, citing that commercial prosthetic feet have different relative advantages and are ultimately limited in their ability to replace the biological foot-ankle. Thus, participants described that it was essential

to recognize their priorities and match the foot selection to the activities that they most frequently want to achieve. This matching reflects the reality that commercial prosthetic feet are designed to optimally perform a specific type of activity, such as walking versus running or providing security over level ground versus accommodating uneven terrain. Thus, weighing the relative performance trade-offs between prosthetic feet in the context of the participant's functional goals is an important component of the selection process. For instance, some active participants mentioned having multiple prostheses to achieve their desired sports or activities. Alternatively, these participants could sacrifice daily comfort (e.g., use a foot that feels overly stiff for typical walking but can withstand higher activity when needed) to avoid managing multiple prostheses. Participants in this study alluded to the personal meaning of the prosthesis and the impact that a well-matched foot, or a poorly-matched foot, can have on their identity and embodiment of the prosthesis as a whole, which agrees with findings from previous qualitative studies assessing the effects of prostheses on users with LLA (Fogelberg et al., 2016; McDonald et al., 2019; Murray, 2004, 2005, 2009). These personal aspects of interacting with a prosthetic foot, and the compromises that are part of the selection process, underscore the importance of allowing the user to try different feet for themselves.

Most participants in this study mentioned that they learned about the differences between prosthetic feet using subsequent prostheses over time. Rarely, however, did the participants have an opportunity to compare multiple different feet as part of their previous clinical foot prescription experiences. The exception to this was for the two individuals who received treatment as Service Members in a military hospital, in which the paradigm for foot prescription and reimbursement was unique. Patients treated at these facilities could test-drive and receive numerous prosthetic feet, including for different specialty activities and sports (e.g., running,

skiing, diving). It is important to note that a strong sense of community was fostered among fellow Service Members with amputations treated simultaneously in daily, intensive therapy. However, these two participants spoke about the value of acquiring experiential knowledge by trying out feet for themselves, above and beyond the knowledge gained through discussion with peers. Their descriptions of the clinical experiences test-driving prosthetic feet aligned with descriptions from other participants who participated in the TeD protocol, highlighting that test-driving was a concrete way to accelerate their education about feet (Figure 3.5c). This acceleration was associated with feelings of empowerment to participate in the decision-making process.

Furthermore, participants felt that their ability to compare feet through test-driving resulted in a superior prosthetic foot match because it reflected their personal preferences. Five out of eleven participants in this study experienced a direct impact on their clinical care (i.e., had sought out and received a new foot) after test-driving. After test-driving, all participants agreed that they wished to be involved in decision-making about their prosthesis in some capacity. Even individuals who endorsed questionnaire items about trusting others to make decisions for them or a neutral desire to be involved in decision-making described the personal value of test-driving and feeling empowered with knowledge. Studies evaluating rehabilitation assistive technology selection practices have also found that providing trial periods is an essential part of educating patients about their options and navigating complicated decision-making processes between clinicians and patients (Johnston et al., 2014; Scherer, Jutai, Fuhrer, Demers, & Deruyter, 2007; Scherer, Sax, Vanbiervliet, Cushman, & Scherer, 2005). The findings from participants in this study agreed that test-driving increased their awareness about options by offering back-to-back comparisons between feet. Further, test-driving may also serve as a way to facilitate discussion

between the patient and the clinician. Participants described an appreciation for how test-driving made things “click” by translating technical jargon that they had heard from clinicians (e.g., stiffness or energy return) into an experiential understanding that they could understand. This aspect of test-driving as a way to educate and cultivate discussion about prosthetic feet may improve the ability of clinicians to encourage patient engagement in the selection process (Sansam et al., 2014). While participants may have arrived at similar knowledge about feet without test-driving, it may have taken more time and trial-and-error or may have required that individuals be more driven to seek an education from their clinician.

Beyond accelerating the pace of education or facilitating discussion about options, one of the unique benefits participants described about test-driving was that it centered the decision-making process on them, as the user (Figure 3.5c-d). As opposed to their earlier experiences in being prescribed a prosthetic foot, in which the decision-making process was in the hands of the clinician who had more knowledge, participants expressed that test-driving made them feel like their voice was a valued contributor to the foot selection process. The benefits of including users’ experiential input have similarly been found in studies of assistive technology selection (Johnston et al., 2014; Scherer et al., 2007). For example, Scherer et al. explained that the user’s priorities, preferences, and expectations should be the starting point for the selection of an assistive device to ensure continued use and satisfaction with the device (Scherer et al., 2007). Previous research of prosthetic device use and compliance further illustrates that providing opportunities for the person with amputation to have a choice regarding their prosthetic components, even if this choice is limited to a few options, is associated with continued use and satisfaction (Murray, 2013; Postema et al., 1999; E. Schaffalitzky et al., 2009; Van der Linde et al., 2007).

In addition to the potential benefits associated with test-driving prosthetic feet, the most common downside that participants identified was that test-driving would inherently require more time in the clinic. However, participants frequently disregarded the importance of this observation because they felt that the short-term time investment was worth longer-term benefits associated with selecting a better prosthetic foot for themselves. Several participants also mentioned economic considerations from the prosthetist or clinic's perspective, such as investing more money to obtain multiple prosthetic feet for patients and more time spent setting up and aligning feet for trial use. Several experienced prosthesis users described that test-driving different feet might feel overwhelming to people with more recent amputations. In contrast, these sentiments were not identified by participants who had more recent amputations themselves.

Study limitations and future directions

There are trade-offs associated with the methodological decisions made in any study. One decision made in this study was to conduct individual, semi-structured interviews instead of focus groups. Using interviews allowed me to have a rich and detailed conversation with each participant because I could delve into individual stories and cover many questions. Therefore, we achieved depth to the data regarding personal experiences that may not have been possible in a focus group. However, focus groups might be useful in future research to probe aspects of the framework developed in this study (e.g., types of individual factors that influence a patient's relationship with their prosthetist) by collecting a broad range of participant opinions for prompts that are more focused than those used during interviews (Agan et al., 2008).

I developed and used an interview guide to structure the interviews and constrain discussion to prosthetic foot prescription and test-drive strategies. Using a semi-structured approach like

this does take away some control from participants to share their most salient ideas regarding prosthetic feet and thus limit the ability to build theory from the data (Corbin & Strauss, 2015). Additionally, the recall period for participants reflecting on their experiences test-driving or receiving a prosthetic foot through the clinic varied across participants. While the challenges of imperfect recall are undoubtedly present, the consistency in participant stories across individuals with different recall periods lends credibility to the overall findings.

Another methodological choice was to conduct all interviews via telephone. This decision emerged from the logistical challenge of recruiting participants from multiple study sites located in different states. It could be argued that important body language or non-verbal communication might be lost since I could not observe participants in person. However, telephone interviews also have the advantage of providing distance between myself and the participants during the interview. Given that I have a pre-existing relationship with participants as the researcher conducting the TeD protocol at the VA Puget Sound site, a connection to the ongoing study, and am a prosthetist-orthotist, there is the potential for a power differential that participants could perceive during the interview. Conducting interviews by phone may have helped mitigate these pressures and allowed participants to express their opinions and experiences freely. Furthermore, conducting interviews by phone allowed me to proceed with human subjects data collection during the Coronavirus (COVID-19) pandemic.

In addition to methodological considerations, philosophical decisions were made that influence the study findings. For example, we elected to use a grounded theory approach in the tradition of Strauss & Corbin (Corbin & Strauss, 2015) and Charmaz (Charmaz, 2014)). This framework is generally aligned with postpositivist philosophy and applies a scientific approach to conducting qualitative research, including rigorous methods for recruitment, data collection,

and coding processes. I also invoked constructivist philosophy by engaging in active knowledge building using my expertise as a clinician to interpret the statements made by participants. Grounded theory was a good match for the goals of this research since I intended to systematically explore the experiences of patients with LLA related to prosthetic foot prescription practices. Other interpretive frameworks and approaches may have been appropriate alternatives, such as phenomenology. However, the use of an approach like phenomenology would be better employed to describe and compare participants' lived experiences related to prosthetic foot prescription thoroughly, rather than to examine the processes and relationships that underlie prosthetic foot prescription practices.

An important aspect of these research findings is that they represent the perspectives of people with LLA, but they do not represent the views of other stakeholders involved in prosthetic foot decision-making. It is probable that clinicians or others involved in the provision of prosthetic feet (e.g., clinical businesses, manufacturers, third-party payers) would have differing views on the advantages and limitations of engaging patients in component selection more directly. While some research has been conducted previously to explore clinician perspectives on prosthetic prescription practices (Sansam et al., 2014), future work is needed to understand the views of other stakeholders on the barriers and facilitators of decision-making for prosthetic feet in particular. Specifically, qualitative research should explore physician, prosthetist, and prosthetic foot manufacturer perspectives on adding test-driving strategies as part of prosthetic foot selection for people with LLA.

Another potential limitation to this study is that I was a relatively inexperienced interviewer and qualitative researcher. I relied on previous coursework related to qualitative research and guidance from my expert mentors to inform the methods and provide training on all aspects of

conducting this research. I also consulted with the VA Puget Sound COIN Qualitative Research Core workgroup regarding the procedures and provided feedback on the interview guide before initiating the data collection for this study. Finally, I practiced interviewing by conducting pilot interviews with study staff and a person with TTA (i.e., a volunteer unrelated to the study) as part of my training and developing the interview guide before interviewing study participants.

Other study limitations pertain to the participants recruited for the interviews because the framework I identified to understand patient experiences of prosthetic foot prescription is specific to the individuals in this study and may not extend to other people with LLA. While qualitative study findings are not intended to be generalizable to broader populations, there are potential systematic differences in these individuals relative to the general population of people with LLA, which ought to be acknowledged. First, all participants were male. This resulted from recruiting from the previous TeD protocol because participants used study feet sized between 26-29cm, which excluded most females. Additionally, all participants in this study were willing to engage in longitudinal research because they had previously completed the TeD protocol. Therefore, they might differ systematically from the general population in terms of characteristics that could influence their perceptions of prosthetic foot prescription. For example, participants who could be considered more curious about technology and foot options may wish to participate in the study to begin with. Or else, participants in the study may have been more inclined to spend time at appointments related to their prosthetic leg than the general population. Further, the perspectives captured in these data may not represent perceptions or experiences of the broader population of people with LLA, given the urban location of study sites and the Veteran population. However, travel to the study sites for the TeD protocol was reimbursed and thus permitted participants from rural areas to participate. For example, most participants lived

more than 10 miles from the study site cities, and some lived over 150 miles away. In addition, attempts were made to mitigate the effects of the study site by purposively recruiting participants with a variety of personal characteristics across study sites. Another potential limitation could have been my prior relationship as the researcher conducting the TeD protocol for some participants (i.e., those from Seattle) since I was the interviewer. To assess these potential effects, data from participants at the Seattle site were triangulated with information from participants from Minneapolis who did not interact with me before the interviews. Additionally, to mitigate biases in my coding and interpretation, a second rater independently coded the data (i.e., without a list of existing codes), and the agreement was determined to be very good (i.e., greater than 95%) between raters.

One finding from this study was that participants expressed varying degrees of desire to be involved in decision-making regarding their prostheses. Thus, assessing a given patient's preferences for being involved in the decisions appears to be important. However, the findings from this study did not explore this aspect of the data in great detail. Previous studies similarly suggest that patients are most satisfied with shared decision-making when it aligns with their preferences for involvement and when those preferences are explicitly acknowledged by the clinicians (Rose, Rosewilliam, & Soundy, 2017; Rose, Soundy, & Rosewilliam, 2019; Shay & Lafata, 2015). For instance, there are tools designed for clinicians to quickly assess their patient's preferences for engaging in decision-making (Elwyn et al., 2013). Future research should examine approaches that clinicians could use to assess patient preferences for decision-making related to prostheses. For instance, educational programs for prescribing physicians and prosthetists could teach techniques for explicitly acknowledging the existence of decision-making processes for prosthetic components and invite the patient to share their current level of

interest in being a part of decisions. Importantly, this conversation should likely be revisited between clinicians and patients as the preferences and interest for engaging in decision-making could change over time.

Conclusions

This qualitative study presented a framework for understanding the experience of prosthetic foot prescription from the perspective of people with TTA and how test-driving different prosthetic feet influenced their experience. This study facilitated the direct engagement of prosthesis users to identify the benefits and limitations of test-drive strategies to augment prosthetic foot prescription practices. Participants in this study described the experience of being prescribed a prosthetic foot as a journey in acquiring knowledge about feet and expressed how the relative amounts of knowledge between themselves and their clinicians affected their participation in decision-making.

Test-driving prosthetic feet allowed participants to be informed about relative trade-offs in current prosthetic foot technology and determine for themselves what functional features they prioritized. Based on participants' descriptions, test-driving different prosthetic feet was a tangible way to offer experiential, embodied knowledge about feet. Test-driving also accelerated the pace of education, making it possible for patients with LLA to be more directly involved in selecting their prosthetic feet instead of relying on clinicians' knowledge and experience. Further, participants explained that engaging in test-driving of prosthetic feet made them feel like their opinions were a valued part of prosthetic foot decision-making.

The results of this study provide a more holistic understanding of the perspective of people with LLA to complement the data from our ongoing quantitative research studying test-driving

strategies for prosthetic foot prescription. In addition, the themes identified from this study may inform future directions of inquiry and, more specifically, the use of test-driving strategies to augment the existing paradigm for the prescription of prosthetic feet in clinical practice.

References

Adamczyk, P. G., & Kuo, A. D. (2015). Mechanisms of gait asymmetry due to push-off deficiency in unilateral amputees. *IEEE Trans Neural Syst Rehabil Eng, 23*(5), 776-85.

Agan, J., Koch, L. C., & Rumrill, P. D., Jr. (2008). The use of focus groups in rehabilitation research. *Work, 31*(2), 259-69.

Agrawal, V., Gailey, R., Gaunaurd, I., Gailey, R., 3rd, & O'Toole, C. (2011). Weight distribution symmetry during the sit-to-stand movement of unilateral transtibial amputees. *Ergonomics, 54(7)*(7), 656-64.

Amputees merge with their bionic leg. (2019). *ScienceDaily*. Retrieved from https://www.sciencedaily.com/releases/2019/10/191002144243.htm

Baumann, M. F., Frank, D., Kulla, L., & Stieglitz, T. (2020). Obstacles to prosthetic care—legal and ethical aspects of access to upper and lower limb prosthetics in germany and the improvement of prosthetic care from a social perspective. *Societies, 10*(1), 10.

Behrens, K. M., Walker, N. R., Hansen, A. H., Brousseau, L. M., Childers, W. L., Caputo, J. M., . . . Morgenroth, D. C. (2020). *Determining the relationship between prosthetic foot preference and self-reported and performance-based outcome measures in veterans and service members with transtibial amputations.* Paper presented at the 2020 American Orthotic and Prosthetic Association (AOPA) National Assembly, Las Vegas, NV.

Boonstra, A., Fidler, V., & Eisma, W. (1993). Walking speed of normal subjects and amputees: Aspects of validity of gait analysis. *Prosthet Orthot Int, 17(2)*(2), 78-82.

Brousseau, L. M., Childers, W. L., Hansen, A. H., Walker, N. R., Behrens, K. M., Caputo, J. M., . . . Morgenroth, D. C. (2020). *Predicting prosthetic foot preference among service members and veterans with unilateral transtibial amputations*. Paper presented at the 2020 Military Health System Research Symposium (MHSRS), Kissimmee, FL.

Charmaz, K. (2014). *Constructing grounded theory* (2nd ed.). Thousand Oaks, CA: Sage.

Chewning, B., Bylund, C. L., Shah, B., Arora, N. K., Gueguen, J. A., & Makoul, G. (2012). Patient preferences for shared decisions: A systematic review. *Patient Educ Couns, 86*(1), 9-18.

Choi, C. Q. (2020). An open-source bionic leg. *IEEE Spectrum: Technology, Engineering, and Science News*. Retrieved from https://spectrum.ieee.org/the-human-os/biomedical/bionics/opensource-bionicleg

Control, C. f. D., & Prevention. (2020). National diabetes statistics report, 2020. *Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services*, 12-5.

Corbin, J., & Strauss, A. (2015). *Basics of qualitative research* (4th ed.). Thousand Oaks, CA: Sage Publications.

Creswell, J. W., & Poth, C. N. (2018). *Qualitative inquiry & research design : Choosing among five approaches* (Fourth edition. ed.). Thousand Oaks, California: Thousand Oaks, California : SAGE.

Czerniecki, J. M. (2005). Research and clinical selection of foot-ankle systems. *JPO, 17*(4), S35-S7.

Elwyn, G., Barr, P. J., Grande, S. W., Thompson, R., Walsh, T., & Ozanne, E. M. (2013). Developing collaborate: A fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Educ Couns, 93*(1), 102-7.

Finlay, L. (2002). "Outing" the researcher: The provenance, process, and practice of reflexivity. *Qual Health Res, 12*(4), 531-45.

Fogelberg, D. J., Allyn, K. J., Smersh, M., & Maitland, M. E. (2016). What people want in a prosthetic foot: A focus group study. *JPO, 28*(4), 145-51.

Gajewski, D., & Granville, R. (2006). The united states armed forces amputee patient care program. *JAAOS, 14*(10), S183-S7.

Gallagher, P., & MacLachlan, M. (2001). Adjustment to an artificial limb: A qualitative perspective. *J Health Psychol, 6*(1), 85-100.

Galletta, A., & Cross, W. E. (2013). *Mastering the semi-structured interview and beyond from research design to analysis and publication*: NYU Press.

Hafner, B. J., Sanders, J. E., Czerniecki, J., & Fergason, J. (2002). Energy storage and return prostheses: Does patient perception correlate with biomechanical analysis? *Clin Biomech 17(5)*(5), 325-44.

Harrell, M. C., Bradley, M., National Defense Research Institute . Intelligence Policy, C., & Rand, C. (2009). *Data collection methods : Semi-structured interviews and focus groups*. Santa Monica, CA: Santa Monica, CA : RAND.

Hennink, M. M., Kaiser, B. N., & Marconi, V. C. (2017). Code saturation versus meaning saturation: How many interviews are enough? *Qual Health Res, 27*(4), 591-608.

Hofstad, C., Linde, H., Limbeek, J., & Postema, K. (2004). Prescription of prosthetic ankle-foot mechanisms after lower limb amputation. *Cochrane Database Syst Rev*(1), Cd003978.

Houdijk, H., Wezenberg, D., Hak, L., & Cutti, A. G. (2018). Energy storing and return prosthetic feet improve step length symmetry while preserving margins of stability in persons with transtibial amputation. *J Neuroeng Rehabil, 15*(Suppl 1), 76.

Jefferies, P., Gallagher, P., & Philbin, M. (2018a). Being “just normal”: A grounded theory of prosthesis use. *Disabil Rehabil, 40*(15), 1754-63.

Jefferies, P., Gallagher, P., & Philbin, M. (2018b). Staying “just normal”: Preservation strategies in prosthesis use. *Disability and Rehabilitation: Assistive Technology*.

Johnston, P., Currie, L. M., Drynan, D., Stainton, T., & Jongbloed, L. (2014). Getting it "right": How collaborative relationships between people with disabilities and professionals can lead to the acquisition of needed assistive technology. *Disabil Rehabil Assist Technol, 9*(5), 421-31.

Kistenberg, R. S. (2014). Prosthetic choices for people with leg and arm amputations. *Phys Med Rehabil Clin N Am, 25*(1), 93-115.

Klute, G. K., Kallfelz, C. F., & Czerniecki, J. M. (2001). Mechanical properties of prosthetic limbs: Adapting to the patient. *J Rehabil Res Dev, 38*(3), 299-307.

Krueger, R. A. (2014). *Focus groups: A practical guide for applied research*: Sage publications.

Lin, S. J., Winston, K. D., Mitchell, J., Girlinghouse, J., & Crochet, K. (2014). Physical activity, functional capacity, and step variability during walking in people with lower-limb amputation. *Gait Posture, 40(1)*(1), 140-4.

Littman, A. J., Bouldin, E. D., & Haselkorn, J. K. (2017). This is your new normal: A qualitative study of barriers and facilitators to physical activity in veterans with lower extremity loss. *Disabil Health J, 10*(4), 600-6.

MacKay, C., Cimino, S. R., Guilcher, S. J. T., Mayo, A. L., Devlin, M., Dilkas, S., . . . Hitzig, S. L. (2020). A qualitative study exploring individuals' experiences living with dysvascular lower limb amputation. *Disabil Rehabil*, 1-9.
Mackenzie, R. L., Morris, M. E., Murphy, G., & Hodge, M. C. (2018). The prosthetist role expectations scale: Development and initial validation of a scale for clinical settings. *Prosthet Orthot Int, 42*(2), 171-8.
McDonald, C. L., Cheever, S. M., Morgan, S. J., & Hafner, B. J. (2019). Prosthetic limb user experiences with crossover feet: A pilot focus group study to explore outcomes that matter. *JPO, 31*(2), 121-32.
McDonald, C. L., Kramer, P. A., Morgan, S. J., Halsne, E. G., Cheever, S. M., & Hafner, B. J. (2018). Energy expenditure in people with transtibial amputation walking with crossover and energy storing prosthetic feet: A randomized within-subject study. *Gait Posture, 62*, 349-54.
Messinger, S. D. (2009). Incorporating the prosthetic: Traumatic, limb-loss, rehabilitation and refigured military bodies. *Disabil Rehabil, 31*(25), 2130-4.
Messinger, S. D. (2010). Rehabilitating time: Multiple temporalities among military clinicians and patients. *Medical Anthropology, 29*(2), 150-69.
Messinger, S. D., Bozorghadad, S., & Pasquina, P. F. (2018). Social relationships in rehabilitation and their impact on positive outcomes among amputees with lower limb loss at walter reed national military medical center. *J Rehabil Med, 50*(1), 86-93.
Miles, M. B., Huberman, A. M., & Saldaña, J. (2014). *Qualitative data analysis: An expanded sourcebook* (3rd ed.). Thousand Oaks, CA: Sage Publications.
Morgan, S. J., McDonald, C. L., Halsne, E. G., Cheever, S. M., Salem, R., Kramer, P. A., & Hafner, B. J. (2018). Laboratory- and community-based health outcomes in people with transtibial amputation using crossover and energy-storing prosthetic feet: A randomized crossover trial. *PLoS One, 13(2)*(2), e0189652.
Morse, J. M., & Field, P. A. (1995). *Qualitative research methods for health professionals*. Thousand Oaks, CA: Sage.
Murray, C. D. (2004). An interpretative phenomenological analysis of the embodiment of artificial limbs. *Disabil Rehabil, 26*(16), 963-73.
Murray, C. D. (2005). The social meanings of prosthesis use. *J Health Psychol, 10*(3), 425-41.
Murray, C. D. (2009). Being like everybody else: The personal meanings of being a prosthesis user. *Disabil Rehabil, 31*(7), 573-81.
Murray, C. D. (2013). 'Don't you talk to your prosthetist?'communicational problems in the prescription of artificial limbs. *Disabil Rehabil, 35*(6), 513-21.
Murray, C. D., & Forshaw, M. J. (2013). The experience of amputation and prosthesis use for adults: A metasynthesis. *Disabil Rehabil, 35*(14), 1133-42.
Murray, C. D., & Fox, J. (2002). Body image and prosthesis satisfaction in the lower limb amputee. *Disabil Rehabil, 24*(17), 925-31.
Nielsen, C. C. (1991). A survey of amputees: Functional level and life satisfaction, information needs, and the prosthetist's role. *JPO, 3*(3), 125-9.
Ostler, C., Ellis-Hill, C., & Donovan-Hall, M. (2014). Expectations of rehabilitation following lower limb amputation: A qualitative study. *Disabil Rehabil, 36*(14), 1169-75.
Pasquina, P. F. (2004). Optimizing care for combat amputees: Experiences at walter reed army medical center. *J Rehabil Res Dev, 41*(3B), VII.
Pogash, C. (2008). A personal call to a prosthetic invention. *The New York Times*.

Postema, K., Van der Donk, V., Van Limbeek, J., Rijken, R. A., & Poelma, M. (1999). Prosthesis rejection in children with a unilateral congenital arm defect. *Clin Rehabil, 13*(3), 243-9.

Raschke, S. U., Orendurff, M. S., Mattie, J. L., Kenyon, D. E., Jones, O. Y., Moe, D., . . . Kobayashi, T. (2015). Biomechanical characteristics, patient preference and activity level with different prosthetic feet: A randomized double blind trial with laboratory and community testing. *J Biomech, 48*(1), 146-52.

Reid, L., Thomson, P., Besemann, M., & Dudek, N. (2015). Going places: Does the two-minute walk test predict the six-minute walk test in lower extremity amputees? *J Rehabil Med, 47*.

Resnik, L., Borgia, M., & Silver, B. (2017). Measuring community integration in persons with limb trauma and amputation: A systematic review. *Arch Phys Med Rehabil, 98*(3), 561-80.e8.

Rose, A., Rosewilliam, S., & Soundy, A. (2017). Shared decision making within goal setting in rehabilitation settings: A systematic review. *Patient Educ Couns, 100*(1), 65-75.

Rose, A., Soundy, A., & Rosewilliam, S. (2019). Shared decision-making within goal-setting in rehabilitation: A mixed-methods study. *Clin Rehabil, 33*(3), 564-74.

Sansam, K., O'Connor, R. J., Neumann, V., & Bhakta, B. (2014). Clinicians' perspectives on decision making in lower limb amputee rehabilitation. *J Rehabil Med, 46*(5), 447-53.

Sarroca, N., Valero, J., Deus, J., Casanova, J., Luesma, M. J., & Lahoz, M. (2021). Quality of life, body image and self-esteem in patients with unilateral transtibial amputations. *Sci Rep, 11*(1), 12559.

Schaffalitzky, E., Gallagher, P., Maclachlan, M., & Ryall, N. (2011). Understanding the benefits of prosthetic prescription: Exploring the experiences of practitioners and lower limb prosthetic users. *Disabil Rehabil, 33*(15-16), 1314-23.

Schaffalitzky, E., Gallagher, P., MacLachlan, M., & Wegener, S. (2012). Developing consensus on important factors associated with lower limb prosthetic prescription and use. *Disabil Rehabil, 34*(24), 2085-94.

Schaffalitzky, E., NiMhurchadha, S., Gallagher, P., Hofkamp, S., MacLachlan, M., & Wegener, S. T. (2009). Identifying the values and preferences of prosthetic users: A case study series using the repertory grid technique. *Prosthet Orthot Int, 33*(2), 157-66.

Scherer, M. J., Jutai, J., Fuhrer, M., Demers, L., & Deruyter, F. (2007). A framework for modelling the selection of assistive technology devices (atds). *Disabil Rehabil Assist Technol, 2*(1), 1-8.

Scherer, M. J., Sax, C., Vanbiervliet, A., Cushman, L. A., & Scherer, J. V. (2005). Predictors of assistive technology use: The importance of personal and psychosocial factors. *Disabil Rehabil, 27*(21), 1321-31.

Shay, L. A., & Lafata, J. E. (2015). Where is the evidence? A systematic review of shared decision making and patient outcomes. *Medical Decision Making, 35*(1), 114-31.

Sherwood, A., Brinkmann, J., & Fatone, S. (2018). Review of benefits to practitioners of using good patient-practitioner communication. *JPO, 30*(1), 5-12.

Stark, G. (2005). Perspectives on how and why feet are prescribed. *JPO, 17*(Supplement), S18-S22.

Stevens, P. M., Rheinstein, J., & Wurdeman, S. R. (2018). Prosthetic foot selection for individuals with lower-limb amputation: A clinical practice guideline. *JPO, 30*(4), 175-80.

Suckow, B. D., Goodney, P. P., Nolan, B. W., Veeraswamy, R. K., Gallagher, P., Cronenwett, J. L., & Kraiss, L. W. (2015). Domains that determine quality of life in vascular amputees. *Ann Vasc Surg, 29*(4), 722-30.

Tolley, E. E., Ulin, P. R., Mack, N., Robinson, E. T., & Succop, S. M. (2016). *Qualitative methods in public health : A field guide for applied research* (Second edition. ed.). San Francisco, CA: San Francisco, CA : Wiley.

Turner, A. T., Halsne, E. G., Hansen, A. H., Walker, N. R., Behrens, K. M., Childers, W. L., . . . Morgenroth, D. C. (2020). *Use of a robotic prosthetic foot emulator to predict prosthetic foot preference*. Paper presented at the 2020 Military Health System Research Symposium (MHSRS), Kissimmee, FL.

Van Der Linde, H., Geertzen, J. H., Hofstad, C. J., Van Limbeek, J., & Postema, K. (2003). Prosthetic prescription in the netherlands: An observational study. *Prosthet Orthot Int, 27*(3), 170-8.

Van Der Linde, H., Geertzen, J. H., Hofstad, C. J., Van Limbeek, J., & Postema, K. (2004). Prosthetic prescription in the netherlands: An interview with clinical experts. *Prosthet Orthot Int, 28*(2), 98-104.

Van der Linde, H., Hofstad, C. J., Geertzen, J. H., Postema, K., & Van Limbeek, J. (2007). From satisfaction to expectation: The patient's perspective in lower limb prosthetic care. *Disabil Rehabil, 29*(13), 1049-55.

Ziegler-Graham, K., MacKenzie, E. J., Ephraim, P. L., Travison, T. G., & Brookmeyer, R. (2008). Estimating the prevalence of limb loss in the united states: 2005 to 2050. *Arch Phys Med Rehabil, 89*(3), 422-9.

Tables and Figures

Table 3.1. Summary of participant demographics.

Demographic	N
Sex	
Male	11
Female	0
Amputation Etiology	
Dysvascular	5
Trauma	3
Trauma (elective amputation)	2
Infection	1
Race	
White	7
Black or African-American	1
American Indian or Alaskan Native	1
Pacific Islander or Native Hawaiian	1
Ethnicity	
Hispanic or Latino	2
Not Hispanic or Latino	9
Veteran Status	
Veteran	8
Non-Veteran	3
Highest Education	
Some high school	1
High school/GED	1
Some college/technical degree/AA	7
College degree	1
Advanced degree	1
Current Prosthetist Care Location	
VA prosthetist	6
Private practice prosthetist	5
Study Site Location	
Seattle	9
Minneapolis	2
Study Group	
Low Mobility	3
High Mobility	8

Table 3.2. Individual participant characteristics.

ID	Age (yrs)	Race	Ethnicity	Veteran Status	Education	Time Since Amputation (yrs)	Amputation Etiology	Number of Prosthetic Feet Used*	Study Mobility Group	Requested Study Foot After Test-Driving†
Martin	73	NR	Hispanic	Yes	Advanced degree	1.8	Dysvascular	2	Low	No
Jeff	47	White	Non-Hispanic	No	AA	4.1	Dysvascular	3	Low	No
Wayne	70	White	Non-Hispanic	No	College degree	4.2	Dysvascular	2	High	Yes
Chris	68	Black	Non-Hispanic	Yes	Some high school	17.1	Dysvascular	3	Low	Yes
Larry	63	White	Non-Hispanic	Yes	High school	1.8	Trauma	3	High	Yes
Frank	58	White	Non-Hispanic	Yes	AA	2.3	Trauma	3	High	No
Ray	50	Pacific Islander	Non-Hispanic	Yes	AA	15.7	Trauma (elective)	7	High	No
Tom	74	White	Non-Hispanic	No	College degree	3.9	Infection	2	High	Yes
Eduardo	40	America n Indian	Hispanic	Yes	AA	12.1	Trauma (elective)	9	High	No
Sam	47	White	Non-Hispanic	Yes	AA	5.6	Trauma	1	High	Yes
William	63	White	Non-Hispanic	Yes	AA	5.5	Dysvascular	3	High	No

Note: IDs are pseudonyms, NR indicates "Not Reported"; AA indicates Associates degree, some college, or technical degree; *number of prosthetic feet used refers to total number of prosthetic feet each participant had experience using, excluding the test-driving protocol; †indicates

participant who reported during the interview that they had requested a new prosthetic foot from their prosthetist after experiencing the test-driving protocol

Table 3.3. Five themes with descriptions on the relationship between knowledge and decision-making power with respect to prosthetic feet, from the perspective of the person with LLA.

Theme	Description	Sub-theme	Representative Quotes
I started with no knowledge about prosthetic feet. As I learned more over time, the knowledge was empowering.	This theme comprises the temporal process associated with gaining knowledge about prosthetic foot options over time, starting with almost no knowledge about prosthetics or awareness of options for feet. Participants described feelings associated with the knowledge states, marked by a growing sense of empowerment as they became more knowledgeable about prosthetic feet.	Lack of knowledge about prosthetic feet, especially at first More knowledge gained over time with experience Acquired knowledge as empowerment Types of knowledge differ across stakeholders	"Now that I think about it, it did not occur to me at the time that there was any consideration as to what the foot was about. That there were other choices." "And being a new amputee, that was kind of a hard thing to figure out because you know until you've actually worn a prosthetic, you don't know. That's why I had to take my prosthetist's input as to what was the better foot. But now that I've had experience with eight different styles of feet, when I talk to my prosthetist, I can talk to them in a more educated or more informed way."
My external relationships (with clinicians and peers) affect the prosthetic foot decision-making process	This theme comprises the nature, quality, and importance of relationships with other stakeholders in prosthetic foot decision-making, including clinicians and a community of peers who have lower limb amputations. The prosthetist was seen as a primary source of knowledge and was often noted to be the foremost relationship for determining prosthetic foot selection.	Clinicians as a source of knowledge and education about prosthetic feet Trust in clinicians versus reliance on clinicians Function of the rehabilitation team in decision-making Advocating for yourself Importance of peers/community of people with amputations	"When I went in there, our discussion was more about, 'What do you want to do? What are you trying to get out of your leg? You know, what do you need?' I told [the prosthetist] specific things, and he offered a foot which was a [foot model], and I took his expertise and I said okay and I just went with it. It was just what I had." "I think [the prosthetists] should make suggestions. You know, they see a lot of people. They know more people without limbs than I do, so they have a lot of experience and they have a lot of knowledge from the feedback they get from the multitude of patients. For me, it's the prosthetists above the doctors."

			"[The clinicians] were so focused on making it feel comfortable, the socket itself, that we probably just glanced at the foot, if they mentioned it. We glanced over foot selection or it wasn't brought up at all. So that might be helpful to spend a little bit of time maybe describing to a new amputee what to expect." "Like I want [the prosthetist] to have their input and everything, but at the end of the day, it's going to be my leg."
My identity and individuality influence my involvement in the prosthetic foot decision-making process	This theme comprises the individual factors that impact one's involvement in prosthetic foot decision-making. This theme includes pre-injury identity and evolving self-image and functional goals. It also includes differences in preferences for involvement in healthcare decision-making across individuals.	Self-image and identity Differences in goals and priorities between people Individual personality and differences in preferences for decision-making	"This is not a one-size-fits-all situation." "Everyone's amputation is its own beautiful little snowflake. We're all different." "So [test-driving] actually gives the person the ability to see what foot would work better for them in a certain situation. And actually feel comfortable in their own skin. It takes the guess work away. It actually empowers the person who is going to be the one using it." "I think that [the person with LLA] has got a lot to do with it, you know? I'm the one that has got to wear the foot and the more comfortable I feel, the better off- happier that I am."
Different feet for different folks (and activities!)	This theme comprises the stakes involved in prosthetic foot decision-making. It highlights the importance of matching the foot technology to the	The prosthetic foot isn't always the biggest priority	"Everybody is made different, different feet work better for different people."

	individual and the activity at hand to maximize outcomes, once other aspects of prosthetic care are in place (e.g., healing, socket fit). This theme includes the benefits associated with a well-matched foot as well as the consequences associated with a poorly matched foot.	Better outcomes when the foot was a good match, worse outcomes when the foot was a poor match Prosthetic feet have limits and trade-offs, one foot cannot do everything	"Trying out different ones would make [patients] feel good. 'Cause I am sure one foot that works for somebody is totally different than one that works for somebody else. It's like having a car. If we all drove the same car, some would be happy some would not." "Well I have four legs because we don't have one foot like that can do all four of those situations like your normal foot. If we did, fucking sign me up."
Test-driving prosthetic feet was a meaningful experience	This theme comprises the impact that having an opportunity to test-drive different types of prosthetic feet had on participants. This theme includes accelerating the pace of education about prosthetic feet and encouraging participants to provide feedback about their preferences among feet.	Test-driving as a means of education Benefits of test-driving from the patient perspective Limitations of test-driving from the patient perspective Essential components of the test-driving experience	"I think [test-driving] would be very beneficial. You would give each person the opportunity to see how their body reacts to each of the different types of feet. I think most people are aren't really given a choice, you're just given one and there you go, that's it." "As it turned out, test-driving worked. When I brought them home and I used them around here…everything seemed to go just the way they did in the lab." "I don't know if there is a downside to [test-driving]. Give someone a choice in the foot. There's never a downside in giving someone a choice, because you leave it up to the individual. And it's always going to be on the individual. Giving someone a choice is just empowering someone. Giving them stake in their own rehabilitation, their own life."

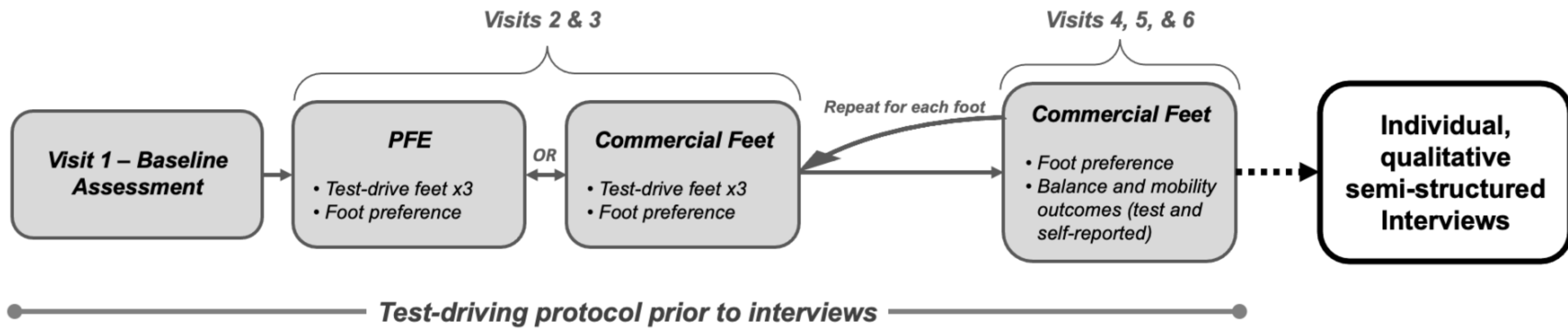

Figure 3.1. Schematic of test-driving protocol participants had completed prior to participating in semi-structured interviews.

- Walk me through how your most recent prosthetic foot was chosen.
- Describe how you think clinicians (e.g., a doctor or prosthetist) should be involved in deciding which foot a person wears.
- Describe how you think a person should be involved in deciding which foot they wear.
- What was it like to try out, or “test-drive,” different types of feet as part of the study?
- What would be the advantages, if any, for you being able to “test-drive” different kinds of feet?
- What would be the downsides, if any, for you being able to “test-drive” different prosthetic feet in the clinic the next time you need a prosthetic foot?

Figure 3.2. Sample questions from the semi-structured interview guide used to conduct interviews.

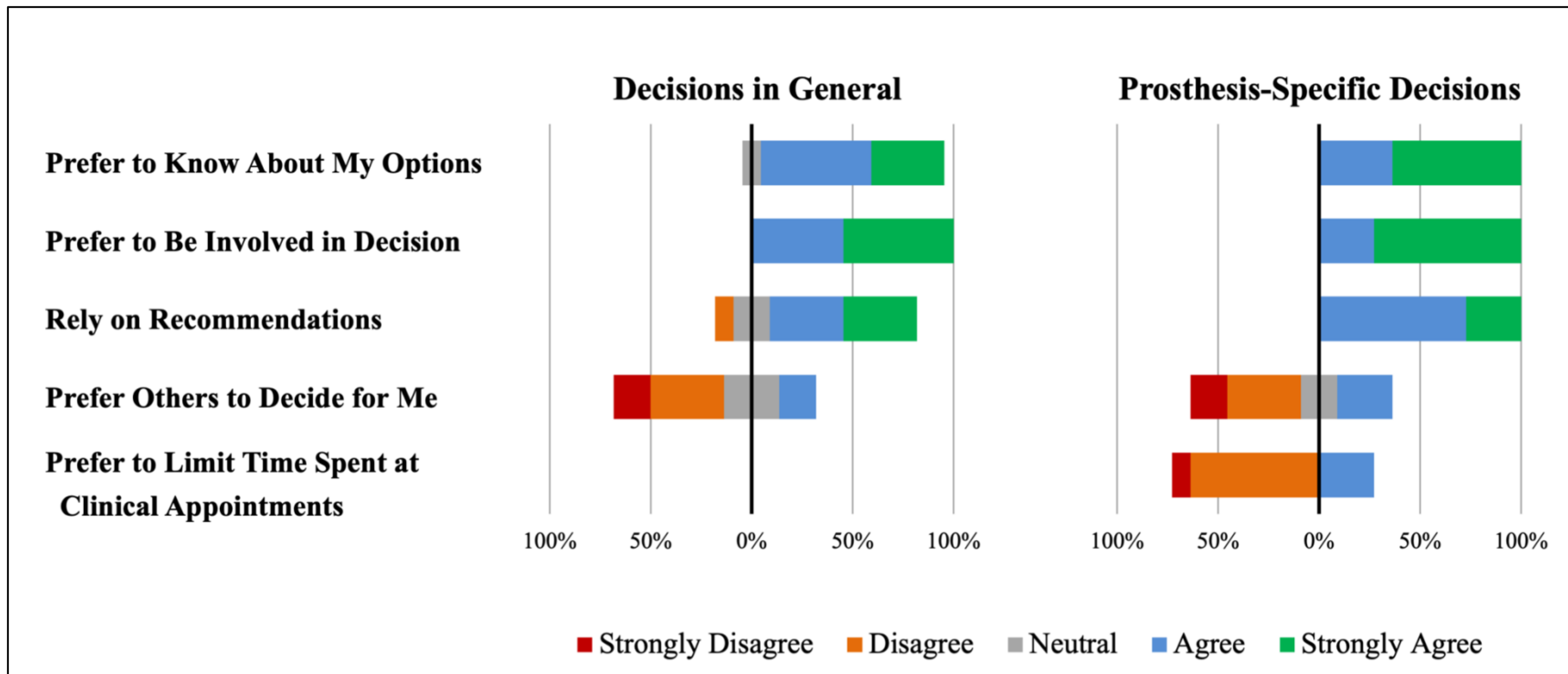

Figure 3.3. Bar chart showing results (n=11) for questionnaire items on preferences for decision-making in general (left) and decisions related to the prosthesis (right). Proportion of total participant responses for each item, ranging from Strongly Disagree to Strongly Agree, are displayed.

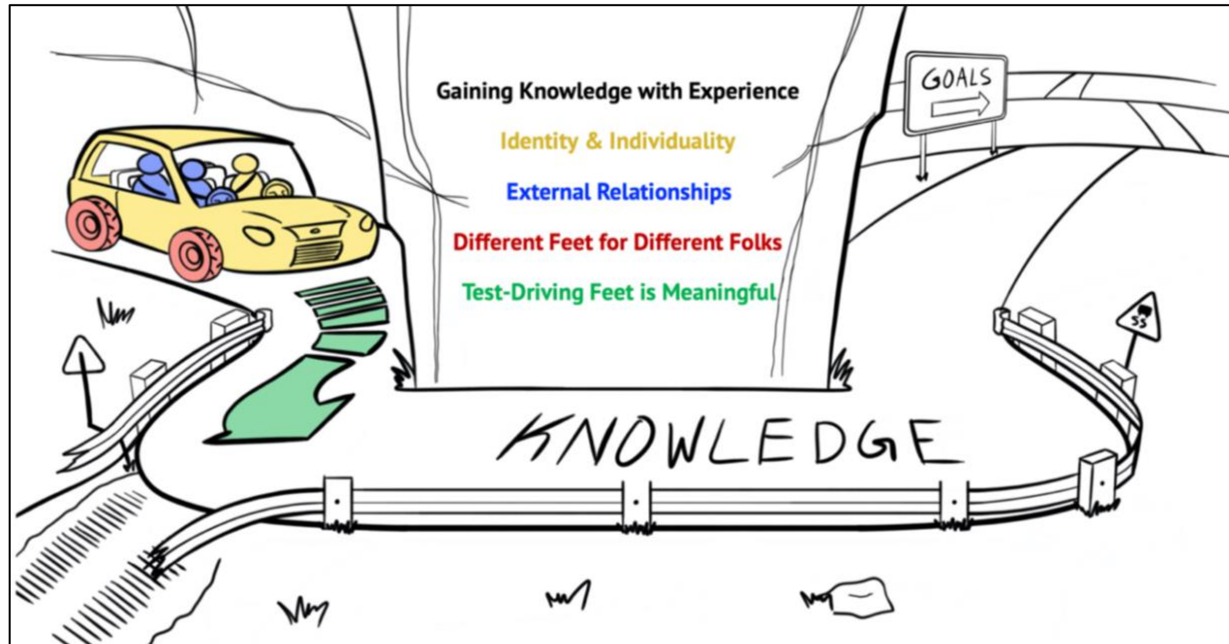

Figure 3.4. Metaphor for the experience of prosthetic feet prescription from the patient's perspective as a journey in acquiring knowledge and experience over time. As the driver (i.e., prosthesis user) accumulates mileage (i.e., knowledge) and gains experience driving their own car, they may wish to negotiate for greater control from the front passenger (i.e., prosthetist) who has dual controls over the car. The rear passengers (i.e., physician and peers with LLA) provide directions, like a navigation system, to direct the driver(s) and orient the car towards the improvements in health-related outcomes and participation in life goals. The tires of the car (i.e., prosthetic foot) should be suited to each car and the types of functional goals and activities that the driver wishes to accomplish. While the car has forward momentum such that it will accumulate mileage over time regardless of what the driver(s) are doing, test-driving acts as the gas pedal to accelerate the pace of learning.

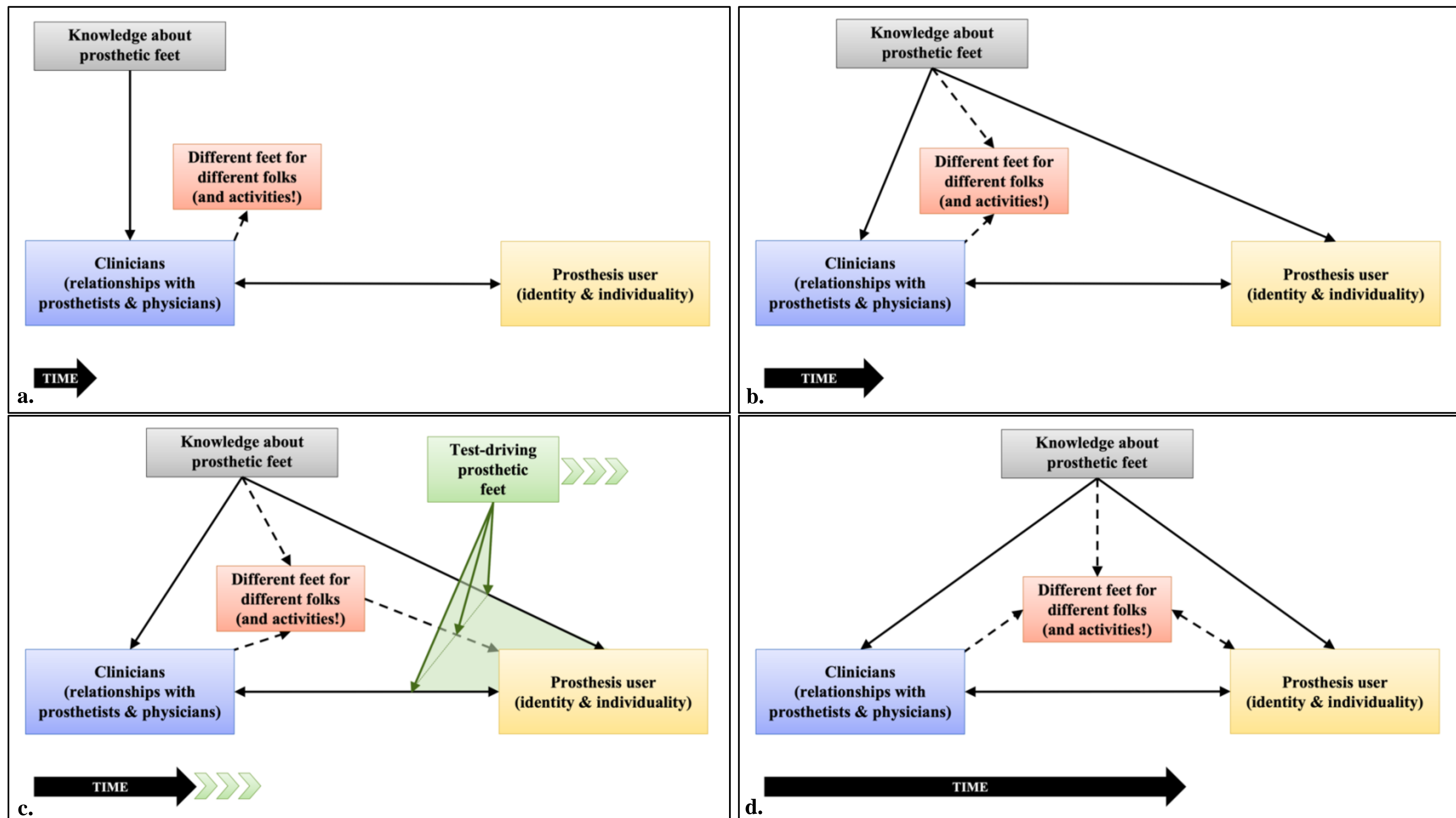

Figure 3.5. A theoretical framework for the relationship between acquisition of knowledge about prosthetic feet and the balance of decision-making power between clinicians and the individual with LLA: a) In the early stages, the decision-making for the foot centers on the clinician and their judgment; b) As time progresses, the prosthesis user will gain knowledge through experience with a foot, but may not have direct experience comparing different types of feet. This shift in relative knowledge may influence the individual's relationship dynamic with their clinicians related to decision-making; c) Through test-driving prosthetic feet, the prostheses user accelerates their experiential knowledge about differences between feet. The experience also invites them to take an

active role in providing feedback on the prosthetic foot decision which may further affect the relationship dynamic with their clinicians; d) Ultimately, with time or because of test-driving, the individual with LLA may seek to achieve an equilibrium in their desired role for prosthetic foot decision-making. Given the extent of desired involvement varies across individuals, the balance in decision-making illustrated here indicates fulfillment of the individual's desired participation, rather than implying that equal participation in decisions is a universal goal.

Chapter 4

Conclusion

In current clinical practice, the selection of a prosthetic foot for a patient with lower limb amputation (LLA) is primarily decided based on clinician judgment (Czerniecki, 2005; Sansam, O'Connor, Neumann, & Bhakta, 2014). My advisor, Dr. Morgenroth, is leading a novel test-drive (TeD) study for prosthetic foot prescription, to make the foot selection process more patient-centered. This TeD study is evaluating two parallel test-drive approaches: trialing different commercial prosthetic feet using the actual feet themselves or using emulated versions of the feet with the robotic prosthetic foot emulator (PFE). Participants tried both test-drive approaches to complete a range of mobility and walking activities in the laboratory before taking the actual prosthetic feet home for several weeks to use in the community. For my dissertation, I led two complementary yet distinct scientific inquiries related to this line of research. I focused on 1) configuring the PFE and performing a mechanical testing validation in anticipation of its use for test-driving feet as part of the TeD study (Chapter Two), and 2) characterizing patient experiences of prosthetic foot prescription practices, comparing the current prescription paradigm to test-drive strategies (Chapter Three). Although each dissertation study involved distinct scientific methodological approaches (i.e., quantitative vs. qualitative), the results of both inform the overall goal of this line of research to improve the prosthetic prescription process.

Conclusions from Chapter Two – Emulating Commercial Forefoot Properties using the PFE

In order to use the PFE to accomplish the aims of the TeD study, we mechanically tested dozens of commercial prosthetic feet to measure their angular stiffness. Subsequently, we

parameterized the experimental data from each commercial foot, converting them into emulated 'foot profiles' for input to the PFE. Thus, for each commercial foot (i.e., foot type, size, and stiffness category), we defined a corresponding Bezier curve to recreate the forefoot angular stiffness using the PFE. Once all commercial feet had corresponding emulated versions in the PFE, I selected a subset of feet to repeat the mechanical testing procedures using the PFE in place of the actual feet to assess the accuracy of emulation. Based on the findings from Chapter Two, the PFE was able to successfully emulate the forefoot properties of commercial prosthetic feet under identical mechanical testing procedures.

Overall, the methods presented in this study enabled an accurate (within <5%) estimation of commercial prosthetic forefoot angular stiffness properties using the PFE at a pylon progression angle representative of late stance phase (i.e., +20°). The Bezier curves provided an effective method for parameterizing the experimental data, with R^2 values exceeding 0.99 for all tested commercial prosthetic feet; the nonlinear Bezier curves used to fit the data in this study improved the representation of commercial foot angular stiffness properties, reducing the RMSE to approximately 0.002. On average, the emulated feet slightly overestimated ankle torque compared to the commercial feet by less than 1 Nm (i.e., 0.76 Nm), or less than 1%. These findings suggest that the PFE can emulate the angular stiffness of the different types of prosthetic feet used in the TeD study.

While the validation testing results revealed a strong, significant correlation between respective emulated and commercial foot angular stiffness, there were areas identified for future research that could improve the use of the PFE for test-driving. Concerning the quality of the emulation, some minor changes could be made to the methods to improve the fit of continuous functions to the nonlinear prosthetic foot stiffness. For example, adding DOF to the Bezier curve

fitting, rather than constraining the curve inflection point (P_1) to be along the midline between P_0 and P_2, could enhance consistency in the quality of the Bezier curve fit across types of feet with varying nonlinear features (i.e., peak bend or skew in the offset from midline). Additionally, the use of alternative optimization schemes for curve fitting, such as minimizing the total difference in area between the Bezier curve and the experimental data from the commercial foot, could improve the accuracy of the emulated foot properties. However, while these adjustments in methods may improve the fit of the Bezier curves to the commercial foot data, they would likely represent marginal improvements due to the already overall high accuracy of emulation. Therefore, future research directions focusing on evaluating and extending the ability of the PFE to facilitate test-drive strategies may be more impactful than future research focusing on optimizing the Bezier curve fit used in the PFE control. One method to further evaluate the emulation accuracy of the PFE is to compare emulated feet with the respective commercial feet during walking for prosthesis users. As opposed to subjecting the PFE to identical mechanical testing conditions as the commercial feet, this type of validation testing would reveal differences in real-world use of the PFE to test-drive prosthetic feet compared to the actual feet. For example, the PFE emulation is currently based solely on forefoot angular stiffness data collected from a single pylon progression angle. However, during walking, people with LLA load the PFE throughout stance phase (i.e., loading both the heel and forefoot). Furthermore, the dynamics involved in walking exceed the capabilities of the mechanical testing procedures (e.g., loading rate), and gait adaptations will vary across individuals.

Future research should consider modifying the physical appearance and form factor of the PFE end effector to improve its ability to emulate the experience of wearing and walking with different commercial prosthetic feet for prosthesis users. For instance, the PFE heel component

has a narrow surface area (approximately 1.5 x 2in), which is more narrow than prosthetic feet and certainly than the plantar surface of a shoe that would typically be used with commercial feet. There are currently only three options for PFE heels to match a range of heel stiffnesses observed across commercial feet. For the forefoot, the PFE end effector has a square profile and a range of foot lengths used to adjust the COP motion and effective foot length, rather than the physical length of the prosthetic foot that a patient with LLA might see visually. Finally, the PFE end effector is not used with a shoe. The emulated forefoot angular stiffness includes the interaction between the foot and a standard, athletic walking shoe. However, people with LLA may want to test-drive feet while wearing various types of shoes (e.g., steel-toed boot, canvas shoe), which would not be reflected accurately by the emulated feet. Therefore, the quality of the emulated foot experience may be less reflective of the experience test-driving the corresponding commercial prosthetic foot, even if the programmed forefoot properties are accurate. To evaluate the PFE during use with people with LLA, I submitted and received funding for an Orthotic and Prosthetic Education and Research Foundation (OPERF) Fellowship Award. This upcoming study will assess differences in foot-ankle biomechanics between emulated and corresponding commercial feet while people with LLA walk in the laboratory. These findings will complement the self-reported and performance-based outcomes comparing participants walking with the PFE and with corresponding commercial feet in the TeD study.

Other future directions of research should expand the ability of the PFE to emulate commercial foot properties during use more comprehensively. The PFE used in the current TeD study was restricted to emulating forefoot properties in the sagittal plane. Future design iterations of the PFE might include additional actuated DOF, such as adding the ability to actuate the heel component or adding control of coronal plane stiffness (i.e., 2-DOF). These additions introduce

complexities in the mechanical hardware design and the software control scheme for the PFE but could enhance the emulation of commercial foot properties to use in a test-driving strategy. Additionally, the mechanical testing procedures used to program the PFE were simplified to forefoot unloading collected from a single pylon progression angle due to the lack of heel actuation. Therefore, future research to expand the mechanical testing data collection to be more similar to physiological loading patterns of a commercial foot may also enhance the accuracy and experience of test-driving feet with the PFE.

Similarly, emulating multiaxial stiffness would be more representative of the physiological loading of prosthetic feet during use. Multiaxial stiffness may be an important aspect of emulation since lower limb prosthesis users are at a disadvantage to accommodate to uneven terrain compared to people without amputation, and therefore stability can be influenced by the foot properties in the coronal plane (Gates, Dingwell, Scott, Sinitski, & Wilken, 2012; Paysant, Beyaert, Datié, Martinet, & André, 2006). Additionally, test-driving prosthetic feet on uneven surfaces, such as the terrains that people with LLA would typically encounter during daily walking outside of a laboratory, might be valuable. Dr. Morgenroth recently received funding for a new Department of Defense grant to address a number of these issues by studying a multiaxial test-drive strategy for prosthetic feet ("A Prosthetic Foot Test-Drive Strategy for Improving Stability and Falls-Related Outcomes in Veterans With Leg Amputations," Department of Defense OPORP Award No. W81XWH-20-1-0291). I have been hired to work as a researcher on this new grant, which will assess differences in walking stability and falls-related outcomes for people with LLA test-driving prosthetic feet of differing multiaxial stiffness using actual feet and a 2-DOF PFE. Additional test-drive strategy research emphasizing the replication of real-world environments would be helpful to people with LLA to test how different types of feet respond

across varying terrains or activities that they find important for their own daily walking conditions.

Another potential limitation of the PFE for use in test-driving, compared to actual prosthetic feet, is that users cannot visualize differences between feet which could influence their relative aesthetic preference across types of feet. For example, some commercial feet have more exaggerated curvature in their keel shape, which may not be compatible with some cosmetic leg covers or be easily concealed under pants. Additionally, participants have commented on differences in the foot shell cosmesis between prosthetic foot types (e.g., lack of a split-toe for use with a sandal or the shape of the foot shell), which influenced their preference for one foot over another. For instance, one participant from the TeD study remarked that one of the commercial feet did not fit easily into his shoes because of the shape of the cosmetic foot shell and that this negatively affected his preference for that foot. These details about the cosmesis that differ across commercial feet are not captured by the PFE but can impact a person's foot preference. Thus, the mechanical properties of a foot are not the only aspects of test-driving feet that users are considering when they rate their relative preferences for prosthetic feet. Future research might investigate ways to have visual features of commercial prosthetic feet incorporated into the test-driving experience when using the PFE. For example, this could be as simple as showing the person with LLA photos of the respective commercial feet to compare or as complicated as adding augmented reality to create a simulated visual comparison for the person. Alternatively, future research could determine that the PFE is best suited to supplement foot prescription by narrowing the selection of commercial prosthetic foot options. However, short-term trial periods with one or more corresponding actual feet remain an important part of test-drive strategies if they were to be incorporated into clinical practice.

Finally, while the five types of commercial prosthetic feet used for the TeD study were representative of a range of foot options commonly prescribed for both low- to high-mobility users, they comprise only a fraction of the feet that are available for people with LLA. Future research efforts should expand the 'library' of emulated commercial foot profiles to include many more manufacturer makes and models. For instance, commercial feet now frequently have advanced component features that allow them to adapt their properties or behaviors to differing environmental conditions or activities (e.g., hydraulic ankles, microprocessor-controlled devices). It is currently unclear how to best capture these advanced technologies' mechanical properties for accurate input and emulation using the PFE. Furthermore, only certain prosthetic foot sizes were tested and programmed into the PFE for the TeD study (i.e., 26-29cm). Unfortunately, the foot sizes commonly used by women (i.e., smaller than 26cm) were not included, and thus women with smaller foot sizes were unintentionally excluded from participation. Expanding both the types and sizes of prosthetic feet available to emulate from a library of foot profiles does present a logistical challenge. Since prosthetic foot manufacturers do not publish stiffness properties, mechanically testing would need to be performed on each type of foot in all sizes and all stiffness categories required to accommodate different users. One way to accomplish this expansion of feet might be to test a representative foot of each type (i.e., in a specific foot size and stiffness category) and establish a technique for scaling the measured foot stiffness for different foot sizes and stiffness categories. Future research might evaluate how prosthetic foot stiffness varies across foot sizes and stiffness categories to develop methods for generalizing the properties of a representative foot to those of a differing size or stiffness category.

Using the PFE to Accomplish the Aims of the TeD Study

Regardless of the limitations of the current iteration of the PFE, using emulated feet with methods described in Chapter Two facilitated using the PFE for human subjects data collection within the TeD study. Between Chapters Two and Three of this dissertation, as part of the TeD study, we conducted a multi-year randomized, crossover trial across three data collection sites (i.e., VA Puget Sound Health Care System, Minneapolis VA Health Care System, and the Center for the Intrepid at the Brooke Army Medical Center). This work is ongoing and nearly completed, with more than 60 participants having finished thus far. In addition to the findings from quantitative performance-based and patient-reported outcomes from the TeD study, I sought to explore how participants described the qualitative experience of test-driving compared to their previous clinical experiences being prescribed prosthetic feet.

Conclusions from Chapter Three – The Value of Test-Driving Prosthetic Feet

As described in the Introduction chapter, while conducting the human subjects data collection visits for the TeD study, I heard unsolicited feedback from participants about the value of test-driving prosthetic feet. Thus, I proposed and conducted individual semi-structured interviews with participants to understand their experiences with prosthetic foot prescription as part of current clinical practices compared with their experiences test-driving feet. From the interviews, we developed a theory for the experience of being prescribed a prosthetic foot. We identified a core category of the relationship between the amount of knowledge about prosthetic feet that each stakeholder (i.e., clinicians and the patient) has access to, and the corresponding amount of power they wield in the decision-making process.

The study participants that I interviewed described their experiences as prosthetic foot users as an educational journey in which they started with no knowledge, and incrementally gained knowledge over time. Participants associated these points in time with increasing empowerment and recognition of their own preferences concerning prosthetic feet and for being involved in the decision-making process. They described the relationship dynamic with their clinicians, and the prosthetist in particular, as shifting over time. In the early stages following amputation, the clinicians represented a source of knowledge and expertise about the prosthesis, on which patients with LLA relied. Over time, however, the prosthesis user gained more knowledge and developed different approaches for relating to the clinical decision-making process, depending on their individual preferences. Some of these individuals wished to be actively engaged in a discussion regarding foot selection, viewing the clinicians as a committee of advisors and wanting to position themselves as the final decision-maker. These individuals pointed to the differing types of knowledge that clinicians add to the foot selection process compared to the user (e.g., technical information about foot compatibility, third-party payer reimbursement considerations). Similarly, they valued the embodied knowledge that they held as the user, which they felt that the clinicians did not have access to (e.g., personal priorities for feet). In contrast, other individuals wished to contribute to the decision-making process by asking the right questions throughout the process but ultimately saw the clinicians as being responsible for the final selection of the foot and trusted in their expertise.

Thus, we posited that the goal for people with LLA was not necessarily to achieve equal decision-making power. As with any medical prescription, the responsibility for determining a prosthetic prescription ultimately lies with the clinician. Instead, the goal may be for the patient to feel that they have acquired sufficient knowledge to recognize and then realize their

preferences for involvement in prosthetic foot decision-making. In this way, the proposed theoretical framework demonstrates a shift in the balance of decision-making from a process centered around the clinician to one that engages both the patient's and clinician's knowledge in order to inform the selection of a prosthetic foot, to the extent the patient desires.

Regardless of differences in individual preferences for involvement in decisions, all participants reported the value of test-driving prosthetic feet as a means of education which provided experiential knowledge from using different feet and facilitating discussion with the clinicians. We were surprised to discover that nearly half of the eleven participants interviewed had requested a change in their prosthetic foot from their clinical team directly because of their experience with test-driving feet. Upon learning this, our study team contacted previous participants who had completed the TeD study across data collection sites to examine whether this finding was consistent across the study sample. We found that approximately one-third of the total participants from the TeD study sample thus far had returned to their prosthetist with the information about their most preferred prosthetic foot from the study to request it for their prosthesis (i.e., favored one of the study feet over their currently prescribed foot). This finding indicates that the test-drive approach, even when limited to the three study feet experienced, may have enabled participants to perceive a choice in foot that was superior to that of the standard of care prescription they had received. Participants described that engaging in test-driving made them feel like their opinions were a valued part of decision-making. Additionally, test-driving allowed patients to be informed about the relative trade-offs among different prosthetic feet and determine for themselves what functional features they prioritized. This finding suggests that test-driving different prosthetic feet was a tangible way to offer experiential, embodied knowledge about feet to involve the user in selecting their prosthetic foot.

Future research directions could inform the use of test-driving strategies to augment current prosthetic foot prescription practices. Several aspects of the test-driving procedures were identified that prosthesis users considered essential to the experience. These fundamental aspects included trying several feet back-to-back and using each one to perform a range of mobility activities to explore how different feet respond to the functional tasks that are important to the individual user. Future work should evaluate the types of activities (e.g., walking on level ground at a range of speeds, going up or down an incline, turning, uneven ground) most important to users to distinguish functional differences between feet. Additionally, the amount of time with each foot that the users felt was needed to determine their relative foot preferences requires further evaluation. Many clinic environments have limited space and time in which to conduct test-driving procedures like those used in the TeD study. Thus, identifying the key components of test-driving prosthetic feet could inform how test-drive strategies might be best incorporated into clinical practice. In addition, the research thus far has focused on the patient perspective. However, future work should seek to understand the views of other stakeholders on the barriers and facilitators of decision-making in prosthetic foot prescription. It is probable that clinicians or others involved in the provision of prosthetic feet (e.g., clinical businesses, manufacturers, third-party payers) would have differing views on the advantages and limitations of engaging patients in component selection more directly. Specifically, qualitative research should be conducted to explore physician, prosthetist, and prosthetic foot manufacturer perspectives on using test-driving strategies as part of prosthetic foot selection for people with LLA.

In addition to future research to improve test-drive strategies, there may also be alternative approaches to promote balance in the decision-making power for people with LLA. One possible effort could be to increase clinician awareness about the value that patients perceive in

contributing to component selection for their prosthesis, having more education about available options, and transparency in the selection process. While clinicians have reported the importance of using information from patients (e.g., individual functional goals) to inform their selection of components (Sansam et al., 2014; Stevens, Rheinstein, & Wurdeman, 2018), they may be incorporating this information “behind the scenes” rather than making this decision-making process apparent to the patient. Raising awareness in prosthetist and physician training programs about the value of inviting patients to engage in conversation regarding component selection could resolve the sense of disempowerment that people with LLA described feeling. Additionally, clinicians should be mindful of how patient preferences for being involved in decision-making vary. Future work should explore techniques for eliciting a patient’s preference for decision-making involvement as part of the patient evaluation. However, these efforts would still rely on the clinician to provide and facilitate these conversations. Therefore, there are likely solutions that could target patients to increase awareness and education about options for prosthetic feet directly. For example, educational materials regarding prosthetic foot selection could be made publicly available to reduce the knowledge gap between clinicians and patients, regardless of the treating clinician’s approach to engaging patients in discussing components. Future work should evaluate what types of information about prosthetic foot selection that patients desire to be educated about and how best to make that information accessible and effectively disseminate it to patients with LLA.

A Vision for the Future of Prosthetic Foot Prescription Practices

Based on what I learned from participants about their experiences being prescribed a prosthetic foot and their perceived value in the experience of test-driving, I propose a future

vision for how clinical practices for prosthetic foot prescription might incorporate test-driving strategies. Rather than replacing what is currently being done by clinicians, who are using their expertise and best intentions to select prosthetic feet, I envision test-driving as another tool that clinicians can use to supplement their current practices for prosthetic foot selection. As a prosthetist myself, I would feel less uncertainty about component selection if I could provide patients the opportunity to provide input into the decision-making process. Thus, any proposal for clinical translation of test-driving strategies should seek to leverage the existing strengths of the clinicians' expertise and current approaches for prosthetic foot selection rather than seek to substitute them.

I propose one potential strategy for test-driving prosthetic feet could use robotic PFEs installed at designated specialty prosthetic care centers, which would likely be associated with metropolitan hospital systems that already have established multidisciplinary amputation rehabilitation clinics. I could imagine a scenario similar to how regional, diagnostic radiological centers are used in the United States. For example, rather than installing a complex, expensive set of equipment (e.g., PFE) in every clinic, a prescribing physician or prosthetist could send their patient to a regional center with the engineers or technicians on staff to run diagnostic tests and return the results. In this model, the clinicians would first use their current practices for prosthetic foot decision-making, which may include engaging the patient in a discussion about their priorities and functional goals, to hone in on a subset of commercial prosthetic feet that might be appropriate for the patient. Then, the clinician could send their patient to a regional center with this specified list of foot options for them to try out using the PFE to offer experiential input and help select the final foot to include in their prosthesis. Several participants mentioned sharing a similar vision during the qualitative interviews. For example:

"I think [test-driving] would be great because it gives you a chance to really try different feet out. Instead of your prosthetist having to spend all this time trying out different feet before they find a foot that makes you comfortable, now you walk into the clinic and put this robot foot on. Even if [the robotic feet] were regional, right? If they had one in the Pacific Northwest, one in the Southwest, one in the Northeast, whatever. You could just go to one of these major clinics and try all these different feet at one time. Overall, it's going to save time and resources…because you're not wasting all your time and having to wait to get all these other feet and plus the alignment and everything else." – Frank

Alternatively, if future PFE technology advancement permitted more mobile use of the device (e.g., outside of a laboratory environment, if the PFE could be powered with body-worn actuation instead of requiring 3-phase power), then other options become possible for using the PFE to test-drive feet in the clinic. Use of the PFE is not the only option for facilitating test-drive strategies nor the only approach evaluated in the TeD study. Instead, actual commercial prosthetic feet could be used for brief trial periods in the clinic. However, there is currently no mechanism available from prosthetic foot manufacturers to requesting multiple types of feet for a single patient to trial before purchasing. In theory, prosthetists could request a loaner PFE to temporarily use for a patient to test-drive different types of feet, similar to how loaner units are provided for some prosthetic knee components before selecting a final one to use in a prosthesis in certain circumstances. However, even if such a mechanism were in place, trialing multiple feet requires an ordering process to receive the feet from each supplier and a substantial amount of time for the prosthetist to set up and align each prosthetic foot with the patient's socket.

Undoubtedly, clinical implementation of test-drive strategies will include numerous challenges. However, the findings from this dissertation establish evidence for the benefits of incorporating test-drive strategies from the patient perspective. The results of the qualitative study also identified known downsides associated with test-driving, particularly the amount of additional time that it requires. While patients couched the disadvantages of test-driving as being "worth it" in comparison to the perceived benefits, clinicians and other stakeholders may feel differently. Thus, further examination of the benefits and limitations from other key perspectives would inform clinical implementation efforts for adopting test-drive strategies – either with the PFE or with actual commercial feet – as part of prosthetic foot prescription practices.

In my dissertation, I used quantitative methods to assess the accuracy of emulating commercial forefoot angular stiffness with the PFE, which was a crucial step in evaluating the PFE test-driving strategy. Subsequently, I used a qualitative approach to develop an understanding of prosthesis user experiences with test-driving and prosthetic prescription practices, in general. Optimizing prosthetic foot selection for people with LLA remains an important objective to support them in attaining their functional goals. Test-driving strategies may enhance prosthetic foot prescription by facilitating a personalized approach for people with LLA to be engaged in selecting their own prosthetic foot by providing experiential input to the decision-making process. Future work should continue to assess how test-driving prosthetic feet could augment current prescription practices to positively impact both the experience of prosthetic prescription and the optimal selection of prosthetic feet, enabling improved mobility and functional quality of life in people with LLA.

References

Czerniecki, J. M. (2005). Research and clinical selection of foot-ankle systems. *JPO, 17*(4), S35-S7.

Gates, D. H., Dingwell, J. B., Scott, S. J., Sinitski, E. H., & Wilken, J. M. (2012). Gait characteristics of individuals with transtibial amputations walking on a destabilizing rock surface. *Gait Posture, 36*(1), 33-9.

Paysant, J., Beyaert, C., Datié, A., Martinet, N., & André, J. (2006). Influence of terrain on metabolic and temporal gait characteristics of unilateral transtibial amputees. *J Rehabil Res Dev, 43*(2), 153-60.

Sansam, K., O'Connor, R. J., Neumann, V., & Bhakta, B. (2014). Clinicians' perspectives on decision making in lower limb amputee rehabilitation. *J Rehabil Med, 46*(5), 447-53.

Stevens, P. M., Rheinstein, J., & Wurdeman, S. R. (2018). Prosthetic foot selection for individuals with lower-limb amputation: A clinical practice guideline. *JPO, 30*(4), 175-80.