Frameworks for the design of passive prosthetic knee components using user-centered methods and biomechanics of level-ground walking

by

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Abstract

Passive knee prostheses in developing countries use low-cost components driven primarily by the need to prevent falls, resulting in undesirable gait deviations during walking. There is a severe lack of reliable data on the specific needs of low-income amputees, which poses a significant challenge towards developing globally appropriate prosthetic technology. This thesis presents the analysis of user-centered needs and relevant lower leg dynamics as frameworks for the design of passive prosthetic knee components that can enable transfemoral (above-knee) amputees to ambulate with minimal gait deviations leading to higher user satisfaction. The goal of developing these frameworks is ultimately to design a low cost, fully passive prosthetic knee device for persons with transfemoral amputations living in the developing world.

To identify user needs, structured oral interviews of 19 transfemoral amputees in India were conducted regarding 22 different Activities of Daily Living (ADLs). A scale of relative importance for different needs was compiled, which can help designers, doctors, and administrators provide better clinical solutions to amputees. Cross-legged sitting was identified as the most critical user need with the potential for highest improvement in the quality of life of amputees. Two identical rotator prototypes were designed and validated for cross-legged sitting on 9 amputees in India.

To compute and replicate the target knee moment profile for a prosthetic knee device, the dynamics of level-ground walking were analyzed using a conceptual link-segment model of the prosthetic leg with the knee joint modeled as a combination of passive linear springs and dampers. The effects of changes in inertial properties (mass, radius of gyration, and center of mass location) of the prosthetic leg on the lower leg kinetics were also quantified in the model. The knee moment required for achieving normative joint kinematics at the hip, knee and ankle by the optimal engagement of spring and dampers was replicated computationally with a maximum R^2=0.90 in an idealized clutching scheme.

Multiple prototypes of modular knee mechanisms were built to replicate the model, including (i) an automatic locking module for stability during early stance, (ii) a linear spring module for facilitating knee flexion-extension during early stance, and (iii) a rotary damping module for control during terminal stance and swing. Qualitative feedback from two unilateral transfemoral amputees in India showed the automatic locking module provided the predicted performance for timely stance to swing transition. Fluid-based viscous damping was found to provide more optimal control compared to friction-based damping.

A comprehensive biomechanical framework was developed that predicted the range of optimal damping coefficients for transfemoral amputees. The framework used the results from the link-segment model and empirical data of transfemoral gait characteristics such as slower walking speeds and asymmetries in the stance-swing duration. An experimental prosthetic knee with five different damping conditions was built and tested on three subjects with unilateral transfemoral amputation in a motion capture lab. Increased damping led to reduced peak knee flexion during terminal stance and swing, as predicted by the framework. The framework predicted the optimal damping value for achieving normative peak knee flexion to within one standard deviation of the able-bodied value during the swing phase.

Thesis Supervisor: Amos G. Winter, V
Title: Associate Professor of Mechanical Engineering

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Contents

Chapter 1

Introduction

The goal of this thesis was to use the tools of biomechanics, mechanical design, and user-centric design process to (1) develop theory and frameworks to analyze and design passive prosthetic knee systems, and (2) to develop the different mechanism modules required to assemble a fully passive, low-cost prosthetic knee that can enable able-bodied gait for users in India with above-knee amputation (termed as transfemoral amputation in biomechanics [1]).

In 2011, *Bhagwan Mahaveer Viklang Sahayata Samiti* (BMVSS, a.k.a., "Jaipur-foot") and the Massachusetts Institute of Technology (MIT) initiated a collaboration to develop a prosthetic knee for transfemoral amputees in India. BMVSS, a non-governmental organization (NGO) based in Jaipur, India, is a major developer, manufacturer and distributor of prosthetic, orthotic, and assistive devices throughout India and one of the largest organizations in the world serving people in need of prostheses [2]. Since it's inception in 1975, it has helped rehabilitate more than 1.3 million amputees and polio patients, mostly in India [2]. Using outside funding sources, they distribute all their products free of charge to amputees.

In January 2012, an initial project meeting was held with BMVSS, and the following design requirements for a new design of the prosthetic knee were given by clinicians and prosthetists at BMVSS [3]:

- Allows normal gait on flat ground
- Provides stability on uneven terrain
- Costs less than $100 to manufacture

Since 2012, a number of research studies have been conducted at MIT with the overall goal of designing a prosthetic knee that can meet the design requirements laid out by BMVSS. The prior work by Narang and Winter [3] at MIT informed the initial direction of research presented in this thesis. The relevant parts of their work have been summarized in the background section of each chapter of this thesis.

1.1 Thesis Outline

The thesis describes four different studies, organized as chapters:

- **Chapter 2**: This chapter presents an extensive list of user needs as articulated by transfemoral amputees in India. A scale of relative importance for different needs is reported, which can help designers, doctors, and administrators provide better clinical solutions to transfemoral amputees. A novel design of the transfemoral rotator is also discussed, which was validated by Indian amputees with high user satisfaction for cross-legged sitting.
- **Chapter 3**: This chapter presents an early prototype mechanism of a fully passive prosthetic knee designed to enable able-bodied kinematics. The design was informed by a comprehensive set of functional requirements for prosthetic knees in the developing world and the biomechanical analysis of human gait for level-ground walking. The mechanism was implemented using two functional modules: an automatic early stance lock for stability and a differential friction damping system for late stance and swing control. For preliminary qualitative validation of the knee mechanism, a field trial on four above-knee amputees in India was carried out, which showed satisfactory performance of the automatic early stance lock.

- **Chapter 4**: This chapter presents the design and preliminary testing of two distinct mechanisms relevant for passive prosthetic knees: the stability module and the damping module. These mechanisms were designed to enable the users of single-axis, passive prosthetic knees to walk with able-bodied kinematics on level-ground, specifically during the transition from the stance phase to the swing phase of the gait cycle. For preliminary user-centric validation, a prototype with the stability module and two different dampers (with varying damping coefficients) was tested on a single above-knee amputee in India. The stability module was found to function as expected, enabling smooth stance to swing transition and timely initiation of knee flexion. The dampers also performed satisfactorily as the increase in the damping coefficient was found to decrease the peak knee flexion angle during swing.

- **Chapter 5**: This chapter presents a framework to estimate the range of optimal damping coefficients required to achieve normative knee flexion kinematics. The damping coefficient estimate from transtibial data was compared to the able-bodied damping coefficient to determine a range of optimal damping coefficients for transfemoral amputees. This range was adjusted based on the scaling effects of the relevant asymmetric gait compensations made by transfemoral amputees. Knee kinematics data from three unilateral transfemoral amputees walking with a broad range of damping coefficients were analyzed. The estimated optimal damping coefficient range was validated by the experimental damping coefficients that led to normative peak knee flexion in the prosthetic leg.

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Chapter 2

Human-centered design and testing of a globally appropriate transfemoral rotator

The thesis author was the lead contributor to this body of research, which was conducted in collaboration with Y. Narang, M. Chun, M. Cavuto, J. Austin-Breneman, and A. G. Winter, V.

2.1 Background

Based on the limited number of past studies [1, 2] that are available, it is estimated that there are at least 230,000 transfemoral amputees in India, the country of focus for this study. Other estimates put this number at 6.7 million transfemoral amputees in Asia, most of whom live in China and India [3]. A majority of these amputations are the result of diverse factors such as inadequate or unaffordable health care, unsafe working conditions, transportation accidents, diseases, and unhealthy lifestyles [1,4,5]. Most of these amputees belong to low-income families, who are often compelled by circumstances to change their occupation or become unemployed after their amputation [6, 7]. The resulting economic deprivation, coupled with socio-cultural discrimination and lack of access to rehabilitation services, leads to severe degradation in the quality of life and mental health of a large majority of these amputees [3, 8].

Multiple research studies and technical reports have been published on design, evaluation, manufacturing, and dissemination considerations for prosthetic technologies in the developing world [9–14]. A major consensus of this literature is a clear definition of "appropriate technology" [15] as applied to the field of prosthetics: "a system providing proper fit and alignment based on sound biomechanical principles which suits the needs of the individual and can be sustained by the country at the most economical and affordable price" [10]. In the past few decades, there has been a renewed user-centric focus by for-profit companies, academics, and philanthropic NGOs in designing appropriate prostheses for amputees in South Asia and other emerging markets [3, 14, 16, 17]. However, a majority of prosthetic devices designed for the developing world have focused on price reduction, often at the cost of functionality or quality. Despite the lower price points, many of these recent innovations are yet to be adopted at a scale that is commensurate to the large population of amputees in need, due to limitations in the biomechanical performance, clinical training, manufacturing processes, supply-chain management, and maintenance [3, 16, 18, 19]. The biggest limitation in making an informed, efficient tradeoff between cost, scale, and functionality is severe lack of reliable data and studies on the needs of amputees in low-income countries.

Identifying the "needs of the individual" is a challenge for designers of low-cost prostheses, particularly those in academia or industry, as it often requires significant and frequent interaction with stakeholders who live hundreds to thousands of miles away from research laboratories [20, 21]. Only a few studies have been published that provide specific information gathered from Indian amputees regarding the performance of existing devices, or on desired features [7, 8]. The most comprehensive study found was that of Narang et al [7], who surveyed 124 transfemoral amputees in Pune, India in 1984. The study recorded the demographics of amputees and evaluated their ability to perform a wide range of Activities of Daily Living (ADL) [22]. Most ADL, such as dressing, bathing, and using the toilet, are generally no different in India compared to other countries, but certain attributes distinguish how Indian people perform these activities. Wyss and Mullholland [23] conducted one of the few studies to examine these attributes in detail. The study noted that floor-sitting postures such as kneeling, squatting, and cross-legged sitting were uniquely critical in South Asia to perform basic ADL like using the toilet and bathing, as well as instrumental ADL like praying and socializing. Additionally, some ADL have been found to be completely different in India relative to developed countries, such as walking across uneven village terrain from place to place [24].

In this chapter, two studies of relevance to the needs of transfemoral amputees in India are presented. First, a survey of transfemoral amputees is presented, which was conducted to understand the relative importance of different ADL in India. Second, the user-centric design and validation of a novel prosthetic component is discussed, informed by the results of the aforementioned amputee survey.

The novel prosthetic component discussed in this study is a transfemoral rotator, which is an adapter that is attached between the socket and the distal prosthetic leg assembly (comprising the prosthetic knee, pylon, and the prosthetic foot). The transfemoral rotator (hereby referred to simply as the rotator) facilitates rotary motion in the transverse plane about the longitudinal axis of the residual limb, enabling amputees to cross their prosthetic leg over the contralateral leg. This additional degree of freedom can help amputees sit cross-legged on the floor or chair, wear pants and shoes with ease, and get in and out of confined spaces such as a car [25]. Existing rotators on the market have not been designed specifically to meet the goals of appropriate technology. They are almost exculsively available to high-income amputees, both in the developed and the developing world. Designed and manufactured by large and established multi-national companies in the west [26, 27], these rotators are made of complex mechanisms that need advanced manufacturing processes and high-strength materials to minimize the size. These limitations indicated the need for a simpler, lower-cost, and more robust architecture for a rotator. The design presented in this study seeks to bridge these gaps in rotator technology.

2.2 Methods

2.2.1 Amputee Survey Methodology

An oral survey was administered to 19 transfemoral amputees at the BMVSS (*Bhagwan Mahaveer Viklang Sahayata Samiti*) limb fitment center in Jaipur, India. The BMVSS organization, also known as the Jaipur-Foot organization, is a non-profit NGO focused on providing affordable prosthetic care to low-income amputees in India [28]. The survey was approved by the Massachusetts Institute of Technology Committee on the Use of Humans as Experimental Subjects, in collaboration with the respective administrative body at the BMVSS organization. Subjects were selected according to the following criteria: a) they were at least 15 years old, b) they were unilateral transfemoral amputees, and c) they had at least 6 months of experience walking with their current prostheses. These selection criteria were chosen to ensure that each subject had a fully developed walking ability, that the effects of bilateral and unilateral amputation were not confounded, and that each subject had become fully accustomed to his or her current prosthesis. A consent form was administered prior to each survey, and both the consent form and the survey were presented orally. The documents were presented with the assistance of a translator.

The survey focused primarily on answering two major research questions: (i) what ADL are Indian transfemoral amputees unable to perform easily with existing low-cost prostheses? and (ii) of the difficult ADL, which could significantly improve the lives of the amputees if they were made easier? We asked interviewees about 22 predetermined activities that represented a broad range of ADL in India. The list of 22 activities in the survey was derived from multiple sources. First, the survey by Narang et al. [7] and a study on non-Western ADL [23] were used to generate baseline ADL that could be relevant to Indian prosthesis users. Second, prior to administering the survey, we spent significant time interacting with Indian amputees and their families. During this time, we observed and documented ADL performed by the amputees. Third, various types of terrain in India were identified in order to subdivide the ADL of walking on uneven terrain into more specific activities. For

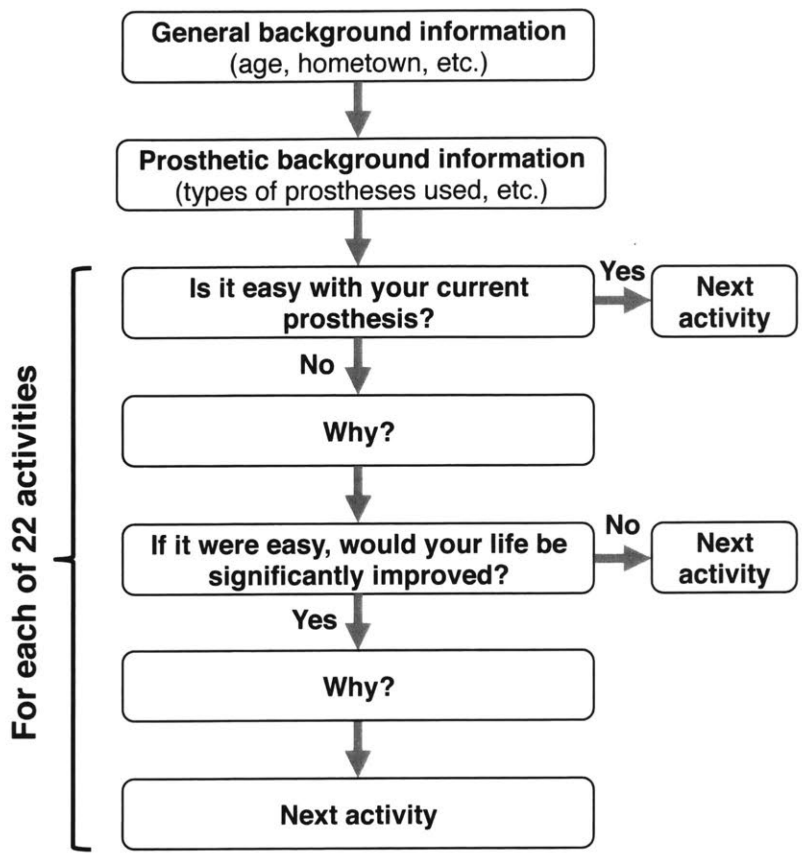

Figure 2-1: Flow chart of the protocol of amputee survey for each subject.

example, walking on rocks, walking on snow, and walking on dirt were listed as separate activities. At the beginning of the survey, we asked questions about the subject's personal background and history of prosthesis use. Then, for each activity within the list of 22 activities, we asked the subject whether or not the activity was easy, and if not, whether or not their lives would be significantly improved if they were able to perform it easily with an alternative prosthesis (Figure 2-1).

Preliminary conversations with interviewees influenced the design of our survey questionnaire. Interviewees often found it overwhelming to answer open-ended questions that required them to identify activities based on their perceived difficulty or potential impact for improvement. For example, they had trouble responding to "What are some activities that you find difficult?". To mitigate these difficulties, a binary form question was framed for each activity from the predetermined list. For example, "Is squatting easy or not easy?" was one of the questions in the survey

(Figure 2-1).

2.2.2 Preliminary user trials of the rotator prototype

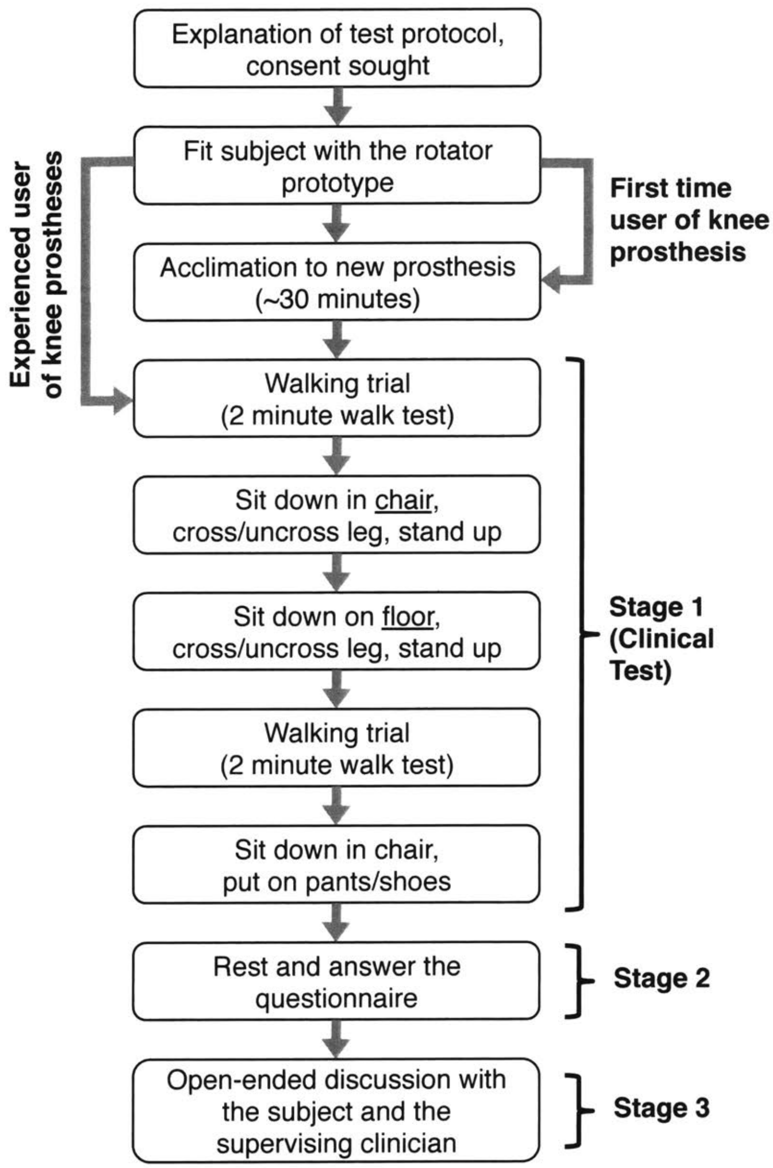

Figure 2-2: Flow chart of the protocol of user trial for the rotator (for each subject).

The rotator prototype was tested on nine subjects with unilateral transfemoral amputation in India. The trials were conducted at two locations: (i) the BMVSS limb fitment center in Jaipur, India, and (ii) the Mobility-India clinic in Bengaluru, India. The BMVSS organization and Mobility-India organizations are non-profit NGOs focused on providing affordable prosthetic care to low-income amputees in India. The user trial protocol was approved by the MIT Committee on the Use of Humans as Experimental Subjects, in collaboration with the respective administrative bodies at BMVSS and Mobility-India.

The protocol was organized in three sequential stages for each subject (Figure 2-2): (i) Clinical test, conducted to assess the functional performance of the rotator, (ii) Structured oral questionnaire, to record the subject's response to the trial, and (iii) Open-ended discussion, conducted with the subject and the supervising clinician to elicit qualitative feedback about the rotator performance. The structured questionnaire was designed to assess user satisfaction and performance of the rotator along four major themes: (i) Ease of use, (ii) Stability, (iii) Appearance, and (iv) Overall quality of life improvement. A total of 16 questions were asked with responses recorded using a 4-point Likert scale (1=Strongly disagree, 2=Disagree, 3=Agree, 4= Strongly Agree) [29].

2.3 Results

2.3.1 Amputee Survey Results

Subject Demographics

Table 2.1 presents the demographic characteristics of the subject population.

Quantitative Results

Figure 2-3 shows the importance of each ADL investigated versus the perceived difficulty of the ADL. The horizontal axis shows the percentage of respondents who rated each activity as difficult. Of the respondents who rated the ADL as difficult, the vertical axis shows the percentage who answered that their lives would be significantly improved if they could perform the activity easily with an alternative prosthesis. Only ADL with 14 or more responses are plotted in Figure 2-3. These results can be grouped into three relevant categories. The upper-left corner consists of ADL that

Table 2.1: Amputee survey: summary of subject demographics (N=19)

Attribute	Value
Gender	100% male, 0% female
Age	36.3 ± 15.6 years
Home state	Uttar Pradesh (42%), Bihar (16%), Madhya Pradesh (16%), Chattisgarh (5%), Haryana (5%), Jammu (5%), Punjab (5%), Rajasthan (5%)
Hometown	Village (76%), City (18%), Town (6%)
Cause of amputation	Transportation accident (74%), Cancer (16%), Infection (5%), Violent crime (5%)
Occupation before amputation	Student (32%), Non-agricultural manual laborer (26%), Farmer (16%), Driver (11%), Manager (11%), Shop-worker (5%)
Current occupation	Unemployed (42%), Manager (21%), Non-agricultural manual laborer (11%), Student (11%), Security guard (11%), Farmer (5%)
Knee joint type	BMVSS locked exoskeletal (53%), Jaipur-Foot single-axis (26%), Jaipur-Stanford four-bar (16%), ICRC locked (5%)
Uses other assistive devices	64% yes, 36% no
Falls per month	Average: 0.7, Range: 0-4

were important for the small number of respondents who felt they were difficult. The lower-right corner consists of ADL that were perceived as difficult by many respondents but were not considered important to solve. The upper-right corner consists of ADL that were considered both difficult to do and important to solve by a large portion of the subjects. These ADL, such as sitting cross-legged, represent opportunities for new knee designs that would make the greatest impact on the largest segment of the target market. The ADL in the lower-right and upper-left corners still represent opportunities for improvement, but for a smaller segment of the market.

Limitations of Current Prostheses During Floor-sitting Postures

Although the survey consisted of binary questions, it prompted more open-ended responses, which were also recorded. Many of the subjects reported that the three floor-sitting postures - sitting cross-legged, squatting, and kneeling were difficult to perform. When asked why the ability to do certain activities easily would significantly

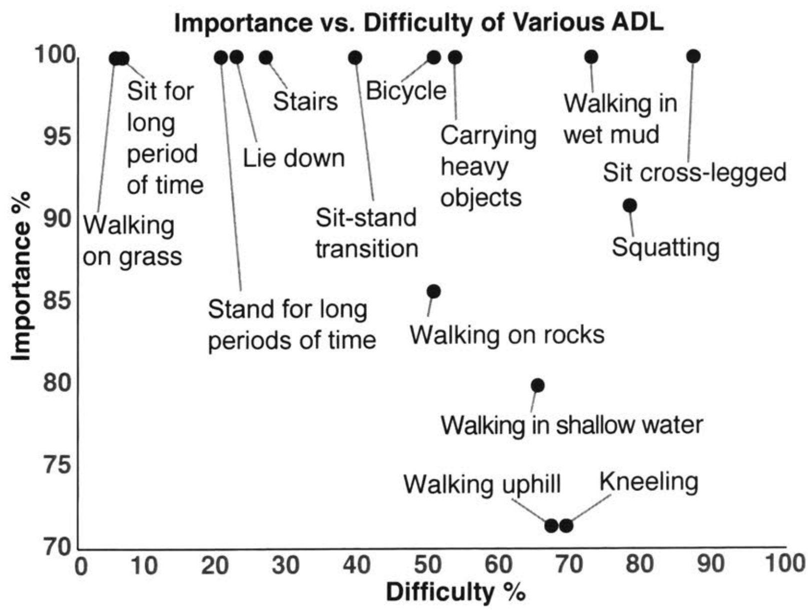

Figure 2-3: Quantitative survey results showing the difficulty and the importance of the various activities of daily living (ADL). The horizontal axis is the percentage of respondents who rated each activity difficult. For each who rated ADL difficult, the vertical axis shows the percentage who answered that their lives would be significantly improved if they could perform the activity easily with an alternative prosthesis.

improve their lives, subjects typically provided reasons related to work and general well-being. Seventy-two percent specifically said that the ability to carry heavy objects, walk on uneven terrain, walk fast, and sit cross-legged easily would allow them to get a better job or do more work. As anticipated, many subjects also stated that the ability to squat easily would allow them to use outdoor toilets or Indian toilets without additional help. Fifty percent said that the ability to do additional activities would give them confidence, allow them to live a better life, and feel that they were not impaired.

On cross-legged sitting, subjects stated that their prosthesis did not bend in the varus direction, because the knee joint only allowed flexion in the sagittal plane. Most subjects expressed that cross-legged sitting posture would enable them to eat with their family or perform work such as tailoring on the floor. Cross-legged sitting was identified as the ADL with the largest potential for positive impact, as confirmed by the quantitative results of the survey (Figure 2-3), which led us to explore the design of a globally appropriate rotator technology.

2.3.2 Design of the Rotator

Functional Requirements

A list of functional requirements was collated to guide the prototype design and evaluation along three major considerations (Table 2.2): (i) Socio-cultural, (ii) Biomechanical and Safety, and (iii) Industrial. The list was derived from multiple sources: (i) published academic literature in of knee biomechanics [23, 30], developing world prosthetics [3, 5, 16–18, 31], and lower-limb amputation [1, 7, 32–34]; (ii) conversations with amputees, device manufacturers and practicing clinicians in India [24, 35]; (iii) industry and manufacturing standards (ISO 10328) [12]; and (iv) analysis of the prior art and performance specifications of existing rotators on the market [25–27, 36–38].

Table 2.2: Major functional requirements for the rotator design

Socio-cultural Requirements	• Concealable under pants • Ease of operation over the pants • Minimal operation noise
Biomechanical and Safety Requirements	• Net build weight < 200g • Net build height < 32mm • Maximum static load of 115kg • Wobble in transverse plane < 1 degree (when locked)
Industry Requirements	• Standard pyramid connection at both ends • Fully enclosed locking mechanism • Ease of serviceability • Resistant to ambient water, dust, and dirt • ISO 10328 structural compliance • Manufacturing cost < $20 • Product lifetime of at least 2 years

Rotator Prototype

The Rotator Prototype was designed in a concentric cylinder architecture with a spring-loaded lock operated manually by a push-button. The assembly and operation of the mechanism is explained in detail in Figure 2-4. The combination of a

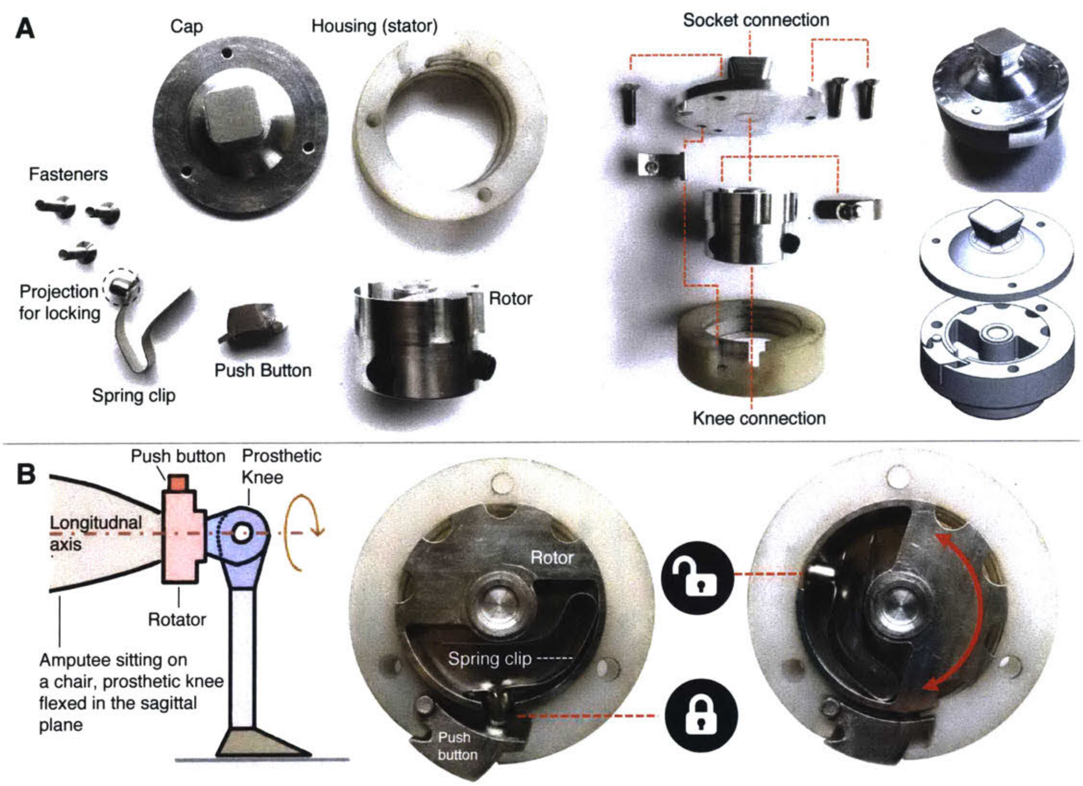

Figure 2-4: A. Disassembled view of the rotator assembly: the rotor is held coaxially within the housing, which is attached to the cap by fasteners. The cap connects to the socket on the top and the rotor connects to the prosthetic knee at the bottom. B. Operation of the mechanism (top view with the cap removed): The push-button, when pressed inwards into the housing cavity, dislodges the projection of the spring clip inside the rotor cavity. The rotor, along with the compressed spring clip, becomes free to rotate within the housing. Upon rotation back to the same location, the rotator locks again as the projection of the compressed spring clip snaps into the housing cavity with an audible clicking sound. The width of the housing cavity is sized exactly for the projection of the spring clip to expand into the housing, as shown in the locked state.

push-button and a spring clip implemented in the mechanism is a low-cost, robust, and fully passive solution to achieve switchable rotational or sliding constraint between two components. Spring clips are widely available across the world, and are commonly used in assistive devices featuring telescoping tubes, such as crutches and walkers. Each part in the assembly was designed to be manufacturable by small volume processes (such as 2D milling), as well as low-cost, mass-manufacturing techniques like injection molding and die-casting. Commonly available materials such as acetal and aluminum were used in the design and fabrication of the prototype, and stainless steel fasteners were used in securing the assembly. The biomechanical and structural functional requirements (Table 2.2) were validated through a finite element analysis of the mechanism under expected loading conditions in the three anatomical planes from the ground reaction forces of overground walking [30]. Two identical prototypes were fabricated for user trials. The novel construction of this design, as compared to the complexity of existing rotator designs, has been discussed in detail in the patent application filed in 2017 [39]. A previous study reported the different exploratory concepts of mechanisms considered to achieve the desired functionality [40]. We found only one design of a rotator in the literature of developing world prosthetics [25]. This design was not chosen for implementation in this study because of the complex and intricate arrangement of mechanical parts. Additionally, it was not universally compatible with different prosthetic knee designs.

2.3.3 Results of preliminary user trials of the rotator prototype

Each of the nine subjects was able to complete the clinical tests with the rotator prototype. Each of them was also able to cross and uncross their legs while sitting on a chair and on the ground. Besides cross-legged sitting, the subjects used the degree of freedom enabled by the rotator to move their shank and foot assembly in the lateral and medial direction to wear and remove their pants, and tie/untie their shoes (Figure 2-5). The addition of the rotator prototype in the prosthetic leg assembly did

Figure 2-5: Subjects using the rotator prototype with their prescribed prosthetic knee: A. Sitting cross-legged on the floor (rotator unlocked) B. Walking on a ramp (rotator locked) C. Tying shoelaces (rotator unlocked) D. Putting on pants (rotator unlocked).

not interfere with their previous ability to walk, stand up, or sit down. Furthermore, none of the nine subjects displayed any conspicuous gait deviations while walking on level ground because of the rotator. The results from the structured questionnaire, shown in Figure 2-6, indicated high user satisfaction along all four major themes of performance (ease of use, stability, appearance, and overall improvement in the quality of life).

The open-ended discussion with the subjects and the supervising clinicians conducted at the end of the questionnaire led to many specific insights. First, many subjects preferred the audible click of the spring clip which reassured them that the rotator was locked for normal weight bearing. Second, most subjects expressed strong approval of the push-button design, which let them operate the rotator over their pants (Figure 2-4B). Third, the supervising clinicians articulated the need to redesign sockets to accommodate the build height of the rotator. For the purpose of trials, most subjects were asked to walk without shoes only on the amputated side, to ensure that the build height of the rotator was compensated by the extra height of the shoes on the sound side. Fourth, the supervising clinicians and subjects also expressed strong approval of the straightforward design of the rotator. They were both able to open up the assembly by unscrewing the three fasteners, and found the spring replacement process to be intuitive, in case of failure or repair.

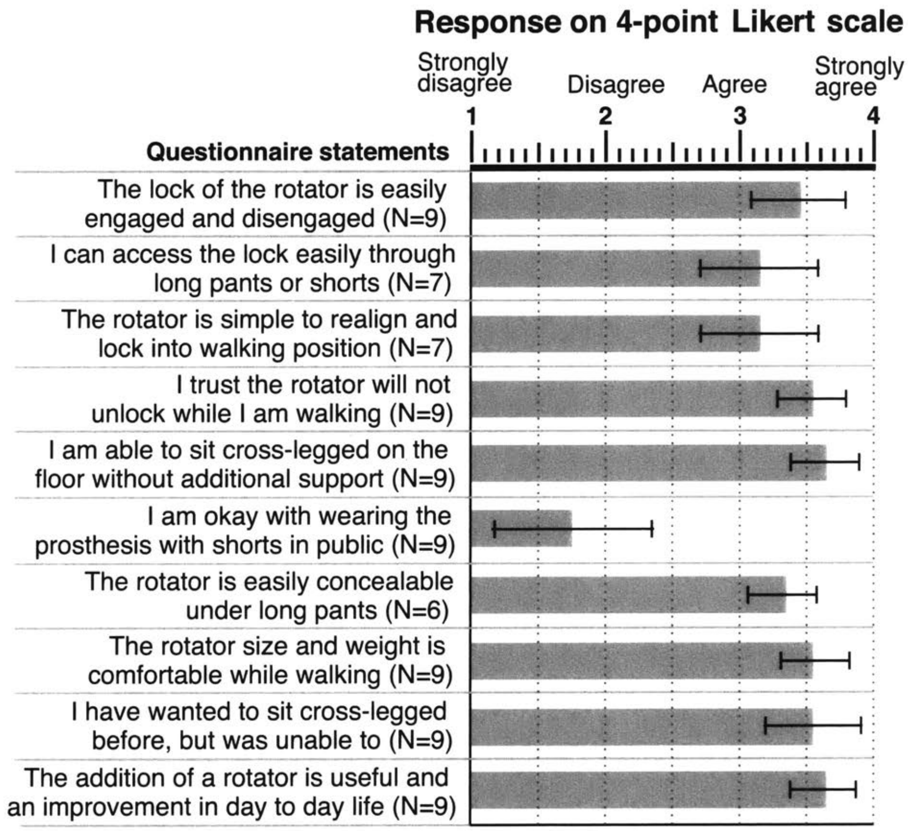

Figure 2-6: Response of subjects to different statements in the structured oral survey conducted immediately after the clinical test with the rotator. The confidence intervals display one standard deviation from the average. Not all of the 16 statements in the form were of relevance to each subject; only responses with N>5 are shown.

2.4 Discussion

The majority of current transfemoral prosthetic knee designs focus on the needs of users in industrialized markets with high per capita income and well-funded insurance systems (such as the United States and western Europe). The traditional model of prosthetic care has been driven by categorization of modules of the knee and foot prosthesis based on activity levels, such as the traditional K-level classification system used by Medicare in the United States [41]. The modules designed for high activity levels (K3 and K4) are extremely expensive for a majority of the amputee population in developing countries such as India. The prostheses used in India, while affordable, do not provide a level of performance similar to those in other markets [3,16]. In addition, even if they were affordable, the high-performance devices do not take into account the secondary functionalities which may be important to users in the Indian market, such as sitting cross-legged. This study lays out the relative scale of importance for different user needs in India, which can help designers, doctors, and administrators provide better clinical solutions to transfemoral amputees. The results of the amputee survey highlight the importance of understanding the unique needs of amputees in developing countries, based on a detailed analysis of socioeconomic and cultural requirements.

A human-centered approach was employed in the design and preliminary validation of the rotator prototype. The implementation of the rotator mechanism was simpler in design, more robust, easier to repair, and potentially amenable to local, high-volume manufacturing within the cost budget of $20 per unit. These features in the rotator prototype are particularly relevant in comparison to existing rotational adapters on the market, which implement complex mechanisms with many specialized components, often made out of expensive structural materials such as titanium [26,27,36–38]. For instance, the design by *Ossur* [36] uses more than 17 unique components to implement a complex locking mechanism in a compact arrangement, which is difficult to replicate in a globally appropriate architecture. Based on the conversations with clinicians in India, the local market price of commercially available rotators was estimated to be between $200 and $300 (Indian Rupees 15,000-20,000), which is unaffordable for most low-income amputees in India.

2.4.1 Limitations of the study

The amputee survey and the user trials of the rotator prototype had a limited sample size (N=19 and N=9, respectively). The sample size may also have been insufficient to capture the demographic diversity of a large country such as India. For example, the unavailability of female subjects and Muslim subjects may have skewed the relative ranking of ADL (Figure 2-3) and the identification of socio-cultural requirements for the rotator design. Operation of the rotator by women in India wearing traditional clothes such as a *saree* or *salwar-kameez* could pose additional requirements on the design of the user-interface of the rotator. The limited availability of subjects, translators, and clinicians and the long duration of interaction required from each participant to complete the study was a significant challenge. These difficulties have been documented in past studies focused on prosthetics in countries with large populations and diverse demographics [20, 21]. Our experience indicates that more local resources would be needed in the future to conduct similar studies with more participants at multiple geographic locations within India.

Additionally, self-reporting of user needs through surveys and interviews has been shown to have drawbacks with regards to completeness and accuracy [42]. However, research has demonstrated that a sample size of 20 to 30 respondents is sufficient to capture a significant majority, if not all of the user needs in a market segment [43]. A similar tradeoff study on the importance of different ADL versus the cost of incorporating the functionality of each additional ADL would be very informative. The results from such an analysis would help in the identification of opportunities for straightforward cost reduction. Additionally, such an analysis might also inform evidence-based exploration of disruptive, low-cost innovations focussed on desired functionality, which are currently too expensive to be incorporated. These innovations may also have the potential of changing or disrupting the global market for prostheses, as many of the unmet needs are shared by amputees worldwide. Past studies have shown that accommodating the uniquely extreme needs of lead users in emerging markets can aid in more efficient product development and widespread technology adoption among median users in mature markets [44, 45].

The prototype was not tested in the lab or the field over a long period of time comparable to the typical lifetime of the prosthesis, which is about two years of continuous daily outdoor and indoor usage. Scaling up this technology for widespread adoption at an affordable price will also require a deeper analysis of the cost of supply-chain and manufacturing processes. In the future, standardized measures of quality of life could be considered for a more complete evaluation of rehabilitation outcomes, such as the Medical Outcomes Study (MOS) short-form health survey (SF-36) [46]. However, the preliminary results from the user trials and the overall feedback from amputees and practicing clinicians in India have been encouraging towards further development of this technology for widespread adoption.

2.5 Conclusion

A quantitative inspection of relative importance of activities of daily living (ADL), as identified by Indian amputees, showed that many high-level activities such as sitting cross-legged, squatting, and walking in muddy conditions are critical for improving the overall quality of life of amputees in developing countries such as India. These ADL were identified as critical not only because of the unique socioeconomic context, but also because of the limited functionality of commonly available low-cost prostheses in India. Having identified cross-legged sitting as the ADL with the most potential for improvement in the quality of life of amputees, we designed and validated a globally appropriate rotator technology that enabled amputees to sit cross-legged on the floor, in addition to facilitating activities such as tying shoelaces and wearing pants. Beyond this specific context of transfemoral amputees in India, this process could be implemented for other assistive devices, which could lead to disruptive innovation and development of high-value products for lead users in developing countries, as well as for mature markets in the rest of the world.

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Chapter 3

Design and preliminary field validation of a fully passive prosthetic knee mechanism

The thesis author was the lead contributor to this body of research, which was conducted in collaboration with A. G. Winter, V.

3.1 Introduction

This work is focused on designing a low-cost, passive prosthetic knee that can facilitate normative gait and is appropriate for the daily life activities of above-knee amputees in developing countries. It is estimated that there are currently 30 million people across the world in need of prosthetic and orthotic devices [1–3]. In India alone, we estimate the total number of above-knee amputees to be in excess of 230,000 [4]. Other studies have estimated a number of 6.7 million above-knee amputees in Asia, with a majority living in India and China [3]. According to an estimate by the World Health Organization, 90-95% of amputees in developing countries do not receive any prosthetic device [5] and only 20% of amputees are able to afford currently available prostheses in the market [6].

A majority of Indian amputees belong to poor families [10]. In a past study by

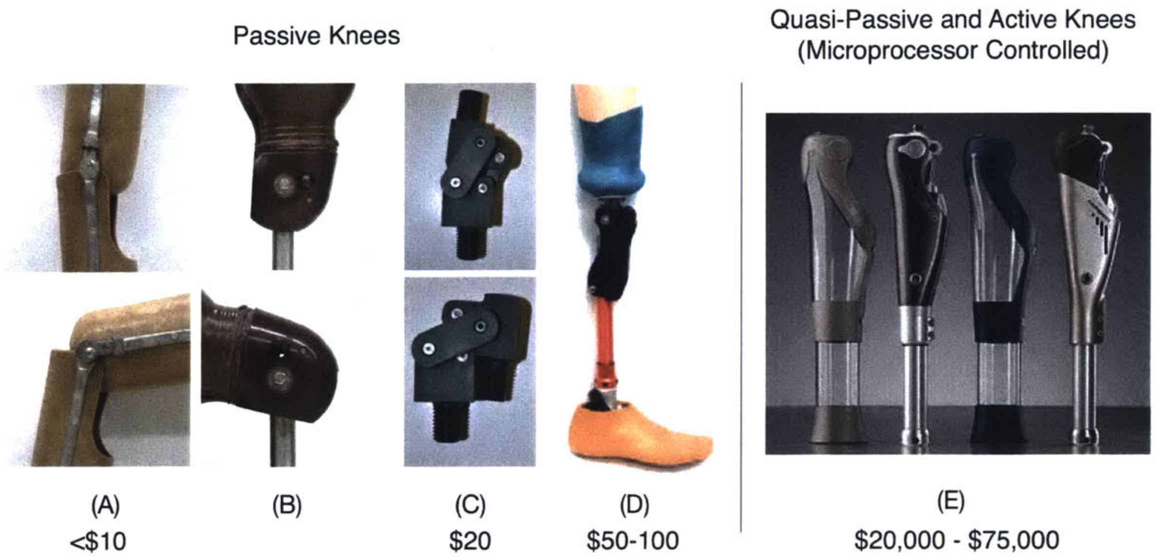

Figure 3-1: Different Prosthetic knees available in the developing and developed world markets and their selling prices: (A) BMVSS (Jaipur-foot) manual-locking knee, shown fully extended and at full flexion [7]. (B) The International Committee of the Red Cross (ICRC) manual locking, single-axis knee. (C) Jaipur-Stanford four-bar knee joint, also used by BMVSS [3, 7]. (D) LCKnee designed by J. Andrysek [8], with an automatic locking mechanism (E). The popular Ottobock range of quasi-passive and active, microprocessor- controlled prosthetic knees: C-leg and Genium Microprocessor controlled knees have been widely adopted in the developed world markets and they can enable a wide range of activities and motions [9]. Pictures adapted from [4], [8], and [9].

Narang et al. [11], 47% of Indian amputees reported changing their occupation after amputation, as most of the amputees were earlier employed in jobs that demanded physical exertion such as agriculture and manual labor involving long hours of standing, walking and lifting heavy weights. In the interviews conducted as a part of our earlier work [4], amputees reported social discrimination in their families and communities because of their conspicuous disability and unnatural gait. The severe social consequences and stigma endured by people who undergo lower-limb amputation in the context of different cultures have been well documented [12–14]. Acute financial constraints coupled with socio-economic considerations project an urgent need for a low-cost product that can deliver high levels of functional performance.

Although a number of advanced prosthetic limbs and assistive devices have been designed for the developed world in the last few decades (Fig. 3-1), very few of them have been suitable for large-scale use in developing countries due to vastly different and complex socio-economic considerations and resource-constrained settings. Prosthetic knee joints in the United States and Europe cost several thousand dollars to manufacture and distribute. Popular active above-knee prostheses that deliver very high performance can cost more than $50,000 [9]. Even the passive knee joints in developed countries are too expensive to meet the requirements of amputees in the developing world.

In biomechanical terms, the cyclic motion of walking is defined as the "gait cycle". Qualitatively, the gait cycle is often divided into phases based on whether the specified leg is in contact with the ground. "Stance" is when the foot of a specified leg is in contact with the ground, and "swing" is when the foot of the leg is off the ground. Stance and swing of one leg alternate with those of the other with a short overlap of "double support" phase when both the feet are on the ground.

Current above-knee prostheses being distributed in developing countries are typically passive, low-cost, and simple in design [5] (Fig. 3-1). Single-axis joints with and without manual locks have been found to be the most widely distributed across developing countries such as India [5]. These prostheses inhibit normative gait, and suffer frequent mechanical failures with low-user satisfaction [5]. The single axis joints with manual locks constrain the user to a peg-leg gait, which necessitates circumduction to enable ground clearance during the swing phase and hip hiking during stance phase. The single axis joints without manual locks lead to hyper-stable gait, wherein the transition from stance phase to swing phase (through knee flexion) is delayed. If not aligned correctly, they can lead to buckling of the knee joint during early stance causing the user to stumble or fall. The low-cost four-bar polycentric joint developed by D-Rev [3] has been adopted recently in India and other developing countries (Fig. 3-1). It has shown better performance but still possesses the problems of impeding early stance flexion-extension at the knee and delaying late-stance flexion. The four-bar knee, as the name suggests, uses a four-bar mechanism to generate a moving instantaneous center of rotation for the knee joint to achieve early stance stability and delay late stance flexion.

A comprehensive review of the recent developing-world knee technologies has been compiled by J. Andrysek [5]. An innovative technology, developed by Andrysek himself, is the LCKnee [8]. The knee locks at the end of swing and unlocks in late stance, mitigating the delayed initiation of late stance flexion, which is often the problem in alignment-stabilized single axis knees, braking knees, and four-bar knees (Fig. 3-1). It uses a single-axis architecture with an automated mechanical lock to enable early stance stability and late-stance flexion. Currently, fully passive prosthetic knees designed for the developing world do not enable early stance flexion and accurate swing phase damping. More importantly, most designs have been adaptations of existing designs in the developed world and have not been designed with a strategy to best replicate the kinematics of each phase of the gait cycle, without compromising on stability [5]. The specific design limitations associated with the kinematics vs. stability tradeoff are discussed in further detail in this chapter.

In this context, the overarching goal of our research is to design a low-cost, passive prosthetic knee joint that can facilitate able-bodied kinematics (thereby minimizing the total metabolic energy expenditure) and meet the relevant socio-economic, cultural and aesthetic needs of users with transfermoral amputation in developing countries. In this chapter, we present an early mechanism design and prototype of the prosthetic knee, which is specifically focused on the following:

1. Mechanical architecture with the potential to meet the biomechanical goals and user-needs of able-bodied walking. The primary focus of the prototype was on stability and facilitation of able-bodied kinematics.

2. Preliminary field validation of an early prototype in India through user-trials and interviews for qualitative feedback.

We build upon our earlier work, which was focused on theoretical biomechanical analysis of able-bodied walking, inertial factors and mechanical components affecting amputee gait [15–17], and determining the user-needs of above-knee amputees in

India [4].

3.2 Background

3.2.1 Biomechanical Requirements of a Transfemoral Prosthesis

The Fundamental requirements of functional human walking have been well established in the literature through theoretical biomechanical modeling and experimental gait data analysis [18–21]. For the purpose of our design, these requirements of able-bodied walking were grouped under the following three categories:

1. Kinematics: Movement of human body parts facilitating clearance in swing, adequate step length and smooth transitions between swing and stance.

2. Stability: Support of bodyweight, during both the single support and double support phases of gait. This is also the primary requirement of stable standing.

3. Energy Conservation: Achieving ideal kinematics and stability while minimizing energy expenditure.

The fundamental biomechanical objective of our transfemoral prosthesis design was to restore all the above three functions of able-bodied walking gait and stable standing at rest. Based on past studies of metabolic cost of walking, we postulate that by replicating able-bodied kinematics with adequate stability, it might be possible to minimize the mechanical work expenditure and thereby the metabolic cost of walking [22]. Meeting the first two requirements of walking listed above can also potentially aid in fulfilling the important third requirement of conserving energy and minimizing the metabolic cost of walking with a prosthetic limb.

Functional requirements	
Biomechanical Requirements	1. Able-bodied kinematics 2. Stability 3. Energy conservation
Requirements articulated by users	1. Ability to stand for long 2. Easy sit-stand transition 3. Ability to walk on wet mud 4. Ability to walk carrying heavy objects 5. Sitting cross-legged (important in Indian culture) 6. Ability to squat and climb stairs
Requirements articulated by stakeholders	1. Cost per device within \$100 - \$150 2. Normal looking gait on flat ground 3. Stability on uneven terrain 4. ISO 10328 compliance 5. Mass-manufacturable 6. Ease of fitment, alignment and maintenance 7. Appropriate for amputees with long residual limbs 8. Aesthetically pleasing cosmesis

Table 3.1: Functional requirements established based on biomechanical considerations and a user-centric approach [4]

3.2.2 Determination of Functional Requirements through a User-centric Approach

As part of our earlier work [4], in addition to the biomechanical requirements of walking and standing, a user-centric approach was used to establish the design requirements based on activities of daily living, fitment, manufacturing, distribution, maintenance, and compliance to international standards (Table 3.1). There were three important components to this approach:

1. Collaboration and interaction with Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS, also known as the Jaipur Foot organization) based in Jaipur, India. BMVSS has distributed more than 400,000 low-cost prosthetic limbs in India and other developing countries since 1975 and is currently the largest organization in the world manufacturing and distributing low-cost prosthetic limbs [7].

2. Interviews of Stakeholders: Technicians, engineers, physicians, professors and administrators at different prosthesis fitment clinics, rehabilitation hospitals, and academic institutions across India.

3. A structured user-needs survey of 19 transfemoral amputees in Jaipur, India to identify the specific needs with respect to their common activities of daily living.

A wide range of functional requirements was established and ranked in order of importance based on quantitative and qualitative data, which served as the guidepost for further analysis and design of the prosthetic knee mechanism (Table 3.1) [4].

3.2.3 Primary Functional Requirement for Early Stage Design and Validation

As discussed, we lay out a multitude of functional requirements important for meeting most needs of transfemoral amputees in developing countries, specifically in India. For the purpose of this study, the most critical functional requirement of the design was identified as enabling able-bodied kinematics and stability for walking at normal cadence. The biomechanical reason for enabling stability and able-bodied kinematics during normal cadence is well documented in literature [18, 23, 24], and was also articulated repeatedly by the Indian users in our survey, albeit not for biomechanical reasons [4]. Most users explicitly expressed the need for the prosthesis to help them look able-bodied. Past studies of amputees in both developing and developed countries have also reported the need to rehabilitate amputees with the aim of making the effects of their amputation as inconspicuous as possible [12–14]. Users in India also wanted the prosthesis to look aesthetically as close to their biological limbs as possible [3, 4].

Although the primary focus of the design was to enable stability and able-bodied gait, many constraints were imposed on the design to make future enhancements possible. These future additions would have to be practical, low-cost, and amenable to adoption in the developing world. The most important constraint, relevant for the prototype presented in this chapter, was to use only passive elements to keep the design robust and to reduce the eventual manufacturing cost.

3.3 Analysis and Design of the Mechanism

3.3.1 Optimal mechanical component coefficients to achieve able-bodied kinematics

Prosthetic knee designers have used components such as springs and dampers and optimized them with an aim of replicating ideal knee moment required for walking with able-bodied kinematics [25]. The work of Narang et al. theoretically established mechanical feasibility of achieving able-bodied kinematics by using low-cost passive mechanical components such as linear springs and friction dampers (Fig. 3-2) [15, 17]. Their study also optimized the mechanical component coefficient values accounting for changes in inertial properties of prosthetic legs, which typically weigh significantly less than physiological legs [16]. Their study concluded that using a single linear

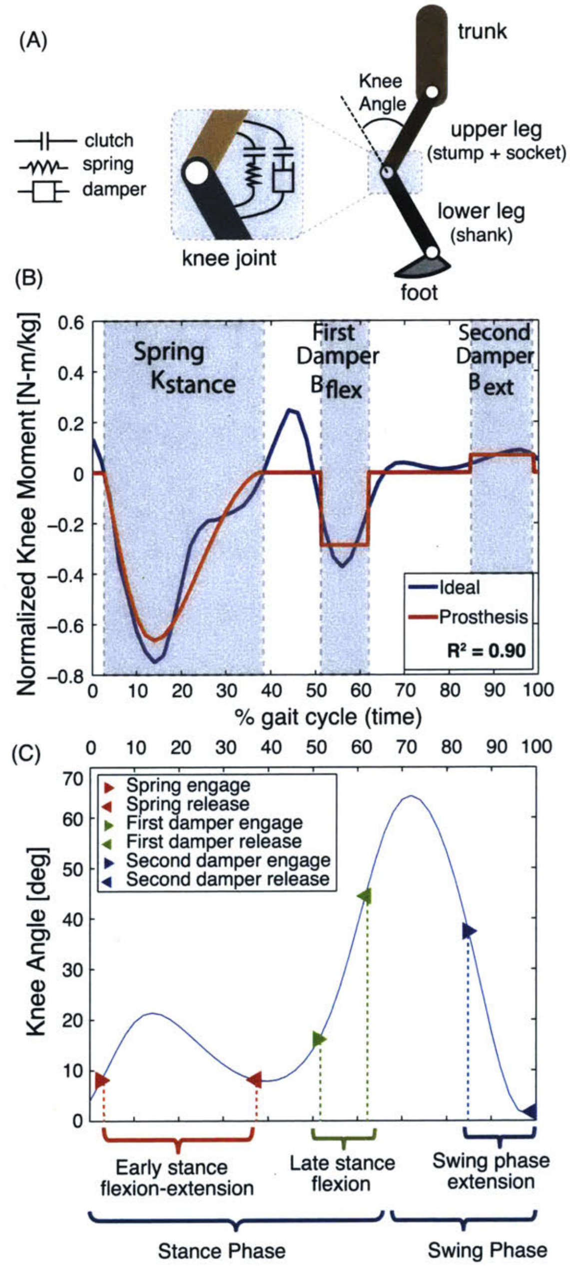

Figure 3-2: Determination of optimal mechanical component coefficients for replicating able- bodied knee moment. (A) Narang et al. [16] used a rigid body model comprising the foot, ankle joint, lower leg, knee joint, and upper leg. (B) Using inverse dynamics, they predicted the spring stiffness coefficient (K_{stance}) and the frictional damping coefficients (B_{flex} and B_{ext}) required at the knee joint for replicating able-bodied moment with R^2=0.90 [15]. (C) The engagement-disengagement points during each gait cycle were also established as a part of this analysis for one spring and two friction dampers. Increase in the positive value of the knee angle denotes flexion (and decreasing positive value denotes extension).

spring and two friction dampers of appropriate mechanical component coefficients, it is possible to accurately replicate the physiological knee moment (adjusted to the change in inertial properties of prosthetic components compared to able-bodied leg segments).

A mechanical embodiment of such a knee would need a mechanism to engage and disengage the spring and dampers at optimal points of time in the gait cycle. These studies [15–17] serve as the theoretical foundation for our design of a low-cost prosthetic knee mechanism because linear springs and friction dampers are available widely and are relatively inexpensive. By tuning the spring stiffness and damper friction coefficients to the prescribed values based on the weight of the person and weight of the prosthesis, it should be possible to closely replicate the desired knee moment for able-bodied kinematics.

3.3.2 Achieving reliable stance control with able-bodied stance kinematics

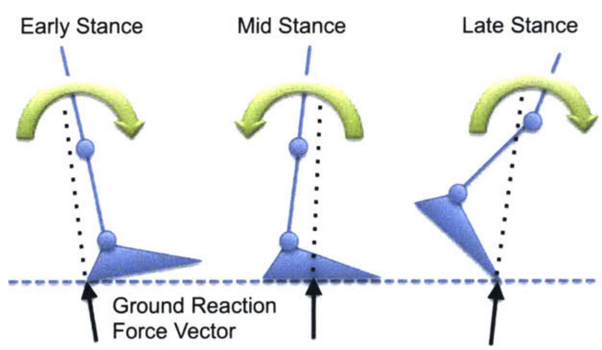

Figure 3-3: Relative position of the Ground Reaction Force (GRF) vector and the knee. The GRF vector is posterior in early stance and late stance causing a flexion moment at the knee (clockwise direction, with respect to the upper leg frame). During mid-stance, the vector is anterior to the knee. The curved arrow depicts the direction of the net resultant moment at the knee during each stage because of the GRF vector, inertial forces and the hip moment. The moment exerted by hip muscles and the inertial forces are not shown.

One of the fundamental design challenges in replicating able-bodied kinematics in a passive knee joint is achieving reliable stance control, which is important for stable locomotion and avoiding falls during early stance [23]. During early stance (Fig. 3-3), the Ground Reaction Force (GRF) acting at the Center of Pressure (COP) is posterior to the physiological location of knee axis and causes a large flexion moment at the knee. However, despite this large flexion moment, the physiological knee does not buckle as the extensor muscles in the physiological leg provide an opposite internal extension moment and limit early stance flexion of the knee to a maximum of about 20 degrees (Fig. 3-2). This initial 15-20 degree flexion is also important because it ensures that the center of mass of the body transitions smoothly from swing phase into the stance phase at the beginning of gait cycle [21]. Advanced electromechanical knee joints (Fig. 3-1) counter this large flexion moment by either providing a counter extension torque using an active, powered component or regulate the resistance of the joint based on electromechanical sensing of the center of pressure [25,26]. In a passive knee joint, which does not have any sensors or battery driven active component, stance control is a serious challenge (Fig. 3-3).

Different designs of passive prosthetic knees (Fig. 3-1) tackle this problem of stance control by compromising on early stance flexion through mechanical means, which have been well documented in literature and practiced widely by clinicians and prosthetists [5]. For example, single axis knee joints rely on voluntary control of hip musculature to resist flexion during early stance. Single axis locking knee joints such as ICRC knee use a mechanical latch engaged by the user to provide extra stability, which leads to a stiff legged gait suited only for new amputees or low-activity elderly users who demand hyper-stability [5, 23]. Polycentric mechanisms, using a four-bar mechanism or six-bar mechanism, rely on a moving instantaneous center of rotation to provide stability. The instantaneous center of rotation starts off posterior to the GRF vector at the beginning of stance and moves anterior to the GRF vector just before toe-off enabling some late stance flexion [23]. The LCKnee, recently developed by Andrysek et al. [8], uses an automatic stance locking mechanism to lock the knee during early stance and unlocks it during late stance to enable late-stance flexion for transition into swing. A similar automatic stance locking mechanism was earlier developed by Farber and Jacobson [27].

Achieving correct kinematics and kinetics during stance involves early stance flexion (kinetic energy storage) followed by extension (kinetic energy release) (Fig. 3-2). This early stance flexion-extension involves energy storage and energy release in nearly equal proportion [24]. A late stance flexion of up to 45-50 degrees with appropriate damping is also essential for a smooth transition into swing. However, most passive knee designs, as discussed above, do not facilitate appropriate early stance flexion-extension and appropriately timed late stance flexion. Our prototype aims to tackle this tradeoff between kinematics, kinetics and stability. However, the mechanism presented in the next section only enables late-stance flexion. Possible methods to incorporate an additional early stance flexion-extension within the presented architecture are discussed later.

3.3.3 Architecture of the mechanism

The mechanism was designed with two major functional modules in the prototype: the automatic locking-unlocking mechanism using a mechanical latching element (referred to as the lock) and a friction based differential damping system using brake material mounted on a one-way roller clutch. Figure 3-4 illustrates the functioning of the prototype through each phase of the gait cycle.

The automatic stance locking-unlocking mechanism in the prototype is similar in function to the mechanism implemented in the LCKnee by Andrysek, et al. [8] and Farber [27]. This feature was designed to provide stability to the user while the knee was locked from early stance to mid-stance. The locking axis was positioned anterior to the GRF vector but posterior to the knee axis to enable timely unlocking of the knee necessary for kinematics of late stance flexion. Compared to the earlier designs by Andrysek and Farber, our prototype is simpler in architecture because of the rear-locking feature, which needs only one lever arm for actuation of the lock, which is positioned posterior to the knee axis. In comparison, the LCKnee architecture used two levers to engage the lock, which was positioned anterior to the knee (front-locking feature intended to leave room for flexion of more than 90 degrees after unlocking [8]). However, by laying out the latch with a much longer length (along the length

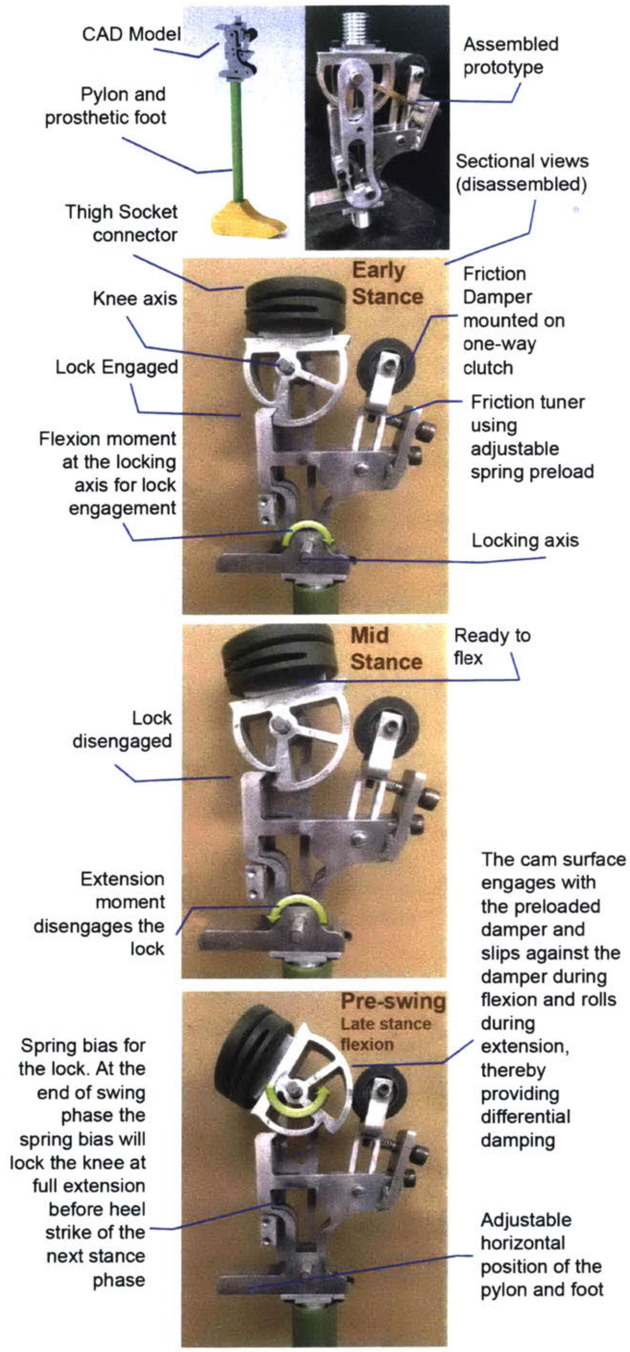

Figure 3-4: Architecture and function of the prototype mechanism. During early stance, GRF direction (Fig. 3-3) causes a flexion moment at the locking axis while the lock is engaged. During mid stance, the extension moment at the locking axis disengages the lock (as the locking element and rest of the lower leg assembly is mounted about the locking axis). During late stance, when the GRF vector passes posterior to the knee axis, late stance flexion at the unlocked knee joint can take place. During late stance flexion and early swing phase, the cam surface of the knee rotates about the knee axis and slips against the stationary brake lining, resulting in large damping torque (B_{flex}). During late swing extension, the brake, which is mounted on a one way roller-clutch, also rotates along with the cam surface and provides a much lesser damping torque (B_{ext}).

of the leg) in the posterior position, the rear-locking feature in our prototype was implemented to maintain flexibility of more than 90 degrees flexion. A similar rear-locking feature was also recently implemented by Wyss [28]. Using a single element as a lock is also advantageous as it can be much simpler to design the latch member to be compliant in compression (with a normalized torsional stiffness coefficient $K_{stance} =$ 2.86 N-m/kg/rad [15]). As the latch locks the knee during early stance, the compliance offered by the latch can enable elastic, early stance flexion-extension of up to 20 degrees (Fig. 3-2), while keeping the knee secure from accidental flexion, which may result in loss of control and possible fall. The prototype presented in this chapter (Fig. 3-4) does not incorporate this elastic flexion-extension module. However, our ongoing work has been focused on adding this module to the design, as described in the discussion section.

The second module in the prototype is the differential damping system for appropriate late stance flexion and swing extension. As shown by Narang and Winter [15,16], the magnitude of damping (with normalized, zero order rotational damping coefficient, Bflex = 0.29 N-m/kg) needed during late stance flexion is an order of magnitude higher than the damping required during swing extension (Bext = 0.069 N-m/kg). This differential damping is realized in the mechanism by mounting the braking surface on a one-way rolling clutch which provides slipping friction during late-stance flexion and much lower rolling resistance during swing extension. The braking surface used in the prototype is the common brake lining used in automotive applications with a high coefficient of friction (0.4-0.5 between the braking surface and Aluminum 6061 alloy). The preload on the braking surface is controlled by an adjustable screw mechanism (Fig. 3-4), this preload helps in controlling the normal force and thereby the slipping friction which is the product of the normal force and the coefficient of friction between the brake lining and the rotating aluminum module of the prosthesis. The differential damping system implemented in the prototype, however, can be improved further, so that the exact values of damping required during late stance flexion and swing extension could be dialed-in. The current prototype only provides an approximately accurate damping force during flexion but future iterations would implement a different embodiment of the similar concept to provide hermetically sealed, accurate and repeatable damping in both directions [29].

3.4 Preliminary Field Validation

Although the physical design of the prototype was only at a preliminary stage, early qualitative feedback of performance was sought from potential users for validation of the mechanism architecture and basic functionality of the two modules discussed in the previous section. Four subjects with transfemoral amputation were fitted with the prototype with the help of trained prosthetists at the BMVSS clinic in Jaipur, India [7]. Three out of the four selected subjects previously used the Jaipur-Stanford four-bar polycentric knee joint [3] for more than two years. The fourth subject was using the single axis knee joint for more than three years [7]. All four subjects were males and less than 35 years of age.

The evaluation protocol included the 2-minute walk test [21], walking up and down on an incline of 25 degrees, climbing stairs and walking outdoors on dirt. At the end of evaluation, each subject was interviewed in his/her local language for qualitative feedback. Subjects were also asked to compare the performance of the prototype with the prosthetic device that they had been using. The MIT committee on the use of humans as experimental subjects approved this field validation study.

All four subjects were able to walk in the 2-minute walk test after a period of acclimatization and learning to use the prototype knee. As articulated by the clinicians at BMVSS and the subjects themselves, the gait with the prototype was deemed "relatively comfortable". All four subjects were able to disengage the lock midway through stance and found the late stance flexion using the prototype to be more comfortable than the polycentric four-bar knee they had been using (Fig. 4-6). Walking on an upward incline and climbing stairs was difficult for all four subjects. The engagement of the lock before stance was found to be loud. Each subject reported this as an undesirable feature. The subjects also voiced their concern regarding the lack of aesthetically pleasant appearance of the prototype. None of the subjects felt the prosthesis to be heavy in comparison to their current prosthetic devices. These observations were recorded and mapped to strategies for further improvement in the next iteration of the prototype as described in the following discussion section.

Figure 3-5: Preliminary field evaluation. (A) Subject 1 using the prototype for the 2-minute walk test. (B) Subject 2 during the 2-minute walk test, late stance flexion of up to 40 degrees can be seen. (C) Subject 2 walking comfortably outdoors on a relatively flat, muddy terrain.

3.5 Discussion

3.5.1 Design Strategy

For normative, level-ground walking gait, the physiological knee is a net power dissipater over the gait cycle as compared to the physiological hip or the ankle [24], which are net power generators over the gait cycle. This implies that achieving able-bodied gait performance using a passive knee prosthesis is not restricted by any theoretical biomechanical limitation. With the advent of electromechanical devices in the prosthetics industry over the last three decades, passive devices have not been optimized for enabling able-bodied gait, especially in the case of passive prostheses for the developing world. Though electromechanical devices have shown excellent results in terms of reducing metabolic cost of walking and enabling able-bodied gait, their high-cost remains a barrier for globally scaled adoption, particularly in developing countries. The approach presented in this work, therefore, can also benefit users in developed world markets as passive knees could potentially be used as lower-cost, high-performance alternatives to the more expensive, active prostheses.

Enabling able-bodied kinematics based on our theoretical analyses [4, 15, 16] was helpful in making design decisions for stance-control and swing-control in a quantitative manner. In our design of the early stance lock, it was possible to precisely position the locking axis (with respect to the knee axis and the foot) by using center of pressure data and GRF data (Fig. 3-6). By locating the locking axis in the correct horizontal position, we ensured that the lock disengages only after the early flexion-extension phase of stance but before the engagement of the damper during late stance flexion (Fig. 3-2). During field evaluation, this locational accuracy for different subjects was achieved by horizontal adjustment of the pylon-foot assembly (Fig. 3-4).

Extending this approach to enable early stance flexion-extension (Fig. 3-2), an improved concept of the knee can be designed that implements an "early stance flexion (ESF) axis" (Fig. 3-7) [29], which is positioned posterior to the knee axis and about which, the knee can elastically flex up to 20 degrees (even when the knee is locked

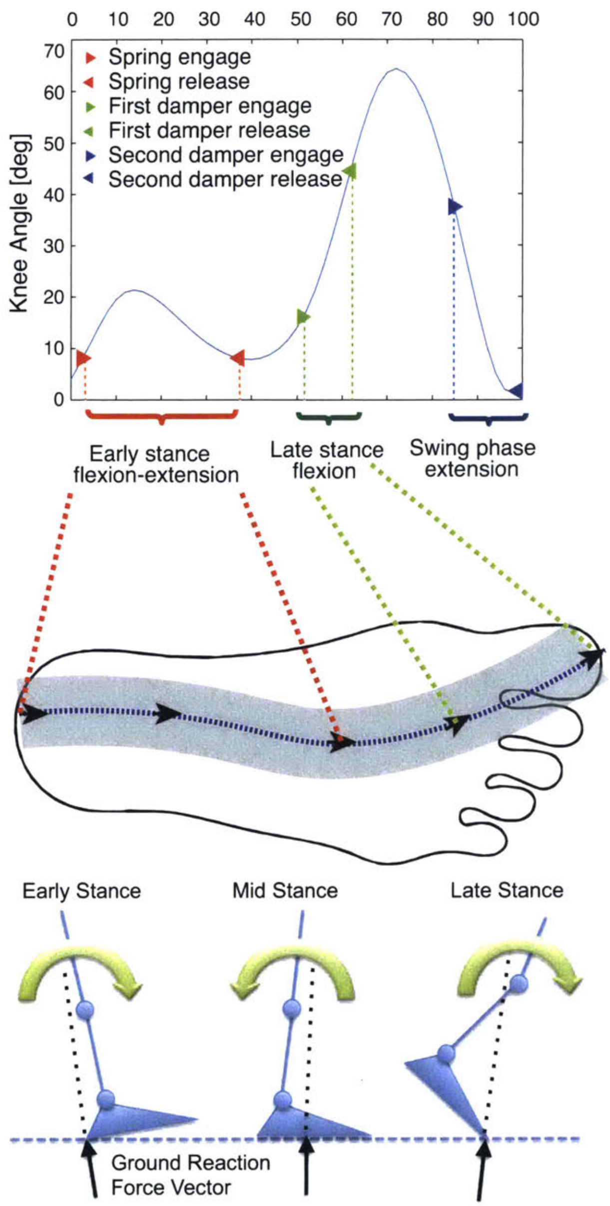

Figure 3-6: The movement of the Center of Pressure on the foot during stance phase of gait (as a function of time) has been determined in past studies [24]. The magnitude and direction of the GRF vector is also known through the stance phase [24]. This provides complete information about the physical location of the GRF vector as a function of time during stance phase of gait. The positioning of the locking axis (Fig. 3-4) is optimized in 2D space (the sagittal plane) to achieve the following: the GRF vector originating from the center of pressure is posterior to the locking axis during early stance, keeping the knee locked. During mid stance, the center of pressure advances, moving the GRF vector anterior to the knee and locking axis, releasing the latch. During late stance just before toe off, the latch remains disengaged (Fig. 3-4), as the GRF vector moves posterior to the knee axis. This strategy can also be potentially used to enable early-stance flexion and extension.

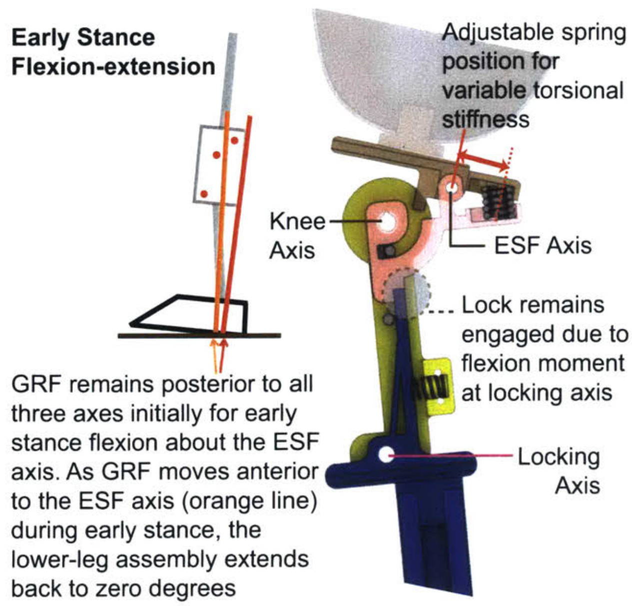

Figure 3-7: By incorporating an early stance flexion (ESF) axis, about which a spring is mounted for elastic early stance flexion-extension (Fig. 3-2), an additional module could be added to the proposed architecture of the prosthetic knee mechanism (Fig. 3-4). Illustration adapted with permission from [29].

during early stance). This is possible because the ESF axis is positioned in space such that the GRF vector causes flexion about the ESF axis during early stance and engages the spring mounted at a specific lever length to provide a normalized torsional stiffness coefficient, K_{stance} = 2.86 N-m/kg/rad [15]. As the COP moves anterior during early stance phase of the gait, the GRF vector moves anterior to the ESF axis and results in elastic extension of the mechanism about the ESF axis back to zero degrees (Fig. 3-7). An alternative approach is to make the locking member compliant in compression during early stance with the precise stiffness coefficient (K_{stance}). Our ongoing work is also exploring the design of a compliant locking member in compression, which can potentially replace the concept with an additional ESF axis and a large stiff spring (Fig. 3-7).

Based on the analysis of swing phase (Fig. 3-2), which requires two dampers of different coefficients of friction, we postulated that an extension assist spring was not necessary for accurate swing phase control. Extension assist springs have been used widely in many passive above-knee prostheses [30] for achieving resistance-free extension during swing and high-resistance flexion during late stance and early swing. Use of extension springs without sufficient damping leads to a large terminal impact at the end of swing phase [30] and is also far from the ideal in terms of kinetics, as springs do not dissipate energy. Prosthetic knee designs with extension springs commonly use viscoelastic dampers to cushion the impact at the end of swing extension, further adding to the cost and functional complexity of the product. Basing our design on theoretical analysis, we used a differential damping system in our prototype with an aim of achieving more controlled, resistance-free extension with negligible terminal impact.

3.5.2 Limitations of the study

The current prototype was found to have the following functional limitations as identified by comparison with theoretical biomechanical analysis (Fig. 3-2) and preliminary field evaluation:

1. The absence of early stance flexion-extension: There was no feature in the prototype to allow for energy storage and return during early stance, which is critical to meet the requirement of able-bodied gait during stance. This feature is being incorporated for next iteration of the prototype as discussed previously [29].

2. The current design necessitates full extension of the knee at the end of swing phase to engage the lock before stance (Fig. 3-4). Failure to lock the knee before stance can lead to unstable stance and possible buckling of the knee and fall [5,8].

3. The use of braking elements in the device could lead to variable damping as reported in some of the earlier designs [5] due to wear, changes in humidity and exposure to outdoor dust and rain.

4. During field evaluation tests, subjects found it difficult to walk on steep inclines

and climb stairs using the prototype due to the knee being locked at the beginning of stance. All subjects also deemed the loud clicking noise of the lock at the end of swing as undesirable.

5. Secondary user-needs of Indian transfemoral amputees such as squatting, cross-legged sitting were not met by this prototype.

Future work to develop this design further should take these limitations into account. Our ongoing work is focused on clinical gait data analysis of subjects using the prototype required for quantitative evaluation of our design, as benchmarked against able-bodied kinematics and kinetics of walking. Biomechanical testing of the prototype will highlight the exact deviant phases of amputee gait, which might necessitate changes in the prosthetic knee design. Experimental testing in a clinical gait lab will also establish the best use case for the prototype, which can provide an insight into the best training practices for users in developing countries. Additionally, a comprehensive cost reduction analysis needs to be done to ascertain the price of the potential product that can use a similar mechanism. For example, the preliminary prototype discussed in this chapter was primarily fabricated using aluminum 6061 alloy, which is expensive but could easily be replaced by appropriately engineered components using cheaper plastics such as Delrin, a common material used in existing passive knee prostheses in the developing world [3]. A comprehensive commercialization strategy, which accounts for selection of appropriate local manufacturing resources, design-for-manufacturing analysis and design-for-assembly analysis would also be crucial in further reducing the cost of the future product using the mechanism discussed in this chapter.

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Chapter 4

Design of a four-bar latch mechanism and a shear-based rotary viscous damper for single-axis prosthetic knees

The thesis author was the lead contributor to this body of research, which was conducted in collaboration with N. Petelina, W. B. Johnson, M. Major, and A. G. Winter, V.

4.1 Introduction

In this chapter, we present the mechanism design and preliminary testing of two distinct modules relevant to single-axis, passive prosthetic knees. This study builds upon our prior research focused on the biomechanical analysis, mechanical design, and user-centric testing of a new passive prosthetic knee for low-income amputees in developing countries [1–8].

According to a recent estimate from the World Health Organization, over 30 million people are in need of prosthetic and orthotic devices across the world [9]. Past studies have reported widespread occurrence of lower limb amputation in developing countries, with close to 300,000 above-knee amputees in India, where our research is focused [8,10,11]. The majority of above-knee amputations in developing countries are carried out due to a multitude of factors such as poor health care, lack of emergency response, unsafe work conditions, traffic accidents, and lifestyle choices [8,12,13]. Past studies have reported that about 50% of the amputees in India lose or change their jobs immediately after their amputation. The resulting economic deprivation is often exacerbated by the social stigma associated with disability and amputation [14–16]. Amputees repeatedly report the need for an inconspicuous gait to mitigate the socio-economic discrimination that they face, demanding prosthetic performance that can enable able-bodied gait kinematics [8, 11, 17]. However, only a small number of commercially available prostheses have been designed to enable able-bodied kinematics of walking among low-income amputees [12, 13]. Most of these solutions are yet to be adopted at scale due to limitations in the biomechanical performance, mechanical design, manufacturing processes, supply chain, clinical training, and maintenance [8,12,13]. There is thus an urgent need for high-performance, low-cost prostheses that can enable able-bodied gait, increase metabolic efficiency for the users, and mitigate socio-economic discrimination faced by amputees in the developing world.

In this chapter, we present the design and preliminary testing of two passive

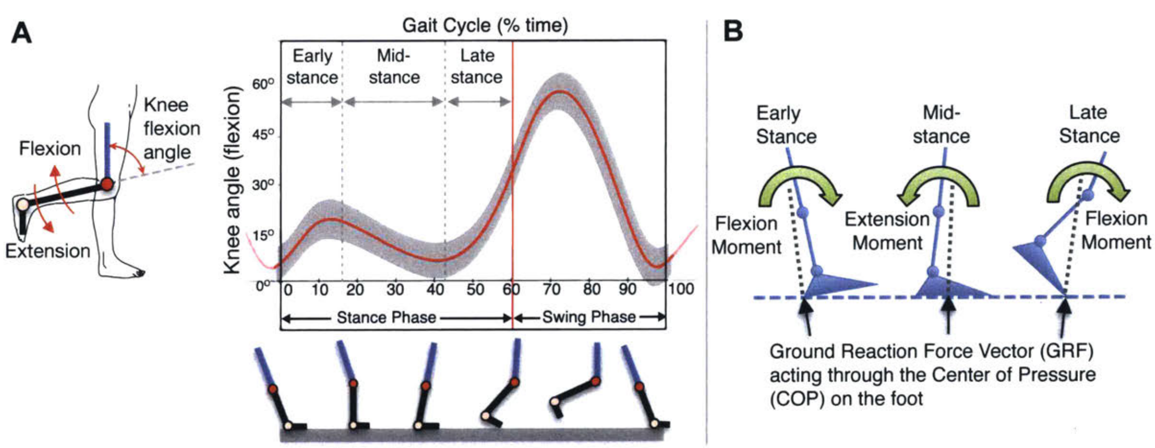

Figure 4-1: A. Able-bodied knee angle kinematics through the gait cycle (red curve), ±1 S.D. shown by the grey band. The illustration below the horizontal axis shows the corresponding leg trajectory through the gait cycle. B. The direction of torque exerted by GRF changes through stance phase due to COP progression and the relative orientation of the leg.

mechanism modules with the goal of achieving able-bodied kinematics of level-ground walking, specifically during the transition from the stance phase to the swing phase of the gait cycle. The first module, called the "stability module", is a novel latch mechanism implemented with a four-bar linkage with the specific function of achieving stability during the early stance phase and initiating timely knee flexion in preparation for the swing phase. The second module, called the "damping module", is a rotary viscous damper that can provide appropriate flexion control during the transition from the stance phase to the swing phase. These two mechanism modules offer unique advantages in achieving the desired functions of stability and damping as compared to the mechanisms that are currently being used in commercial passive knee prostheses. Additionally, these modules involve novel implementation of mechanisms that can be readily integrated into the architecture of existing single-axis prosthetic knee units without major mechanical alterations.

This chapter is organized in three parts. First, we present the mechanism design of the stability module and the damping module (in separate sections). Second, we report the experimental protocol and the validation results from the testing of a fully functional prosthetic knee prototype on a single above-knee amputee in India. The two modules were integrated into the prototype for testing. Finally, we discuss the modular adaptability, clinical implications, and limitations of the two modules.

4.2 Stability module: Four-bar latch

4.2.1 Stability in the prosthetic knee function

The gait cycle of able-bodied level-ground walking for each leg can be divided into the stance phase and the swing phase (Fig. 4-1A). During stance, the foot is in contact with the ground. The corresponding interaction force between the foot and the ground is the ground reaction force (GRF) and the point of application of GRF is the center of pressure (COP). The knee flexion angle is less than 20° during early-stance to mid-stance. During the transition from stance to swing, the foot takes off from the ground and reaches a peak knee flexion of about 64° during mid-swing, followed by an extension back to zero degree at the end of swing (Fig. 4-1A) [18,19]. The foot comes in contact with the ground again at the end of the swing phase (called "heel strike"), which begins the stance phase of the next gait cycle.

As the COP progresses from the heel towards the toe during able-bodied walking, the GRF vector exerts a flexion torque at the knee during early stance, an extension torque during mid-stance, and a flexion torque during late stance (Fig. 4-1B) [20]. In an able-bodied human, the large flexion torque exerted by the GRF at the knee during early stance is stabilized by the physiological knee musculature exerting an opposite extension torque, which peaks at an average of 0.7 N-m/kg (normalized to body mass) [21]. In an above-knee amputee, if the prosthetic knee joint does not provide this counter torque, it can collapse due to uncontrolled knee flexion and cause the amputee to fall during early stance (referred to as "buckling" of the knee joint). During mid-stance, the prosthetic knee is safe against buckling as the direction of torque changes to extension. During late stance, the torque changes again to a flexion torque due to the anterior position of the physiological hip with respect to the foot, which helps the knee flex up to 40 degrees before transitioning into swing (Fig. 4-1A). At the end of swing phase, the physiological knee extends back to zero degrees without going into hyperextension.

During early stance, the most critical function of a prosthetic knee joint is to provide stability and prevent buckling. During late stance, controlled instability or a free joint with some damping is required to achieve flexion in the prosthetic knee, which helps the leg transition to swing phase. An ideal prosthetic knee seeks to provide both these functions, which are in conflict with each other due to the opposite nature of the desired mechanical response. However, both these functions are crucial to replicate able-bodied knee kinematics in amputees (Fig. 4-1A). Active prosthetic knees achieve this dual function efficiently by using electromechanical actuators and sensors, which can be controlled precisely by a programmable microprocessor [19]. However, to achieve the same in passive prosthetics is challenging and often requires a compact implementation of complex mechanisms [19,22,23].

Different mechanisms have been designed to achieve this tradeoff between stability during early stance and controlled flexion during late stance. Most affordable, passive prosthetic knee mechanisms designed for the developing world prioritize stability over achieving timely and optimal late stance flexion [13, 19, 24]. This prioritization is driven by the need to prevent accidental falls due to buckling [23]. The prevention of buckling in the passive knee mechanisms designed for the developing world can be analyzed using flexion zone diagrams (Fig. 4-2).

The Jaipur exoskeleton knee (Fig. 4-2A) is a single-axis knee with a large flexion zone, which necessitates the use of a mechanical lock at all times to prevent the knee from buckling [25]. This hyper-stability against buckling prevents any flexion at the knee during stance or swing. The amputee is forced to employ an undesirable "peg-leg" gait, which involves circumduction and vaulting of the prosthetic leg to clear the ground during swing.

Polycentric knees, such as the Jaipur four-bar knee (Fig. 4-2B), use a four-bar linkage to create a virtual knee axis, which is posterior to the anatomical knee axis [11, 23]. This virtual posterior shift of the knee axis prevents buckling during early stance as the GRF vector causes a stable extension torque about the virtual knee

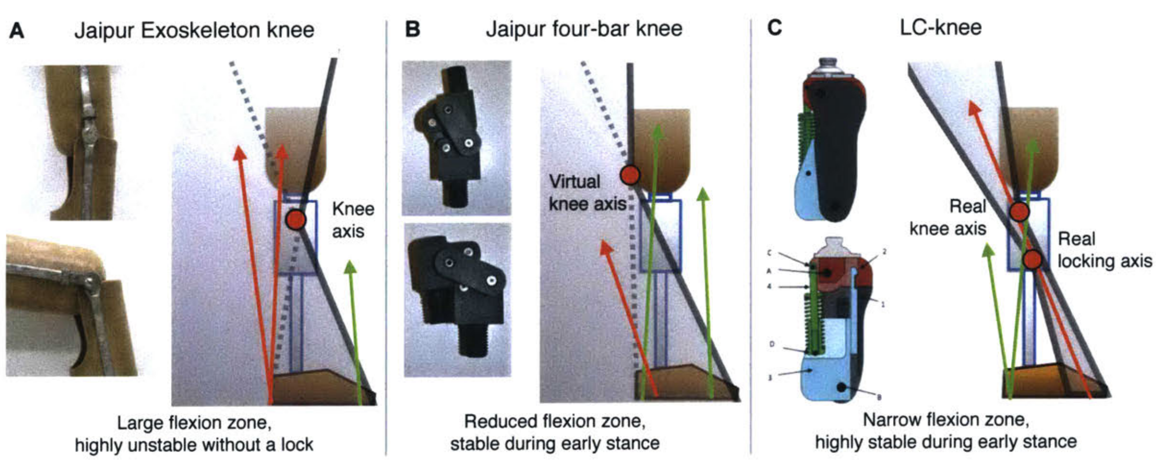

Figure 4-2: Flexion zone diagrams for passive prosthetic knee mechanisms specifically designed for the developing world. Flexion zone is shaded in grey. Vectors in red show the GRF orientation that falls within the flexion zone and can cause the knee to buckle during early stance. Vectors in green show the GRF orientation outside the flexion zone that will keep the knee stable and locked in full extension.

axis, keeping the knee locked at full extension (equivalent to zero degrees of flexion). The resulting flexion zone is smaller in area compared to the exoskeleton knee, which makes the polycentric design more stable. During late stance, the virtual axis is shifted continuously in the anterior direction by opening up the four bar linkage, achieved by conscious exertion of a flexion torque from the amputee hip. The anterior shift of the virtual axis also aids the flexion torque from GRF, which enables knee flexion in late stance. Although the four-bar polycentric mechanism prevents hyper-stability, it can still delay flexion and cause an untimely transition from late stance to swing, resulting in a conspicuous, asymmetric gait.

The LC-knee (Fig. 4-2C) mechanism achieves the dual functionality efficiently in a single-axis knee architecture [20]. It provides a narrow band of flexion zone by implementing a latch mounted on a physical locking axis. This latch is biased to keep the knee locked during early stance, reinforced by the flexion torque exerted by GRF about the locking axis. The latch unlocks during mid-stance due to the extension torque of GRF, which frees up the knee for flexion much earlier compared to the polycentric mechanism. However, the flexion zone in the LC-knee is a very narrow band, which requires the amputee to actuate flexion by consciously orienting the GRF within this narrow band using the hip. Additionally, the LC-knee may also lead to hyper-stability during walking on slopes and inclines due to the narrow band of flexion zone around the knee joint.

4.2.2 Mechanism design and operation

We present a novel mechanism of the stability module, which was designed to achieve the dual function of stability during early stance and controlled instability that allowed knee flexion during late stance. The mechanism of this module was implemented by a latch mounted on a four-bar linkage with a low and distal virtual locking axis, which widened the flexion zone near the knee but kept it narrow near the foot.

The main components of the mechanism include (Fig. 4-3A,E): (i) the knee piece, which is connected proximally to the socket and rotates about the knee axis (KA), (iii) the links of the four-bar mechanism that are mounted on the body frame of the

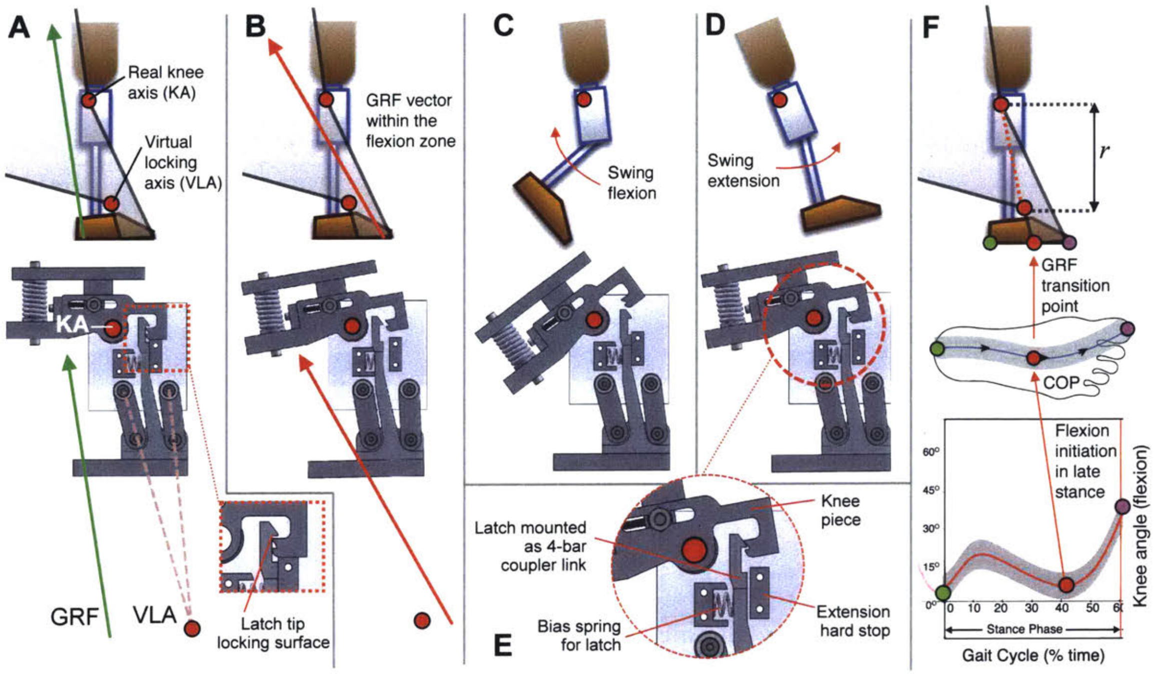

Figure 4-3: Operation of the stability module mechanism through the gait cycle (A-D). A. Early stance: The knee piece is locked, the latch is engaged, and the GRF vector reinforces the latching action between the latch tip and the knee piece. The spring in the knee piece was incorporated to enable flexion-extension of about 10°-20° as discussed in chapter 3. B. Late stance: The GRF vector is oriented in the flexion zone, the latch is disengaged and flexion can be initiated. C. Swing phase flexion: The latch is ready to be engaged. D. Swing phase extension: The latch engages with the knee piece at the end of swing. E. The inset shows a close-up of the latch tip interaction with the knee piece during locking at the end of swing. F. The GRF transition point is the point at which the latch is disengaged, which was chosen to coincide with COP that corresponds to initiation of knee flexion in able-bodied walking.

mechanism and create a virtual locking axis for the latch, (ii) the latch, which serves as the coupler link for the four-bar linkage. The latch is connected distally to the pylon and proximally to the body shell of the mechanism (through the four-bar linkage). Additionally, there is a hard stop that limits the rotation of the knee piece and the latch beyond zero degrees, preventing any hyperextension. The stepwise operation of the stability module at key points during the gait cycle is described with a sectional view of the mechanism (Fig. 4-3A-D).

The latching mechanism involves four major steps, the first two occurring during stance and the latter two occurring during swing:

1. Locked position (Fig. 4-3A): As the amputee's heel strikes the ground during early stance, the mechanism experiences a GRF flexion torque about the knee axis. The latch is in a pre-locked position due to the pre-loaded bias spring. Buckling is prevented by the mechanical engagement of the proximal knee piece with the latch tip. The locking action is also reinforced by the flexion torque about the virtual axis of the four-bar linkage, which ensures that the latch remains engaged against the knee piece during early stance.

2. Latch unlocking (Fig. 4-3B): During mid-stance, the amputee rolls over on the foot and the GRF vector moves anterior to the knee axis and the virtual axis. The proximal knee piece experiences an extension torque about the knee axis, which disengages it from the latch tip and also presses it against the hard stop. The latch also experiences an extension torque about the virtual axis, which allows it to move freely backwards (through the four-bar linkage) compressing the bias spring. With the latch in the unlocked position, the knee is made free to initiate flexion. The knee flexes under a GRF flexion moment during late stance, as the GRF vector passes through the flexion zone, which is the area posterior to the knee axis and anterior to the locking axis.

3. Latch repositioning (Fig. 4-3C): Once the knee has flexed through late stance and swing has been initiated, there is no GRF torque on the four-bar linkage. The restoring force from the bias spring returns the latch to the forward position, ready to lock again at the end of swing.

4. Latch relocking (Fig. 4-3D): As the lower leg and foot swing forward to extend the knee at the end of the gait cycle, the knee comes down on the latch tip, pushing it back against the spring until the knee has extended far enough to allow the restoring spring force to relock the knee. In the relocking step (Fig. 4-3E), there is a unique feature in the knee piece that allows for relocking at two different points, referred to as a double latch. This feature allows the mechanism to lock at an intermediate point before reaching full extension (designed to be at 10° of knee flexion). This feature prevents accidental buckling as it ensures

that the knee will lock even if the amputee does not fully extend the knee before heel strike of the next gait cycle, as may happen while walking up inclines.

A fully functioning prototype of the stability module mechanism was built using CNC machined parts. Finite element analysis of the latch under maximum flexion moment from GRF informed the safety factor and material selection of the latch. Aluminium 7075 alloy was used to achieve a safety factor of 1.2 in the latch for the maximum flexion moment during stance exerted by an amputee with 100 kg body mass. Aluminium 6061 alloy was used for the rest of the parts in the assembly. To prevent fatigue-induced failure, the prototype was not subjected to more than a few hundred cycles of loading during human subject testing. Therefore, fatigue analysis was not performed to account for the failure modes due to the cyclic loading of the mechanism.

Placement of the virtual locking axis

In a normal gait cycle, the COP moves continuously on the foot from the heel to the toe during stance (Fig. 4-3F). The COP location and the corresponding orientation of the GRF vector in space was deterministically used to unlock the latch at the desired instance in the gait cycle, called the GRF transition point. In order to replicate the able-bodied knee kinematics through stance, the GRF transition point was chosen at the COP that corresponds to the initiation of late stance flexion in an able-bodied knee (Fig. 4-3F) [21]. As the COP passes through this selected GRF transition point, it was desired that the latch would go from being locked to unlocked, which would allow the knee to flex into swing.

To ensure this timely unlocking of the latch at the GRF transition point, the position of the locking axis was constrained to the line connecting the GRF transition point and the knee axis (Fig. 4-3F). The final location of the locking axis along this line was made with the additional goal of minimizing hyperextension. Hyperextension results in a small backward wobble that the amputee feels as the latch unlocks during mid-stance extension. The relationship between the hyperextension angle and unlocking movement of the latch was modeled by a simple angle-arc length relationship:

$$s = r\theta \tag{4.1}$$

where s is the latch movement when it unlocks, r is the vertical distance between the knee axis and the locking axis (Fig. 4-3F), and θ is the hyperextension angle at the knee. Amputees were able to distinctly feel 3° of hyperextension in the earlier prototype of the mechanism that implemented a physical locking axis [3]. In this mechanism, less than 1° of hyperextension was desired to minimize the backward wobble for the amputee. Since the latch movement was set at 5 mm (from design), the virtual locking axis was therefore located 30 cm distal to the knee axis for a typical amputee [21], which was realized using the four-bar latch. A low, distal locking axis was therefore implemented to reduce hyperextension. Additionally, this maximized the area of flexion zone at the knee while keeping it narrow near the foot. This flexion zone can allow a wider orientation of GRF vectors in the toe region to flex the knee during late stance without compromising stability during early stance.

4.2.3 Advantages over prior art

The stability module mechanism offers distinct mechanical advantages over prior art:

1. The locking axis could be implemented either through a physical axis or through a virtual axis using a four-bar linkage. The physical axis uses fewer parts but requires a longer body shell to place the locking axis sufficiently away in the distal direction (implemented in the LC-knee [20]). The choice of a virtual axis implementation using a four-bar linkage allowed flexibility in placing the locking axis distally further with a more compact mechanism as compared to the LC-knee.

2. The mechanism provides an optimal flexion zone by widening the flexion zone near the knee while maintaining a narrow flexion zone near the foot. This layout of the flexion zone allows for easy flexion during late stance without

compromising on stability during early stance. This was made possible due to the low, distal location of the virtual locking axis enabled by the four-bar linkage. Additionally, this distal location also minimized the hyperextension angle at the knee.

3. We used a geometric method to compute the location of the virtual locking axis, which informed its precise location. In the clinical context, this knowledge of the exact location of the locking axis in space can help the prosthetist easily align the prosthetic knee with respect to the prosthetic foot. The relative position of the foot and the knee could be manipulated systematically by the prosthetist to further widen or narrow the flexion zone available to the amputee.

4.3 Damping module: Rotary viscous damper

4.3.1 Damping in the prosthetic knee function

Damping in prosthetic knees is primarily required to decelerate the flexion of the knee during the transition from stance to swing. This transition starts in late stance and ends in mid-swing with a average peak knee flexion of around 64°(Fig. 4-4A) [18]. A smaller amount of damping is also required to control the knee extension in late swing before the stance phase of the next gait cycle.

In the absence of sufficient damping during knee flexion, the prosthetic knee can overshoot well beyond the peak flexion of the knee required for ground clearance, delaying the swing phase for the prosthetic leg. Conversely, if the damping torque is greater than the optimal value, the knee does not flex enough, which can force the amputee to employ alternative strategies to achieve ground clearance in swing such as hip-hiking, vaulting, and circumduction [26]. Such asymmetric gait patterns between the able-bodied leg and the amputated leg are undesirable, as they can increase the metabolic energy expenditure [26]. Additionally, in the context of developing countries such as India, the focus on achieving able-bodied gait behavior has been shown to be one of the most important design requirements for amputees [8, 17].

A wide array of prosthetic knees have been designed to provide damping control of knee flexion in late stance and swing. Primarily designed for amputees in developed countries, popular knee prostheses have incorporated fluid-based (pneumatic or hydraulic) systems, which can be controlled passively, or through programmable, microprocessor-controlled actuators that deliver high performance [19,27]. Affordable prosthetic knee joints designed primarily for the developing world have incorporated passive friction brakes that provide fixed resistance during flexion [27]. The implementation of friction brakes is commonly achieved through the use of bolts with adjustable pre-load. This technique is simple and cost effective but presents many practical challenges. The friction torque changes with continued usage due to wear and changing environmental conditions, such as humidity or rain [4]. Moreover, friction brakes provide constant resistance, which makes them unresponsive to changes in walking speed. The damping torque required in a prosthetic knee changes appreciably with walking speed [19, 28].

In prosthetic technology, the most common passive architecture of fluid-based dampers is the hydraulic cylinder. It commonly incorporates a piston to push a viscous oil between two chambers through a small orifice with adjustable diameter [29,30]. This architecture borrows from the prevalent design of hydraulic cylinders in other hardware industries (automotive vehicles, construction technology, consumer goods etc.) [31]. Hydraulic dampers have been preferred over friction brakes as they offer smooth, speed-based resistance. However, hydraulic cylinders in prosthetics are expensive, heavy, and require periodic maintenance to prevent oil-leaks [27]. Mechanical integration of hydraulic cylinders about a rotating knee joint requires an additional linkage, which makes the prosthetic assembly bulky and heavy. The resistive force offered by hydraulic cylinders is proportional to the square of piston velocity (piston velocity changes linearly with walking cadence). This non-linear relationship is relevant for a small fraction of amputees who can change their walking speeds over a large range (1-1.8 m/s) [19]. However, most amputees walk slower and require resistance that is only linearly proportional to small changes about their preferred walking speed (0.8-1.2 m/s) [29, 30].

In order to address the limitations of traditional hydraulic dampers, we present the design and testing of a rotary viscous damper that is compatible with low-cost, single-axis prosthetic knees. This damper provides torque that is linearly dependent on walking speed by implementing a shear-driven, first-order resistance to fluid flow. Additionally, the rotary architecture enables easy assembly of the damper in the existing architecture of low-cost, single-axis prosthetic knee units.

4.3.2 Target damping coefficient

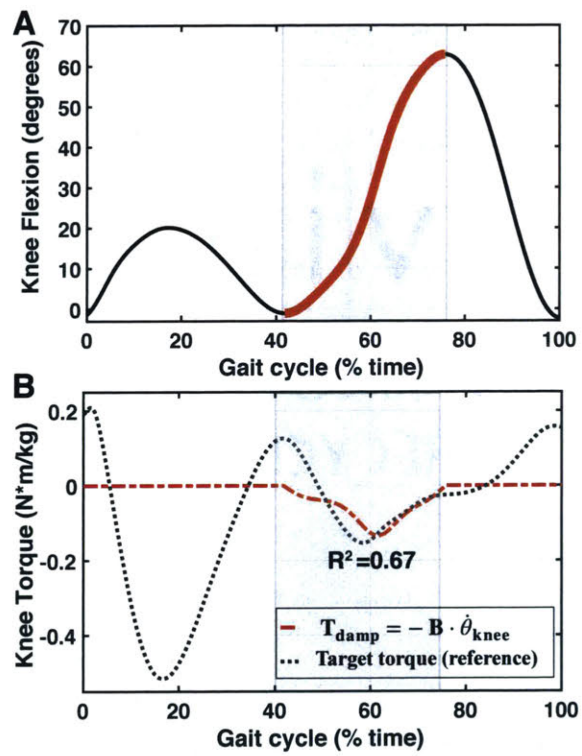

Figure 4-4: A. Knee flexion data for a below-knee amputee using a passive prosthetic foot [32–34]. The damping zone of interest is highlighted. B. Target knee torque was used to estimate the optimal damping torque in the damping zone (T_{damp} in Eq. (4.2)).

As a first step towards designing the damping module, the target damping coefficient was computed. Reference gait data from a transtibial (below-knee) amputee were used and the computation was performed by inverse dynamics and optimization, in accordance to the methods presented by Narang et al [1, 2]. A brief summary is presented here.

Knee kinetics (torque) and knee kinematics (flexion angle and angular velocity) data collected from a below-knee amputee walking at self-selected speed on level-ground were used as reference targets (Fig. 4-4). Data from a below-knee amputee was used to account for the influence of the passive prosthetic foot on the physiological knee [32–34]. It has also been shown that the knee kinematics of below-knee amputees are nearly identical to able-bodied values, despite changes in the knee kinetics due to the prosthetic foot [34].

A rotary viscous damper was modeled to engage at the knee during the transition from stance to swing. The corresponding section of the knee flexion curve is highlighted in Fig. 4-4A, hereby referred to as the "damping zone" of the gait cycle. The rotary hydraulic damper acting at the knee was modeled as an ideal, first-order, shear-based viscous damping element, formulated mathematically as

$$T_{damp} = -B \cdot \dot{\theta}_{knee}, \tag{4.2}$$

where T_{damp} is the damping torque (N-m), expressed as the product of the reference knee angular velocity over the damping zone, $\dot{\theta}_{knee}$ (rad/s), and B, the damping coefficient (N-m/rad/s).

In order to estimate the optimal damping coefficient, the damping torque T_{damp} profiles were computed for a range of damping coefficients (0 - 5 N-m/rad/s) using Eq. (4.2) and Fig. 4-4. Over the damping zone, each T_{damp} profile was compared with the reference knee torque. The damping torque profile with the highest coefficient of determination (R^2) was selected (Fig. 4-4B). The corresponding damping coefficient was identified as the optimal damping coefficient, $B_{optimal}$. The value of $B_{optimal}$ was found to be in the range of 0.5 - 2 N-m/rad/s for amputees with body masses ranging between 60 - 90 kg [2]. This range of $B_{optimal}$ served as the target range of damping coefficients to be achieved through the mechanism design of the damping module.

4.3.3 Mechanism design and operation

The damping module was constructed to generate a high damping torque by shearing a thin film of high viscosity silicone oil. The principle of shearing a thin film of fluid to generate a high braking force has been used widely across many industries in different mechanical embodiments. Common examples include automotive viscous couplings, engine vibration dampers, tripod joints, and press brakes. [35, 35, 36]. In active knees, the magnetorheological (MR) fluid damper has been implemented in the shear-mode for low-speed walking [37–39]. However, this principle has not been explored in passive prosthetic knees due to the widespread adoption of traditional cylindrical and rotary hydraulic dampers.

The detailed construction of the rotary damper prototype is illustrated in Fig. 4-5. The damping torque is generated by shearing a highly viscous liquid trapped between the stator plates and the rotor plates, which are ring-shaped plates that are coaxially stacked about the knee axis. The stator plates are coupled to the cylindrical housing by four projecting tabs on the outer edge, which mesh into the keyways on the inner circumferential wall of the housing (Fig. 4-5A). The rotor plates are coupled to the rotating shaft of the prosthetic knee by four projecting tabs on the inner edge, which mesh into the keyways on the rotor clutch. This coupling ensures that the rotor plates turn along with the prosthetic knee shaft, as the knee rotates in flexion. The housing is static relative to the rotating shaft as it is rigidly coupled to the prosthetic knee assembly (Fig. 4-5C). Spacers of specific height are placed between the consecutive stator and rotor plates. The small gap between the neighboring plates is fully filled with viscous liquid (Fig. 4-5B). As the knee flexes, the rotor plates rotate with respect to the stator plates, shearing the viscous liquid in between. The resulting damping torque between the neighboring stator-rotor plate combination is quantified by the following relationship, derived by integrating the viscous shear stress caused by Couette flow of the liquid along the annular area of the plates [40]:

$$B_{plate} = \frac{T_{damp}}{\dot{\theta}_{knee}} = \frac{\pi\mu}{2t}(R_2^4 - R_1^4), \tag{4.3}$$

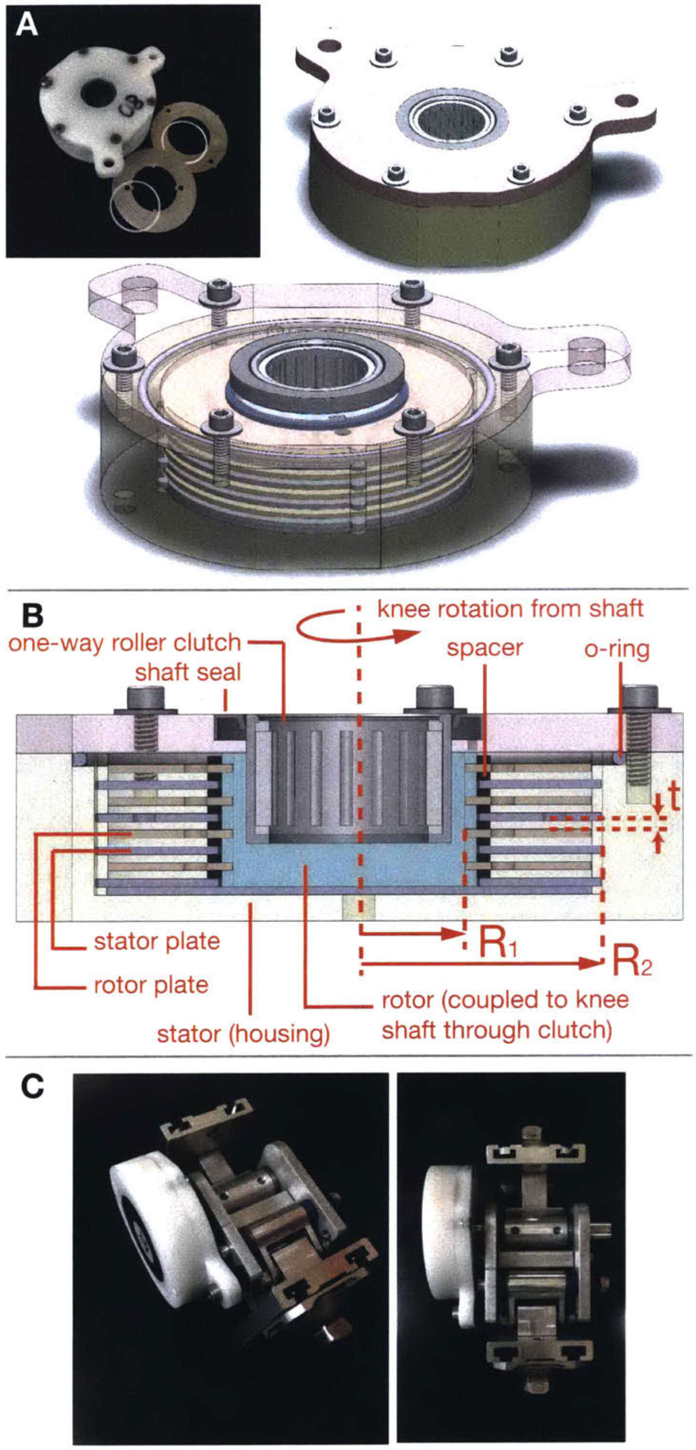

Figure 4-5: Design of the damping module: A. Prototype: photograph and CAD of the final assembly. The stator plates, rotor plates, and spacers are shown in the photograph. B. Cross sectional view of the prototype. Silicone oil is entrapped between the rotor and stator plates. C. The damping module was mounted coaxial to the prosthetic knee axis, as shown. The damper housing was bolted to the shell of the prosthetic knee to provide rotational constraint.

where B_{plate} is the resultant damping coefficient, T_{damp} is the viscous damping torque, $\dot{\theta}_{knee}$ is the angular velocity of the knee joint, μ is the dynamic viscosity of the fluid, t is the thickness of the gap between the stator plate and rotor plate, R_2 is the outer radius of the stator or rotor plate annulus, and R_1 is the inner radius of the stator or rotor plate annulus. These variables are annotated in Fig. 4-5B.

The total damping torque for multiple neighboring stator-rotor plates, as illustrated in Fig. 4-5, is

$$B_{total} = (2n) \cdot B_{plate}, \tag{4.4}$$

where n is the number of rotor plates stacked between two neighboring stator surfaces; $n = 4$ in Fig. 4-5B.

The housing and the housing cap of the damper prototype were machined out of Polyacetal (Delrin). The stator and rotor plates were made using Aluminum 7075 alloy sheets (Fig. 4-5A). The spacers placed between the stator and rotor plates were made out of precision shim stock of Polyacetal (+/- 25 microns tolerance). The rotor plates were coupled to a one-way roller clutch, which in turn was coupled to the rotating knee shaft (Fig. 4-5B). The one-way roller clutch ensured that damping was enabled only within the damping zone. During knee extension, there was no damping torque generated and the knee shaft rotated freely within the roller clutch. The viscous fluid used in the damper consisted of Polydimethylsiloxane, a silicone oil with a very high kinematic viscosity of 100,000 centistokes. The dynamic viscosity of the oil is 100 Pa-s; for comparison, the dynamic viscosity of water is 1 mPa-s. The oil displays a characteristic shear thinning behavior, with the apparent reduction in viscosity as the shear rate increases. To account for this dynamic change in viscosity, the damping torque calculation was adjusted based on the shear-thinning data provided by the manufacturer [36].

The prototype was assembled in multiple stages. Starting from the bottom surface of the housing, a stator-rotor plate pair was stacked between the housing and the rotor (concentric to the knee axis). A small, incremental volume of viscous oil was then injected into the housing sufficient to fill up the space between the plates. The prototype was then placed in a vacuum chamber to minimize the entrapment of air bubbles in the oil. Two small, diametrically opposite holes were also incorporated in the plates to facilitate complete filling of the space between the plates (the oil was injected from the top). This process was repeated in vacuum for each addition of stator-rotor plate pair in the stack. After all the plates were installed with oil between them, the fully assembled stack was sealed off with an O-ring between the housing and the cap, which was bolted on top of the housing. A rotary shaft seal was incorporated between the rotating assembly and the stationary housing (Fig. 4-5B).

Two prototypes of the damping module were built with five and six pairs of rotor-stator plates respectively ($n=5$ and $n=6$, $R_2 = 30$ mm, $R_1 = 17.5$ mm, and $\mu = 100$ Pa-s). The average damping coefficients for the two prototypes were 1.11 N-m/rad/s and 1.33 N-m/rad/s, respectively, as calculated using Eq. (4.3) and Eq. (4.4). These damping coefficients were close to the median of the target range of optimal damping coefficients, as laid out in the previous section (0.5 - 2 N-m/rad/s).

4.3.4 Damper characterization

The theoretical model for the design of the damper prototypes (Eq. (4.3) and Eq. (4.4)) was investigated by a damper tester built specifically for the empirical characterization of the torque-velocity relationship of the two damper prototypes (Fig. 4-6A). A velocity-controlled DC motor (VexRobotics) was used to apply a constant velocity profile to the damper and a magnetic encoder was used to record and control the angular velocity. A load cell (Omega Engineering LC101-250) measured the force experienced by the damper at a fixed lever length. The velocity control and the data collection were performed on a Visual Basic platform supported by VexRobotics. This tester was first validated with two commercially available viscous dampers (ACE controls FDT-57 and FDT-63 [41]). The experimentally measured torque-velocity relationship matched the values provided by the data sheet for both the commercial dampers within an error margin of +/-0.5 N-m (<10% of damping magnitude).

The two damper prototypes ($n = 5$ and $n = 6$) were characterized on the tester.

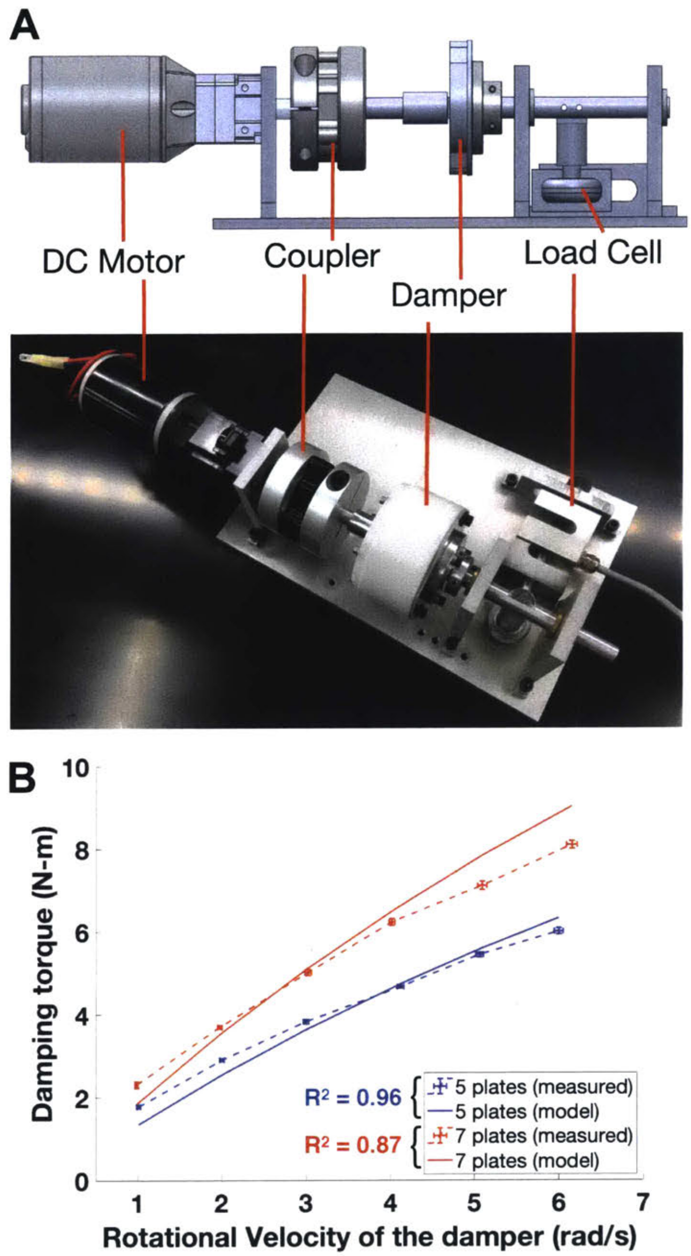

Figure 4-6: A. Damper tester used for torque-velocity characterization of the damper prototype. The housing of the damper prototype is connected to a load cell through a lever arm to measure the torque, and the shaft is driven by the velocity-controlled DC motor. B. The measured damping torque for 0 - 6 rad/s from the tester matched the model based prediction closely

In order to map the torque-velocity relationship, the motor was used to apply five different constant angular velocity profiles. These five values were chosen at equal intervals between the minimum (0 rad/s) and the maximum angular velocity (6 rad/s). This range was chosen based on the range of knee angular velocities observed in the gait of able-bodied people [21]. At each value of the chosen constant velocity, a total of ten rotations were completed and the damping torque was recorded continuously through the load cell. The average damping torque was computed for each of these five values of angular velocities, along with the corresponding standard deviation.

The results from the torque-velocity characterization of the two prototypes showed that the experimentally measured damping coefficients followed the model prediction well, with R^2 values of 0.96 (5-plate damper) and 0.87 (6-plate damper) (Fig. 4-5B). The average damping coefficients of the two prototypes across the velocity range were within 2% of the modeled average values. Overall, the data matched the model well (within 10%) at higher angular velocities and showed a higher difference at lower speeds (within 30%). The difference between the measured coefficients and the modeled values could be attributed to a combination of factors such as changes in the gap between the stator and rotor plates due to the tolerance stackup or wear, changes in viscosity due to heat generation, and uncertainty in the viscosity value of the oil. The viscosity of the oil was only accurate to within $\pm 10\%$ of the nominal value, as specified by the manufacturer. Overall, the theoretical model was found to be a useful design tool for sizing the damper prototypes accurately.

4.4 Preliminary testing on an above-knee amputee

A prototype prosthetic knee was assembled by integrating the stability module and the damping module (Fig. 4-7B). The primary goal of the preliminary experimental trial was to investigate the basic functionality and safety of the prototype in the real-life scenario of level-ground walking with the full magnitude of GRF exerted on the knee mechanism by an above-knee amputee (Fig. 4-7).

4.4.1 Experimental protocol

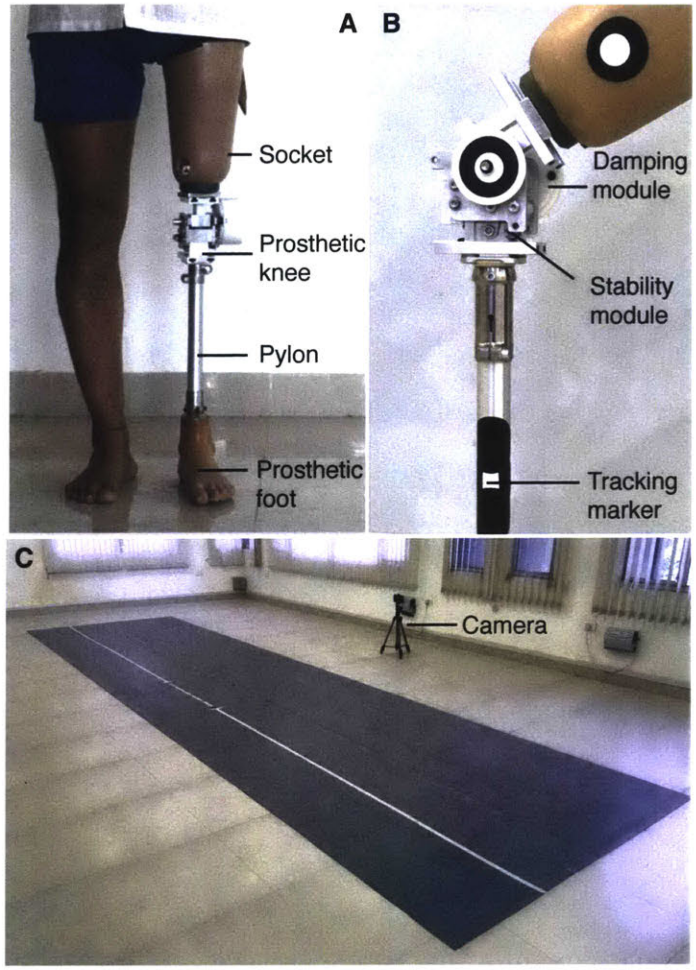

Figure 4-7: Preliminary testing on a single above-knee amputee in India: A. The prosthetic leg assembly. B. Both the modules were assembled and tested together C. The indoor walking track used for walking trials. Each trial was recorded using an iPhone camera at 240 frames per second. [4] .

The experimental trial was conducted at the Jaipur-foot clinic in Jaipur, India [25]. The MIT Committee on the Use of Humans as Experimental Subjects and the Jaipur-foot clinic approved the experimental protocol. One male, above-knee amputee was recruited as the subject for the study (body mass 75 kg, Body Mass Index 25.8) (Fig. 4-7). The subject had more than three years of walking experience with a polycentric prosthetic knee joint (Jaipur 4-bar knee) and a single-part passive prosthetic foot made by the Jaipur-foot clinic. Three different damping conditions (no damping, 5-plate damper, and 6-plate damper) were tested in three separate walking trials. A stepwise summary of the protocol is presented here:

1. Fitment: The prosthetic leg was assembled with the prototype prosthetic knee and the single-part prosthetic foot made by the Jaipur-foot clinic (Fig. 4-7A,B). The pylon length was adjusted based on the subject's height and the existing socket used by the subject was used for fitment. The on-site prosthetist at the clinic conducted the fitment.

2. Training: After the fitment, the subject was trained to walk with the prosthetic leg for ten minutes with the support of safety rails. The goal of this exercise was to train the subject to use the stability module correctly by trying to initiate timely knee flexion and transition safely from stance to swing. After the subject felt confident, the safety rails were removed and the subject walked freely on level-ground without any support for about ten to fifteen minutes at a relaxed cadence. The prosthetist observed for any conspicuous gait deviations that could be corrected by changing the alignment of the prosthetic knee and the prosthetic foot.

3. Trials: Three indoor walking trials were conducted with each trial involving level-ground walking for at least 5 minutes. The subject was asked to walk back and forth on a straight track of 15 m length (Fig. 4-7C). In each trial, the stability module remained the same but a different damping condition was tested. Three different damping conditions were tested sequentially: no damping, 5-plate damper, and 6-plate damper respectively. The subject was asked to walk at a comfortable, self-selected speed during each trial. The order of damping conditions was not revealed to the subject.

4. Data collection: Video of each walking trial was recorded using an iPhone camera at 240 frames per second. The camera was mounted on a tripod, parallel to the walking track (Fig. 4-7C). Flat white circular markers with a black background were used on the socket, knee joint and the pylon (Fig. 4-7B). The motion of these markers were used to track and determine the knee angle using

a motion tracking software [42]. The peak knee angle during each recorded step was computed and averaged over the trial. At least five steps were recorded during each walking trial.

5. Feedback: Each trial was monitored by the on-site prosthetist for safety. At the end of each trial, the subject was interviewed with open-ended interview questions designed to elicit qualitative feedback. After the completion of the three trials, the stability module and the two dampers were visually inspected for any signs of wear, mechanical failure, and oil leakage.

4.4.2 Results

Stability module

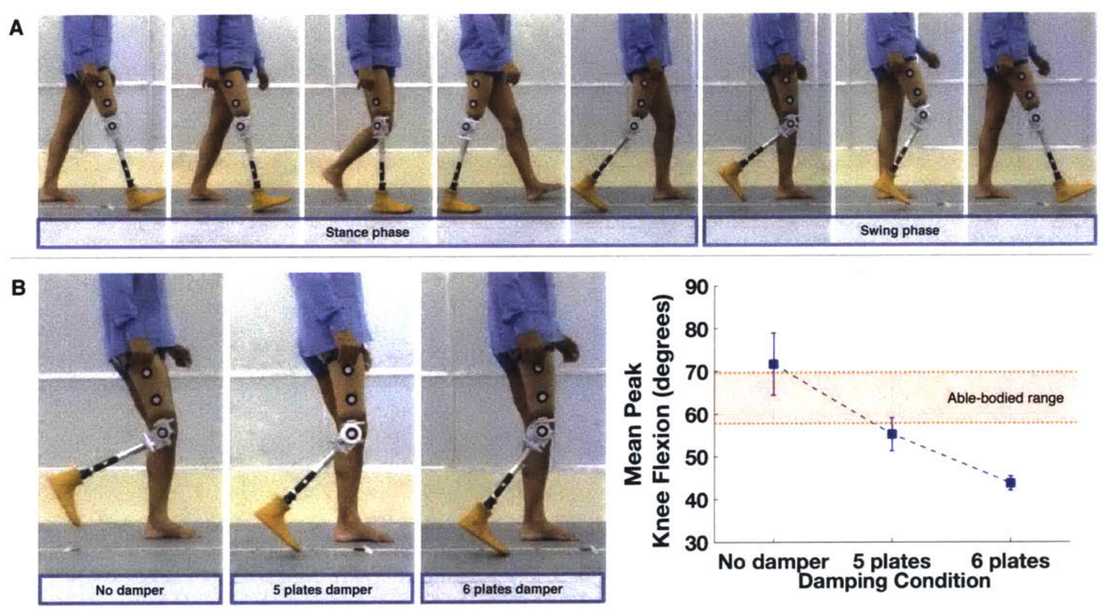

Figure 4-8: Results from preliminary testing. A. Subject walked comfortably on level-ground, snapshots through a full gait cycle are shown for the first walking trial (read left to right). B. Snapshots of the peak knee flexion angle in the swing phase for the three walking trials. The mean peak knee flexion angle decreased with the increase in the damping coefficient. The damping coefficient could be tuned to achieve able-bodied range of peak knee flexion (shown in the shaded band)

The subject was able to use the latch mechanism efficiently during the training period. The stability module functioned as expected, enabling smooth stance to swing transition while allowing the knee to flex during late stance (Fig. 4-8A) . No stumbles were observed during the three walking trials. Inspection of the mechanism after the trials showed no signs of mechanical failure.

In the feedback interview, the subject reported "smooth and intuitive" control and appreciated the locking feature of the stability module. In comparison to the polycentric knee that the subject had been using, the subject reported a "greater sense of safety" during early stance. The subject expressed a strong disapproval of the loud, clicking noise of the latching mechanism and emphasized the need to have an aesthetically pleasing cosmesis to cover the mechanism of the prototype.

Damping module

Each of the three damping conditions had a direct effect on the peak knee flexion angle achieved by the amputee during the walking trials (Fig. 4-8B):

1. In the first walking trial, no damper was incorporated in the prosthetic knee and the average peak knee flexion was 71.7 $\pm 7.3°$(S.D.).

2. In the second walking trial, the 5-plate damper prototype was used. The damper had an average damping coefficient of 1.10 N-m/rad/s, as characterized by the damper tester. The average peak knee flexion angle was 55.2 $\pm 3.9°$.

3. In the third walking trial, the 6-plate damper was used, which had an average damping coefficient of 1.32 N-m/rad/s. The average peak knee flexion angle was 43.7 $\pm 1.6°$.

In the feedback interview, the subject reported discomfort in initiating flexion due to "heavy resistance" in the third walking trial with the 6-plate damper. The subject was not able to perceive any significant difference between the no damping condition and 5-plate damper. The dampers were visually inspected after the walking trials. No conspicuous signs of mechanical failure or leakage were found.

4.5 Discussion

4.5.1 The effect of damping on peak knee flexion

The results from preliminary testing of dampers on the above-knee amputee subject showed a clear trend (Fig. 4-8B). An increase in the first-order damping coefficient led to a significant decrease in the peak knee flexion during swing. Multiple studies have reported a similar trend for traditional hydraulic dampers and friction-based dampers. In the no damping condition, the peak knee flexion was slightly higher than the able-bodied range. The average peak knee flexion in the able-bodied population is around $64 \pm 6°$ [18]. The 5-plate damper achieved knee flexion closer to the able-bodied range. With the 6-plate damper, the knee flexion was much smaller than the able-bodied target. These results clearly indicate the importance of damping during late stance and swing phases of walking. With the appropriate magnitude of first-order damping tuned for each amputee, knee flexion in the able-bodied range can be achieved.

4.5.2 Mechanism innovation

The combination of the two mechanism modules presented in this chapter address the mechanical limitations of existing passive prosthetic knees designed for low-income amputees in the developing world. With the advent of active lower-limb prostheses in the developed world over the last two decades, a majority of studies in lower limb prosthetics have focused on the optimization of electromechanical systems to achieve better clinical outcomes for amputees. Over the same time period, fewer innovations have been commercialized in passive, low-cost prosthetics [11–13]. A large fraction of amputees in the developing world cannot afford the active prosthetic technology being developed for the high-income, insurance-driven markets of Europe and the Americas [25]. The stability and damping modules offer high-performance, passive solutions towards improving amputee kinematics, with the eventual goal of ameliorating the socioeconomic deprivation resulting from amputation among low-income amputees.

The study incorporated novel mechanism designs in both modules that were informed by deterministic models. The design of the four-bar latch in the stability module implemented a quantitative, geometric method to optimize the flexion zone available to amputees to initiate late stance flexion. The first-order, shear-based damping mechanism incorporated in the damping module extends its prior application from other industries to the field of lower-limb prosthetics. Further, we presented a deterministic sizing model and an assembly technique that can enable researchers and designers of passive prosthetic knees to tailor the damping mechanism to specific amputee needs. Medical devices that require high braking torques in small confined spaces such as exoskeletons and orthotic braces could implement the damping mechanism presented in this chapter. The patent applications filed for these mechanisms lay out the detailed construction and alternative embodiments that may be applied to different contexts [43, 44].

Finally, a distinct feature of both the mechanisms is their modular applicability to existing single-axis prosthetic knees. For example, the four-bar latch could be incorporated in the LC-knee to further improve its stability performance. The 3R80 passive prosthetic knee made by Ottobock uses a conventional rotary hydraulic damper, which may be substituted with the co-axial, rotary damper designed in this study [45].

4.5.3 Limitations

The development of the mechanisms had a few limitations in different stages of the design process. The flexion zone analysis for the stability module was presented only for level-ground walking, whereas amputees in the developing world often need to navigate uneven terrains [10, 46]. A similar analysis could be carried out using able-bodied gait data for walking on slopes and inclines. This could further optimize the location of the virtual locking axis and the corresponding flexion zone.

The structural design of the prototype did not account for the cyclic loading of walking, which could lead to fatigue-induced failure of the four-bar latch prototype. A full fatigue analysis of the mechanism would be required before long term trials, in compliance with the ISO-10328 guidelines for prosthetic devices [47].

A significant future innovation in the damping module could be the addition of an adjustment mechanism to tune the magnitude of damping. This remains a significant mechanical design challenge. Traditional hydraulic cylinders achieve this flexibility by providing adjustment of the orifice diameter between the two fluid chambers [31]. An innovative adjustment mechanism that does not drastically change the rotary damper architecture could enable the adoption of the damping module at scale. It could also drastically reduce the setup time in clinical practice and potentially allow amputees to tune the damping magnitude based on their comfort.

4.6 Conclusion

In this study, we presented the design and preliminary validation of two distinct mechanisms relevant to applications in single-axis prosthetic knees.

We presented a novel mechanism in the stability module, which was designed to achieve the dual function of stability during early stance and controlled instability that allowed knee flexion during late stance. The mechanism of this module was implemented by a latch mounted on a four-bar linkage with a low and distal virtual locking axis, which widened the flexion zone near the knee while maintaining a narrow flexion zone near the foot. The distal location of the virtual locking axis also minimized the possible hyperextension to within 1°. The damping module was implemented with a concentric stack of stationary and rotating pairs of plates shearing thin films of high-viscosity silicone oil. The first-order damping torque was applied co-axial to the knee axis, which provided the required resistance to achieve smooth, able-bodied knee flexion during late stance and swing.

For preliminary user-centric validation, a prototype prosthetic knee with the stability module and two dampers with different magnitudes was tested on a single above-knee amputee in India. The stability module was found to function as expected, enabling smooth stance to swing transition and timely initiation of knee flexion. The dampers also performed satisfactorily as the increase in the damping magnitude was found to decrease peak knee flexion angle during swing. Possible applications and further innovations in existing single-axis prosthetic knees were discussed that can significantly improve the kinematic performance of low-cost, passive prostheses designed for the developing world.

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Chapter 5

A framework to estimate the range of optimal damping coefficients for a passive prosthetic knee joint

The thesis author was the lead contributor to this body of research, which was conducted in collaboration with N. Petelina, W. B. Johnson, M. Major, J. Kent, J. Brinkmann, and A. G. Winter, V.

5.1 Introduction

This chapter is focused on the role of the prosthetic knee in mimicking the kinematics of physiological knee flexion in unilateral transfemoral amputees during level-ground walking. Particularly, we focus on the quantitative estimation of the damping coefficient in a passive prosthetic knee joint. The study builds upon our previous research focused on the biomechanical analysis, mechanical design, and user-centric testing of a new passive prosthetic knee and a passive prosthetic foot for low-income amputees in the developing world [1–8].

The fundamental goal of an ideal prosthetic knee is to mimic the biomechanical function of the physiological knee by enabling kinetics and kinematics that lead to safe and stable locomotion at a low metabolic cost [9–12]. The physiological knee is a

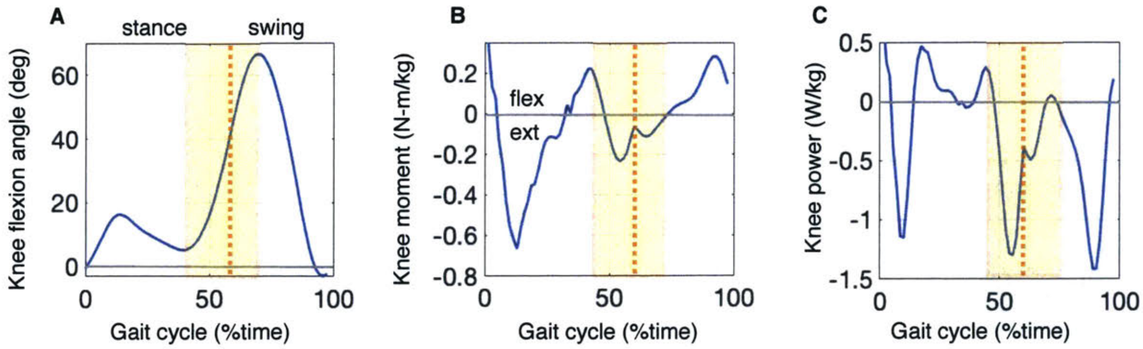

Figure 5-1: A. Able-bodied knee angle kinematics through the gait cycle. The knee flexion zone is shown is highlighted B. Knee moment C. Knee power. Data from [9] for a female of 56.7 kg body mass and 0.83 m leg length

complex, polycentric joint that primarily enables motion in the sagittal plane. It plays a critical role in enabling level-ground walking, both during the stance phase and the swing phase of the gait cycle. The biomechanical function of the physiological knee is characterized by the kinetics, kinematics, and energetics of the joint through the gait cycle (Fig. 5-1A-C). The able-bodied gait cycle of level-ground walking consists of two distinct cycles of flexion and extension at the knee [12] (Fig. 5-1A). At the beginning of stance, the first cycle of flexion and extension (10°- 20°) aids in shock absorption [11]. The second cycle occurs during the transition from stance to swing. The flexion starts during terminal stance and pre-swing and continues well into swing, reaching a peak knee flexion angle ranging between 58°- 70° [13]. The knee reaches full extension at the end of swing before the heel-strike is made by the swinging leg, which begins the next gait cycle. This second cycle of flexion and extension helps propel the limb forward with adequate clearance for the foot [11]. Henceforth, the term "knee flexion" in this chapter will be exclusively used to refer to the full range of knee flexion that begins during terminal stance and ends in mid-swing at the peak knee flexion angle (highlighted in Fig. 5-1A).

During knee flexion, the physiological knee musculature predominantly exerts an extension moment in the opposite direction of motion, preventing uncontrolled knee flexion beyond the range of 58°- 70° [9,13] (Fig. 5-1B). The resulting power absorption leads to net negative mechanical work at the knee joint during flexion (Fig. 5-1C)

[14]. Passive prosthetic knee units most commonly replicate this negative work by incorporating dampers that dissipate power over the time period of knee flexion. Based on the cost constraints and performance requirements of the prosthesis, these dampers can be friction-based, pneumatic, or hydraulic [10].

In order to adequately mimic the physiological knee, it is critical for the prosthetic knee damper to offer an optimal range of damping moment magnitude. If the damping moment is smaller than the optimal range, a 'free' knee joint would flex well beyond 70 degrees, resulting in excessive heel rise through the swing phase [15]. This high flexion is unnecessary to achieve the required ground clearance as about 45°- 50° is sufficient [11]. Excessive knee flexion also delays swing extension, leading to a jarring terminal impact right before the heel strike. This phenomenon can also slow down the amputee and lead to asymmetric gait [15]. On the other hand, if there is excessive damping moment, the knee cannot flex sufficiently for the foot to clear the ground during swing. In this case, amputees display conspicuous gait deviations such as vaulting and circumduction to achieve ground clearance during swing [12, 15]. From a clinical perspective, these compensatory gait deviations are undesirable because of their high metabolic costs and adverse stress on the hip and the back [15].

Changes in walking speeds also affect the damping moment, as a faster walking speed is accompanied by an increase in the extension moment during knee flexion [10, 11]. Fluid-based dampers, either pneumatic or hydraulic, have been designed to provide cadence-based resistance in passive prosthetic knees. Among amputees with active lifestyles, fluid-based dampers have become increasingly popular over friction-based dampers as they provide resistance that adapts to changes in walking speed [10].

With the recent advent of active knees, variable damping can be implemented using actuators and motors whose impedance is controlled by a microprocessor and multiple sensors [16, 17]. These recent innovations offer high performance through the use of electromechanical systems. However, they are expensive and unaffordable to a majority of low-income amputees across the world [18–20]. Additionally, unlike the ankle, the physiological knee is energetically passive over the entire gait cycle [14]. Therefore, the knee function can be theoretically replicated with an idealized combination of passive springs and dampers, without the need for active power generation [2].

Multiple studies have estimated damping coefficients using idealized mathematical models of knee joints and complex impedance control algorithms to generate the optimal damping moment at the knee [16, 21, 22]. A few studies have extended this approach to practice by designing and implementing controllers in electromechanical prosthetic knee systems with encouraging results [16, 17]. In the context of passive prosthetics, a prior study by Narang et al. [2] applied the modeling approach used for active knees to passive systems by determining the zero-order and first-order damping coefficients required for replicating the able-bodied knee moment in a passive prosthetic knee joint. However, this approach was idealized and had multiple limitations in terms of practical considerations relevant to clinical applications. First, transfemoral amputees typically walk at lower speeds than the able-bodied population as well as transtibial amputees, which may have an effect on the damping coefficient [10, 11]. Second, the prosthetic ankle was assumed to fully substitute the function of the physiological ankle. It did not account for the influence of the passive prosthetic foot which cannot generate the full power required for push-off during level-ground walking [23]. Third, the transfemoral gait with passive prostheses is characterized by asymmetric spatiotemporal measures such as stance phase duration, swing phase duration, step length, and step width [24]. These asymmetries affect the kinetics and kinematics of amputee gait, which may alter the magnitude of the damping coefficient required for target kinematics. Therefore, this study presents a framework that can account for these aforementioned characteristics of transfemoral gait in estimating the optimal range of damping coefficients.

In the clinical context, multiple studies have benchmarked the performance of different passive and active flexion control mechanisms based on experimental walking data from transfemoral amputees using commercially available prosthetic knees [24–31]. There are specific qualitative guidelines and software recommended to prosthetists by commercial manufacturers (Ottobock, Ossur, etc.) for tuning damping magnitudes in each model of the prosthetic knee [32, 33]. However, there is an absence of studies that have systematically explored and generalized the effect of the damping magnitude on knee flexion. Additionally, prosthetists still tune the damping in passive knees by trial and error, sometimes requiring multiple visits by patients [11]. The absence of a prescriptive and quantitative biomechanical model and publicly accessible empirical data that explain the effect of the damping magnitude on knee flexion has thus led to a gap in the transfer of practical knowledge to clinicians and prosthetists.

This chapter seeks to bridge this gap in literature and clinical practice by developing a framework to estimate the range of optimal damping coefficients required to achieve normative knee flexion kinematics. In contrast to previous studies, the kinetics and kinematics data for able-bodied walking at different speeds were used from published literature to compute the optimal damping coefficient for each speed. Additionally, kinetics and kinematics data from a transtibial amputee were considered to account for the effect of a passive prosthetic foot on the knee performance. The damping coefficient estimate from the transtibial data was compared to that of the able-bodied value to determine a range of optimal damping coefficients for transfemoral amputees. Finally, this range was adjusted based on the scaling effects of the relevant asymmetric gait compensations employed by transfemoral amputees. This adjusted range of optimal damping coefficients prescribed by the framework was experimentally investigated. Knee kinematics data from three unilateral transfemoral amputees walking with a broad range of damping coefficients were analyzed. The estimated optimal damping coefficient range was validated by the experimental damping coefficients that led to normative peak knee flexion in the prosthetic leg.

5.2 Framework to estimate the range of optimal damping coefficients

We present a four-step framework to compute the range of optimal damping coefficients applicable to passive prosthetic knees with the overall goal of enabling able-bodied knee flexion kinematics. First, the optimal damping coefficient, $B_{optimal}$, was computed from able-bodied gait data. Second, the dependence of walking speed on the damping coefficient was investigated. Third, $B_{optimal}$ was computed from transtibial gait data to account for the influence of a passive prosthetic foot and a range of $B_{optimal}$ was defined. Fourth, this range was adjusted based on longer stance and shorter swing phase duration commonly observed in transfemoral amputees who use passive prostheses.

5.2.1 Damping coefficient from a single able-bodied gait dataset

The optimal damping coefficient ($B_{optimal}$) was computed from a single reference dataset from a typical, unimpaired female subject of 56.7 kg body mass and 0.83 m leg length [9]. The reference data included a complete kinematic and kinetic dataset for level-ground walking at a self-selected speed of 1.42 m/s.

The knee flexion-extension moment data and knee flexion angle data were used to compute $B_{optimal}$. The knee flexion angle from the reference was set as the target for an ideal single-axis prosthetic knee. An ideal rotary, first-order damper was modeled to engage at this prosthetic knee during the transition from stance to swing, i.e. at the onset of knee flexion when the angular knee velocity is in the same direction as the knee flexion. The damper was disengaged at the peak knee flexion angle, i.e. when the angular velocity of the knee becomes zero and changes direction. The corresponding section of the knee flexion curve is highlighted in Fig. 5-1A, referred to as the flexion zone. The first-order damper was formulated mathematically as

$$T_{damp} = -B \cdot \dot{\theta}_{knee}, \tag{5.1}$$

where T_{damp} is the computed damping moment (N-m/kg), expressed as the product of the damping coefficient, B (N-m/rad/s/kg) and the reference knee angular velocity over the flexion zone, $\dot{\theta}_{knee}$ (rad/s). Both T_{damp} and B were normalized to body mass.

In order to estimate $B_{optimal}$, multiple T_{damp} profiles were computed for a range of values of B (0 - 0.1 N-m/rad/s/kg) using Eq. (5.1). Over the flexion zone, each T_{damp} profile was compared with the reference knee moment. The damping moment profile with the highest coefficient of determination (R^2) over the flexion zone was selected (Fig. 5-2). The corresponding damping coefficient was identified as the optimal damping coefficient, $B_{optimal}$. The value of $B_{optimal}$ was found to be 2.35×10^{-2} N-m/rad/s/kg ($R^2 = 0.33$).

It was hypothesized that $B_{optimal}$ implemented in a prosthetic knee damper would be able to best replicate the knee moment required to achieve the target able-bodied knee flexion kinematics. The relevant assumptions made by this hypothesis are analyzed in the following sections, which inform the revisions to the current hypothesis.

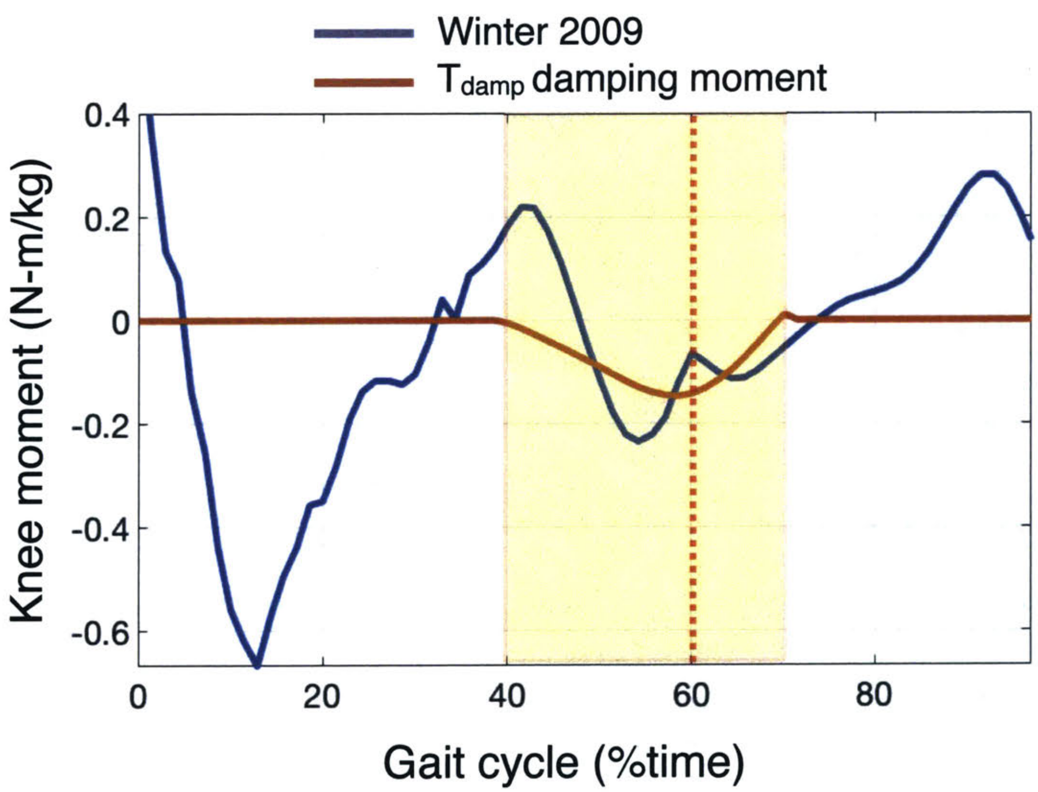

Figure 5-2: Least squares fit over the flexion zone: optimal T_{damp} profile with $B_{optimal}$ = 2.35×10^{-2} N-m/rad/s/kg

5.2.2 The effect of walking speed

It has been well documented that the knee kinetics for the able-bodied population change as the walking speed changes [10,14]. Specifically, the extension knee moment during knee flexion increases in magnitude with increasing walking speed and vice versa. Fluid-based dampers used in prosthetic knees mimic this trend by providing a first-order and second-order damping moment, wherein the damping moment is proportional to $\dot{\theta}_{knee}$ and $\dot{\theta}^2_{knee}$, respectively. The first-order moment is generated using pneumatic systems or through shear-based laminar flow in hydraulic systems. The second-order moment is a result of turbulence induced by oil flow through a small orifice (at high Reynolds number) [34,35]. Advanced designs of passive and active hydraulic dampers implement intelligent systems that can provide first-order moment applicable for normal walking speeds and switch to a second-order at faster walking speeds [10,27,34,35]. However, there is a lack of publicly accessible studies that have systematically and quantitatively investigated the effect of changes in walking speeds on the damping coefficient in transfemoral amputees.

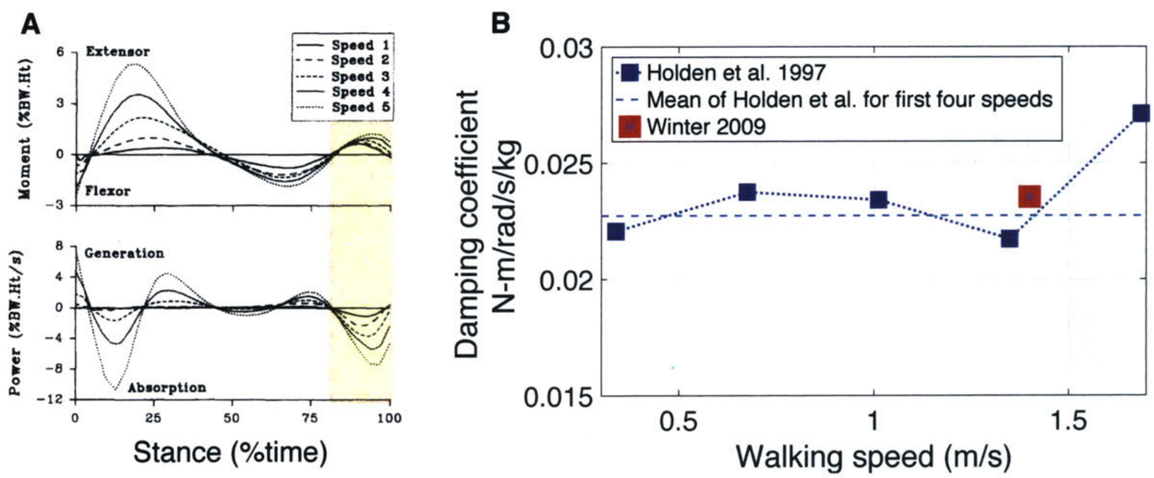

Figure 5-3: A. Knee moment and power curves were digitized for negative work phase (highlighted) for five different walking speeds (0.33 - 1.68 m/s). Plots adapted from [36]. B. Optimal damping coefficient did not vary appreciably for the first four walking speeds.

To address this gap, we surveyed the literature for knee kinematics, kinetics, and energetics datasets of able-bodied, level-ground walking over a wide range of walking speeds. A few relevant studies were found [13, 36–43].

The data reported by Holden et al. [36] were chosen for detailed analysis for two reasons. First, the study reported changes in the knee joint function over a wide range of walking speeds (0.33 - 1.68 m/s) using data from a large number of able-bodied subjects (N=18). Second, the slow and normal walking speeds in the study were in the range of 0.33 - 1.35 m/s, which fully covered the range of self-selected walking speeds preferred by transfemoral amputees, 0.9 - 1.1 m/s [11]. Furthermore, data were reported with speeds normalized by body height, which ruled out any confounding effects of leg length on walking speed [44]. However, the study only reported data for the stance phase of the gait cycle. No other study was found in the literature that reported the averaged data of slow walking by a large number of able-bodied subjects.

Figure 5-3A shows the relevant data from Holden et al. Over the highlighted flexion zone, the values for knee power and knee moment curves were obtained for five different walking speeds (0.33 m/s, 0.67 m/s, 1.01 m/s, 1.35 m/s, and 1.68m/s). As discrete numerical data were not available, the curves were manually digitized using an image processing software [45]. The knee angular velocity data was also not available. It was calculated by using the digitized values of knee power and knee moment at closely spaced intervals in the flexion zone as,

$$\dot{\theta}_{knee}(i) = \frac{P_{knee}(i)}{T_{knee}(i)}, \tag{5.2}$$

where i denotes the chosen time instance for digitization in the flexion zone (Fig. 5-3A). For each chosen digitized point i, $\dot{\theta}_{knee}(i)$, $P_{knee}(i)$, and $T_{knee}(i)$ denote the corresponding knee angular velocity, knee power, and knee moment respectively. At least 20 points were digitized in the flexion zone for each curve ($i \geqslant 20$).

For each walking speed, the computed knee angular velocity, $\dot{\theta}_{knee}(i)$, and the knee moment data, $T_{knee}(i)$, were used to calculate $B_{optimal}$ over the flexion zone using the least-squares curve fitting technique discussed in Section 5.2.1.

For the first four walking speeds (0.33 m/s, 0.67 m/s, 1.01 m/s, 1.35 m/s), $B_{optimal}$ did not vary significantly (Fig. 5-3B). The mean of $B_{optimal}$ over this range, B_{mean}, was 2.27×10^{-2} N/m/rad/s/kg. The value of each $B_{optimal}$ was found to be within 5% of B_{mean}. The value of $B_{optimal}$ computed from the full able-bodied dataset, discussed in Section 5.2.1, was 2.35×10^{-2} N-m/rad/s/kg at 1.42 m/s, which was also close to B_{mean} within 3.5%. From these observations, it was concluded that $B_{optimal}$ does not vary appreciably for slow and normal walking speeds preferred by able-bodied persons (0.33 -1.38 m/s). However, for the fastest walking speed (1.68 m/s), $B_{optimal}$ was 36% higher than B_{mean} (Fig. 5-3B).

These observations confirmed the accepted qualitative consensus in clinical prosthetics that first-order dampers can be used for relatively slow walkers while second-order dampers are needed for faster and more active amputees. For the purpose of our study, $B_{optimal}$ was considered independent of walking speed as most transfemoral amputees using passive prosthetic knees choose to walk slower than 1.4 m/s [11, 24].

5.2.3 The influence of a passive prosthetic foot

One of the critical factors influencing the leg kinetics in a lower-limb amputee is the prosthetic foot [23]. A passive prosthetic foot cannot fully replicate the function of the physiological foot and ankle, especially during push-off from stance into swing. The physiological ankle produces up to 60% of the total positive mechanical work performed by the leg during stance [9]. A passive prosthetic foot cannot produce any net positive work over the entire gait cycle, which could have an effect on the extension knee moment required during knee flexion over the flexion zone (Fig. 5-1B). In determining the value of $B_{optimal}$ in Sections 5.2.1 and 5.2.2, able-bodied datasets were used and the influence of the prosthetic foot was not accounted for.

In order to address this gap, the leg kinematics and kinetics data of a transtibial amputee were used as the target reference, which were collected in a previous study by Olesnavage et al. [7, 8]. A brief summary of the study by Olesnavage et al. is reported here. A new passive prosthetic foot with an energy storage and return mechanism was designed and optimized using a quantitative metric called the Lower Leg Trajectory Error (LLTE) [5,6]. The optimized LLTE prosthetic foot was experimentally tested on a single female transtibial amputee with 55.6 kg body mass and 0.87 m leg length. The kinetics and kinematics data were collected from level-ground walking trials in a gait lab. The self-selected speed for the trial was 1.31 m/s. The LLTE foot was experimentally validated to provide kinetic accuracy of the prosthetic leg within 17% and kinematic accuracy (Fig. 5-4A) within 21% when compared to able-bodied kinematics and kinetics data from [9].

Transtibial amputees walking with energy storage and return feet such as the LLTE foot can achieve knee flexion kinematics that are comparable to the able-bodied population [7,8,23]. Therefore, it was hypothesized that for a transfemoral amputee to walk with target kinematics of able-bodied walking, the moment enabled at the knee would have to closely replicate the transtibial knee moment, provided the same LLTE prosthetic foot was used by the transfemoral amputee. The corresponding $B_{optimal}$ from transtibial reference data can be calculated using the knee angular velocity and knee moment data using the least-squares curve fitting technique discussed in Section 5.2.1.

The value of $B_{optimal}$ was found to be 2.92×10^{-2} N-m/rad/s)/kg for a transfemoral amputee with the inertial properties of the prosthetic leg set to able-bodied values (as the mass of the LLTE foot used in the transtibial reference was comparable to average able-bodied value [5–8, 46]) (Fig. 5-4). This value of $B_{optimal}$ was found to be 19.5% higher than the corresponding $B_{optimal}$ computed from able-bodied data in Section 5.2.1 (2.35×10^{-2} N-m/rad/s/kg). This difference could be attributed the presence of the LLTE prosthetic foot in the transtibial amputee, which was fully passive and was shown to have up to 17% change in leg kinetics.

The two values of $B_{optimal}$ offer a range of optimal damping coefficients between 2.35×10^{-2} N-m/rad/s/kg and 2.92×10^{-2} N-m/rad/s/kg. It was hypothesized that this range of $B_{optimal}$ implemented in a prosthetic knee damper would be able to best replicate the knee moment required to achieve the target able-bodied knee flexion kinematics.

5.2.4 The effect of longer stance and shorter swing

A critical factor influencing the damping coefficient of a prosthetic knee joint is the asymmetric nature of stance and swing in a transfemoral amputee. Transfemoral gait has been shown to have many asymmetric features between the sound side and the prosthetic side of the body as compared to able-bodied gait and transtibial gait [24].

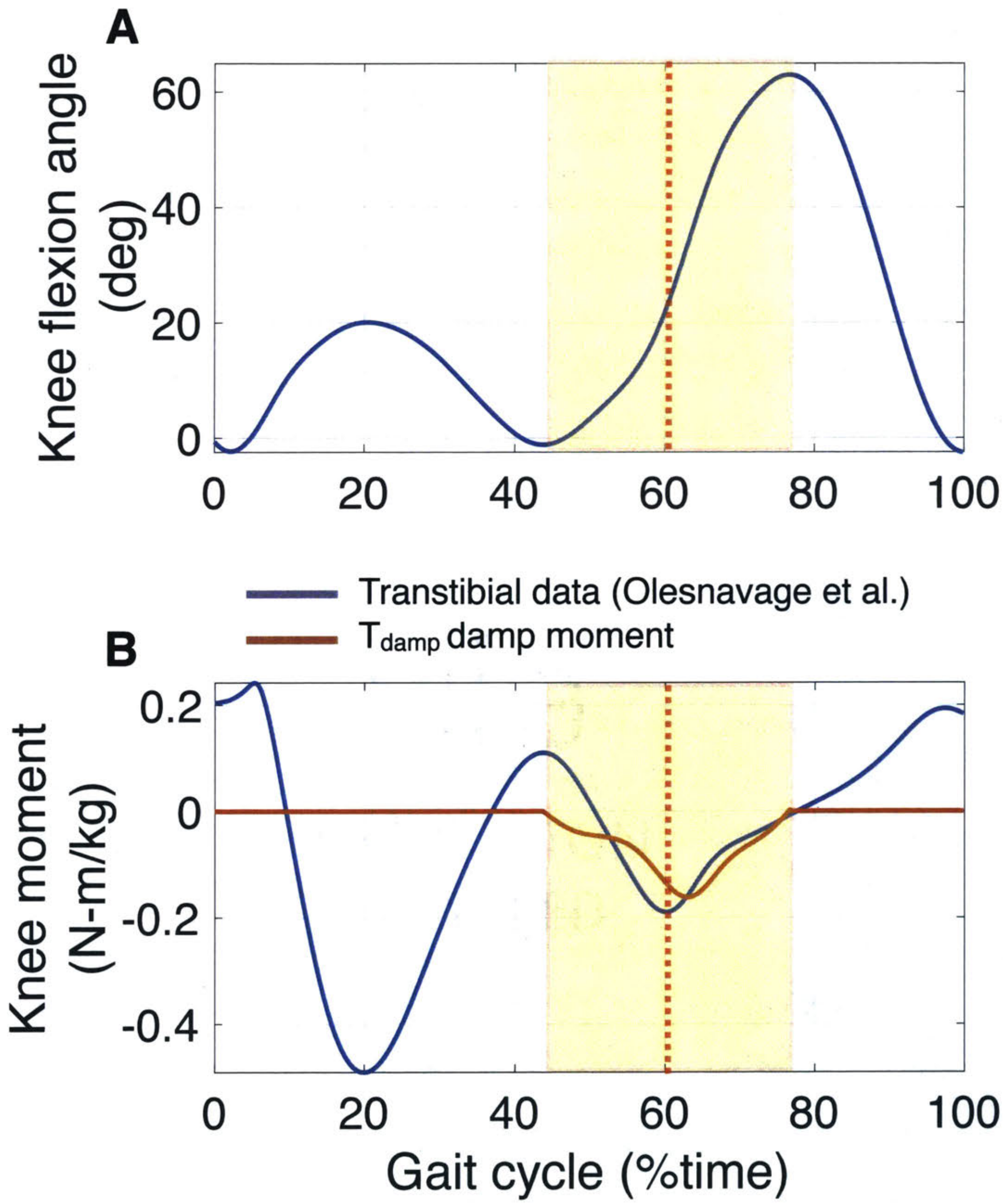

Figure 5-4: Data from a transtibial amputee, least squares fit over the flexion zone: optimal T_{damp} profile with $B_{optimal} = 2.92 \times 10^{-2}$ N-m/rad/s/kg

This is important since any gait parameters that affect the knee moment and angular velocity can have a direct impact on the first-order damping coefficient (SI unit N-m/kg/rad/s). In order to estimate which asymmetric features might be important to adjust or scale the damping coefficient $B_{optimal}$, it is useful to analyze the normalized knee moment and knee angular velocity separately.

The knee moment (N-m/kg) during the stance phase is primarily caused by the moment exerted at the knee axis by the GRF vector. The magnitude of GRF, when normalized to body weight, has not been found to be significantly different on the prosthetic leg compared to the able-bodied value during the double support phase of terminal stance and pre-swing (referred to as the flexion zone in this chapter) [47]. The moment arm for the GRF vector is also not significantly different for amputees using most single-axis knees, as the prosthetic knee axis is close to the anatomical location of the physiological knee during flexion [48]. It was concluded that the normalized knee moment due to GRF does not change significantly between the prosthetic leg

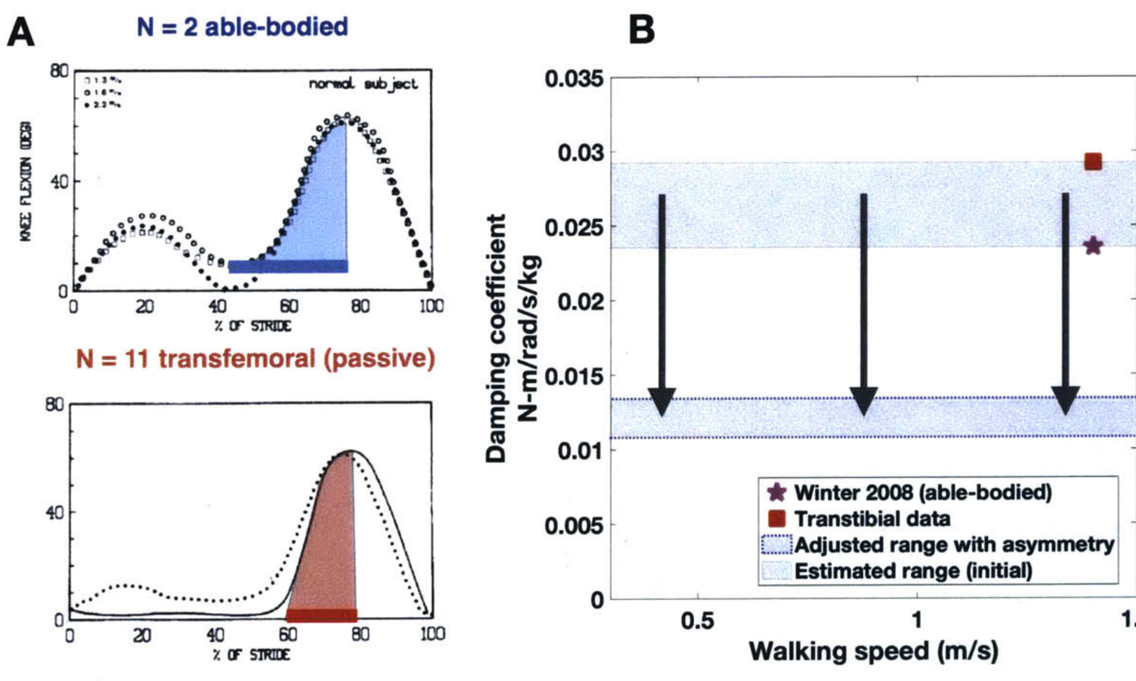

Figure 5-5: Revision in the range of optimal damping coefficients based on shorter duration of knee flexion. A. Time spent in knee flexion for a prosthetic leg is 46% lesser than in able-bodied people for the same walking speed (from Jaegers et al. [24]). B. The initial estimated range of optimal damping coefficients was revised and scaled down to account for the reduced time spent in knee flexion by transfemoral amputees.

and the able-bodied leg.

The knee angular velocity (rad/s) over the flexion zone is nominally the ratio of knee flexion angle (rad) and the time spent in knee flexion (s). In this study, the target peak knee flexion angle (rad) was set to be similar to the able-bodied equivalent (58-70 degrees). The knee flexion range in able-bodied people is consistent across different walking speeds [13]. As shown in Fig. 5-5A, a common compensation strategy employed by transfemoral amputees is to decrease the duration of single support on the prosthetic side, as compared to the sound side [11], A study by Jaegers et al. [24] compared the time spent in stance for 11 transfemoral amputees with 2 able-bodied controls for two different walking speeds. The study reported a delayed knee flexion on the prosthetic side. The delay in the initiation of flexion was averaged to 20% of the stride time. Based on the results reported by Jaegers et al, the total time spent in knee flexion was found to be approximately 46% less than the able-bodied equivalent (Fig. 5-5A). This implies that the knee angular velocity for the prosthetic side was nearly twice the velocity of the able-bodied equivalent. As a consequence, $B_{optimal}$ was adjusted to 46% of the initial range as computed previously from able-bodied data and transtibial data (Fig. 5-5B).

5.2.5 Summary of the estimation framework

Incorporating the increase in rotational velocity, a scaled empirical estimate of the damping coefficient was arrived at, which was 46% of the initially estimated target range based on $B_{optimal}$ values from able-bodied data and transtibial data (Section 5.2.2).

It was hypothesized that for a transfemoral amputee walking at self-selected speed (0.6-1.3 m/s) with a LLTE passive foot and a passive prosthetic knee that allows flexion during terminal stance, $B_{optimal}$ needed for able-bodied knee flexion would scale approximately within the adjusted range shown in Fig. 5-5B. The values in this range were between 1.15×10^{-2} and 1.43×10^{-2} N-m/kg/rad/s.

5.3 Experimental investigation of the optimal range of damping coefficients

5.3.1 Prototype prosthetic knee and prosthetic foot

Previously designed prototypes of a passive prosthetic knee and a passive prosthetic foot were used for the experimental study conducted with three unilateral transfemoral amputees in a gait lab (Fig. 5-6A-D). The prosthetic knee was implemented with a passive, single-axis architecture, with an automatic latch that was designed to allow for timely knee flexion during terminal stance and pre-swing while providing stability after heel-strike during early stance [3,49,50] (chapter 3 and chapter 4). The prosthetic knee prototype was previously validated to provide smooth stance to swing transition in preliminary qualitative walking trials on two transfemoral amputees in India [3,50]. Eight shear-based, rotary viscous dampers of different damping magnitudes were designed and characterized for the experimental study. The braking moment in the damper was generated by shearing thin films of high-viscosity silicone oil trapped between concentric stack of rotating and stationary plates. The magnitude of the eight damping coefficients were 0.37, 0.56, 0.80, 1.00, 1.10, 1.32, 1.44, and 1.80 N-m/rad/s. These eight dampers spanned the full range of required normalized damping coefficients from 0.4×10^{-2} - 3.6×10^{-2} N-m/rad/s/kg for a range of body masses from 50 - 90 kg. (Fig. 5-5B)

A prototype of the LLTE prosthetic foot was used in the study (discussed in Sec-

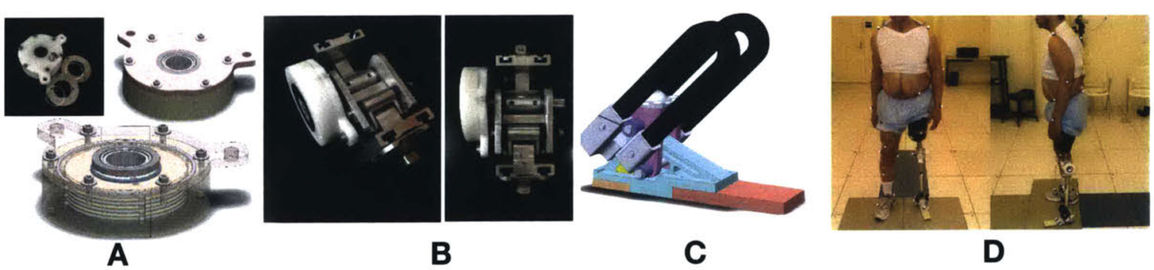

Figure 5-6: A. Dampers provided first-order resistance by shearing thin films of trapped oil between the rotating plates. B. Prosthetic knee assembled with the damper. C. The LLTE foot. D. Subjects were fitted with the knee and foot prototype in the experimental study.

tion 5.2.3, Fig. 5-6C). The prosthetic foot, designed with an energy storage and return mechanism, was previously validated to enable close replication of the trajectory of the lower leg in a single transtibial amputee [7, 8].

5.3.2 Data collection

Three subjects with unilateral transfemoral amputation were recruited for this study. The first subject was male (84.3 kg body mass). The second and third subjects were female (68.7 kg and 54.9 kg respectively). Due to timing constraints and to avoid fatiguing the subject, the training for data collection was performed in the first visit and data collection was carried out in the second visit. In the first visit, the subject was trained to walk with the prototype prosthetic knee and foot leg assembly on a treadmill with a safety harness. A qualified prosthetist fitted the prosthetic foot and knee prototype to the usual socket used by the subject. The objective of the training session was to familiarize the subject with the safe usage of prosthetic knee and foot on level-ground. No quantitative data was collected.

In the second visit, the subject was fitted with the prosthetic knee and prosthetic foot and given as much time as was needed to acclimate to the knee and the foot. Five different damping conditions were tested sequentially on each subject. The first condition involved no damping and the next four conditions incorporated equally-spaced damping coefficient magnitudes around the range predicted by the framework in an increasing order.

Reflective markers were then placed on the subject according to a Helen Hayes marker set [51], with additional markers on the prosthetic foot such that each component of the foot had a minimum of two markers defining its position. A digital motion capture system (Motion Analysis Corporation (MAC), Santa Rosa, CA) was used to collect kinematic data at 120 Hz. Six force plates (AMTI, Watertown, MA) embedded in the floor collected kinetic data at 960 Hz.

For each of the five damping conditions, a static trial was performed and the subject was instructed to walk back and forth along a 10 m walkway at a self-selected comfortable speed. The subject continued walking until five clean steps were collected on both the prosthetic and the sound side. Steps were only used if the entire foot landed on a single force plate, and the opposite foot did not contact that same force plate. After five steps were collected on each side, the damper was substituted for the next damping condition without removing the rest of the prosthesis. With the new damper in place, the trial procedure was repeated starting with the acclimation period. After the data collection was complete, a commercial motion tracking software (Orthotrak) was used to extract and filter the kinematics of the markers. Inverse dynamics were performed on MATLAB to compute the joint moments.

5.4 Results

Figure 5-7 summarizes the results from the experimental study:

1. Fig. 5-7A and Table 5.1 : The five damping conditions tested on each subject spanned a broad range of damping coefficients with two conditions lying close to the optimal range. The damping coefficients reported in the figure are 'true' coefficients experienced by the subject. The values of these coefficients were computed from inverse dynamics by dividing the knee moment by the knee angular velocity during knee flexion. The true damping coefficients and walking speeds for each condition are reported with one standard deviation.

2. Fig. 5-7B, C: The two damping conditions closest to the optimal range enabled knee flexion within one standard deviation of the able-bodied target range (58°-70°). The damping conditions larger than the optimal range inhibited knee flexion lower than 58°. Conversely, the damping conditions smaller than the optimal range led to greater than 70°of knee flexion. The peak knee flexion of the prosthetic knee showed a consistent decrease in magnitude with increasing damping coefficient. The peak knee flexion of the sound side was invariant to changes in the damping coefficient.

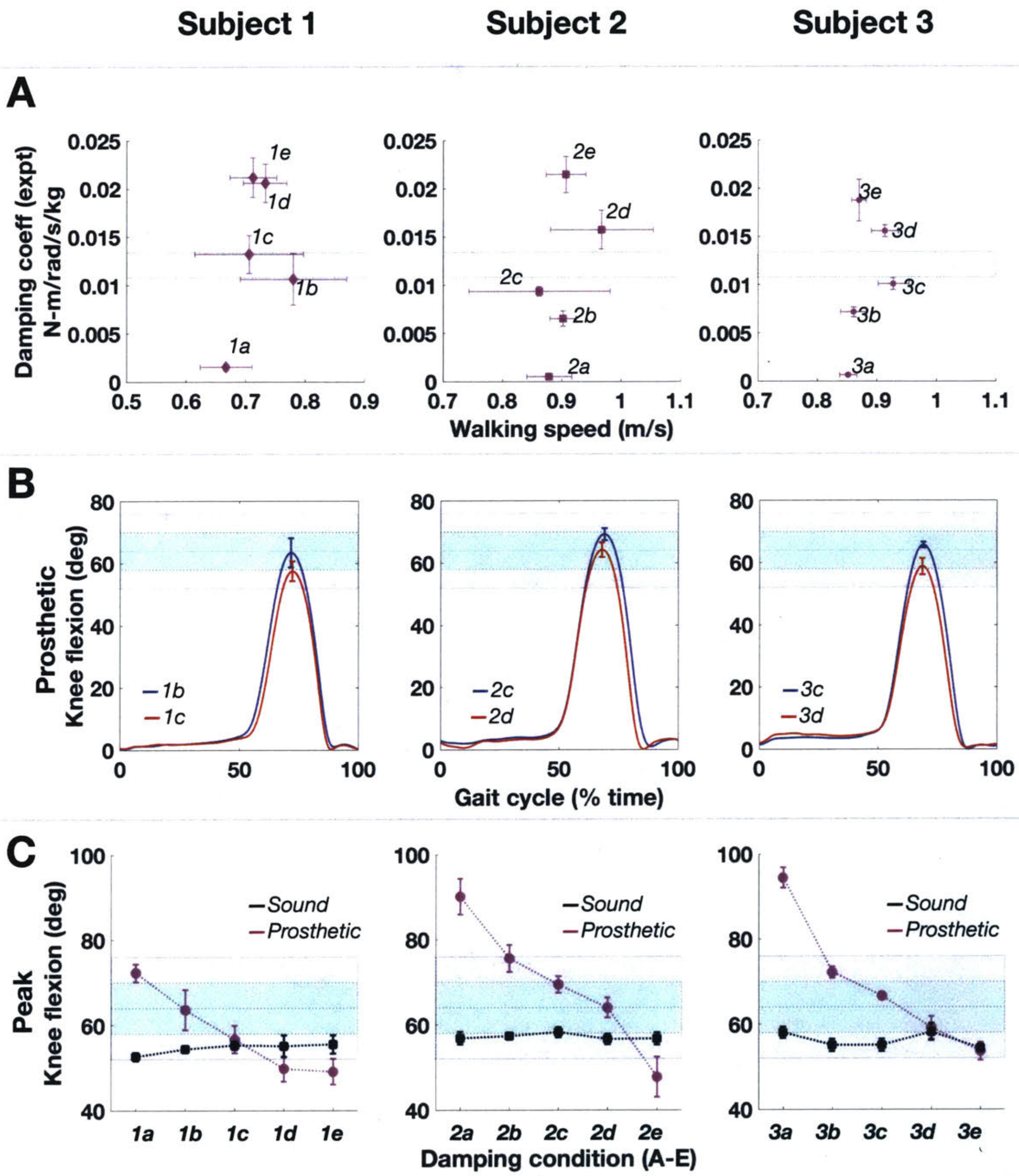

Figure 5-7: Results: A. True damping coefficients vs. walking speed for 5 damping conditions (a-e). Grey band is the optimal range of damping coefficients estimated by the framework. B. Prosthetic knee flexion for the two damping conditions closest to the optimal range (1b, 1c, 2c, 2d, 3c, 3d) was in the able-bodied range. The shaded bars indicate the able-bodied range with two standard deviations. C. Peak knee flexion for the prosthetic leg decreased consistently with increase in the damping magnitude (a-e) and stayed invariant for the sound leg.

		True (measured) damping coefficient for each condition (N-m/rad/s)				
Subject no.	Body mass (kg)	*a*	*b*	*c*	*d*	*e*
1	84.3	0.13	0.90	1.11	1.74	1.79
2	68.7	0.04	0.45	0.64	1.08	1.47
3	54.9	0.03	0.39	0.55	0.85	1.03

Table 5.1: True (measured) damping coefficient for each condition (N-m/rad/s)

5.5 Discussion

5.5.1 Validation of the framework for optimal damping coefficient estimation

In this chapter, we presented a framework for an a priori estimation of the damping coefficient for a prosthetic knee that can replicate able-bodied knee flexion in unilateral transfemoral amputees (Fig. 5-5B). Of the five damping conditions, two damping conditions for each subject had coefficients that were either within this range, or were very close to it. These two damping conditions enabled peak knee flexion in the able-bodied range, as shown in Fig. 5-7B, C. The hypothesis laid out by the framework was therefore validated by the experimental results. The range of damping coefficients predicted by the framework, indicated by the grey band in Fig. 5-7A and Fig. 5-5B, were found to induce the desired knee flexion kinematics in amputees.

This framework can serve as a useful quantitative metric for practicing clinicians, researchers, and designers of prosthetic knees. For prosthetists, these data can inform the trial and error method employed during the fitment process. For example, a recently amputated patient may prefer less resistance in the damper at the beginning of the rehabilitation process. As the gait symmetry improves for this patient with walking experience and training, our analysis points at the need to increase the damping coefficient to ensure that the knee flexion remains within the able-bodied range of 58°- 70° (Fig. 5-8). It can also be a useful tool for designers of prosthetic knees. For example, a polycentric prosthetic knee may use a 4-bar mechanism that folds fully inwards during swing. This behavior of the mechanism leads to effective

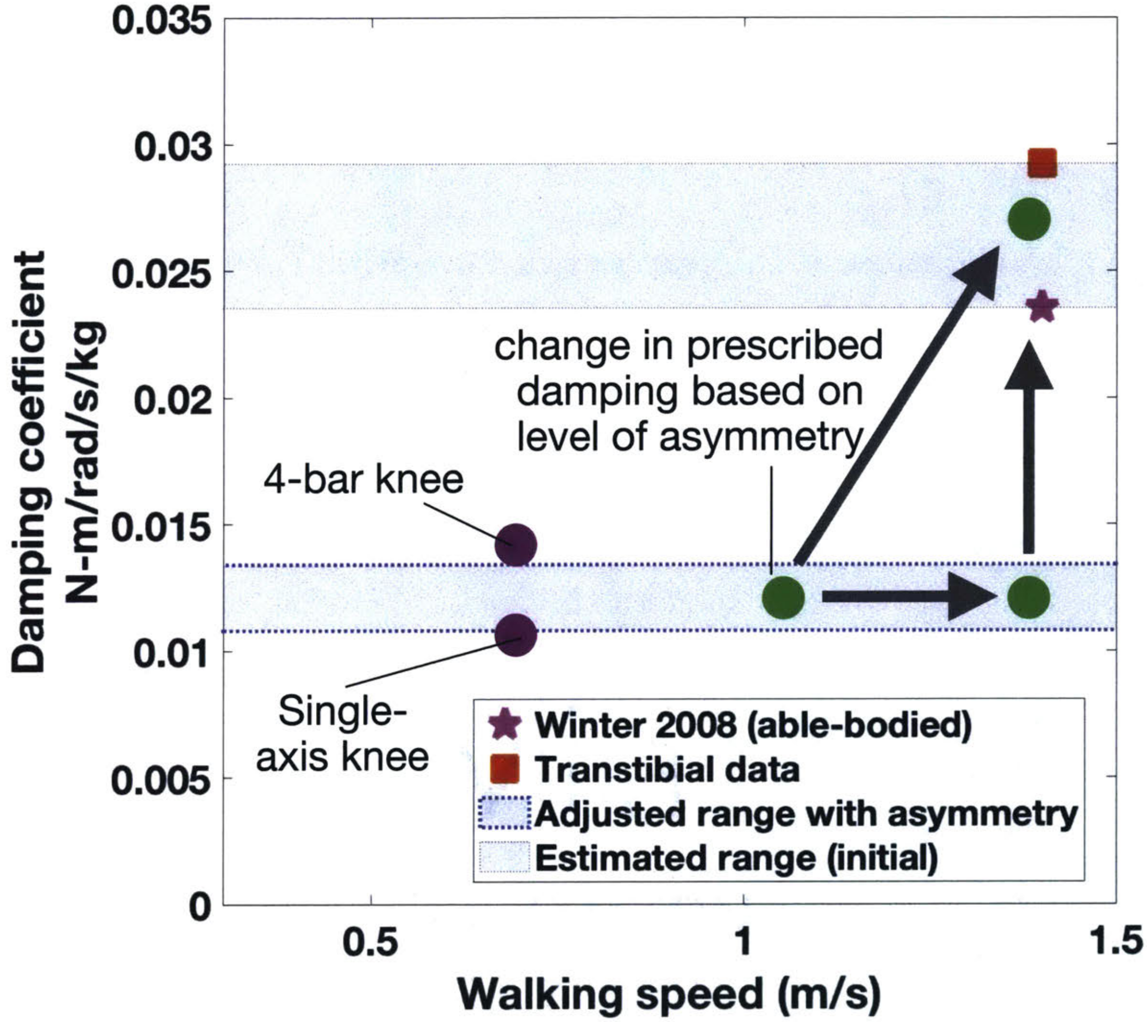

Figure 5-8: The range of optimal damping coefficients can be used by clinicians and designers of prosthetic knees to determine the magnitude of damping required for a particular outcome. A 4-bar knee will need to have higher damping than a single-axis knee. A patient with recent amputation could be prescribed a systematic increase in the damping coefficient based on the asymmetry factor.

shortening of the lower leg, which is helpful in achieving ground clearance by the swinging foot [11]. A polycentric 4-bar knee, therefore, may require higher resistance that is closer to the upper bound of the predicted coefficient range to prevent knee flexion beyond 70° (Fig. 5-8). However, a single-axis knee mechanism primarily relies on knee flexion to clear the ground, which points to the need for less resistance closer to the lower bound of the predicted damping coefficient range.

5.5.2 Comparison to previous work

A prior study by Johansson et al. [27] compared the variable-damping and mechanical passive prosthetic knees through experimental data collection on eight unilateral transfemoral amputees. The study reported a longer single support time during stance, which confirmed the need for the adjustment factor incorporated in our framework (Fig. 5-5B). The knee moment and knee velocity data for self-selected walking speed were reported for three different prosthetic knees (C-leg, Rheo knee, and Mauch SNS). The Rheo knee uses an active MR damper that implements a linear damping relationship comparable to the rotary shear-based dampers in this study. Using the peak knee moment and peak knee velocity data, a nominal damping coefficient for the Rheo knee could be calculated during the flexion zone, which was found to be 1.10×10^{-2} N-m/kg/rad/s. This value was within 5% of the lower value of the predicted optimal range of damping coefficients, showing close agreement with the framework presented in our study (Fig. 5-5B). A similar comparison could not be made for the Rheo knee and Mauch SNS knee as they implement hydraulic cylinders with second-order damping relationship.

Studies by Sup et al. [16] and Martinez et al. [17] used an idealized spring-damper model based on able-bodied gait data to optimize the impedance of an active prosthetic knee. The results from these studies are not directly comparable to our study due to the active nature of the prosthesis used. However, the damping coefficient preferred by subjects in both the studies was significantly lower than the idealized, computed value from the respective models. This is in agreement with our framework, which accounts for delayed knee flexion. The corresponding adjustment of the required damping coefficient reduces the magnitude significantly (by about 46% in our study).

5.6 Conclusion

The goal of our study was to bridge the gap in literature and clinical practice by developing a framework to estimate the range of optimal damping coefficients required to achieve normative knee flexion kinematics. In contrast to previous studies, the kinetics and kinematics data for able-bodied walking at different speeds were used from published literature to compute the optimal damping coefficient for each speed. The optimal damping coefficient was mostly invariant to changes in walking speed. Additionally, kinetics and kinematics data from a transtibial amputee were considered to account for the effect of a passive prosthetic foot on the knee performance. The damping coefficient estimate from the transtibial data was found to be 19.5% higher than the corresponding estimate from able-bodied data. The damping coefficients between the two values determined a range of optimal damping coefficients for transfemoral amputees. Finally, this range was adjusted based on the scaling effects of the relevant asymmetric gait compensations employed by transfemoral amputees. This adjusted range of optimal damping coefficients (1.15×10^{-2} - 1.43×10^{-2} N-m/kg/rad/s) prescribed by the framework was experimentally investigated. Knee kinematics data from three unilateral transfemoral amputees walking with a broad range of damping coefficients were analyzed. The optimal damping coefficient range estimated by the aforementioned framework was validated by the experimental damping coefficients that led to peak knee flexion of the prosthetic leg in the able-bodied range.

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Chapter 6

Conclusions

This thesis presented four different studies that document the biomechanical theory, novel mechanisms, and empirical data that can be used towards building a fully passive, high-performance prosthetic knee for the developing world. Chapter 2 presented the design of a transfemoral rotator that can be incorporated into most designs of passive knees in the developing world. The relative scale of importance developed for different user needs can be used by researchers and designers of prosthetic knees in the developing world. Chapter 3 presented a preliminary design of the prosthetic knee that translated an idealized, mathematical model into a practical design. The prototype combined all the hardware modules required to theoretically replicate able-bodied kinematics in transfemoral amputees. Chapter 4 presented the deterministic design of two specific mechanism modules that can be readily adopted into existing single-axis prosthetic knees designed for the developing world. Chapter 5 presented an estimation framework for optimal damping coefficients required in a passive prosthetic knee. This framework can be used by prosthetists, clinicians, and designers of passive prosthetic knees.

The thesis provides hardware platforms and theoretical foundations for future work that can address many current limitations and assumptions. Future efforts to commercialize the innovations described in this thesis will need to take into consideration the additional challenges of supply chain, manufacturing, and the budgetary constraints of different distribution models. Current academic and industrial research is predominantly focused on building the theoretical knowledge and hardware components required for creating advanced electromechanical prostheses that provide high-performance. However, the resulting technology remains unaffordable to a majority of amputees in the developing world. This thesis presented a concerted scientific and technological effort to bridge this gap in addressing the needs of transfemoral amputees in the developing world.

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