

IMPROVING THE DESIGN METRICS OF WALKING ASSISTIVE DEVICES

A Dissertation

by

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ABSTRACT

There are millions of people who are unable to be mobile without the use of mobility aids. Being mobile, and more specifically walking, has a great impact on a person's quality of life. Not being able to walk, as well as walking abnormalities, can have many long term affects both physically and psychologically. Although walking aids are designed to help with walking, sometimes how they impact the body can have negative impacts, such as arthritis, scoliosis, and increased energy use. Therefore, designing walking aids optimally is very important. The design methodology proposed in this work to assist in optimal design of walking assistive devices is the user center design approach utilizing and user centered design. This work asserts that in the design of walking assistive devices some biomechanical considerations can be consistent. The considerations this research will analyze are lower limb joint angles, lower limb joint moments, lower limb joint symmetry, interaction forces, and energy expenditure. This dissertation aims to identify design metrics and specify design concepts using these considerations with the user centered design process for two walking assistive devices: an exoskeleton and above the knee prosthesis for amputees with one above the knee amputation.

DEDICATION

This dissertation is dedicated to the woman who it is inspired by: Elizabeth Williams. She is the woman who has been the inspiration behind this work, moved forward despite difficulties, and
been persistent at all times.

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1. INTRODUCTION AND LITERATURE REVIEW

In the United States, Over 6 million people are unable to walk without the use of walking assistive devices [3]. Not being able to walk, as well as gait abnormalities, can have many long term physical and psychological effect [4, 5, 6, 7, 8]. Although walking assistive devices are designed to help with gait, sometimes how they impact the biomechanics of the user can have negative impacts over long periods time [9, 10, 11]. Therefore, designing walking assistive devices that minimize these negative impacts is very important for the individuals that must use them on a regular basis.

Walking assistive devices often end up being modified and altered to better serve users even after they are on the market [11]. This means that the design does not always properly meet the needs of the user or unknowingly creates another need. Currently, many rehabilitation devices utilize User Centered Design (UCD), also known as Human in the Loop (HITL) design. HITL design is when we consider the desired user at every part of the design process [12]. Often rehabilitation devices are created with the user in mind, but do not include them in the process. This can lead to devices being created, but not used by the community they are intended for. Instead of assisting the user, they actually hurt or hinder the user. The design process is not very always clear and is not consistent across walking assistive device designs. I propose that the best way to create an optimal design for walking assistive devices is to take a modified Human in the Loop (HITL) design approach that uses biomechanics and user desires to inform the design process in a systematic way. In each stage of design we fully include the user desires, and biomechanical/ physical needs and responses.

With this in mind we will utilize this concept to improve design metrics for two walking assistive devices: an exoskeleton for those with paraplegia and an above the knee prosthesis for unilateral transfemoral (TF) amputees. It is important to investigate what the optimal specifications and metrics are for these new systems and if biomechanical outcomes and user satisfaction can be improved by using a biomechanics and user centered HITL approach.

1.1 Design Methodologies for Walking Assistive Devices

As the number of wheelchair users grows [13] , there needs to be a focus on the design of walking assistive devices to minimize the issues from long term wheelchair use. Most walking assistive devices are designed to replace aspects needed for gait (lower limb prosthetics), correct gait (orthoses, rehabilitation exoskeletons), assist with gait (canes, walkers), or impose gait (exoskeleton devices). The reasons for using walking assistive devices are numerous, however the goal is the same: *to walk with a symmetric gait pattern that resembles able bodied walking biomechanics without pain*. Considering the shared desired outcomes there can be a commonality in design approach.

Design is an iterative process, but generally flows in a pattern. Although there are many engineering design methodologies, most follow a similar pattern[13]. There are four general phases: (1) problem clarification, (2) conceptual design, (3) embodiment design and (4) detail design[13]. Although these design phases are applicable, they serve as more of a general guide and not a specific approach for a device type. Most papers discussing the design of walking assistive devices review the development of the specific device, but not the specific design methodology used in the creation of the devices. More specific methodologies may be useful to have improved design for specific device types.

The general research methodology for rehabilitation devices is UCD. UCD is very broad which simply means that the user is involved in the design process in some way. This type of design process can greatly reduce the modification needed to be done by users and physiotherapists [11]. UCD has been shown to have improved usability of designs [12]. It has also been shown to shorten the development time and cost by decreasing the iterations in the later stages [5]. This concept is not new; Donald Norman introduced this idea in 1986 in his book, User-Centered System Design: New Perspectives on Human-Computer[14]. Buurman also presented this method in 1997 for smart products [12]. A similar method presented by Marinissen [15] includes user input after concepts have been developed.

Common approaches to UCD are found in the standard International Organization for Stan-

dardization (ISO) 9241-210. The standard focuses on activities that are in user centered design [16] and are not specific to walking assistive devices. This standard is more so for those who plan and manage design projects and does not give details on design techniques or methodologies [16].

Current assistive devices are often redesigned and modified by users and physical therapists in order to properly suit the user [11]. The method of redesign and modification has even been proposed as a macro framework for the design of rehabilitation devices called Design for (every)one [17]. Design for (every)one attempts to identify and use redesigns and modifications in the community- based rehabilitation contexts[17]. However, with more walking assistive devices becoming powered and more complicated this concept is more difficult to apply due to the gaps in knowledge between the user and creators. Also, these redesigns or modifications need to be properly assessed to see how they are impacting the biomechanics of the user and to assure the redesigned and modified devices will not cause more damage.

1.2 Proposed Approach

The design of walking assistive devices is inherently interdisciplinary. It heavily leans on engineers for the design, but also can involve those in the rehabilitation field, such as physicians, physical therapists, orthotists, and prosthetists. Due to UCD being so broad, and design of walking assistive devices being so interdisciplinary it can be difficult to pinpoint when and how to involve the user. While the range of user involvement can vary, there are somethings that consistently be considered to properly assess needs of the potential user and maximize positive outcomes. For this work we will use a more specific version of UCD to improve designs for walking assistive devices. The common desired outcomes of walking are, minimizing pain, symmetry and aligning as closely with able-bodied walking without causing further damage. This leads us to some common types of user involvement and analysis in assessment of user needs, determining the metrics and specifications of the device. This will hopefully lead to improved outcomes and less walking assistive devices that are not used.

1.2.1 Gait Cycle

For this research, we will be looking at improving walking gait, however the approach can be expanded to different gait types. Understanding an individual gait is critical in assessing the effectiveness of walking assistive devices. During flat ground walking, most humans follow a certain pattern called the gait cycle (Figure 1.1). The walking gait has a stance phase, from heel strike to toe off, and swing phase, from toe-off to heel strike. The gait cycle is composed of seven events: initial contact, load response, heel off, opposite initial contact, toe off, feet adjacent, tibia vertical, and next initial contact.

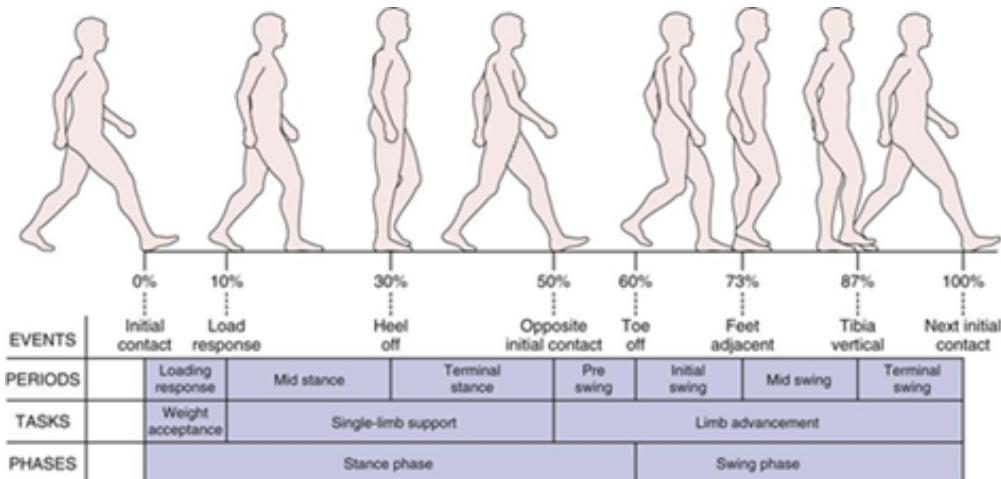


Figure 1.1: Gait Cycle [1]

During these phases, certain strategies are typically used in healthy able-bodied people [1]. Some of these strategies are knee flexion (bending of the knee) in the stance phase, dorsiflexion at initial contact and plantar flexion at terminal stance [18]. Knee flexion in the stance phase and dorsiflexion at initial contact are method for shock absorption. While plantar flexion at terminal is essential for push off.

1.2.2 Problem Clarification

For user centered design to be used for walking assistive devices, the user must be considered during the problem clarification stage .to properly analyze the problem and establish design criteria. The problem clarification stage is when the needs of the user are identified and validated by the user, thus improving the chances of long term usage [11]. There are several ways to involve and assess the needs of the user. We first need to define the targeted user. The target user will always include the population that will need to walking assistive device to walk however additional users depend on the setting and desired use of the device. The setting of use of walking assistive devices can fall under three general categories:

- Rehabilitation center
 - This will primarily be used in a rehabilitation space. Users will include physical therapist and intend population group
- Primary source of mobility
 - This primarily used alone needs to able to be used in a variety of location
- At home training and exercise
 - This can be used possibly alone or assisted. Generally this can be used in a stationary or small space.

After this is established, you need to assess the target user. For walking assistive devices, we will need to survey users desires and determine the physical needs of the users. Although users can articulate what they need (via surveys), the biomechanics of the users' body can provide additional information unknown to the user. To properly assess needs for walking assistive devices, the biomechanics (gait abnormalities,kinetics, kinematics, muscle, and bone density, etc.), of the user without the device, desired impact on the biomechanics of the user, and the predicted and realized biomechanics of the user with the device needs to be evaluated. Desires can be assessed

through round tables, and surveys. Physical needs can be assessed by observing biomechanics when walking with and without a walking assistive device as well as energy expenditure. Since we are looking at walking some of the biomechanical considerations that must be observed are: Joint moments, joint angles, joint symmetry, interaction forces, energy expenditure, and muscular usage during walking. If the population can not walk these can still be considered, but differently. For example: muscle activity, muscle mass, range of motion available, energy from sit to stand, etc. There may be additional for groups, but these will always need to be assessed in some way when creating a walking assistive device.

1.2.3 Considerations in other Design phases of Walking Assistive Devices

Thinking back to the other three design phases there are common considerations that can be taken there as well. In conceptual design we can consider how the concept can impact walking for targeted population. If testing with the targeted population is not an option see if we can emulate the impacts on able bodied individuals or models. In the embodiment design phase and detail design phase it is imperative to do similar considerations in the problem clarification phase with the targeted population in some way. If not then the final design could not meet the needs and desires of the user.

Whether designing a completely new device or redesigning an existing device, this evaluation is important to optimally meet user's desires and needs. The strategy proposed in this research includes user needs and biomechanics as the focal point in the development of design metrics and concepts.

1.3 Background of Target Devices

This dissertation will look at improving design metrics for two walking assistive devices (i) a powered transfemoral prosthesis and (ii) an exoskeleton device for those with paraplegia. We will also come from two approaches a redesign and setting up a new design.

1.3.1 Impact of Exoskeleton Devices for those with limited mobility

There are approximately 276,000 people in the United States that have spinal cord injury (SCI) and every year there are approximately 12,500 new spinal cord injuries occur[19]. Many with paraplegia as a result of spinal cord injury cannot achieve independent standing or walking even after rehabilitation [20]. Also, about 90 percent of people with complete SCIs have to rely on a wheelchair for mobility [21]. Long periods of time in wheelchair have many negative side effects, such as osteoporosis, spasticity , urinary tract infections, increased body mass index, impaired digestive, lymphatic, and vascular functions, sores, and depression [22, 8, 4, 5, 7]. For individuals that are restricted to a wheel chair, opportunities for standing and being eye level with others are very positive psychosocially [7]. Creating new ways to facilitate upright mobility is very important, due to the many physical and psychosocial issues associated with sitting for long periods of time in a wheelchair. One of the main ways to assist those with paraplegia in walking is using a passive HKAFO (Hip-Knee-Ankle-Foot-Orthosis) or a powered exoskeleton.

The first FDA approved exoskeleton was the ReWalk[TM] [23, 7]. The ReWalk is a motorized exoskeleton that provides actuation at the hips and knee. There are similar exoskeleton devices such as HAL [24, 25], EKSO [26, 27], Indego [28, 29, 30], MINA[31], eLegs [32] and the Vanderbilt Exoskeleton [33]. With all of the powered exoskeletons being researched there has been little surveying of the needs of those who would have to use them in order to walk.

One of the main drawbacks of the ReWalk and similar exoskeletons, is that they require the use of crutches. This means that those without significant upper body strength may find these devices more difficult to use [34]. Also, long term use of crutches can cause secondary issues such as hematoma formation and pain [35]. Other exoskeletons, such as REX does not require crutches but utilizes a joystick and provides active assistance for the ankle joint. However, the REX walking pattern is unnatural and very slow is due to the use Zero Moment Point (ZMP) control. ZMP is a stable method of walking, but does not lead to natural human like walking [36]. The slow and unnatural walking would not be ideal for gait rehabilitation or a primary use for mobility. However, due to its stability it does allow for the device to be used for a larger group of spinal cord

injury patients. REX is used for in rehabilitation facilities to help those with paraplegia complete movements and exercises that are very helpful. When powered exoskeleton devices interact with a user interaction forces are present [37]. Excessive interaction forces can cause sores and can lead to device migration [37]. People with complete paraplegia have limited to no feeling in their lower bodies. This means if there are increased interactions forces that could be damaging and there would be no way for them to identify this. In all existing exoskeleton devices, the exoskeleton knee is modeled as a hinge joint even though the human knee is not really a hinge. The knee moves forward by combining a rolling and gliding motion[38]. Because of this the joint center between the user and exoskeleton are micro misaligned[39]. This could lead to harmful interaction forces. Although there are several exoskeletons on the market if they do not adequately meet user desires and/or cause increased interaction forces they can result in injury and device abandonment. There is a major need to assess the needs and desires of the paraplegic community and find ways to reduce interaction forces.

1.3.2 Impact of Prosthesis on Transfemoral Amputees

There are a large number of prosthesis currently on the market. However, even with this large number long term use of prosthesis continue to cause problems with users. Transfemoral amputees are able to implement very few of the important walking strategies mentioned in Section 1.2.1. Unilateral amputees often over compensate with the intact side. This over compensation leads to between 45- 55% more energy use when walking than able bodied individuals. [40, 41]. This also leads to a number of asymmetries when walking, such as a longer stance phase in the intact limb and prolonged knee extension [18]. These asymmetries can lead to injuries if not corrected[9, 10].

1.3.2.1 Overview of Prosthetic Knees

The most commonly used prosthesis are passive and microprocessor knees. However, these knees currently do not solve the problems with asymmetries mentioned earlier. Microprocessor knees often outperform passive knees in terms of symmetry, and energy expenditure [42, 43]. However they still do not greatly improve kinetics. This is more than likely due to the lack of

active extension at the knee and inactive ankles often used with them. Powered prostheses are the least prevalent, but have the potential to solve some of the shortcomings of current prosthetic. There is currently only one powered knee on the market, Ossür power knee[44]and one powered ankle, iWalk BiOM [45]. However, several powered prostheses have been developed for research purposes[46, 47, 48, 49]. Powered knee and ankle systems benefit the user by putting power into the systems and adding more variability during the stance and swing phases. This can allow for knee flexion in the stance phase, which helps to optimize walking. Powered prostheses utilize motors to provide actuation at the joints. Powered ankles use active plantar flexion in the terminal stance period to aid in push off. Amputees tend to use less energy while using powered prostheses [41]. There are other passive aspects that work with a powered prosthesis that could make it more effective, such as novel prosthetic feet. However, prosthetic feet are almost exclusively studied in transtibial amputees and not transfemoral. In order to know if we can improve design metrics in powered prosthesis this must be explored.

Previous work has shown the potential for powered prosthetic to improve the movement of unilateral amputees [50, 51, 52]. A biomechanical analysis was done on a powered transfemoral prosthesis (AMPRO II) from Texas A&M. This analysis showed several flaws in the design were identified such as heavy weight, lack of shock absorption, flat ridged foot, and ankle control. From this work some changes were made to the AMPRO II to improve outcomes. Recently, an adaptable control algorithm for a custom-designed powered transfemoral (TF) prosthesis (AMPRO II) was developed. This algorithm enables robust walking on various terrains without any detection or measurement of surface slopes [53]. It also minimizes tedious calibration procedures. There is a new design for the prosthetic device based on these findings. However, some aspects of the design need to be more refined. The specifications foot stiffness and shock absorption techniques will be determined by observing the biomechanics. There has been substantial research on prosthetic feet for transtibial amputees, but very few studies have observed the impacts of foot design on transfemoral amputees.

1.4 Problem Statements

The goal of this dissertation is focused on utilizing this specific design approach for walking assistive devices in order to further define and improve metrics for both a powered exoskeleton device and a powered prosthesis.

Problem 1: There are several powered exoskeletons currently on the market for those who have mobility impairment. However, there is no research that has determined the actual needs and desires for those who will need them. Engineering a user-centric device will improve wearability and comfort towards great user compliance. To determine what parameters, are the most desirable to the end user a survey will be used to rank and rate potential needs.

Impact: The knowledge of user needs will aid in the optimal design of powered exoskeleton devices. Important areas of focus can be identified.

Problem 2: Most walking devices employ joints that are incompatible with the polycentric nature of human joints. Conventionally used joints are either single axis joints or polycentric with a predefined centrode. This results in a mismatch between the users' knee and centrode of the device which can cause increased interaction forces that can cause sores and pain. There has been no study that look purely at the knee mechanisms and the impact on migration, interaction forces and gait dynamics. This study will look at the difference in the impact of a uniaxial mechanism, and a polycentric mechanism with a predetermined centrode. Currently most exoskeletons use a single axis hinge, however due there have been some desires to create powered exoskeletons with polycentric joints with a predefined center. However, these will have to utilize more difficult control mechanisms and may not be more beneficial.

Impact: Knee mechanism for orthotics can be further developed. This will improve all orthotics that involve the knee both passive and active devices.

1.4.1 Powered Prostheses

Unilateral transfemoral amputees have higher incidences of scoliosis, osteoporosis, and increased energy during walking. This due to asymmetries that occur from missing a knee and an

ankle on one side. Powered prostheses have been shown to have some improvement in energy expenditure, joint angles, and moments due to the energy put back into the system.

Problem 3: There is much research on prosthetic feet and their impacts on transtibial amputee. However very little on the impacts for transfemoral amputees with powered knee and ankle. This research will answer the question of how varying the stiffness of a toe joint can improve outcomes while using a powered knee ankle prosthesis.

. **Impacts:** Impact of toe joint stiffness for transfemoral amputees can be determined. This will improve outcomes and optimize performance for future users of powered prosthetic knee and ankles.

The structure of the this dissertation will be as follows: Chapter 2:Pilot Study on the Needs of Prospective Exoskeleton Users with Impaired Mobility, Chapter 3: Evaluation of Knee Brace Mechanisms using Device Migration and Interaction Forces, Chapter 4:Biomechanical analysis of a powered prosthesis, Chapter 5: Summary and Future Works

2. PILOT STUDY ON THE NEEDS OF PROSPECTIVE EXOSKELETON USERS WITH IMPAIRED MOBILITY

2.1 Abstract

Patients with paraplegia and spinal cord injuries stand to benefit greatly from powered exoskeletons physically, socially, and psychologically. Yet, most powered exoskeletons are limited to usage in rehabilitation clinics or academic facilities. To overcome the challenge of commercialization it is necessary to better understand the needs of potential exoskeleton users. A customer needs survey was conducted among 14 participants with mobility disorders. The data collected was analyzed using a House of Quality. The results emphasized a need to direct research towards designing exoskeletons that can balance without crutches and impose minimal interaction forces upon the user. While doing so, researchers should also pay keen attention to the cost of the exoskeleton.

2.2 Introduction

A 2016 study showed that 28% of the US population suffer from walking disabilities [54]. A major cause of such disabilities is Spinal Cord Injuries (SCI) with an annual estimate of 17,700 newly reported cases. Of the cases reported since 2015, 20.2% suffer from complete paraplegia while 20.4% suffer from incomplete paraplegia [19]. Also, about 90% of those with complete SCI rely on wheelchairs for mobility [21]. Extended usage of wheelchairs has many side effects such as osteoporosis, spasticity, urinary tract infections, increased body mass index, impaired digestive, lymphatic, and vascular functions, pressure sores, and depression [4, 5, 22, 7, 8]. For individuals that are restricted to wheelchairs, the ability to stand at eye level with others carries high psychosocial significance [7, 55]. There are also studies that show walking over long periods of time can improve the quality of life and result in psychological benefits. Utilizing powered exoskeletons could solve several problems SCI patients face. There are currently many research groups focusing on the development of powered lower-limb exoskeletons [56, 57, 58, 59, 60]. These groups employ

an actuated hip and knee design. The powered exoskeletons Ekso GT by Ekso Bionics and ReWalk Personal by ReWalk utilize a spring loaded ankle joint [56, 57]. A notable aspect of the Ekso GT is that the assistance provided by the robotic system to the user can be varied. Thus, it may be used by patients with minor mobility disorders (like foot drop) to severe disabilities like paraplegia. The ReWalk is one of the few commercially available exoskeletons that can be used as a personal device on a daily basis. Mina V2 by IHMC is one of the few exoskeletons with a powered ankle joint [60]. While all of the previously mentioned exoskeletons depend on hand-held crutches for balance, the Rex exoskeleton from REX Bionics is a self balancing exoskeleton [59]. It implements Zero-Moment-Point (ZMP) based controllers to ensure stability. But, to achieve said stability, the speed of the generated gait was greatly reduced. Additionally, it is the only exoskeleton that employs 5 actuators per limb [59].

Despite the advances made by such groups, the application of most powered lower-limb exoskeletons is limited to rehabilitation clinics and academic facilities. To understand the cause of said limitation, clinical studies were conducted to investigate the efficacy, safety, and ergonomics of the designs. A European study conducted at rehabilitation centers revealed that extensive usage of exoskeletons led to ankle swelling and pressure sores [?]. It is believed that the straps used to affix the exoskeleton to the user shear against the user's limbs and ultimately lead to pressure sores [61, 62]. Another commonly reported complaint is the extensive amount of time required to don the exoskeleton [61]. Additionally, several sessions are necessary to fine-tune the adjustments and ensure a fit to the subject [61]. The lack of actuation at the ankle in most exoskeletons is a concerning fact since the ankle is responsible for bearing the user's weight and providing the propulsion required for healthy walking. Another possible improvement is the elimination of crutches for balance without having to reduce the walking speed.

The prior passages presented an account from a developer's perspective. However, for successful commercialization of exoskeletons, it is critical to present an account from a customer's perspective by gathering information on customer needs. By designing in accordance to the user's needs, one is assured of user satisfaction and fewer design iterations; thereby strengthening the

socio-economic impact of the product [63]. Unfortunately, to the authors' knowledge, there is no published data on the needs of SCI patients. This paper aims to address this gap in knowledge and lay the foundation for establishing target specifications or quantified standards for exoskeleton design. The primary method utilized a customer-needs survey wherein participants rated the importance of subjective needs such as comfort and durability (Section 2.3). These needs were then translated into design metrics using a House of Quality (HOQ)—the first step of Quality Function Deployment (QFD) [63]. In addition to studying the relationship between the needs and the metrics, the HOQ also studies how the metrics correlate. The results of the HOQ include the absolute and relative weights of the metrics. The HOQ has been detailed in Section 2.4 while its results have been discussed in Section 2.5.

2.3 Customer Survey

2.3.1 Participant Population

The desired population for this study were spinal cord injury (SCI) patients and those with extremely limited lower limb mobility. Participants must be dependent on mobility aids to walk on a regular basis. So far 14 responses from the desired population have been recorded.

The disorders of the participants included muscular dystrophy and SCI. All subjects currently use wheelchairs for mobility. When asked whether they would be interested in using an exoskeleton, all but one responded positively. Nonetheless, all participants quoted a strong desire for independence and mobility with an exoskeleton.

2.3.2 Survey Design

The survey was conducted online utilizing Qualtrics. Participants for this study were recruited using Texas A&M Bulk email, and social media posts. This survey was approved by Texas A&M University's Institutional Review Board (IRB) (IRB2017-0788). Participants gave their consent on the first page of the survey. The survey included screening questions to exclude able-bodied participants and those who do not use mobility aids.

The goal of the survey was to assess the needs that are most important to potential users. The

Table 2.1: List of needs, their description and scores. A higher rating and lower rank signifies more importance.

Need	Description	Rated Score	Ranking score	Final score (F_i)
Comfort	Does not cause pain or uneasiness	4.4	3.4	8.6
Hands free	No need for crutches/walker	3.8	4.1	7.7
Easy to put on	Can be donned with little to no additional assistance	3.8	5.2	7.4
Light weight	Easy to move the exoskeleton to another location	3.9	7.1	6.9
Battery life	The amount of time a single battery charge can last	3.7	6.9	6.8
Easy to assemble	Minimal work to assemble	3.6	6.7	6.7
Easy to operate	Straight forward operation strategy	3.5	6.4	6.7
Durability	Longevity of the device	4.1	8.7	6.5
Natural walking	Walking mimics able-bodied walking	3.5	8.2	6.1
Low Maintenance	Minimal maintenance to ensure the device is operational	3.5	10.5	5.3
Compact	Amount of space when wearing	3.1	10.2	5.1
Speed	Ability to select a preferred walking speed	2.6	10.4	4.5
Appearance	Visually appealing or sleek	2.4	10	4.4
Storage space	Availability of a storage compartment in the exoskeleton	2.8	12.9	3.8
Economical	Preferred price brackets	3.3	–	6.6

questions asked in the survey fell under the following categories:

- Demographics
- Screening Questions
- Injury type/ Muscle usage
- Use of mobility aids

- Reasons for discontinuing use of mobility aids
- Importance of design needs of exoskeletons
- Amount willing to invest
- General interest in using an exoskeleton

The goal for asking about previous mobility aids was to determine possible factors to consider when developing an exoskeleton device. The participants were asked about their history of usage and/or reason for ceasing use of wheelchairs, Hip-Knee-Ankle-Foot-Orthoses (HKAFO), and powered exoskeletons. The design needs for the exoskeleton were determined after speaking with Dr. Kelly Lobb, a physician at a local rehabilitation hospital, and by surveying literature. The survey also allowed users to include custom design needs and rank them as well. Table 2.1 lists the needs and their description.

The subjects were asked to rate the needs as: *Very Important, Rather Important, Important, Not that important, Not required*. The ratings were converted to a numerical scale of 5 to 1, with 5 corresponding to *Very Important*. The average score of each need has been recorded in the third column of Table 2.1. Subjects were also asked to rank the needs in the order of importance. The fourth column of Table 2.1 reports the average ranking. Note that values closer to one reflect a higher ranking. The need pertaining to the exoskeleton's cost was represented by six price brackets: *Less than \$20,000, \$20,000-\$40,000, \$40,000-\$60,000, \$80,000-\$100,000, \$100,000-\$150,000, and \$150,000 or more*. The recorded selections were converted to 1-5 linear scale, with 5 corresponding to *Less than \$20,000*.

2.4 Processing survey results

To combine the scores from the rating and ranking, the latter was converted to a scale similar to that of ratings (i.e. scale of 1 to 5) and then summed with the rating scores. The final value has been reported in the final column of Table 2.1. The rating score regarding cost was doubled. A HOQ was used to convert the needs and their importance values to quantified metrics. The template was

acquired from QFD online [2]. A total of 25 metrics were established based on exoskeleton design parameters reported in literature. Further, the relationship between the metrics and the needs were categorized as *strong*, *moderate*, or *weak*. Among the 25 resulting metrics a few notable ones have been presented below. Also noted is the relationship between the listed metrics and some of the needs.

Volume of the deployed exoskeleton: The volume occupied by the exoskeleton and a user of average height and weight, while standing. This metric shares a strong relationship with the needs regarding compactness, appearance, and whether the system is hands-free, while it is weakly related to the need for easy assembly and operation.

Range of operable stride lengths: The range of stride lengths that can be accommodated while walking. This metric is strongly related to the user's comfort and desired walking speed. The accommodation of different stride lengths also results in human-like walking.

Steps to get in and out of the system: The number of steps required to wear and remove the exoskeleton should be reduced to make the exoskeleton easier to don.

Battery life in hours: The amount of time the device's battery lasts on a single charge while standing. This metric is also dependent on whether the device is hands-free.

Peak motor torque: The maximum motor torque required while a user (of average height and weight) walks with the exoskeleton. Naturally, this metric depends on the walking speed and whether the device is hands-free.

Maximum factor of safety of structural elements: The factor of safety used to design structural elements of the exoskeleton. A higher factor of safety generally implies a more durable product.

Maximum difference from human trajectories: The amount by which the generated joint trajectories of the user with the exoskeleton deviate from natural human walking trajectories.

Maximum interaction forces between the user and the exoskeleton: The maximum force recorded while walking at the exoskeleton's straps. As reported by studies [61, 62], considerable interaction forces at the straps lead to pressure sores. This metric is thus related to user comfort.

Ability to balance without crutches: A binary evaluation of whether crutches are required for

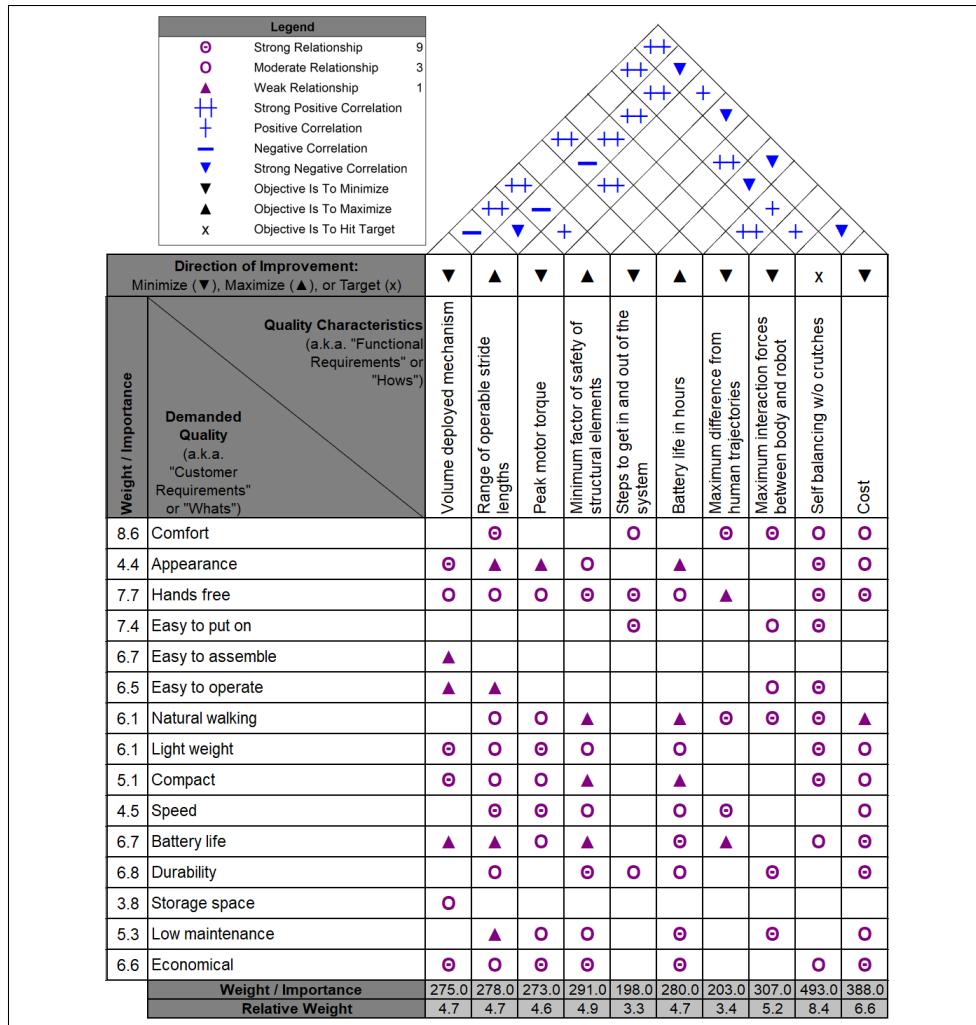


Figure 2.1: House of quality depicting the metrics discussed. Powered by QFD Online [2]

balancing while using the exoskeleton for walking. In addition to deciding whether the exoskeleton is hands-free, this metric is also related to needs such as appearance and compactness of the device.

Cost: The amount required to manufacture one unit of the product (exoskeleton). This metric is strongly impacted by all needs except the ease of donning, assembly, and operation.

A comprehensive list of the 25 metrics has been provided in the appendix. Fig. 2.1 depicts the relationship between the prior listed metrics and the needs. The row immediately above the metrics reflects the desired direction of improvement in metrics; i.e. whether a metric should be

increased or decreased. Note that the metric regarding the *ability to balance without crutches* is a binary target. The roof of the HOQ also consists of the correlation between metrics. For instance, increasing the *range of stride lengths* accommodated by the device will likely lower the *battery life* and increase *peak motor torque*. On the contrary, customizing the *stride length* to the user's comfort will likely lower *interaction forces* between the exoskeleton and user. The correlations between metrics are categorized as *strong positive, positive, negative, strong negative*. The metrics that have no correlations are left blank. These correlations help to understand the design challenge associated with optimizing each metric. A metric with more negative correlations is one that is considered harder to optimize. Note that a metric with more positive correlations does not imply ease of optimization. It must be stressed that the HOQ in Fig. 2.1 only analyzes the previously discussed metrics. The results from the HOQ have been presented in Table 2.2.

The absolute weight of a metric, k , is determined by a weighted sum (W_k) of the relationships between the metric under consideration and the needs (refer Fig. 2.1). Let R_{ik} represent the relationship between need i and metric k . A *strong* relationship is assigned a score of 9, while *moderate* and *weak* relationships are assigned scores 3 and 1, respectively. The weight (F_i) of the sum is equal to the final score of need i from Table 2.1.

$$W_k = \sum_{i=1}^{15} R_{ik} F_i \quad (2.1)$$

Among the metrics discussed the most important metric was the ability to balance without crutches.

Table 2.3 lists the 25 metrics considered in the HOQ and their relative weights. In addition to the interaction forces between the user and exoskeleton, the list includes a metric regarding the interaction forces at the user's joints. Note that the metric regarding gait symmetry encompasses both kinematic and kinetic symmetry.

2.5 Discussion

The survey data revealed that potential users want an exoskeleton that is (i) comfortable, (ii) hands-free, and (iii) easy to don. The three most important metrics of the HOQ are the *ability to balance without crutches*, *cost*, and *interaction forces between the user and the exoskeleton*. This section discusses the relationship between the highly weighted needs and metrics. Though the participants did not rate the need related to cost highly, the associated metric received a high relative weight. This is due to the strong relationships shared by the *cost* metric with other needs. Since comfort received the highest score, it is reasonable that the metric regarding *interaction forces* was weighted highly in the HOQ. A possible method of reducing interaction forces is by redesigning the straps of the exoskeletons. Another major design challenge, while assuring the user's comfort, is accommodating the knee's complex motion. Unlike the conventional knee mechanisms found in exoskeletons, the human knee is not a pin-joint [38]. Thus, the rotational axis of the exoskeleton and the user's knee tend to misalign. To compensate for the misalignment, the exoskeleton's straps tend to shift around, thereby increasing the interaction forces that eventually cause pressure sores. The misalignment in rotational axes also increases the time required to don the exoskeleton since wearers are required to spend an extended period of time reducing the misalignment [64]. Despite the highly scored need for easy donning, the metric *steps to get in and out of the device* was

Table 2.2: List of the metrics and their relative weights.

Metric	Relative weight
Volume of deployed mechanism	4.7
Range of operable stride length	4.7
Steps to get in and out of the system	3.3
Battery life in hours	4.7
Peak motor torque	4.6
Maximum factor of safety of structural elements	4.9
Maximum difference from human trajectories	3.4
Maximum interaction forces	5.2
Ability to balance without crutches	8.4
Cost	6.6

Table 2.3: List of all metrics and their relative weight.

Design Goal	Design Metrics	Relative Weight
×	Self balancing w/o crutches	8.3
▼	Cost	6.3
▼	Volume deployed mechanism	5.4
▲	Battery life in hours	5.3
▼	Maximum interaction forces between body and robot	5.2
▲	Minimum factor of safety of the designed structural elements	4.7
▲	Range of operable stride lengths	4.6
▲	Range of body support that can be provided	4.5
▼	Peak motor torque	4.5
▼	Weight of final product	4.1
▲	Range of acceptable user weight	3.9
▲	Range of acceptable user height	3.9
▲	Life cycles	3.8
▼	Maximum error between joint trajectories to human joint trajectories	3.4
▼	Heat generate	3.3
▼	Power consumed	3.3
▼	Volume of packaging box	3.3
▼	Steps to get in and out of the system	3.2
▼	Steps to operate	3.1
▲	Symmetry in gait	3.1
▼	Human energy consumption in one gait cycle	3
▼	Steps to assemble	2.8
▼	Interaction forces at lower-limb joints	2.5
▲	Range of angular heading that is automated	2.2
▲	Range of operable speeds	2.1

deemed to be of low importance by the HOQ. This is because the metric is not related to the other needs. A possible approach to combating misalignment of the axes is to implement a self-aligning mechanism. Some researchers have attempted this [64, 65], but there is room for improvement in simplifying the mechanisms.

The metric, *range of operable stride lengths*, was found to have the most negative correlations with other metrics; making it the hardest to optimize. This metric is directly related to the allowable range of walking speed. Exoskeleton developers are struggling to overcome this challenge

due to limitations in current motor technology. Motors with the required torque will result in increased weight and cost, making the device infeasible to use. Further, the dependence of the state of the art exoskeletons on crutches (for balance) severely limits the walking speed. This fact is apparent in the roof of the HOQ, which indicates a strong positive correlation between the metrics *range of operable stride lengths* and *self balancing without crutches*. By exploiting this positive relationship, one could possibly optimize the *range of operable stride lengths* without severely affecting the other metrics. In other words, eliminating the need for crutches could help alleviate some concerns surrounding the optimization of *range of operable stride lengths*.

Balancing without crutches is important since most powered exoskeletons on the market utilize crutches for balance. The associated metric is strongly related to most of the other needs, thus making it the highest weighted metric. Its high relative weight emphasizes the need for designing self-balancing exoskeletons. The REX exoskeleton assures self-balancing at the expense of walking speed [59]. Another group that has attempted to solve the issue of balancing exoskeletons is the Delft Biorobotics Lab. Their solution utilizes a gyroscope to assist in balancing [66]. It is hoped that their tests with human subjects will be successful and the results can be incorporated with exoskeletons. Prior to designing balance mechanisms one must describe balance in terms of quantified metrics. This study limited itself to a binary metric of whether or not the crutches are required to balance. Further studies are required to better define walking balance. Some potential metrics include angular momentum of the user and exoskeleton, and the extent of push recovery.

Other metrics that could be better defined include the *steps to get in and out of the exoskeleton*. This metric may change based on whether the user is seated or standing prior to wearing the device. The survey could also be improved by asking the user their preferred way of donning the device (i.e. from a seated or standing position). Another potential question is whether users would appreciate steering assistance since current exoskeletons require users to manually orient themselves using their crutches. Further, any user of an exoskeleton device must undergo training sessions to get acclimated. Such training sessions necessitate the presence and involvement of therapists. Thus, there is a strong need to study and understand the needs of therapists.

In addition to refining the survey and better defining metrics, there is a need to establish target values for the metrics. For instance, the maximum amount of interaction forces that is admissible should be investigated. Such target specifications can be established through clinical studies and analysis using biomechanical models.

2.6 Conclusion and future work

A survey conducted among 14 participants with reduced mobility revealed a strong need for hands-free exoskeletons that assure comfort and mobility. The needs of the participants were translated into engineering metrics using a HOQ. The HOQ analysis revealed that the most important design metrics are self-balancing, cost, and minimal interaction forces between the user and the exoskeleton. Designers must consider these factors to help design powered exoskeletons that fully meet user needs. Doing so will also increase the social and psychological benefits of the device.

In order further solidify these findings more participants are required. The survey will be improved upon to ensure that all questions and choices are clear and easy to understand. In order to properly use an exoskeleton, patients must be trained. Therapists are typically needed for this process. Therefore, in the future the survey will be extended to therapists in order to fully assess the needs that exoskeletons must satisfy.

Biomechcanical studies will be conducted to better define balance using an exoskeleton. Consecutively, target values for the resulting metrics will be determined. In regards to the interaction forces between the user and exoskeleton, studies will be conducted to pin-point what aspects of the exoskeleton lead to high interaction forces. Additionally, attempts will be made to measure the amount of interaction forces that is acceptable before causing discomfort to the users.

3. EVALUATION OF KNEE BRACE MECHANISMS USING DEVICE MIGRATION AND INTERACTION FORCES

3.1 Abstract

State-of-the-art knee braces use a polycentric mechanism with a predefined locus of the instantaneous center of rotation (centrode) and most exoskeleton devices use a knee mechanism with a single axis of rotation. However, human knees do not share a common centrode nor do they have a single axis. This leads to misalignment between the assistive device's joint axis and the user's knee axis, resulting in device migration and interaction forces, which can lead to sores, pain, and abandonment of the device over time. There has been some research into self-aligning knee mechanisms; however, there is a lack of consensus on the benefit of these mechanisms. There is no research that looked purely at the impact of the knee mechanisms, either. In this paper, we compare three different knee brace mechanisms: single axis (SA), polycentric with predefined centrode (PPC), and polycentric with a self-aligning center of rotation (PSC). We designed and conducted an experiment to evaluate different joint mechanisms on device migration and interaction forces. Brace material, weight, size, cuff design, fitment location, and tightness were consistent across trials, making the knee joint mechanism the sole variable. The brace mechanisms had no significant effect on walking kinematics or kinetics. However, the PPC brace had greater interaction forces on the top brace strap than the SA and PSC. The PSC and SA had significantly lower interaction forces on the bottom strap compared to the PPC brace. The PSC had significantly less migration than both the SA and PPC braces. These results show that a PPC mechanism may not be beneficial for a wide range of users. This also shows that the PSC mechanisms may improve mechanism alignment and lessen device migration.

3.2 Introduction

The human knee is not simple a pin joint; instead, the femur rotates and slides on the tibia as it flexes or extends [67]. This results in a joint with a varying center of rotation. At any time instant,

the joint's axis is termed as the Instantaneous Center of Rotation (ICR) and the locus of the ICR is called a centrode. Exoskeleton joint design typically requires that the joint's axis to be coincident with the user's knee axis. Designing an exoskeleton joint that accurately mimics this polycentric action is a mighty task, and it is further compounded by the fact that the centrode is unique to the user. Although knee assistive devices have existed since the 1960s, the aforementioned problem persists. In this paper, we will investigate different solutions to this challenge in a human subject experiment.

3.2.1 Solutions to knee joint design

The Single Axis (SA) joint knee mechanism is the simplest design to manufacture and actuate in powered devices. However, the misalignment between device joint axis and the user's knee axis is unavoidable, which can lead to increased interaction forces and device migration [68]. High interaction forces may result in skin sores, additional pain or injuries [61, 62]. Studies such as [69, 70, 71] have shown that interaction forces are strongly related to safety, comfort, and quality of walking with lower limb orthotics/exoskeletons.

Some researchers have implemented polycentric knee mechanisms, which are of two types: (i) Polycentric mechanism with a Predefined Centrode (PPC) (ii) Polycentric mechanism with a Self-aligning Center of rotation (PSC). PPC solutions either adopt a centrode which is believed to suit a diverse group of users [72] or customize the centrode to the user [73]. The most commonly implemented PPC mechanism has meshed spur gears with a third link connecting the centers of the gears [74] (also refer to Figure 3.1C). Other PPC joint designs employ cam mechanisms [75, 72]. Despite efforts to establish a generalized centrode for a large user base, discrepancies are to be expected. On acknowledging this, some researchers chose to customize the gear or cam mechanism (thereby the associated centrode) to the user [73]. While the performance with customized joints is expected to be better, the process of designing and manufacturing custom joints can be highly demanding. There has been some research to use a PPC for powered exoskeleton devices. Although these may be more closely follow the knee's centrode. They can also be difficult to actuate for the use of powered exoskeletons. There has not been research comparing single axis and polycentric

knee mechanisms in regards to interaction forces and device migration. In this paper, we will strive to resolve this dilemma by comparing all the two common types of knee mechanism designs (i.e. SA, PPC).

3.2.2 Evaluating Knee Brace Mechanisms

Studies such as [76] have examined how different knee brace designs impact migration. While the designs belonged to the PPC category, they all varied in size, material, nature of fit, and cuff design. Work by [68] evaluated different hinges looking at forces at the straps of custom brace cuffs. However, the study did not look at the self-aligning hinges or device migration. To our knowledge, no studies have compared different joint mechanisms on the basis of interaction forces and migration. Moreover, the studies [76, 68] do not account for variances in the brace fitment—i.e. tightness of the cuffs—at the beginning of each trial, which heavily influences the performance of the brace. In order to perform a consistent analysis of the joint mechanisms, we must make uniform the material, weight, size, cuff design, and tightness of fit. Current experimental protocols do not account for the impact of the previously mentioned variables and limit their performance metrics to primarily device migration. Thus, there is significant room for improvement in designing experiment protocols for joint mechanism comparison. In this paper, we will fill this gap in knowledge by proposing a systematic experiment protocol that evaluates both device migration and interaction forces.

Our primary contributions include the experiment protocol and evidence that will help identify the superior joint mechanism design. The paper is organized as follows. Section 4.2 presents the experiment setup, protocol, and details on the recruited subjects. The results are presented in Section 3.4 followed by the discussion in Section 4.4. The final section will consist of our concluding remarks.

3.3 Materials and Methods

We designed an experiment to evaluate different the joint mechanisms on device migration and interaction forces. The variables accounted for were brace material, weight, size, cuff design,

fitment location and tightness. The first four and the last two variables were considered in the experiment setup and testing protocol respectively.

3.3.1 Participants

Twelve healthy subjects were recruited. The method of determining outliers has been detailed in Section 3.3.3. Out of the twelve subjects, one was deemed an outlier and another subject was omitted from the study due to a failure in data collection. The results presented pertain to ten healthy participants (age 28 ± 2.5 years, mass 70.5 ± 11.2 kg, height 171.3 ± 5 cm, 7 male and 3 female). Individual participant details can be found in Table 3.1. The experimental protocol was explained beforehand, and each subject signed an informed consent approved by Institutional Review Board (IRB) at Texas A&M University (TAMU IRB2018-0837D).

Tables

Table 3.1: Individual details for the final 10 participants

Participant	Mass(kg)	Height(cm)	Age	BMI	Knee Width(cm)	Sex
1	59.3	170.2	28.0	20.5	10.1	M
2	51.0	164.0	28.0	19.0	9.3	F
3	74.7	180.3	27.0	23.0	10.4	M
*4	85.3	177.8	26.0	27.0	10.2	M
5	65.2	172.7	28.0	21.9	9.7	M
6	69.7	169.5	27.0	24.2	11.2	F
7	71.0	170.0	32.0	24.6	11.2	M
8	79.9	172.7	30.0	26.8	11.3	F
9	63.2	166.0	23.0	22.9	9.8	M
10	85.3	170.0	30.0	29.5	12.0	M
Average	70.5	171.3	27.9	23.9	10.5	F - 3
Standard deviation	11.2	4.9	2.5	3.2	0.9	M - 7

3.3.2 Experimental setup

Compression braces, such as VIVE [77], consist of a fabric sleeve with a slot for a geared PPC mechanism. Figure 3.1A shows the VIVE brace and highlights the slot for the mechanism (*mechanism-slot*). Such braces have the benefit of the mechanism being removable. We procured three VIVE braces and designed different 3D printed mechanisms to fit the brace's *mechanism-slot*. Figure 3.1 presents all three braces. The brace in Figure 3.1A had no constraining mechanism and served as our control case, while Figure 3.1B was the SA version. Figure 3.1C was PPC mechanism that was included with the VIVE brace. The analysis was limited to the sagittal plane and consisted of the brace acting in parallel with a four-bar approximation of the human knee. The design shown in Figure 3.1D has allowances of 5 mm. Notice that the SA, and PPC braces only vary in the joint mechanism.

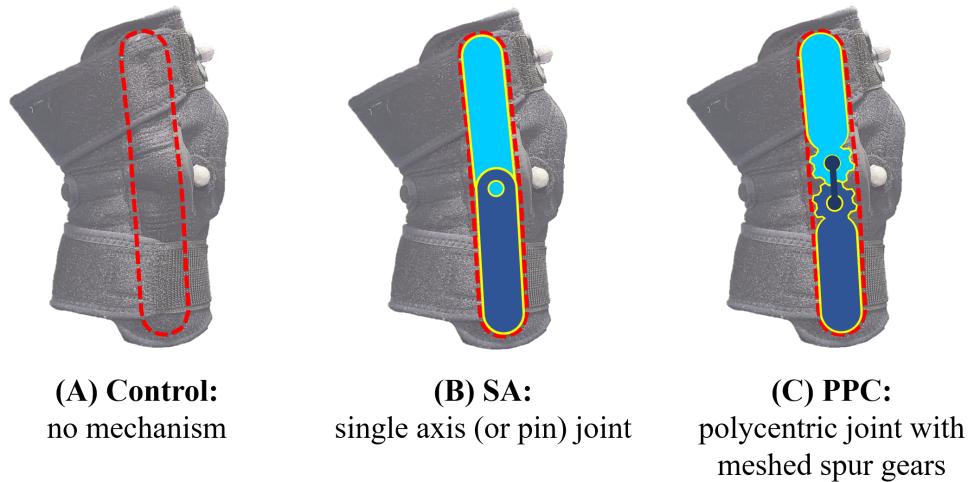


Figure 3.1: Knee brace mechanisms: (A) *Control* brace with no mechanism, (B) SA brace with a single axis mechanism, (C) PPC brace with a polycentric mechanism having spur gears

All braces were fitted with two Tekscan FlexiForce A502 flexible force sensors (Figure 3.2B) which served to measure the interaction forces at the user's thigh and shank. These locations were chosen for two reasons: (i) they are along the knee brace straps—where interaction forces are

expected to be the highest; (ii) the mounted force sensors would always be in contact with the participant's limb. Unlike the sides of the brace, the front section is not always in contact with the participant's limb, making this spot not ideal for measuring interaction force. Specifically, this section of the brace comes apart from the limb (forming a gap) during knee flexion. The sensor readings were collected and transmitted using a wireless processing unit consisting of an Arduino Micro and XBee Pro wireless module. The unit was affixed to a vest worn around the participant's torso. The receiver unit consisted of a XBee Pro wireless module and an Arduino Uno, which transmitted the received data to a computer for storing. The experiment included walking on an instrumented treadmill (Force-sensing treadmill, AMTI, Watertown, MA [78]) in a motion capture facility that uses 46 motion capture cameras (Vantage, Vicon Motion Systems, Oxford, UK [79]). Reflective markers were placed on bony landmarks of the pelvis, lateral knee joint, toe, heel, and ankle. Additional markers were placed on the thigh, tibia and front of the brace. The marker placement can be seen in Figure 3.2A.

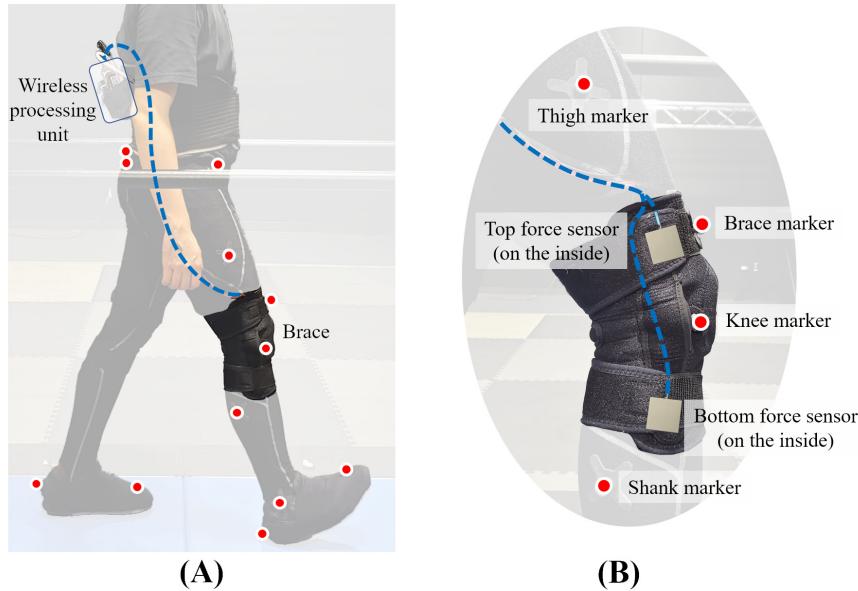


Figure 3.2: Experiment Setup: (A) subject with markers and a brace, (B) markers and sensors mounted on the brace

3.3.3 Experiment Protocol

Each participant was instructed to wear workout leggings or tights and tennis shoes. The participants were then asked to wear the Control brace to their comfort. Once worn, the brace position was marked with tape on the thigh. Each participant was then given a period of 2 minutes to get accustomed to the brace, during which they were asked to walk at a comfortable pace and raise their knee. After the 2 minute period, device migration was measured by the distance from top of brace to top of the tape (refer Figure 3.3). If the device migration exceeded 1 cm, the brace

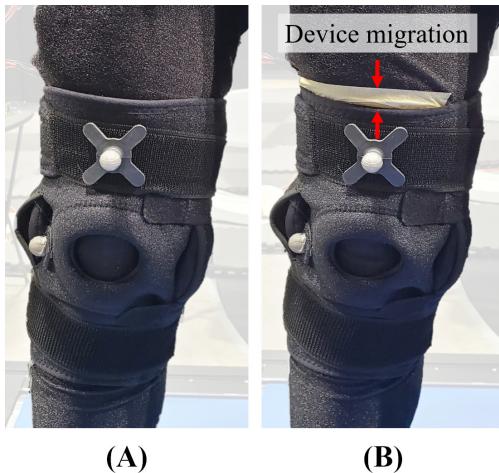


Figure 3.3: Device Migration, (A) the brace at the beginning of the trial, (B) the brace at the end of the trial with the white tape marking the reference for measuring device migration.

was re-attached and the process was restarted. If participants failed the < 1 cm device migration requirement after three attempts, they were ruled as an outlier and were omitted from the study. Such participants were expected to experience even larger device migration and consequently discomfort during the rest of the trial which consisted of higher paced walking trials and several knee raises. Typically, participants with a more tapered lower limb (i.e. a larger ratio of above knee to below knee diameter) were found to be outliers. Once a suitable fitment was determined, the position of the brace was marked using the tape. All other braces that followed were mounted at

the same position, fixing the point of fitment across all trials.

The order of the constrained braces (i.e. SA and PPC) that followed was randomized. During the first constrained brace trial, the tightness of fit was measured using the force sensors. The force readings at the bottom and top force sensors were referred to as f_{bottom}^0 and f_{top}^0 . The constrained braces that followed were then fitted to within ± 1 N of said measured forces. While measuring forces, participants were asked to stand erect and still. This procedure standardized the tightness of fit across all constrained braces. Note that the forces were not measured for the Control brace because the absence of a constraining mechanism always resulted in a lower force reading.

Once fitted with each brace, the participants were asked to perform an exercise regime that included 20 knee raises, 7 minutes of fast walking at 1.23 m/s and 20 more knee raises (refer to Figure 3.4). Motion marker data were collected before knee raises, during walking (to monitor walking quality), and after knee raises. The force sensor readings were gathered throughout the trial. Due to the data being used to assess the potential impact in walking assistive devices, the exercise routine was designed not to be labor intensive. The goal was to see the impact primarily during walking. Device migration was measured after the exercise routine for each brace device.

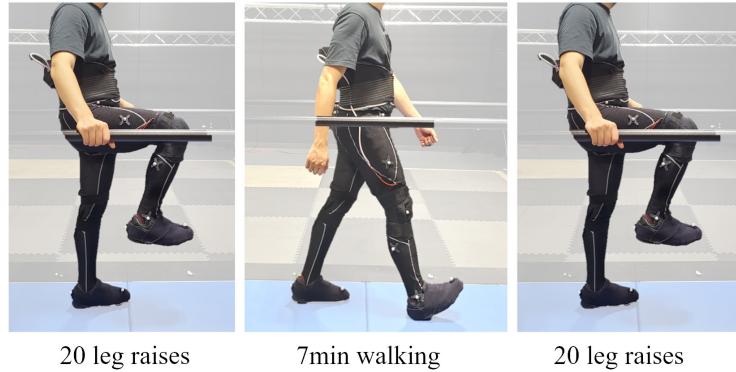


Figure 3.4: Each trial consisted of 20 leg raises, followed by 7 minutes of walking at 1.23 m/s speed, and concluded with another 20 leg raises

3.3.4 Metrics and data analysis

Three metrics were used to compare the knee braces: (i) device migration; (ii) maximum interaction force at the bottom and top force sensors; (iii) knee angles and moments during walking.

The device migration, M_i , for each constrained brace ($i = \text{SA, PPC}$) was defined as follows

$$M_i = \frac{m_i - m_{Control}}{m_{Control}} \quad (3.1)$$

where m_i is the raw (un-normalized) migration for each constrained brace ($i = \text{SA, PPC}$) and $m_{Control}$ is the migration with the Control brace. The normalization process helps account, to some extent, the impact of the compression sleeve on device migration, leaving behind the impact of the mechanism alone. The set of normalized migration values for each brace, across all subjects, was checked for normality using the Shapiro–Wilk test ($\alpha = 0.05$, *scipy’s stats* library for Python). One-way repeated measures ANOVA was used to find the effect of the knee mechanism on device migration ($\alpha = 0.05$, the *statsmodels* library for Python). Post hoc tests used Fisher’s least significant difference. Note that the device migration with the constrained mechanisms were not compared against the Control brace. Device migration with the Control brace is known to be lesser than the constrained ones and the objective of this paper is to compare different constraining mechanisms.

The force values were first filtered using a Butterworth low pass filter with a cut-off frequency of 10 Hz, following which the maximum value was determined. Let f_{bottom}^* and f_{top}^* be the maximum force values at the bottom and top sensor, respectively. These values were then normalized for each constrained brace as follows.

$$F_{bottom}^* = \frac{f_{bottom}^* - f_{bottom}^0}{f_{bottom}^0} \quad (3.2)$$

F_{top}^* was calculated in a similar manner. Similar to M_i , the set of all normalized force values were also checked for normality. Significant effect of the mechanism on force values was found via

one-way repeated measures ANOVA, followed by the post hoc tests with Fisher's least significant difference.

The joint angles and moments were derived using motion capture and forces collected with the AMTI instrumented treadmill, and processed with the Vicon Nexus analysis system. The moments and angles were averaged for each participant for 30 seconds of the 7 minute walking trial in each brace. The braced knee angle is determined to be the angle between the thigh and shank segments with the leg fully extended being 0 degrees. The range of motion for each braced knee was termed the difference between maximum and minimum knee angle in each walking trial. These values were, averaged across all participants for each brace. The result was called the average range of motion. The braced knee moments were derived using inverse dynamics with the Vicon Nexus Plug-in Gait Model, after which the peak sagittal plane knee moments were determined. We checked if the nature of brace mechanism impacted the peak knee moments and the knee ranges of motion using one-way repeated-measures ANOVA.

3.4 Results

The following subsections presents the results for the final 10 subjects in Table 3.1. Figure 3.5 and Figure 3.6 present the knee angle and knee moment results respectively. The normalized device migration and interaction force values have been shown in Figure 3.7.

3.4.1 Kinematics and Kinetics

Data from Participant 4 was not processed for biomechanical analysis due to an error in the data collection, leaving 9 participants' knee angles and moments to be analyzed. The ANOVA test revealed that the bracing mechanism did not significantly impact the knee range of motion ($p = 0.51$) (refer to Figure 3.5) nor the knee moments ($p = 0.276$) (refer to Figure 3.6).

3.4.2 Brace Migration and Interaction Forces

The Shapiro Wilk test revealed the normality hypothesis cannot be dismissed for migration data ($p > 0.109$ across all braces), top force sensor readings ($p > 0.205$ across all braces), and bottom force sensor readings ($p > 0.135$ across all braces). The one-way repeated measures

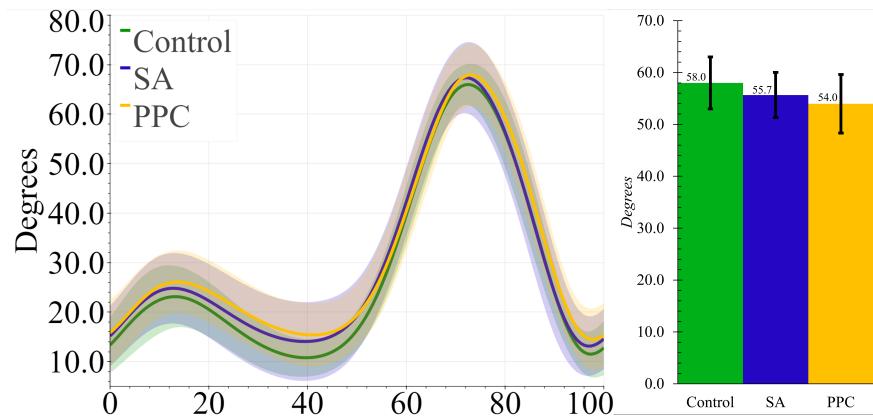


Figure 3.5: (A) Average knee angles for all three braces. The shaded region represented 1 standard deviation. (B) Average knee range of motion for all braces. The ticks represent 1 standard deviation.

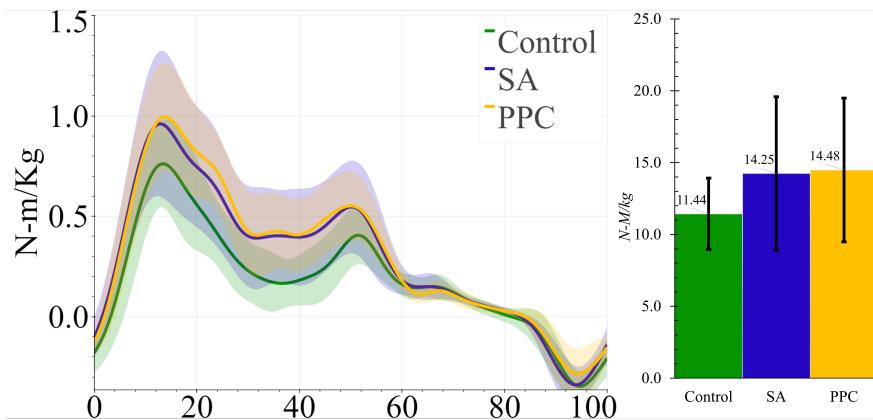


Figure 3.6: (A) Average knee moments for all three braces. The shaded region represented 1 standard deviation. (B) Average peak knee moment for all braces. The ticks represent 1 standard deviation.

ANOVA revealed that the type of mechanism significantly affects device migration ($p = 0.0043$), top force sensor readings ($p = 0.007$), and bottom force sensor readings ($p = 0.0029$). The device migration with SA was lower than that of PPC, the difference was not significant. The interaction forces on the top of the PPC brace was found to be significantly greater than SA brace ($p = 0.004$). The interaction forces on the bottom strap for the PPC brace was found to be significantly greater

than the SA ($p = 0.016$). These results can be seen in Figure 3.7.

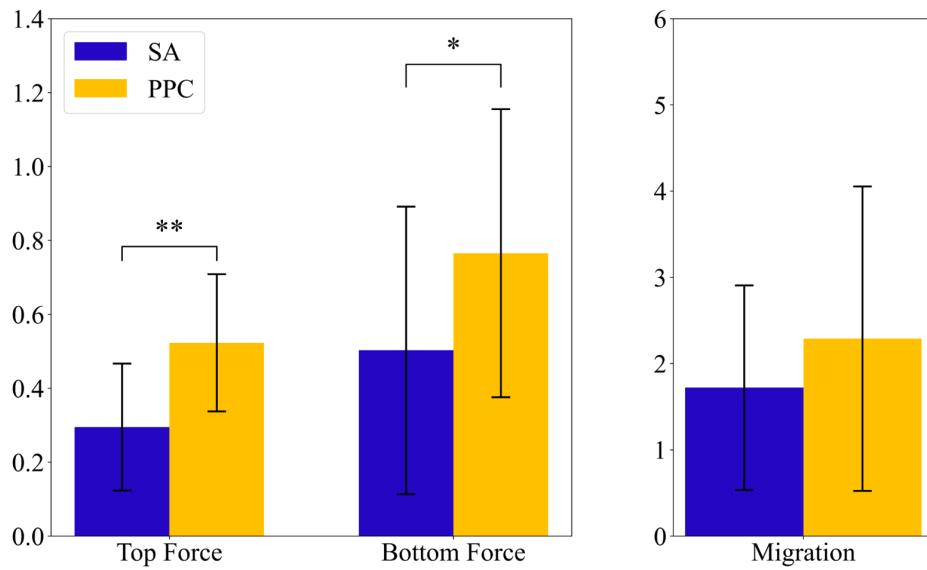


Figure 3.7: Average interaction force at top and bottom force sensors, and average device migration results. The ticks represent 1 standard deviation. The symbol * signifies $p < 0.05$ and ** implies $p < 0.005$.

3.5 Discussion

The brace type had no significant effect on the knee range of motion. This showed that none of the braces significantly altered walking gait kinematics. On the other hand, the knee moments with the Control brace was significantly lower than those with the other braces, which can be attributed to the absence of a constraining mechanism in the Control brace. In other words, the participants had to exert additional knee moment or work to overcome the constraints. Among the constrained mechanisms, no significant differences were observed. Thus, any observations made regarding device migration and interaction forces is solely due to the nature of the constraining mechanism and not the walking kinematics or kinetics.

In regards to device migration, SA performed better—but not significantly better—than PPC. The SA brace did however result in significantly lower interaction forces than PPC at both the top and bottom force sensor. We may infer that having a polycentric design alone is insufficient to perform better than SA mechanisms. That said, the same polycentric design could perform better with certain types of knees over others. Going forward, we wish to investigate the relationship between knee widths and the performance (in terms of migration and interaction forces) of PPC mechanisms. If a relationship does exist, designers can use it to customize PPC designs to sections of the user population. This also leads to rational of developing a PSC knee mechanism for braces and exoskeletons.

In the future we wish to improve the force sensing mechanism. The current mechanism only measures forces at the side of the thigh and shank. Studies such as [80] have measured forces around the limb using multiple pressure sensors along the curvature of the strap. Finally, we also hope to expand the study to include participants with more tapered limbs (i.e. greater ration of above knee diameter to below knee diameter).

3.6 Conclusion

We propose an experiment protocol and analysis that compares the impact of knee mechanisms on interaction forces, migration, knee angles and moments. This experiment protocol standardized the weight, material and tightness of straps across all mechanisms. We compared two mechanisms: (i) Single axis (SA) and (ii) Polycentric joint with a Predefined Centrode. Although initially thought to increase interaction forces and migration, the SA mechanism produced consistently less interaction forces than the PPC mechanism. This leads to the idea that the PPC mechanism does not improve the mismatch between the mechanism and the knee for most users owing to the uniqueness of the centrode. Although it did not have significantly different interaction forces from the SA mechanism, we believe this requires further investigation. The consistantly lower migration and interation forces of the SA knee mechanism compared to the PPC mechanism shows that PPC may not be the optimal choice in knee mechanism for exoskeleton devices. If researchers continue to use PPC mechanisms there needs to be further research on customizing the joint to improve

alignment and overall performance.

4. BIOMECHANIC IMPACTS OF FLEXIBLE FOOT ON TRANSFEMORAL AMPUTEES USING A POWERED KNEE-ANKLE PROSTHESIS

4.1 Introduction

There are over 1.3 million lower limb amputees in the United States alone [81]. Over the next 50 years, this number is predicted to increase to 3.6 million [81]. Out of this number, more than half are transfemoral (25.8 %) or transtibial (27.6 %) amputations [82]. Transtibial (below knee) amputees do not have an ankle and metatarsophalangeal (MTP) joints. Transfemoral (above knee) amputees lack a knee joint in addition to the prior listed joints. The performance with prosthesis relies on the nature of feet, the extent of actuation, comfortable fit, etc. Studies have shown that current prosthesis do not account for all customer needs. Long-term use of current prosthetic feet can cause many issues such as osteoarthritis, osteopenia, and scoliosis [9]. This is due to walking asymmetries, and the missing joints and muscles required to propel the body forward during walking [43, ?]. In particular, the ankle and MTP joints are vital to help with push-off [83, 84, ?, 85]. Although there are many prosthetic feet currently on the market, none can replicate the complex dynamics of MTP joints.

4.1.1 Evaluation of Prosthetic feet

The most common type of prosthetic feet on the market are conventional feet (CF), and Energy Storage and Return (ESR) feet [86]. ESR feet are claimed to be more beneficial for amputees due to a flexible keel that possibly aids with push-off during walking [87]. However, the improvements seen in energy storing and cost of transport were found to be very small [88]. Further, the push-off assistance offered by CF and ESR feet is far lesser than that of able-bodied feet. This has led researchers to attempt increasing push-off assistance by attempting to replace the action of the MTP joints by adding a toe-joint. A study by [89] added a toe-joint to a passive ankle-foot prosthesis and found no significant differences to kinetics and kinematics. However, a passive foot with a flexible toe-joint by [85] showed there was a difference using a custom foot with a wider

base, longer arch and a toe-joint. So there is no consistency in the benefits of passive feet with flexible toes. While these studies only looked at the impact of a toe-joint on transtibial amputees, the impact on transfemoral amputees is yet to be explored.

4.1.2 Powered Prosthetic Ankles

Lower limb prostheses are either powered or passive, with the latter being more popular. There is currently only one powered prosthetic ankle on the market, the BiOM. This powered ankle has significantly improved ankle power and cost of transport for transtibial amputees [90, 91]. Several other powered prostheses have been explored in the research community [92, 93, 94, 95, 96]. There has been some work on combining powered ankles with toe-joints [93]. This study's foot design has an active toe-joint and active ankle, which produced more symmetric walking than passive feet in terms of joint angles and GRF. However, none have investigated the impact of MTP toe-joints on the performance of powered knee-ankle prosthesis. Due to the positive impact of the MTP joint and powered ankles for transtibial amputees, we must study whether transfemoral amputees also stand to benefit from such joints. Given that transfemoral amputees make up almost 26 percent of the ever growing lower limb amputee community, it is of paramount importance that we address this gap in knowledge [82]. When researching powered prostheses, we can not limit our observations to the impact of the toe-joint alone. We must also consider the nature of the prosthesis control, which affects how the user interacts with the device as well as kinetic and kinematic outcomes.

This study analyzed the use of an actuated knee-ankle prosthesis with a toe-joint for transfemoral amputees. We explore how three different toe-joint stiffnesses impact spatiotemporal measures, kinetics and kinematics. Our hypothesis is that the lower stiffness spring will provide less push-off power during walking compared to a stiffer and rigid stiffness foot. The paper is organized as follows. Section 4.2 presents the equipment overview, experiment setup, protocol, and data processing methods. The results are presented in Section 3.4 followed by the discussion in Section 4.4. The final section consists of our concluding remarks.

4.2 Methods

4.2.1 Equipment Overview

This study utilized AMPRO II, a powered knee and ankle prosthesis (Figure ??, which is operated by a micro-processor (element14, BeagleBone Black) that controls an actuated ankle and knee joint. The prosthesis is equipped with a 3D printed foot with a MTP joint. The toe-joint was equipped with a leaf spring utilizing spring steel sheets. The stiffness of the joint was varied by varying the number of spring steel sheets. Further, a force sensor (Tekscan, FlexiForce A502) placed under the heel helps detect heel-strike, while an Inertial Measurement Unit (SparkFun Electronics, MPU 9150) affixed to the user's thigh measures the thigh angle. This thigh angle is used to estimate user's walking progression and thereby the user's intent [97]. This powered prosthesis is controlled using impedance control during stance and trajectory tracking control during swing. Details can be found in [53]. The torque generated by the impedance control strategy is given by

$$\tau = K(\theta - \theta_{ref}) + D\dot{\theta} \quad (4.1)$$

where K and D are the joint stiffness and damping parameters. The term θ_{ref} is the joint's reference or equilibrium angle. Finally, θ and $\dot{\theta}$ are the joint's instantaneous position and velocity. The impedance control scheme is very responsive to the amputee's kinematics. The amputee can increase the amount of generated torque by deviating more from θ_{ref} . Thus, the amputee has some control over the generated torque or push-off assistance [?].

All experiments were conducted in a motion capture lab that utilizes 45 Vicon motion capture cameras and a tandem instrumented treadmill (AMTI). The motion capture camera was collected at 100 Hz and the treadmill force plate data was collected at 1000 Hz.

4.2.2 Experiment Overview

This study had one participant who is unilateral transfemoral amputee (female, 164cm, 66kg w/o prosthesis). She currently utilizes a X3 microprocessor Knee (Ottobock) with a Freedom

Runaway Foot (Ottobock). In order to collect motion capture data, the full-body plug in gait marker set from Vicon Nexus was used [98].

4.2.2.1 *Protocol*

The participant underwent eight practice sessions to get accustomed to the powered prosthesis and different feet. The participant was most comfortable walking at a speed of 0.67 m/s. The participant walked with three joint stiffness conditions: 0.83 Nm/deg, 1.25 Nm/deg, and Infinite (Rigid). Motion capture and force plate data were collected for each foot variation. Each walking trial lasted 90 seconds with 10 min breaks between foot changes. The participant was allowed to rest for longer if desired.

4.2.3 **Data Processing**

All post-processing was done in Vicon Nexus (Vicon) and Visual 3d (C-Motion). The marker trajectories and the force data were filtered in Vicon Nexus with a low-pass third-order butter worth filter at 10 and 20 HZ, respectively. The hip, knee, and ankle angle and moment, and ankle power were calculated in the sagittal plane using Visual 3D.

The following spatiotemporal metrics were collected using marker data and force data: total step length, step time, swing time and stance time. These were collected for both the intact and prosthetic limbs. Step length was calculated to be the total distance from heel-strike of one foot to heel-strike of the opposite foot. Step time is the time from heel-strike of one foot to heel-strike of the opposite foot. Swing time is measured to be the time from toe-off to heel-strike. Stance time is measured to be the time from heel-strike to toe-off.

To see how much the stiffness impacts symmetry between the intact and prosthesis side, the symmetry index (SI) was calculated for each of the measured spatiotemporal metrics. Ideally, the step time, swing time, and step length should be relatively close. The higher these values are the less symmetric the walking [99]. We will use Equation 4.2 where X_P is the spatiotemporal metric on the prosthesis side and X_I is the metric on the intact leg. If this value is negative, the dominant leg for the corresponding metric is the intact leg. The desire is for this value to be as close to zero

as possible.

$$SI = \frac{(X_P - X_I)}{0.5(X_P + X_I)} \quad (4.2)$$

For all spatiotemporal metrics one-way repeated-measures ANOVA was done using python's statsmodel library with $\alpha = 0.05$. If this showed significant impact of toe-joint stiffness, two-tailed paired t-tests were conducted for all combinations of toe-joint stiffness using python's scipy library with $\alpha = 0.05$.

4.3 Results

4.3.1 Spatiotemporal Data

On the prosthesis side, there was a significant impact of toe-joint stiffness on step time ($p = 0.0004$), stance time ($p = 0.001$), swing time ($p = 0.0010$), and step length ($p = 0.0235$). Mean step time with the 0.83 Nm/deg joint stiffness, was shown to be significantly greater than with the 1.25 Nm/deg and rigid joint stiffness ($p <= 0.0028$ for both comparisons). This is also true for step length ($p <= 0.03$), stance time ($p <= 0.0008$) and swing time ($p <= 0.02$) metrics.

On the intact side, there was a significant impact of toe-joint stiffness on step time ($p = 0.0000$), stance time ($p = 0.0001$), swing time ($p = 0.000$), and step length ($p = 0.0006$). Per t-tests, step time ($p <= 2.14E - 05$), swing time ($p <= 0.0004$) and stance time ($p <= 0.003$) were significantly greater with 0.83 Nm/deg joint stiffness than that with the 1.25 Nm/deg and rigid joint stiffness. The aforementioned p values are for both pairwise comparisons: 0.83 Nm/deg vs. 1.25 Nm/deg and 0.83 Nm/deg vs. rigid. When using the 0.83 Nm/deg joint stiffness there was significantly greater step length and step time on the intact side than in the rigid case ($p <= 0.001$ for both). This can be seen in Figure 4.1.

Although the step lengths and step times were significantly greater while using the 0.83 Nm/deg joint stiffness, the SI index for all spatiotemporal values were found not to vary significantly with toe-joint stiffness ($p > 0.3378$). The 1.25 Nm/deg joint stiffness was found to be slightly more symmetric for stance and swing time, but these differences were not found to be significant 4.2.

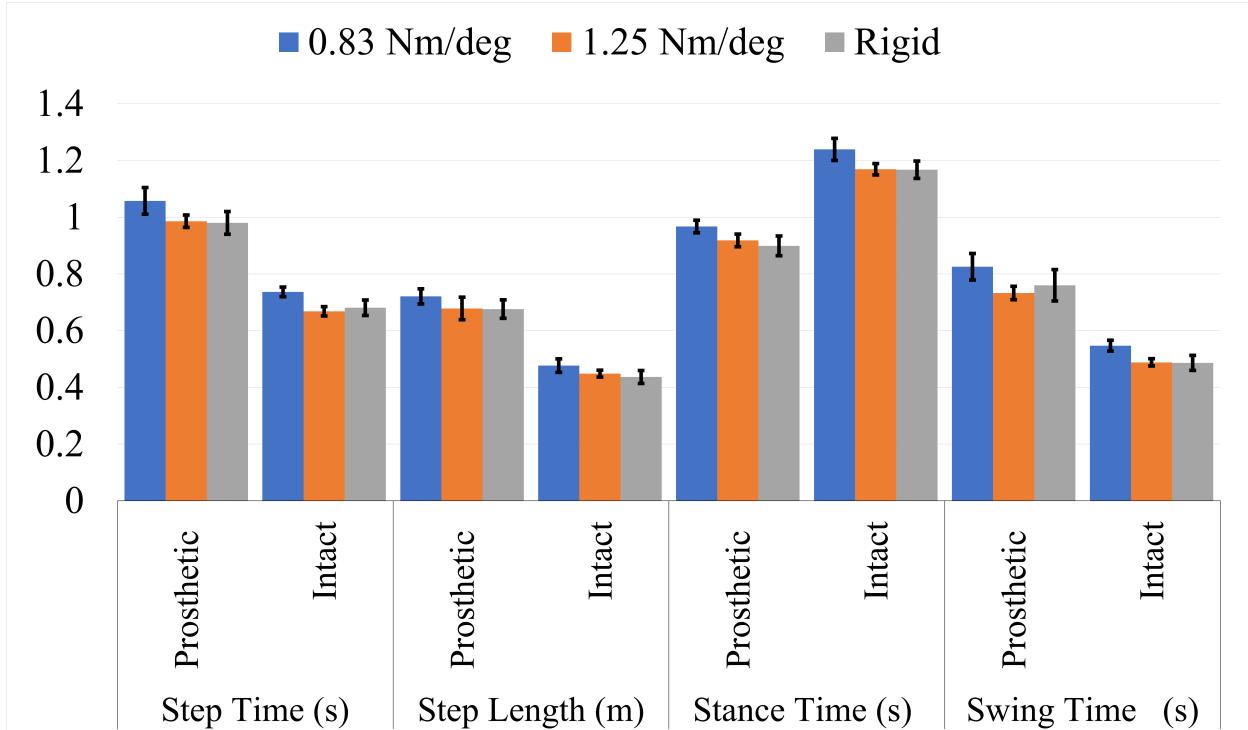


Figure 4.1: Spatiotemporal Metrics for intact and prosthetic legs

4.3.2 Kinetics and Kinematics

With the 0.83 Nm/deg joint stiffness, there was increased hip flexion at the end of swing (Figure 4.3 A1). The maximum hip torque increased with stiffness (Figure 4.3 A2).

There was very little change in knee range of motion for different toe stiffness. On the prosthesis side there was lower flexion torque in stance and increased extension torque during swing (Figure 4.4 A2) when using the 0.83 Nm/deg joint stiffness. There were also higher peak knee moments for the 0.83 Nm/deg joint stiffness (Figure 4.4 B1). On the prosthesis side, ankle range of motion was very similar (*pm* 2 degrees) (4.4 A1).

The intact ankle resulted in more dorsiflexion at the end of stance for the 1.25 Nm/deg and rigid joint stiffness (4.5 B1). However, both the rigid and the 0.83 Nm/deg joint stiffness had more plantarflexion than the 1.25 Nm/deg foot. There was also increased minimum ankle moment before push-off with the 0.83 Nm/deg joint stiffness. As seen in Figure ??, average power does increase with stiffness on the prosthesis side. On the intact side, the power produced decreased in

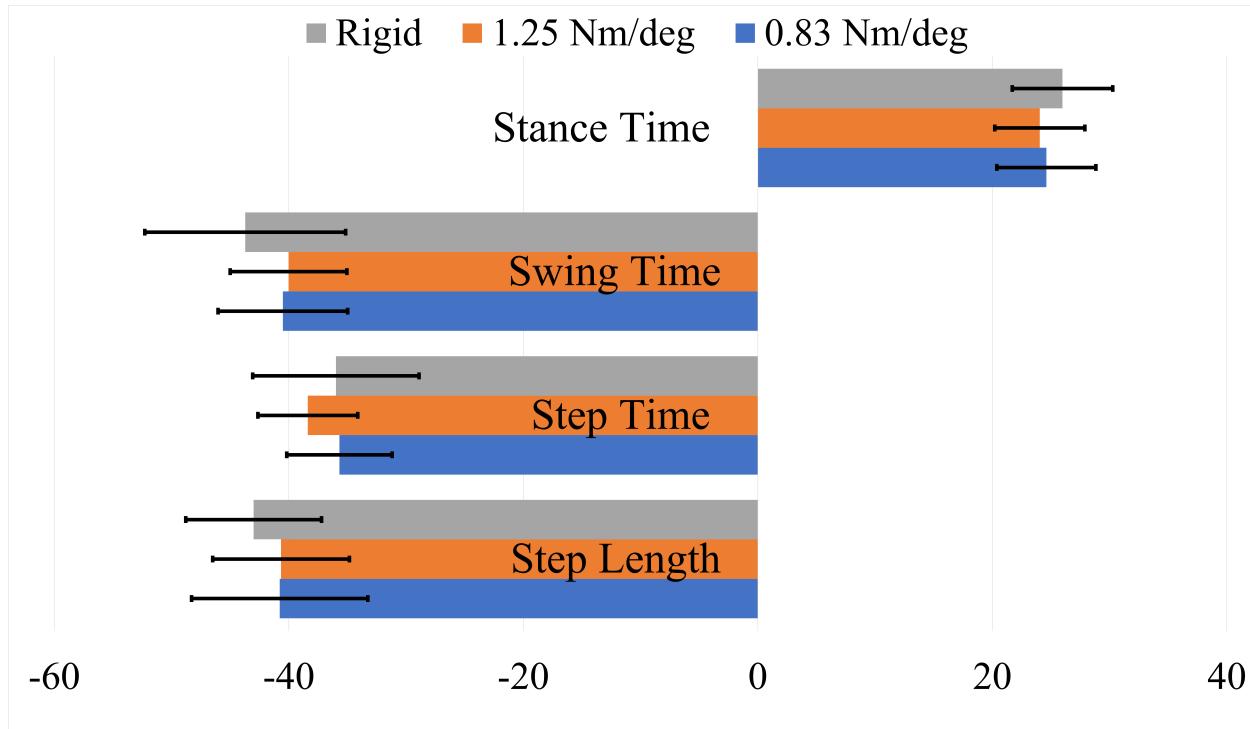


Figure 4.2: Symmetry Index for Spatiotemporal Metrics

the order 0.83 Nm/deg , rigid, and 1.25 Nm/deg.

4.4 Discussion

While steps with the 0.83 Nm/deg joint stiffness were longer, they did not produce a more symmetric gait. While it is beneficial to have a longer stance time on the prosthesis side, it should also be symmetric. In this case (0.83 Nm/deg), there were some compensatory motions that resulted. The motions were increased hip flexion at the end of stance on the prosthesis side, on the intact side increased peak knee moments,increased knee flexion and dorsiflexion on heel strike increased plantar flexion before toe-off. As stated in Section ??, deviating from the reference angle increases the generated joint torque. With the lower toe-joint stiffness, it is possible the participant is attempting get more push-off support by elongating the step. Despite these efforts, the resulting ankle push-off torque and power were lower compared to those of 1.25 Nm/deg and rigid joint stiffnesses (Figure 4.6). This shows the toe-joint stiffness of 0.83 Nm/deg counters the positive impact of the powered knee-ankle prosthesis in terms of push-off assistance. In order to achieve

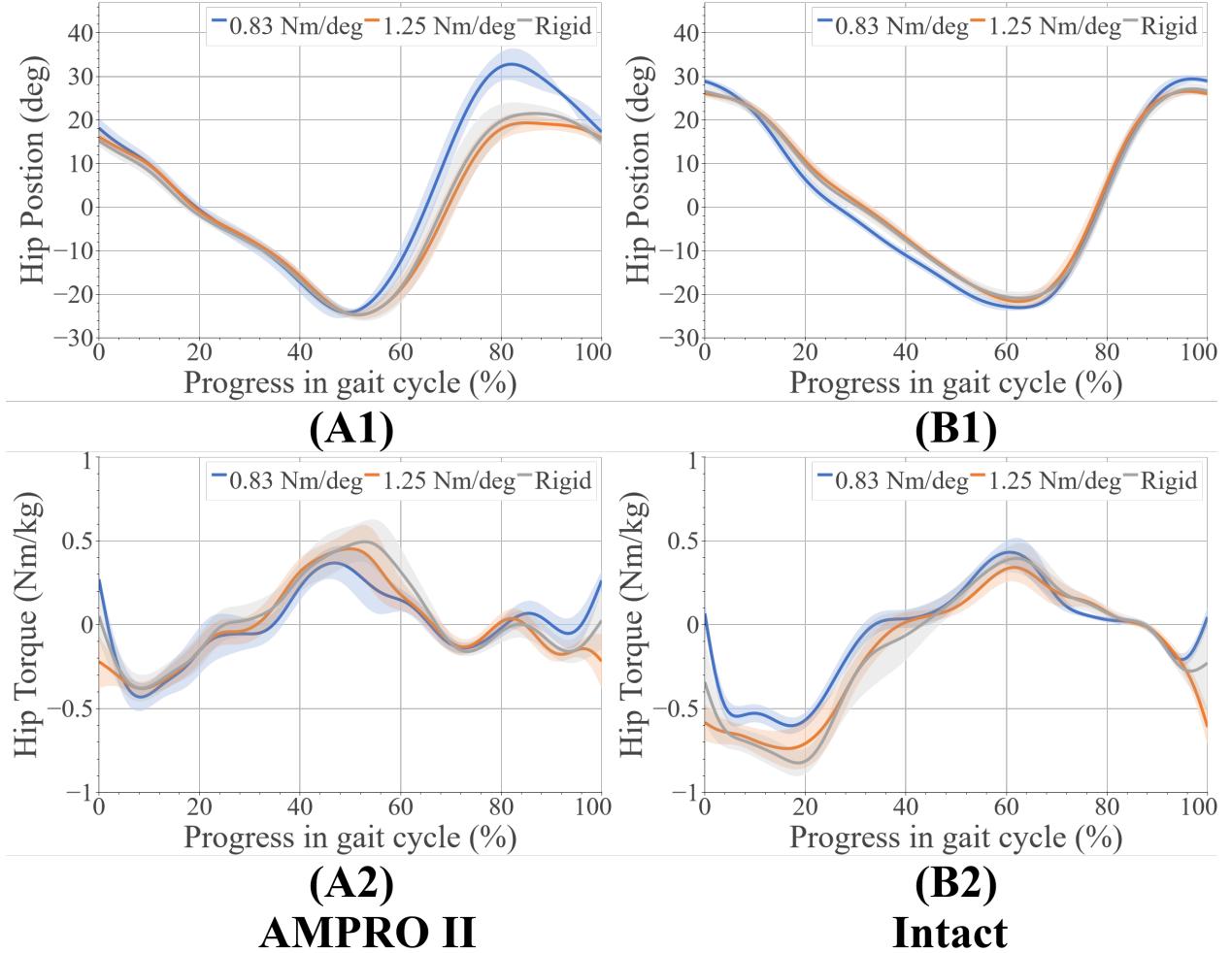


Figure 4.3: **(A1)**Hip Angles on Prosthesis Side ,**(A2)**Hip Moments on Prosthesis Side, **(B1)**Hip Angles on Intact Side ,**(B2)**Hip Moments on Intact Side

these longer steps, the participant had to increase hip flexion during swing. The peak hip moments on the prosthesis side increased with foot stiffness. This value was more similar to the intact leg's hip moment values. This indicates more similar loading trends between the intact leg and the prosthesis as stiffness increases.

The increased knee flexion moments on the intact limb in the 0.83 Nm/deg case (Figure 4.4 B2) indicates that this stiffness overloads the limb. These higher moments over time has been associated with osteoarthritis [100]. Using this stiffness with a powered prosthesis could counter the benefits reported in previous studies [92, 93, 94, 95]. This overloading of the intact leg is also

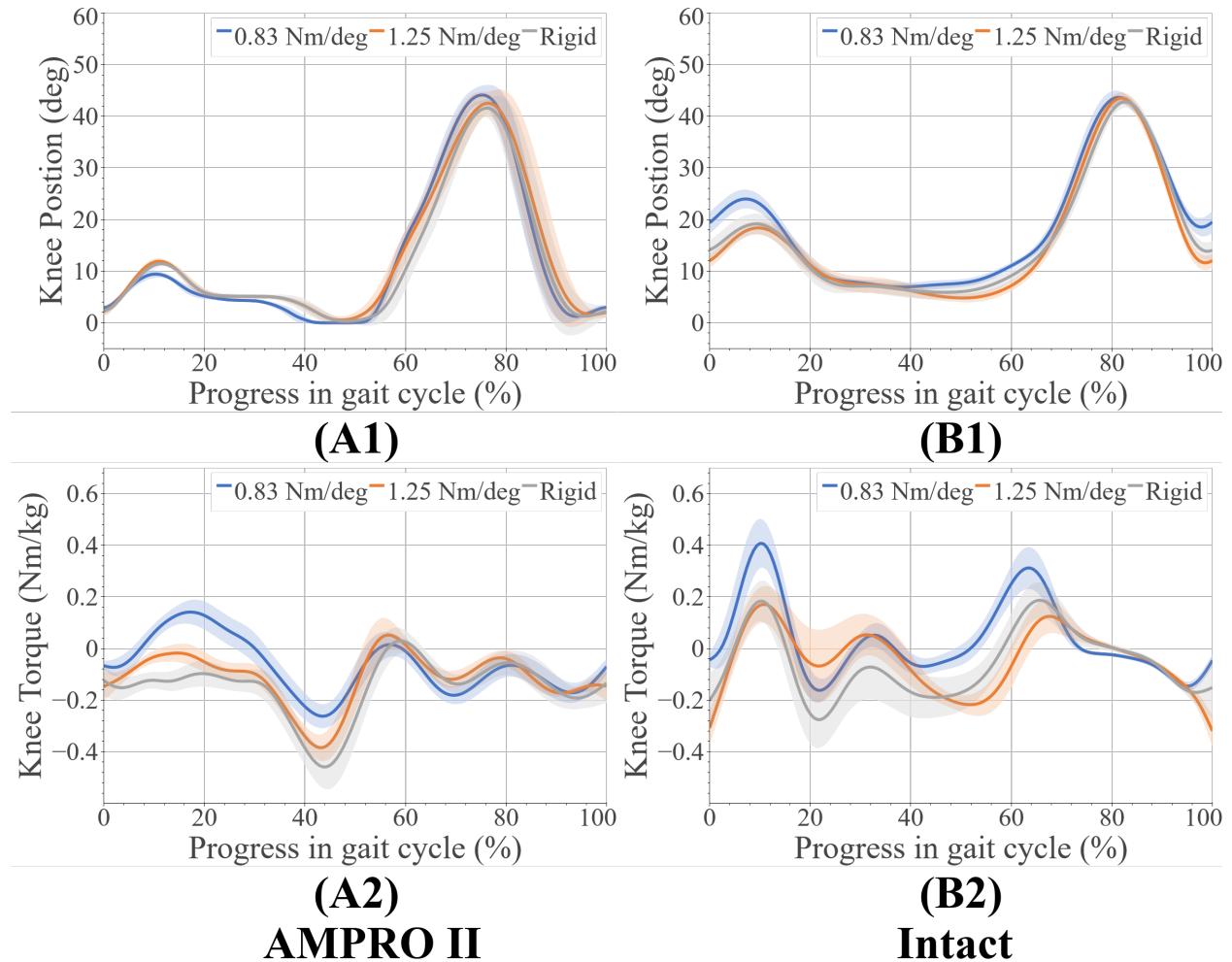


Figure 4.4: **(A1)**Knee Angles on Prosthesis Side ,**(A2)**Knee Moments on Prosthesis Side, **(B1)**Knee Angles on Intact Side ,**(B2)**Knee Moments on Intact Side

seen in the higher intact ankle peak power values (Figure 4.6). Use of this foot also led to increased of dorsiflexion moment at the beginning of stance on the intact leg, indicating an increased need for more stability at push-off. The participant was seen compensating more with their intact leg in order to walk forward at this level of toe-joint stiffness.

The difference in moments and power production between the prosthesis and intact leg, as well as the compensatory motion mentioned above, are some of reasons for high incidences of arthritis in amputees [101]. One of the main reasons for device abandonment is discomfort [102]. If a user has to make these compensatory motions with a heavier powered device they may not wish

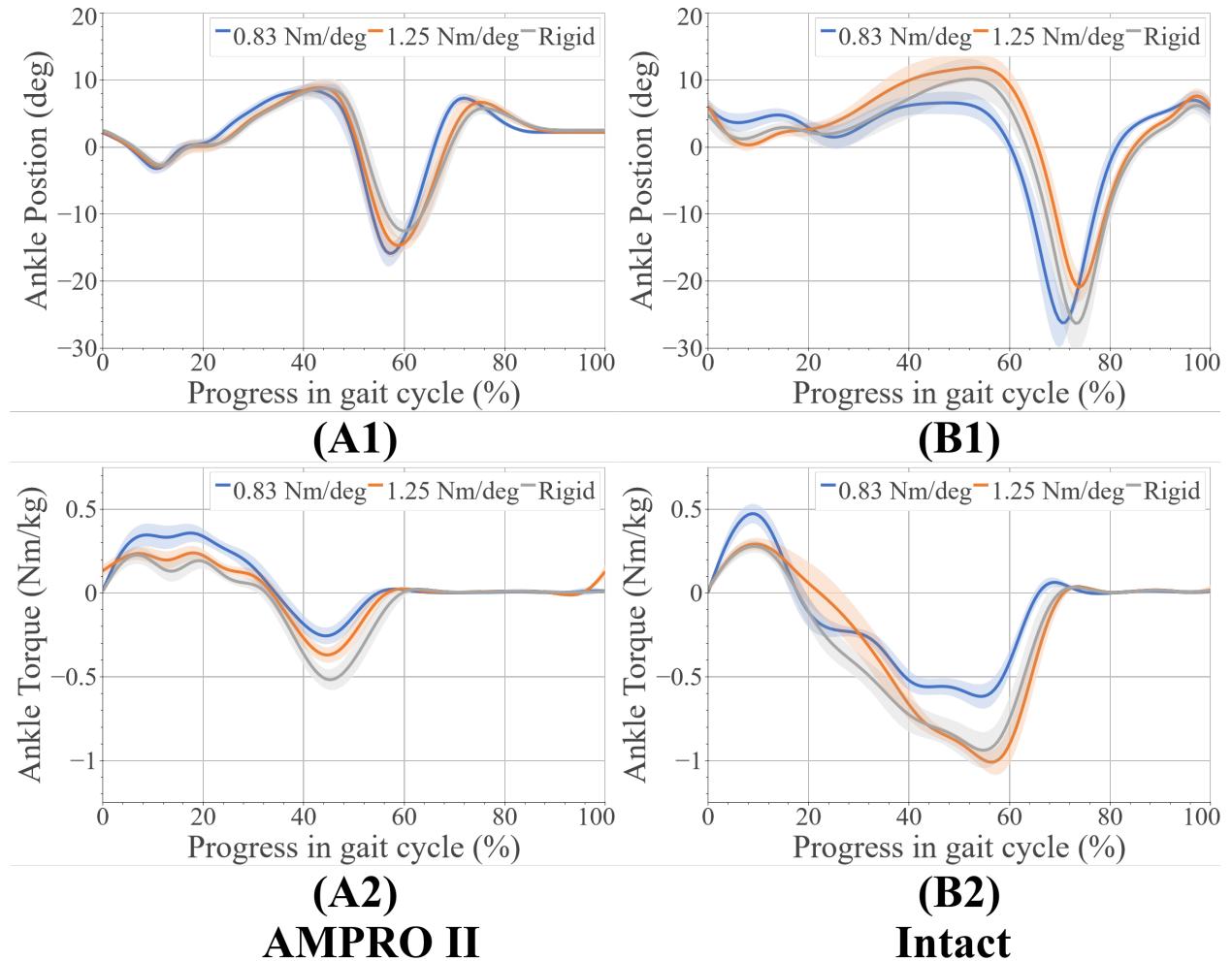


Figure 4.5: **(A1)**Ankle Angles on Prosthesis Side ,**(A2)**Ankle Moments on Prosthesis Side,
(B1)Ankle Angles on Intact Side ,**(B2)**Ankle Moments on Intact Side

to use it. It is possible with the 0.83 Nm/deg toe-joint the participant could feel less stable during heel-strike and push-off resulting in the compensatory movements mentioned above.

These compensatory responses were not observed in the cases pertaining to 1.25 Nm/deg and the rigid foot. The latter performed best in terms of power production on the prosthesis side. This could mean that the stability provided by a locked toe-joint through stance could prove to be beneficial with some transfemoral amputees and powered devices. The rigid and 1.25 Nm/deg toe-joint scored relatively close in terms of other metrics. Although the rigid foot produced the most power on the prosthesis side, that did not result in the least power production on the intact

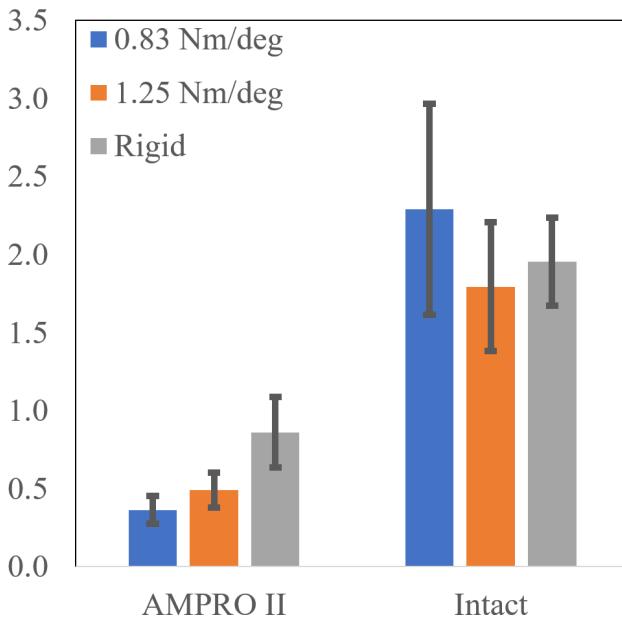


Figure 4.6: Peak Ankle Power

side. The 1.25 Nm/deg case resulted in the least power production on the intact side. This shows that increased power production on the prosthesis side does not always result in lesser demand for power from the intact side. In other words, this increased power does not always minimize overloading. Given that the results with 1.25 Nm/deg case were slightly more symmetric, this could indicate that using a toe-joint can help reduce intact limb overloading.

We postulate that the addition of a toe-joint can make a difference while walking with a powered knee-ankle prosthesis. However, different stiffness need to be tested in order to verify if this is true. Two of the shortcomings of this study is that it involved only three stiffnesses and a single participant. Using a foot that has a stiffness greater than 1.25 Nm/deg but not fully rigid could improve the results observed in this study [103].

4.5 Conclusion

From this study, we determined the impact of using a toe-joint with a powered prosthesis for a transfemoral amputee. We tested three different stiffness. It was determined that foot stiffness is related to power production on the prosthesis leg, with higher stiffness resulting in higher push-off

assistance. The lowest stiffness had the least push-off power, demanding more power production from the intact leg. The 0.85 Nm/deg case resulted in longer step time and step length, and compensatory movements that could negatively impact users over time. We conclude that a toe joint with a stiffness that is too low can negatively impact the user. However a toe joint with a suitably selected stiffness can reduce the loading on the intact leg. Power production alone is not enough of a metric to indicate the effectiveness of lower limb prosthesis. We have to look at spatiotemporal changes as well as kinetic and kinematic responses. More stiffness and toe-joint designs need to be explored with transfemoral amputees to determine if they are able to replicate the benefits of the human MTP joints.

5. SUMMARY AND CONCLUSIONS

With the large number of wheel chair users and secondary issues that result in from wheel chair use there is a major need to improve the design of walking assistive devices. Many walking assistive devices are redesigned by the user, not consistently used, or can cause walking abnormalities resulting in pain and injury overtime. The goal of this dissertation was to present a design strategy for walking assistive devices due to a shared goals of symmetric walking, normal kinetics and kinematics and minimal pain. This design method utilizes user needs and biomechanic analysis through out the design process in order to optimize user outcomes. This strategy was used in order to determine design metrics and fine tune design concepts for two different walking assistive devices: an exoskeleton and a powered knee ankle prosthesis system.

In order to determine design metrics for the powered exoskeleton device a user survey was completed for those who suffered from paralysis. There were a total of 14 participants. The highest rated needs were comfort, ability to be hands free and easy to put on. This lead the highest rated metrics to be self balancing, volume deployed and maximum interaction forces between user and the robot. These metrics go beyond just the physical needs alone, but incorporate the user desires as well. The finding from this study can better direct exoskeleton research in the future and hopefully improve user outcomes. This shows that research efforts are misplaced. There is currently no research that is putting

The second study that was completed focused on the interaction force metric by determining the impacts of different knee mechanisms on walking, interaction forces and device migration. This study applies to exoskeletons and all knee orthosis. This study looked at a single axis hinge brace and a polycentric hinge brace. There were no differences in the using the mechanisms in the joint moments or angles. However, the polycentric hinge did not out perform the single axis mechanism in interaction forces or migrations. This leads researchers to believe that polycentric hinge needs to be modified in order to meet the needs of a large range of users. Also the lack of difference in walking outcomes leads us to believe that the performance metric for the use of these

mechanisms can no be solely gait dynamics. Experiment design from this study can be used to test additional knee mechanisms design for knee orthosis use. The findings also indicated that if polycentric hinges are to be used in orthosis more needs to be done to determine the appropriate design for a wider number of users.

The last device researched in this dissertation was a powered knee ankle prosthesis. The goal of this study was to assess if utilizing a toe joint would improve the walking of a transfemoral amputee. Most other studies only observed these impacts on transtibial amputees. Walking dynamics and symmetry was measure using three different toe stiffnesses. The lower toe stiffness resulted in a reduction in performance and compensatory movements that can cause damage over time. The rigid foot resulted in greater power production, but also result in more work demand from the intact leg. Due to their being no major differences in dynamics it is possible that a toe joint with a higher stiffness can be beneficial in reducing overloading the intact limb. This can improve potentially improve energy use outcomes for users of powered knee ankle systems in the future.

All research presented in this dissertation assists in improving design metrics and outcomes of walking assistive devices.

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