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Development Of A Variable Stiffness Locally Adjustable And Repairable Low-Cost Energy Storage And Return Carbon Fiber Prosthetic Foot: A Feasibility Study

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DEVELOPMENT OF A VARIABLE STIFFNESS LOCALLY ADJUSTABLE AND REPAIRABLE LOW-COST ENERGY STORAGE AND RETURN CARBON FIBER PROSTHETIC FOOT: A FEASIBILITY STUDY

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Dedication

Dedicated to my Father, Aaron Randell Bowen Ph.D. M.D., and my Mother, Ruth Davis Bowen. Dad, thank you for being a dedicated father and for always setting an example of love, humility, and hard work. Mom, thank you for your love and dedication to your boys.

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by

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THESIS

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For much of this process I have felt inadequate and overwhelmed by the task at hand. I would like to thank my God and Savior Jesus Christ for His grace and mercy in my life to open doors I could not have seen or knocked on, for giving me favor among my peers and superiors, and for working in and through my weakness. May I continue forever to be weak so that He may forever be strong.

> *"Blessed be the name of God forever and ever, to whom belong wisdom and might. He changes times and seasons; he removes kings and sets up kings; he gives wisdom to the wise and knowledge to those who have understanding; he reveals deep and hidden things; he knows what is in the darkness, and the light dwells in him. To you, O God of my fathers, I give thanks and praise, for you have given me wisdom and might, and have now made known to me what we asked of you, for you have made known to us the king's matter." (Daniel 2:20b-23 ESV)*

> *He is the image of the invisible God, the firstborn of all creation. For by him all things were created, in heaven and on earth, visible and invisible, whether thrones or dominions or rulers or authorities-all things were created through him and for him. And he is before all things, and in him all things hold together. And he is the head of the body, the church. He is the beginning, the firstborn from the dead, that in everything he might be preeminent. (Colossians 1:15-18 ESV)*

Abstract

Background: Energy storage and return (ESAR) prosthetic feet were developed to improve the mobility and function of lower-limb amputees. Amputees in the Developing World amputees lack this technology. Most current Developing World prosthetic solutions do not adequately address the needs of active amputees and were not designed to pass international standard tests. Developing a low-cost, repairable, adjustable, energy storage and return prosthetic foot would close this technological gap and improve the mobility and function of active amputees. The goal of this research is to determine the feasibility of fabricating a low-cost, adjustable, ESAR, repairable prosthetic foot manufactured from carbon fiber using methods and techniques that could be replicated in the Developing World and meet international test standards.

Methods: Carbon Fiber plies were hand laid into compression molds to construct the prototype prosthetic components. Static test proof loads of 2065 N and ultimate loads of 3098 N were applied to the toe and heel sections of the prosthesis. Cyclic loads of 1158 N and 1173 N were applied to the toe and heel, respectively. Three unilateral amputees performed walking trials to collect gait parameters and quantitatively and qualitatively assess the prototype prosthetic foot.

Results: Less than $100 of carbon fiber was used to construct the prosthesis. Three nested toe layers and one heel layer with an overload spring withstood static loads with no visual damage. Stiffness could be altered by varying layer stiffness and exchanging layers. Heel components withstood 1,000,000 fatigue cycles with no visual damage. Toe components withstood 150,000 fatigue cycles before delamination caused stiffness to be reduced. Toe components were replaced at 450,000 cycles. Hysteresis measurements showed the Prototype Prosthetic foot's toe returned 5% less energy than the targeted value and the heel returned 31% less energy than the targeted value. Experimental test subjects maintained temporal gait parameters within 10% of their standard prosthetic feet. Subjects' braking and propulsive energies from their amputated leg decreased greatly compared to their standard prosthetic foot. Subjects' qualitative assessments showed difficult transitions from heel strike to toe-off, an increased walking effort, and a need to improve energy return.

Conclusion: The study demonstrated the feasibility of fabricating a low-cost, adjustable, ESAR, repairable prosthetic foot manufactured from carbon fiber using methods and techniques that could be replicated in the Developing World and meet international test standards. Future work should focus on improving energy storage and return properties, increasing fatigue life, and conduct field tests.

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Glossary[1]

Activity Level – see K-Level

Ambulate – to move from place to place: walk

Amputate – to remove by or as if by cutting; especially: to cut (as a limb) from the body

Amputee – one that has had a limb amputated

Developing World – there is no agreed upon definition for the Developing World, but it is typically characterized by a country with low literacy rates, low incomes, instability of exports of goods and services, undernourishment is prevalent in the general population (United Nations, 2012).

Dorsiflexion – flexion in a dorsal direction; especially: flexion of the foot in an upward direction—compare plantar flexion

Eversion – the condition (as of the foot) of being turned or rotated outward—compare inversion

Fatigue Strength – cyclic load which can be sustained by the prosthetic device/structure for a given number of cycles (ISO, 2006a).

Gait – a manner of walking or moving on foot

Inversion – the condition (as of the foot) of being turned or rotated inward – compare eversion

K-Level – K-levels are defined by Medicare based on an individual's ability or potential to ambulate and navigate their environment. Once it is determined in which K-level an individual resides, it can be determined which prosthetic components are covered by Medicare (OandP, n.d.).

K-0 – This patient does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility (OandP, n.d.).

K-1 – This patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence - a typical limited or unlimited household ambulator (OandP, n.d.).

K-2 – This patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces - a typical community ambulator (OandP, n.d.).

[1] Definitions taken from Merriam-Webster's online dictionary (Encyclopedia Britannica Company, 2013) unless otherwise noted.

K-3 – The patient has the ability or potential for ambulation with variable cadence - a typical community ambulator with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion (OandP, n.d.).

K-4 – The patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels - typical of the prosthetic demands of a child, active adult, or athlete (OandP, n.d.).

Lamina – A lamina is a flat (or sometimes curved) arrangement of unidirectional (or woven) fibers suspended in a matrix material. A lamina is generally assumed to be orthotropic, and its thickness depends on the material from which it is made (Fibre Reinforced Plastic, 2010).

Laminate – a stack of lamina bonded together by Epoxy (Fibre Reinforced Plastic, 2010).

Layer – X number of plies of Carbon Fiber laminated together to make a single toe or heel piece that can be nested together with other layers to make a toe or heel section. For this research, a layer is typically 25 plies of carbon fiber laminated together in a compression mold.

Limb – one of the projecting paired appendages (as an arm, wing, fin, or parapodium) of an animal body made up of diverse tissues (as epithelium, muscle, and bone) derived from two or more germ layers and concerned especially with movement and grasping but sometimes modified into sensory or sexual organs; especially : a human leg or arm

Plantar-flexion – movement of the foot that flexes the foot or toes downward toward the sole—compare dorsiflexion

Ply – Single thickness of carbon fiber fabric.

Proof Strength – static load representing an occasional severe event, which can be sustained by the prosthetic device/structure and still allow it to function as intended (ISO, 2006a).

Prosthesis – an artificial device to replace or augment a missing or impaired part of the body

Prosthetic – of, relating to, or being a prosthesis

Sound Limb – amputee's good/uninjured limb (NO SOURCE).

Transtibial – occurring across or involving the tibia

Transfemoral – occurring across or involving the femur

Ultimate Strength – static load representing a gross single event, which can be sustained by the prosthetic device/structure but which could render it thereafter unusable (ISO, 2006a).

Abbreviations

CF – Carbon Fiber

FF – Flex-Foot

H – Hard

ICRC – International Committee of the Red Cross

IPC – International Paralympic Committee

LFL Limbs for Life

LIMBS – LIMBS International

M – Medium

MOI – Mobility Outreach International

PPF – Prototype Prosthetic Foot

S – Soft

SPF – Standard Prosthetic Foot

Chapter 1: Introduction

Losing a foot due to amputation has tremendous living and biomechanical consequences, especially with regards to gait. Compared with abled bodied persons, amputees demonstrate reduced biomechanical function in several areas: walking speed, muscle activation, gait symmetry, and energy needed to ambulate. Prosthetic limbs attempt to restore as much of the functional abilities lost to amputation as possible (Meanley, 1995; Strait, 2006; Ventura et al., 2011). Advances in prosthetic technology enables more of these functions to be restored. However, prosthetic limb technology in the Developed World (previously known as the 1st World Countries) has significantly outpaced modular[2] prosthetic technology in the Developing Countries (previously known as 2nd and 3rd World Countries, respectively). The populations of amputees in the Developing World exceeds the population of amputees in the Developed Countries (Cummings, 1996; Ziegler-Graham et al., 2008). However, they lack the advances in prosthetic technology and rehabilitations sciences. Researchers have recognized this gap in technology and are working to improve prosthetic technology in Developing Countries.

As of 2006, approximately 1.6 million amputees lived in the Unites States (Ziegler-Graham et al., 2008), where as in Africa, Asia, and Latin America an estimated three million people need a prosthetic device (Cummings, 1996). Trauma and a lack of appropriate medical care are the leading causes for amputation in Developing Countries, and the rate of amputations appears to be increasing (Esquenazi, 2004; Aleccia, 2010). Amputee stories listed by LIMBS International often cite a lack of appropriate medical care complicating an infection or injury leading to the amputation. In these cases, amputation is necessary to save the patient's life, which contrasts with the United States, where trauma accounts for less amputations and diseases are the leading causes for amputation (Snyder et al., 1995, Aleccia, 2010).

Amputating an individual's foot and/or leg negatively impacts physical and psychological abilities (Esquenazi, 2004). Exacerbating their physical limitations, reactions to amputees vary depending on local culture and beliefs. Disabled persons in the Developed World benefit from organizations like the

[2] Modular is used to distinguish this prosthetic technology from internal or implanted (en vivo) prosthetic technology e.g. a knee or hip replacement device introduced via arthroplasty. Modular prostheses are artificial limbs "assembled from components or modules usually of the endoskeletal type, where the supporting member (pylon) may have a cosmetic covering (cosmesis) shaped and finished to resemble the natural limbs" (ACA, 2008). For purposes of this thesis, remaining references to "prosthetic technology" will refer to Modular Prostheses unless otherwise noted.

International Paralympic Committee (IPC), which promotes equality and seeks to "break down social barriers of discrimination," amputees in the Developing World lack these types of advocates (IPC, n.d.). Without these advocates and educational organizations stigmas abound and stigmas associated with amputation can be severe as noted by Peter Mbuvi: "society sees us as a cast generation that should be eradicated" (LIMBS International, 2012). Often unable to work, due to the physical nature of work, amputees become dependent on their families for care. This may lead to rejection in some countries leaving a person to beg and live on the street (World Health Organization, 2011).

Organizations such as LIMBS International (LIMBS); the International Committee of the Red Cross (ICRC); Limbs for Life (LFL); and Jaipur are attempting to supply the millions of people needing a prosthesis, but this challenge is monumental. The ICRC (whose 2010 budget was approximately $1 Billion (ICRC, 2012a)) deployed 19,740 prosthetic devices in 2011 and over 374,000 prosthetic devices since 1979 (ICRC, 2012b). Jaipur has fit approximately 400,000 patients in more than 40 countries since the 1970's (Creel, 2013). LFL donates used equipment from the United States and Europe to Developing Countries. LIMBS International partners with universities around the world to research and develop prosthetic devices that meet the challenges and demands of the Developing World. LIMBS also partners with prosthetic clinics internationally and provides training for clinicians. They also used this as an avenue to distribute their technologies. However, these organizations struggle to meet the growing demand and bridge the technological gap between prosthetic devices available in the Developed World and the rest of the world. The United States, in response to over a decade of war, has invested over $70 million into prosthetic limb development (Dishneau, 2007). New computer controlled prostheses that can connect to residual nerves signals have resulted from this research and development (Veterans Affairs, 2014).

Developing countries benefit from these developments through LFL donations, but modern prostheses do not function well in the developing countries. These components are not designed to meet the rigorous environmental conditions found in these locations (Sam, 2004). In the Developing World, a person's work is often physical in nature and lacking a functional prosthesis inhibits the individual's ability to find employment. Surveying LIMBS's patient list, many biographies mention that the prosthesis provided by LIMBS enables the patient to return to work and regain his/her independence (LIMBS, n.d.c).

Esquenazi (2004) noted that for the amputee in the Developing World, the prosthesis restores his/her ability to live. Prosthetic components developed for the Developing World lack the performance of Developed World components. Technology for the Developed World overlooks specific challenges facing components in these locations, i.e. social and cultural factors, climatic factors, local availability of resources, and reliability/maintainability (Cummings, 1996). CNN noted that women will walk an average of 6 kilometers a day to collect clean water and then transport nearly 25 kilograms of water back home (Ure, 2011). Studies of amputees in the Developing World note many walk more than 1 kilometer a day (Jensen & Raab, 2007). These increased distances and loads increase the need for robust components, especially for prosthetic feet (Sam, 2004). The necessity for the prosthetic device to be robust is paramount especially for the feet. The lifespan of the prosthetic foot will dictate the life of the entire prosthesis (Day, 1996).

In many Developing Countries, infrastructure is failing, insufficient, or non-existent (USAID, 2012). This increases the difficulty providing prosthetic clinics and amputees with the supplies they need. To overcome this challenge, LIMBS and the ICRC turned to local manufacturing of their prosthetic technology. The M1 LIMBS prosthetic knee was designed to be manufactured by hand in local clinics (LIMBS, n.d.a). ICRC, similarly, attempted to use locally available materials to manufacture its orthopedic components (ICRC, 2012b). This freed local clinics to manufacture parts as needed and allowed them to operate independently of LIMBS or ICRC. However, controlling the quality of products produced locally was not possible, and both organizations returned to centralized manufacturing. “In the early 1990s the ICRC started the process of standardizing the techniques used in its various projects… to improve the quality of the services to patients” (ICRC, 2006). In 2011, LIMBS partnered with United Surgical in Bangladesh to produce its prosthetic knee (LIMBS, n.d.b). Although LIMBS has centralized its manufacturing, the LIMBS knee continues to be the only locally sustainable knee in the world by using standard size parts and allowing for local repairs using simple materials and tools (LIMBS, n.d.a).

Once deploying components to a country, the challenge of finding qualified prosthetists confronts organizations like LIMBS, ICRC, and LFL. Prosthetists in the Developing World do not have the same training as Prosthetists in the Developed World. This leads poorly fitting prostheses, inadequate

maintenance of the prosthesis, and improper rehabilitation of the patient. Poorly fitting prostheses are not going to be worn long by patients or they may be modified in a way that compromises the integrity of the part. Should the prosthesis fail prematurely, the amputee may suffer additional injuries (Waldera et al., 2012).

Amputees in the Developed World have over 120 prosthetic foot designs to choose from when selecting a prosthetic foot (Stark, 2012). The amputee's prosthetist will recommend a prosthetic foot based on the patient's height, weight, activity level[3], and functional goals (Stark, 2012). The amputee will then walk with the recommended prosthetic foot while the prosthetist assesses the amputees gait and the amputee provides feedback on how the prosthetic foot feels, all before a final prosthetic foot is prescribed (Stark, 2012). The same is not true in the Developing World. Solid Ankle Cushion Heel (SACH) and Jaipur Feet are the most commonly used prosthetic feet in the Developing World. In 2007, Jensen and Treichl analyzed 21 prosthetic feet commonly used in developing countries; all but the 4 Jaipur feet were SACH style feet. SACH feet are intended for low activity patients. Ottobock recommends SACH feet for activity levels K1 and K2 (Ottobock 2014). 57% of amputees involved in a field study on 2 styles of SACH Feet in Tanzania were classified as intense users (Jensen & Raab, 2004). In another study, 81 amputees who commonly walked more than 1 kilometer a day tested two styles of Jaipur feet (Jensen & Raab, 2007). SACH feet and Jaipur feet continue to be widely used regardless of the user's activity level.

The Jaipur foot is a rubber-based foot developed in India in the 1970's to address cultural issues not addressed by SACH feet (Arya & Klenerman, 2008). The foot's design and construction allow it to be flexible. However, this is not ideal considering a loss of forefoot support can lead to early knee flexion collapsing the knee for above knee (AK) patients (Jensen & Treichl, 2007). The Niagara Foot was developed by Robert Gabourie of Montebello, Quebec, and was designed for active users in rugged

[3] Amputees in the United States are classified by their activity level or K-Level. K0, the amputee has the potential or ability to ambulate, and can transfer safely with or without assistance. K1, the amputee has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, and is household ambulatory. K2, the amputee has the ability or potential for ambulation with the ability to transverse low level environmental barriers such as curbs, stairs, or uneven surfaces, and has limited community ambulatory. K3, the amputee has the ability or potential for ambulation with variable cadence, and is a community ambulatory who has the ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion. K4, the amputee has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy, typical of the prosthetic demands of a child, active adult, or athlete (Ossur 2014). See additional information in the Glossary.

conditions (Niagara Foot, n.d.) (Gabourie et al., 2003). Made from injection molded Delrin, the Niagara foot is probably the only foot available for the Developing World that offers any energy storage and return. However, the deployment of this device is unknown.

Lacking among prosthetic feet currently available in the Developing World is a prosthetic foot with energy storage and return (ESAR) that is adjustable and field reparable. LIMBS International has partnered with The University of Texas at El Paso (UTEP) to improve prosthetic technology available for the Developing World. The goal of this research is to determine the feasibility of fabricating a low-cost, adjustable, ESAR, repairable prosthetic foot manufactured from carbon fiber using methods and techniques that could be replicated in the Developing World and meet international test standards.

Chapter 2: Background

Prosthetic feet used in the Developing World do not function at the levels needed to accommodate active users and users with physically demanding work. They lack the performance characteristics needed to be effective and few meet international testing standards or accommodate specific needs of the Developing World. As this problem gains more attention, more research and development is being performed around the globe. Developing World prosthetic technologies are not always successfully transferred to the developing countries because cultural differences are not considered (Sethi et al., 1978). The International Society for Prosthetic and Orthotics defined appropriate prosthetic technology for the Developing World as "a system providing proper fit and alignment based on sound biomechanical principles which suits the needs of the individual and can be sustained by the country at the most economical and affordable price" (ISPO, 2001). Poonekar (1992) notes design criteria specific to India should include: low-cost, locally available, capable of manual fabrication, considerate of local climate and working conditions and foot wear, durable, simple to repair, local manufacturing, technically sound, biomechanically appropriate, lightweight, adequately cosmetic, and psychosocially acceptable. Researchers must attempt to balance these needs as they develop prosthetic technology for the Developing World.

Improving biomechanical performance and improving durability should remain an important goal for prosthetic components targeting the Developing World (Andrysek, 2010). Fatigue tests per ISO 10328 and ISO 22675 recommend two-million-cycle fatigue tests (ISO, 2006a; ISO, 2006b). Murdoch observed amputees average 2498 steps per day (Murdoch et al., 1988). This means prosthetic feet tested to these standards may only last two years, and may wear out sooner if an amputee walks further. Based on recommendations from humanitarian aid groups, Craig recommended the lifespan for prosthetic feet in the field should be three years as a minimum (Craig, 2005). Most testing is performed in ideal conditions (Jensen & Treichl, 2007). Most prosthetic feet prescribed in the Developing World do not meet these durability standards (Jensen & Treichl, 2007).

2.1 SACH FOOT

SACH Feet (Figure 1) continue to be the most common prosthetic feet used in the Developing World (Meanley, 1995; Day, 1996; Jensen & Treichl, 2007; Andrysek 2010). SACH feet are best suited for low-activity users; as Ottobock (2014) recommends SACH feet for activity levels K1 and K2. When compared with prosthetic feet that provide some energy return, SACH feet "required greater output from the natural limb" in order to maintain a fast walking pace (1.3 m/s) (Schneider et al., 1993). Studies have estimated that SACH feet dissipate 70-81% of the energy the user inputs to walk (Schneider et al., 1993) (Barr et al., 1992).

Figure 1: SACH Feet are the most commonly used prosthetic feet used in the Developing Worlds. Picture from Ottobock.com.

The popularity of the SACH foot may be because it is easy to manufacture and looks cosmetically pleasant. SACH feet are manufactured all over the world in countries such as Vietnam, Cambodia, Myanmar, Mozambique, and Thailand (Jensen et al., 2006; Jensen & Treichl, 2007). This ability to be locally manufactured is beneficial in deploying the prosthesis to where it is needed, but there can be problems with attempting to locally manufacture components. Both the ICRC and LIMBS International have attempted to locally manufacture products before moving to centralized manufacturing to improve quality. Mechanical testing performed by Jensen on 17 Developing World SACH feet yielded only one that passed the static proof test per ISO 10328 P5 Loading condition (Jensen & Treichl, 2007). Furthermore, the performance of these feet degrades with exposure to environmental conditions. Jensen concluded that strength testing should be performed prior to releasing newly designed prosthetic feet on to the market (Jensen & Treichl, 2007).

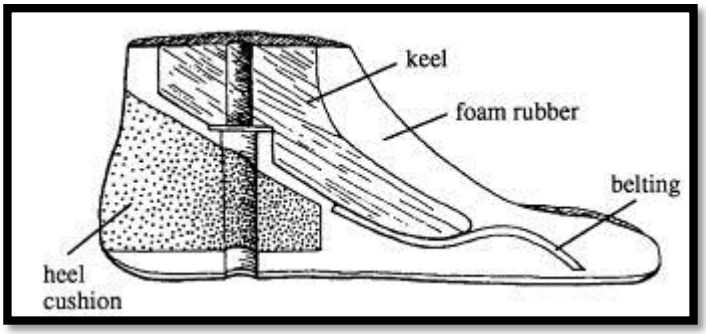


Figure 2: SACH Foot cutaway revealing the foot's construction. The "SOLID ANKLE" of solid wood, the "CUSHION HEEL" of foam. Photo from www.oandplibrary.com.

2.2 JAIPUR FOOT

The Jaipur Foot (Figure 3) was developed in India in the 1970's (Arya & Klenerman, 2008). The foot was initially designed in response to "socio-economic and cultural needs" of amputees in India (Arya et al., 1995). The rubber-based construction (Figure 4) makes a cosmetically appealing and flexible foot that allows amputees to squat, sit cross-legged, and walk barefoot (Arya et al., 1995). While similar in appearance to the SACH foot, the Jaipur foot is fundamentally different in that it is made of a wooden ankle and uses several layers of sponge rubber (Sam et al., 2004). This construction allows for the foot to be locally manufactured in approximately three hours for approximately $5 (Strait, 2006).

Figure 3: JAIPUR Foot developed in India in the 1970's. The foot was developed to meet the particular cultural needs from India. Photo courtesy of Aaron Nystrom.

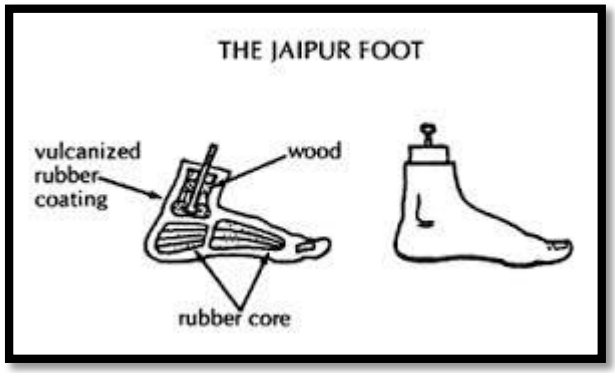


Figure 4: Jaipur foot cross-section showing the construction of the foot. Photo from www.dinf.ne.jp.

Ultimate static tests per ISO 10328 to 4480 N (ISO, 2006a) on Jaipur feet resulted in permanent deformation (Jensen & Treichl, 2007). Given the flexibility of these feet, this is not unexpected, but not ideal for AK patients (Jensen & Treichl, 2007). The flexibility reduces forefoot support leading to early knee flexion collapsing the knee of an AK (Jensen & Treichl, 2007) Cyclic testing per ISO 10328 was performed on Jaipur feet taken from various locations. After 2 million cycles the feet were cut to determine how the internal structure had performed through the cyclic test, all feet had some form of delamination in the foam layers (Jensen & Treichl, 2007).

2.3 NIAGARA FOOT

The Niagara foot (Figure 5) was developed by collaboration between Hippo Design, Prècicad, DuPont, and engineers from Queen's University (Niagara, n.d.). An injection molded Delrin core is covered with a rubber cosmesis and costs $35 (Sandford, 2003). This ensured that damage to the cosmetic

cover would not impair the biomechanics of the foot (Gabourie et al., 2003). Designed specifically for active users in rugged conditions (Gabourie et al., 2003), this foot has been static and fatigue tested per ISO 10328. The foot passed ISO static testing and did not show significant wear or failure after 3 million cycles in the cyclic test (Gabourie et al., 2003). Energy storage and return characteristics of the foot make it the only available foot for the Developing World in this category. In field studies patients reduced their walking cadence and increased their stride length when comparing a Niagara Foot versus a SACH foot (Gabourie et al., 2003). This foot offers a small amount of adjustability as it can be shaped and sanded down to change the stiffness of the foot and better accommodate a smaller patient. The foot cannot be adjusted for a larger person, as the adjusting is performed by removing material. This also means the foot cannot be certified or tested for smaller, lighter weight patients.

Figure 5: Niagara Foot was developed by Canadian Researchers for the harsh wet environments in South America, where its plastic construction would not corrode due to the water. Photo courtesy of Aaron Nystrom.

2.4 OTHER FEET IN DEVELOPMENT

A number of prosthetic feet are being designed and tested by various universities. A number of these feet are being tested to ISO Standards and even a couple have been field tested. However, their use is not wide spread and their deployment is limited.

Shape&Roll Prosthetic Foot

The Shape&Roll (Figure 6) prosthetic foot is a "rocker foot" developed by a team at Northwestern University based on Andrew Hansen's research on roll-over shape (Sam et al., 2010). This foot uses a polypropylene keel that uses cuts and notches in the center beam controlling the deflection of the foot as the patient walks. The foot was successfully fatigue tested per ISO 10328 with no failures (Sam et al., 2010). Field trials in El Salvador compared the Shape&Roll

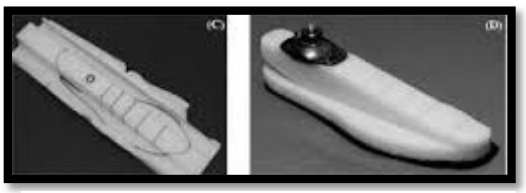


Figure 6: Northwestern SHAPE&ROLL foot was developed around ankle Roll-Over Shape studies done by Dr. Hansen. Photo from www.nupoc.northwestern.edu.

foot to SACH feet. Findings showed the Shape&Roll foot was more comfortable to walk in and allowed patients to walk further (Meier et al., 2010). The Shape&Roll foot provides some adjustability by altering the number of notches cut from the keel (Figure 7).

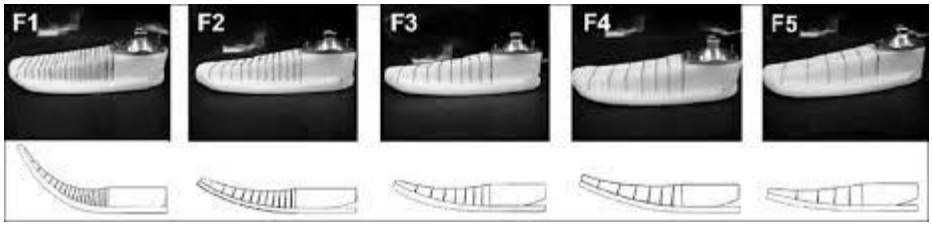


Figure 7: Adjustability demonstration of the Shape&Roll Foot. Photo from www.rehab.research.va.gov.

The Shape&Roll foot is currently being manufactured and used at Mobility Outreach International (MOI) clinics in Sierra Leone (MOI, n.d.). The foot machined from Delrin, and approximately 36 patients have been fit with the foot (MOI, n.d.). Elegant Design Solutions reports the Shape&Roll foot is also being fit alongside the LIMBS International M1 prosthetic knee (Pennington, 2011). Craftsman in Sierra Leone have also found a way to add a cosmesis to the Shape&Roll (Pennington, 2011) foot improving its cosmetic appeal and improving the cultural response to the foot.

2ft Prosthetic Foot

2ft prosthetic foot (Figure 8) was developed by a team at Brigham Young University (Salmond, 2010). The team focused development on using locally available low-cost materials. The 2ft prosthesis is made using PVC pipe cut up and shaped to make the keel. The design costs $25 to make using materials found in the United States (Salmond, 2010). The prosthetic foot was given an eight out of ten for durability (ten being excellent) (Salmond, 2010), but according to 2ft's website, durability testing is ongoing and recommends the prosthesis for limited use (2ft, n.d.). The foot has received limited field testing in Guatemala (14 patients), Tonga, and El Salvador (2ft, n.d.).

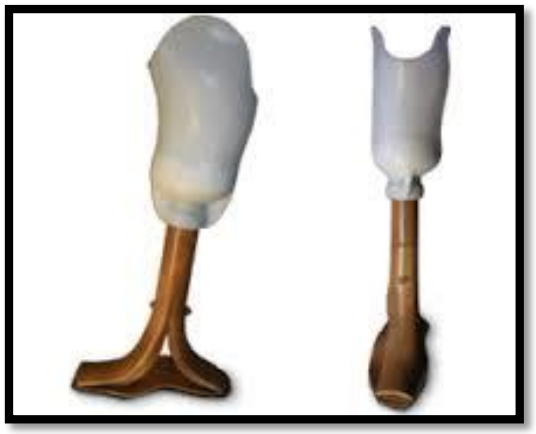


Figure 8: BYU's 2ft Prosthesis manufactured from PVC pipe. Photo from www.2ftprosthetics.org.

Mobility for Each One Prosthetic Foot

Mobility for Each One Prosthetic Foot (Figure 9) was developed by Canadian designer Sebastien Dubois to help victims of landmines. The prosthetic foot can be produced for approximately $8 from fiberglass (ICSID, 2007, OandP, 2007). The prosthesis won the INDEX Design Award in 2007 (INDEX, 2014). The Mobility for Each One Prosthetic foot has been tested and prototypes have been fit to patients.

Figure 9: Mobility for All's Prosthetic Foot made from Fiberglass. Photo from http://www.icsid.org/database/images/display/sb4758677e0970f.jpg.

2.5 ENERGY STORAGE AND RETURN PROSTHETIC FEET

ESAR Feet are "designed to restore some functions of the ankle plantar flexors and improve amputee walking by storing and releasing elastic energy during stance" (Fey, 2011, Hafner et al, 2002a, 2002b). In general, ESAR feet store energy during mid-stance and release the energy during push off (Postema et al., 1997a). Early ESAR feet appeared to be modified versions of SACH feet, i.e. Seattle Foot, SAFE Foot, and Dynamic Foot. In 1987, Flex-Foot, Inc. (Aliso Viejo, CA) released The Flex-Foot (FF) (Figure 10). The FF prosthesis utilized a carbon fiber shank and heel spring that previous ESAR feet did not contain, in addition to the toe sections which allowed the entire foot to flex, absorb energy, and return energy to the users (Hafner et al., 2002a, 2002b).

Figure 10: Ossur's FLEX-FOOT VARI-FLEX is an ESAR prosthetic foot currently available. A version of this foot made available by LIMBS International was used in the development process of this research and was the foot the researchers attempted to mimic. Photo from www.ossur.com.

Clinical analysis of ESAR feet gives varied and conflicting results (Hafner et al., 2002b). As one researcher put it, "these prosthetic feet have not shown sufficient improvement in overall performance in comparison with "conventional" SACH and Uniaxial feet" (Pitkin, 1995). Looking at the effects of prosthetic foot stiffness on gait, temporal parameters changed less than 7% of the target prosthesis parameters and GRFs were within one standard deviation of the target prosthesis (South, 2008).

Comparisons of two ESAR feet (Otto Bock Dynamic Pro and Hanger Quantum) and two conventional feet (Otto Bock Multi Axial and Otto Bock Lager) showed velocity changed less than 0.02 m/s and cadence changed less than 0.01 steps/min, and other changes were small and insignificant (Postema et al., 1997a). The changes lead the researcher to state, "The size of the differences however, are again small and are unlikely to be clinically relevant" (Postema et al., 1997a). These findings contradict the feedback from patients using ESAR feet, especially from active users (Hafner et al., 2002b). Postema et al. followed up their comparison study with a questionnaire (1997b). While no foot was clearly favored by the patients, seven of ten patients selected ESAR feet as their first choice (Postema et al., 1997b). Murray et al.'s comparison study found similar results with the ESAR foot being more desirable (1986). Patients perceive increased velocities and increased stability when using ESAR's over conventional prosthetic feet (Hafner et al., 2002b). The minute changes the ESAR feet make, maybe statistically insignificant, but clinically significant leading to the perceived improvements from patients (Hafner et al., 2002b).

Regardless of the clinical results, ESAR feet are the most commonly used prosthetic feet in the Developed World. A survey of major prosthetics manufacturers such as Ossur, Ottobock, Endolite, and Freedom Innovations show the dominance of ESAR feet. The benefits of these feet have enabled increasing numbers of veterans to return to active duty military status. Twenty-four percent of military amputees wounded in Operation Iraqi Freedom and Operation Enduring Freedom have been able to return to active duty, compared with seven percent from Vietnam (Mason et al., 2011). The

Figure 11: Ohio Willow Wood Pathfinder II is the prosthetic foot used by SSGT Joseph Kapacziewski to return to direct combat and requalify for the U.S. Army Rangers. Photo from www.willowwoodco.com.

benefits and strength of ESAR feet aided Staff Sargent Joseph Kapacziewski, amputated below the knee, to return to active duty and become the 1st military amputee to return to direct combat with the Army's 75th Ranger Regiment (Zoroya, 2011). Using Ohio Willow Wood's Pathfinder II (Figure 11), SSG Kapacziewski re-qualified for direct combat without a waiver or special consideration by running five miles in under 40 minutes and hiking 12 miles with a 40-pound rucksack in three hours (Zoroya, 2011; Martin, 2011). ESAR feet such as the Freedom Innovation's Sierra, the Ossur Re-flex VSP, and the Ohio Willow Wood Pathfinder II are the most common prosthetic feet prescribed to wounded service members (Mason et al., 2011). ISO 10328 P5 Static and Fatigue testing performed on the Freedom Innovation's Sierra (Figure 12), the Ossur Re-flex VSP (Figure 13), and the Ohio Willow Wood Pathfinder II (Figure 11) showed all feet were able to successfully complete the tests; including Static Proof-2240 N, Static Ulimate-4480 N, and 2,000,000 fatigue cycles at 1330 N on the toe and heel (Mason et al., 2011; ISO, 2006a). After 2,000,000 fatigue cycles, the Freedom Innovation's Sierra, the Ossur Re-flex VSP, and the Ohio Willow Wood Pathfinder II did not show any sign of failure (Mason et al., 2011).

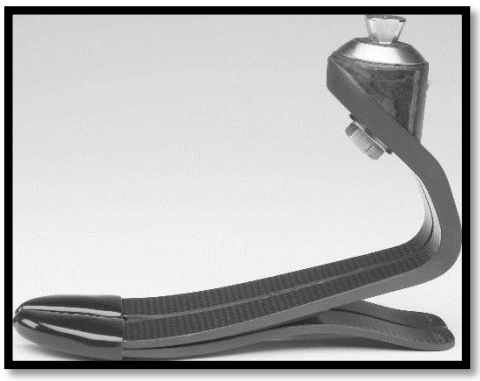


Figure 12: Freedom Innovation Sierra Prosthetic foot. One of the three prosthetic feet most commonly prescribed by the VA to active duty soldiers. Photo from www.medicalexpo.com.

Figure 13: Ossur Vari-Flex VSP Prosthetic foot. One of the three prosthetic feet most commonly prescribed by the VA to active duty soldiers. Photo from www.oandp.com.

Advancements in ESAR technology have led to running specific feet such as the Ossur Flex-Run, the Ossur Cheetah, the Freedom Innovation Catapult, and the Freedom Innovation Nitro (Ossur, n.d.a; Freedom Innovation, n.d.). In 2012, Oscar Pistorius, running on two Ossur Cheetah prosthetic feet, qualified for the men's 400 meter relay in the Summer Olympics. He became the first ever double amputee to qualify for the Olympics. Even though Pistorius was a double amputee, some people argued that the energy return characteristics of the prosthetic feet he wore gave him an advantage over abled body athletes

(Epstein, 2012; Eveleth, 2012). These high performance prosthetic feet are the direct results of the continued advancements made on the flex foot first seen in the Paralympic Games in 1988 (Nolan, 2008).

Flex-Foot

The Flex-Foot VARI-FLEX (Figure 10), currently sold by Ossur (Reykjavik, Iceland), is an ESAR foot currently available on the market. Approximately 11 different models of prosthetic feet using similar CF components as the VARI-FLEX. The structure used for the VARI-FLEX provides a comfortable, dynamic, and light-weight foot to the users (Ossur, n.d.b). The VARI-FLEX can be configured for patients from 45 KG to 166 KG. LIMBS International currently owns a VARI-FLEX foot and this foot was considered as the benchmark prosthetic foot for this research and development. Force/deflection curves and transitions from heel to toe from the VARI-FLEX were observed and emulated in the designs of this research. The specific model on hand was rated as Size 27, Category 4 foot (Table 1), allowing it be used for low-impact, moderate impact, and high impact for patients weighing 78-88 KG, 69-77 KG, and 60-68 KG respectively (Ossur, n.d.b). The foot category and impact ratings correlate to the user's K-Level and weight – indicating the appropriate use of the prosthesis.

Table 1: Chart numbers from Ossur's specification manual for the VARI-FLEX prosthetic foot. The foot made available by LIMBS International for the purposes of this research was SIZE 27, CATEGORY 4 (Ossur, n.d.b).

Category Selection Chart										
Weight (KG)	**45-52**	**53-59**	**60-68**	**69-77**	**78-88**	**89-100**	**101-116**	**117-130**	**131-147**	**148-166**
Low Impact Level	1	1	2	3	4	5	6	7	8	9
Moderate Impact Level	1	2	3	4	5	6	7	8	9	Special Order
High Impact Level	2	3	4	5	6	7	8	9	Special Order	Special Order

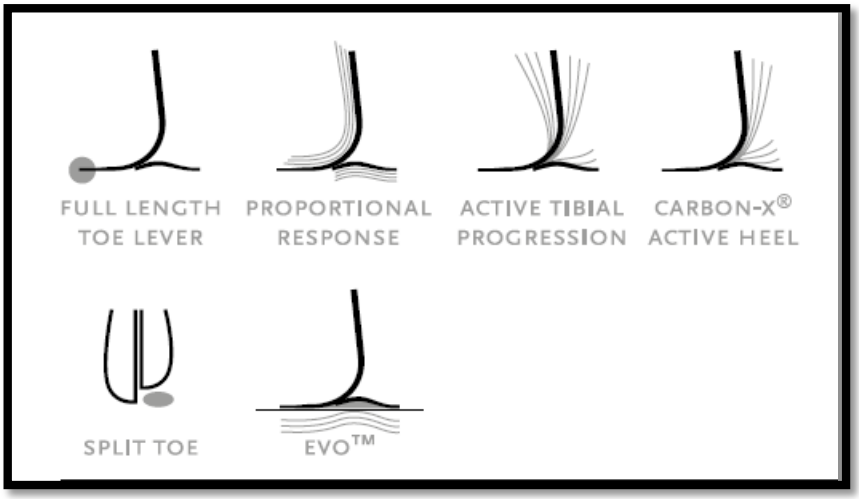


Figure 14: Benefits of the VARI-FLEX prosthetic foot (Ossur, n.d.b). Photo from http://assets.ossur.com/library/19173/Vari-Flex with Evo.pdf.

2.6 TESTING

The developed prosthetic foot was tested to determine the performance of the foot and compare it to other prosthetic feet. Testing will guide future development and later confirm improvements. Static tests will ensure the prosthesis will meet minimum load requirements. Fatigue tests will determine how the prototype performs over time. Prior to any human experimentation testing will confirm the safety of the prosthesis.

Biomechanical testing will quantify how the developed prototypes perform. Qualitative questionnaires will evaluate human perception of the device. The predominant support for ESAR style feet comes not from significant gait improvements, but from patient feedback, perception, and functional assessment questionnaires (Hafner et al., 2002b). Capturing and understanding subject feedback will improve future designs, and their perception will influence the acceptance and use of the prosthetic foot.

2.6.1. Mechanical Testing

Testing per international standards ensures "products and services are safe, reliable and of good quality" (ISO, n.d.). Standardized test protocols ensure similar test methods from various organizations, assuring consumers that minimum standards were achieved. ISO Standard 10328 "*Prosthetics – Structural testing of lower-limb prostheses – Requirement and test methods*" will be used for static testing. ISO Standard 22675 "*Prosthetics – Testing of ankle-foot devices and foot units – Requirements and test*

methods" will be used for fatigue testing. Both documents govern static and cyclic tests and load levels for lower-limbs prosthetic devices and are similar in function, but differ in the specific load applications to the prosthesis.

Deflection tests, which measure the Force/Deflection curved prosthetic feet generate during loading and unloading of prosthetic feet in a static test set up, have been to characterize the stiffness of prosthetic feet (Jaarsveld et al.; 1990; South et al.; 2010; Mason et al., 2011). This method has been used to compare different prosthetic feet (Jaarsveld et al., 1990; Mason et al., 2011) and measure the effects different shoes have on prosthetic foot stiffness (Jaarsveld et al., 1990). Researchers have used Deflection Testing to determine if a new prototype prosthetic foot generates similar curves as a target prosthesis and helps control the desired variations in these curves enabling the researcher know when the prototype foot reaches a desired goal (South et al., 2010).

Hysteresis tests based on the Force/Deflection curves generated by the prosthetic feet can be used to determine the mechanical energy stored and released during loading and unloading the prosthetic foot. "Hysteresis is defined by the energy loss as a part of the total deformation energy" (Jaarsveld et al., 1990). Minimizing the hysteresis will reduce the energy cost of walking, provided the energy is returned to the users in a useable manner (Jaarsveld et al., 1990). Excess energy in a prosthetic foot dissipates in the form of heel whip during initial swing rather than provide propulsion for the user (Hafner et al., 2002b)

2.6.2. Subject (Amputee) Tests

The ultimate purpose of the prosthetic foot is to restore the function and performance of the human foot (Ventura et al., 2011). Testing the biomechanical performance and the human response to the prosthesis will benefit and improve future designs. Biomechanical analysis yields quantitative data useful for comparing the performance of various prosthesis, and allowing researchers to determine how close to the performance of the human foot the new prosthesis comes. However, support for ESAR feet has come primarily through questionnaires (Hafner et al., 2002b). Feedback from amputees is used in tandem with a clinician's experience as the primary method for selecting a prosthetic foot (Fey, 2011).

Gait trials measuring ground reaction forces and kinesiologic parameters (e.g., self-selected velocity, cadence, stride length) determine changes in subject's gait when wearing various prosthetic feet.

Considering that previous studies showed gait parameters changed little when amputees wear ESAR feet compared to non-ESAR feet, gait parameters should change little when comparing the Prototype Prosthetic Foot (PPF) to the patient's standard foot (Hafner et al., 2002; Pitkin, 1996, Zmitrewicz et al., 2007). Comparing the GRF data from various studies, Hafner et al. shows vertical GRF did not increase or decrease for ESAR feet when compared to a conventional prosthetic foot (2002b). Vertical heel strike forces of the FF increased by 8.4% (Snyder et al., 1995) and 11.9% (Schneider et al., 1993), but also decreased by 2.4% (Powers 1994). Vertical toe-off forces of the FF increased by 1.1% (Snyder et al., 1995) and 15.1% (Schneider et al., 1993) but in Powers et al., no change was found (1994). The variations of these studies may be due to the amputee population involved, i.e. children versus adults (Hafner et al., 2002b).

Comprehensive biomechanical analysis measuring kinematic, kinetics, and muscle activity help researchers determine the effect prosthetic feet have on the amputee (Fey et al., 2011). These studies analyze changes in muscle activation and mechanical efficient seek to improve prosthetic foot selection and prescription, moving towards a more scientific approach to prescribing prosthetic feet (Fey et al., 2011). They may also help explain what early study missed and help quantify the benefits of ESAR technology. Experimental tests have shown that adding ESAR ankles to a prosthetic foot reduce muscle activity needed to propel the body, improved socket pressures, and increased ankle range of motion (Ventura et al., 2011). Biomechanical data from subjects is being used to model amputees and test different prosthetic feet without the need to conduct trials with amputees, allowing more insight into the effect variation in the prosthetic foot may have on the amputee (Fey et al. 2012; Silverman et al., 2012; Fey et al., 2013).

While certain gait parameters are only expected to change slightly, some changes should be evident. Feet with less stiffness should require more muscle input to support the body (Fey et al., 2011). Decreasing the stiffness should increase braking forces for the sound and amputated limbs, while the vertical toe-off force should decrease (Fey et al., 2011).

Chapter 3: Development Goals

To aid LIMBS International in its goal of developing highly-functional prosthetic components for the Developing World, this research study was commenced. The purpose of this research is to determine the feasibility of fabricating a low-cost, adjustable, ESAR, repairable prosthetic foot manufactured from carbon fiber using methods and techniques that could be replicated in the Developing World and meet international test standards. The following development goals were used to aid the design process and set measureable deliverables for the project.

3.1 DESIGN

1. Cost – Less than $100 for materials.
2. Maximum Dimensions – 267 millimeters (mm) long, 76 mm wide, 127 mm tall, this would allow for a cosmetic cover developed by a LIMBS International university partnership with the Tech de Monterey in Guadalajara Mexico.
3. Split Toe – Split toes enable eversion and inversion of the foot allowing for improved stability on rough terrain.
4. Repairable – Components should be replaceable with basic hand tools (e.g. crescent wrench, screw drivers, or Allen keys). The alignment of the foot should not be altered by replacing components.
5. Adjustable – The prosthetic foot's force/deflection curve should have the ability to be altered to accommodate various patients.

3.2 PERFORMANCE

Performance goals based on ISO P4 test level, which corresponds to an 80 kg (176 lb.) patient.

1. ISO 10328 Static Test – Static testing will ensure the structural integrity of the prosthetic foot and give confidence that the prosthesis will withstand human walking tests. Static proof and ultimate test loads shall be performed.
2. ISO 22675 Fatigue Test – Fatigue testing will determine how the prosthetic foot will perform over a given number of cycles.

3. Force/Deflection Curve – A force/deflection curve will be determined for an Ossur Flex-Foot currently owned by LIMBS International. Ossur Flex-Foot is rate for moderately active person of 69-77 kg.
4. Patient Qualitative Assessment – Qualitative assessments capture test subjects' perception of the Prototype Prosthetic Foot. Understanding and interpreting the test subjects' perception will characterize the function and feel of the prosthesis.
5. Gait Parameters – Gait parameters should change little. Based on previous research it would be expected that the subjects' gait parameters give similar results showing changes of less than 7% regardless of the qualitative assessment.

Chapter 4: Methods

4.1 Foot Design

Autodesk Inventor (San Francisco, CA) was used to layout an overall prosthetic foot envelope based on design goals (Chapter 3). The envelope positioned the ankle and the ground contact points (Figure 15). Various foot design were laid out within the envelope. Figure 18, Figure 16, and Figure 17 show design changes from the initial concept to the final design used for testing and human trials. Optimization of the composite layers occurred throughout the development process. However, these changes did not alter the physical design features as shown in Figure 18, Figure 16, and Figure 17.

The outer envelope was based partially on a cosmesis developed by another LIMBS sponsored research project from the Tech de Monterrey in Guadalajara, Mexico. This would enable future use of their cosmesis without the need to develop a cosmesis specifically for this prosthetic foot. The Ossur Vari-Flex provided by LIMBS provided ground contact points. Surveying ESAR feet available on the market influenced the design changes from the initial concepts to the final design. Many ESAR feet use a single variable radius curve in the toe design. A single radius arc was used for the toe section to emulate these designs. A single radius was used versus a variable radius to simplify the mold design and the fabrication processes. The single radius design also enabled toe layers to be nested together. Endolite's elite2 provided inspiration for the final heel designs. It utilizes an independent e-carbon spring that provides vertical shock absorption and energy return (Endolite, n.d.)

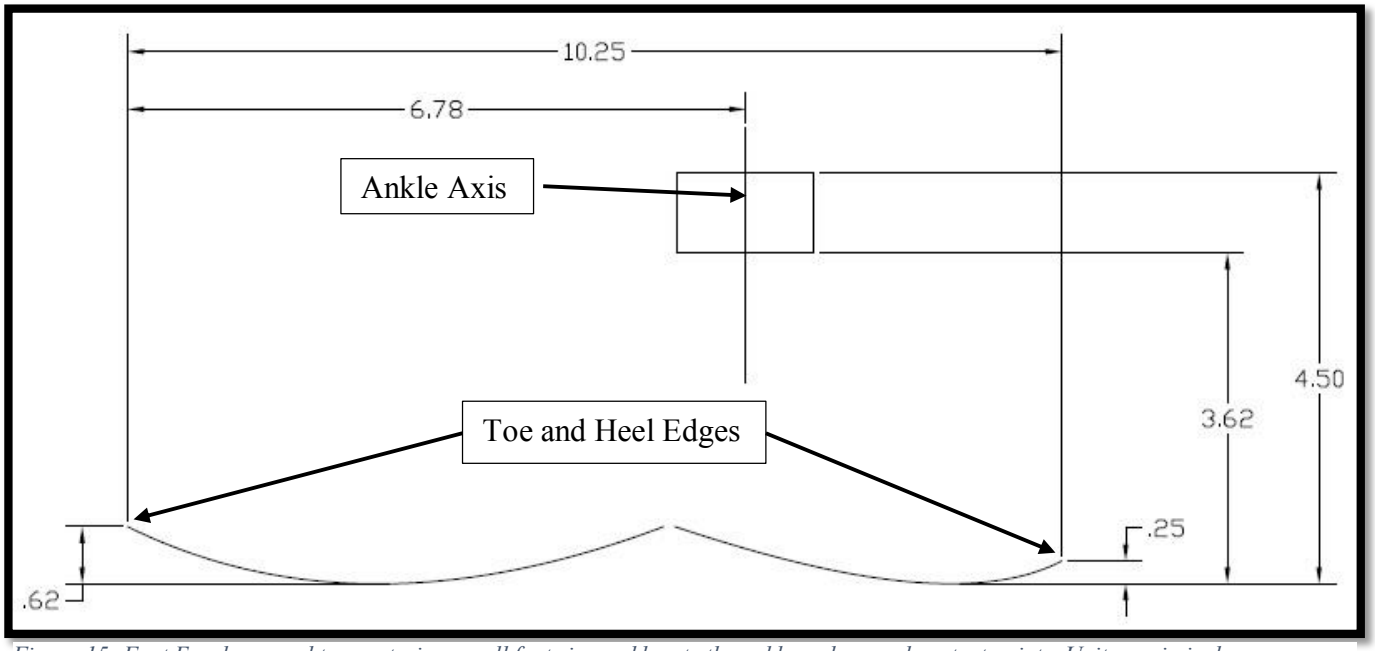


Figure 15: Foot Envelope used to constrain overall foot size and locate the ankle and ground contact points. Units are in inches.

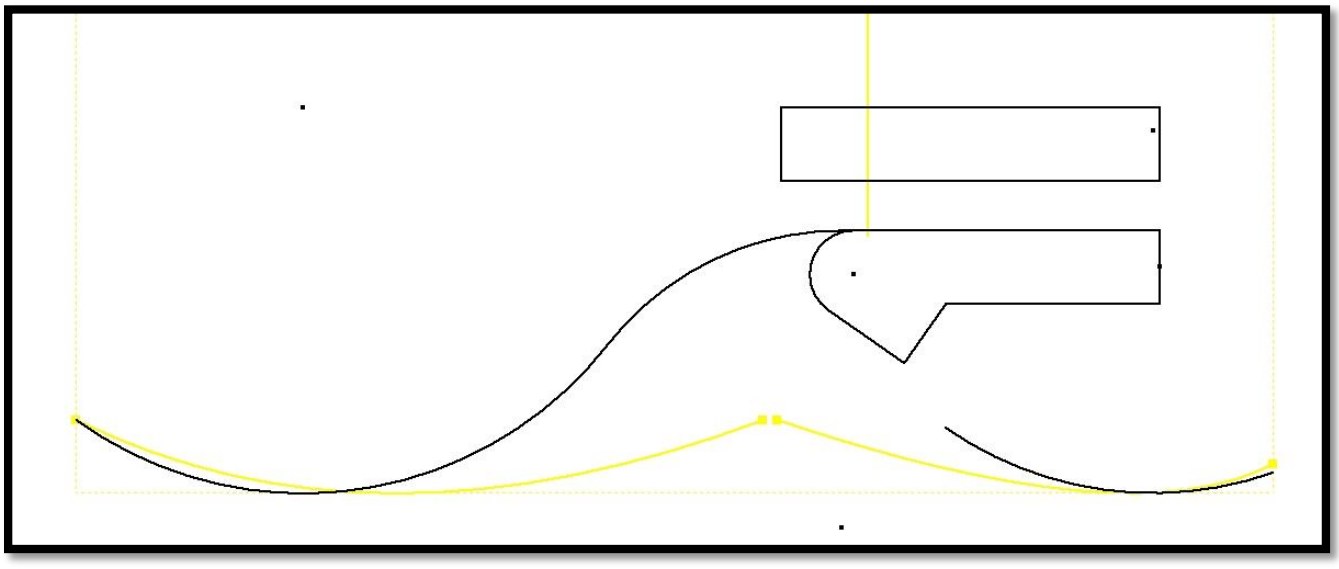


Figure 16: Initial Concept 1 (IC1) shows an initial design concept lying out the toes, heel, and ankle.

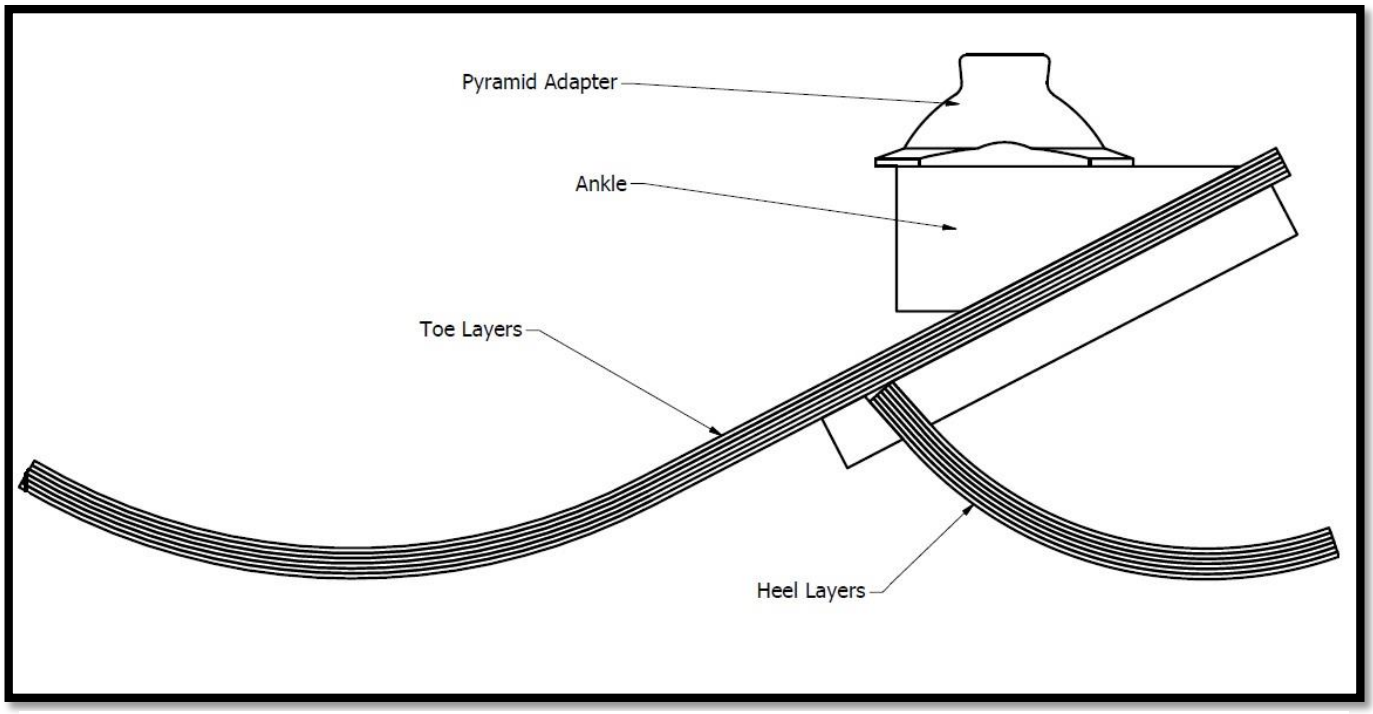


Figure 18: Concept 2 (C2) this design was chosen for the design of prototype 1.

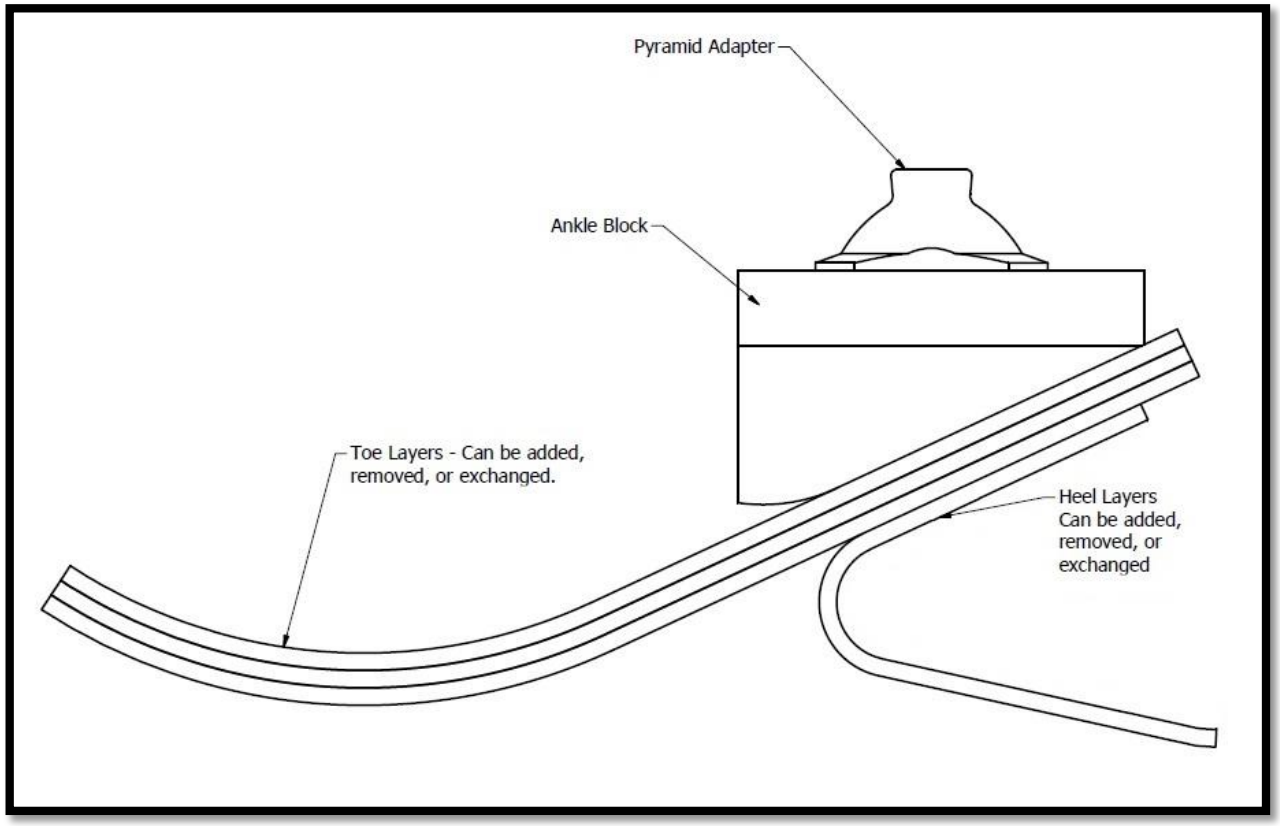


Figure 17: Final Design (FD). This sketch shows the layout of the final design used to manufacture the prototype feet for testing and human trials.

It was hypothesized that nesting (Figure 19) or stacking laminated composite layers together could adjust the stiffness of the prosthetic foot so that it could be used to create a patient-specific prosthetic foot. Layers laminated together from composite plies could be added or removed from the prosthetic foot, thus altering its stiffness. Prosthetists could vary the prosthetic foot's stiffness based on the needs or desires of the patient. Initial testing revealed that simply adding layers would increase the stiffness of the prosthesis. However, adding or removing layers would not ensure that the prosthesis could withstand ultimate static test loads. For example, prosthetic feet customized for patients weighing 61 kg and 75 kg, are both required to pass ISO 10328 Static Tests. P4 test loads per ISO 10328 are based on a maximum patient weight of 80 kg and require the foot to withstand ultimate loads of 3098 N and proof loads of 2065 N. Both prosthetic feet for the 61 kg and 75 kg patient would be required to withstand test loads. Similar composite thicknesses would be needed to achieve these loads regardless of the patient size. In order to accommodate various patient sizes, the stiffness of the prosthetic foot would need to vary. Developing a prosthetic foot made from three interchangeable composite layers would enable the foot to withstand static tests. Varying layer stiffness would allow the foot's stiffness to be adjusted to the individual patient. Reviewing initial design concepts, the design shown in Figure 16 was selected over the design in Figure 18 because it allowed for the layers to be nested easily. The single curve designs would also function well for compression molding.

Figure 19: Toe Section of the Prototype Prosthetic Foot showed with three toe layers nested together. White paper was placed between the layers to distinguish layers. Photo courtesy of Aaron Nystrom.

The initial proof-of-concept pieces were manufactured from Prepreg 3K, 2x2 twill weave carbon fiber (CF) fabric (Fibre Glast, Brookville, OH) and wooden compression molds. The wood molds proved the mold designed functioned as expected prior to manufacturing aluminum molds. Plain Weave Carbon Fiber (CF) with 3K strands and 820 Epoxy with medium fast hardener from ADTECH Plastic Systems (Oklahoma City, OK) were used to fabricate the remaining prototypes. The plain-weave carbon fiber

fabrics allowed simple undammed compression molds to be used and ensured manufacturing techniques could be replicated globally.

4.1.1 Layers Development

Table 2 (Toe Layer Development) and Table 3 (Heel Layer Development) summarize the composite layer development. Major development included altering the number of CF plies per layer and altering ply orientation to achieve more or less flexibility.

Table 2: Toe Layer Development summarizes the iterations the layers development went through. Configuration # is the iteration #, # of Plies notes the number of composite lamina used per layer, ply orientation notes the angular direction the plies were oriented in the layers, results give a brief description for how each iteration worked, and design notes which design was used to manufacture the layers.

Configuration #	# of Plies	Ply Orientation	Results	Design
1	5	0°	Weak layers, assembled foot couldn't support any weight.	C2
2	15, 20, 25	0°	Layers performed well during deflection testing. Separate left and right toes shifted during walking tests.	C2
3	25	Variable 0° and 45°	Layers performed well during deflection testing. Varying the ply orientation varied the layer stiffness. 3 combined layers passed static tests and were fatigue tested to over 250,000 cycles.	FD

Table 3: Heel Layer Development summarizes the iterations the layers development went through. Configuration # is the iteration #, # of Plies notes the number of composite lamina used per layer, ply orientation notes the angular direction the plies were oriented in the layers, results give a brief description for how each iteration worked, and design notes which design was used to manufacture the layers.

Configuration #	# of Plies	Ply Orientation	Results	Design
1	5	0°	Weak layers, assembled foot couldn't support any weight.	C2
2	15, 20, 25	0°	Assembled foot bore weight, but layers showed permanent deformation within a few hundred meters of walking.	C2
3	26	Various 0° and 45°	Layers performed well in deflection tests, but experienced delamination in fatigue testing.	FD
4	26	Various 0°, 15°, 30°, 45°	Layers performed well in deflection test, passed static testing, and fatigue tested to over 1 million cycles.	FD

Prototype 1

Prototype 1 (Figure 20) was assembled from layers five plies thick of pre-impregnated CF. five layers nested together to make the left and right toe sections and left and right heel sections. The assembled foot could not support the weight of a person. Prototype could be manipulated by hand. Each layer of five plies was not stiff enough itself to have any beneficial additive effect when nested together with additional layers.

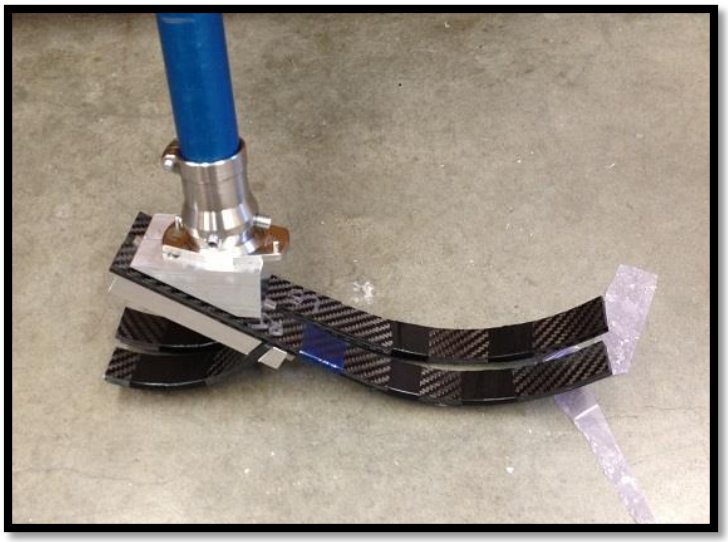


Figure 20: Prototype 1 - First Prosthetic foot assembled pre-impregnated CF. Each layer built up with 5 plies of CF; 5 layers were used for each section (20 total). Prosthetic foot was weak and 5 ply layers were far too flexible to work as initially expected.

Following the failure of Prototype 1, it was realized that it would be beneficial to experiment with the layer thickness to determine how various thicknesses would deflect under a given load. It was also necessary to determine how the layers, when nested together, would add to the overall stiffness of the combined layer. Layers built up with 15, 20, and 25 plies were attached to the foot ankle and

an 11.3 kg weight was added and the deflection was measured. It was determined that layers from 15 plies continued to be extremely compliant and when nested together with other thicker layers had almost no additive effect. Most of the initial layer development was performed using toe sections of the foot, lessons learned from these experiments were used for heel layers.

Figure 21: Boots made so that a prosthetic foot can be attached and walked on by the researchers. Two boots are worn and researcher can feel the relative difference between two prosthetic feet.

Prototype 2

Prototype 2 was assembled from layers 25 plies thick. Prototype 2's design was the same as Prototype 1. The prototype was robust enough to support weight and researchers walked on the foot using a set of modified boots that the prosthetic feet can be attached to (Figure 21). Researchers noted from walking on Prototype 2 the stiffness of the heel was uncomfortable to walk on. The heel did not deflect enough to adequately allow the toe sections to contact the ground. As the researchers walked the roll-over (transition from heel strike to station phase to toe-off) was very abrupt. The foot did not smoothly transition support from the heel to the toes. Walking tests revealed that the independent left and right toe sections shifted independently at the attachment point causing additional stresses in the composite layers. The heel sections also laterally shifted as well they permanently deformed where they were attached to the aluminum ankle. It was determined that the split toe should not have completely separate left and right sections but that they should be jointed in the ankle of the foot. It was also determined that the heel needed to be redesigned in order to reduce the stiffness of the foot and ensure that it would not permanently deform.

Additional Layer Development

Observations noted from walking on Prototype 2 resulted in left and right toe sections being joined into single laminated layers, laminating layers from 25 plies of CF, widening the toe layers, and cutting toe layers up the middle to create the split toe. The heel was also redesigned and new molds were

manufactured to build the new heel. A series of deflection and mechanical static tests were conducted to determine how the new heel performed. Engineers from Boeing (Seattle, WA) with expertise in composites also analyzed layers containing plies oriented at 45 degrees to increase flexibility. Three layers of varying stiffness were then developed: Soft Layer (S), Medium Layer (M), and Hard Layer (H) (Table 4). Soft, medium, and hard layers were loaded until failure to determine their maximum load capacity and then layers were combined to assemble an entire toe section of the foot and Static Proof and Static Ultimate tests were performed to ensure that the feet would meet ISO 10328 requirements.

Table 4: The Ply Orientation and Stiffness for the Soft, Medium, and Hard Toe Layers.

Layer	Ply Orientation	Stiffness (N/mm)[4]
Soft	10 Plies at 45° 5 Plies at 0° 10 Plies at 45°	11.2
Medium	7 Plies at 45° 11 Plies at 0° 7 Plies at 45°	13.7
Hard	4 Plies at 45° 17 Plies at 0° 4 Plies at 45°	22.6

The heel layer development closely followed the development of the toe layers. The final design configuration chosen for the heel did not allow for nesting as originally intended. Deflection tests showed the heel performed well within deflections less than 12.7 mm, but larger deflections needed to achieve ultimate test loads were destructive to the heel. It was determined that the heel would need an overload spring installed to limit the overall deflection of the heel layer and to enable it to meet the ultimate strength tests. Once Static Proof and Ultimate Load were achieved, the prototype prosthetic foot was subjected to fatigue testing. Fatigue testing showed that the heel layer delaminated where the plies transitioned from

[4] Based on Force/Deflection measured at 25.4 mm.

45 to 0 degrees. To reduce the interlaminar stresses plies were oriented at 45, 30, 15, 0, 15, 30, 45 degrees. Later heel layers made with this did not show any delamination.

Table 5: Shows the ply orientation and stiffness of the heel layer used for the final design and prototype.

Layer	Ply Orientation	Stiffness (N/mm)[5]
Heel Layer	7 Plies at 45° 2 Plies at 30° 2 Plies at 15° 4 Plies at 0° 2 Plies at 15° 2 Plies at 30° 7 Plies at 45°	22.8

Final Prototype

Based on mechanical testing, it was determine that the aluminum ankle originally machined for the feet caused high stress concentrations where the toe sections connected to the ankle. A new ankle was designed from Delrin to include radii to reduce the stress concentrations and to so the feasibility of using a Delrin ankle for the prosthesis. The prototype passed static ultimate and proof tests with no visual damage. Following this testing multiple Soft, Medium, and Hard layers were built so that human trials and the fatigue test could take place simultaneously. Human trials did not commence until the foot passed 50,000 fatigue cycles.

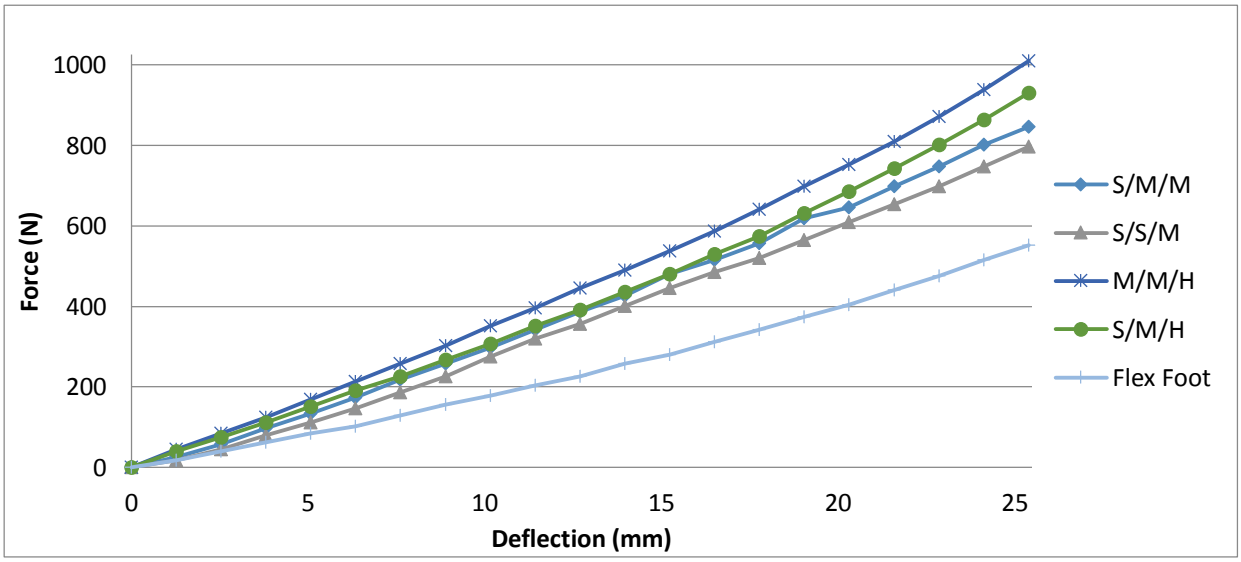


Figure 22: Changes in the Force/Deflection curve when the Final Prototype has been assembled with a variation of soft (S), medium (M), and Hard (H) layers and compared with the target flex-foot.

[5] Based on Force/Deflection measured at 10.2 mm.

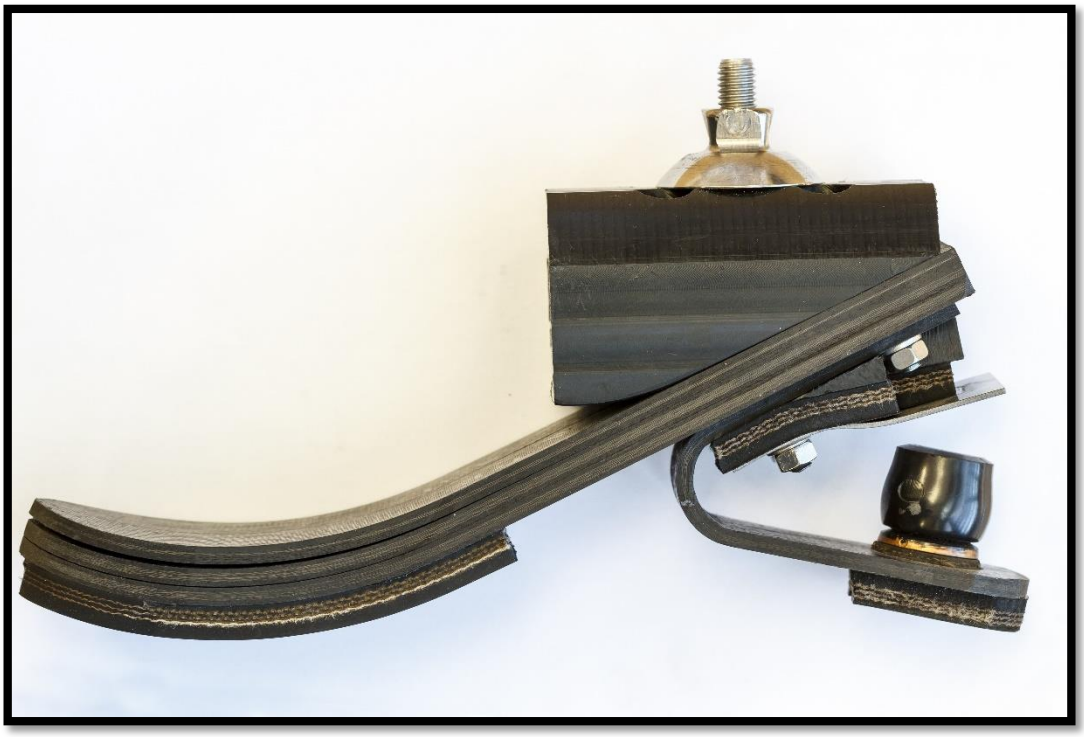


Figure 23: Final Prototype Prosthetic Foot assembled with delrin ankle and the overload spring in the heel. This configuration was used for all mechanical testing and experimental testing. Photo courtesy of Aaron Nystrom.

4.2 MANUFACTURING

Composite layers were laminated using a hand lay-up method. Meguiars (Irvine, CA) Mold Release Wax #8 was applied to the molds prior to laying up the CF. CF plies were then laid onto the compression molds (Figure 24), then clamped together using C-Clamps. C-Clamps were tightened to approximately 24 N*m. Layers were then oven cured or room temperature cured per the 820 Epoxy technical specification. Layers were cured for a minimum 24 hours before finishing. Once cured, toe and heel pieces were cut out using a dremel. Initial rough cuts were made to remove excess material. Then three layers were stacked and assembled onto the ankle and the final shape was cutout so an assembled foot would have a uniform cut. A belt sand rounded the corners.

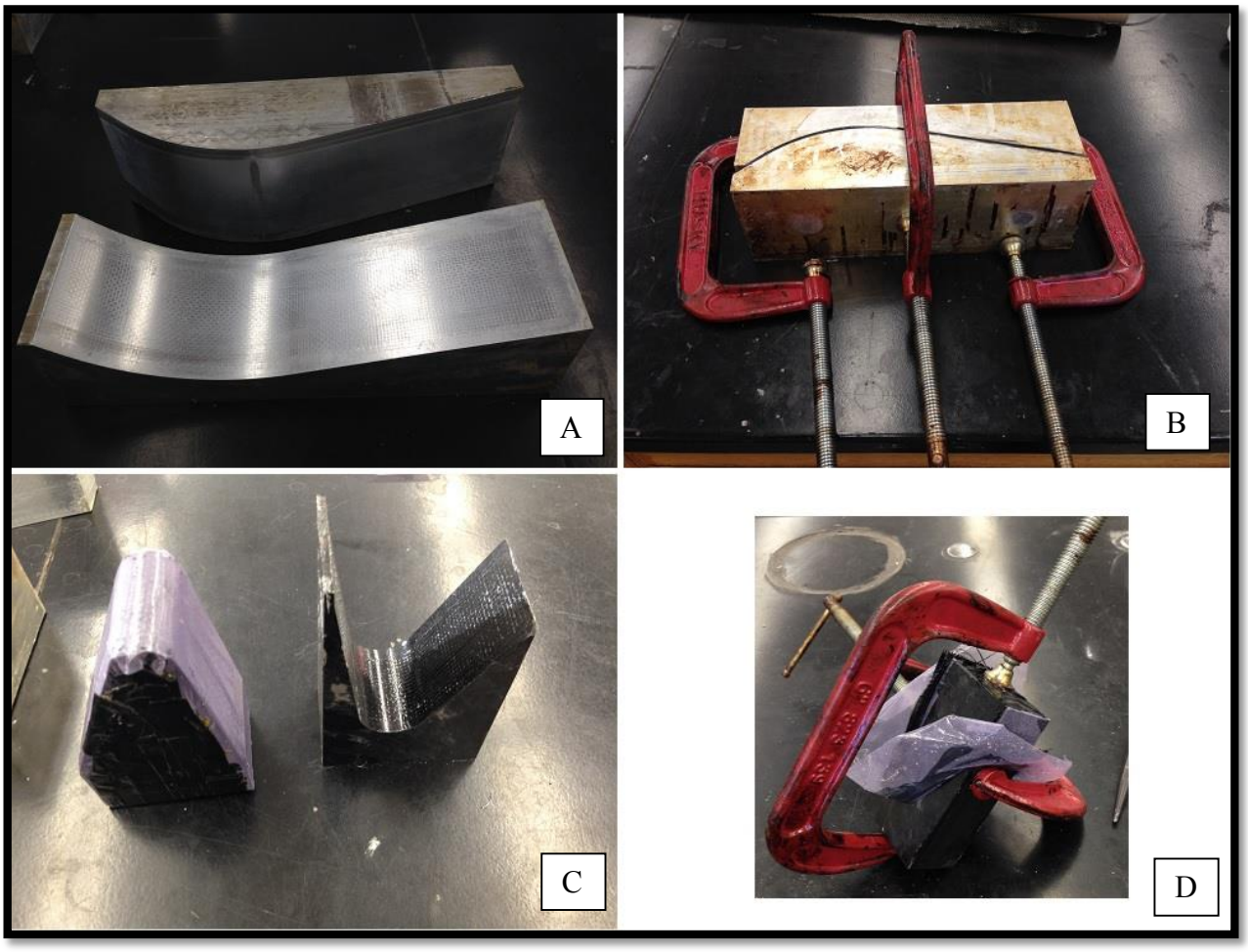


Figure 24: Compression molds used to manufacture the toe and heel layers. (A) Toe molds separated. (B) Toe molds clamped together during curing. (C) Heel molds separated. (D) Heel molds clamped for curing.

4.3 MECHANICAL TESTING

ISO standard tests were performed to determine the structural performance of the prosthetic foot. Static testing was performed per ISO 10328, and fatigue testing was performed per ISO 22675. Both standards group prostheses into categories based on the maximum patient weight. This research targeted the P4 loading range, which is intended for a maximum patient weight of 80 kg (176 lbs.) (ISO, 2006a, 2006b).

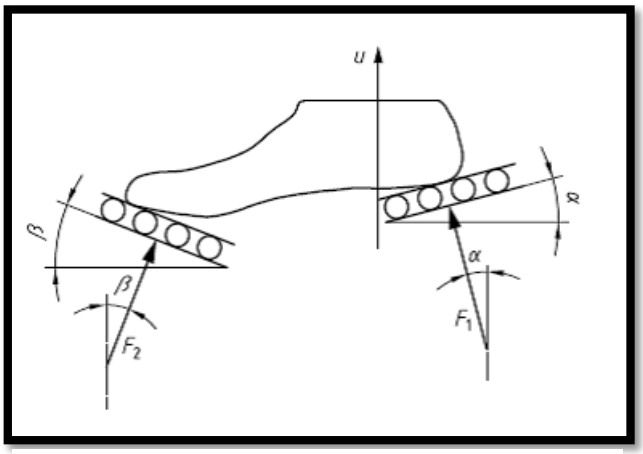


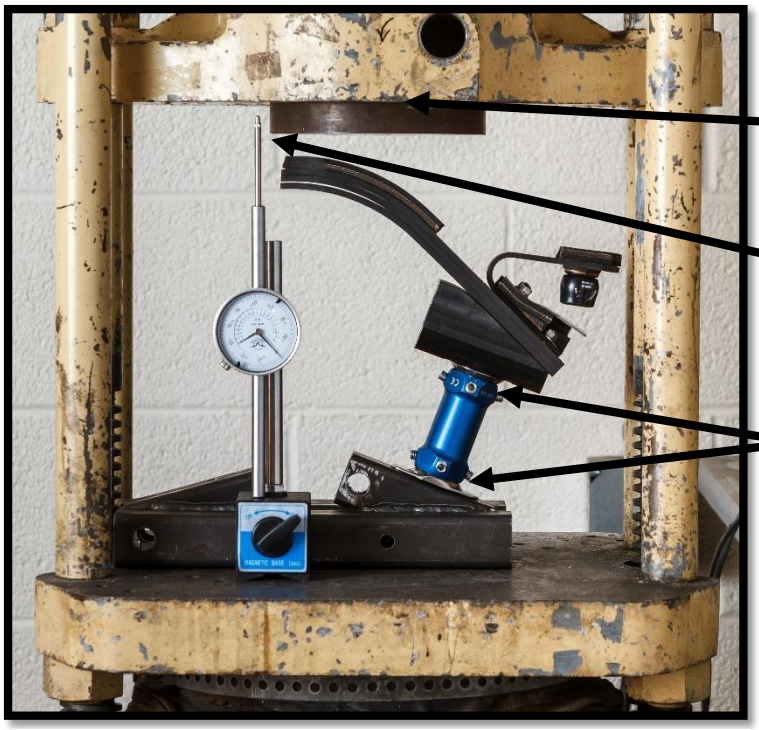
Figure 25: ISO 10328 instruction for orientation of test loads (ISO, 2006a). Photo from ISO 10328.

4.3.1 Static Tests

Static testing of the prosthetic feet was performed using a hydraulically controlled tensile testers. Cross-head movement was measured using a dial indicator (accuracy of ±0.025 mm) and a pressure transducer connected to the hydraulic system measured force and displayed onto the computer. Loading and off-loading was controlled via hydraulically valves. Loading rates were not controlled numerically. Similar valve positions were used throughout loading and unloading. Loading rates were held to approximately 0.063 mm/sec and off-loading rates were held to approximately 0.084 mm/sec. A video camera recorded the computer force output display and the linear displacement of the dial indicator (Figure 26). Later the video was reviewed to gather data. Readings were taken at 1.27 mm intervals. During testing and after testing the parts were visually inspected for any sign of failure or permanent deformation. Prosthetic feet were tested in two parts, one for the toe section and one for the heel section. Loads were applied at angles specified by ISO 10328 (Figure 25), 20 degrees at the toe and 15 degrees at the heel. A test fixture was built to constrain these angles during testing.

Figure 26: Screen shot from video recording the force display form the computer and the linear deflection from the dial indicator. Readings were recorded ever 1.27 mm.

Figure 28: Tensile Machine provided by UTEP Material Department and used for Static Tests. Picture shows the Prototype Prosthetic Foot set up for Toe Testing. The set-up does not show the camera that was used to record the dial indicator and force read out simultaneously. Photo courtesy of Aaron Nystrom.



Tensile Cross-Head Adjusted up or down to the prosthetic foot being tested.

Dial Indicator adjusted to measure the cross-head deflection while compressing the prosthesis.

Pyramid Adapters set to correct angle.

Figure 27: Static Testing Set-Up. Shown with the Prototype Prosthetic foot set up for testing. Arrows show the various pieces that needed to be set-up. Photo courtesy of Aaron Nystrom.

4.3.1.1 Static Ultimate and Proof Test

Static proof loads represent a momentary overload that the foot must sustain without significant damage or loss of function (Jensen & Treichl, 2007; ISO, 2006a). Ultimate loads represent a maximum single load that can be withstood by the prosthesis without catastrophic failure, however the prosthesis is allowed to loose function after the ultimate load.

Table 6: ISO 10328 Static Load Forces (ISO, 2006a)

P4 Test Loads	Toe Load	Heel Load
Static Proof	2065 N	2065 N
Static Ultimate	3098 N	3098 N

4.3.1.2 Deflection Test

Force/deflection curves generated for prosthetic feet have been used to characterize the foot stiffness; by applying a known force within the working limits of the prosthesis and measuring deflection the foot stiffness can be characterized (Mason et al., 2011; South, 2008; South et al., 2010; Pitkin, 1995; Jaarsveld et al., 1990). For this study maximum deflection was constrained to 25.4 mm (1.0 inches) for the toe sections and 12.7 mm (0.5 inches) for the heel section. Deflection was constrained versus applying a maximum known load because composite layers were measured individually and a single maximum

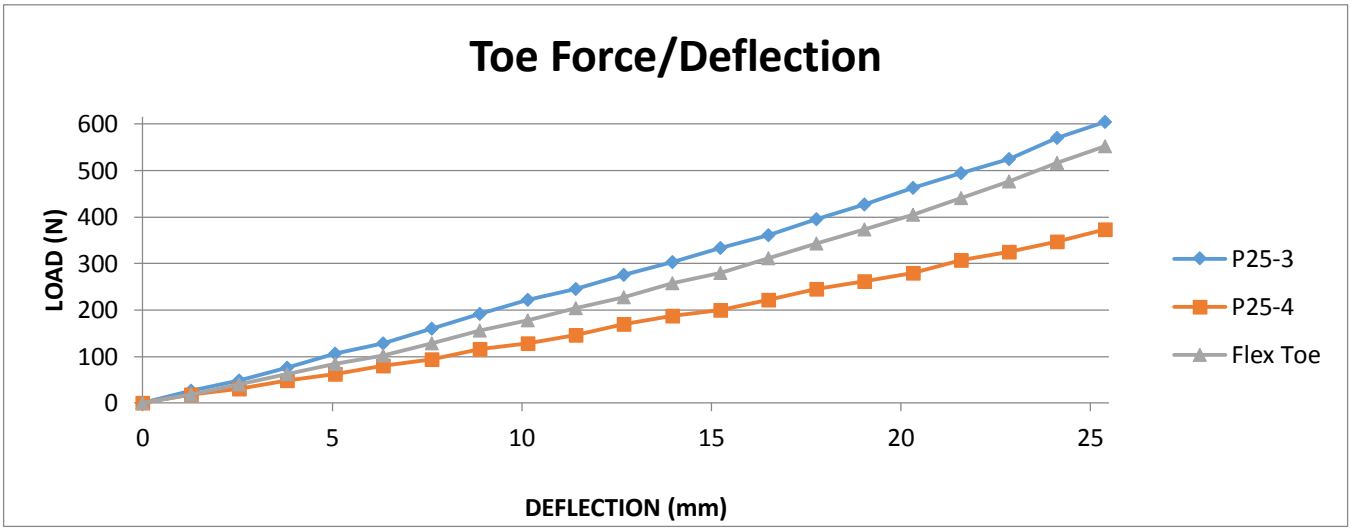


Figure 29: Force/Deflection Graph comparing two layers of varying stiffness compared with the Flex-Foot. The Flex-Foot was the Ossur Vari-Flex, Size 27, Category 4 Prosthetic Foot provided by LIMBS International (El Paso, TX). P25-3 and P25-4 identify the prototype layer. P25-3 was manufactured from 25 plies of Carbon Fiber with all plies oriented at 0°. P25-4 was manufactured from 25 plies of Carbon Fiber 7 plies oriented at 45°; 11 plies oriented at 0°; and 7 plies oriented at 45°.

load would have overloaded the individual layer. Constraining deflection to 25.4 mm and measuring force output allowed the same data to be collected without damage to composite layer or the prosthetic feet.

The deflection test was also used to measure the hysteresis of the prototype prosthetic foot to determine how much energy was lost between loading and unloading the prosthesis. Force/Deflection curves will be generated while loading and off-loading the prosthetic foot. Loading and off-loading Force/Deflection curves were integrated separately. The integral value for unloading was subtracted from integral value for loading and then divided by the integral value for loading to calculate percent of energy lost.

Figure 30: ISO 22675 Fatigue Tester provided by LIMBS International.

4.3.2 Fatigue Test

Fatigue Testing of the prosthetic foot was performed using a custom ISO 22675 fatigue tester built to the toe and heels to be 1158 N and 1173 N respectively. Force application follows a curve pattern as a rocker plate simulates walking on the foot.

Fatigue Testing was interrupted periodically to perform a Deflection Test (4.3.1.2 Deflection Test) to quantify the degradation of the prosthetic foot over time. Visual inspection of the prosthesis was also performed during these breaks.

Figure 31: Prototype Prosthetic Foot in the Fatigue Tester.

4.4 Experimental Data Collection

Three case studies (two below-knee amputees and one above-knee amputee) were performed to gather initial performance data on the prototype prosthetic foot and determine an

initial human response to the foot. All subjects were in good physical condition and were recommended by their prosthetist for the study. Subjects were identified as strong walkers, with activity level of K3 or above, would adapt well to a new foot, and were not experiencing any medical problems. A licensed prosthetist was present during data collection and fit the prototype to the subjects' prostheses. Subjects' ages ranged from 32 to 50 years old, with amputation time being at least 1.5 years. The subjects were provided informed consent according to the guidelines set forth by The University of Texas at El Paso.

Patients were tested with their standard prosthetic foot (SPF)[6] and the prototype prosthetic foot. For each walking trial subjects walk along a walk way containing a single AMTI (Watertown, MA) force plate at a self-selected walking speed (SSWS). Patients were instructed to walk at a SSWS that would be comfortable for them and a speed they felt they could maintain for all the trials. Trials were repeated until at least 10 force plate hits were recorded for each leg per condition. After reaching the end of the walk way, patients walked across a GAITRite (Sparta, NJ) Mat; 10 trials were collected for each condition on the GAITRite Mat. When fitted with the prototype prosthetic foot, subjects given time to adjust to the new foot. Trials were not collected until subject felt comfortable enough to start walking trials.

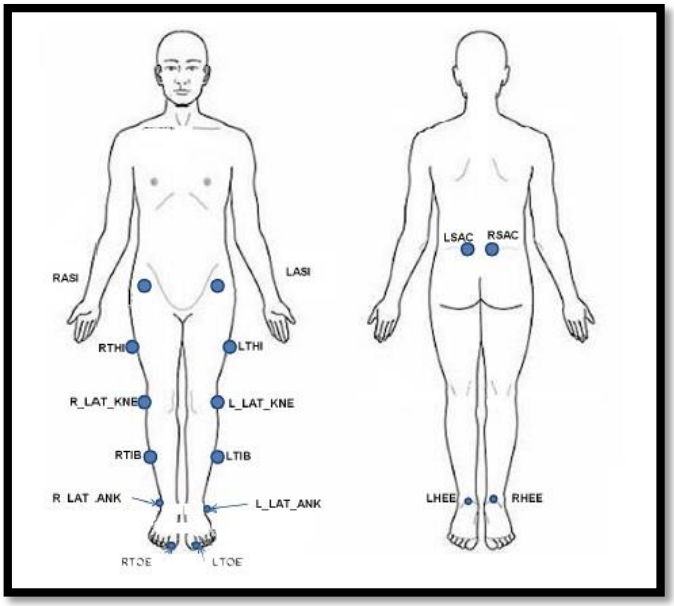


Figure 32: Marker Locations used to collect motion capture data.

[6] Subjects used their SPF as they normally would have. Meaning the SPF remained in its cosmesis and the shoes the patient used for the experimental tests.

VICON™ (Oxford, UK) motion capture system tracked 18 reflective markers positioned on the patient at 120 Hz. Ground reaction forces (GRF) were collected at 120 Hz. Reflective markers were placed on the posterior superior iliac spine, anterior superior iliac spine, lateral and femoral condyles, lateral malleoli, heel, toe, and bilaterally on the shank and thigh (Figure 32).

4.5 Experimental Data Analysis

Vertical, fore, and aft GRFs were plotted for each trial. Vertical peak forces for heel strike and toe-off were recorded. Peak braking and propulsive forces (fore and aft) were recorded. Braking and propulsive energies were calculated by integrating braking and propulsive force graphs with respect to the foot's center of pressure. GRFs were averaged for all trials of a single foot and single condition and combined into single graph showing the average, standard deviation, maximums, and minimums. All trials were normalized to the gait cycle. GRFs were compared across foot conditions and across legs.

GAITRite (Sparta, NJ) data was processed using GAITRite version 4.7.5 software. Bilateral temporal gait characteristic collected for each prosthetic foot condition were step length, stride length, cadence, and velocity. All data were averaged and compared across foot condition.

Chapter 5: Results

5.1 Mechanical Testing of the Foot

5.1.1 Deflection Tests

Three different toe layers were developed: Hard Layer (H) (least compliant), Medium Layer (M), and Soft Layer (S) (most compliant). Varying the ply orientation between 0° and 45° altered the layer's stiffness. Three layers nested together assembled the toe section of the prototype prosthetic foot. Assembling the toe section from varying H, M, and S layers the overall stiffness of the prosthetic foot could be adjusted. The heel layer developed included plies oriented at 0, 15, 30, and 45 degrees to reduce the interlaminar stresses. Table 7 shows the stiffness (N/mm) measured for each layer developed.

Figure 33: Toe Layer during Deflection Test.

Table 7: Results of the layers developed for the toes and the heel, including ply orientation and stiffness.

Layer	Ply Orientation	Stiffness (N/mm)[7]
Toe Layer Soft	10 Plies at 45° 5 Plies at 0° 10 Plies at 45°	11.2
Toe Layer Medium	7 Plies at 45° 11 Plies at 0° 7 Plies at 45°	13.7
Toe Layer Hard	4 Plies at 45° 17 Plies at 0° 4 Plies at 45°	22.6
Heel Layer	7 Plies at 45° 2 Plies at 30° 2 Plies at 15° 4 Plies at 0° 2 Plies at 15° 2 Plies at 30° 7 Plies at 45°	22.8

[7] Based on Force/Deflection measured at 25.4 mm Toe Deflection and 10.2 mm Heel Deflection.

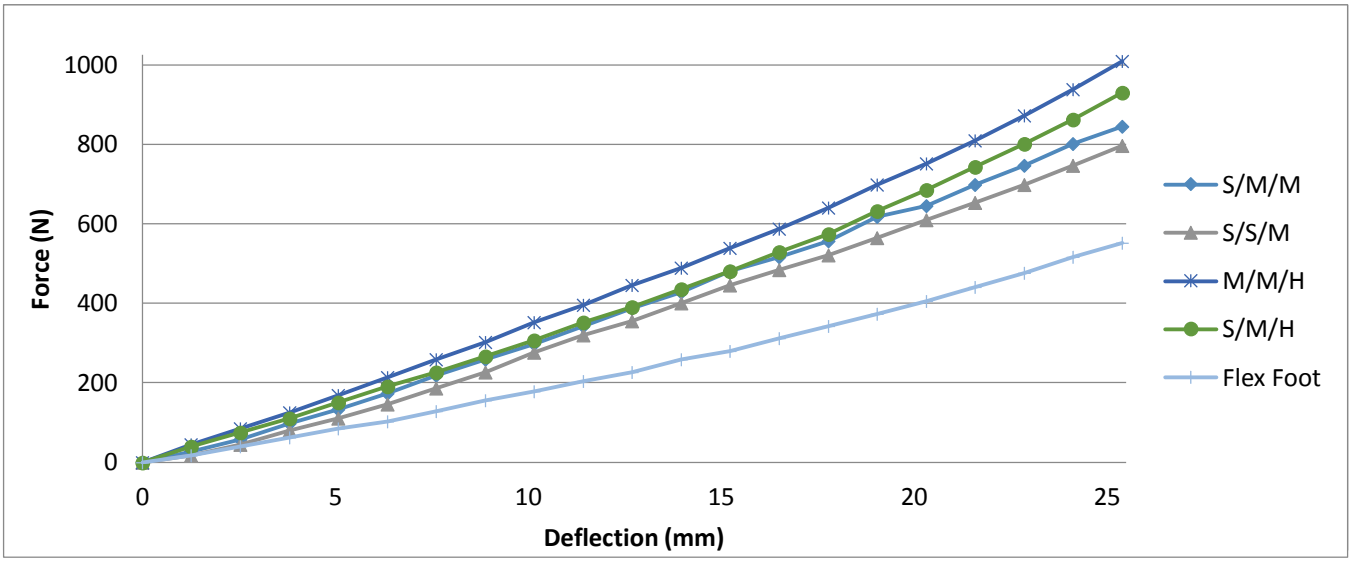


Figure 34: Varying toe stiffness when the Prototype Prosthetic foot is assembled from Soft (S), Medium (M), and Hard (H) layers. Note the stiffest is (MMH) and the least stiff is (SSM). The results have been compared with the Flex-Foot's stiffness.

Table 8: Stiffness characteristics of the Prototype Prosthetic Foot when assembled with the different layers. Comparisons are made to the flex foot which was the desired outcome.

	Stiffness (N/mm)	% Deviation from FF
Flex Foot Toe	21.7	--
Prototype SSM Toe	31.3	44.4%
Prototype SMM Toe	33.3	53.2%
Prototype SMH	36.6	68.5%
Prototype MMH	39.8	83.1%
Flex Foot Heel	25.0	--
Prototype Heel	22.8	-8.6%

The assembled prosthetic foot's toe overall stiffness varied 27.2% from 31.3 N/mm (most compliant configuration) to 39.8 N/mm (least compliant configuration) (Table 8 and Figure 34). Compared with the FF toe's stiffness of 21.7 N/mm, the prototype toes' were 44.4% to 83.1% stiffer than the FF's. Prototype heel 22.8 N/mm stiffness was 8.6% softer than the FF's heel stiffness of 25.0 N/mm.

5.1.2 Static Tests

Static proof and static ultimate tests (Figure 35) per ISO 10328 P4 loads (ISO 10328, 2006) were performed on the Final Design Prototype (Figure 23). The foot was visually inspected to determine if any failure or delamination had occurred during the test. Force and deflection measurements were taken to ensure the prototype prosthetic feet meet Static Proof and Static Ultimate Tests. The prototype prosthetic feet met the required loads without any visible damage.

Figure 35: Toe Section during Static Testing. Photo courtesy of Aaron Nystrom.

5.1.3 Fatigue Test

Fatigue testing performed per ISO 22675 P4 (ISO, 2006b) was performed on a prototype prosthetic foot assembled with Hard, Medium, and Soft Layers. Static deflection test determined initial foot stiffness, then the prototype was tested using an ISO 22675 fatigue tester provided by LIMBS International. Static deflection tests were performed periodically throughout the test to measure the degradation of the foot. Measurements were taken at 53,000; 100,000; 150,000; 200,000; 300,000; 400,000; 450,000; 600,000, and 1,000,000 cycles. Figure 45 and Figure 36 record the results from static deflection testing. Initial time between testing was set to 50,000 cycles and then increased. If daily visual inspection or data showed a reduction in the foot stiffness then addition tests were added to quantify the changes.

Toe Layers

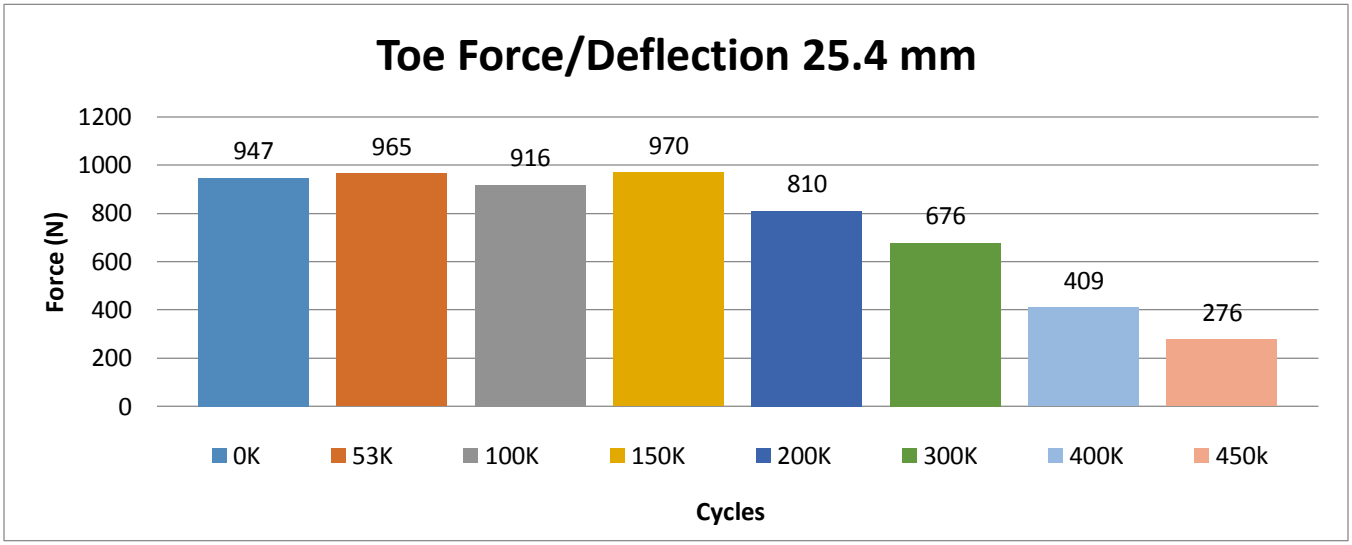


Figure 36: Results of Deflection Testing performed on the TOE periodically throughout the Fatigue Test. Force measurements were taken at 25.4 mm. Initial tests were performed 50,000 cycle increments to collect ensure a record of the degradation was made. The toes only lasted 450,000 cycles before they needed to be replaced.

The toe sections showed notable stiffness loss after 150,000 cycles. Toe sections were replaced after 450,000 cycles. Toe sections maintained stiffness from 0 to 150,000 cycles measuring 37.3 N/mm at 0 cycles, 38.0 N/mm at 53,000 cycles, 36.1 N/mm at 100,000 cycles, and 38.2 N/mm at 150,000 cycles before dropping to 31.9 N/mm at 200,000 cycles, 26.6 N/mm at 300,000 cycles, 16.1 N/mm at 400,000 cycles, and finally 10.9 N/mm at 450,000 cycles. The Toe Sections began to delaminate at where the orientation of the CF transitioned from 0° to 45°. After 450,000 cycles, the toes section lost more than 50% of their original stiffness. Demonstrating the reparability of the PPF, the toe sections were replaced with new Soft, Medium, and Hard Layers and testing continued. The heel layer was not replaced. The following pictures show the toe layers after 450,000 cycles of testing.

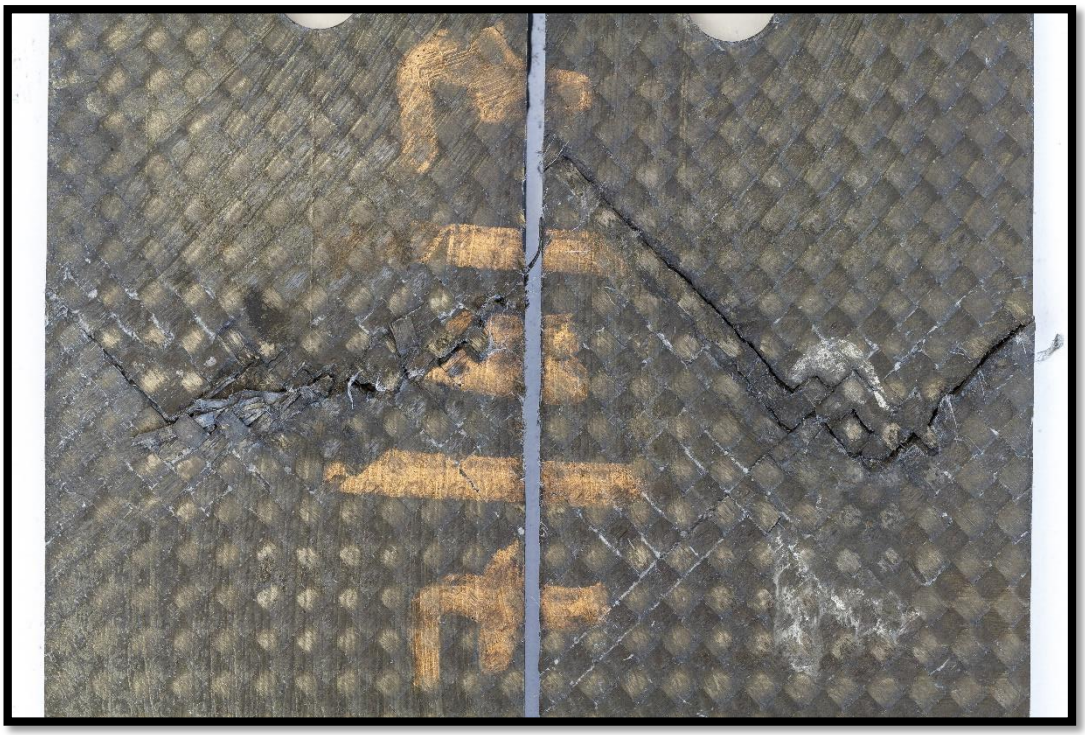


Figure 39: Top Toe Layer used for Fatigue Testing. Layer was removed after 450,000 cycles. This toe layer was a Medium Layer. Photo courtesy of Aaron Nystrom.

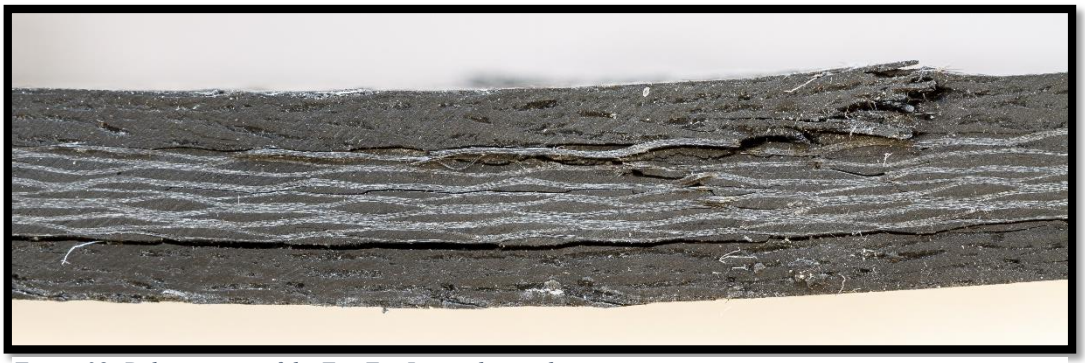


Figure 38: Delamination of the Top Toe Layer shown above.

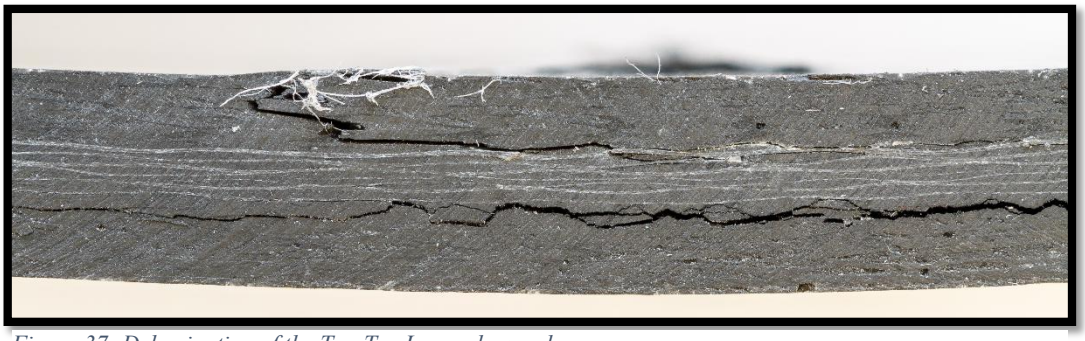


Figure 37: Delamination of the Top Toe Layer shown above.

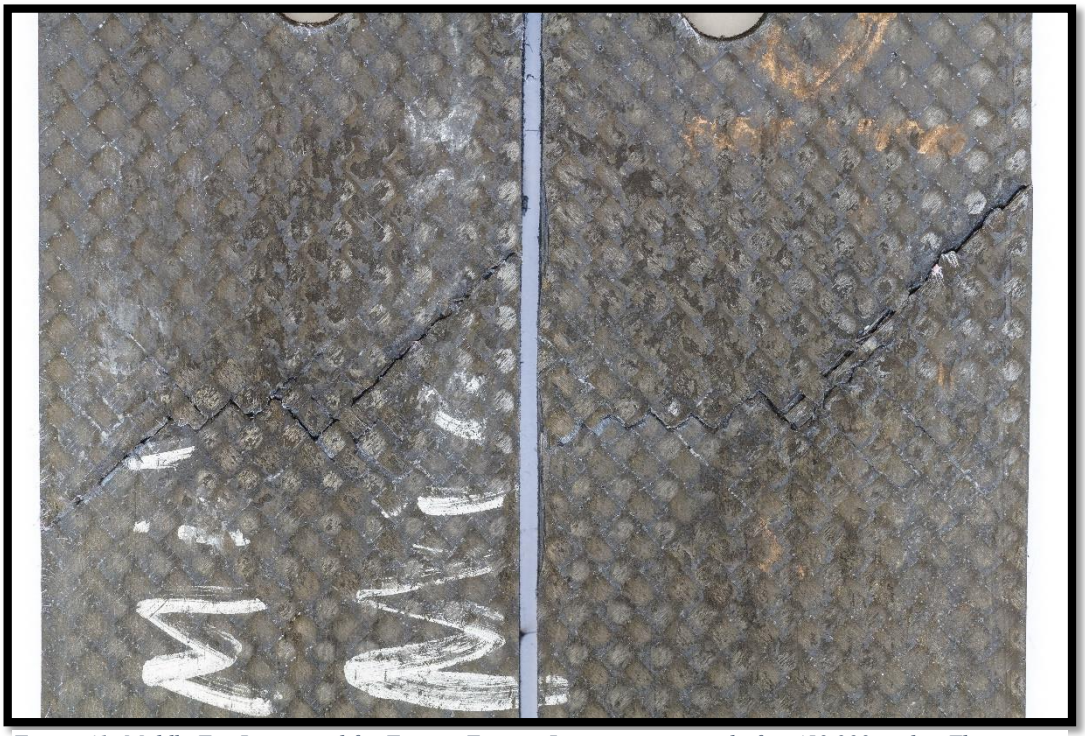


Figure 41: Middle Toe Layer used for Fatigue Testing. Layer was removed after 450,000 cycles. This toe layer was a Soft Layer. Photo courtesy of Aaron Nystrom.

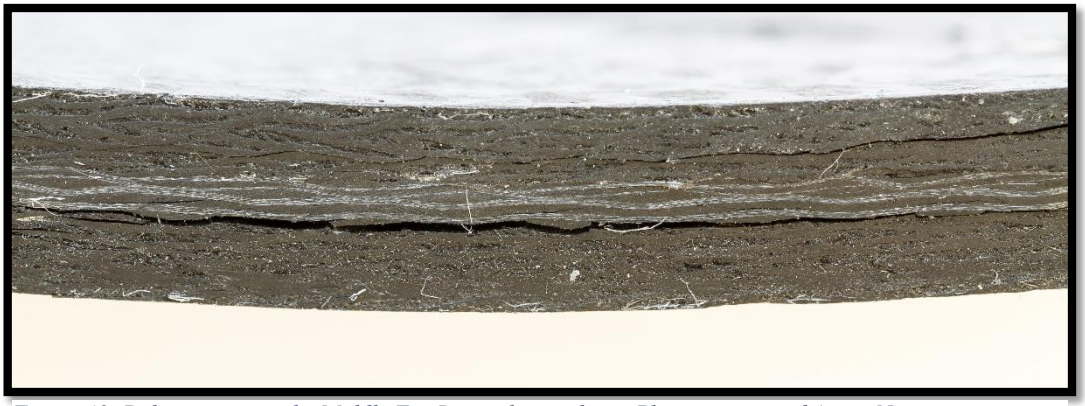


Figure 40: Delamination in the Middle Toe Layer shown above. Photo courtesy of Aaron Nystrom.

Figure 42: Bottom Toe Layer used for Fatigue Testing. Layer was removed after 450,000 cycles. This toe layer was a Hard Layer. Photo courtesy of Aaron Nystrom.

Figure 44: Delamination of the Hard Layer shown above.

Figure 43: Delamination of the Hard Layer shown above.

Heel Section

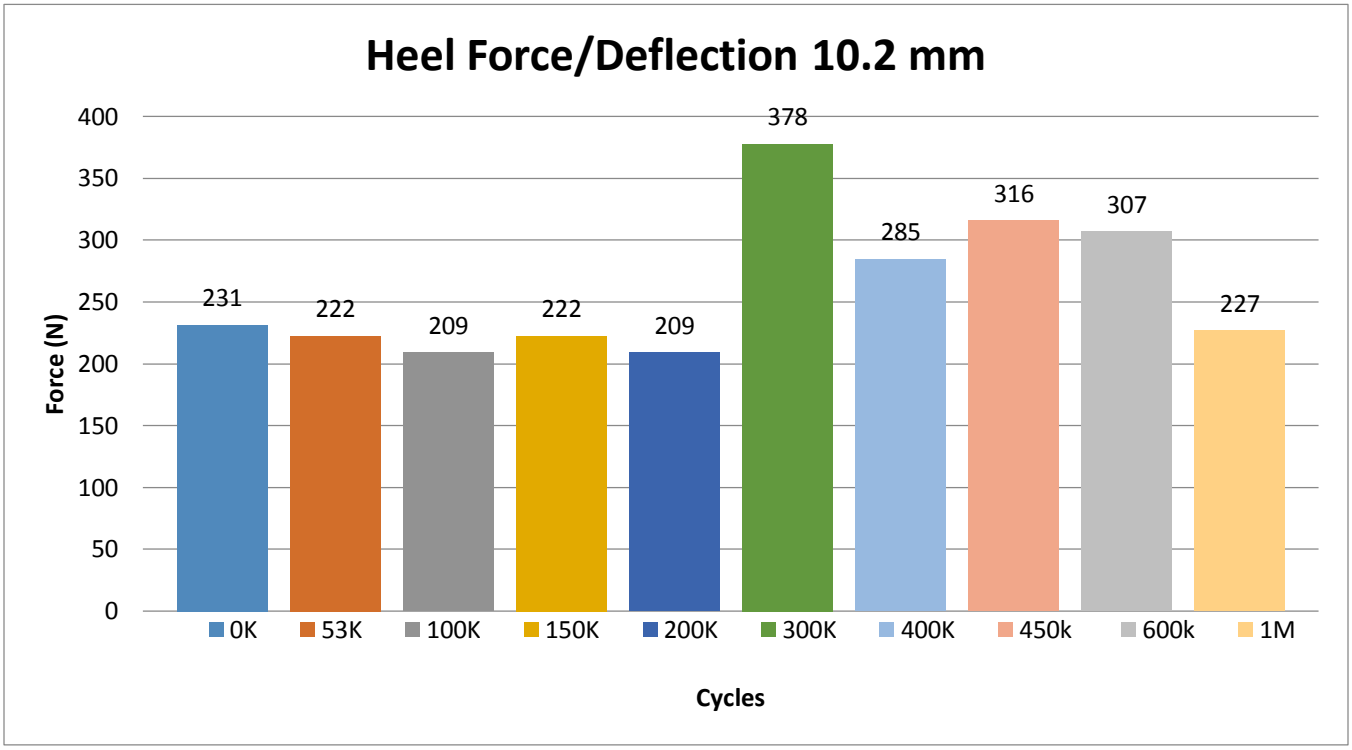


Figure 45: Deflection Testing performed on the HEEL periodically throughout the Fatigue Test. Force measurements were taken at 10.2 mm. Initial tests were performed 50,000 cycle increments to collect ensure a record of the degradation was made. The toes were replaced at 450,000 cycles and testing was continued until the heel reached one million cycles. The sudden increase measured at 300,000 cycles is likely caused by variations in the test set up which would have activated the overload spring earlier than expected increasing the stiffness measurement. This would have resulted in measuring a combination of the overload spring and the heel layer, not the heel layer alone, which was the goal of the intermittent deflection tests.

The heel section withstood 1,000,000 cycles before the test was stopped. Heel stiffness, beginning at 22.7 N/mm at 0 cycles and ending with 22.2 N/mm at 1,000,000 cycles. While the beginning and ending stiffness appears to be similar, the heel stiffness varies from 22.7 N/mm at 0 cycles, to 21.8 N/mm at 53,000 cycles, to 20.5 N/mm at 100,000 cycles, to 21.8 N/mm at 150,000 cycles, to 20.5 N/mm at 200,000; before increasing to 37.1 N/mm at 300,000 cycles. Stiffness remains relatively high (compared with 0 to 200,000 cycles) varying from 27.9 N/mm at 400,000 cycles, 31.0 N/mm at 450,000 cycles (toe removal), 30.1 N/mm at 600,000 cycles, before the final measurement of 22.2 N/mm at 1,000,000 cycles. Visual inspection of the heel layer showed no delamination or noticeable deformation (Figure 46, Figure 47, Figure 48, Figure 49). The exact cause for the sudden increase in stiffness at 300,000 cycles is unknown. Test set ups for the Deflection test contained four points of variability: two adjustments on the test fixture, the initial starting point for the tensile tester's cross-head, and the initial measuring point of the dial

indicator. These variations likely caused the overload spring to be activated earlier than expected resulting in stiffness measurement combining the overload spring and the heel layer, not the heel layer alone, which was the goal of the intermittent deflection tests. . Measurements taken at 300,000 to 600,000 cycles to be questionable.

Figure 46: Heel Layer after 1,000,000 cycles of fatigue testing. Visual inspection showed no delamination occurred.

Figure 47: Close up view of the Heel Layer after 1,000,000 cycles of fatigue testing. No visual delamination occurred. Photo courtesy of Aaron Nystrom.

Figure 48: Heel layer used for fatigue testing compared to a heel layer that was unused. Photo courtesy of Aaron Nystrom.

Figure 49: Close up photo of the above picture. Showing the permanent deformation of the heel layer used for fatigue testing. Compared to an unused heel layer. Heel layer with silver paint was the layer used for 1,000,000 fatigue cycles. Less than 2 mm separate the end of the heel layers. Photo courtesy of Aaron Nystrom.

5.1.4 Hysteresis/Energy Return

Hysteresis measurements were calculated based on the integration of the Force/Deflection curves generated during loading and off-loading of the PPF. Results were compared to the benchmark Ossur Vari-Flex Prosthetic Foot. The Ossur Vari-Flex toes absorbed 6.2 Joules (J) and released 4.6 J during loading and off-loading, respectively. This equated to a 26.3% loss of energy between loading and unloading. The PPF's toes (assembled with Soft, Medium, and Hard Layers) absorbed 10.7 J and released 7.3 J for 31.8% energy loss. The Vari-Flex heel absorbed 2.0 J and released 1.8 J for 8.4% energy loss. The PPF's heel absorbed 1.8 J and released 1.1 J for 39.2% energy loss.

Table 9: Hysteresis Results of the Ossur Vari-Flex Size 27 Category 4 Prosthetic Foot provided by LIMBS International (El Paso, TX) and the Prototype Prosthetic Foot (PPF). The PPF toe section was assembled with Soft (S), Medium (M), and Hard (H) layers.

	Toes		**Heels**	
Prosthetic Foot	**Energy (J)**	**% Lost**	**Energy (J)**	**% Lost**
Vari-Flex Loading	6.2	26.3	2.0	8.4
Vari-Flex Unloading	4.6		1.8	
SMF PPF Loading	10.7	31.8	1.8	39.2
SMF PPF Unloading	7.3		1.1	

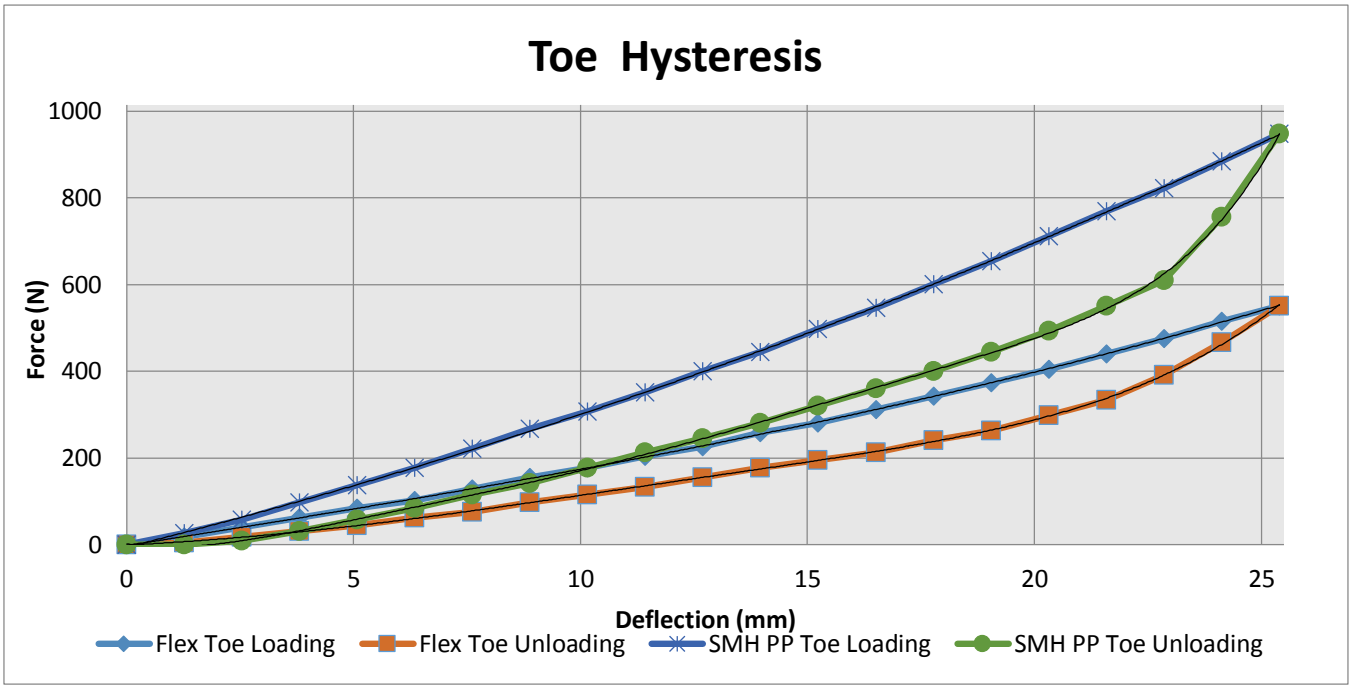


Figure 51: Toe Force/Deflection Curves generated by loading and off-loading the prosthetic feet. The Ossur Vari-Flex Size 27 Category 4 Prosthetic Foot provided by LIMBS International (El Paso, TX) compared to the Prototype Prosthetic Foot (PPF). The PPF toe section was assembled from Soft (S), Medium (M), and Hard (H) toe layers. Force/Deflection curves were integrated to find the energy absorbed and released by the prosthetic feet.

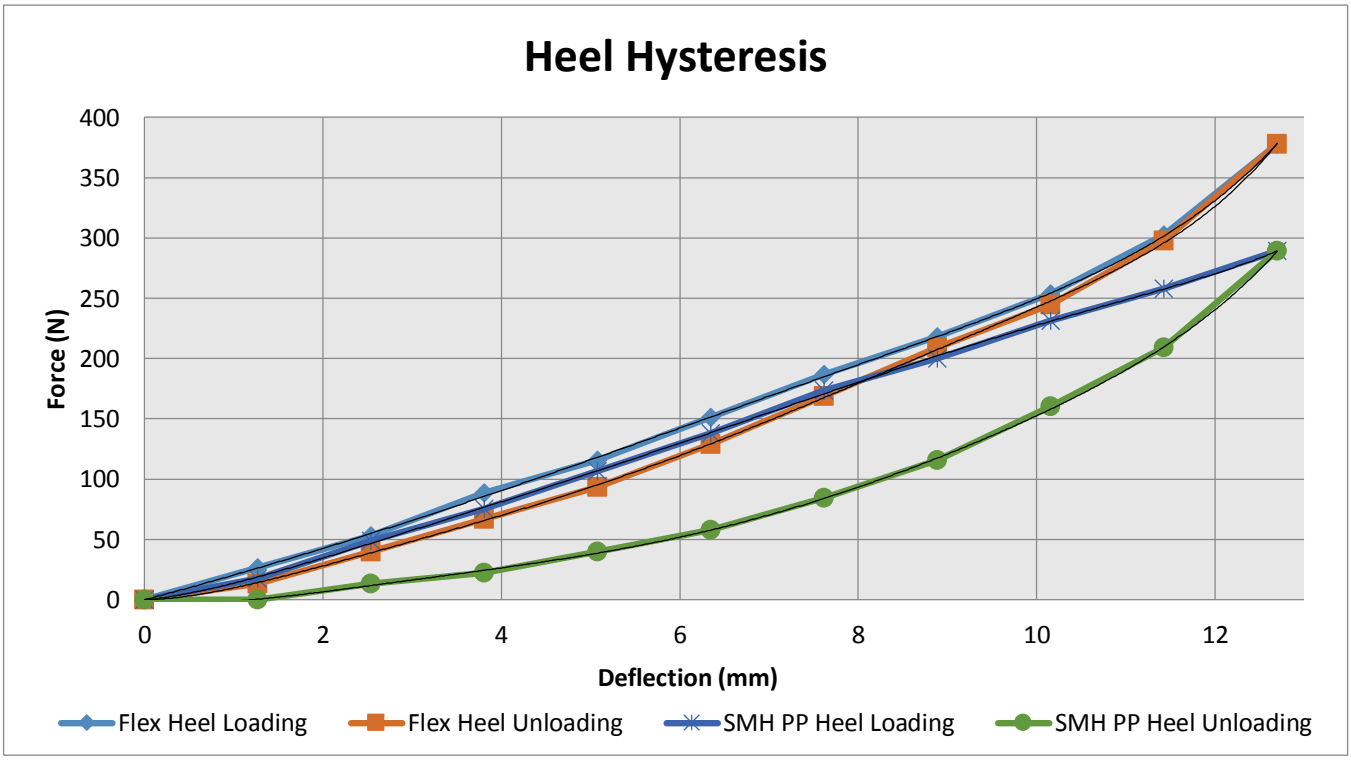


Figure 50: Heel Force/Deflection Curves generated by loading and off-loading the prosthetic feet. The Ossur Vari-Flex Size 27 Category 4 Prosthetic Foot provided by LIMBS International (El Paso, TX) compared to the Prototype Prosthetic Foot (PPF). The PPF toe section was assembled from Soft (S), Medium (M), and Hard (H) toe layers. Force/Deflection curves were integrated to find the energy absorbed and released by the prosthetic feet.

5.1.5 Cost Analysis

One development goal of this research was to use less than $100 in materials to manufacture the prosthesis. Plain Weave 3K Carbon Fiber was procured for $17.22/m^2 from Soller Composites (Franklin, NH). Approximately 0.02419 m2 of material was used for each Toe Ply, and approximately 0.01032 m2 of material was used for each Heel Ply. AdTech 820 Epoxy (1 Gallon) with Medium Fast Hardener (0.25 Gallon) were purchase from Soller Composites (Franklin, NH) for $114.98. The epoxy came with hand pumps to automatically dispense the correct ratio of epoxy and hardener – approximately 0.9 ounces per pump of epoxy and hardener ($0.72/ounce). The compression spring procured from McMaster-Carr (Elmhurst, IL) for $22.71. Material purchased to assemble foot cost $72.67. Approximately one hour was spent cutting out CF plies from the roll of CF for each Toe and Heel layer, and approximately 1.25 hours was preparing the compression molds and laying up the CF plies onto the molds (this was similar for both toe and heel layers). Toe layers were oven cured for approximately one hour and then allowed to cool for four to six hours before removing the layer, and preparing the molds for the next layer. Heel layers were not oven cured due to the Delrin molds. Heel layers were allowed to cure for 12 hours before removing layer from the molds. Approximately three hours was spent finishing toe and heel layer before a completed foot could be assembled. Total approximated labor hours per prototype prosthetic foot (not including curing time) is 12.

Table 10: Cost Analysis of materials needed for the prototype prosthetic foot.

m^2 of Carbon Fiber	**Cost per Ply**	**Plies per Prototype**	**Cost per Foot**
0.02419/Toe Ply	$0.42	75	$31.25
0.01032/Heel Ply	$0.18	26	$4.62
Oz Epoxy per Layer	**Cost/Layer ($0.72/oz.)**	**Layers/Foot**	**Cost per Foot**
4.5/Toe Layer	$3.24	3	$10.20
5.4/Heel Layer	$3.89	1	$3.89
		Compression Spring	$22.71
		Total Material Cost	**$72.67**

5.2 BIOMECHANICAL TESTING OF THE FOOT

Figure 52: Subjects 1 and 2 during experimental testing. Photo courtesy of Aaron Nystrom.

5.2.1 Subject 1

Subject 1 was a 45-year-old male, with a unilateral below-knee amputation on the right leg. Subject was 1.73 m tall and weighed 73.26 kg. Subject was a K4 activity level and a proficient walker with no current medical complications. Subject 1 used an Ossur VARI-FLEX as their SPF.

Temporal Parameters

Table 11: Subject 1 Temporal Gait Parameters comparison between the Amputated and Sound Leg when walking with the Prototype Prosthetic Foot and his Standard Prosthetic Foot (SPF).

SUBJECT 1					
PARAMETER	**PROSTHESIS**	**AMPUTATED LIMB (RIGHT)**		**SOUND LIMB (LEFT)**	
		Value (std-dev)[8]	**Deviation from SPF**	**Value (std-dev)**	**Deviation from SPF**
Step Length (cm)	Prototype	79.0 (1.59)	0.4%	70.9 (0.83)	-2.5%
	SPF	78.7 (1.85)	--	72.7 (1.29)	--
Stride Length (cm)	Prototype	149.1 (3.14)	-2.0%	150.0 (1.85)	-1.2%
	SPF	152.2 (2.56)	--	151.8 (2.52)	--
		Value (std-dev)		**Deviation from SPF**	
Cadence (step/min)	Prototype	106.2 (1.32)		-0.6%	
	SPF	106.8 (3.64)		--	
Velocity (cm/sec)	Prototype	132.7 (1.65)		-1.3%	
	SPF	134.5 (5.17)		--	

Subject 1's temporal gait parameters changed less than 5% when walking with his SPF compared to walking with the Prototype Prosthetic Foot (PPF) (Table 11). Velocity showed 1.3% from 134.5 cm/sec to 132.7 cm/sec. Cadence slowed 0.6% from 106.8 step/min to 106.2 step/min. All parameter values fell when walking with the PPF an average of 3.8%, except for step length. Subject 1's step length increased from 78.7 to 79.0 cm when walking with the Prototype. Standard Deviations were less for the PPF versus the SPF, except for the Right (Amputated) Step Length.

[8] Standard Deviation (std-dev).

GRF Subject 1

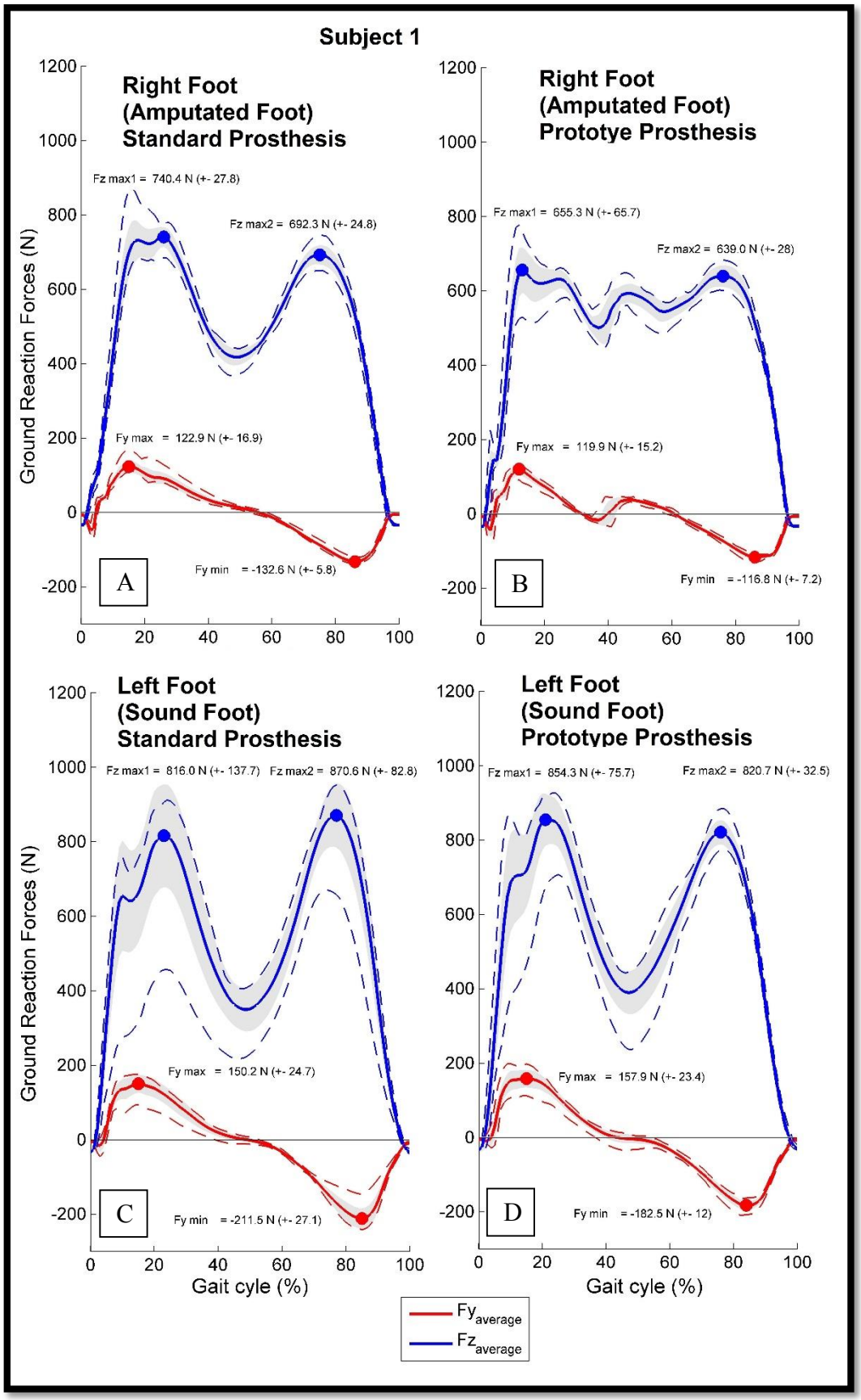


Figure 53: Ground Reaction Forces of Subject 1. Graphs show the average of 9 trials for the Right (Amputated) Foot and 10 trials for the Left (Sound) Foot in solids lines, ±1 standard-deviation in shaded grey, and the maximum and minimum values in dotted lines. Blue lines show vertical forces and red lines show fore and aft (braking and propulsive) forces. Average peak values are noted with their standard-deviation. (A) Results of the Right (Amputated) Foot while wearing the Subject's Standard Prosthetic Foot (SPF) compared with (B) the Right (Amputated) Foot wearing the Prototype Prosthetic Foot. (C) Results of the Left (Sound) Foot while wearing the Subjects SPF compared with (D) the Left (Sound) Foot wearing the Prototype Prosthetic Foot.

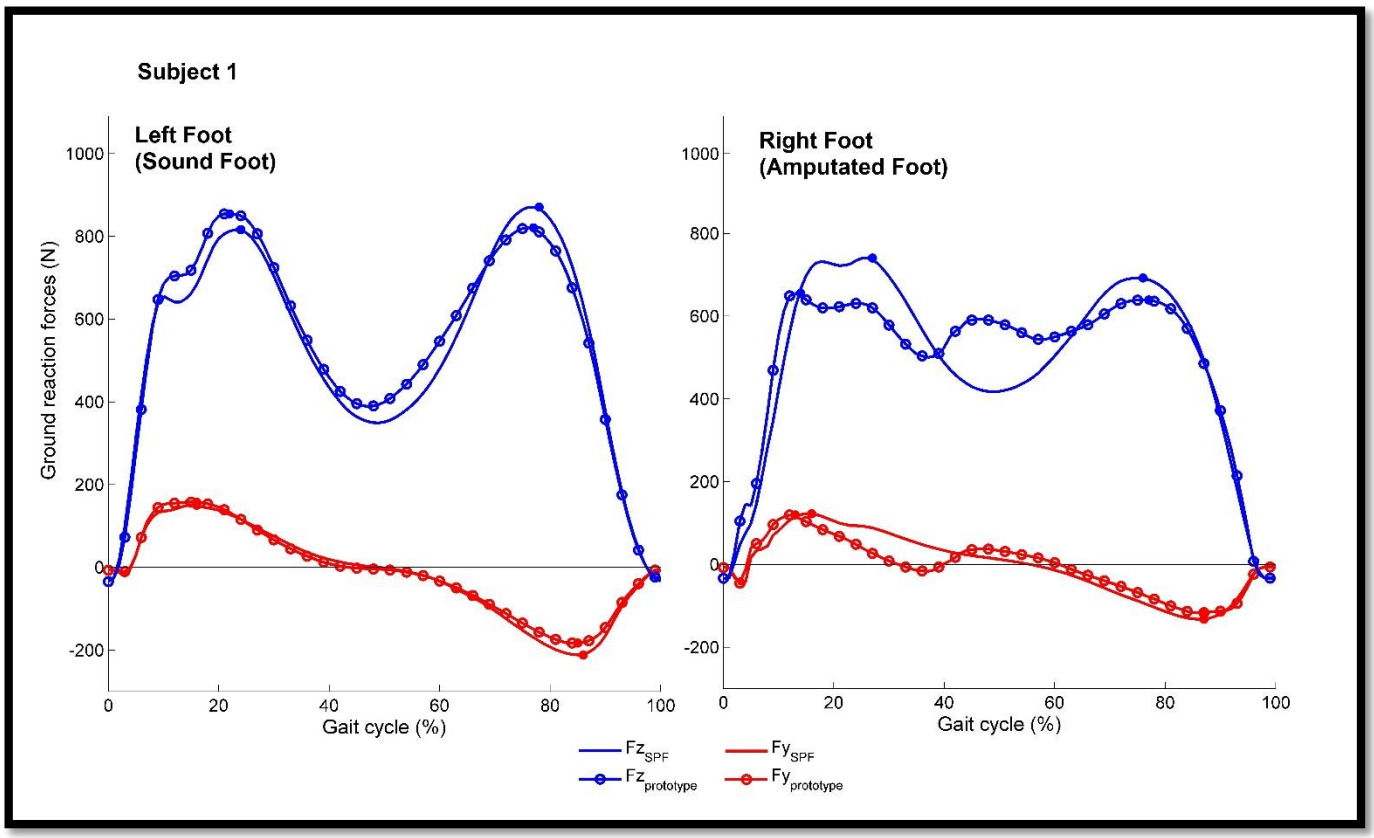


Figure 54: Subject 1 average Ground Reaction Forces when walking with the Prototype Prosthetic Foot overlaid on top on the Ground Reaction Forces when walking in his Standard Prosthetic Foot (SPF).

Table 12: Comparison of Subject 1 GRFs when walking with the Prototype Prosthetic Foot versus his Standard Prosthetic Foot (SPF).

SUBJECT 1 Ground Reaction Forces and Energy					
PARAMETER	**PROSTHESIS**	**AMPUTATED LIMB (RIGHT)**		**SOUND LIMB (LEFT)**	
		Force (N)	**Deviation from SPF**	**Force (N)**	**Deviation from SPF**
Vertical Heel Strike Force	Prototype	655.3	-11.5%	854.3	4.7%
	SPF	740.4	--	816.0	--
Vertical Toe-off Force	Prototype	639.0	-7.7%	820.7	-5.7%
	SPF	692.3	--	870.6	--
Braking Force	Prototype	119.9	-2.4%	157.9	5.1%
	SPF	122.9	--	150.2	--
Propulsive Force	Prototype	116.8	-11.9%	182.5	-13.7%
	SPF	132.6	--	211.5	--
PARAMETER	**PROSTHESIS**	**Energy (J)**	**Deviation from SPF**	**Energy (J)**	**Deviation from SPF**
Braking Energy	Prototype	8.4	-79.2%	33.2	1.8%
	SPF	40.3	--	32.6	--
Propulsive Energy	Prototype	26.1	-38.9%	52.7	-0.2%
	SPF	42.7	--	52.8	--

Table 12 summarizes peak GRFs and Braking and Propulsive Energy (Figure 53 and Figure 54). While temporal parameters changed less than 5% for Subject 1, GRFs and energy levels varied from -79.2% to 5.1%. Propulsive forces and propulsive energy level dropped when walking in the Prototype 11.9% and 38.9%, respectively. Vertical Heel Strike Forces, Braking Force, and Braking Energy all increase slightly in the Sound Foot, when Subject 1 wears the PPF. Energy levels output by the PPF are greatly reduced from the SPF, down 79.2% for braking energy and 38.9% for propulsive energy.

5.2.2 Subject 2

Subject 2 was a 50-year-old male, with a unilateral above-knee amputation on the right leg. Subject was 1.80 m tall and weighed 89.81 kg. Subject was a K3 activity level and a proficient walker with no current medical complications. Subject 2 used Rheo prosthetic knee and an Ossur Ceterus as their SPF.

Temporal Parameters

Table 13: Subject 2 Temporal Gait Parameters for the Amputated Leg and Sound Leg Compared when the subject walks with the Prototype Prosthetic Foot compared with his SPF.

SUBJECT 2					
PARAMETER	**PROSTHESIS**	**AMPUTATED LEG (RIGHT)**		**SOUND LIMB (LEFT**	
		Value (std-dev)	**Deviation from SPF**	**Value (std-dev)**	**Deviation from SPF**
Step Length (cm)	Prototype	74.3 (1.98)	-5.7%	67.3 (1.46)	1.4%
	SPF	78.8 (0.84)	--	66.4 (1.06)	--
Stride Length (cm)	Prototype	141.7 (3.01)	-2.7%	142.0 (2.67)	-2.5%
	SPF	145.6 (1.73)	--	145.6 (1.61)	--
		Value (std-dev)		**Deviation from SPF**	
Cadence (step/min)	Prototype	96.4 (1.31)		2.8%	
	SPF	93.8 (1.06)		--	
Velocity (cm/sec)	Prototype	113.3 (2.12)		-1.4%	
	SPF	114.9 (6.04)		--	

Subject 2's temporal gait parameters changed less than 5% when walking with his SPF compared to walking with the PPF (Table 13) with the exception of step length. Subject 2's right step (amputated leg) was 5.74% shorter when walking with the PPF versus the SPF. Velocity slowed 1.4% from 114.9 to 113.3 cm/sec when walking in the PPF. Cadence increased with walking with PPF from 93.8 to 96.4 step/min. All parameters except Cadence and Sound Limb Step Length decreased when walking in the PPF.

GRF Subject 2

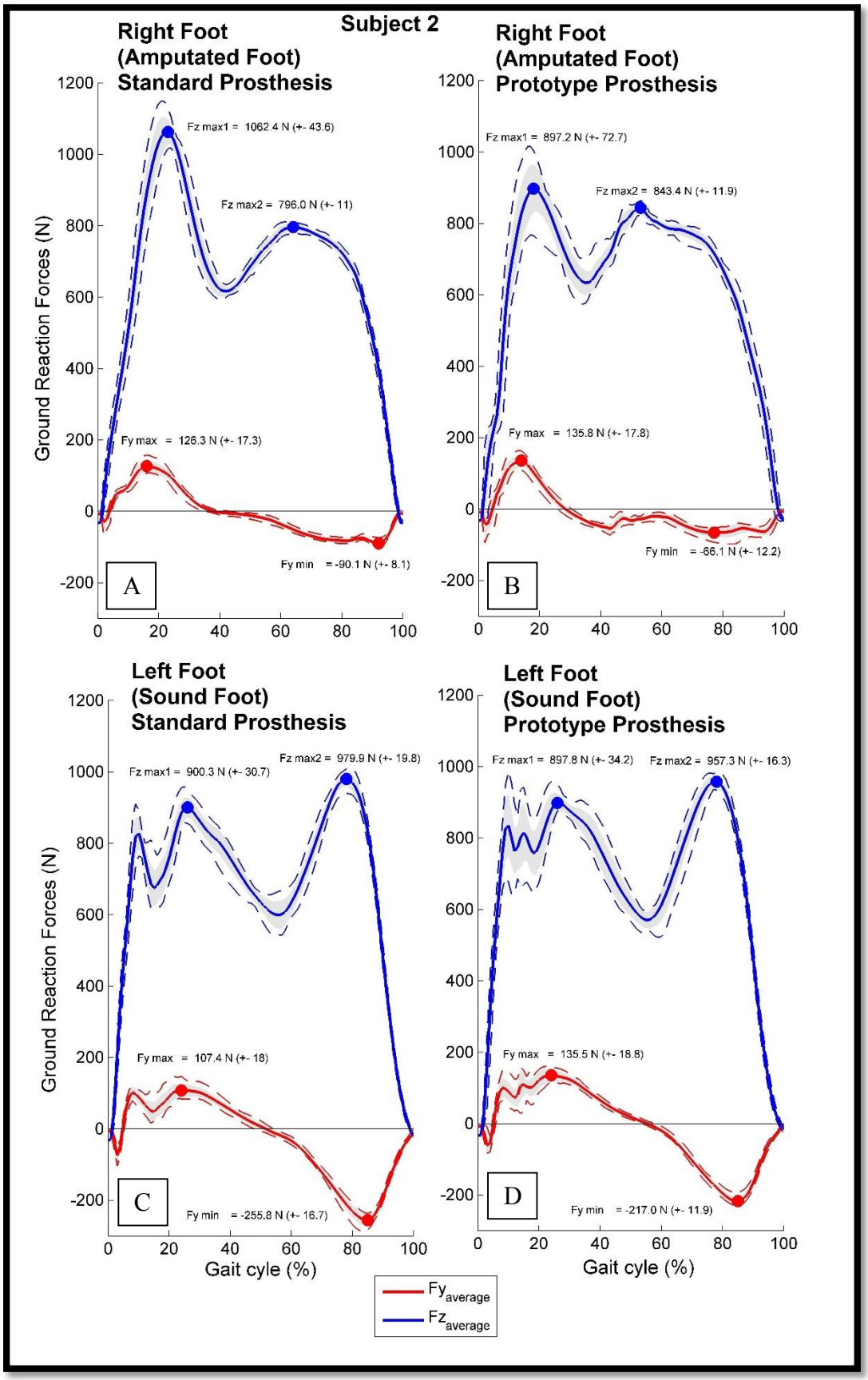


Figure 55: Ground Reaction Forces of Subject 2. Graphs show the average of 9 trials in solids lines, ±1 standard-deviation in shaded grey, and the maximum and minimum values in dotted lines. Blue lines show vertical forces and red lines show fore and aft (braking and propulsive) forces. Average peak values are noted with their standard-deviation. (A) Results of the Right (Amputated) Foot while wearing the Subject's Standard Prosthetic Foot (SPF) compared with (B) the Right (Amputated) Foot wearing the Prototype Prosthetic Foot. (C) Results of the Left (Sound) Foot while wearing the Subjects SPF compared with (D) the Left (Sound) Foot wearing the Prototype Prosthetic Foot.

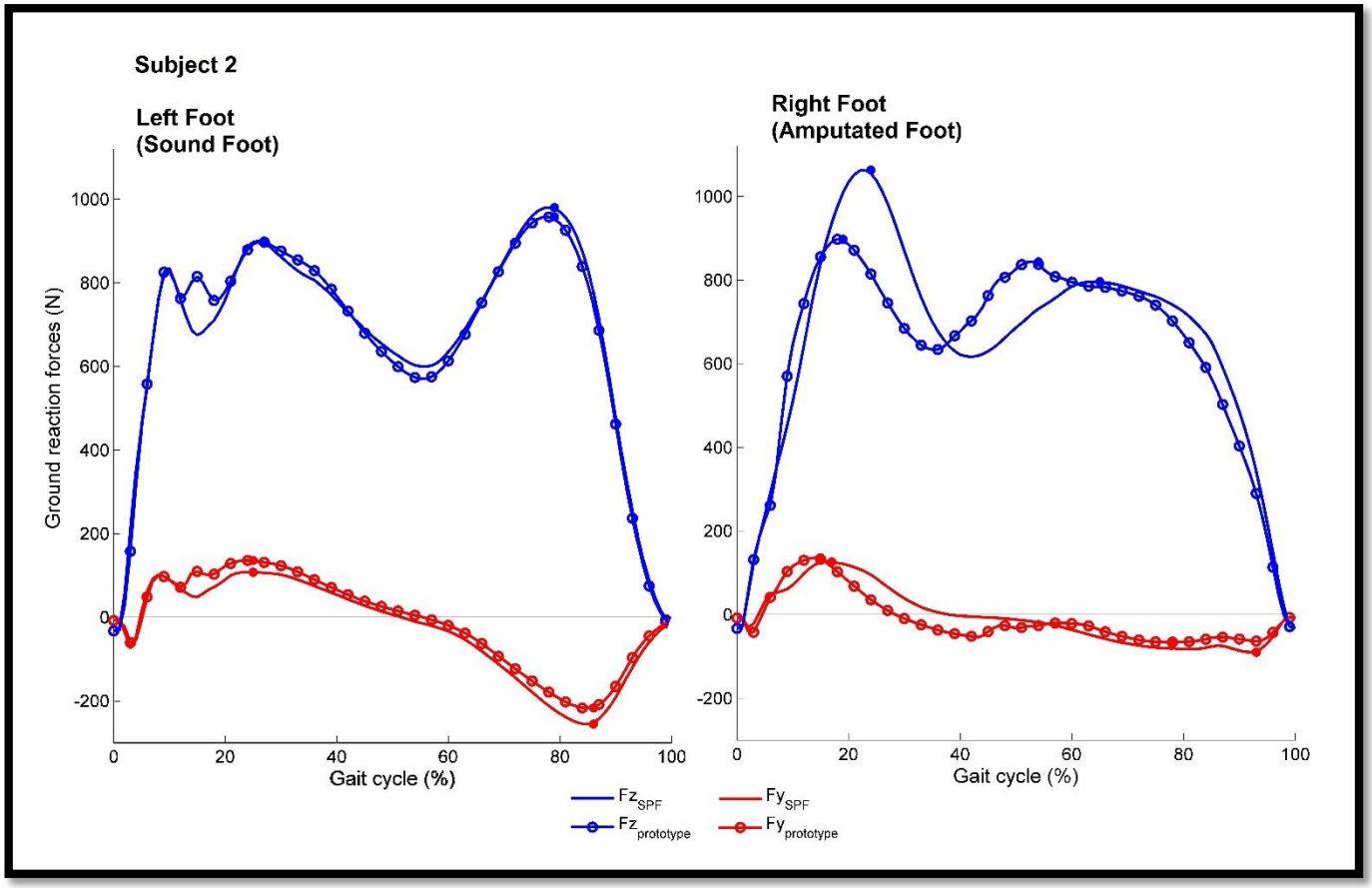


Figure 56: Subject 2 average Ground Reaction Forces when walking with the Prototype Prosthetic Foot overlaid on top on the Ground Reaction Forces when walking in his Standard Prosthetic Foot.

Table 14: Comparison of Subject 2 GRFs when walking with the Prototype Prosthetic Foot versus their Standard Prosthesis Foot (SPF).

SUBJECT 2 Ground Reaction Forces					
PARAMETER	**PROSTHESIS**	**AMPUTATED LEG (RIGHT)**		**SOUND LIMB (LEFT)**	
		Force (N)	**Deviation from SPF**	**Force (N)**	**Deviation from SPF**
Vertical Heel Strike Force	Prototype	897.2	-15.5%	897.8	-0.3%
	SPF	1062.4	--	900.3	--
Vertical Toe-off Force	Prototype	843.4	6.0%	957.3	-2.3%
	SPF	796.0	--	979.9	--
Braking Force	Prototype	135.8	7.5%	135.5	26.2%
	SPF	126.3	--	107.4	--
Propulsive Force	Prototype	66.1	-26.6%	217.0	-15.2%
	SPF	90.1	--	255.8	--
PARAMETER	**PROSTHESIS**	**Energy (J)**	**Deviation from SPF**	**Energy (J)**	**Deviation from SPF**
Braking Energy	Prototype	8.0	-60.6	32.9	50.9%
	SPF	20.3	--	21.8	--
Propulsive Energy	Prototype	34.8	-20.5%	33.9	-23.6
	SPF	43.8	--	44.4	--

Table 14 summarizes peak GRFs and Braking and Propulsive Energy (Figure 55 and Figure 56). While temporal parameters for Subject 2 changed less than 10%, the GRFs vary from -26.6% to 26.2% difference. The PPF propulsive forces decreased 26.6% while breaking forces increase 7.5% when compared to the SPF. The Sound Foot propulsive force decreased 15.2% while braking force increase 26.2%. Propulsive and Braking Energies change from -60.6% to 50.9%. Propulsive and braking energy decreases 20.5%, and. 60.6%, respectively, when wearing the PPF. Sound Limb braking energy increases 50.9% when wearing the PPF and propulsive energy decreases 23.6%.

5.2.3 Subject 3

Subject 3 was a 32-year-old male, with a unilateral below-knee amputation on the right leg. Subject was 1.83 m tall and weighed 127 kg. Subject was a K4 activity level and a proficient walker with no current medical complications. Subject 3 used a College Park Velocity as their SPF.

Temporal Parameters

Table 15: Subject 3 Temporal Gait Parameters for the Amputated Leg and Sound Leg Compared when the subject walks with the Prototype Prosthetic Foot compared with their SPF.

SUBJECT 3					
PARAMETER	**PROSTHESIS**	**AMPUTATED LEG (RIGHT)**		**SOUND LIMB (LEFT**	
		Value (std-dev)	**Deviation from SPF**	**Value (std-dev)**	**Deviation from SPF**
Step Length (cm)	Prototype	56.4 (1.62)	-8.3%	66.7 (1.99)	-5.3%
	SPF	61.5 (1.77)	--	70.4 (1.17)	--
Stride Length (cm)	Prototype	123.2 (2.19)	-6.8%	123.2 (3.05)	-6.5%
	SPF	132.2 (2.53)	--	131.8 (2.92)	--
		Value (std-dev)		**Deviation from SPF**	
Cadence (step/min)	Prototype	97.9 (4.43)		4.3%	
	SPF	93.9 (1.34)		--	
Velocity (cm/sec)	Prototype	98.3 (4.30)		-4.6%	
	SPF	103.1 (3.17)		--	

Subject 3's temporal gait parameters changed less than 5% when walking with his SPF compared to the PPF except for step lengths. His step lengths decrease an average of 6.3% when walking with the PPF. Velocity decrease 4.3% from 103.1 to 98.3 cm/sec. Cadence increase 4.3% from 93.9 to 97.9 step/min. All parameters decreased when walking in the PPF expect for Cadence.

During Subject 3's experimental sessions, lab equipment necessary to collect GRFs and Energy levels were not functioning. Multiple attempts to correct the problems failed, so no GRF data was collected for Subject 3.

5.2.4 Subject Qualitative Assessments

Following walking trials, subjects were given a questionnaire to qualitatively assess the human response to the PPF. The following table summarizes the results of the questionnaire. Subject 1 (S1), Subject 2 (S2), and Subject 3 (S3) responded to the questionnaire within 10 minutes of finishing the experimental walking sessions. See Appendices for the individual responses.

1. How happy are you with your current prosthesis? *Average Response – 9.33*
2. Does the prototype feel similar to your standard prosthesis? *Average Response – 3.00*
3. How heavy does your prosthesis feel to you? *Average Response – 3.33*
   - *3.1.* If Heavy - does the weight bother you? *Weight did not bother any of the subjects.*
4. How the prototype feel heavier or lighter compared to your standard? *Average Response – 3.00*
5. Rate the comfort of your prosthesis while standing. . – *Average Response – 10.00*
6. Rate the comfort of the prototype while standing. . – *Average Response – 8.00*
7. Rate the comfort of your prosthesis while walking. . – *Average Response – 9.33*
8. Rate the comfort of the prototype while walking. . – *Average Response – 4.33*
9. Does the prototype take more or less energy to walk with compared to your standard? *Average Response – 8.33*
   - *9.1.* Should the Prosthesis take less energy to use? *Subjects agrees that any prosthesis should take less energy to walk.*
10. Rate your overall satisfaction with your prosthesis. – *Average Response – 9.33*
11. Would you be willing to use a prosthesis like the prototype? *S1 and S2 both said they would not be willing to use a prosthesis like the prototype. S3 felt that if this was all that was available to him, he could make do with it.*
12. How does the heel strike feel? *Average Response – 3.67*
13. How does the toe-off feel? *Average Response – 5.67*
14. How fast does the Roll-Over feel? *Average Response – 3.00. S1 did not answer the questions saying that due to the ratcheting feel of the transition, the roll-over did not feel good.*
15. Does the Roll-Over feel abrupt or smooth? *Average Response – 5.00. S1 and S2 did not answer the question, feeling that the roll-over did not feel right, so that the question did not apply.*

16. Could you walk at a normal, comfortable pace with the prototype? *S1 and S2 felt it was uncomfortable to walk in the prototype, it took more energy and input from the residual limb to control the PP. S3 felt that he could walk at a normal, comfortable pace as needed, although based on the temporal parameters that was slightly slower than when wearing his SPF.*
17. Could you change your pace as needed? *All Subjects felt they could change their pace as needed.*
18. Could you walk slowly? *All subjects felt they could walk slowly.*
19. Comments of the foot were similar between S1 and S2. Both felt the heel was too soft, while the toes felt good. Both S1 and S2 did not like the transition between heel strike and toe-off. GRF from S1 while walking in the PPF (Figure 53and Figure 54) give evidence to the difficult transition S1 had while walking.

Qualitative assessments of the PPF varied greatly between Subjects 1 and 2 and Subject 3. Subjects 1 and 2 found the PPF difficult to walk with, taking much more effort than their SPF. The heel was too soft and the transition from heel strike to toe-off was not smooth. Subject 1 describe the transition like a ratchet, jerking forward through the motion. Subject 2, the only above-knee amputee of the group, noted the foot required a lot more muscle input from his amputated leg to control the foot. All agreed the toe felt good. Subject 3 felt the heel was too stiff and didn't rebound the way he expected. Subjects 1 and 2 agreed walking on the PPF was not comfortable, while Subject 3 said it wasn't bad and if it was all he had he could use it. All subjects used ESAR prosthetic feet and were happy with their current feet. They noticed the PPF was lighter than their SPFs which was good, but the PPF did not perform the same.

Figure 57: Researcher going over the questionnaire with Subject 1. Photo courtesy of Aaron Nystrom.

Chapter 6: Discussion

6.1 DISCUSSION

6.1.1 Manufacturing

Manufacturing processes needed to be easily replicable overseas to ensure LIMBS International could manufacture the prosthesis through existing partnership with United Surgical. Manufacturing processes used for this research are easily replicated as all the manufacturing methods used were done by hand. Based on visits to United Surgical and input from LIMBS; these processes could be replicated there. Working the composite material would require similar skills to working with wood or soft metals. The composite can be cut and shaped similar to wood. However, special precautions should be taken to protect workers from the dust created when cutting a composite material. The dust can irritate the lungs and skin. Training books and videos are available to teach someone how to work with composite materials. For this research, *Composite Materials: Fabrication Handbook #1* by John Wanberg was used when learning to work with the composites. It is necessary that a person be trained how to work with the composite and fabricate pieces so that the products produced achieve optimal performance and quality.

Fabrication of the composite pieces for this research was performed by hand using compression molds. C-Clamps clamped the mold pieces together forcing out excess epoxy and holding the CF fabric and epoxy in place until the pieces had cured. C-Clamps were tightened to approximately 24 N*m. However, hand tightening the C-Clamps and epoxy contaminating the threads on the C-Clamps may have cause a variation in the actual clamping force on the molds. While care was taken during the fabrication of the toe and heel layers, it is unknown how the variation in clamp force affected the composite pieces.

Each toe and heel layer required approximately two to three man-hours to fabricate. Approximately 45 minutes to 1 hour was needed to cut out all the necessary CF plies, 45 minutes to lay-up the CF onto the compression molds, and then 45 minutes to finish the part after curing. Each completely assembled foot required approximately 10 to 12 man-hours to complete. These times do not include curing time or post curing times. Toe sections heat cured at 350° F for one hour required four to six hours for the mold to cool before laminated toe layers could be removed and the mold prepared for the next toe layer. Preparing the molds for each lamination required 30 to 45 minutes of time. 10 to 20 minutes was used to

clean residual epoxy and hardened wax from the previous toe layer, and 10 minutes to reapply additional mold release wax. Time figures for the heel layers were similar to the toe layers except for curing time. Curing time for the heel layers required a minimum of 12 hours. The delrin molds would not allow for heat curing.

The two delrin ankles were manufactured for the PPF. The delrin was excess material from previous LIMBS projects. Since a new ankle was not manufactured for each prosthetic foot and both ankles were reused for mechanical and experimental tests, the amount of time and cost for these components was not computed or accounted for in the cost analysis. Neither were the pyramid adapter or hardware accounted for in the cost analysis. The pyramid adapter and hardware would be needed for any prosthetic foot. The purpose of this research was to develop the composite components of the prosthetic foot and lay the ground work for future development. Future prosthetic feet from this technology would only need to have the composite pieces and cosmesis replaced. The remaining pieces could be reused. This means only consumable parts are included in the cost analysis.

Centralized manufacturing would enable LIMBS International to control costs and maintain high product quality. However, prosthetic components must remain simple to repair or replace, allowing maintenance to be performed by local clinics and possibly the users. Given the distances amputees in the Developing World may need to walk to the local clinic, and the often rugged environment of developing countries (Cummings, 1996; Craig, 2005), the prototype prosthetic foot can be assembled and maintained using simple hand tools such as hex wrenches and an adjustable wrench. Repairing the PPF would only require the replacement of any broken toe or heel layer. Toe and heel layers are all removable without altering the alignment of the prosthesis. The toe and heel layers are independent of the ankle piece's connection to the pyramid adapter. Composite layers could be removed and replaced by the users or local craftsmen without having to return to the clinic.

6.1.2 Prosthetic Foot Needs of the Developing World

Adjustability and Reparability

A key design aspect of the PPF is the ability to remove and replace the various components without altering the prosthesis's alignment. Layers connect directly to the ankle independent of the pyramid

adapter. Repairs and adjustments can be made by removing and replacing toe and/or heel layers. Reparability of the prosthesis was demonstrated during the fatigue testing. Toe layers were replaced after 450,000 cycles, while the same heel layer was used throughout the fatigue test. This benefits the amputee because repairs could be made by the amputee or by the local clinic. Repairs are simple because the prosthesis does not need to be realigned. Amputees who live far away from the clinic could be provided with additional components, or a local clinic could stock replacement parts. Either way, the design of the foot allows this to be optional. Replacing components of the prosthesis will be less expensive than replacing the entire prosthesis and will increase the prosthesis's lifespan. Prosthetic feet currently available in the Developing World, such as the SACH feet and Jaipur Feet, cannot be repaired. When these feet are damaged or worn out, they must be replaced and the prosthesis must be realigned. This problem has not been addressed by either the Niagara foot, the Shape&Roll foot, or any low-cost prosthesis reviewed by this research.

Varying the PPF's stiffness, a prosthetist can customize the prosthesis to the user. A prosthetist could recommend stiffness levels for the patient, and additional adjustments could be made based on patient input. Layers would be identified by the manufacturer as Soft, Medium, or Hard layers, and when a patient is fitted, they would know what layers make up their prosthesis.

Split Toe

Split toe prosthetic feet offer additional stability on rough terrain (Ossur, n.d.b). The split toe on the PPF was noticed and commented on by Subject 3. Amputees who live in environments with rough terrain should benefit from the additional stability of a split toe. Currently, there is not a prosthetic foot available to the Developing World with a split toe. Additional testing should confirm these benefits.

Cost

High cost associated with ESAR prosthetic feet limits their affordability. Reducing the cost of ESAR feet could have a worldwide impact. Producing highly functional and low-cost prosthetic components is a challenge, but necessary to make advances in prosthetic technology more available. Material costs for the PPF is $72.67. This costs more than the $35 Niagara Foot (Sandford, 2003) and the $5 SACH Foot (Sandford, 2003, Strait, 2006). The cost is low enough that sponsorship programs could

be set up to give or partially give the prosthesis to an amputee. LIMBS International's "Project Mobility" is a sponsorship program where $300 donations cover the cost to fit an amputee with an entire prosthesis. Confirming the benefits of this ESAR foot through field studies would allow a program similar to Project Mobility to be used to deploy a low-cost ESAR Foot.

Durability

To maintain international test standards, the prototype was tested throughout its development. A minimum of three nested toe layers are needed to withstand the 2065 N proof test load and 3098 N ultimate test load for ISO 10328 P4 static testing (ISO, 2006a). P4 load conditions were lower than the P5 loads tested by previous research (Jensen & Treichl, 2007), the Flex-Foot this used to develop the PPF was rated for a subject size of 75 kg. ISO P-levels indicate the maximum patient weight (ISO, 2006a). Based on the Flex-Foot, test levels were reduced to P4.

Improved fatigue life is imperative for prosthetic feet destined for the Developing World, amputees may take 2498 steps per day (Jensen & Treichl, 2007). Extrapolating from this number and using the average size from Subjects 1, 2, and 3, an amputee taking 2498 steps per day will walk approximately 1.8 kilometers a day. Two million cycles should theoretically simulate approximately two years of use (Jensen & Treichl, 2007). While two years is an accepted international standard, prosthetic feet targeting the Developing World should target three to five year life span for the feet (Craig, 2005). This should be done to reduce the need for amputees to return to the clinic and accommodate the increased distances they walk. Two million steps may be less than a year of walking for an amputee in the Developing World. However, producing an ESAR foot to withstand two million cycles should be possible. Mason et al. completed fatigue testing on three ESAR feet commonly prescribed to veterans returning to active duty and found that all the feet tested passed fatigue testing per ISO 10328 P5 loads (2011). However, fatigue tests only test prosthetic under idealized conditions (Mason et al., 2011). Field testing would ultimately be needed to prove the value of any prosthetic foot in actual use.

The toe sections showed significant deformation and loss of stiffness after 150,000 cycles and required replacement after 450,000 cycles (significantly shorter than the desire two million cycles).

Replacement of the toe sections demonstrated the reparability of the PPF. The heel layer was not replaced. The toe sections began to delaminate where the ply orientation transitioned from 45° to 0°. At 450,000 cycles, when the toe section was removed all of the layers showed some delamination at one or more of these transitions points. Transitions in ply orientation cause high interlaminar stresses. Similar failures were observed during development of the heel layers. Early heel layers only used CF plies at 0° and 45°. Initial fatigue tests on these parts resulted in the heel layers delaminating before 1,000 cycles was reached. Adding CF plies at 15° and 30° to the heel layers greatly improved its fatigue life. Redesigning the toe layers to include plies oriented at 15° and 30°, similar to the heel layer, should reduce interlaminar forces and improve fatigue life. Adding CF plies at 15° and 30° should not inhibit the ability to adjust the PPF stiffness. Heel stiffness did not change after these ply orientations were introduced, and based on these results, the toe layers stiffness should be maintained as well.

Figure 58: Endolite elite2 prosthetic foot is rated for activity level's 3&4 (Endolite, n.d.). Picture from Endolite elite2 webpage. Photo from www.endolite.com.

Force/Deflection tests performed on the heel layers during fatigue testing showed a large increase in the heel stiffness from 20.5 N/mm at 200,000 cycles to 37.1 N/mm at 300,000 cycles. The stiffness remained high: 27.9 N/mm at 400,000; 31.0 N/mm at 450,000; and 30.1 N/mm at 600,000 cycles. The final measurement was 22.2 N/mm at 1,000,000 cycles. It is unknown exactly what caused this increase in stiffness. Although the increase may have been caused by variations in the Force/Deflection test set-up and wearing on the rubber heel pad. The test stand used for the Force/Deflection test and other static tests, contained two separate adjustment points. The tensile test machine allowed the cross-head to be adjusted up and down causing the test set-up to vary. The dial indicator used to measure the cross-head travel was also set up and adjusted each test. It is possible that each of these variables contributed to the increase in stiffness seen at 300,000 cycles. The heel layer withstood 1,000,000 cycles with no visible delamination.

Comparisons between the heel layer used for the fatigue test and another heel layer that was not tested and the heel layer used for experimental tests, do not reveal any significant changes.

6.1.3 Mechanical Properties

PPF's toe stiffness ranged from 31.3 to 39.8 N/mm, and the heel stiffness was 22.8 N/mm. The PPF's toe, used for experimental trials, was assembled from Soft, Medium, and Hard Layers. The SMH Toe stiffness was 36.6 N/mm. These figured were above the targeted characteristics of the Flex-Foot, which had 21.7 N/mm toe stiffness and 25.0 N/mm heel stiffness. The mismatch stiffness between the toe and heel was thought to be less than ideal, but measurements (Table 16) from Freedom Innovation's Highlander foot yield a toe stiffness of 50.2 N/mm and heel stiffness of 20.5 N/mm (South, 2008). Stiffness measurements taken from Freedom Innovation's Sierra Foot, Ossur's Re-Flex VSP, and Ohio Willow Wood' Pathfinder II (Table 16), show the heel stiffness being higher than the toe stiffness, 72.2% more for the Sierra, 59.6% more for the Re-flex VSP, and 5.9% more for the Pathfinder II (Mason et al., 2011). It should be noted that these prostheses use interdependent toe and heels. When the heel is compressed part of the toe section is deflected as well; the overall heel stiffness is partially dependent on the toe. The PPF's toe and heel section are separate so that compression of the heel does not act on or affect the toe. This function is similar to Endolite's elite2 (Figure 58) prosthetic foot, where the heel and toe sections are only connected at the ankle and do not interact. Comparing the PPF to a prosthetic foot utilizing an independent toe and heel such as Endolite's elite2 could give insight into an improved design for future work.

Table 16: Stiffness measurements of the Prototype Prosthetic Foot used for Experimental Tests compared with stiffness measurements from other Energy Storage and Return feet from published data. Prototype Prosthetic Foot was assembled with Soft (S), Medium (M), and Hard (H) toe layers and is compared to the Freedom Innovation (FI) Highlander, FI Sierra, Ossur Re-Flex VSP, and the Ohio Willow Wood (OWW) Pathfinder II. FI Highlander data gather from Brian South 2008. FI Sierra, Ossur Re-Flex VSP, and OWW Pathfinder II data gathered from Mason et al., 2011).

Prosthetic Foot	Toe Stiffness (N/mm)	Heel Stiffness (N/mm)
Prototype (SMH)	36.6	22.8
FI Highlander	50.2	20.6
FI Sierra	100.3	172.8
Ossur Re-Flex VSP	48.8	77.9
OWW Pathfinder II	55.9	59.2

PPF's heel section did not allow for nesting layers together like the toe section because of the limited space in the heel section. Attempts were made to nest the heel section, in its current design, but the second layer had bolt holes next to the curved radius of the heel section creating high stress concentrations. A greater understanding of how heel stiffness and toe stiffness interact and affect each other would be beneficial. As noted in Table 16 toe and heel stiffness are not matched, nor is one always more stiff than the other. The FI Highlander's toe is 2.5 times stiffer than its heel. The FI Sierra's toe is less stiff than its heel. Researchers at The University of Texas at Austin studied the variation in prosthetic foot stiffness as it relates to amputee gait with hopes of being able to better predict the optimal prosthetic foot stiffness for a given patient (Fey et al., 2011). However, to date, heel and toe stiffness were not changed independently; the heel and toe were softened or stiffened simultaneously (Fey et al., 2008). Subject 3's SPF (College Park Velocity) was set up with a stiffer heel. Subject 3 noted during walking trials that he was trained to walk by loading the heel and allowing the rebounding of the heel to assist in propelling him forward. The subject's weight alone activated the overload spring giving an apparent stiffness of 58.3 N/mm. The increased stiffness of the heel may have been the reason for Subject 3's contrasting qualitative review compared to Subjects 1 and 2.

6.1.4 Patient Data and Response

Mechanical Properties and Qualitative Data

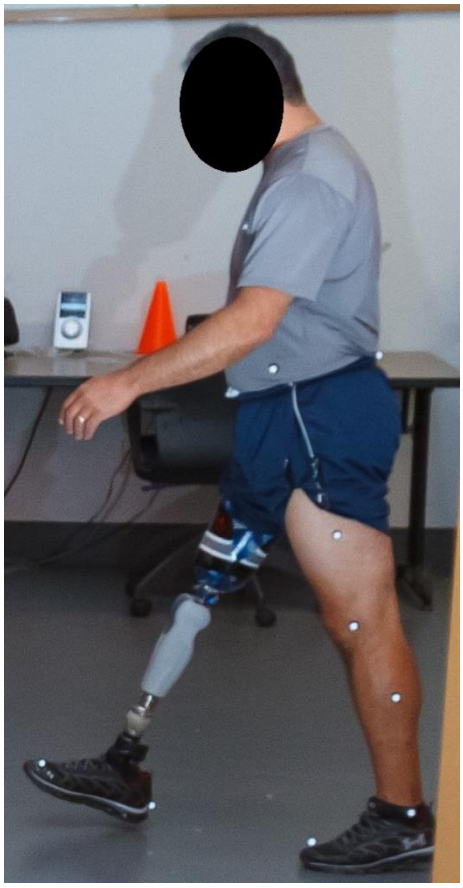


Figure 59: Subject 2 during walking trial. Notice his standard prosthetic foot is inside his shoe. Photo courtesy of Aaron Nystrom.

Subject 1 and Subject 2 reviewed the PPF similarly. They noted heel was too soft and the foot required additional effort to walk. Force/deflection curves generated for the PPF were based on Category 4 Flex-foot rated for low impact when the user weighs above 78 kg (Table 1). The SPFs for both subjects were Category 6, which would have had an increased stiffness compared to the PPF. ESAR Feet noted earlier were Category 6 feet (Table 16). Observations of below-knee amputee gait suggested an amputee requires more muscle input to support the body when the prosthetic foot stiffness decreases (Fey et al., 2011). The increased effort noted by both Subject 1 can most likely be contributed to a reduced stiffness of the foot. The description of "soft" and reduction in the peak vertical GRF both point to a reduction in the prosthesis stiffness. Decreasing prosthetic foot stiffness should result in an increase in braking forces for both the sound and amputated feet, and a decrease in the vertical toe-off force of the sound foot (Fey et al., 2011). These changes can be observed in the GRFs of Subject 1 except for the increase in braking force of the amputated leg.

Subject 3's response was more favorable compared to Subject 1 and Subject 2. Subject 1 and Subject 2 gave the PPF an overall rating of 2.5/10 while walking, Subject 3 gave the foot an 8/10. The apparent stiffness Subject 3 would have felt while walking in the prototype was 58.3 N/mm, much closer to the category 6 feet noted in (Table 16). In his qualitative assessment Subject 3 notes the heel feels too stiff, probably resulting from the lack of deflection in the overload spring. However, this increased stiffness may have been more familiar to Subject 3 and be the primary reason for the difference in his assessment. Subject 3 also states the Prototype required more effort to walk. This may be because the heel did not offer the propulsion he was expecting – the difference between the apparent felt stiffness of the prosthesis and the actual stiffness of the heel layers.

Measured Experimental Data

GRFs from Subject 1 and Subject 2 showed large decreases (Table 12 and Table 14), yet the temporal parameters (Table 11 and Table 13) showed little changes. It would be expected that temporal parameters change less than GRFs, as previous research has shown temporal parameters change little when comparing various feet (Hafner et al., 2002b; Pitkin, 1995). Decreases in GRF and the reduction in propulsive energy most probably result from a reduced stiffness in the PPF versus the SPF. Previous studies comparing Flex-foot to a Conventional Prosthetic Foot (CPF), measured peak vertical heel strike force to be between 8.4% and 11.9% higher in the Flex-Foot than the CPF (Schneider, 1993; Snyder, 1995). Subject 1's peak vertical heel strike force was 11.5% higher with his SPF, and subject 2 was 15.5% higher. Comparisons between the Flex-Foot and CPF showed peak vertical toe-off forces to 1.1% to 15.1% higher for the Flex-Foot. Subject 1's peak vertical toe-off force was 7.7% higher with his SPF, and Subject 2's was 6.0% higher with the PPF. Both Subjects 1 and 2 indicated the stiffness of the toe felt good, indicating that the toe section of the PPF performed more like the ESAR feet they wore. The decrease in stiffness should have increased the braking forces (Fey et al., 2011). This was observed for both Subjects 1 and 2 in their sound limb when using the PPF. It is unclear if the difference in GRFs for Subjects 1 and 2 could be attributed to differences between their SPF and the PPF, as the PPF was not set up to match the SPF.

Subject 3's step length decreased 8.3% when walking with the PPF compared to his SPF. Subject 3 was 1.83 meters tall (the tallest subject) and the foot size for his SPF was much larger than the PPF. The PPF foot size is better suited for a person of 1.7 meters. The shorter prosthetic foot (compared to his standard foot) would have contributed to shorted step length. Subject 3's step decrease of 8.3% is the only temporal parameter change for all subjects larger than 7%.

Experimental Data and Qualitative Data

Looking for the Qualitative Data in experimental data may confirm what subjects may or may not have felt. Subject 1's difficult transition in the PPF is evident in the GRF graphs (Figure 54). The SPF's GRFs create a smooth graph with two distinct peaks typical of vertical GRFs. The braking and propulsive force of the SPF shows a similar flow from braking to propulsion. PPF's GRF graphs are not smooth and

do not transition as expected. The PPF's vertical GRF peak from the heel strike as expected but then jerks up and down until toe-off. Braking forces peak begin trending towards propulsion before oscillating at mid-stance and then continuing to propulsion.

Subject 1 and Subject 2 mentioned that the heel felt too soft. This was exhibited in a comparison between the GRFs of the PPF and the SPFs for both subjects. As mentioned earlier this is most likely because of the reduced heel stiffness. Subject 2 does not mention the transitional problems that Subject 1 experienced. The GRF Graphs from the PPF are closer in shape to his SPF. Unlike Subject 1, Subject 2's GRFs produced results closer to his SPF.

Qualitative Data

All the subjects were able to walk on the PPF and maintain their temporal parameters. Subject 3's favorable review of the PPF may be because he walked slower than the other subjects and his velocity reduced 4.6% in the PPF. The slower the walk the less difference will be noticed between the feet. Overall, Subjects' data and qualitative responses follow the expectation shown in the research. Their temporal parameters changed less than 7% (with the exception of Subject 3's step length) even though Subjects 1 and 2 had difficulty walking with the PPF. This seems to confirm the results of Hafner et al. (2002b), Pitkin (1995), and Postema et al. (1997a) where the variations in temporal parameters were small. How patient perception correlates to their preferred prosthesis choice is unknown. The goal for the experimental testing for this research was to acquire base line performance data and quantify an initial human response to the PPF. Measuring the Subjects oxygen consumption would have quantified the "increased effort" the Subjects mentioned.

6.2 LIMITATIONS

SPF vs Prototype

Experimental data relied upon a comparison with the Subjects' SPFs. As noted earlier, all three subjects wore Category 6 feet. The stiffness measurement of each SPF was unknown, thus the stiffness difference between the SPF and the PPF was unknown. Based on the data in Table 14, it is probable that the SPFs were stiffer than the PPF. Knowing the stiffness of the SPFs would have allowed the stiffness of the PPF to be match and a more direct comparison between the feet to be made. For this study it was not

possible to directly measure the subjects SPF. The possibility of damaging an expensive prosthesis; the amount of time require to borrow a Subject's primary limb for the test (leaving them immobile); and the need to realign the foot by a prosthetist prohibited any measurements from being taken.

Subjects' SPFs were encased in cosmetic covers and inside their shoes during the experimental tests. The additional layers to the prosthesis change the stiffness characteristics of the feet (Jaarsveld et al., 1990) and add another variation between the feet being compared. Subject 3 noted at the end of his experimental testing that he wondered how the PPF would feel if it had been in a shoe. The addition of a shoe may reduce the stiffness of the foot, but the corresponding changes to Subject response and gait is not known. The difficultly of testing the PPF in a shoe, is matching the shoe on the PPF to the shoes being worn by the Subject. Heel rise varies according to shoes types. To account for this, each test subject's shoe would need to be known and the heel rise measured. Then the PPF would have to be adapted to the shoe before testing could begin.

Experimental data only compared the SPF to the PPF. Testing additional prosthetic feet (i.e. SACH, Jaipur, and ESAR feet of various categories) would allow for additional comparisons to be made. Comparing the PPF's performance to SACH and Jaipur feet would prove the benefit of the foot, or show the need to further improve it.

Self-Selected Walking Velocity

Subjects were allowed to walk at a self-selected velocity for experimental testing. While the average velocity changed less than 5% for patients, controlling their gate would have allowed for improved data comparison. Subject 3 walks slower than Subject 1. Slower walking velocities reduce perceptible difference between feet, and studies have shown GRFs and joint work are not always consistent across walking speeds (Fey et al., 2010; Silverman et al., 2008). At a minimum it would be beneficial to ensure subjects maintains similar velocity throughout their experimental tests. Controlling the steady state speed may help to reduce inconsistencies

ESAR Feet Data

Data regarding ESAR foot performance is limited, especially with modern feet. Manufacturers don't publish data regarding prosthetic feet, except what is needed for the prosthetist to fit the patient.

Data regarding Subjects wearing modern ESAR feet is limited to studies looking at various gait parameters, but little research looks at the effects these various foot technologies have on amputee gait, muscle activation, and joint loading. Research regarding ESAR effects on amputees and additional mechanical performance regarding ESAR feet would be helpful for future designs.

The correlation between a patient's preferred prosthetic foot and walking effort is unknown. Why patients choose one prosthesis over another is often attributed to personal preference. But it is possible the chosen prosthesis reduces the patient's walking effort. Slight variations in how different prosthetic feet transfer GRFs up through the prosthesis to the residual leg may also influence a patient's choice. A better understanding of these influences of the amputee may reveal quantifiable reasons patients choose one prosthesis over another.

Amputee Population

The population of amputees available to collect experimental data was limited. Pooling from four prosthetic clinics in El Paso for six months yielded three willing subjects. Two of these subjects were transtibial amputees. Comparing gait cycles between transtibial and transfemoral amputees is not beneficial considering the extreme variations in gait patterns between them. Transfemoral amputees have reduced leg function compared to transtibial amputees. In addition to their foot, they have also lost the muscles connecting to the tibia, which the transtibial amputee can still use for locomotion. The difference in step length from Subject 1's Sound Limb to his Amputated Limbs compared to Subject 2's is evidence of this reduced function. Subject 1's step lengths are 78.7 cm (Stepping off the sound leg) (Table 11) and 72.7 cm (Stepping off the amputated leg) compared to Subject 2's 78.8 cm and 66.4 cm (Table 13).

Another issue with testing amputees in the United States is that they do not represent the target population of the Developing World. They are comparing their SPF which may cost several thousand dollars to a PPF that cost less than $100, and they may have never even walked with a SACH foot or any other low-activity prosthetic foot. It is interesting that Subject 3's response to the PPF was favorable overall, and yet he was, by a number of years, the newest amputee of the test subjects. In the future, researchers may need to test on smaller amputees (less than 80 kg) or use subject who have been walking on a SACH style foot.

6.3 FUTURE WORK

As with any research, there is still work to be done. This section presents the future work that needs to be done in order to build on this research. Future work is broken down into three categories that would need to be investigated before a viable and marketable foot would be produced: Design of the PPF, Manufacturing, and Testing.

6.3.1 Design

Four key design areas of the PPF need to be improved: the roll-over transition from heel strike to toe-off, the fatigue test, energy storage and return, and the cosmesis. Subjects 1 and 2 both complained the heel was too soft, and the transition from heel strike to toe-off was difficult. Subject 1's GRF (Figure 53) from the PPF clearly show the difficulty he is referring too. Refining the transition from heel strike to toe-off is important to improve the walking comfort of the PPF.

Fatigue life of the PPF must be significantly improve and further quantified. As mentioned previously the fatigue life of prosthetic feet for the Developing World should not be two years but three to five years. Little data has been collected the fatigue life of prosthetic feet over two million cycles. The toe section of the PPF only last 150,000 cycles, and the heel was only tested for one million cycles.

The low propulsive forces of the PPF may show a lack in energy return compared to the SPF. This could be caused by the stiffness differences between the subjects' category 6 prosthetic feet and the PPF, which was based on a category 4 prosthetic foot. Energy storage and return should be optimized to give users the maximum benefits of this technology.

The physical appearance of a prosthetic foot is extremely important depending on where an amputee lives. Developing an adequate cosmesis for the PPF would be beneficial to users in areas where cosmetic appeal is more important, and would better allow the PPF to be used within a shoe.

Testing future prototype prosthetic feet inside a subject's shoe and developing a cosmesis for the prosthetic foot will require that a subject/patient's foot size (on their sound limb) be accounted for and matched. As noted earlier, Subject 3's shortened step length may have been cause by the size difference in the PPF compared to his SPF. Future work must find a way to adapt this technology to various sizes of feet so that more amputees can benefit from this technology.

6.3.2 Manufacturing

Manufacturing a high quality prosthesis is extremely important as it directly relates to the overall performance of the prosthesis. A study should be taken to understand the effects of various composite manufacturing technics to optimize fatigue life and energy storage and return. Using vacuum molding instead of compression molding or in addition to compression molding could change the performance of the composite.

For this research, plain weave carbon fiber fabric was used because of its low-cost and its usability. However, unidirectional carbon fiber fabrics or a combination of plain weave and unidirectional fabrics might improve the overall performance and fatigue life of the prosthesis. In addition to this, the optimal layering for the various stiffness should be determine to optimize the layers. These methods could also be used overseas.

6.3.3 Testing

Future testing will be important to continue to understand how future designs have improved in their performance and to ensure the designs are continually improving.

Matching stiffness of the PPF to a Subject's SPF will help determine if the performance of the PPF is similar to the Subject's SPF. As it currently stands, the different performance and the various reactions to the PPF may be due to the variations in stiffness between the PPF and the SPF. Matching the stiffness of the SPF would help that understanding. Testing the PPF with a shoe would also help in comparing the difference between the PPF and the SPF. Adding stiffness to the PPF and inserting it into a shoe and retesting the PPF would aide in determining how the PPF could be improved. Additionally, allowing patients a longer time to acclimate to a new prosthesis would be beneficial. Experimental data was collected from subjects after they have spent 10 to 20 minutes acclimating to the PPF. In the future, allowing more acclimation time may allow them to become more comfortable with the prosthesis.

Future testing should include 10 to 15 subjects. A larger sample size would enable more concrete conclusions to be drawn. For example, in the current testing two subjects found walking on the PPF difficult, while the third subject did not seem to have the same difficulty. Future testing should also include field tests with amputees from clinics partnered with LIMBS International. The response to the PPF from

users in the Developing World would be valuable. Observing the real world performance of the PPF overseas would enable researchers to determine the actual value to an amputee overseas. Additionally, allowing the target population input into the design of the PPF would be beneficial as they would have insight into their everyday needs.

Comparative gait analysis on prosthetic users often measures muscle activations and joint moments to determine at a deeper level how the prosthesis is affecting the patient. Measuring patients oxygen consumption would allow help quantify an increase in effort needed to walk in a new prosthesis. Measuring and comparing these parameters on future experimental tests will able researchers to understand more fully the variations being caused by the PPF compared to a subjects SPF.

6.3.4 Additional Future Work

To fully utilize the adjustability of the PPF, a chart should be created that would allow for a prosthetist to predict the optimal foot stiffness for a patient. The chart would recommend the foot stiffness based on the patient's height, weight, and activity level. The stiffness could then be adjusted based on the patient's response to the prosthesis.

Chapter 7: Conclusions

The goal of this research was to determine the feasibility of fabricating a low-cost, adjustable, ESAR, repairable prosthetic foot manufactured from carbon fiber using methods and techniques that could be replicated in the Developing World and meet international test standards. The study confirmed the feasibility of fabricating a low-cost, adjustable, ESAR, repairable prosthetic foot manufactured from carbon fiber using methods and techniques that could be replicated in the Developing World and meet international test standards.

This research designed and fabricated a prototype prosthetic foot by hand using methods that could be repeated around the world. The prototype prosthetic foot passed static tests per ISO 10328. Toe and heel sections withstood 450,000 and 1,000,000 fatigue cycles, respectively, per ISO 22675. Nested layers with varying stiffness allowed the toe stiffness to change from 31 N/mm to 40 N/mm. Hysteresis tests show the toe and heel section return 68% and 61%, respectively, of their storage energy. Three test subjects walked on the prototype prosthetic foot and were able to maintain temporal parameters within 7% of their standard prosthesis, with the exception of Subject 3's step length. Test subjects reflected previous research showing temporal parameters changed little regardless of their perception of a prosthetic foot.

The mission of LIMBS International is to "transform lives…one step at a time." The success of this research is a step in that transformation. A step to providing ESAR feet to amputees around the globe. Technology developed from this research could increase the availability of ESAR feet by manufacturing them with methods that can be replicated globally, by fabricating and assembling them by hand without expensive machinery, and by providing a high performance, customizable foot unlike anything currently available. No other low-cost prosthetic foot available can be customized to the user and then altered by exchanging layers. No other low-cost foot can be repaired at the clinic or at home without realigning the prosthesis. The technology developed here can do these things and is ready to transform the lives of amputees around the globe by providing a low-cost, adjustable, ESAR, repairable prosthetic foot.

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Appendix I: Subject 1 Questionnaire

Subject 1 was a 45-year-old, below-knee (right), unilateral amputee (1.73 m, 73.26 kg). Subject was rated at a K4 activity level and is very active and proficient walker. Subject's standard prosthesis was an Ossur VSP or an Ossur VARI-FLEX. Amputation was due to medical complications and infection. Subject was in good physical condition with no medical disorders or pain. A licensed prosthetist was present during data collection and fit the PPF to the subject. Subject was provided informed consent according to the guidelines set forth by The University of Texas at El Paso.

Subject 1 Questionnaire

1. How happy are you with your current prosthesis?
   Extremely Happy - 10 9 8 7 6 5 4 3 2 1 0 - Extremely Unhappy
2. Does the prototype feel similar to your standard prosthesis?
   Very Similar - 10 9 8 7 6 5 4 3 2 1 0 - Not Similar
3. How heavy does your prosthesis feel to you?
   Heavy - 10 9 8 7 6 5 4 3 2 1 0 - Light | *6 for the VSP/1 for the Vari-Flex*
   3.1. If Heavy - does the weight bother you?
   Yes – No | VSP
4. How the prototype feel heavier or lighter compared to your standard?
   Heavier - 10 9 8 7 6 - Same - 4 3 2 1 0 - Lighter
5. Rate the comfort of your prosthesis while standing.
   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible
6. Rate the comfort of the prototype while standing.
   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible
7. Rate the comfort of your prosthesis while walking.
   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible | *Both Prostheses (VSP & Vari-Flex)*
8. Rate the comfort of the prototype while walking.
   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible
9. Does the prototype take more or less energy to walk with compared to your standard?
   Much More - 10 9 8 7 6 - Average - 4 3 2 1 0 - Much Less

9.1. Should the Prosthesis take less energy to use?

Yes - No

10. Rate your overall satisfaction with your prosthesis.

Very Satisfied - 10 9 8 7 6 5 4 3 2 1 0 - Not Satisfied

11. Would you be willing to use a prosthesis like the prototype?

Yes - No

12. How does the heel strike feel?

Too Hard - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Too Soft

13. How does the toe-off feel?

Too Hard - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Too Soft

14. How does the Roll-Over feel?

~~Too quick - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Too Slow~~ (NOT APPLICABLE)

15. Does the Roll-Over feel?

~~Abrupt - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Slow~~ (NOT APPLICABLE)

16. Could you walk at a normal, comfortable pace with the prototype?

Yes - No

17. Could you change your pace as needed?

Yes – No | Yes but compensated for the problems in the prototype.

18. Could you walk slowly?

Yes – No | Yes but compensated for the problems in the prototype.

19. COMMENTS

The prototype has a “Dead Spot” in the Roll-Over. The transition from heel to toes isn’t smooth it is abrupt. Felt the roll-over was separated and serrated like it was ratcheting through the transition. Toe feels great though.

Appendix II: Subject 2 Questionnaire

Subject 2 was a 50-year-old, above-knee (right), unilateral amputee (1.80 m, 89.81 kg). Subject was rated at a K3 activity level and is a proficient walker. Subject's standard prosthesis is a Rheo Prosthetic Knee with an Ossur Ceterus Prosthetic Foot. Amputation was due to a motorcycle accident. Subject was in good physical condition with no medical disorders or pain. A licensed prosthetist was present during data collection and fit the PPF to the subject. Subject was provided informed consent according to the guidelines set forth by The University of Texas at El Paso.

Subject 2 Questionnaire

1. How happy are you with your current prosthesis?

   Extremely Happy - 10 9 8 7 6 5 4 3 2 1 0 - Extremely Unhappy

2. Does the prototype feel similar to your standard prosthesis?

   Very Similar - 10 9 8 7 6 5 4 3 2 1 0 - Not Similar

3. How heavy does your prosthesis feel to you?

   Heavy - 10 9 8 7 6 5 4 3 2 1 0 - Light

   3.1. If Heavy - does the weight bother you?

   Yes - No

4. How the prototype feel heavier or lighter compared to your standard?

   Heavier - 10 9 8 7 6 - Same - 4 3 2 1 0 - Lighter

5. Rate the comfort of your prosthesis while standing.

   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible

6. Rate the comfort of the prototype while standing.

   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible

7. Rate the comfort of your prosthesis while walking.

   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible

8. Rate the comfort of the prototype while walking.

   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible

9. Does the prototype take more or less energy to walk with compared to your standard?

   Much More - 10 9 8 7 6 - Average - 4 3 2 1 0 - Much Less

9.1. Should the Prosthesis take less energy to use?

Yes - No

10. Rate your overall satisfaction with your prosthesis.

Very Satisfied - 10 9 8 7 6 5 4 3 2 1 0 - Not Satisfied

11. Would you be willing to use a prosthesis like the prototype?

Yes - No

12. How does the heel strike feel?

Too Hard - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Too Soft

13. How does the toe-off feel?

Too Hard - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Too Soft

14. How does the Roll-Over feel?

Too quick - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Too Slow

15. How does the Roll-Over feel?

~~Abrupt - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Slow~~ (NOT APPLICABLE)

16. Could you walk at a normal, comfortable pace with the prototype?

Yes - No

17. Could you change your pace as needed?

Yes - No

18. Could you walk slowly?

Yes – No

19. COMMENTS

Roll-over and transition from heel to toe was tough.

Had to use a lot more thigh movement to control the leg

Appendix III: Subject 3 Questionnaire

Subject 3 was a 32-year-old, below-knee (right), unilateral amputee (1.83 m, 127.01 kg). Subject was rated at a K4 activity level and is highly active and a proficient walker. Subject's standard prosthesis is a College Park Velocity set up with a stiffer heel. Amputation was due to injury and later medical complications. Subject was in good physical condition with no medical disorders or pain. A licensed prosthetist was present during data collection and fit the PPF to the subject. Subject was provided informed consent according to the guidelines set forth by The University of Texas at El Paso.

Subject 3 Questionnaire

1. How happy are you with your current prosthesis?

   Extremely Happy - **10** 9 8 7 6 5 4 3 2 1 0 - Extremely Unhappy
2. Does the prototype feel similar to your standard prosthesis?

   Very Similar - 10 9 **8** 7 6 5 4 3 2 1 0 - Not Similar
3. How heavy does your prosthesis feel to you?

   Heavy - 10 9 8 7 6 5 4 3 2 1 0 - Light

   3.1. If Heavy - does the weight bother you?

   Yes - No
4. How the prototype feel heavier or lighter compared to your standard?

   Heavier - 10 9 8 7 6 - Same - 4 3 2 1 0 - Lighter
5. Rate the comfort of your prosthesis while standing.

   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible
6. Rate the comfort of the prototype while standing.

   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible
7. Rate the comfort of your prosthesis while walking.

   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible
8. Rate the comfort of the prototype while walking.

   Excellent - 10 9 8 7 6 5 4 3 2 1 0 - Terrible
9. Does the prototype take more or less energy to walk with compared to your standard?

   Much More - 10 9 8 7 6 - Average - 4 3 2 1 0 - Much Less

   9.1. Should the Prosthesis take less energy to use?

   Yes - No

10. Rate your overall satisfaction with your prosthesis.

    Very Satisfied - 10 9 8 7 6 5 4 3 2 1 0 - Not Satisfied

11. Would you be willing to use a prosthesis like the prototype?

    Yes - No

12. How does the heel strike feel?

    Too Hard - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Too Soft

13. How does the toe-off feel?

    Too Hard - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Too Soft

14. How does the Roll-Over feel?

    Too quick - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Too Slow

15. How does the Roll-Over feel?

    Abrupt - 10 9 8 7 6 - Just Right - 4 3 2 1 0 - Slow

16. Could you walk at a normal, comfortable pace with the prototype?

    Yes - No

17. Could you change your pace as needed?

    Yes - No

18. Could you walk slowly?

    Yes – No

19. COMMENTS

    The heel needs more rebound to propel me forward. The heel felt too stiff, and did not spring forward. Foot should be tested with a shoe because that will change the feel of it. Overall the foot felt comfortable, I didn't notice the weight. I've only worn three feet in my life (Amputee had only been an amputee for approximately 17 months, but was very active and had recently participated in a 5K race) – the initial prosthetic foot after surgery, my College Park Foot, and this prototype. The split toe felt stable especially side to side, gave good balance.

Appendix IV: ISO 10328:2006 Summary

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization (ISO, 2006a).

ISO 10328 is the result of international concern over the need to produce safe prosthetic devices (ISO, 2006a). Static tests are designed to replicate worst load generated in any activity, while cyclic loads relate to normal walking activities (ISO, 2006a). These tests are not designed to predict service life, and controlled field trials should be used in additional to these laboratory tests (ISO, 2006a). ISO 10328:2006 describes the procedures for static and cyclic strength tests on lower-limb prosthetic components (ISO, 2006a). These tests include: principal static and cyclic tests, separate static test in torsion, separate static and cyclic tests on ankle-foot devices and foot units for all ankle-foot devices, separate static ultimate strength test in maximum knee flexion on knee joints and associated parts, and separate static and cyclic tests on knee locks for all mechanisms (ISO, 2006a).

For the purposes of this research ISO 10328:2006 was used to govern static tests on the Prototype Prosthetic Foot. The following summarizes the test procedure. Table 11 in ISO 10328:2006 on page 19 shows all test loads for ankle-foot devices. For this research P4 load levels were used. Angles shown in are govern in Table 10 in ISO 10328:2006 on page 18.

1. Test fixture is used to hold the ankle-foot device rigidly to allow proper application of the load was used. β was held at 20° and α was held at 15° as specified in Table 10 on page 18 of ISO 10328:2006.
2. Proof and ultimate loads were applied to the toe and heel separately at a rate of 100 to 250 N/s to the test force.
3. Proof test force of 2065 N is applied to the toe and heel separately.

4. Ultimate test force of 3098 N is applied to the toe and heel separately (this is for Ultimate Lower levels).
5. After loading parts were moved and inspected for damage.

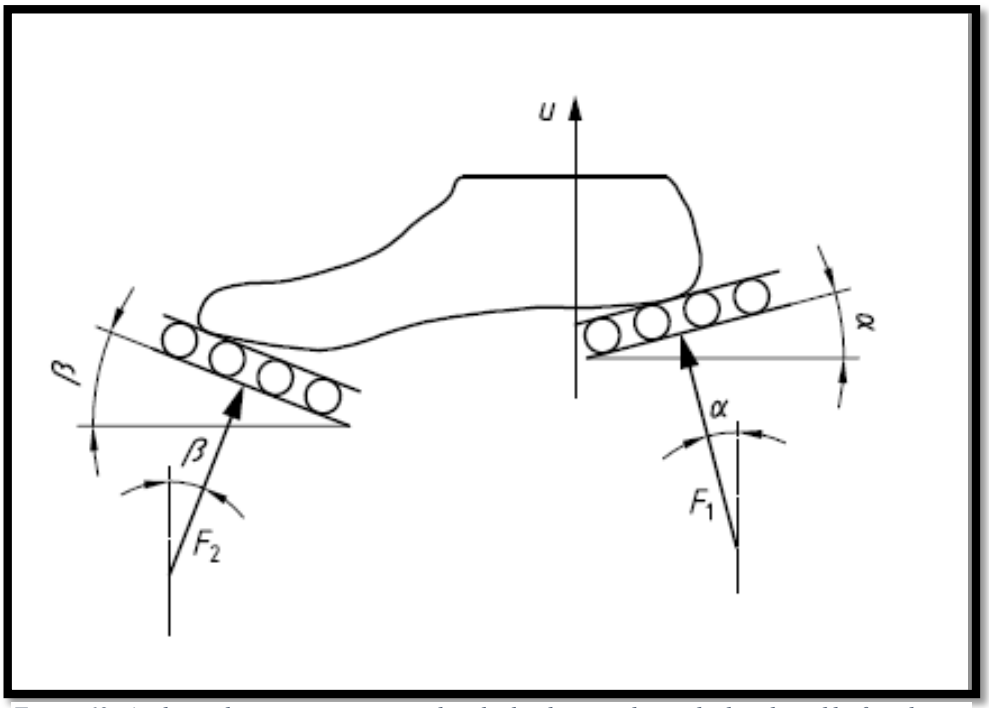

Figure 60: Angles and orientation static and cyclic loads are to be applied to the ankle-foot device according to ISO 10328:2006. Angles are governs per Table 10 in ISO 10328:2006 on page 18. Loads are governed per Table 11 in ISO 10328:2006 on page 19. Picture from ISO 10328:2006 page 30.

Appendix V: ISO 22675:2006 Summary

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization (ISO, 2006b).

ISO 22675 governs structural tests on ankle-foot devices. This is an alternative test standard to ISO 10328:2006. ISO 22675 seeks to improve upon ISO 10328 weaknesses such as "a) the inconsistency of the lines of application of the heel and forefoot test forces with those of the test forces of test loading conditions I and II for the principal structural tests specified in 16.2 (static tests) and 16.3 (cyclic test) of ISO 10328:2006; b) the unrealistic course and magnitude of loading in the phase between the instants of maximum heel and forefoot loading during the cyclic test; c) the effect of periodical "stepping in a hollow" during the cyclic test, resulting from simultaneous heel and forefoot loading at different angles" (ISO, 2006b).

For purposed of this research, ISO 22675 was used to govern the fatigue testing. The following summarizes the test procedures:

1. The foot is installed into the test fixture and fixture is set up per Figure 61.
2. Point "TA" from Figure 61 is the plate pivot point. Plate simulates the ground with respect to the foot during walking.
3. Plate rocks back to -20° to simulate heel strike and the foot is forced down at 100 to 250 N/s until the specified load requirement is met. For the purposes of this testing P4 loading was used. Maximum heel strike force is 1173 N (points 'b-c' in Figure 62) (Forces per Table 9 in ISO 22675:2006).

4. Plate rocks forward to +40° to simulate toe-off. The force maintained on the prosthetic foot follows the profile shown in Figure 62. Center force (points ‘d-e’ in Figure 62, when the plate is flat at 0°) is 850 N. Maximum toe-off force (points ‘f-g’ in Figure 62) is 1158 N (Forces per Table 9 in ISO 22675:2006).
5. The typical loading cycle from heel strike to heel strike is one second.
6. After concluding test a final static test force of 2053 N and 2026 N is applied to the heel and toe, respectively.
7. Full number of prescribed fatigue cycles is 2,000,000 (per Table 9 in ISO 22675:2006).

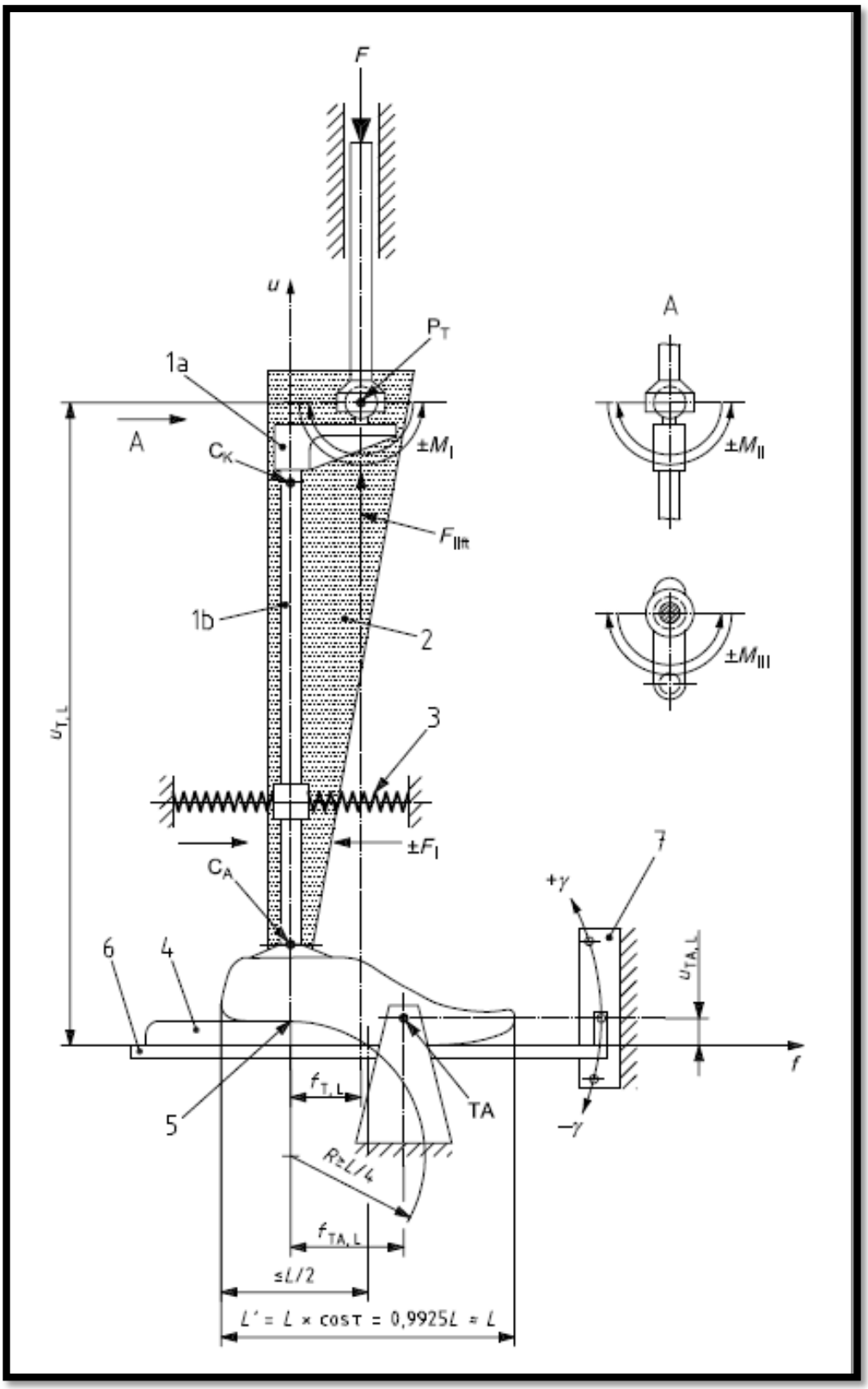

Figure 61: Fixture Dimensions for fatigue testing. Dimensions set per Table 7 in ISO 22675:2006 page 12. Image taken from ISO 22675:2006 page 34.

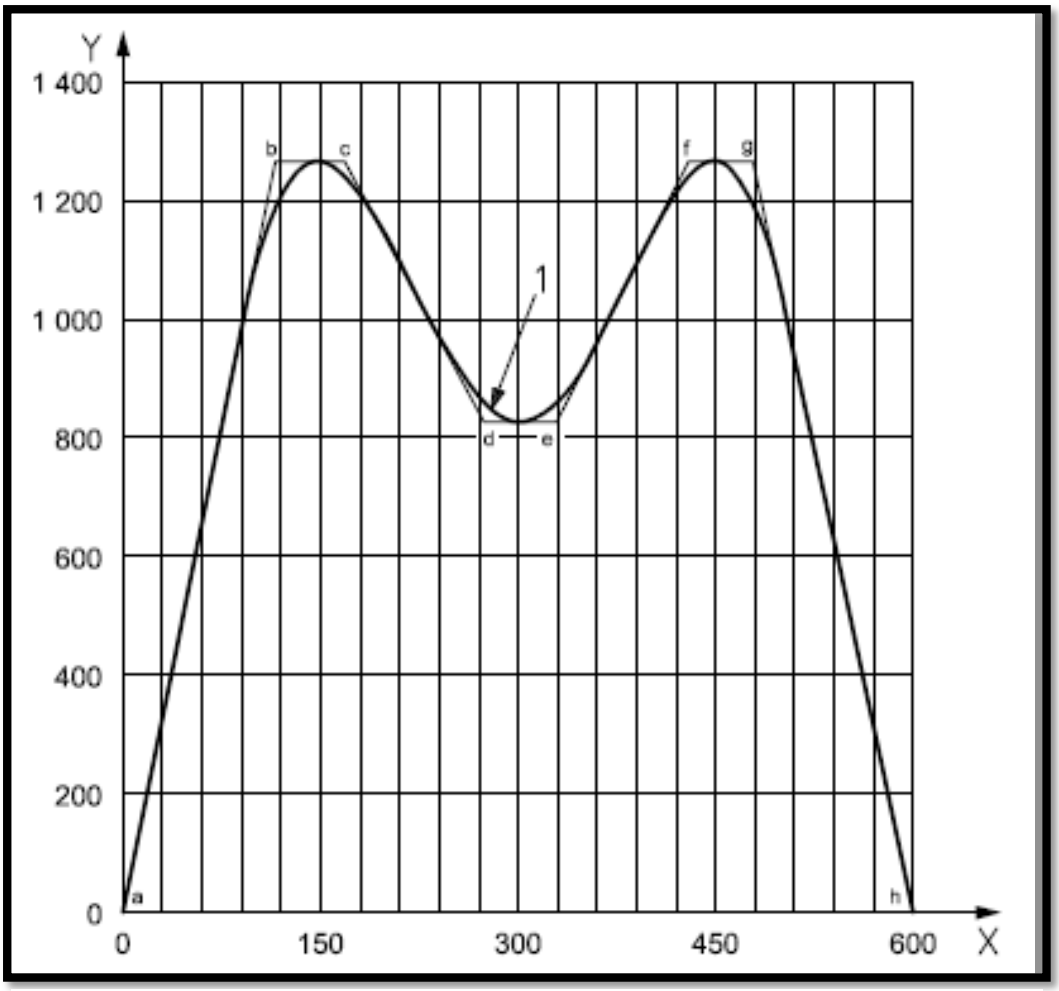

Figure 62: Force profile for fatigue testing. X-Axis is time in millisecond. Y-Axis is force in Newtons. Graph taken from ISO 22675:2006.

Vita

Joshua Scott Bowen was born April 13, 1983 in Loma Linda, California to Dr. Aaron R. Bowen and Ruth E. Bowen. He graduated from Champion Christian School in Chico, California in June of 2002. Joshua attended Letourneau University and received a Bachelor of Science in Engineering degree in Engineering Concentration Mechanical in May 2007. He worked at QED/Inc. (Santa Ana, California) from September 2007 to December 2011.

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