Design and Evaluation of a Cantilever Beam-Type Prosthetic Foot for Indian Persons with Amputations

by

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Abstract

The goal of this work is to design a low cost, high performance prosthetic foot in collaboration with Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS), in Jaipur, India. In order to be adopted, the foot must cost less than $10 USD, be mass-manufacturable, and meet or exceed the performance of the Jaipur Foot, BMVSS' current prosthetic foot. This thesis investigates different metrics that are used to design and evaluate prosthetic feet and presents an analysis and evaluation of a solid ankle, cantilever beam - type prosthetic foot.

Methods of comparing prosthetic feet in industry and in academia are discussed using a review of literature. These comparisons can be categorized into mechanical, metabolic, subjective, and gait analysis comparisons. The mechanical parameters are the most useful for designing a new prosthetic foot, as they are readily translated into engineering design requirements; however, these are the furthest removed from the performance of the foot. On the other end of the spectrum are metabolic and subjective parameters, which are useful in evaluating prosthetic feet because the objectives of minimizing energy expenditure and earning user approval are clear. Somewhere between these is gait analysis. The literature review reveals that not enough information is available to bridge these categories, that is, there is no consensus on how any particular mechanical parameter affects the subjective ranking of a prosthetic foot. Two mechanical parameters emerge as necessary, but not sufficient: the roll-over shape and the energy storage and return capacity of a prosthetic foot.

A simple model of a solid ankle, cantilever beam - type prosthetic foot is analyzed in the context of these two parameters. By applying beam bending theory and published gait analysis data, it is found that an unconstrained cantilever beam maximizes energy storage and return, but does not replicate a physiological roll-over shape well regardless of bending stiffness. Finite element analysis is used to find the roll-over shape and energy storage capacity from the same model when a mechanical constraint is added to prevent over deflection. The results show that for very compliant beams,
the roll-over shape is nearly identical to the physiological rollover shape, but the energy storage capacity is low. For stiff beams, the opposite is true. Thus there is a trade-off between roll-over shape and energy storage capacity for cantilever beam-type feet that fit this model. Further information is required to determine the relative importance of each of these parameters before an optimal bending stiffness can be found.

A proof-of-concept prototype was built according to this model and tested in India at BMVSS. It was found that another parameter — perception of stability, which is perhaps dependent on the rate of forward progression of the center of pressure — is equally important as, if not more than, the other parameters investigated here. Perception of stability increased with bending stiffness. The prototype foot received mixed feedback and has potential to be further refined. However, the solid ankle model is inappropriate for persons living in India, as it does not allow enough true dorsiflexion to permit squatting, an important activity that is done many times a day in the target demographic. Future work will use a similar method to design and optimize a prosthetic foot with a rotational ankle joint to allow this motion.

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

1 Introduction 13
  1.1 Typical Human Gait and Biomechanics ..................... 15
  1.2 Preliminary Interactions with People Using Jaipur Limbs .......... 20
  1.3 Design Requirements for New Prosthetic Foot .................. 24
  1.4 Outline of Thesis ........................................ 24

2 Evaluating and Measuring Prosthetic Foot Performance 31
  2.1 Introduction ............................................ 31
  2.2 Prosthetic Foot Comparisons In Industry ..................... 32
    2.2.1 American Orthotic and Prosthetic Association Prosthetic Foot
          Project ................................................ 32
    2.2.2 ISO 22675 ........................................... 34
  2.3 Prosthetic Foot Comparisons in Academia .................... 35
    2.3.1 Method ............................................. 35
    2.3.2 Results and Discussion ................................ 36
  2.4 Discussion .............................................. 48
  2.5 Conclusion .............................................. 51

3 Theoretical Considerations for a Mechanically Constrained Cantilever Beam - Type Foot 59
  3.1 Introduction ............................................. 59
  3.2 Unconstrained Cantilever Beam Model ....................... 65
  3.3 Constrained Cantilever Beam ................................ 68
# List of Figures

1-1 Internal Cross-Section of a Jaipur Foot ........................................ 14
1-2 Anatomical Reference Planes ......................................................... 16
1-3 Ankle Plantar and Dorsiflexion ...................................................... 17
1-4 Ankle/Foot Anatomical Terms of Location ....................................... 18
1-5 Power Output at Ankle During Typical Gait Cycle ......................... 20
1-6 The roll-over shape of a foot ......................................................... 21
1-7 Semi-structured interview responses for ease and importance of various activities ................................................................. 23

3-1 Transition from gait analysis parameters to beam bending parameters 65
3-2 Hypothetical force versus displacement curve for cantilever beam ... 67
3-3 Analytical roll-over shapes for unconstrained cantilever beams with uniform cross-section for various bending stiffnesses .............. 68
3-4 Force versus displacement curves for cantilever beams that are too compliant, too stiff, and ideal ................................................. 69
3-5 FE model of constrained cantilever beam foot .................................. 71
3-6 Calculating roll-over shape from FEA results .................................. 73
3-7 Roll-over shape results from FEA of constrained cantilever beams of various bending stiffnesses ......................................................... 76
3-8 Force versus deflection curves resulting from FEA of constrained cantilever beams of various bending stiffnesses .......................... 78
3-9 Trade-off between roll-over shape and energy storage capacity for constrained cantilever beams of various bending stiffnesses .......... 79
3-10 Implications for energy storage capacity for hypothetical foot that engages second cantilever beam in late stance . . . . . . . . . . . . . . . 82
3-11 Subject taking a step with the proof-of-concept prototype prosthetic foot at BMVSS headquarters in Jaipur . . . . . . . . . . . . . . . . . 86
List of Tables

1.1 Phases of Gait Cycle [18] ................................................. 18
1.2 Demographic information for semi-structured interview participants . 22
1.3 Design requirements for prosthetic foot ................................. 25

2.1 Search criteria used in Compendex Database and Inspec Database 36
2.2 Description of metrics, test setup and feet investigated in mechanical
foot comparison studies .................................................. 38
2.3 Outcomes of studies using mechanical metrics to compare prosthetic feet 39
2.4 Descriptions and outcomes of studies using subjective comparisons of
prosthetic feet ................................................................. 42
2.5 Descriptions of studies using metabolic parameters to compare prosthetic
feet ................................................................................. 42
2.6 Outcomes of studies using metabolic parameters to compare prosthetic
feet ................................................................................. 43
2.7 Outcomes of studies using gait analysis to compare prosthetic feet . . 46

3.1 Example of effects of material choice on cantilever beam for range of
bending stiffnesses investigated herein ................................. 80
Chapter 1

Introduction

Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS), an NGO headquartered in Jaipur, India, is the largest organization serving persons with disabilities in the world [3]. Since its inception in 1975, BMVSS has fitted and/or distributed more than 1.3 million prosthetic limbs. In 2013, they provided over 24,000 limbs. The organization is sustained entirely through donations and government subsidies - all of the limbs and other assistive devices are supplied free of charge to people in need. This service is much needed; according to a report by the Indian Ministry of Statistics and Programme Implementation, published in 2003, 1,008 out of every 100,000 people in India have a locomotor disability, and 77 out of every 1,000 of those locomotor disabilities are due to loss of limb [15]. Based on these survey results, 0.08% of the population, or nearly 960,000 people are missing some part of a lower limb [4]. The global prosthetics market as a whole is expected to reach US$23.5 billion by 2017 [6].

The most widely known product from BMVSS is a prosthetic foot called the Jaipur Foot - in fact, the organization itself is commonly referred to as Jaipur Foot. The foot was developed in Jaipur in 1968 in response to the SACH foot - or Solid Ankle, Cushioned Heel foot - failing to suit the specific needs of Indian persons with amputations [21]. Unlike the SACH foot, which has a rigid keel, or internal structure, the Jaipur Foot allows users to squat, sit cross-legged, walk through mud and over rough terrain. The Jaipur Foot also mimics the appearance of a biological foot and
The Jaipur Foot is handmade from wood and several types of rubber, as shown in Figure 1-1. Skilled technicians carve an ankle block from wood and a heel, forefoot, and toes from microcellular rubber compounds. The heel, forefoot, and toes are each coated in a vulcanizing cement, then wrapped with tire cord - a fiber-reinforced rubber tape. Next, the ankle block, heel, forefoot, and toes are assembled using the tire cord in a pattern mimicking the internal structure of a biological foot. The entire foot is then wrapped in a skin-colored rubber, enclosed in a mold and pressurized in an autoclave. Once removed, it is ready to be fixed to the rest of the prosthetic limb and used. The foot costs approximately $5-$10 to fabricate.

In addition to being inexpensive and suitable for the needs of Indian persons with amputations, the Jaipur foot is widely regarded as a relatively high performance prosthetic foot. A study that compared the Jaipur foot to the SACH foot and the Seattle foot, a commercially available energy storing foot, using ground reaction forces found that the Jaipur foot allowed the most natural gait and enabled users to most closely replicated typical walking[1]. In another study, the roll-over shape, or path of center
of pressure along the bottom of the foot (see Section 1.1 for more detailed description of roll-over shape), was measured for eleven types of prosthetic feet used across the developing world; of these, only the Jaipur Foot exhibited a circular roll-over shape, which is closest to the physiological shape, albeit the radius was smaller, which is likely due to increased dorsiflexion to allow squatting[19].

In 2002, BMVSS began working with the Indian Space Research Organization (ISRO) to design a polyurethane (PU) version of the Jaipur Foot[8]. The resulting foot would be lighter weight and mass-manufacturable, which is more efficient in terms of both time and money, and would allow for more consistent quality. Several PU prototypes have been made in collaboration with Dow Chemical, but none have matched the durability of the original rubber Jaipur Foot.

The goal of this work is to design a mass-manufacturable prosthetic foot that performs as well as, if not better than, the Jaipur Foot. In order to meet these difficult constraints, it is necessary that we fully understand the governing behavior of prosthetic feet as well as the social factors that determine the design requirements.

1.1 Typical Human Gait and Biomechanics

Before any further discussion, several terms and parameters related to typical human biomechanics must be defined. Throughout the course of this thesis, the adjective "typical" will be used to describe anything pertaining to a person without amputation or other impairment, e.g. typical gait.

Biomechanical Terms

The three planes which are most commonly used to describe anatomical motions are the sagittal, coronal, and transverse planes, as shown in Figure 1-2. For the ankle joint, the primary motion during flat ground walking occurs in the sagittal plane. This motion is called dorsiflexion when the toes lift up toward the knee, and plantar
flexion when the toes point down away from the knee, as shown in Figure 1-3. The reference axes and the anatomical terms of location for a foot-ankle system are shown in Figure 1-4.

![Figure 1-2: Anatomical Reference Planes [20]](image)

**Typical Gait Cycle**

The gait cycle covers one stride, or one complete sequence from the time one heel makes contact with the ground to the next time that same heel makes contact with the ground. There are many ways to break this cycle up into different phases. The simplest division is stance phase and swing phase. Stance phase occurs when the foot is in contact with the ground; the rest of the gait cycle is swing phase. Note that when one foot is in swing phase, the contralateral foot is always in stance phase. Each leg is in stance phase for about 60% of the gait cycle, and in swing phase the other 40%. This means that there is a period in time when both feet are in stance phase. This is called double limb support, as opposed to single limb support. The gait cycle
is further broken down by Perry into eight different phases, described in Table 1.1.

Palmer and Gates provide a different set of phases to describe the same events: controlled plantar flexion, controlled dorsiflexion, powered plantar flexion, and swing phase [17, 5]. The definitions for these come from plotting the angle versus torque curve for the ankle, which can be broken up into these four segments. In each of these segments, the ankle exhibits a particular behavior, as described by the names of the phases. These are very useful in designing powered prosthetic foot-ankle systems, as sensors can be used to detect which of these phases the prosthesis is in at any given time and alter the output of the ankle according [2]. In passive prostheses, these phases are less useful, as the behavior of the prosthesis cannot be altered during gait. Most passive prostheses focus only on mimicking the behavior of the ankle during
Table 1.1: Phases of Gait Cycle [18]

<table>
<thead>
<tr>
<th>Phase</th>
<th>Functional Task</th>
<th>Percentage of Gait Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stance Phase</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial Double Limb Stance</td>
<td>Initial Contact</td>
<td>0% to 2%</td>
</tr>
<tr>
<td></td>
<td>Loading Response</td>
<td>2% to 12%</td>
</tr>
<tr>
<td>Single Limb Support</td>
<td>Mid Stance</td>
<td>12% to 31%</td>
</tr>
<tr>
<td></td>
<td>Terminal Stance</td>
<td>31% to 50%</td>
</tr>
<tr>
<td>Terminal Double Limb Support</td>
<td>Pre-Swing</td>
<td>50% to 62%</td>
</tr>
<tr>
<td><strong>Swing Phase</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swing</td>
<td>Initial Swing</td>
<td>62% to 75%</td>
</tr>
<tr>
<td></td>
<td>Mid Swing</td>
<td>75% to 87%</td>
</tr>
<tr>
<td></td>
<td>Terminal Swing</td>
<td>87% to 100%</td>
</tr>
</tbody>
</table>

controlled plantar flexion and controlled dorsiflexion.

Two events that occur during the gait cycle that will be used frequently in this work are heel strike and toe-off. Heel strike refers to the instant that the heel hits the ground, and is usually the start of what is considered the gait cycle. Toe-off occurs when the toe of the foot leaves the ground; this marks the transition from stance phase to swing phase.
Ankle Power During Gait

A parameter that will be frequently discussed in prosthetic foot design is the energy storage and return capacity of a prosthetic foot. In order to investigate the function of this property, the mechanical energy provided by a biological ankle must be understood. A plot of the power output at the ankle during the gait cycle is shown in Figure 1-5. The ankle does more positive work than negative work over the course of the gait cycle, and therefore is a net generator. During early and mid stance, the ankle absorbs energy. At push-off, there is a large burst of power that aids in transitioning to the contralateral foot. During swing phase, the biological ankle does a negligible amount of work in positioning the foot in preparation for heel strike. For the typical gait cycle measured and published by Winter, the ankle did 26.3 J of positive work and 4.9 J of negative work over the step for a subject of body mass 56.7 kg [23]. This and all other gait data used in this thesis comes from Winter’s Biomechanics and Motor Control of Human Movement.

Roll-over Shape

Another recurrent parameter in prosthetic foot design is the roll-over shape. The roll-over shape is defined as the path of the center of pressure along the bottom of a foot from the time the heel hits the ground (heel strike) until heel strike on the opposite foot. This path is then rotated from the lab reference frame into the ankle-knee based reference frame, as shown in Figure 1-6. The concept of a roll-over shape builds on pre-existing rocker or rigid cam models of prosthetic feet [7, 11, 22, 18, 12, 10, 9, 13]. The resulting shape is roughly circular with a radius of 0.3 times the leg length [13].
Figure 1-5: Power output at ankle during typical gait cycle as measured by Winter for a person of body mass 56.7 kg [23]. Green area represents positive work, red area represents negative work. The ankle did 26.3 J of positive work and 4.9 J of negative work during the gait cycle shown here.

1.2 Preliminary Interactions with People Using Jaipur Limbs

In January 2012, 19 people were interviewed with the help of a translator as they waited to receive limbs at BMVSS in Jaipur, India. Each participant provided informed consent verbally in accordance with a COUHES approved protocol. The participants were all persons with unilateral amputations. Demographic information about the participants is provided in Table 1.2.

Given a list of activities, each subject was asked whether they were able to perform each activity with no difficulty, with some difficulty, or with great difficulty
Figure 1-6: Illustration of obtaining the roll-over shape of a foot. The roll-over shape of a foot is defined as the path of the center of pressure along the foot from heel strike to opposite foot heel strike, rotated from (a) the laboratory reference frame to (b) the ankle-knee reference frame. The roll-over shape (c) comes from following this center of pressure through an entire step, and is shown here in red. The data used to create these plots comes from Winter's Biomechanics and Motor Control of Human Movement [23].

and whether each activity was very important, somewhat important, or not at all important. Thus the ease and importance of each activity was ranked from 0 (great difficulty / not at all important) to 2 (no difficulty/ very important). The average ease and importance ratings across all 19 subjects are given in Figure 1-7. The activities are displayed starting with the easiest activity at the top down to the most difficult at the bottom. The number of subjects that provided responses to the questions about the ease of each activity are provided in the activity description, as some people did not do all of the activities and thus could not answer.
Table 1.2: Demographic information for semi-structured interview participants

<table>
<thead>
<tr>
<th>Age in Years</th>
<th>Average: 32.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Deviation: 15.2</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>18 Male, 1 Female</td>
</tr>
<tr>
<td>Reason for Amputation</td>
<td>17 Trauma, 1 Sepsis, 1 Cancer</td>
</tr>
<tr>
<td>Years Using Prosthesis</td>
<td>Average: 9.1</td>
</tr>
<tr>
<td>Standard Deviation: 7.0</td>
<td></td>
</tr>
<tr>
<td>Urban/Rural Residence</td>
<td>5 Urban, 14 Rural</td>
</tr>
</tbody>
</table>

The general order of the activities is as could be expected; activities such as walking indoors and walking outdoors on flat terrain were ranked easier than running, walking in wet mud or water, and walking up or down hills. The importance of most activities is less than or equal to the ease of those same activities, which suggests that these activities did not present any issue for the persons using the Jaipur Foot. However, a few of these activities, namely standing for long periods of time, carrying heavy objects, sitting cross-legged and squatting, were ranked as important and difficult. Upon further investigation and discussion with the Jaipur Foot users, most of these are due to problems with the prosthesis as a whole, and cannot be addressed by a new foot alone. Sitting cross-legged, squatting, and standing for long periods of time were difficult primarily due to discomfort caused by the socket. A new foot does however provide an opportunity to address difficulties in carrying heavy objects. Subjects reported that carrying heavy objects - particularly uphill - is difficult as the foot gets "stuck". It seems to the author that under the increased load, the foot dorsiflexes more than preferred. As a result, the user must first unload the prosthetic limb by lifting it straight up before he can proceed to move forward. It should be noted that the Jaipur Foot provides a greater degree of dorsiflexion than many feet in order to allow users to squat, so there may be a trade-off between the stiffness required to carry heavy objects and the compliance required to squat.

Other activities participants reported doing without difficulty included caring for
<table>
<thead>
<tr>
<th>Activity</th>
<th>Ease of Activity</th>
<th>Importance of Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use public transportation (n=19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk indoors (n=18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk on soft mud or sand (n=18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drive a motorcycle (n=11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk outdoors on flat terrain (n=18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ride a bicycle (n=17)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do household chores (n=11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Go up/down stairs (n=19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swim (n=5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk long distances (&gt;1km) (n=18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk on rough or uneven terrain (n=18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drive a car (n=6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stand for long periods of time (n=19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk up/down hills (n=16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carry heavy objects (n=18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sit cross-legged (n=18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Squat (n=19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk in wet mud/water (n=16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Run (n=16)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 1-7: Semi-structured interview responses for ease and importance of various activities. Perception of ease of activities is generally as expected. Three activities stand out as being difficult and important: standing for long periods of time, sitting cross-legged, and squatting, and carrying heavy objects. While all of these present potential areas for improvement, standing for long periods of time, sitting cross-legged, and squatting were perceived as difficult due to socket discomfort rather than the prosthetic foot technology. A stiffer foot could improve users abilities to carry heavy objects, but this is in opposition to the increased ankle dorsiflexion required for squatting.

Children, playing cricket, and watering wheat plants in a field. Additional activities that participants stated they would like to be able to do included running in races, climbing electrical poles to return to a job held prior to amputation, driving an rickshaw, and general farming.

The majority of the complaints participants had were about the socket - several complained of poor fit, pistoning, and discomfort, sweating, and chaffing due to the fully enclosed socket in India’s hot, humid environment. These subjects were at the
BMVSS facility in order to be fit with a new prosthesis, so it is possible that these socket issues were mostly due to the subjects' residual limbs changing size and/or shape since their last visit to the facility. The only areas for improvement suggested by subjects about the foot were that it is slippery in muddy or wet conditions, and that they wish it lasted longer. The Jaipur Foot lasts comparably long to feet used in the western world, but it is the least durable of the components that make up a prosthesis. Thus, most of the time when Jaipur Foot users return to BMVSS to get a new limb, it is because the previous foot broke. Increasing the durability of the foot would let the people using the Jaipur Foot go longer between limbs, which would require fewer trips to BMVSS, which can take days. People have been known to lose their jobs when taking time off to travel to BMVSS and receive a new limb, decrease the frequency of these trips by increasing prosthetic foot durability will result in a huge improvement.

1.3 Design Requirements for New Prosthetic Foot

Based on interaction with the leadership team at Jaipur Foot, interviews with persons using Jaipur limbs, and a review of literature, a set of design requirements has been elucidated in order for a new prosthetic foot to be a viable product. The design requirements are as listed in Table 1.3 below. Several of these will be elaborated in the body of this thesis.

1.4 Outline of Thesis

This thesis describes the work that lead to the design and testing of a preliminary prototype. A literature review was used to determine what metrics can be used to design and evaluate prosthetic feet. The literature review suggested that two metrics are required to achieve symmetric and efficient gait: the roll-over shape and energy
Table 1.3: Design requirements for prosthetic foot

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Measurable Parameter</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass-Manufacturable</td>
<td>Binary</td>
<td>Improves consistency while decreasing cost and time required to produce each foot.</td>
</tr>
<tr>
<td>Durable</td>
<td>Lasts 3 - 5 years in the field</td>
<td>Requires patients to travel to BMVSS less frequently, which in turn increases number of patients BMVSS can fit.</td>
</tr>
<tr>
<td>Light Weight</td>
<td>&lt; 0.8 kg</td>
<td>Increases comfort, decreases energy required for walking [14].</td>
</tr>
<tr>
<td>Compatible with Global Standards</td>
<td>Passes ISO 22675</td>
<td>Provides assurance to potential BMVSS investors.</td>
</tr>
<tr>
<td>Compatible with Global Prostheses</td>
<td>Can be attached via radial wood screws, a center bolt, or a standard pyramid adapter</td>
<td>Allows organizations from across the world to adopt the Jaipur Foot without changing their preferred socket technology.</td>
</tr>
<tr>
<td>Allow Squatting</td>
<td>≥ 30° dorsiflexion</td>
<td>Permits users to use squat toilets, sit to eat, etc.</td>
</tr>
<tr>
<td>Biological Appearance</td>
<td>Must fit in envelope of a typical foot; must have foam</td>
<td>Mitigates social stigma associated with disabilities</td>
</tr>
<tr>
<td>Weather Proof</td>
<td>Entire foot should be encased in a durable foam-like material</td>
<td>Allows foot to be submerged in water, used in rain, etc., in accordance with needs of subjects.</td>
</tr>
<tr>
<td>High Performance</td>
<td>Meets or exceeds Jaipur Foot in terms of metabolic cost and subjective ranking</td>
<td>Discussed in Chapter 2</td>
</tr>
</tbody>
</table>

storage and return. A simple model of a cantilever beam-type prosthetic foot was created. The roll-over shape and energy storage and return capacity of such a foot were calculated using beam bending theory and FEA. A prototype was built and tested at BMVSS in Jaipur, India. An outline of the thesis is as follows:

Chapter 2: Evaluating and measuring prosthetic foot performance

Methods of quantifying differences between prosthetic feet, both in industry and in academia, were reviewed in order to determine what metrics are useful for a) designing and b) evaluating a prosthetic foot. Various categories of types of measurements that can be made with prosthetic feet are described; the merits and limitations of each are discussed. The implications of this literature review for prosthetic foot designers are presented.

Chapter 3: Analysis and testing of a cantilever beam-type foot

A prosthetic foot is modeled simply as a cantilever beam fixed beneath a solid ankle. Using published gait data and beam bending theory, the roll-over shape of this foot is found over a range of beam bending stiffnesses. This reveals that a rigid constraint is necessary to mimic a physiological roll-over shape. A constraint is added to the model. Finite element analysis is used to approximate the roll-over shape and energy storage capacity for this model; trends emerge for each of these as the bending stiffness is varied. A
proof-of-concept prototype foot is built based on these models and tested in the gait lab in BMVSS in Jaipur. Gait data and subjective feedback are discussed.

Chapter 5: Conclusion The important results from the preceding chapters are discussed. Future work is recommended based on the results found herein.
Bibliography


Chapter 2

Evaluating and Measuring Prosthetic Foot Performance

2.1 Introduction

As explained in Chapter 1, the motivation behind this work is ultimately to design a low cost, high performance foot for persons with amputations in India. In order to be adopted by the author’s partner organization in India, Jaipur Foot, a prosthetic foot needs to cost less than $10 USD, be mass-manufacturable, and meet culturally specific user needs, such as allowing squatting and walking barefoot in harsh environments, as well as allowing the user to walk comfortably. In order to accomplish these goals, it is critical that we understand how individual features of prosthetic feet, such as stiffness and energy storage and return affect the performance of the prosthetic foot. By fully understanding the relationship between features and function, the design of the foot can be optimized to minimize the cost while maintaining high performance.

While there are a wide variety of passive prosthetic feet commercially available, there is a lack of information available to quantify and understand differences in prosthetic feet [16, 30, 3]. Many studies have attempted to characterize types of prosthetic feet based on mechanical testing, gait analysis, energy consumption, and user perception, but results have been inconsistent and largely unable to distinguish differences be-
The purpose of this literature review is to 1) identify metrics that can be used to evaluate performance of a prosthetic foot, 2) determine design requirements based on these metrics, and 3) develop an understanding of the state of the science in prosthetic foot design so that work can be focused in a direction that fits with existing literature and contributes to the field. In order to accomplish this, methods of comparing prosthetic feet are broken down into two categories. First, methods that are used by prosthetic foot manufacturers to compare prosthetic feet are discussed along with their merits and limitations. Then a review of selected literature is presented covering methods that have been used to compare prosthetic feet in academia. From this, conclusions are drawn about which metrics are best to focus on for design and evaluation of prosthetic feet. Because the strict constraints on cost and durability in order for the foot to be adopted in the developing world, this review is focused only on passive prosthetic components.

2.2 Prosthetic Foot Comparisons In Industry

2.2.1 American Orthotic and Prosthetic Association Prosthetic Foot Project

Medicare Healthcare Common Procedure Code System (HCPCS) assigns codes to commercially available prosthetic feet and uses these for reimbursement purposes. The purpose of these codes is to label prosthetic feet according to function and ensure that prosthetic feet are appropriately prescribed based on activity levels and needs of the patient. Beginning in 2007, the American Orthotic and Prosthetic Association (AOPA) Coding & Reimbursement Committee (CRC) established a Prosthetic Foot Project Task Force to create and recommend coding standards for prosthetic feet. The Prosthetic Foot Project Task Force worked with prosthetic foot manufacturers to develop these tests based on what was known about existing feet.
Eight different mechanical tests using a material testing machine, such as an Instron or an MTS, were established in the final report. For full details and images of each of these tests, see the AOPA Prosthetic Foot Project Report [4].

Each of these tests dictates a setup to test the displacement of the foot in a particular plane at a prescribed load. Threshold result values are given for each of these tests. Based on whether or not the foot exceeds the threshold value, it falls into a certain category. Codes, called 'L' codes, are assigned to prosthetic feet for insurance purposes depending on the categories into which it falls. For example, one test, the keel test, is described below in detail.

The keel test measures dorsiflexion of the foot to determine keel type. The foot is positioned at an angle of 20 degrees relative to a flat plate with the toes in contact with the plate. The foot is loaded to 1230 N and then unloaded. If the foot displaces less than 25 mm under a load of 1230 N, it is considered to have a rigid keel. If the foot displaces more than 25 mm, and the ratio of the area under the load versus displacement curves during unloading is less than 75% of that during loading (that is, of the work the loading machine does on the foot, the foot does less than 75% of that on the machine during unloading - the rest is dissipated), then the foot is considered to have a flexible keel. If the foot displaces more than 25 mm and the ratio of the area under the load versus displacement curves during loading and unloading is greater than 75%, the foot is considered to have a dynamic keel.

Other tests classify the foot as having a dynamic or a cushioned heel based on energy return and displacement during heel loading, single axis based on amount of dorsiflexion, multiaxial based on compliance in motions other than sagittal dorsiflexion, namely sagittal plantar flexion and coronal inversion. Further tests less relevant to the work at hand include the axial torque absorption test, the vertical displacement test, the dynamic pylon test, and the horizontal displacement test.
It is noted in the final report that the threshold testing values are based off of commercially available products and are not indicative of clinical safety or effectiveness. However, these are the most widely used tests in industry and thus merit some discussion.

A negative consequence of these tests and of HCPCS L codes is that some researchers misinterpret the categories defined by the tests and L codes as binary, and neglect that most of the properties fall on a spectrum with a threshold defined such that the foot falls into one of two categories. An example is that dynamic keel feet are sometimes called energy storage and return (ESAR) feet. Feet are often discussed as though they either store and return energy, or they do not. In reality, the amount of energy a foot can store, the amount of energy a foot can return, and the manner in which that foot stores and returns energy all vary and have significant affects on the performance of the foot. Several researchers have grouped feet based on these categories and expected to find similar behavior within one category, even though the feet are vastly different mechanically. These studies have failed to find consistent behaviors within categories of feet [25, 26, 12].

However, these tests do provide a consistent set of metrics across prosthetic feet that are helpful in prescribing and comparing prosthetic feet.

2.2.2 ISO 22675

The purpose of ISO 22675 is to prove safety and durability of a prosthetic foot. The standard describes a test that replicates the loading a prosthetic foot sees during a step. In order to pass ISO 22675, a prosthetic component must undergo three million cycles of this loading without failure, representing approximately three years of use [19].

Whereas in normal walking the ground is stationary and the foot and knee move,
the testing apparatus described in ISO 22675 loads the foot vertically about a platform that rotates to create the same relative motion. The vertical load on the foot and the relative angle between the foot and the pylon are given at 30 ms intervals for the 600 ms loading cycle, which is repeated with a frequency of 1 Hz. The whole test takes roughly one month to complete.

While ISO 22675 is slow and expensive (ranging from $144,000 to $250,000 for a commercially available testing setup), a prosthetic foot must pass this test to be adopted as a product. No developing world feet were able to pass the previous ISO standard, ISO 10328, a simplified version of ISO 22675 which was the only standard until 2006 and is still in use as an alternative to ISO 22675 [[20]]. Passing ISO 22675 with a prosthetic foot intended for developing countries would open the door for large international organizations, such as UNICEF or USAID to endorse the product. It would also make the product stand out from other options when NGOs that distribute prosthetic feet make decisions about which types of prosthetic components to use.

2.3 Prosthetic Foot Comparisons in Academia

Literature reviews published as recent as 2009 have found insufficient information available from clinical studies to describe the effects of prosthetic foot and ankle components, which are needed to enable prosthetists to make informed prescriptions for their patients [16, 30]. This is largely done based on empirical knowledge and the personal experience of the prosthetist. This section investigates studies that were published after these literature reviews as well as studies dating as early as 2000 that were not included in these literature reviews in order to determine whether any insight can be gained.

2.3.1 Method

A search of the literature was performed using the Compendex Database and Inspec Database from 2000 to present using the criteria shown in Table 2.1. The search was
Based on titles and abstracts, journal articles were included in this review when they compared three or more passive prosthetic feet, either commercially available or experimental prototypes. Studies were excluded when:

1. The study was included in either the Hofstad or van der Linde literature reviews mentioned above.
2. The study used subjects with levels of amputations other than transtibial.
3. The study investigated only powered prostheses.
4. The study was written in a language other than English.

Studies were not evaluated by their methodological quality; that is, sample size, study population homogeneity, randomization, etc. had no effect on whether the study was included.

2.3.2 Results and Discussion

Based on the criteria listed above, 17 studies were selected for inclusion. The metrics used to compare prosthetic feet fell into four categories: mechanical, metabolic, subjective, and gait parameters.
Mechanical comparisons used metrics that can be measured with a test setup independently of anyone using the prosthesis. The AOPA tests and the ISO 22675 test used by prosthetic foot manufacturers as discussed in Section 2.2 fall into this category. Mechanical metrics are the most useful in designing a foot, as they map directly to design requirements and can often be understood in terms of fundamental principles of engineering. However, they are furthest removed from human use scenarios, which ultimately determine the success of a prosthetic foot. The goal of many of the papers discussed herein is to understand how these mechanical features affect the function of prosthetic feet.

At the other end of the spectrum are subjective and metabolic comparisons. These are directly related to the performance of a prosthetic foot, and desirable outcomes are well understood. Since persons with amputations expend more energy to walk than persons without amputations [8], one of the goals of prosthetics is to lower energy expenditure during gait. Subjective comparisons are also very clear - satisfaction of the prosthesis user is the ultimate goal. However, both energy expenditure and subjective rankings are difficult to use as tools during early stage design, as they are dependent on many factors that are not necessarily known and cannot be tested until a foot is built.

In between mechanical comparisons and subjective and metabolic comparisons are comparisons based on gait analysis. Gait analysis provides a wide variety of parameters that can be used for comparison, some of which are clearly mapped to prosthesis superiority (e.g. self-selected walking speed), others of which are less clear (e.g. joint range of motion).

In the following sections, the studies that fall in each of these categories will be discussed and compared in order to understand the usefulness of each of the proposed metrics as both design and evaluation tools.
Table 2.2: Description of metrics, test setup and feet investigated in mechanical foot comparison studies

<table>
<thead>
<tr>
<th>Author</th>
<th>Metrics</th>
<th>Test Setup</th>
<th>Feet Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hansen (2000) [13]</td>
<td>Roll-Over Shape</td>
<td>Prosthetic foot loading apparatus (mechanical device designed to load foot in contact with flat plate in orientations corresponding to several stages of gait)</td>
<td>Flexwalk foot; Quantum foot; SACH foot; Safe foot; Physiological foot</td>
</tr>
<tr>
<td>Geil (2001) [9]</td>
<td>Stiffness; Energy Lost During Cyclic Loading (ie Area within Hysteresis Curve)</td>
<td>Instron with foot in fixed orientation relative to ground surface, representative of push-off. Constant compressive strain loading for stiffness; sinusoidal loading with frequency 1 Hz for hysteresis measurement.</td>
<td>College Park TruStep; FlexFoot Vari-Flex/Split Toe; Kingsley Steplite Flattie; Kingsley Steplite Strider; Ohio Willow Wood Carbon Copy High Performance; Otto Bock Dynamic Plus; Seattle Voyager; Seattle LightFoot II</td>
</tr>
<tr>
<td>Geil (2002) [10]</td>
<td>Stiffness and Damping Coefficients for Standard Linear Viscoelastic Solid Model</td>
<td>Instron with foot in fixed orientation relative to ground surface. Load applied at three different rates.</td>
<td>College Park TruStep; FlexFoot Vari-Flex/Split Toe; Kingsley Steplite Flattie; Kingsley Steplite Strider; Ohio Willow Wood Carbon Copy High Performance; Otto Bock Dynamic Plus; Seattle Voyager; Seattle LightFoot I, Seattle LightFoot II</td>
</tr>
<tr>
<td>Hansen (2004) [15]</td>
<td>Effective Foot Length Ratio (EFLR)</td>
<td>Weight mounted on foot, loaded to weight of person by technician. Pylon rocked from 15deg on heel to 25deg on forefoot.</td>
<td>Quantum; SACH; Endolite DRF1; Single Axis; Carbon Copy 2; IPOS Cinetic; IPOS CTV; Masterstep; Seattle; Cwalk; Endolite DRF2; College Park; USMCE 2; Carbon Copy 3, Flexwalk, Physiological Foot</td>
</tr>
<tr>
<td>Sam (2004) [27]</td>
<td>Mass; Roll-Over Shape; Damping Ratio; Natural Frequency</td>
<td>RO Shape: Weight mounted on foot, loaded by technician in lab to 600N. Pylon rocked from 15 deg to 30 deg relative to the floor.</td>
<td>Dynamic response: Prosthetic foot loading apparatus SACH feet from El Salvador, Guatemala, and the US; C-shaped polypropylene keel foot from El Salvador; Polypropylene keel feet from ICRC Cambodia, ICRC Mozambique, ICRC Ethiopia, ICRC Geneva, and from Handicap International in Mozambique; Rubber, wood, and aluminium foot from Vietnam; Jaipur Foot</td>
</tr>
<tr>
<td>Curtze (2009) [5]</td>
<td>Roll-over Shape: Radius; Center of Curvature; Forward Travel of Center of Pressure; Instantaneous Radius of Curvature</td>
<td>70 kg weight mounted on 1 m pylon on foot (inverted pendulum), rocked by researcher within rig from -15deg to 20deg</td>
<td>Endolite Espirit; Endolite Navigator; Ossur Flexfoot; Ossur Vari-Flex; Otto Bock 1C40; Otto Bock 1D10; Otto Bock 1D35</td>
</tr>
</tbody>
</table>

Mechanical Comparisons

Six of the included studies used mechanical metrics as a mean to compare prosthetic feet. Table 2.2 and Table 2.3 describe the study design and outcomes respectively.

Four of these six studies focus on parameters related to the roll-over shape of a prosthetic foot. Hansen introduces the roll-over shape and defines it as the path of the center of pressure from heel strike to opposite heel strike rotated into the ankle-knee reference frame [13]. It is a convenient metric, as it can be measured either mechanically or from gait analysis, and is equally applicable for all types of feet, including biological feet. He suggests that an objective in designing a new prosthetic foot is to produce a roll-over shape that replicates the roll-over shape as measured on a biological foot during typical walking, and ascertains that a prosthetist’s goal in aligning a
Table 2.3: Outcomes of studies using mechanical metrics to compare prosthetic feet

<table>
<thead>
<tr>
<th>Author</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hansen (2000)</td>
<td>Roll-over shape of a prosthetic is defined and proposed as indicator of performance. Flexwalk foot had roll-over shape nearly identical to physiological roll-over shape, which may explain its high performance in other published studies. Quasistatic properties of prosthetic feet determine the roll-over shape of a foot; prosthetists likely align foot such that roll-over shape of foot most closely matches orientation of physiological roll-over shape.</td>
</tr>
<tr>
<td>Geil (2001)</td>
<td>Feet tested fell into four stiffness categories with little variation within each category. Flex-Foot lost least amount of energy during cyclic loading; College Park TrueStep lost the most. However, Flex-Foot also required the least amount of energy to load, so the percentage of energy lost was around average. All feet except Flex-Foot were tested with a foam cosmesis.</td>
</tr>
<tr>
<td>Geil (2002)</td>
<td>Prosthetic feet generally fit the standard linear viscoelastic solid model, with lowest $R^2 = 0.8982$. The Flex-Foot and College Park feet were least accurately modeled, possibly due to compliant ankles. Flex-Foot showed non-linearity in force versus deflection curve that was not captured. Most feet had similar damper coefficients, but Flex-Foot was significantly lower, most likely due to absence of foam cosmesis. Stiffness coefficients varied more than damping coefficients. A more robust model is needed to capture behavior of all types of feet.</td>
</tr>
<tr>
<td>Hansen (2004)</td>
<td>Effective foot length ratio (EFLR) is defined as the distance from the heel to the most anterior position of the center of pressure during a step over the total length of the foot. For physiological feet during typical walking, EFLR was measured as 0.83. The EFLRs for the prosthetic feet studied here ranged from 0.63 to 0.81. A shorter EFLR may lead to a 'drop-off' effect, in which the person using the prosthesis effectively falls onto his or her biological limb, resulting in asymmetrical step length and higher loads on the biological side.</td>
</tr>
<tr>
<td>Sam (2004)</td>
<td>The mass of the prosthetic feet varied from 193.0 g to 854.6 g. The natural frequencies of all the feet were much higher than loading rate during normal walking; damping ratios were all low, such that dynamic properties were not likely to affect the performance of the feet during walking. All of the feet had SACH-like roll-over shapes, except for the Jaipur Foot, which was circular with a radius smaller than that of a physiological foot. None of the roll-over shapes extended into the toes, which could lead to 'drop-off' effect.</td>
</tr>
<tr>
<td>Curtze (2009)</td>
<td>Radius of roll-over shape for the prosthetic feet varied around 312 mm. Putting the prosthetic feet in shoes reduced the radius of curvature. The horizontal position of the center of pressure on the ground with respect to the shaft angle is an 'S' shaped curve, and may be an important metric to include with roll-over shape measurements.</td>
</tr>
</tbody>
</table>

A prosthetic foot is to orient the roll-over shape of the foot such that it best matches the roll-over shape of a biological foot.

Hansen’s second study in this category investigated the effect of a single attribute of the roll-over shape, which he calls the effective foot length ratio (EFLR) [15]. It is defined as the ratio of the distance from the heel of the foot to the anterior-most point on the roll-over shape (the effective foot length) to the overall length of the foot.

As with the roll-over shape, Hansen proposes that the optimal EFLR that which is closest to the physiological value, which he found to be 0.83. Hansen suggests that a prosthetic foot with too short of an EFLR results in what he calls a "drop-off" effect. In this case, the prosthetic foot is unable to support the weight of the person using the prosthesis as the center of pressure progresses out towards the toe. As a result, the person tends to fall onto his or her other limb, resulting in asymmetrical step lengths and higher ground reaction forces.

Sam measured the roll-over shapes and dynamic properties of 11 different feet used in developing countries, and found that the roll-over shapes of all but the Jaipur foot
resembled that of a SACH foot, which is mostly flat with a steep curve upward at the toes [27]. The Jaipur foot had a circular roll-over shape, which is close to what is seen from biological feet, but the radius was smaller than that of a biological roll-over shape. All of the feet studied here exhibited a small EFLR.

Curtze also investigated roll-over shape of commercially available prosthetic feet, but measured more individual parameters describing the shape: the radius, the horizontal center of curvature, the forward travel of the center of pressure, and the instantaneous radius of curvature [5]. While other studies have discussed radius and center of curvature [23, 24], to the author’s knowledge, this is the first study that has considered the forward travel of center of pressure. This could be an important parameter, as a foot could exhibit a physiological roll-over shape but have very different rates of progression of the center of pressure along that path. Further work is required to determine how this particular metric influences prosthetic foot performance.

In both of his studies, Geil measured static and dynamic properties of feet using an Instron. The prosthetic feet are oriented in a position that mimics push-off and lowered to a flat surface such that the toes come in contact with the ground first. In his first study, Geil found the stiffness of the feet in this position by applying a constant strain rate and measuring stress. He then considered energy recovery properties by applying a sinusoidal strain rate and measuring differences in work done in loading and unloading the foot. He found that stiffnesses of the different prosthetic feet on the market fell into one of four categories, with little variation within each category. Energy recovery varied much more. The Flex-Foot had the least amount of energy loss and was also the only foot tested without a foam cosmesis, which suggests that the cosmesis is responsible for most of the energy dissipation during loaded, as is expected [9].

In his 2002 study, Geil performed a very similar test, but modeled prosthetic feet using a standard model for linear viscoelastic solids - a spring in parallel with a
spring and damper in series. Three different constant strain rates were applied to prosthetic feet oriented relative to a flat plate in a position representative of push-off; the measured stress in each of these cases was used to find the damping coefficient and the stiffnesses in each of the springs in the viscoelastic model. Geil concluded that most of the feet tested fit the viscoelastic model very well, but it failed to capture the non-linearity of the Flex-Foot, which indicates a need for a more robust model. In the force versus displacement plots Geil presents, there is minimal difference in behavior for the different loading rates, which suggests to the author that a linear elastic model might be more appropriate for the loading of prosthetic feet in this manner. It appears that little benefit is gained by adding the complexity of a viscoelastic model [10].

**Subjective and Metabolic Comparisons**

Studies that use subjective questionnaires or metabolic measurements to compare prosthetic feet are discussed together because, unlike mechanical or gait analysis measurements, both subjective and metabolic metrics can clearly show the superiority of a prosthetic foot over another prosthetic foot. A prosthetic foot that allows a user to expend less energy while walking is superior to a prosthetic foot that requires more energy expenditure, and a prosthetic foot that people rank highly is superior to a prosthetic foot that people rank poorly. Determining what mechanical and gait analysis parameters cause feet to be superior lacks a definitive answer. Thus subjective and metabolic metrics both provide useful evaluation tools for existing prosthetic feet.

Of the included studies, three used subjective preferences to compare prosthetic feet (Table 2.4), and five used metabolic parameters (Table 2.5). The outcomes of the studies performing metabolic comparisons are presented in Table 2.6.

Each of the studies using subjective metrics used different methods to achieve the results. Huang had subjects rank the comfort of each prosthetic foot on a scale from 0 - 7 during normal walking, walking on a slope, walking on grass, and fast walking.
Table 2.4: Descriptions and outcomes of studies using subjective comparisons of prosthetic feet

<table>
<thead>
<tr>
<th>Author</th>
<th>Type of Questionnaire</th>
<th>Feet Used</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huang (2001)</td>
<td>Comfortable ambulation score (0 = impossible, 7 = excellent) for normal walking, walking on a slope, walking on grass, and fast walking.</td>
<td>SACH foot; Single Axis foot; Multiple Axis foot</td>
<td>Multiple Axis foot was most comfortable, then Single Axis, then SACH. No significant difference was found in questionnaire between vascular and traumatic groups.</td>
</tr>
<tr>
<td>Klodd (2010)</td>
<td>Preference Ranking</td>
<td>Five experimental prototype Shape&amp;Roll feet of varying flexibility (roll-over shape radius of curvature varied from 15% of leg length for F1 to 55% of leg length for F5)</td>
<td>F3 and F4 both ranked significantly better than F1. F3 was designed to most closely replicate physiological roll-over shape, F4 was slightly stiffer. F1 was most flexible foot.</td>
</tr>
<tr>
<td>Galley (2012)</td>
<td>Self-Report Questionnaires (Prosthesis Evaluation Questionnaire-Mobility Scale, Locomotor Capabilities Index - 5); Two performance-based measures (Amputee Mobility Predictor with a prosthesis and 6-minute walk test); Steps per day and hours of activity per day measured with step activity monitor</td>
<td>SACH foot; SAFE foot; Talux foot; Proprio foot (microprocessor ankle)</td>
<td>None of the self-report or performance measures were able to detect differences between prosthetic feet, suggesting that either these tests are inadequate at measuring these differences, possibly due to a &quot;ceiling effect&quot;, or that K-levels are not adequate. Some of the tests were able to distinguish in pre-training versus post-training and in peripheral vascular disease (PVD) versus non-PVD.</td>
</tr>
</tbody>
</table>

Table 2.5: Descriptions of studies using metabolic parameters to compare prosthetic feet

<table>
<thead>
<tr>
<th>Author</th>
<th>Metrics</th>
<th>Method</th>
<th>Feet Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hsu (2000)</td>
<td>Energy Cost [mL/O2/kg/min]; Gait Efficiency [mL/O2/kg/m]; Relative Exercise Intensity (percentage of age-predicted maximum heart rate)</td>
<td>Oxygen uptake and heart rate measurement during walking on treadmill at five different speeds.</td>
<td>SACH foot; Flex-Foot; Re-Flex Vertical Shock Pylon</td>
</tr>
<tr>
<td>Huang (2001)</td>
<td>Energy Rate [mL/O2/kg/min]</td>
<td>Oxygen uptake measurement during walking on treadmill at three different speeds and three different inclinations.</td>
<td>SACH foot; Single Axis foot; Multiple Axis foot</td>
</tr>
<tr>
<td>Adamczyk (2006)</td>
<td>Net metabolic rate [W/kg]</td>
<td>Oxygen consumption and CO2 production measurement on treadmill at fixed speed and cadence.</td>
<td>Rigid arcs with seven different radii of curvature (0.02, 0.05, 0.10,0.15, 0.225,0.30,0.40 m) attached to boots that limit ankle motion for persons without amputations.</td>
</tr>
<tr>
<td>Klodd (2010)</td>
<td>Oxygen Cost [mL/O2/kg/m]</td>
<td>Oxygen uptake measurement during walking on treadmill at self-selected walking speed.</td>
<td>Five experimental prototype Shape&amp;Roll feet of varying flexibility (roll-over shape radius of curvature varied from 15% of leg length for F1 to 55% of leg length for F5).</td>
</tr>
<tr>
<td>Adamczyk (2013)</td>
<td>Metabolic energy expenditure rate [W/kg]</td>
<td>Oxygen consumption and CO2 production measurement on treadmill at fixed speed.</td>
<td>Five rigid arcs with radius of 0.40 m and lengths 0.203, 0.229, 0.254, 0.279, and 0.305 m; Two others with length 0.354 m and radii 0.30 and 0.60 m.</td>
</tr>
</tbody>
</table>
Table 2.6: Outcomes of studies using metabolic parameters to compare prosthetic feet

<table>
<thead>
<tr>
<th>Author</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hsu (2000)</td>
<td>Energy cost was significantly higher and gait efficiency significantly lower for subjects walking with SACH and Flex-Foot compared to control group of subjects without amputations. No significant difference was found between control and prosthetic groups at lower speeds, and no significant difference was found between control and Re-Flex Vertical Shock Pylon at any speed. All subjects walking with prosthetic feet had significantly higher percentage of age-predicted maximum heart rates at all speeds.</td>
</tr>
<tr>
<td>Huang (2001)</td>
<td>SACH foot had highest energy rate, followed by single axis foot, then multiple axis foot. Results were significant.</td>
</tr>
<tr>
<td>Adamczyk (2006)</td>
<td>Metabolic rate reached a minimum for arc radius of curvature equal to 30% of the leg length, which corresponds to physiological roll-over shape radius as measured in previous studies.</td>
</tr>
<tr>
<td>Klodd (2010)</td>
<td>Prosthetic foot forefoot flexibility was not found to have a significant effect on oxygen cost.</td>
</tr>
<tr>
<td>Adamczyk (2013)</td>
<td>Length of foot affected energy expenditure much more than radius of curvature. A minimum metabolic rate was found at a foot with length approximate 0.285 m, but was not significantly affected by radius.</td>
</tr>
</tbody>
</table>

He found that the Multiple Axis foot was the most comfortable, followed by the Single Axis foot, then the SACH foot [18].

Klodd asked subjects to rank the five experimental prototype feet with varying roll-over shape radii in order of preference. The prototypes were labeled F1 - F5 and had roll-over shapes with curvature varying from 15% of leg length for F1 (the most compliant) to 55% of leg length for F5 (the stiffest). The prototype labeled F3 had a roll-over shape closest to the physiological roll-over shape. Subjects preferred F3 and F4 significantly more than F1, suggesting that 1) prosthetic foot roll-over shapes close to physiological roll-over shapes are preferred, but a range of roll-over shapes are acceptable, and 2) keels that are too stiff are preferred to keels that are too compliant[21].

Gailey’s study focused more on the usefulness of questionnaires and clinical performance tests than on the feet themselves and sought to determine whether these results could be used to determine differences in various commercially available prosthetic feet. He found that none of these were able to measure added functionality due to different feet. He postulates that this is due to a "ceiling effect" - the clinical questionnaires and tests he used focus more on evaluating functional ability of a patient. Since the subjects used were all highly functional ambulators, the questionnaires and
tests were unable to measure small increases in performance. This suggests that these clinical outcome measurements are poor tools for evaluating prosthetic foot performance [7].

Most of the studies that considered metabolic parameters used the energy cost of walking on a treadmill measured through oxygen consumption in milliliters of oxygen per kilogram per minute. Only the two studies conducted by Adamczyk reported the net metabolic rate of walking in watts per kilogram by measuring both oxygen intake and carbon dioxide production and using an empirical formula to calculate power output [1, 2].

Hsu found that persons walking with a SACH foot or a Flex-Foot expended more energy in walking at fast speeds than persons without amputations [17]. Surprisingly no difference was found at lower speeds. Subjects walking with the Re-Flex Vertical Shock Pylon, did not expend significantly more energy than the subjects without amputations during walking at any speed. This suggests that the Re-Flex Vertical Shock Pylon is superior to the SACH foot and the Flex-Foot in terms of energy cost. Nothing can be said about the relative merits of the SACH foot and the Flex-Foot, as the two were not directly compared within the study.

Huang's results in metabolic parameters matched his results in subjective preference - the multiple axis foot, which was rated the most comfortable, required the least amount of energy expenditure, followed by the single axis foot, then the SACH foot, which was rated the least comfortable [18]. This supports the idea that feet that require less energy expenditure are superior to feet that require more.

Both Klodd and Adamczyk used experimental prototype feet to isolate and vary specific features. Both essentially focused on roll-over shape, although went about doing so in different ways. Klodd started with a Shape&Roll foot, a prosthetic foot that was designed to mimic the ideal roll-over shape by bending through a series of
flexural hinges. By changing the number and spacing of the flexural hinges, both the stiffness and the roll-over shape of the prototype foot was altered, resulting in five different feet labeled F1 - F5, as previously discussed [21]. Adamczyk’s prototypes were simply solid arcs of different radii that were attached to the bottom of AirCast Pneumatic Walking Boots, which restricted biological ankle motion of the wearer. The result was an imposed roll-over shape, or rocker radius, with all other variables, such as energy storage, stiffness, etc., eliminated [1]. A follow-up study was performed that also varied the length of the rigid arcs [2].

While Klodd was unable to find a significant difference in energy rate between the prototype feet, Adamczyk found that the metabolic cost of walking reached a minimum for arcs of radius 30% of the leg length [1]. However, his follow up work found that the arc length had a much greater effect on the energetic cost of walking than the radius [2]. The difference in results between Klodd and Adamczyk could be explained by a) alterations in stiffness and roll-over shape unintentionally altering other features of prototypes in Klodd’s study, b) arc length remaining unchanged between prototypes in Klodd, c) use of persons with amputations in Klodd, as opposed to persons without amputations wearing boots to restrict ankle motion in Adamczyk.

Gait Analysis Comparisons

In this discussion, 'gait analysis' pertains to any study which uses any combination of force place, motion capturing systems, and, in the case of Fey [6], EMG electrodes. The studies included were not limited to those using subjects with amputations - Hansen and Adamczyk utilized subjects without amputations with a pseudo-prosthesis boot which restricts ankle motion and to the bottom of which prosthetic feet can be attached. The included studies and their more important outcomes are provided in Table 2.7.

The Adamczyk studies, the Hansen studies, and the Klodd study all focus on the effects of changing different roll-over shape characteristics of the feet. The 2000 Hansen
Table 2.7: Outcomes of studies using gait analysis to compare prosthetic feet

<table>
<thead>
<tr>
<th>Author</th>
<th>Feet Used</th>
<th>Selected Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hansen</td>
<td>Flexwalk Foot; Quantum Foot; SACH Foot; SAFE Foot</td>
<td>Roll-over shape as measured during gait analysis at normal pace and at very slow &quot;quasi-static&quot; pace is very similar to roll-over shape as measured through mechanical testing; thus it can be considered a mechanical property of the foot.</td>
</tr>
<tr>
<td>Huang</td>
<td>SACH foot; Single Axis foot; Multiple Axis foot</td>
<td>Multiple axis foot had highest self-selected walking velocity, cadence, peak ankle dorsiflexion, and ankle range of motion, and shortest stride time. SACH foot had lowest self-selected walking velocity, cadence, peak ankle dorsiflexion, and ankle range of motion, and longest stride time. The single axis foot fell between these feet for each of these gait characteristics.</td>
</tr>
<tr>
<td>Hansen</td>
<td>Three experimental prototype Shape&amp;Roll feet of varying roll-over shape arc length (long arc length foot representative of physiological roll-over shape, additional wedges removed to prevent center of pressure from progressing beyond wedges in 'medium' and 'short' arc length feet)</td>
<td>Shorter roll-over shape lead to lower maximum dorsiflexion moment on prosthetic side at slow, normal, and fast walking speeds, and larger first peaks of vertical ground reaction forces on the sound limb at normal and fast speeds. Describes 'drop-off' effect for shorter roll-over shapes.</td>
</tr>
<tr>
<td>Adamczyk</td>
<td>Rigid arcs with seven different radii of curvature (0.02, 0.05, 0.10, 0.15, 0.225, 0.30, 0.40 m) attached to boots that limit ankle motion for persons without amputations</td>
<td>Average rate of negative work performed on the center of mass decreased quadratically with increasing radius, fitting simple model of dynamic walking presented in the paper.</td>
</tr>
<tr>
<td>Zmitrewicz</td>
<td>SACH foot; SACH foot with multi-axis ankle; Carbon Copy II foot; Carbon Copy II foot with multi-axis ankle</td>
<td>Propulsive impulse on the prosthetic limb was significantly greater (and consequently more symmetric) with the multi-axis ankle and both feet; the prosthetic foot had no effect. No significant difference was found in any case for peak braking or propulsive ground reaction force or impulse durations on the prosthetic side.</td>
</tr>
<tr>
<td>Klodd</td>
<td>Five experimental prototype Shape&amp;Roll feet of varying flexibility (roll-over shape radius of curvature varied from 15% of leg length for F1 to 55% of leg length for F5)</td>
<td>As flexibility increased, prosthetic ankle dorsiflexion increased and the effective foot length ratio decreased. The differences between biological and prosthetic side ankle moments and first peak vertical ground reaction forces also increased with increasing prosthetic foot flexibility. This supports idea of 'drop-off' effect.</td>
</tr>
<tr>
<td>Ventura</td>
<td>Seattle Lightfoot2, stiff ESAR ankle and compliant ESAR ankle assembled in five combinations: no ankle, stiff ankle facing forward, stiff ankle facing backward, compliant ankle facing forward, compliant ankle facing backward. When ankle is facing forward, it stores and returns energy in dorsiflexion; when ankle is facing backward, it stores and returns energy in plantar flexion.</td>
<td>The ankles increased dorsiflexion and energy storage and return on the prosthetic side. All of the ankles decreased the second peak vertical ground reaction force, increased propulsive ground reaction force impulses on the biological side in early stance, and increased biological side knee joint anterior moments. The ankles facing backward increased the first peak vertical ground reaction force on the biological limb. The compliant ankle facing forward increased braking impulses on the residual limb. Increased power return in prosthetic ankle corresponded to increased power absorption in the prosthetic side knee. Hip joint power was expected to decrease with energy storage and return ankles, but did not.</td>
</tr>
<tr>
<td>Pex</td>
<td>Three 3D printed experimental prototype feet of various stiffesses. Nominal foot was modeled off of stiffness of Highlander FS 3000 prosthetic foot. Stiff foot was 50% stiffer, compliant foot was 50% less stiff.</td>
<td>In general, muscle activity as measured with EMG on both prosthetic and biological sides was highest for most compliant foot and lowest for stiffness of foot, possibly due to the compliant foot necessitating stabilization. Prosthetic foot energy storage and return were both highest for compliant foot and lowest for stiff foot, most likely due to increased dorsiflexion at similar loads. Stiff foot was most mechanically efficient, in that it returned the highest percentage of the energy it stored. First peak of vertical ground reaction force increased with increasing stiffness. Author proposes that, based on the evidence found, there is a trade-off between providing body support and providing energy for forward propulsion in selecting prosthetic foot stiffness.</td>
</tr>
<tr>
<td>Adamczyk</td>
<td>Five rigid arcs with radius of 0.40 m and length 0.203, 0.228, 0.248, 0.279, and 0.305 m; Two others with length 0.254m and radii 0.30 and 0.60 m</td>
<td>Average rate of negative work performed on the center of mass decreased with increasing arc length, but did not change with radius. The angular direction change in center of mass velocity in transitioning from one foot to the other decreased with both increasing arc length and radius; arc length had a much greater influence.</td>
</tr>
</tbody>
</table>
The study measured the roll-over shapes of prosthetic feet for persons without amputations in two conditions: walking normally, and walking very slowly in a 'quasi-static' state. The purpose was merely to compare the roll-over shapes obtained from gait analysis to those measured mechanically, as previously discussed. He found that there was very little difference between the different methods, and thus roll-over shapes are mechanical properties inherent to the design of a prosthetic foot [13]. The Adamczyk studies are primarily concerned with metabolic rates, as discussed above, but also use force plates and other sensors to measure the mechanical work done on the center of mass in redirecting it during step-to-step transition [1, 2]. As expected, this is correlated with metabolic rates. The Klodd study compares the same prototype prosthetic feet with changing roll-over shape radius that were investigated in a separate study during the same year that focused on the metabolic rates and subjective preferences of persons using those feet. She found that feet with smaller roll-over shape radii result in increased ankle dorsiflexion, decreased effective foot length ratio, and decreased symmetry in ankle moments and first peak vertical ground reaction forces [22]. For the 2006 Hansen study, the same prototype foot was modified in a different way such that the roll-over shape arc length was shortened, but the radius remained the same. He found that shorter roll-over shape arc lengths lead to increased vertical ground reaction forces on the biological limb, in agreement with Klodd. Hansen and Klodd have coined the term 'drop-off’ effect to describe this.

Both Zmitrewicz and Huang measured some benefit from multi-axis ankles. Huang found that a multi axis foot had highest self-selected walking velocity and cadence compared to a single axis foot and a SACH foot [18]. Zmitrewicz found that the prosthetic side propulsive impulse was larger and consequently more symmetric between legs when a multi-axis ankle was added to both a SACH foot and a Carbon Copy II foot; the prosthetic feet had no measurable effect [32].

Ventura and Fey investigated ankle/foot compliance and energy storage and return. Both provided data for many different gait parameters. The general takeaway from
both papers is essentially that muscles in both legs are more active when a person is using a more compliant prosthetic foot - the increased muscle activity is required for stability, and possibly negates the benefits of energy storage and return feet/ankles [6, 31];

2.4 Discussion

Stiffness and energy loss, as considered by Geil [9], are excellent examples of the convoluted nature of how mechanical properties affect function of prosthetic feet. The amount of energy dissipated during dynamic loading was presented in four different ways: work done on the foot in loading, work done on the foot in unloading, the difference between these two values (ie energy loss), and the percentage of the work done in loading the foot that was dissipated. The only context Geil offers for interpreting these data is that energy recovery is intended to facilitate limb advancement in prosthetic gait. By thinking through a step on a prosthetic foot from an engineering perspective, it is possible to go deeper than this analysis.

If it is assumed that ground reaction forces are dependent only on a person’s mass, then each foot a single person is wearing will see the same load immediately prior to push-off. The amount this foot deflects, or the amount of dorsiflexion it provides, can be determined using the stiffness of the foot. Since the feet in the study exhibited constant stiffnesses during loading, then the differences in energy done on each foot are dependent only on the stiffness of the feet - when a set force is applied to a stiffer foot, it will deflect less and thus less work will be done on the foot than when the same force is applied to the less stiff foot. Of this total strain energy stored in the foot, some of it is dissipated and the rest is available to assist in providing push-off. By this logic, the amount of work done by the foot on the Instron during unloading might be the most important of the parameters presented, as it is the amount of energy a person wearing a prosthetic foot could transfer for propulsion. However, at least one study has shown that with a prototype prosthetic foot, increased positive
power output at the prosthetic ankle resulted in increased power absorption in the knee of the same leg, so a prosthetic foot being able to store and return energy does not in and of itself result in more efficient gait [6].

Additionally, while the initial assumption made in the previous paragraph, that the ground reaction forces are dependent only on a person’s mass, is necessary to think through the meaning of each of these parameters, it is inaccurate. A person’s gait is influenced by the behavior of the prosthetic foot he or she is wearing, as evidenced by all of the gait analysis studies herein; simultaneously, the behavior of the prosthetic foot is affected by the user’s gait. Thus it is very difficult to isolate a single mechanical property and correlate it to a single measurable gait parameter.

From the studies using subjective comparisons, the most useful conclusion is that clinical tests are inadequate for evaluating prosthetic feet [7]. The metabolic studies support mimicking a physiological roll-over shape and foot arc length, which agrees with Hansen’s hypotheses [13, 15, 14].

An issue inhibiting progress in the field of prosthetics is the lack of an agreed upon set of metrics. Inconsistency in mechanical, metabolic, and gait analysis parameters and how they are measured makes it very difficult to draw conclusions across multiple studies. One metric that stands out as a consistent choice is roll-over shape, due in large part to sheer quantity of papers published on the topic from Hansen and the Prosthetics Research Laboratory at Northwestern University. Of the 17 studies included in this review, nine studies (six of which included Hansen as an author) discussed roll-over shape as a metric. Roll-over shape is particularly useful as it can be measured either mechanically or through gait analysis, is applicable for any type of foot [13], and is shown to have an effect on energy cost [1, 2]. The body of work done by Hansen, Klodd, and Adamczyk all seem to be directed toward a similar conclusion - that having a physiological roll-over shape is important to achieve optimal gait, and that the arc length of that roll-over shape has a bigger effect on gait than the radius.
One benefit of Adamczyk’s work is that he provides analytical models of walking, which he uses to predict why and how the different feet will affect energy expenditure. By using this model, he is able to identify that it is specifically the arc length of the roll-over shape, rather than the radius, which effects metabolic rates. The author believes that this analysis is what is missing from the majority of papers on passive prosthetic feet. Too often an abundance of data is presented without an adequate explanation of why the data is what it is based on physics rather than based on previous studies of prosthetic feet. This is particularly true with gait analysis, as once it is performed, there is a profusion of parameters that can be compared: vertical ground reaction forces, propulsive and braking ground reaction forces, moments at each joint, peak angles at each joint, range of motion at each joint, power at each joint, etc. Each of these has different markers that can be compared, e.g. the vertical ground reaction force curve has two characteristic peaks, one during early stance and one during late stance. The value of the ground reaction force at either of these peaks can be compared. Furthermore, there are many bases for comparison - biological limb versus prosthetic limb, different feet on the same limb, persons with amputations versus normative gait data, and persons with amputations due to trauma versus amputations due to vascular disease. The data quickly becomes overwhelming; too many authors present all of this data and leave the onus on the reader to determine what it all means, or they provide a theoretical explanation for the data without sufficiently validating it. In contrast, Adamczyk used physics to predict what will happen, tested his hypothesis without introducing extraneous variables, and found the results he expected.

While a few papers do span multiple categories of comparison above, it is the author’s opinion that more studies should be done that include metrics from each of these categories to better understand particularly the effect of mechanical properties on gait analysis parameters, and gait analysis parameters on energy expenditure, and all of these factors on user satisfaction.
2.5 Conclusion

In order to gain insight into what makes one prosthetic foot/ankle component better or worse than another one, methods of comparing prosthetic feet both in industry and in academia are reviewed. Tests used in industry include the mechanical tests developed by the AOPA Prosthetic Foot Project Task Force in conjunction with many of the major manufacturers of prosthetic feet and ISO 22675. The AOPA tests serve to characterize mechanical differences between prosthetic feet to facilitate the Medicare reimbursement process. ISO 22675 tests the durability of prosthetic foot components and ensures user safety. It is important to know how a new foot will perform in these tests as they will provide indication of how the foot fits into the existing prosthetics market, but these tests are based on existing products rather than scientific knowledge and make it clear that they are not intended to be used as recommendations for what a prosthetic foot should be able to do.

Studies comparing prosthetic feet in academia have largely failed to produce any consistent results. The publications discussed herein fall into one of four categories: mechanical comparisons, metabolic comparisons, subjective comparisons, and gait analysis comparisons. Mechanical comparisons offer the best insight for designing a new prosthetic foot, as mechanical properties can be optimized using engineering principles. However, very little is understood about how these mechanical properties affect the performance of a prosthetic foot. On the other end of the spectrum are metabolic and subjective comparisons. These are useful tools for evaluating prosthetic feet as desirable outcomes are clear, but cannot be applied until a prosthetic foot is built and ready for use, so these are ineffective during early stage design. Gait analysis falls in between these two groupings. There is a need for more studies to bridge the gap between these categories in order to make links between desirable evaluation outcomes and mechanical properties.

From the literature reviewed here, two properties emerge as relatively important: the
roll-over shape of a prosthetic foot and the energy storage and return capacity. Based on the above discussion, a physiological roll-over shape and high capacity for energy storage and return are likely necessary, but not sufficient, in achieving a high level of performance from a prosthetic foot. No passive prosthetic foot has consistently and conclusively been shown to have higher subjective preference or lower metabolic rates of walking than other prosthetic feet. The goal of passive prosthetic foot research should be to achieve this. This literature review suggests that the best way to do this is by focusing on roll-over shape and energy storage and return for initial design, then using subjective feedback and biomechanics gait data to further optimize for other parameters that emerge.
Bibliography


Chapter 3

Theoretical Considerations for a Mechanically Constrained Cantilever Beam - Type Foot

3.1 Introduction

As explained in Section 2.1, there is no consensus as to how mechanical properties affect performance of prosthetic feet. Establishing a better knowledge base regarding how prosthetic foot features, such as stiffness, range of motion, and energy storage and return, affect function would aide prosthesis designers in optimizing the performance of foot/ankle systems. Based on the information that is available in the literature, as discussed in Chapter 2, two mechanical features emerge as useful tools in early-stage prosthetic foot/ankle design: energy storage and return, and the roll-over shape. A brief summary of literature leading to that conclusion is below.

Energy Storage and Return

Persons with lower limb amputations using passive prostheses expend more energy to walk than persons without amputations [12]. Energy expenditure increases for
persons with higher levels of amputations [44] and shorter residual limb lengths [13]. It has been shown that walking with a powered prosthetic foot/ankle can decrease the metabolic cost of walking relative to using a passive prosthesis [4, 8]. There are two major differences between powered and passive prosthetic feet/ankles - powered prostheses can use sensors and controllers to alter function during different stages of gait, and powered prostheses can supply a net positive work. In this work, the strict cost and durability constraints preclude the use of batteries, sensors, controllers or actuators. The best a passive prosthesis can do to mimic the performance of a powered prosthetic foot/ankle is to store and return as much energy to the prosthesis user as possible.

It should be noted that while a few studies have shown that energy storage and return (ESAR) prosthetic feet reduce the metabolic cost of walking compared to the SACH foot [33, 7, 22], numerous studies have not found a significant difference [40, 5, 29, 28, 34, 41, 21]. At least one study found that while a foot with increased ESAR did increase positive work at the ankle, this corresponded to increased negative work, or power absorption, at the knee [10]. The metabolic benefit of powered prostheses together with the inconsistent results for passive prostheses suggest that maximizing energy storage and return is necessary but not sufficient. This work will focus on the magnitude of energy stored and available for return in a prosthetic foot during late stance phase while recognizing that further work needs to be done to understand how to release this energy advantageously.

**Roll-over Shape**

While literature comparing prosthetic feet has not been able to conclusively determine the benefits of different types of prosthetic feet, a handful of studies suggest that the Flex-Foot, when compared to the SACH foot and a few other commercially available prosthetic feet, provides some measurable benefits, such as allowing users to walk faster [33, 39], take longer steps [35, 39], expend less energy [33, 21, 31],
and walk more efficiently (decreased energy expenditure per step) [22, 21, 31]. The Flex-Foot was also perceived as easier to walk with than the SACH foot [30], and preferred over the SAFE foot for stability and mobility [42]. One study showed that subjects using a Flex-Foot exhibited a higher first peak in vertical ground reaction force on the prosthetic limb as opposed to the physiological limb, while the opposite was true for all other feet in the study [35]. Unsurprisingly, the Flex-Foot was also shown to provide more ankle dorsiflexion than the SACH foot [35, 39, 40, 28, 38].

Many studies did not find any significant difference between the Flex-Foot and other prosthetic feet when measuring these same parameters. However, since the Flex-Foot stands out more than any other foot, it is considered to be a high performance passive prosthetic foot. For a review of all these studies and more, see Hofstad [20].

A proposed explanation for the subject preference and other benefits of the Flex-Foot is that the roll-over shape, as defined in Section 1.1 of the Flex-Foot is nearly identical to that of a physiological foot [16].

The roll-over shape is a useful tool for designing a prosthetic foot because it has been shown to be invariant to walking speed [17], carrying weight [15], and heel height [14]. It is applicable for any type of foot-ankle complex, including passive and active prostheses and biological limbs, so it provides a basis of comparison across all feet. Several studies have measured the roll-over shapes of a wide range of commercially available prosthetic feet [16, 19, 9].

One study investigated the roll-over shapes of 11 different types of prosthetic feet used in the developing world [37]. It was found that nearly all of the feet exhibited a SACH-like roll-over shape, which is flat in the midfoot and turns upward very quickly in the toe region, where the solid keel ends and the foot can no longer support the body weight of the person using it. The one exception to this was the Jaipur foot, which had a circular roll-over shape with a much smaller radius than a physiological
roll-over shape. This is likely to accommodate the increased dorsiflexion required for squatting.

Intuitively, if a prosthetic foot mechanically replicates a biological roll-over shape, and if a person using that foot walks in such a way that the center of pressure progresses from heel to toe with ground reaction force magnitudes similar to those measured during typical gait, then the kinematic and kinetic outputs of the foot/ankle will produce typical reaction torques and allow motion replicating expected gait patterns at each of the proximal joints in the leg, which will make typical gait possible. Thus, as suggested by Hansen [16], an objective of prosthetic foot design should be to mimic the physiological roll-over shape.

Experimental Prosthetic Feet/Ankles to Isolate Specific Features

In response to the various studies previously mentioned that were unable to determine how form affects function for existing commercial prosthetic feet, in the last decade researchers began to conduct studies using experimental prototype feet. This enabled them to isolate and modify a single feature at a time and measure the effect of only that change on the performance of the prosthetic foot.

Several of these studies revolved around variations of the Shape&Roll foot, a prosthetic foot intended for use in developing countries and designed to replicate biological roll-over shapes [36]. Hansen varied the arc length of the roll-over shape and found that shorter arc lengths could not support the subject's body weight as the center of pressure progressed toward the toe, causing the subject to fall onto his physiological limb, as observed by a higher initial peak in the vertical ground reaction force on the physiological limb [18]. Additionally, step lengths were more symmetric between the physiological and prosthetic limbs for prosthetic feet with longer arc lengths due to the same effect. Klodd investigated the effect of forefoot flexibility, consequently also altering roll-over shape radius, and found that the most flexible prototypes resulted
in greater dorsiflexion, asymmetrical ground reaction forces, and shorter effective foot length ratios, while the more stiff feet resulted in asymmetrical ankle moments [26]. She also found that the most flexible foot was ranked significantly worse than the feet with flexibility allowing roll-over shapes closer to a physiological roll-over shape. No difference was measured in oxygen cost during walking with the different prototype feet [25].

Adamczyk also investigated roll-over shape or rocker radius, but did so by attaching rigid arc shapes of various curvatures to the bottom of boots that constrained biological ankle motion. He found that the metabolic rate was optimal (lowest) - albeit, still 45% higher than metabolic rates for typical walking - for arcs with a radius of 30% of the leg length, which corresponds to the best fit for physiological roll-over shapes [1, 32]. However, further work suggested that this metabolic benefit is more dependent on the length of the rigid arc rather than the curvature [2].

Fey created prototype prosthetic feet with keels of varying stiffnesses using a selective laser sintering additive manufacturing technique and observed that feet with more flexible keels increase range of motion and energy storage and return, but also require greater muscle activity to provide stability, which diminishes the benefit in total work [10]. Ventura started with a commercially available Seattle Lightfoot2 (Seattle Systems Inc., Poulsbo, WA, USA), and added ankle units that increased dorsiflexion and energy storage and return. This study similarly showed that the increase in energy storage and return in the ankle joint was counteracted by a simultaneous increase in knee power absorption [43].

One flaw of several of these studies is that, excluding Adamczyk, the starting point for the prototypes is a particular geometry of a prosthetic foot that already has inherent characteristic behavior. Thus while the authors claim to be investigating general prosthetic forefoot flexibility, the results have limited meaning to different types of prosthetic feet. This is evidenced by the fact that Fey, Ventura and Klodd all alter the
stiffness of their respective prototypes, but Fey does so by increasing keel thickness, Ventura by adding a compliant ankle, and Klodd essentially by altering mechanical constraints that prevent bending beyond a certain point. Each of these changes have different implications for the mechanics of how the prosthetic foot behaves, which in turn affects biomechanical gait parameters of persons using the feet. By simplifying a prosthetic foot to physical models of its key components and investigating the effect of a single mechanical property from a physical perspective, fundamental insight can be gained and implications can be extrapolated to a much broader range of prosthetic feet.

Finite element (FE) analysis provides a means to evaluate a prosthetic foot without requiring that it be built, which requires time and money, and without introducing variability that arises from human gait. FE methods have been used by others to compare a new model foot to commercially available feet [11], to optimize the design of a prosthetic foot to minimize a cost function, such as external work required at the knee joint [24], and to supplement gait analysis by measuring mechanical properties such as stress and strain of a prosthetic foot [6]. FE requires very little time investment in a particular design and thus enables quick iterations in early design. The information learned is objective and, applied correctly, can provide valuable insight into the effects of different properties on prosthetic feet.

In this work, we use beam bending theory and FE analysis to investigate a simple model of a prosthetic foot as a cantilever beam with and without a mechanical constraint. We vary a single property of the beam, the bending stiffness, to determine its affect on two metrics that are established to be important predictors of prosthetic foot performance - energy storage and return and roll-over shape. Implications of these results for any solid ankle, flexible keel prosthetic foot are discussed.
3.2 Unconstrained Cantilever Beam Model

In gait analysis, the ground reaction force, location of the center of pressure, and the upward motion of the toe with respect to the axis defined by the ankle and knee joints are all measured. These can be equated to the force, length, and deflection of a cantilever beam, as depicted in Figure 3-1.

![Figure 3-1: Data measured during gait analysis (left) translated into a cantilever beam model of a prosthetic foot (right)](image)

Given the force and location of the center of pressure, the stiffness of a cantilever beam can be found such that it deflects the desired amount, using the equation

\[-M = EI \frac{\partial^2 x}{\partial y^2}\]  \hspace{1cm} (3.1)

where \(M\) is the internal bending moment, \(x\) is the distance along the beam, \(y\) is the deflection of the beam, \(E\) is the elastic modulus, and \(I\) is the area moment of inertia. The quantity \(EI\) is also referred to as the bending stiffness of the beam. In the simple case of a cantilever beam with a point load, the equation for the deflection at the
point where the load is applied is

$$\delta = \frac{FL^3}{3EI}$$  \hspace{1cm} (3.2)$$

where $\delta$ is the deflection at that point, $F$ is the load applied perpendicular to the beam, and $L$ is the distance from the supported end of the beam to the application point of the load.

The strain energy stored in a cantilever beam in bending is given by

$$U = \int Fd\delta$$  \hspace{1cm} (3.3)$$

where $U$ is the strain energy stored and $F$ and $\delta$ are as previously defined.

This is a very simple calculation given one static load. What makes this difficult for prosthetic feet is that each of these three quantities changes with time over the course of a step.

The lab reference frame coordinates of every joint and the center of pressure between the foot and the ground, and the magnitude of the ground reaction forces are published by Winter, as measured during gait analysis for a single subject with all limbs intact [45]. These data were collected at a time interval of approximately .014 seconds throughout a step. At each of these time intervals, these data are translated to a measured force applied at a measured distance from the ankle, and (3.2) is used to predict the deflection. Ideally, that deflection is equal to the measured deflection due to dorsiflexion at that time. If that is the case, then the roll-over shape is matched exactly at that point. The theoretical energy stored in the beam at that time is shown in Figure 3-2. Because energy is conserved in this model, the strain energy that is stored immediately prior to push off is available for release to aid in propulsion.
Figure 3-2: Ideal force versus deflection curve for cantilever beam-type prosthetic foot at any given time during stance phase. At the ground reaction force measured during gait analysis for an individual with both limbs in tact, ideally the resulting deflection of the beam should be equal to the measured upward motion due to dorsiflexion at the ankle (i.e., the roll-over shape coordinate at that time). The energy stored in the beam is given by the shaded area under the curve.

Combining the deflections at each time step results in the roll-over shape of the foot. Note that in calculating the deflection in each time step individually, the foot is being treated as quasistatic. This is a common assumption, as the loading frequency of walking is well below the normal frequencies of feet. It has been found that there is little difference between roll-over shapes measured quasistatically and dynamically [16]. Both the horizontal component of the ground reaction force and the horizontal displacement of the beam are also neglected.

The roll-over shapes resulting from this analysis are shown in Figure 3-3 for a prosthetic foot made up of a cantilever beam of constant cross-sectional area and various beam bending stiffnesses. When the center of pressure is directly under the ankle, the beams tend to not deflect enough. However, when the center of pressure moves out towards the toes, the beams deflect too much. If prosthetic feet are not stiff enough, then when the prosthesis user’s weight is over their toes, the amputee is forced to
take an abbreviated step on the prosthetic side, then 'falls' onto the other limb. This results in asymmetric gait and higher impact on the intact limb, both of which may lead to long term injury [16, 26].

![Analytical roll-over shapes for unconstrained cantilever beams with uniform cross-section for various bending stiffnesses, EI.](image)

Figure 3-3: Analytical roll-over shapes for unconstrained cantilever beams with uniform cross-section for various bending stiffnesses, EI.

### 3.3 Constrained Cantilever Beam

The analysis of a cantilever beam prosthetic foot shows that while energy recovery is ideal, a simple cantilever beam is unable to replicate a physiological roll-over shape. A beam of constant cross-section is too stiff near the ankle and too compliant near the toe. In order to keep the beam from over-deflecting, a rigid constraint was added. The resulting model is nearly identical to Knox’s Shape foot, used in experiments that were instrumental in defining the roll-over shape of a foot and its effectiveness as a predictor of prosthetic performance [27]. A foot such as this is convenient for testing in that it decouples the energy storage and return component (the cantilever beam) from the roll-over shape (the rigid constraint). In discussing the design of the Shape foot, Knox states that a beam must be chosen that is compliant enough to

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68
conform to the roll-over shape; thus the amount of energy stored is limited. This thesis builds on Knox's work in quantifying this trade-off between energy storage and roll-over shape.

If the beam is too compliant, it comes in contact with the constraint at a ground reaction force less than the measured physiological ground reaction force magnitude. If the beam is too stiff, the deflection of the beam is less than the deflection required to match the gait data, and the roll-over shape is not achieved. Neither of these situations are ideal energetically, as both store less energy than a beam that deflects exactly the desired amount under the specified load. Figure 3-4 illustrates this concept.

![Comparison of strain energy stored for beams that are too stiff, too compliant, and ideal.](image)

Figure 3-4: Comparison of strain energy stored for beams that are too stiff, too compliant, and ideal. If the beam is either too stiff or too compliant, less strain energy is stored than if the beam were the exact stiffness. If the beam is too compliant (a), it makes contact with the constraint before the full expected load has been applied. After making contact, the force continues to increase, but the deflection does not. If the beam is too stiff (b), it never reaches the necessary deflection for the physiological roll-over shape. If the beam has the correct compliance (c), the constraint is not necessary, and the maximum possible energy is stored. Note that the subscript "target" here refers to values that were obtained in gait analysis of an individual with no amputations and exhibiting typical gait [45].
3.3.1 Finite Element Model

When a constraint is added, using beam bending equations to calculate the roll-over shape and strain energy stored in the beam is no longer the most effective method, as it is time consuming and requires certain simplifications. Finite element analysis is quicker and provides more realistic results.

A finite element model consisting of a flexible cantilever beam, a rigid contact surface defined by the physiological roll-over shape calculated from published gait data [45] above the beam, and a horizontal rigid contact surface below the beam representing the ground was created. The foot was approximated as a 2D solid in plane stress. Figure 3-5 shows the FE model in detail together with a physical prototype of the foot.

The thickness and width of the beam were set to 0.01 m and 0.07 m. Six different bending stiffnesses, selected based on the analysis of unconstrained cantilever beams in Section 3.2, were investigated: 1 N-m², 5 N-m², 10 N-m², 15 N-m², 20 N-m², and 25 N-m². To achieve these, the elastic modulus was varied. Because the analysis presented herein deals exclusively with beam bending and does not discuss stress within the beam, the elastic modulus and the second area moment of inertia never appear independently of one another in the governing equations (3.1) and (3.2) and thus either one could be varied to produce the same results, so long as bending stiffness remains the same.

3.3.2 Method

As with the unconstrained beam in Section 3.2, the foot was modeled quasistatically at several time intervals. The smallest natural frequency of the beam as found by FEA in the condition with the lowest bending stiffness was 16.51 Hz, which is signif-
Figure 3-5: FE model of cantilever beam and rigid contact surfaces representing the ground and the mechanical constraint following a physiological roll-over shape.
icantly higher than the loading frequency during walking of approximately 1 Hz, so this is again verified as a safe assumption.

Roll-over Shape

The portion of the cantilever beam which would be rigidly attached to the ankle was oriented with respect to the ground in 12 different positions covering the range of orientations from heel strike to toe-off. In these 12 different positions, the angle between the theoretical ankle-knee segment and the ground was $-14.6^\circ$ (corresponding to heel strike), $-0.3^\circ$, $3.5^\circ$, $5.6^\circ$, $7.4^\circ$, $9.4^\circ$, $11.3^\circ$, $13.2^\circ$, $16.1^\circ$, $19.8^\circ$, $22.9^\circ$, and $26.8^\circ$ (corresponding to toe-off). These positions were selected by taking the orientations of the ankle-knee segment from the published gait data at approximately equal time steps. Note that fewer orientations were used from heel strike to toe off because there is very little deflection in the cantilever beam when the center of pressure is behind the ankle-knee segment due to the short moment arm; thus the roll-over shape is linear, and only two data points are required to characterize the roll-over shape in this regime. The focus was instead on the foot-flat to toe off regime, where the curvature of the roll-over shape is much higher.

In each of these orientations, a vertical displacement was imposed on the portion of the beam that would be fixed to the ankle (here-on referred to simply as the ankle of the model). As this displacement increased, the sum vertical reaction force acting on the beam from the ground contact surface also increased. The model was used to find the vertical displacement of the ankle which resulted in a sum vertical reaction force equal to the vertical ground reaction force reported in the published gait analysis corresponding to that particular ankle orientation. This represented the actual shape the beam would take if someone were to take a step on it and replicate the published ground reaction forces. Once this position was known, the center of pressure on the ground contact surface in the FE model could be calculated and rotated into the ankle-knee reference frame to produce a data point in the predicted roll-over shape,
as shown in Figure 3-6.

![Diagram](attachment:image.png)

(a)

(b)

Figure 3-6: Illustration of obtaining a point on the roll-over shape plot using an FE model of a single instant during walking. The center of pressure and the ankle position coordinates are measured in the lab reference frame (a), then rotated and translated into an ankle-knee reference frame (b). When this is done for several time steps and plotted on the ankle-knee reference frame, the resulting curve is the roll-over shape.

In order to determine the vertical displacement at the ankle that results in the target net ground reaction force, a displacement was imposed in 1 mm increments. The resulting net ground reaction force was listed at each of these increments. When the target GRF was between two of these incremental net GRFs, the loading was refined such that ten vertical displacements of 0.1 mm were applied between these two displacements. This process was repeated with decreasing displacement step sizes until the GRF at one of the imposed displacements was within 15 N of the target GRF.
When a displacement was prescribed for which the FEA GRF was within 15 N of the target GRF, the reaction force magnitude and the X- and Y-coordinate of each node along the portion of the foot that was in contact with the ground contact surface were exported to a MATLAB script, which returned the location of the center of pressure. This, together with the position and orientation of the ankle at that same prescribed displacement, was used to find the coordinates of a single point on the roll-over shape for that beam stiffness.

In addition to the twelve points resulting from the FEA results in each orientation, a point was added to the roll-over shape directly below the ankle, in line with the ankle - knee segment. At this location the cantilever beam is rigidly attached to the rest of the foot-ankle complex, so when the center of pressure acts at this point, the beam does not undergo any deflection and thus performing a finite element analysis was unnecessary.

In order to quantify how close the roll-over shape for a given beam stiffness was to the physiological roll-over shape, an R² value was calculated comparing the RO shape from FEA to the physiological RO shape. Each of the twelve foot/ankle orientations yield both an x- and a y-coordinate of a point on the roll-over shape for that model. In order to compare these to the physiological roll-over shape, the points on the physiological curve were extrapolated from the data at the x-coordinates of each of the points resulting from FEA. The R² values were calculated by comparing the y-coordinates at these extrapolation points to the y-coordinates from the FEA.

**Energy Storage**

As stated in (3.3) and further illustrated in Figure 3-4, the strain energy stored in a cantilever beam is equal to the integral of the force over the applied displacement, or the area under the curve on a graph of force versus displacement. In the FE model here discussed, the only compliant component is the cantilever beam, which is modeled as a purely elastic element. This means that no energy is dissipated, and the
amount of energy stored in the beam is dependent only on the shape of the beam at a given time, not on the loading that occurred on the way to that shape. This means that the same vertical loading that was applied to the model to obtain the roll-over shape can also be used to obtain the energy stored in the beam, so long as the final position and shape of the beam is the same as it would be during gait. This would not be true if a foam cosmesis or any other dissipator were included in the model.

While the energy stored in the beam can be calculated at each of the 12 orientations of the foot analyzed, the amount of energy stored just before push-off is the most important, as this is the theoretical amount of energy available to be returned as the user propels himself forward. Thus the energy stored in the beam in the position corresponding to this instant during stance was used as an indication of the energy storing capabilities of the beam. This is similar to the test defined by the American Orthotic and Prosthetic Association (AOPA) used by manufacturers to determine whether a prosthetic foot falls into the flexible or dynamic keel categories, in which the foot is loaded at an angle of 20 degrees relative to a surface, similar to the orientation of the foot relative to the ground immediately prior to push-off [3].

To calculate this energy storage, a vertical displacement is imposed at the ankle of the same FE model previously discussed in the final orientation, which corresponds to push-off. At each incremental vertical displacement, the resulting net vertical reaction force on the beam from the ground contact surface was recorded. The displacement at the exact target GRF was linearly interpolated. The energy stored in the beam is equal to the integral of these net vertical reaction forces over the applied displacements, which was approximated from the data using the trapezoidal method of numerical integration.
3.3.3 Results

The roll-over shapes resulting from the finite element model as described above for three of the beam bending stiffnesses analyzed \((EI = 1 \text{ N-m}^2, 15 \text{ N-m}^2, \text{ and } 25 \text{ N-m}^2)\) are shown in Figure 3-7. As expected, the more compliant beams mimic the physiological roll-over shape more closely, as they are more likely to make contact with the rigid constraint under the applied loads.

![Figure 3-7: Roll-over shapes resulting from finite element analysis for three of the beam bending stiffnesses considered. Beams with lower stiffnesses were found to mimic the physiological roll-over shape more closely, since they were more likely to make contact with the rigid constraint defined by the physiological roll-over shape. The stiffer beams do not deflect all the way to the rigid constraint and thus do not replicate the curvature of the physiological roll-over shape as well.](image)

The force versus displacement curves immediately prior to push-off for each of the bending stiffnesses investigated are shown in Figure 3-8. The area under these curves is the amount of energy stored and available for return for beams of the given bending...
stiffnesses. The behavior described above in Section 3.3 and illustrated in Figure 3-4 is clearly exhibited - the most compliant beam makes contact with the rigid constraint at a much lower than desired ground reaction force, at which point the force increases rapidly while the beam is unable to bend any further, resulting in a transition to a nearly vertical force versus deflection curve. Meanwhile, the stiffer beams reach the target GRF without ever reaching the target displacement; this explains the discrepancy between the roll-over shape of the stiffer cantilever beam foot models and the physiological roll-over shape shown in Figure 3-7.

These results, along with the earlier theoretical discussion of a constrained cantilever beam-type foot, suggest that feet that fit this model exhibit a trade-off between roll-over shape and energy storage - very compliant beams fit the roll-over shape well but do not store much energy, whereas very stiff beams store more energy, but do not deflect enough to mimic the physiological roll-over shape. This trade-off is best illustrated by comparing the $R^2$ value of the model RO shape to the energy stored as a function of bending stiffness (Figure 3-9).

### 3.4 Discussion

The above results show the trade-off between energy storage capacity and obtaining a physiological roll-over shape for solid ankle, flexible keel prosthetic feet. Without a mechanical constraint, a simple cantilever beam stores the most energy, but the roll-over shapes either have too large of a radius, which is not optimal metabolically [1], or do not extend far enough in the anterior direction, which could likely lead to asymmetric step length and ground reaction forces seen in other feet with roll-over shapes that curved up too much at the toe [16, 19, 36, 26, 25].
Figure 3-8: Force versus deflection curves calculated from FE model for constrained cantilever beam-type feet of various bending stiffness immediately prior to push-off. The energy stored in the beam and thus available for return during late stance phase is equal to the area under these curves. Feet that are too compliant reach the mechanical constraint at forces much lower than the target GRF (the horizontal dotted line), whereas feet that are too stiff never reach the target deflection (the vertical dotted line).

A mechanical constraint added to the prosthetic foot model, resulting in a model similar to Knox’s Shape foot [27], prevents the beam from over-deflecting, thus enforcing a roll-over shape closer to what is measured during typical walking. However, by limiting the deflection, the constraint also detracts from potential energy storage capacity. More compliant beams make contact with the constraint at lower ground reaction forces, and thus exhibit the target roll-over shape almost exactly, but store significantly less energy than stiffer beams. However, the stiffer beams do not conform to the target roll-over shape as well.
Figure 3-9: $R^2$ value from comparing FE model roll-over shape to physiological roll-over shape (left axis) and strain energy stored in foot immediately prior to push-off (right axis) for each of the bending stiffnesses investigated herein. More compliant beams match the physiological RO shape more closely, while stiffer beams store more strain energy.

Without further information about the relative importance of ESAR and a physiological roll-over shape in terms of user perception and metabolic cost, it is not possible to optimize the bending stiffness of a flexible keel prosthetic foot. However, from Figure 3-9, we see that the energy storage capacity increases quickly for bending stiffnesses up to 10 N-m², while the $R^2$ value for fitting the target roll-over shape does not decrease much in that range. From these results, the ideal bending stiffness is likely at least 10 N-m².

In the FEA model, the thickness of the cantilever beam was left unchanged and
Table 3.1: Example of effects of material choice on cantilever beam for range of bending stiffnesses investigated herein, assuming that each beam is 6 cm wide. The thickness, mass, max stress and factor of safety for two materials, nylon 66 and carbon fiber, for the most compliant and stiffest bending stiffness investigated here, are provided.

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<tbody>
<tr>
<td>Nylon 66</td>
<td>2.8</td>
<td>55</td>
<td>1.38</td>
<td>1</td>
<td>3.57E−10</td>
<td>0.41</td>
<td>85</td>
<td>2.46</td>
<td>22.4</td>
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<td></td>
<td></td>
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<td>25</td>
<td>8.93E−9</td>
<td>1.2</td>
<td>248</td>
<td>6.8</td>
<td>8.1</td>
</tr>
<tr>
<td>Carbon Fiber</td>
<td>230</td>
<td>3600</td>
<td>1.79</td>
<td>1</td>
<td>4.35E−12</td>
<td>0.095</td>
<td>26</td>
<td>468</td>
<td>7.7</td>
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<td></td>
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<td></td>
<td>25</td>
<td>1.09E−10</td>
<td>0.28</td>
<td>75</td>
<td>1300</td>
<td>2.8</td>
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only the elastic modulus of the material was altered to obtain the desired bending stiffness values. This is valid because the roll-over shape and energy storage properties of a cantilever beam depend solely on strain. The two properties that make up bending stiffness - elastic modulus, a material property, and the second area moment of inertia, a geometrical property - do not appear independently in the governing equations. However the equation for stress in a cantilever beam involves the second area moment of inertia. Thus maximum stresses or factors of safety for these beam-type feet require that a material be selected and the geometry of the beam be determined based on the desired bending stiffness. Table 3.1 provides an example of how bending stiffness can be used to design a flexible keel, and how material properties affect the thickness, mass, and stress in a cantilever beam type foot. Since the roll-over shape and strain energy storage are only dependent on bending stiffness, a prosthetic foot with a keel made out of nylon 66 and another with a carbon fiber keel would exhibit the same roll-over shape and energy storage characteristics, assuming they have the same bending stiffness. Their thickness, mass, and maximum stress, however, would differ.

The trade-off observed herein between ESAR capacity and roll-over shape is applicable to any solid ankle, flexible keel prosthetic foot, including the Endolite Espirit$^1$.

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$^1$Endolite, Miamisburg, OH, www.endolite.com
Ossur Flex-Foot Axia\textsuperscript{2}, Ossur Vari-Flex, Quantum Foot\textsuperscript{3}, SAFE foot, Kingsley Flat-tie\textsuperscript{4}, Kingsley Strider, College Park Tribute\textsuperscript{5}, College Park Celsus, Trulife Seattle Energy\textsuperscript{6}, Trulife Seattle NaturalFlex, and the Shape&Roll Foot\textsuperscript{7}. Consider a hypothetical foot similar to the Flex-Foot, for example. The Flex-Foot mechanically behaves in the same way as this model - dorsiflexion is mimicked with a cantilever beam made out of carbon fiber. However, rather than using a rigid constraint to prevent over deflection when the center of pressure is under the toes, a second beam is engaged through a viscoelastic medium, effectively increasing the stiffness. The result is similar to what is shown in Figure 3-8 - when the foot is in a given position and lowered towards the floor, the vertical force versus deflection curve will have a shallow slope in the beginning, when most of the motion is coming from the single cantilever beam, then turn towards a much steeper slope as the second cantilever beam is engaged and stiffens the foot. With this stiffening, the Flex-Foot is able to replicate the physiological roll-over shape \cite{16}, and also store and return energy.

Because the Flex-Foot has a roll-over shape that is nearly identical to a physiological roll-over shape \cite{16}, a change in beam bending stiffness in either direction will result in a worse roll-over shape. However if the primary beam in the Flex-Foot were stiffer, based on trends observed through this analysis, the foot would store slightly more strain energy at the expense of roll-over shape as shown conceptually in Figure 3-10. If the primary beam were less stiff, the roll-over shape of the Flex-Foot would overshoot the physiological roll-over shape, resulting in too much dorsiflexion and a 'drop-off' effect, and store less energy. Based on the positive responses to the Flex-Foot, the foot exhibits a good balance in the trade-off between energy storage and roll-over shape.

\textsuperscript{2}Ossur, Reykjavik, Iceland, www.ossur.com
\textsuperscript{3}Ortho-Europe, Oxfordshire, UK, www.ortho-europe.com
\textsuperscript{4}Kingsley Mfg. Co., Costa Mesa, CA, www.kingsleymfg.com
\textsuperscript{5}College Park Industries, Warren, MI, www.college-park.com
\textsuperscript{6}Trulife, Dublin, Ireland, www.trulife.com
\textsuperscript{7}The 'Shape&Roll' Prosthetic Foot: I. Design and Development of Appropriate Technology for Low-Income Countries \cite{36}
Figure 3-10: Theoretical representation of force versus displacement curve for a prosthetic foot similar to the Flex-Foot, which engages a second beam to effectively stiffen the keel. The Flex-Foot has been found to have a roll-over shape that matches a physiological roll-over shape almost perfectly; thus changing the stiffness of the beam in either direction would result in a worse roll-over shape. However, by stiffening the beam, or making the slope steeper on the force versus deflection slope, the foot can store more mechanical strain energy at the expense of roll-over shape. The green region shows the potential energy gained with a stiffer cantilever beam.

The analysis presented in this section does have some limitations. The roll-over shapes are found by supplying as an input the center of pressure, ground reaction force, and ankle orientation data as measured and published for a subject with typical gait. These roll-over shapes are what would result if that were the case. Persons with amputations do not exhibit typical gait, but the objective here is to design a foot such that, given typical inputs, the outputs enable typical gait throughout the rest of the limb.

The energy stored and available for return here represents a best-case scenario. The beam is treated as linear elastic, and thus there is no energy lost to dissipation through viscoelastic elements, such as a foam cosmesis. Since this condition is the same for each of the bending stiffnesses investigated, the trends observed are still valid. It should also be noted that all mentions of energy storage in this work refer to me-
chanical strain energy stored in the cantilever beam. This is the total amount of mechanical energy available to the user from the prosthesis. Ideally, this energy is released in a constructive manner, reducing the mechanical energy required from the person using the prosthesis, which is correlated to metabolic energy.

All analysis performed in this work was done using a set of published gait data for a single subject with typical gait. The roll-over shapes and energy storage calculated herein could equally be found using the loading conditions defined in ISO 22675, which comes from normative data for typical gait [23]. However, ISO 22675 does not provide any information about where the center of pressure between the foot and the ground surface should be at any given time, and therefore does not allow calculation of a normative roll-over shape to which to compare the FE results. The roll-over shape also could not be compared to the standard of a circle with a radius 30% of the leg length, as no information is known about leg lengths for ISO 22675 loading. Thus a single set of gait data was used rather than the more normative data in the ISO standard.

Further work is required to determine the effects of the mechanical properties here investigated to biomechanical gait parameters, metabolic cost, and subjective ranking. Other factors, such as perception of stability, are likely also dependent on bending stiffness and will affect the performance of the prosthetic foot.

3.5 Prototype Testing

In order to determine how users would respond to a prosthetic foot that exhibited a physiological roll-over shape and energy storage and return by means of a mechanically constrained cantilever beam, a proof-of-concept prototype was built and tested using human subjects and a COUHES approved protocol. Nylon 66 was selected as the material for the cantilever beam, as it has a high yield strength to elastic modulus
ratio, which makes it an effective material for compliant mechanisms due to high strains at failure. The nylon beam was fixed to the bottom of a wooden block using four threaded inserts and machine screws to provide the reaction moment necessary to rigidly constrain the beam such that the assumed boundary conditions were accurately reflected. Nylon beams of different thicknesses were made such that the bending stiffness was approximately $5 \text{ N-m}^2$, $10 \text{ N-m}^2$, $15 \text{ N-m}^2$, $20 \text{ N-m}^2$ and $25 \text{ N-m}^2$.

3.5.1 Method

Before testing was done using subjects with amputations, the investigator fixed the prototype to the bottom of pseudo prosthesis boots. The boots restrict ankle motion so that the only motion achieved is that of the prosthetic feet. This gives persons without amputations an opportunity to experience an approximation of what it feels like to walk using prosthetic feet. This was done a) to verify the safety of the prosthetic feet, after mechanical testing had already suggested that the feet were safe at loads well above what was expected, and b) to experience effects of the different beam stiffnesses that were not captured by the analysis. It was quickly realized that the more compliant beams felt less stable than stiffer beams, in agreement with the literature [10, 43]. For this reason, a bending stiffness of $20 \text{ N-m}^2$ was selected for testing with persons with amputations at the BMVSS facility in Jaipur, India. Note that this perception of stability was not investigated in prior analysis, and is likely correlated with the rate of forward progression of the center of pressure.

Two subjects who were visiting BMVSS to replace worn out prosthetic limbs were recruited for the study. Both had unilateral transtibial amputations due to trauma and were otherwise healthy. The first subject was 62 years old and had a body mass of 65 kg. The second was 21 years old and also had a body mass of 65 kg. Both had been using limbs from BMVSS for over a year. Because the purpose of this test was merely to receive preliminary feedback on an early stage prototype to inform further development, the small sample size of two was not a problem. After a new socket was made and fitted to each of the subjects according to the protocol typically used at
BMVSS, the prototype foot was aligned and fixed to the socket by the organization's prosthetists. The subjects were given at least an hour to acclimate to the new foot. Then the prototype was removed from the socket and a new Jaipur Foot aligned and attached in its place. Again subjects were given at least an hour in the new Jaipur Foot. Following this trial, they were asked what they thought about both feet with the help of a translator.

3.5.2 Results and Discussion

The most notable difference between the Jaipur Foot and the prototype was the capacity of the prototype to store and return energy. The two subjects had very different responses to this characteristic. The older subject hated it, saying that it was pushing his knee forward, and that it was forcing him to walk faster than he would like. He liked the Jaipur Foot much better, due to what he called its 'rigidity'. The younger subject liked the 'springiness' of the foot. He commented that it was letting him walk faster than he could on the Jaipur Foot. Both subjects stated that the prototype was unstable. The younger subject added that if the prototype looked like a biological foot and was more stable, he would prefer it to the Jaipur Foot. The different responses are largely due to the different needs of a young, active person who needs a foot that enables them to do different activities and an older person whose primary concern is stability. Figure 3-11 shows one of the subjects at several stages during a step with the prototype foot.

The larger problem came from an observation from one of the doctors at BMVSS, who noted that the prototype would not allow the user to squat. When Indians squat, their heels remain flat on the ground, and the ankle-knee segment rotates relative to the foot. The prototype, as with all solid ankle, flexible/dynamic keel feet that are commonly used in the developed world, mimic dorsiflexion through beam bending, which does not allow this motion. The younger subject was asked to try to squat in the prototype and was unable to do so.
3.6 Conclusion

This chapter presented an analysis of a simple model of a solid ankle, flexible keel prosthetic foot using beam bending theory and FE analysis. It has been shown that a single unconstrained cantilever beam is insufficient to mimic a physiological roll-over shape. When a mechanical constraint is added, a trade-off becomes evident between roll-over shape and energy storage - as beams become stiffer, the amount of strain energy stored and available for return increases, but the roll-over shape departs from the target physiological shape. This work presents a framework for understanding the effect of bending stiffness on the mechanics of a solid ankle flexible keel prosthetic foot at BMVSS headquarters in Jaipur.
foot that facilitates both evaluation of existing prosthetic feet and design of new feet. Further work is required to connect those mechanical properties to gait parameters.

A prototype prosthetic foot was built based on the analysis done herein and tested first using pseudo-prosthesis boots, then by two subjects with amputations in India. The initial testing with the pseudo-prosthesis boots showed that an important factor not investigated in the FE analysis was perception of stability. This is likely due to the rate of forward progression of the center of pressure. Consequently, a bending stiffness of 20 N-m², which is higher than stiffnesses suggested by the analysis performed herein, was used for subject testing to provide stability. The 62 year old subject disliked the energy storage and return aspect of the foot, while the 21 year old subject liked it. Both subjects stated that the foot was unstable. However, the solid ankle does not allow the dorsiflexion required for squatting, and thus this technology, while promising in theory, is inappropriate for the context of BMVSS. Future prosthetic feet for India must have rotational compliance at the ankle to permit squatting.
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Chapter 4

Conclusion

The motivation of this work is to design a low cost, mass-manufacturable prosthetic foot for Indian persons with amputations. This thesis presented a literature on different metrics that can be used to compare prosthetic feet, a general analysis of how beam bending stiffness affects roll-over shape and energy storage and return capacity for a mechanically constrained solid ankle cantilever beam-type prosthetic foot, and the construction and testing of a proof-of-concept prototype.

Chapter 1 introduces the Jaipur Foot and provides detailed motivation for the work done herein. It describes a preliminary semi-structured interview done with the help of a translator with visitors at the BMVSS headquarters in Jaipur, India. From this interview it was learned that there were very few complaints about the current Jaipur Foot. Most of the issues were due to the socket. The most noticeable contribution that could be made for the persons using the Jaipur Foot would be improving the durability. A set of design requirements is presented as elucidated from these interviews, conversations with doctors and the founder at BMVSS, and from the literature review and analysis presented in Chapters 2 and 3.

Chapter 2 explains the wide variety of methods and metrics that can be used to quantify differences between prosthetic feet. In industry, a set of tests developed by the American Orthotic & Prosthetic Association are used to characterize the mechan-
ical behavior of prosthetic feet primarily to facilitate the reimbursement process for insurance companies. These tests are based on existing products and do not attempt to make any recommendations. ISO 22675 is used to measure the durability and safety of prosthetic feet. In academia, the types of prosthetic foot comparisons can be broken down into mechanical comparisons, gait analysis comparisons, metabolic comparisons, and subjective comparisons. Mechanical measurements are the easiest to use during early stage design, but also the furthest removed from the ultimate objective of the foot. Both subjective and metabolic comparisons are used to evaluate existing prosthetic feet, but are not directly useful for design. Gait analysis falls somewhere in the middle. From the review of literature, two parameters emerge as necessary, but not sufficient: roll-over shape and energy storage and return.

Chapter 3 reduces a prosthetic foot to a very simple model of a cantilever beam attached to a solid ankle, and rigidly constrained to prevent over-deflection. It presents an analysis of how bending stiffness affects both roll-over shape and energy storage. For compliant beams, the roll-over shape replicates the physiological roll-over shape very closely, but stores little energy. For stiff beams, the reverse is true. This was validated using FEA. In order to determine the ideal bending stiffness, information is required about the relative value of each of these properties to the user of the prosthesis. A proof-of-concept prototype prosthetic foot was built to obtain feedback on one such foot. While a few positive comments were made by one of the subjects, the foot does not allow squatting, and thus other options will need to be pursued.

**Future Work**

In order to achieve the 30° of dorsiflexion required for squatting, a rotational joint at the ankle is required. The same analysis that was performed in finding the roll-over shape of an unconstrained cantilever beam in Section 3.2 can be done on a model of a rigid foot with a single degree of freedom rotational joint at the ankle. The stiffness of this joint can be optimized to best mimic a physiological roll-over shape and, if necessary, a rigid constraint can be added to prevent over deflection. In this
case, some of the conclusions from the analysis performed in this thesis will still be valid - when the joint is in contact with the rigid constraint, it will limit the amount of energy stored in the joint. Once this stiffness is optimized, a proof of concept prototype should be built as quickly as possible to perform initial user testing, as was done with the mechanically constrained cantilever beam prosthetic foot discussed herein. If the performance of the foot is satisfactory, the mass should be minimized and the mechanism should be made in such a way that it fits within the envelope of a foot, so that it may be enclosed in foam to provide weather resistance and the appearance of a biological foot. The analysis presented in Chapter 3 is still valid, however, and can be used to evaluate other feet, or to design a foot for a different demographic that doesn’t require squatting.