THE DESIGN AND CONCEPT VERIFICATION OF A CLINICIAN-ADJUSTABLE, IN-SHOE ORTHOTIC TO TREAT DIFFERENT STAGES OF HALLUX RIGIDUS

AN ABSTRACT

SUBMITTED ON THE FIRST DAY OF MAY 2015

TO THE DEPARTMENT OF BIOMEDICAL ENGINEERING

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

OF THE SCHOOL OF SCIENCE AND ENGINEERING

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FOR THE DEGREE OF

MASTER OF SCIENCE IN BIOMEDICAL ENGINEERING

BY

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ABSTRACT

Hallux rigidus (HR) is a progressive and degenerative condition of the first metatarsophalangeal (MTP) joint that is categorized into five stages depending on pain and the range of motion of the joint. It is one of the most prevalent great toe conditions experienced by patients over the age of fifty. Effective treatment can manage discomfort and potentially slow the joint degeneration; however, there is no treatment method on the market that can selectively limit the degrees of dorsiflexion and subsequent pain of the different HR stages. This project highlights the current treatments for HR and their shortcomings while also proposing a better solution. An in-shoe orthotic composed of a base and an easily detachable variable stiffness spring insert is suggested to allow rapid targeting of the specific HR stage. By varying the thickness of the spring steel insert, the orthotic allows the clinician to choose a specific maximum degree of dorsiflexion for the patient's joint based on their diagnosed stage of HR, weight, and activity level. Prototypes were created and tested to establish a user-friendly, clinical chart that allows clinicians to input their patient's weight and stage of HR to determine the appropriate insert for treatment. Finite element analysis and physical testing were done, and the data was used to create the first iteration of the clinical chart. Further work is needed to improve the precision and accuracy of the chart, but the concept of creating variable resistance to movement using an interchangeable, clinician-adjustable orthotic has been proven and is a very promising concept for the future of HR treatment.

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CHAPTER 1: **INTRODUCTION**

1.1 Hallux Rigidus Condition

Hallux rigidus (HR) is the painful limitation of dorsiflexion of the first metatarsophalangeal (MTP) joint. (McMaster 82-87) It is the most common great toe condition behind hallux valgus for patients above fifty years of age, and it occurs in one out of forty people in this age group (Nuñez). Symptoms such as mild to moderate pain usually start to appear between the ages of thirty and sixty. (American Academy of Orthopedic Surgeons)

A typical range of maximum dorsiflexion angle in the healthy first MTP joint varies in the literature. Muscarella et al suggest 55°-65° (Muscarella and Hetherington 313-325) while Botek and Anderson found 65°-75°. (Botek and Anderson 239-243) Maximum movement within the range of 55°-75° will be considered normal if it does not greatly deviate from the opposite foot. Hallux limitus (HL) is the term for the early stages of hallux rigidus. An MTP joint diagnosed with hallux limitus only has 25°-30° of maximum dorsiflexion. This includes the first two stages of HR. As the condition progresses, the maximum angle can be reduced to 10° or no movement in dorsiflexion. (Muscarella and Hetherington 313-325) Symptoms include often progressive ostophytes around the MTP joint, compensatory supination of the foot during gait, and increased pain in the joint during prolonged or strenuous exercise. It is beneficial to be aware of the signs early and begin treating to minimize trauma to the injury, slow the degeneration of the bone and soft tissue, and manage pain. (American Academy of Orthopedic Surgeons)

The etiology of HL and HR is complicated, but potential causes include an elongated metatarsal, osteochondritis dissecans, immobilization, osteoarthritis, acute injury, gout, and rheumatoid arthritis. Excessive range of motion or instability of the big toe can also lead to hallux limitus. Injury to the osteochondrial area produces osteophytes, which prevent the toe from achieving the full range of motion. (Muscarella and Hetherington 313-325; McMaster 82-87) In accordance to Wolff's law, when pressure is increased on an area of bone more osseous tissue is produced as an adaptive mechanism. In each of the conditions mentioned above, there is a change in typical loading of the MTP joint. This aligns the metatarsal head incorrectly, which produces the new pressure that activates the osteoblasts to reinforce the area and create osteophytes. (Shier, Butler, and Lewis)

1.2 Current Treatment

There are many techniques that are currently being used to treat hallux rigidus. These include a variety of surgical and non-surgical methods. The non-surgical techniques avoid higher cost and loss of time due to rehabilitation as a result of the surgical options. In certain cases they can effectively decrease pain and make it possible for the patient to participate in more activities.

Non-surgical procedures aim to reduce inflammation and pain by providing support and limiting movement in the joint. Applying ice to the area and taking anti-inflammatory medications help to minimize the pain and swelling associated with the soft tissue in and around the MTP joint. This reduces the effects of trauma on the joint and may slow the progression of hallux limitus before developing into hallux rigidus. Contrast baths work similarly, alternating soaking the foot in hot and cold water. Many different protocols have been used but the optimal timing intervals seem to be six minutes in hot water and four minutes in cold water or four minutes to one minute respectively. The temperature ranges from106-113°F for hot and 47-60°F for cold. (Breger Stanton, Lazaro, and Macdermid 57-69) The dominant treatment doctors can provide is typically footwear alterations. Shoes with more toe space reduce the pressure on the metatarsal head area, and rigid soles prevent excessive dorsiflexion. Some doctors also recommend a rocker sole on the bottom of the shoe so a patient can still have the typical heel to toe progression, or foot roll, during walking but the foot itself would not have to bend. (American Academy of Orthopedic Surgeons) A popular style of insert is called a Morton's extension that has a rigid material under the hallux that serves as a splint and prevents movement of the MTP joint. Having a hard material directly under the joint can increase the plantar pressure and reduces the shock absorption under the already painful joint. Morton's extensions can also be difficult to fit in shoes (Rosenbloom) because of the rigidity of the entire insert. Other orthotics are available, but these modalities can be uncomfortable or alter the patient's gait. Another concern is that the treatment is not specific to each stage of hallux rigidus resulting in the same amount of dorsiflexion limitation for the early and late stages of HR. The orthotics for hallux limitus vary in construction and function from hallux rigidus, but there is currently no commercially available orthotic on the market that can be adjusted as the condition progresses from early to late stages. (Rosenbloom)

There are also a variety of surgical options to treat hallux rigidus. Since many times hallux rigidus is accompanied by unnatural bone growth or bone spurs in the MTP joint area, a cheilectomy is often recommended by the physician. A cheilectomy is a surgery that removes osteophytes from the metatarsal head and the base of the hallux.

These osteophytes constrain joint space and limit movement--particularly dorsiflexion. This procedure is preferred because it maintains the joint without sacrificing length of bone. (Muscarella and Hetherington 313-325; Nawoczenski ; Harisboure et al.) An osteotomy is a procedure that changes the alignment of a joint by cutting a bone. Since hallux rigidus can sometimes be caused by an abnormally long hallux, this can be effective. (Muscarella and Hetherington 313-325) Arthroplasty is the replacement or remodeling of joint surfaces often with silicone or metal. However, this procedure, if not done well, can also result in unstable joints and deformity. (Taranow, Moutsatson, and Cooper 713-28, ix-x) Arthrodesis is the only surgical treatment that does not aim to increase joint mobility. (Nawoczenski ; Harisboure et al.) Specific to HR, this procedure that fuses the first metatarsal bone to the proximal phalange, effectively removing the joint. It has a similar effect on the joint as Morton's extension, but this procedure is permanent. Arthrodesis completely eliminates motion but is effective at pain management. Unfortunately, the lack of motion may be compensated for at the more proximal joint between the cuneiform and metatarsal and cause degeneration there. (Muscarella and Hetherington 313-325) These issues highlight the need for a more effective way to treat hallux rigidus.

1.3 Project description

The objective of this project was to create a prototype and concept verification of a customizable foot orthotic that allows clinician-selected limits for range of motion in the first MTP joint to provide a better nonsurgical treatment of different HR stages. The new foot orthotic better treats the condition of hallux rigidus by taking into consideration the anatomy of the foot and the progressive nature of the condition. It allows physicians to modify the orthotic's resistance to movement during a clinic visit. The adjustable nature of the orthotic provided the progressive adaption of the device to reduce the impact on the MTP joint by limiting dorsiflexion at particular stages of HR. The design is customized to the patient's foot with an interchangeable spring system (Nuñez) that allows for physician adjustment as the condition progresses or potentially when participating in sports or other vigorous activities that require more support. The removable portion is easy to take out and replace with a firmer or more pliable spring selection. The design allows it to fit in most standard shoes and be easily cleaned. Semisoft and rigid foams coupled with more rigid plastics including polyethylene, polypropylene, and polycarbonate (Nuñez) have already been tested and have proven to be inadequate at reducing bending at thicknesses that would be usable inside the shoe. Stronger materials including stainless steel and spring steel were tested in this study and quantified through finite element models, three-point bending tests, and beam-with-overhang tests. Results from this study were used to create a clinician-usable table to estimate the amount of dorsiflexion allowed for patients of certain weight. Although not clinically tested, the new design shows evidence of the ability to selectively limit dorsiflexion, which could minimize pain, prevent significant alteration in normal gait, and reduce plantar pressure under the first MTP joint. In future development of the device, multiple sizes would need to be created along with a left foot orthotic. The design needs to be modified to be easily manufactured by orthotists, and clinical trials need to be done to collect plantar pressures and measured dorsiflexion angles while in use in a shoe.

1.4 Assumptions and Limitations

The loading pattern on an in-shoe orthotic during gait is complicated. There are forces coming from body weight, ground reaction forces from the floor, and forces from the shoe sole keeping it in contact with the plantar surface of the foot. A perfect modeling of this situation is not possible with the testing system available, but simplified bending tests have been done to approximate the forces felt when the orthotic experiences a certain load. A finite element model and physical test apparatus were modeled after a beam-with-overhang testing setup, and a physical three-point bending test was done to measure the forces to bend the device. The three-point bending test only has three discreet line loads on the orthotic. This is very different than the distributed loads it would feel inside a shoe. The beam-with-overhang set up has constant force holding the proximal half of the orthotic, but again there are only two distinct line loads on the rest of the test. This is partially compensated for by adding a shoe sole in series with the orthotic during testing. Clinical trials must be done next to better approximate the effect of loading on the orthotics while in a use in a shoe.

This test also was limited by only using one size orthotic and only for the right foot. It is assumed that a left side orthotic should behave similarly. Additionally, it is assumed that scaling up or down the height and overall width of the device will not change its properties as long as there is still the same width and thickness of material in place. Future prototype development would have to be done to test this hypothesis.

1.5 Operational Definitions:

Arthrodesis: surgical ossification of a joint, completely eliminating range of motion

Arthroplasty: joint replacement

Cheilectomy: a surgical removal of bone spurs from a joint

Dorsiflexion: the movement that decreases the angle between the foot or toe and the dorsal surface of the foot or lower leg

First metatarsal phalengeal (MTP) joint: the joint in the hallux where the first metatarsal articulates with the first proximal phalange. It is sometimes referred to as MPJ.

Hallux limitus: decreased range of dorsiflexion of the big toe. There is a 25-35° loss in range of motion of the hallux (Muscarella and Hetherington 313-325), and it can be classified as stage two hallux rigidus. (Harris, Smith, and Marks)

Hallux Rigidus: progression of hallux limitus that can be classified into five stages and the range of motion can be limited to 0°-10°. (Harris, Smith, and Marks) It can also be divided into four stages. (Muscarella and Hetherington 313-325)

Hallux valgus: also known as bunions is a deviation of the hallux laterally (valgus) and the first metatarsal medially (varus). This creates the bump, or the bunion, that is seen on the medial aspect of the first MTP joint. This protrusion is initially caused by inflamed tissue but continued pressure on the area can cause the bone to thicken producing osteophytes. It is usually caused by wearing narrow shoes. (Orthogate)

Osteoarthritis: commonly referred to as wear-and-tear arthritis, it occurs when the cartilage at the end of bone begins to break down over time. (Mayo Clinic)

Osteochondritis dissecans: a joint condition where a piece of cartilage and some of the connected bone are detached. This usually happens after a joint injury. (Mayo Clinic)

Osteophytes: bone spurs

Plantar flexion: the movement that decreases the angle of the toe and the plantar surface of the foot or the foot and the ventral surface of the lower leg

Plantar Pressure: the force per unit area on a given portion of the plantar surface of the foot. It is usually measured in KPa.

Pronation: the rolling inward of the foot during gait; weight is concentrated on the medial aspect of the sole of the foot.

Range of Motion: the amount of movement allowed at a joint

Rheumatoid Arthritis: an autoimmune disease that affects the lining of the joints. It normally attacks the small joints of the hands and feet, and the inflammation can lead to bone erosion and joint deformity. (Mayo Clinic)

Supination: the outward rolling of the foot during gait; weight is concentrated on the lateral aspect of the sole of the foot.

CHAPTER 2: **REVIEW OF LITERATURE**

2.1 Anatomy of the Foot

In the foot, there are typically 26 bones, 33 joints, 107 ligaments, and 19 muscles and tendons. The bones include the calcaneus, talus, cubiod, navicular, three cuneiforms (the lateral, intermediate, and medial), five metatarsals, five proximal phalanges, four middle phalanges, and five distal phalanges as seen in Figure 1.

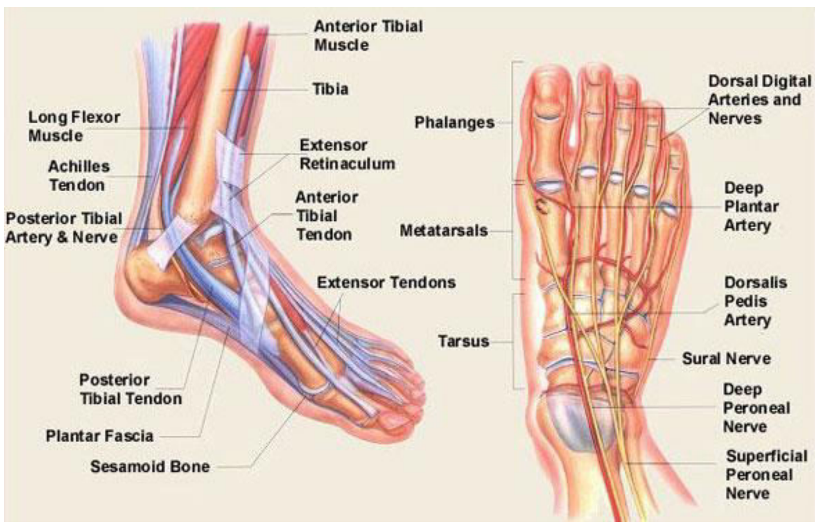

Figure 10: ***Anatomy of the Foot*** **(Ryan Foot & Ankle Clinic)**

The first metatarsophalangeal (MTP) joint is the intersection of the first metatarsal head and the base of the first proximal phalanx. The typical range of motion of dorsiflexion in a healthy joint ranges from 55°-75°.(Botek and Anderson 239-243; Muscarella and Hetherington 313-325) The most common pathology of the joint in the aging population is hallux valgus followed by hallux rigidus. Some other pathologies seen in the foot can cause problems as well including obesity, diabetic foot, gout, unstable ankle joints, and arthritis. Many patients see these issues as comorbidities with the more common hallux valgus or rigidus.

2.2 Gait Cycle

Walking is a very repetitive process that takes the body, specifically the legs, through a repetitive series of similar movements. Each iteration of this motion is considered one gait cycle. When looking at one complete stride or gait cycle, it starts with the initial contact of the heel and ends right before the heel strikes again (Figure 2). This takes approximately one second and is broken down into the stance and the swing phase, where 60% of the time is spent in the stance phase and 40% in the swing phase. The stance phase is when the foot is in contact with the ground, and the swing phase is defined as the period when the foot is in the air transitioning to heel strike and the next stance phase. (Villaroya, Casajus, and Perez 283-295; Perttunen) The toe-off position, or terminal stance to preswing period in Figure 2 is of particular importance to patients with metatarsal head pain because all of the ground reaction force is localized under the joint. This pain is often the result of osteophytes, arthritis, or other joint limiting conditions that do not allow the first metatarsal head to articulate properly with the phalange.

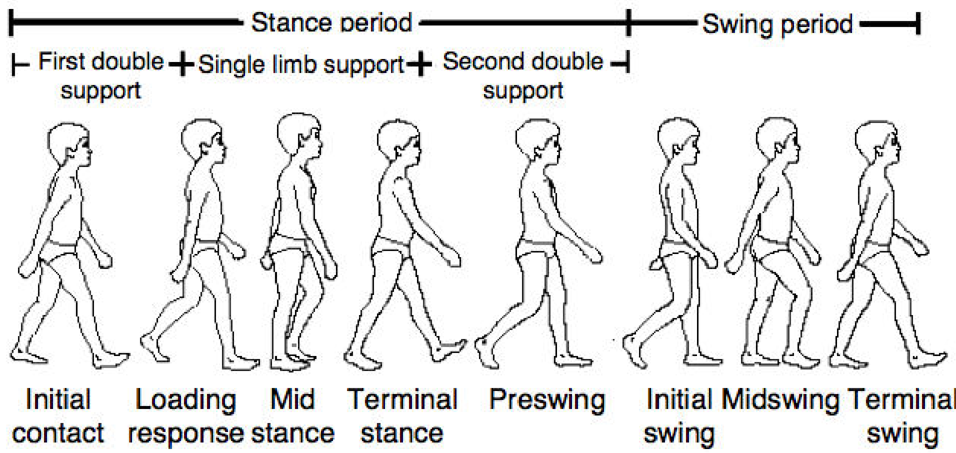

Figure 11: *Stages of the Gait Cycle* (Pataky et al. 790-800)

2.3 Plantar Pressures

Throughout the gait cycle the loading on different parts of the foot changes. This creates dynamic pressures on the planter surface. The bottom of the foot can be broken down into different regions that vary their roles in the different stages of the gait cycle. These regions are the hallux or first ray, second through fifth rays, first metatarsal head, second and third metatarsal heads, fourth and fifth metatarsal heads, midfoot, and rearfoot or heel (Figure 3). (Tsung et al. 767-774)

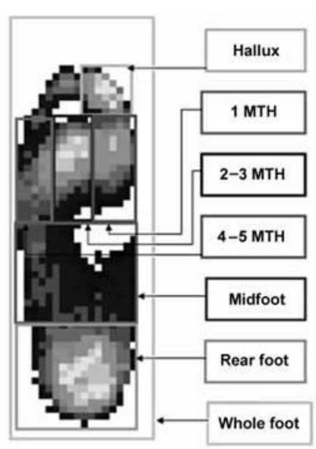

Figure 12: *Divisions of Plantar Areas*(Tsung et al. 767-774)

During standing, walking, and other dynamic activities the pressures on the bottom of the foot are changing as the plantar surface supports asymmetrical loads. During the gait cycle, weight is shifted from the heel to the lateral midfoot to the medial metatarsal heads and eventually the hallux at toe-off. Maximum pressures change and follow the center of pressure under the foot. Plantar pressures are a vital biomechanical marker for understanding human walking. (Villaroya, Casajus, and Perez 283-295) Average walking velocities for men and women are 1.24 m/s with a standard deviation of 0.155 and 0.144 respectively. (Bradley and Sabatier EL210-5) Mobility problems commonly seen in older adults can significantly slow these rates. The plantar surface of the foot experiences loads that exceed body weight while walking at a comfortable speed, and these loads increase with gait speed. (Villaroya, Casajus, and Perez 283-295) Walking at a comfortable speed shows forces around 130% of body weight while running can show forces over two times body weight. (Tongen and Wunderlich) Pathological feet have been found to differ in plantar pressures and loading patterns in comparison to healthy ones, and studies are suggesting that these differences can be used to more accurately diagnose specific conditions. (Nawata et al. 298-301), (Rai and Aggarwal 25-34) Obesity, diabetes, unstable ankle joints, age-related musculoskeletal conditions, and gender-specific conditions have all been shown to alter these pressures. (Hills et al. 1674-1679; Chung and Wang 194-200; Nawata et al. 298-301) Hills et al (2001) found that the foot width of obese patients of both genders was significantly greater. They also found that the plantar pressures increased significantly in these patients in the heel, midfoot, and forefoot of both genders while standing and in most of the same areas while walking. (Figure 4) (Hills et al. 1674-1679)

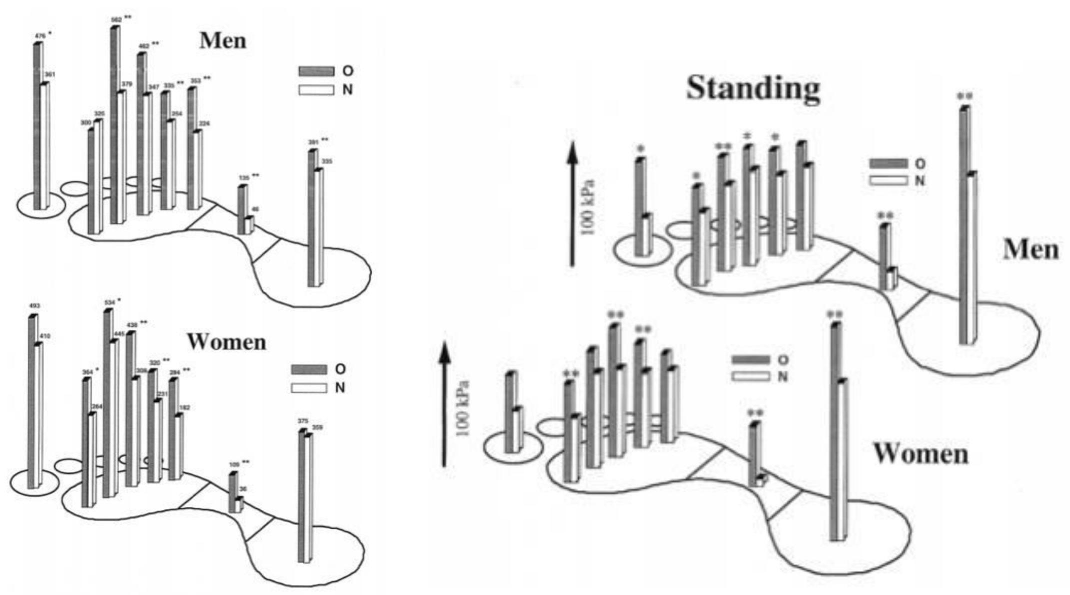

Figure 13: ***Plantar pressures during walking and standing for obese (O) and normal (N) patients. Measured in kPa*** **(Hills et al. 1674-1679)**

Nawata et al (2005) investigated the differences in loading over the course of a step of normal patients and patients with ankle instability. This was measured using a pressure measuring system and calculating the pronation-supination index, which was calculated by dividing the length between the medial footprint border and the center of pressure. They found that the group with instability had a significantly smaller foot angle at 7.9° rather than the 11.8° of normal patient. Also notice the loading of the foot in Figure 5. The center of pressure in normal feet follows the direction of the foot angle, while the center of pressure in patients with functional instability does not. (Nawata et al. 298-301) It is important to consider how changing the loading of plantar surfaces in subjects with atypical gait would affect treatment options. By studying the changes in plantar pressures during gait in healthy and pathogenic populations, diagnosis and treatment of the condition can lead to improved orthotics and surgical interventions.

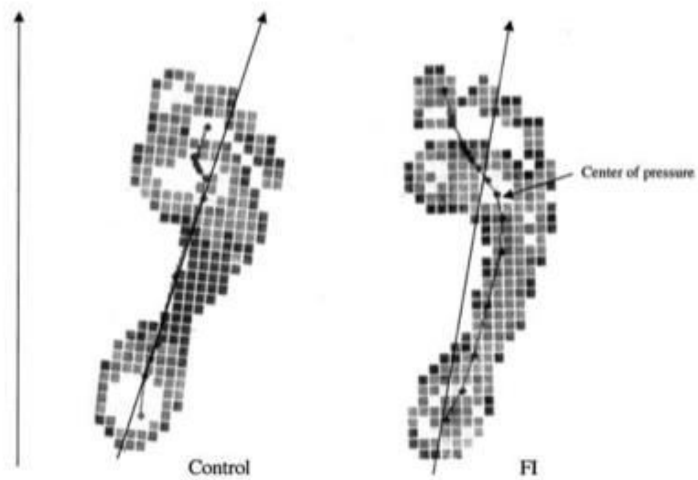

Figure 14: ***The center of pressure of the plantar sole is followed over the course of a step.*** **(Nawata et al. 298-301)**

When considering peak plantar pressures, the maximums in each area should be considered as well as the maximum over the entire foot. Yuk San Tsung et al. measured the peak pressures under six areas of the foot including the hallux, first metatarsal head, second and third metatarsal heads, forth and fifth metatarsal heads, midfoot, and rear foot over a step of eight subjects ages 37 to 74. They found that the largest maximum pressure occurred in the hallux region (36.4 psi) followed by the heel (34.8 psi) and the second and third metatarsals (30.6 psi). The smallest peak pressure was found in the midfoot (16.8 psi). (Tsung et al. 767-774) Chung and Wang also did a similar study but divided their subjects into male and female groups ranging from 20 to 60 years old. There were fifteen in each gender. This study also found that the midfoot had the lowest peak pressure (11.3 psi in males, 11.5 psi in females), but the maximum was found under the second and third metatarsal heads in males (47.1 psi) and under the heel in females (39.0 psi). In males the three areas with the highest peak pressures were still the hallux (21.7 psi), 2nd and 3rd metatarsal heads (47.1 psi), and heel (39.8 psi), but the hallux had a peak pressure of over 21.8 psi less than the 2nd and 3rd metatarsals. (Chung and Wang 194-200) These differences could result from different testing apparatuses or the decision to break it down by gender. It also could suggest a slight shift in the toe off region between sample groups. As seen in Figure 5 the center of pressure finishes through the hallux in the injured subjects and more under the second and third phalanges in the healthy subjects. (Nawata et al. 298-301) This could indicate a tendency for more stress to be experience in the hallux of some types of pathological feet. Chung and Wang's data is probably more accurate because it is more specific by subject group and more subjects were tested. However, we should also consider the data collection frequency differences. Chung and Wang's data was collected at 500 Hz while Tsung's was collected at 50 Hz. The increased frequency could make the data more accurate, but it could also pick up on any noise. In the other study, there might be too few data points at 50 Hz. Considering that the gait cycle takes approximately one second that only collects about twenty-five data points on each foot.

Chung and Wang's data shows that gender plays a role in plantar pressures. Male and female feet are not only different sizes but also different shapes. Females usually have a smaller instep circumference, or the measurement around the foot at the instep, and a higher arch and shorter arch length in all three plantar arches including: the medial, lateral, and transverse arches. Their arches also tend to be less stiff and the ligaments are more lax. These differences account for some of the differing locations of peak pressures.

Males also generally have a greater body weight, which could account for the higher absolute pressures values. Their center of gravity is also higher changing the loading of the foot at different times in the gait cycle. (Chung and Wang 194-200)

Another variable in plantar pressures is age. Bosch et al. investigated these changes by looking at four different age groups: toddlers—around one year old, seven-year-olds, adults—around thirty, and seniors—around seventy years old. There were twenty-six subjects in each of these four groups and each participant had normal gait. The information gathered was arch index, peak pressure, contact time in % of stance phase, contact time in ms, and maximum force in % body weight. These were measured on the total foot, heel, midfoot forefoot, hallux, and the other four toes. The 7-year-olds walked with the highest peak force on their foot with 128.45% of their body weight; the seniors had the highest plantar pressures on every area of the foot except the heel; and the contact area of the midfoot of toddlers is significantly larger than the other groups. Since forces on the feet increase with gait speed, it is reasonable to assume that higher energy 7-year-olds would produce higher forces. Also, throughout life the fat pads on feet move and change as gait begins to alter the locations of peak pressure and the time spent on different areas of the foot. The fat pad begins in the midfoot of infants and travels to the heel and forefoot in the first year of walking. This migration encourages the understood biomechanics of walking, which begins with heel strike, by moving the padding under calcanius—the first point of contact in the cycle. In the later part of life the elastic tissues and fat pads start to deteriorate, accounting for the higher plantar pressures of the older adults. Almost every factor had significant differences in measurements, but this study will focus on the two older groups, adults and seniors, because they better model the targeted demographic of common hallux rigidus patients. As seen in Figure 6, the forefoot and the hallux have the highest plantar pressure values for the two oldest age groups (79.5 psi and 61.9 psi for the adults and 100.1 psi and 68.2 psi for the seniors respectively). Another important value is the maximum force. Both groups have a maximum force of over 100% their body weight with the adults averaging 108.79% on the entire foot and the seniors averaging 110.03%. The average weight of the adults was 153.2 lb and the seniors were 160.9 lb. (Bosch et al.)

	Toddlers		7-Year olds		Adults		Seniors		*P*
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Arch index	0.36	0.02	0.18	0.07	0.19	0.05	0.21	0.06	<0.001
Contact area in % of total contact area									
Total foot	100.01	0.33	99.99	0.04	99.96	0.06	99.93	0.10	n.s.
Hindfoot	23.33	3.73	27.72	3.19	26.99	1.82	26.44	2.63	<0.001
Midfoot	29.49	1.98	15.21	6.48	15.59	4.76	17.60	5.33	<0.001
Forefoot	32.84	3.93	40.49	3.12	39.18	2.51	39.19	2.26	<0.001
Hallux	7.94	1.24	9.35	1.38	9.23	1.33	8.27	1.23	<0.001
Toes 2–5	6.41	2.86	7.22	2.40	8.97	2.61	8.43	1.56	<0.001
Peak pressure in kPa									
Total foot	145.09	33.80	402.12	117.53	611.06	226.20	800.42	217.10	<0.001
Hindfoot	108.60	31.49	383.50	115.64	352.63	57.12	375.46	110.11	<0.001
Midfoot	72.69	12.69	82.81	27.02	89.04	27.77	125.12	39.47	<0.001
Forefoot	76.35	16.06	256.15	86.14	548.14	234.37	690.31	251.83	<0.001
Hallux	129.13	42.08	272.92	84.53	426.77	183.90	470.19	283.52	<0.001
Toes 2–5	42.92	19.90	143.50	62.84	203.96	98.89	239.92	94.66	<0.001
Contact time in % of stance phase									
Total foot	100.00	0.00	100.00	0.00	100.00	0.00	100.00	0.00	n.s.
Hindfoot	65.98	9.92	52.03	8.26	54.55	7.66	54.84	8.61	<0.001
Midfoot	78.10	6.57	53.07	10.25	58.21	8.85	62.04	9.04	<0.001
Forefoot	89.99	4.01	84.06	3.59	85.70	2.24	87.80	2.15	<0.001
Hallux	61.97	18.07	56.59	10.09	74.10	8.17	65.89	14.30	<0.001
Toes 2–5	55.06	24.25	51.67	10.75	70.68	11.47	69.54	10.95	<0.001
Contact time in (ms)									
Total foot	541.69	117.14	554.38	67.25	696.38	75.13	721.15	78.28	<0.001
Hindfoot	363.65	102.08	291.69	72.88	380.42	69.02	398.31	87.11	<0.001
Midfoot	427.04	110.38	298.15	81.05	405.50	78.13	450.38	93.94	<0.001
Forefoot	487.00	105.31	466.23	62.57	596.19	64.08	633.38	72.98	<0.001
Hallux	329.96	108.24	312.62	63.71	515.00	72.42	474.31	112.27	<0.001
Toes 2–5	295.69	148.54	284.08	63.08	491.58	92.71	504.62	112.05	<0.001
Maximum force in % of body weight									
Total foot	102.54	11.71	128.45	12.93	108.79	6.97	110.03	6.47	<0.001
Hindfoot	53.15	14.89	93.61	13.59	69.40	7.30	66.48	10.23	<0.001
Midfoot	43.06	8.51	16.13	11.16	10.20	5.91	16.17	9.27	<0.001
Forefoot	49.85	11.20	91.85	10.09	86.61	9.19	87.42	8.09	<0.001
Hallux	16.93	7.00	29.09	8.54	20.07	5.82	17.88	6.57	<0.001
Toes 2–5	6.27	4.20	11.72	7.59	8.40	4.10	8.04	2.94	0.002
n	26		26		26		26		

Figure 15*: Comparing values over different age groups* (Bosch et al.)

Rai and Aggarwal studied the time during the gait cycle that the different areas of the foot felt the maximum pressure. To begin the stride the subjects contacted the ground with the posterolateral part of the heel, and the stance phase ends with a "toe off" mainly from the hallux. Through the stance phase the pressure is transferred laterally to medially toward the midfoot and posteriorly to anteriorly in a diagonal across the foot toward the hallux (Figure 7). When the heel midfoot and forefoot were all in contact with the ground, the maximum peak pressure occurred at about 18-36% of the way through the stance phase. The heel was in contact with the ground for approximately 59% of this phase. The forefoot saw its maximum pressure around 70-82% through the stance phase while toe region didn't have a peak pressure until 80-91% through. In almost 90% of subjects, the maximum peak pressure was in the 2nd and 3rd metatarsal region. (Rai and Aggarwal 25-34) This is in agreement with the other studies previously discussed. In this study, forty percent of the subjects showed early metatarsal termination, which might suggest that toes do not play an important role in transferring load. (Rai and Aggarwal 25-34)

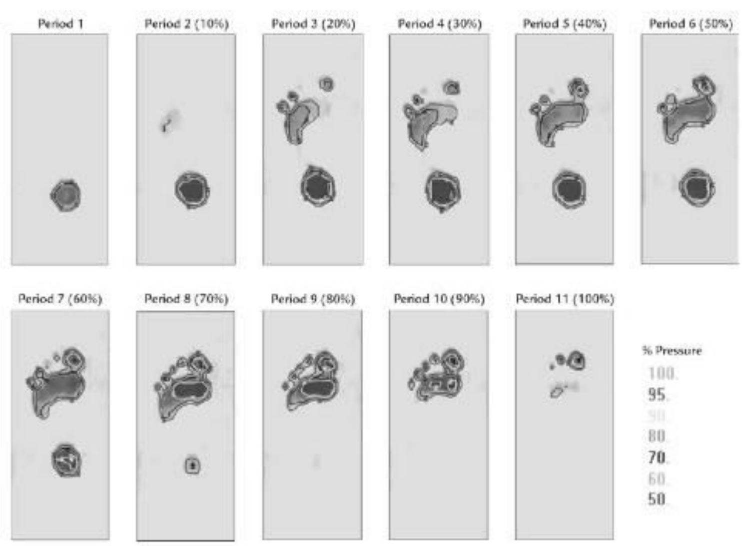

Figure 16: Plantar Pressure Locations During Gait(Rai and Aggarwal 25-34)

2.4 Techniques for Measuring Changes in the Foot

Scientists all over the world have done research on the foot to try to understand the healthy and pathological characters and risk factors. A variety of techniques have been developed to conduct their experiments.

To construct a 3-D finite element model that would be able to show the pressures throughout the foot during the different stages of gait a combination of the Contact Pressure Display (CPD) Method and the Digital Radiographic Fluoroscopy (DRF) method was used. The CPD method measures the foot to ground pressure distribution using monochromatic polarized light to produce concentric circles under each contact point and calculate the diameter based on the contact load. This is determined by a matrix of pins with spherical tips. The DRF method is a computer based X-ray tool that can record both skeletal and soft tissue movement. This was able to show the orientation of joints during gait. (Gefen et al. 630-639) Both of these techniques can be seen in Figure 8.

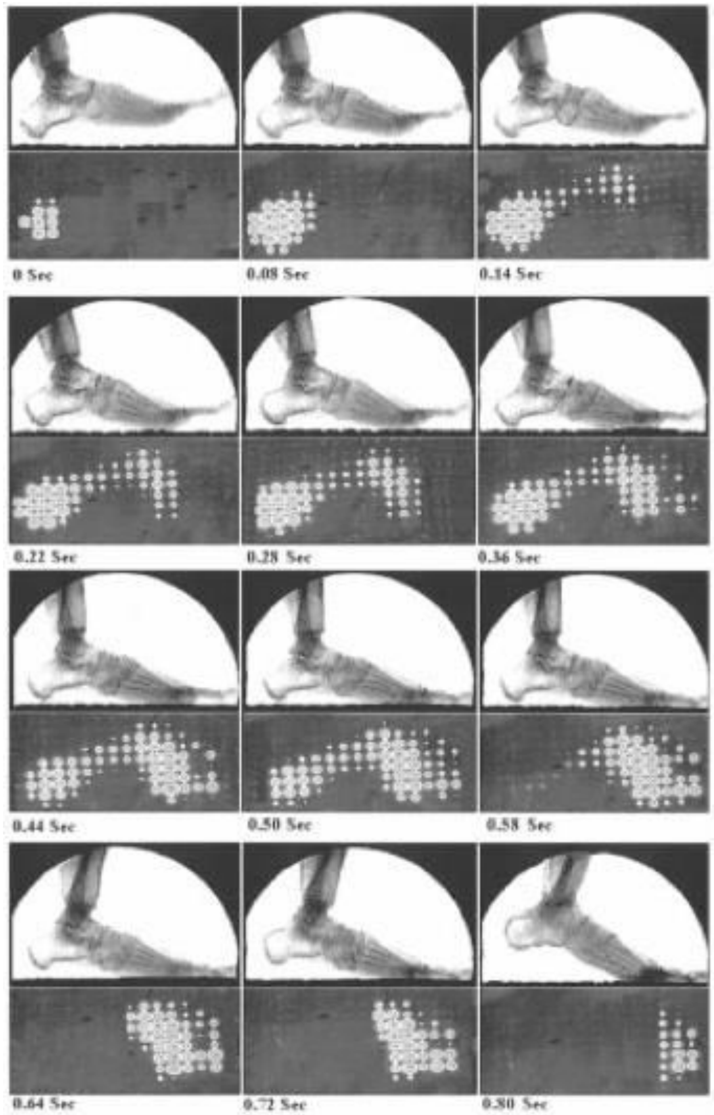

Figure 17: ***Skeletal and Soft Tissue Movement During Gait*** **(Gefen et al. 630-639)**

Rai and Aggarwal used an optical pedobarograph installed on a walkway that measured the plantar pressures of the subjects. A charge-coupled device (CCD) camera was connected to a computer that had Asha 3D software to receive and analyze the information recorded from the camera. (Rai and Aggarwal 25-34) Kellis did a study on the plantar pressure of barefoot preschool boys. She also used a walkway fitted with sensors. It was a Musgrave pressure platform system made with 2048 force sensing resistors with an active area of 390 mm x 195 mm. Data was collected at 60 Hertz. (Kellis 92-97)

Tsung et al measured plantar pressures of healthy patients and patients with diabetes mellitus using a pressure sensor built into a thin insole rather that on the walkway because they were trying to use insoles to distribute the pressure. The measuring device was 0.18mm thick and called a flexible F-Scan® insole sensing system. Previous studies suggested that they may be sensitive to temperature, certain surface conditions, and loading speed. Each subject was instructed to walk in the insoles for three minutes before measurements were taken to regulate temperature and speed. The data was recorded for 10 seconds at 50 Hertz. (Tsung et al. 767-774) Villarroya et al measured the plantar pressures of their subjects with one-millimeter thick insoles equipped with sensors as well. The system was called the xPression telemetric system and consisted of insoles with six piezoresistive sensors. One was in the heel and the other five were located under each metatarsal head. The sensors could measure up to 60,000 Pascals and recorded data at a rate of 80 Hertz. (Villaroya, Casajus, and Perez 283-295) The small number of sensors limit the areas that plantar pressure data can be collected, but could be effective in comparison tests on the specific areas available.

2.5 Hallux Rigidus

Hallux rigidus (HR) was first described by Davies-Colley in 1887 as hallux flexus. Cotteril then termed it hallux rigidus in 1888. (Harisboure et al.) HR is a condition characterized by pain and limited dorsiflexion of the metatarsophalengeal joint. The condition is typically associated with osteophytes, which create the physical impedance of the joint movement. It affects one in forty people over the age of fifty, and is the second most common great toe condition in this age group following hallux valgus. Other studies have reported the prevalence of halux rigidus in the general population ranging from 2%-20%. (Nawoczenski ; Welsh et al.) Usually symptoms appear after the age of thirty, but there have been very advanced cases in younger patients. (McMaster 82-87) The etiology is complicated and the condition has been known to be caused by many things including abnormal joint alignment, acute injury, or preexisting conditions including arthritis.

2.5.1 Degrees and Stages

HR does not appear the same in every patient, and is usually progressive, getting worse if the joint is not protected. Hallux limitus is the name for the early stages of hallux rigidus when dorsiflexion is decreased to approximately 25°-30°. This usually falls under the first couple of stages. HR has been categorized by many different investigators, and a summery of the different ways to categorize the condition can be seen in Table 1. Another common classification of the condition can be seen in Table 2. Studies have been done to find a "gold standard" for classifying HR, but they found that none exist. (Botek and Anderson 239-243) The Coughlin and Shurnas classification seems to be the most all encompassing, so it is going to be used in this projects classification. There are treatments available for all stages of the condition, but the intensity of physician intervention depends mostly on the patient and their pain tolerance.

Investigator	Stage I	Stage II	Stage III	Stage IV
Rzonca et al.[1]				
Clinical	DF = 25°-45° Reducible contractures Preschool to teens	DF+ = 5°-20° Minimally reducible contractures Teenaged to geriatric years	No ROM Variable age	None
Radiographic	No osseous pathology	Osseous pathology consistent with severity	Joint fusion	None
Drago et al.[21]				
Clinical	Pain at end ROM Minimal adaptive change	Limited ROM Structural adaptation	Painful ROM Crepitation	< 10° ROM
Radiographic	Metatarsal primus elevatus	Small dorsal exostosis	Nonuniform joint space	Loss of joint space
	Plantar subluxation proximal phalanx	Flattening of metatarsal head	Osteophytic production	Loose bodies
	Pronation of rearfoot	Possible osteochondral defect	Large dorsal exostosis Marked flat metatarsal head	Inflammatory arthritis
Bonney and McNab[10]				
Clinical only	DF = 35° PF = 15°	Limitation of either df or pf	Limitation of df and pf	Loss of ROM
Hattrup and Johnson[17]				
Radiographic only	Mild osteophytes	Narrow joint space Moderate osteophytes Subchondral sclerosis	Loss of joint space Marked osteophytes Possible subchondral cyst	None
Regnauld[12]				
Clinical	DF = 40° Pain at end	Decrease in ROM Painful ROM	Little ROM Crepitation	None
Radiographic	Slight decrease of joint space Periarticular osteophytes Decreased metatarsal head convexity No sesamoid disease	Narrow joint space Incomplete osteophytes Flattening/broadening of joint surface Osteochondral defect Elevatus of first ray	Loss of joint space Marked osteophytes Incomplete sesamoid involvement Osteochondral defect Loose bodies Hypertrophy of joint	None

Abbreviations: DF, dorsiflexion: PF, plantar flexion; ROM, range of motion

Table 1: ***Categorizing HR (Muscarella and Hetherington 313-325)***

	Range of Motion	Radiographic Findings	Clinical Findings
Grade 0	DF 40°-60° and/ or 10%-20% loss compared with normal side	Normal or Minimal	No pain, stiffness, loss of passive motion on examination
Grade 1	DF 30°-40° and/ or 20%-50% loss compared with normal side	Dorsal spurring, minimal joint narrowing, minimal sclerosis, and metatarsal flattening	Mild or occasional pain and stiffness, pain at extreme DF and/or PF on examination
Grade 2	DF 10°-30° and/ or 50%-75% loss compared with normal side	Dorsal, lateral and possible medial osteophytes; flattened metatarsal head; no more than one-fourth dorsal joint space involvement on lateral view; mild to moderate joint space narrowing and sclerosis; sesamoids typically not involved.	Moderate to severe pain and stiffness, pain before maximal DF and/or PF on examination
Grade 3	DF < 10% and/or 75%-100% loss compared with normal side	As in grade 2, but substantial narrowing, possible cystic changes, more than one-fourth dorsal joint space involvement, sesamoid hypertrophy or cystic changes	Near-constant pain and stiffness, pain throughout range of motion on examination
Grade 4	Grade 3 plus pain at mid-range of motion on examination		

Table 2: ***Coughlin and Shurnas Hallux Rigidus classification (Nuñez)***

2.5.2 Current Treatments

There are a variety of surgical and non-surgical methods to treat HR. Optimally nonsurgical treatments would be effective. However, when nonsurgical interventions are unsuccessful, surgical procedures are considered. Many times patients are faced with these options.

These are less desirable because of the increased risk associated anesthesia and possible infections from incisions. Rehabilitation is required with some procedures and may be delayed to allow time for healing. Each of these interventions has it's own limitations.

Many times these conditions are accompanied by unnatural bone growth or bone spurs in the MTP joint area. A cheilectomy is a surgery that removes osteophyes from the metatarsal head and the base of the hallux. These osteophytes limit joint space and movement and the cheilectomy "cleans up" the area. This procedure is preferred because it maintains the joint without sacrificing length of bone. (Nawoczenski ; Muscarella and Hetherington 313-325) Unfortunately, the osteophytes have the potential to grow back. Cheilectomies are also used to remove osteophytes from the anterior side of cervical vertebrae that interfere with the patients swallowing. In a ten-year study by Miyamoto et al, the authors evaluated the recurrence of the osteophyte regrowth on cervical vertebrae. Two out of the seven subjects experienced a recurrence of the osteophytes. (Miyamoto et al. 1652-1658)

An osteotomy is a surgery done to change the alignment of a joint by cutting a bone. Since hallux rigidus can sometimes be caused by an abnormally long hallux, this can be effective. There are many different techniques that have been used. The Bonney-Kessel procedure removes part of the base of the phalanx and aligns it more dorsiflexed. The Waterman procedure directs the articular cartilage in a plantar direction. This is only for patients with no degeneration of bone or cartilage. There is also a plantarflexory osteotomy at the metatarsal cuneiform joint. This should allow the proximal phalanx more dorsiflexion. (Muscarella and Hetherington 313-325)

Arthroplasty is the replacement or remodeling of joint surfaces. This is sometimes replaced with silicone or metal. The silicone has been found to fail due to wear and create an immune reaction. These procedures can also result in unstable joints and deformity if not done properly. (Taranow, Moutsatson, and Cooper 713-28, ix-x)

Arthrodesis is the only surgical treatment that does not aim to increase joint mobility. (Nawoczenski)This is a procedure that fuses the bones together, removing the joint. It has a similar effect on the joint as Morton's extension (Figure 9); however, this procedure is permanent. This completely eliminates motion but is effective at pain management. However, the lack of motion at the MTP joint may be compensated for at the more proximal joint between the cuneiform and metatarsal and cause degeneration there. (Muscarella and Hetherington 313-325)

Figure 18*: Custom orthotic with carbon-reinforced Morton's extension under hallux* (shopsite)

The more conservative way to treat HR is though nonsurgical methods. The first step currently in treating this condition is to try basic anti-inflammatory interventions. Rest, ice, nonsteroidal anti-inflamitory medicines, and physical therapy can be helpful to reduce inflammation of the joint. Shoes with more cushioned soles and larger toe areas can also be worn to reduce impact force and reduce loading on the hallux. Rigid soles can limit dorsiflexion, and shoes with a rigid rocker sole can maintain a comfortable foot roll while keeping the key joints from bending.

Custom orthotics are made that address excessive joint range of motion in the foot. Welch et al (2010) investigated the change in MTP joint pain in response to orthotics. The orthoses in the study increased sagittal and frontal plane pronation control and were made from ethyl-vinyl acetate. The area under the first metatarsal head was removed as seen in Figure 10 to further reduce plantar pressures. They found that after using these orthotics for multiple weeks there was a reduction in the patients pain. (Welsh et al.)

Figure 10*: Orthotic with area under hallux and first metatarsal head removed to reduce 1st MTP joint pain.* **(Welsh et al.)**

A more common orthotic design used to treat hallux rigidus is Morton's extension. (Figure 9) It is a rigid carbon plate that extends under the big toe. The extension minimizes movement and changes the loading on the toe. It is effective at treating pain and minimizing joint movement, but it is still considered only an option to try before surgery. (Nawoczenski) Unfortunately by inserting a rigid material underneath an already sore joint it is adding increased plantar pressure to the injury site.

There is a need for a nonsurgical treatment of hallux rigidus that targets the late stages of the condition. It should be noninvasive and customizable by the physician or patient to an individual's problem and lifestyle.

2.6 Orthotic Materials and Construction

Foot orthoses are designed to treat a variety of pathologies; therefore they are designed and produced in many different shapes, with many different materials, and for many different purposes. The main goals for orthotics are as follows: to provide softness, cushioning and shock absorption, to reduce pain under boney prominences and provide relief from excessive plantar pressures, reduce plantar shearing forces, help balance the joints in the foot, and correct functional deformities. Every orthotic has certain physical properties including elasticity, hardness, flexibility, compressibility, durability, density, resilience and response to temperature. To create an effective design there must be an optimal balance of these properties because each of them targets different issues. High-density materials are very effective at redistributing loads, but are ineffective at shock absorption while low-density materials are the opposite. The most common materials used for construction are plastics, acrylics, composites, foams, leathers, and corks. (Lockard October 17, 2013; Nicopoulos, Black, and Anderson 1-3)

Plastics are either thermoplastic or thermosetting. These materials can be molded into the shape of the foot, and thermoplastic materials have the advantage of being able to be reheated and remolded. When choosing a plastic, the glass transition temperature must be taken into consideration. (Lockard October 17, 2013) This is the temperature at which a material undergoes a reversible transition from a hard brittle state to a rubber-like state.

The categories of orthoses are usually broken down into are soft, semirigid, and rigid inserts. A soft orthotic is made from low-density foams and is used for extra cushioning or shock absorption. They are sold over the counter and can correct minor issues of the feet. These serve less for support and gait alteration, so unlike other types there is no need to slowly adjust to wearing them. As humans age, the fat pads on the sole of the foot are reduced. This reduction puts stronger forces on the bones of the foot, and can alter the direction of the loading, increasing the risk for injury. According to Bosch et al (2009) the average peak pressure in the total foot of toddlers is 21.04 psi while it increases to 116.09 psi in seniors. This peak pressure in seniors is approximately a 29.0 psi increase from the 88.63 psi in adults. (Bosch et al.) Since pressure is calculated by dividing force by area, it can be assumed that this change is at least partially due to the deterioration of the fat pads because there is not a significant change in foot size or weight (153.22 lb and 160.94 lb respectively) between adults and seniors. (Bosch et al.) Another benefit of soft inserts is that they automatically conform to the shape of the inside of the shoe, while with rigid or semirigid inserts must add or take away material on the inferior aspect. (Lockard October 17, 2013; Nicopoulos, Black, and Anderson 1-3)

Rigid orthotics are incorporated to correct abnormal lower body motion and caused by abnormal joint alignment. These are made from hard plastics and the superior surface must be molded to the neutral position of a patient's foot. Usually no more than 0.118, they are able to accomplish their task while not taking up too much room in the shoe. Unlike soft orthotics, patients should wear them periodically in the beginning to avoid injury and to allow the body to adjust to the biomechanical alteration. (Lockard October 17, 2013; Nicopoulos, Black, and Anderson 1-3)

To treat Hallux rigidus an insert should fall somewhere between rigid and soft orthotics. Semirigid orthotics are made from materials of medium durometer and are able to redistribute plantar pressures while also providing some cushioning and shock absorption. This makes them the most optimal for sports and high impact activities. They are usually made from low-temperature thermoplastics and must be molded to the shape of the foot. HR patients need pressure removed from under the metatarsal head by cushioning the area to reduce pain. (Lockard October 17, 2013; Nicopoulos, Black, and Anderson 1-3) However there still needs to be a restriction of joint movement to prevent the progressive injury.

Orthotics not only come in different materials but also in different sizes. They are usually either three quarters in length or full length extending all the way under the toes. The three quarter length inserts extend from the heel to just proximal of the metatarsal heads. Soft orthotics can easily be made in any size, but rigid ones are almost always three quarters so as not to interfere with toe break during gait. (Lockard October 17, 2013) One exception mentioned above is Morton's extension. It has a rigid extension that reaches under the entire length of the great toe. However, since this does interfere with toe break, there is a need to create a stabilizing mechanism without altering walking biomechanics.

Nunez (2013) designed a spring-loaded device using a combination of EVA foam and a harder plastic. There were three different durometers of foam tested, and the plastics used were polyethyline, polypropylene, and polycarbonate. In each of the combinations the peak load and the mean extension were found. This data shows when it would fail from too much force and how much movement the toe would be allowed during gait. No statistical difference was found from varying the foam portion, but a difference in results was seen when the harder plastics were used. Generally the polycarbonate had the largest peak load and the lowest average extension, while polyethylene was the opposite. This shows that a combination of polycarbonate with a foam in an orthotic under the hallux would limit movement effectively, and poly ethylene would allow a much larger range of motion. However, in this experiment the forces applied were not even half as large as the ones seen under the foot. (Nuñez) The thickness of the material would have to be increased to produce the strength needed. Considering that most rigid orthotics are no more than 3 mm (0.118 in) in thickness and some sort of cushion must be added on to provide padding and shock absorption, there will have to be a way to reduce the thickness or determine another material with similar properties that would need less volume. There are some spring steel materials that may not need to be as thick to produce similar properties. Bosch et al (2009) found that the maximum force for adults in the total foot is 108.79% of body weight, (Bosch et al.) while Tongen and Wunderlich found that comfortable walking speeds produced forces under the foot 130% of body weight while running can create forces up to 200% body weight. (Tongen and Wunderlich) The average weight of an adult in North America is 80.7kg or 177.9lb, which means the maximum forces on the foot seen while walking should be 192.1lb-231.27lb. The material chosen for the orthotic should have material properties that can support these loads in bending before excessive plastic deformation.

One thing to keep in mind is that orthotics cannot be worn without some risk. It is important to carefully choose which insert works best for which condition. Too much motion control from orthotics can cause other problems. Excessive varus control has been known to cause iliotibial band syndrome or trochanteric bursitis. Lower back pain and hip rotator muscle strain have been the result of too much neutral foot control. Having devices press into the plantar fascia has also caused plantar fasciitis.

2.7 Steel types and properties

	AISI 304 Stainless Steel	AISI 1095 Spring Steel
Density	0.289 lb/in^3	0.284 lb/in^3
Young's Modulus	28000-29000 ksi	27577-30458 ksi
Poisson's Ratio	0.29	0.0.27-0.30
Yield Tensile Strength	31200 psi	76100 psi
Ultimate Tensile Strength	73200 psi	99400 psi

Table 3: ***Material Properties of Steel (AZO Materials)***

Steel is used in many applications including construction, transportation, energy, packaging and making of appliances. It can be expensive, but is easy to clean and is resistant to corrosion. Its strength to weight ratio allows the use of a smaller amount of material with a strong strength. This is promising that it will not have trouble fitting in a shoe. The material properties are listed in Table 3 of two different steel types, a 304 stainless steel and a1095 carbon spring steel.

Mirambell and Real investigated the deformation properties of stainless steel construction beams using a finite element model and a physical testing setup. A three-point bending test was performed on these beams. They were able to effectively model the beam in ABAQUS and were able to get a similar deflection versus load curve in both the model and the physical data. The numerical model is a good predictor of the results of the bending, but the data deviates because it does not take into account elements buckling. (Mirambell and Real 2/15/15) This concept will be used to predict the amount of deflection seen in the new orthotic design during walking.

CHAPTER 3: **MATERIALS AND METHODS**

3.1 Design Methods

The purpose of this project was to create an easily-adjustable, in-shoe orthotic that could selectively limit the maximum angle of dorsiflexion in the first MTP joint and attenuate pain associated with exceeding a comfortable range of motion in HR patients. A set of design criteria were established to identify key components of a two-part orthotic consisting of a base section and a variable spring insert. The design requirements are listed in Table 4.

Initial design concepts of the insert (Figure 11) incorporate a cutout portion for the MTP joint and a long attachment piece that suitable for inserting into the base component. Early prototypes were conceptualized using ductile materials including plastic and aluminum and cut using a band saw. (Figures 11) Both were intended to be positioned on the lateral side of the foot so as not to interfere with the medial arch or the medial plantar fascia as addressed in design requirement 8. The first extends under all the distal phalanges distributing the force across all the toes. The second design was closer to the Morton's extension with some modifications. It extended under the first and second phalanges, leaving a space for the first MTP joint. This addressed design criteria 7. The design in Figure 11 a and c was chosen.

Design Requirements

1. Base will be constructed of material that is rigid or of sufficient stiffness to hold an interchangeable insert in place

2. Base will not extend distally to any of the five MTP joints

3. Interchangeable insert will be constructed out of a variety of thicknesses to allow for the selective manipulation of the range of motion of the MTP joint

4. No point on the orthotic will exceed 1.25 inches in thickness

5. Insert will be no more than 0.125 inches thick

6. Medial edge of the base will be less than or equal to 54% of the total length of the foot

7. Orthotic will avoid rigid material directly under 1^{st} MTP joint

8. Orthotic will account for the dynamic nature of the foot/ shoe interface and avoid irritation the plantar fascia

9. Orthotic will reduce alterations in gait when compared to traditional rigid insoles (Morton's Extension) and non-plantar footwear (rocker soles)

Table 4: *Design Requirements*

Figure 11: ***Original Prototypes made from aluminum and plastic***

Baseline quantitative measures were taken from patient x-ray data and served as the basis of the size ratios used in the orthotic design. Thirty x-rays of patients with HR were taken and measured at fourteen different locations. Some of these measurements can be seen in Table 5. Only the values with Standard Deviations of less than 0.5 were used in the design of the orthotic.

	Mean	Standard Deviation	Median
WF/ ball width[1]	2.38375	0.14268	2.39045
WF/ ball width[2]	2.69215	0.14190	2.71510
WF/ MTP length	8.84992	1.24263	8.75641
WF/ MTP width	9.57230	1.14977	9.68000
WF/ MTP depth	10.44567	1.22511	10.39565

Table 5: ***HR Patient Foot Data WF: Whole foot (calcanius to tip of hallux), ball width[1]: width from most medial to most lateral metatarsal head plus tissue, ball width[2]: width between metatarsal heads minus the tissue, MTP length: length of the MTP joint in the on the line of the metatarsal, MTP width: length of the joint medially to laterally, MTP depth: half of length of MTP joint superiorly to inferiorly***

A tangible replica of a foot with HR was created using a clay mold. There are different ways to create a mold of a foot, but clay was chosen because the materials were readily available. (Figure 12)

Figure 12: ***Clay foot Mold***

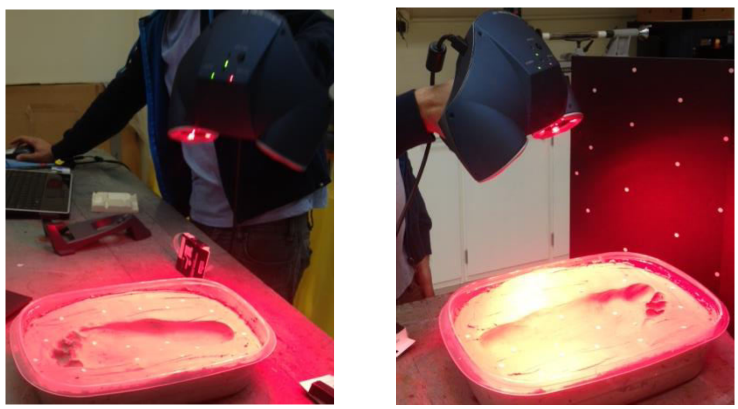

Figure 13: Creating a 3D scan of the mold

To create a positive model of the sole of the foot, a 3D scanner was used as seen in Figure 13. White markers were placed around the mold. They are used to help the scanner more easily determine depth. The handheld scanner used laser triangulation to record the data to be transferred to the computer. This is most easily seen in Figure 13b. This data collected was opened in a program called Rhino that shows a 3D model of the surface scanned. (Figure 14) This was then saved as an .stl file that could be opened in SolidWorks or other virtual modeling programs. It was also converted into G code that could be read by the Computer Numerical Control (CNC) machine.

Figure 14: ***Virtual 3D Model of foot sole***

To produce a 3D physical model, a CNC machine was used to accurately cut the foot model out of hardwood. A block of maple wood was secured to the base of the CNC machine and progressively larger milling bits were used to cut the shape as seen in Figures 15. The finished product from a CNC machine produces a smooth and very accurate replica of the footbed. This replica was used to create the first iteration of the orthotic design.

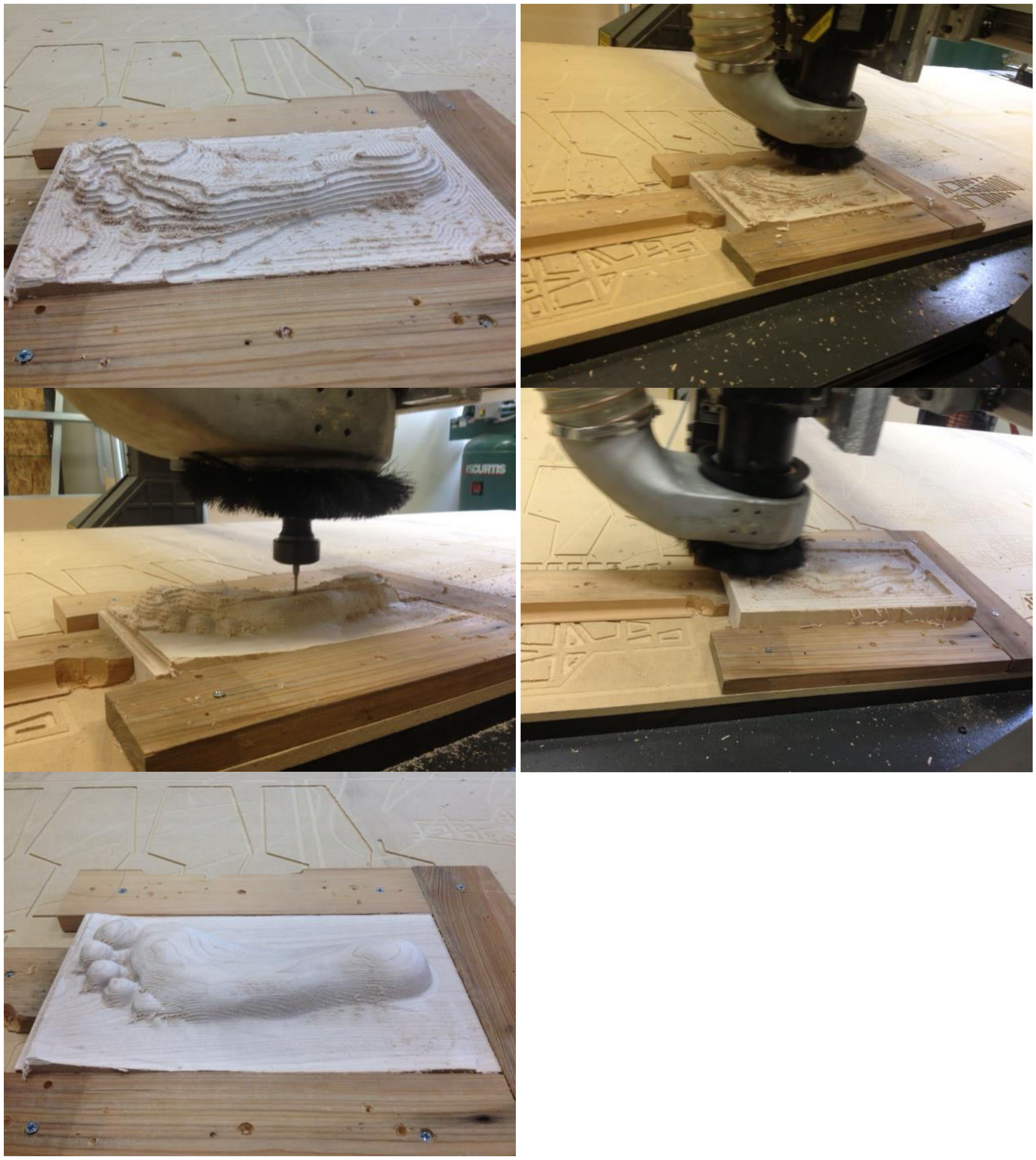

Figure 15: ***Five time points captured while CNC machine creates wooden foot***

Using dimensions from the model of the foot and data collected from the x-rays, a virtual model was created in Solidworks. The base and spring components for the current design are shown in the figure below. The cut out portion in the base (Figure 16 a) aligns with the bottom portion of the insert (Figure 16 b) allowing for easy removal for a different insert.

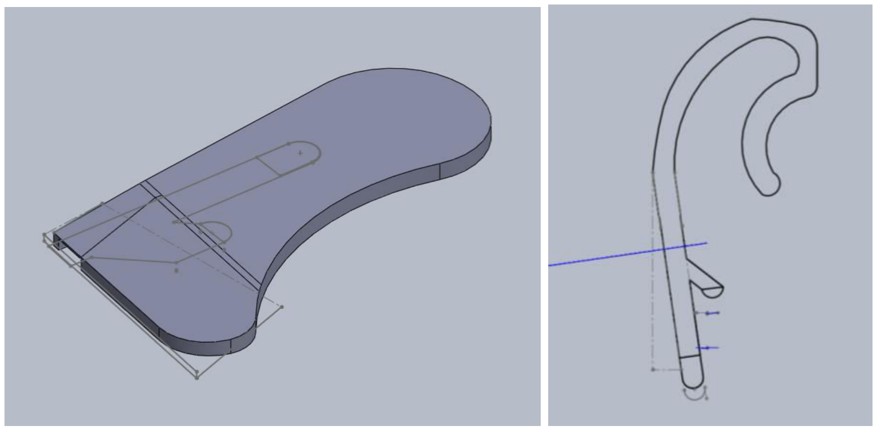

Figure 16: ***SolidWorks Prototype parts***

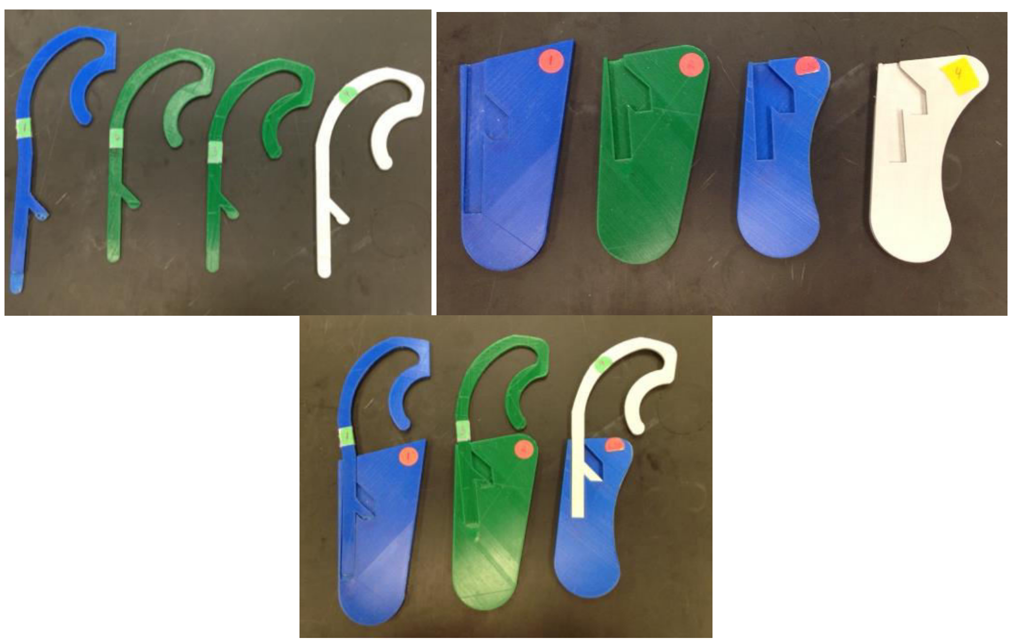

Figure 17: ***Multiple generation 3D printed prototypes***

Prototypes of the pieces were printed on a 3D printer using PLA plastic. Four different generations are shown in Figures 17. The final prototype was created using a PLA base and 1095 carbon spring steal for the interchangeable spring component. Four different thicknesses: 1/32", 1/16", 3/32", and 1/8" of spring steel material were laser cut for physical testing. The two thickest sizes were machined down at the base interface to fit into the receiver of the base. The steel insert prototypes can be seen in Figure 18.

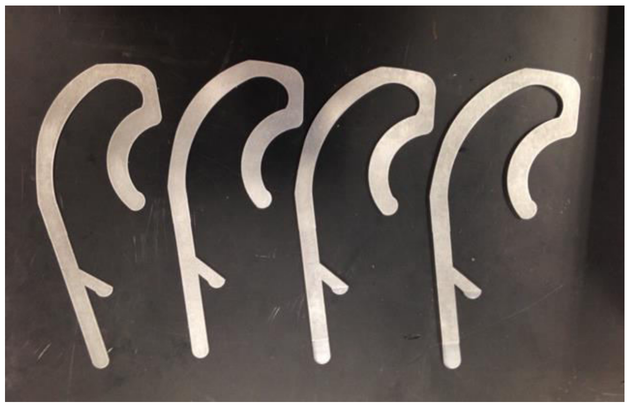

Figure 18: ***Four different thicknesses of 1095 Spring Steel***

3.2 Materials

Initially AISI 304 stainless steel and AISI 1095 carbon spring steel were chosen to be tested as the material for the spring inserts due to their corrosion and rust resistant qualities and their elastic properties. To reduce overhead costs during development, the base components were 3D printed from PLA plastic because of the rapid prototype capabilities and capacity to withstand the torsional loads of the spring section.

	AISI 304 Stainless Steel	AISI 1095 Spring Steel	Polyurethane	Concrete
Density	0.289 lb/in³	0.284 lb/in³	0.0361 lb/in³	0.0868 lb/in³
Young's Modulus	28000-29000 ksi	27577-30458 ksi	3625.9 psi	2000ksi
Poisson's Ratio	0.29	0.0.27-0.30	0.49	0.2
Yield Tensile Strength	31200 psi	76100 psi	N/A	N/A
Ultimate Tensile Strength	73200 psi	99400 psi	N/A	N/A

Table 6: ***Material Properties (ASM Aerospace Specification Metals Inc. ; AZO Materials)***

3.3 Computational Modeling

Since the design was created in Solidworks, it can be virtually tested with a finite element model. To determine an effective mesh size for the computational Abaqus model, a simpler but similar model was constructed. It was tested using multiple mesh sizes from one unit (inch) edges to 0.03 unit edges. In the images below (Figure 19) the coarsest mesh and the finest mesh tested can be seen. When larger mesh sizes are used there is large variability between results, but the models run much faster than the finer meshes.

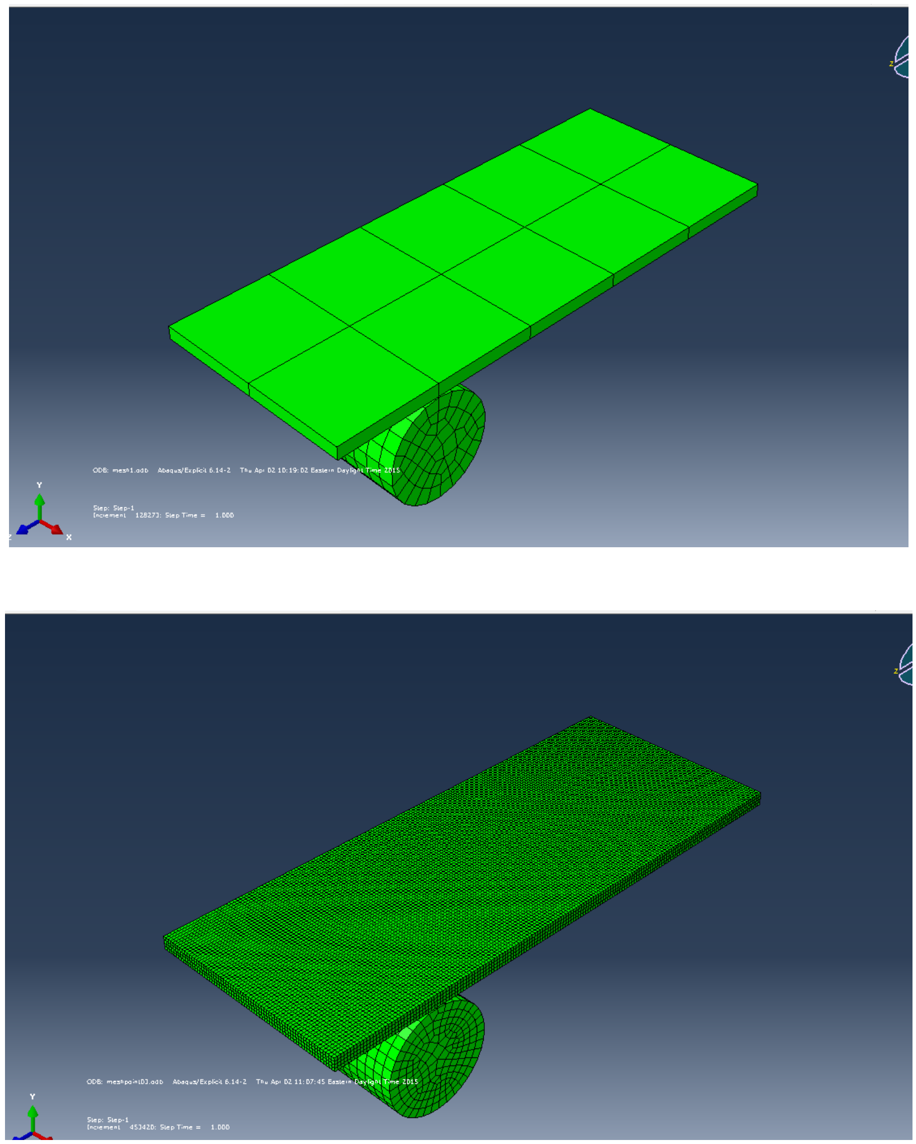

Figure 19: ***Coarse and fine mesh***

The CAD model of the orthotic was transferred to ABAQUS and put in bending to simulate the forces felt across the MTP joints during the gait cycle. A modified beam-with-overhang setup was chosen for the simulation. A polyurethane foam shape and a concrete cylinder were added to the assembly. The polyurathane was simulating a tennis shoe sole, which is typically one of the softest shoe soles. The concrete was used as the overhang and was simulating the radius of the ball of the foot (2.75 in diameter). Concrete was chosen because it would not deform under the loads applied, which would ensure bending of the insert. To simplify and reduce the running time of the model the plastic base was removed. This should not affect results because the portion of the insert in the base was completely constrained in the model. This constraint is anatomically accurate because the joints of the foot more proximal than the MTP joints experience negligible bending. The assembly can be seen in the figure below.

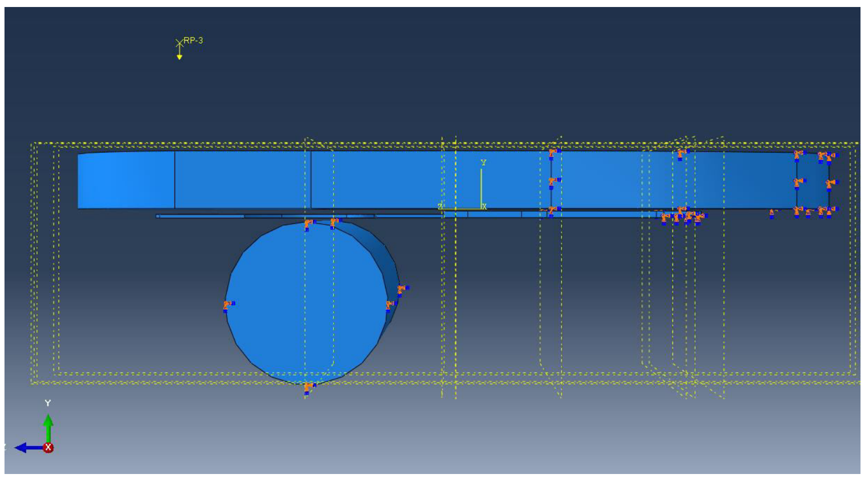

Figure 20: ***Computational model assembly that shows load placement***

The concrete and the back of the shoe sole were also completely constrained in the X, Y, and Z directions. A force was applied in the negative Y-direction and can be seen in the top left corner of the last figure (Figure 20). It is coupled with the area underneath which is simulating the area underneath where the toes would be. This can be seen in the figure below (Figure 21). The concrete cylinder is hitting the model in the same place that the MTP joints would be positioned.

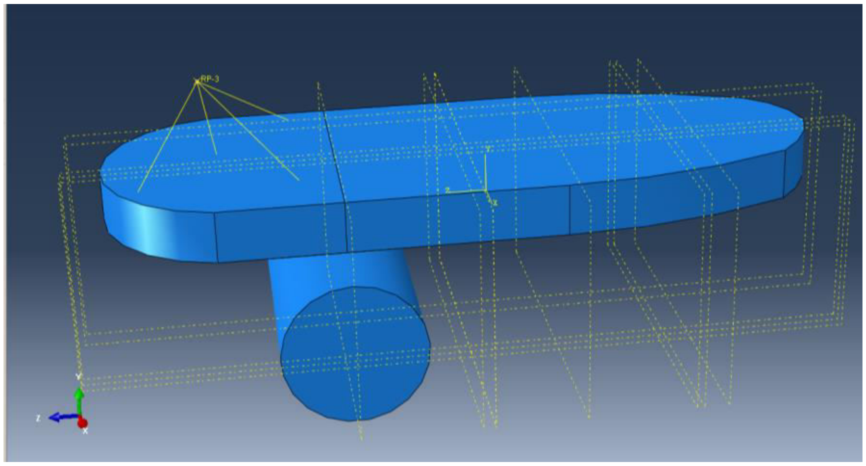

Figure 21: ***Computational assembly that shows coupling of loading point to "shoe sole"***

The force was chosen to be 200 pounds in the negative y-direction. This is slightly larger than average American body weight to account for the increased ground reaction force during locomotion. This force was tested on four different thicknesses of insert including: 1/8”, 3/32”, 1/16”, 1/32”. The displacement of the end of the insert was recorded along with the maximum von Mises stress. The angle of deflection from the contact point at the concrete cylinder to the tip of the insert was calculated to determine the angle of dorsiflexion the first MTP joint would experience. The same technique was then done varying the forces while holding the thickness constant at 1/16”. The forces chosen were 150lb, 175lb, 200lb, 225lb, and 250lb.

3.4 Physical Testing

This can also be done physically using a mechanical test stand. The prototypes were tested using two different bending methods—a three point bending test and a modified beam-with-overhang test. A test figure had to be created for the ADMET

MTEST Quattro for both procedures. Figures 22 and 23 show the two set ups. The three-point bending test jig was created using an aluminum I beam with rollers attached between the flanges. An aluminum cylinder was attached to the load cell to create the third bending point. The second testing fixture, modeled after a beam-with-overhang, was built that clamps the end of the prototype rigidly between two aluminum plates. One of the rollers was removed from the I-beam to create only one point of force from above while the orthotic bends around the same aluminum cylinder.

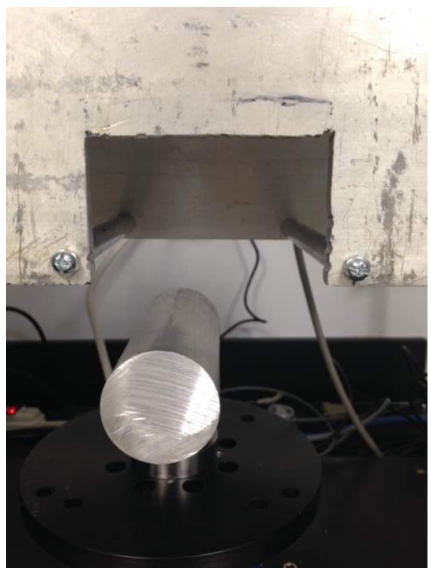

Figure 22: ***Three-point bending test apparatus***

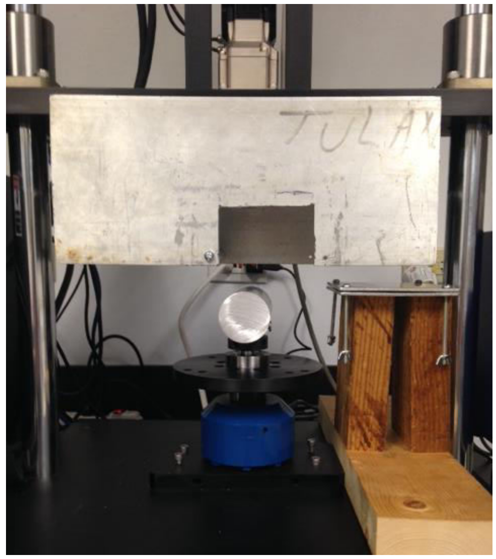

Figure 23: ***Beam-with-Overhang test apparatus***

In both tests the different sized steel inserts were placed in series with the sole of a tennis shoe and a foam covering as seen in Figures 24. The foam covering allows easier interfacing between the test stand and the prototype, and the shoe sole creates a bending over the entire width of the orthotic.

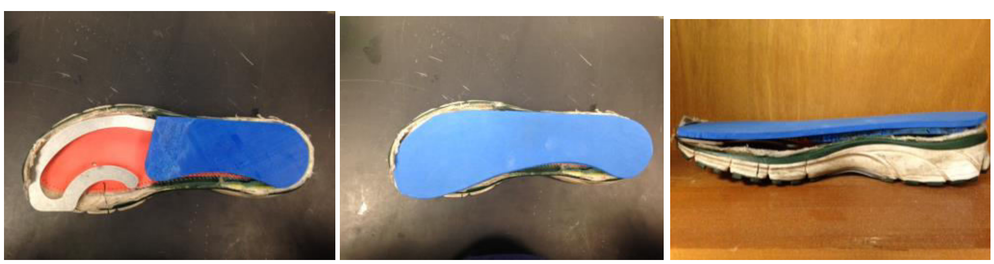

Figure 24: ***Prototype preparation before bending tests***

For the three point bending test, the shoe with the orthotic was loaded in the testing set up and the top portion of the machine was lowered until the test piece was held tightly in place. (Figures 25) A displacement was then applied at a constant rate. To validate the concept that the thicker inserts require more force to deform, one test was done on the 1/8”, 1/16”, and 3/32” thickness with a displacement of one inch. The forces felt at the load cell during the test were recorded along with the plastic deformation on the insert after the test. An angle of ~36-37° was chosen to do in bend in both test stands.

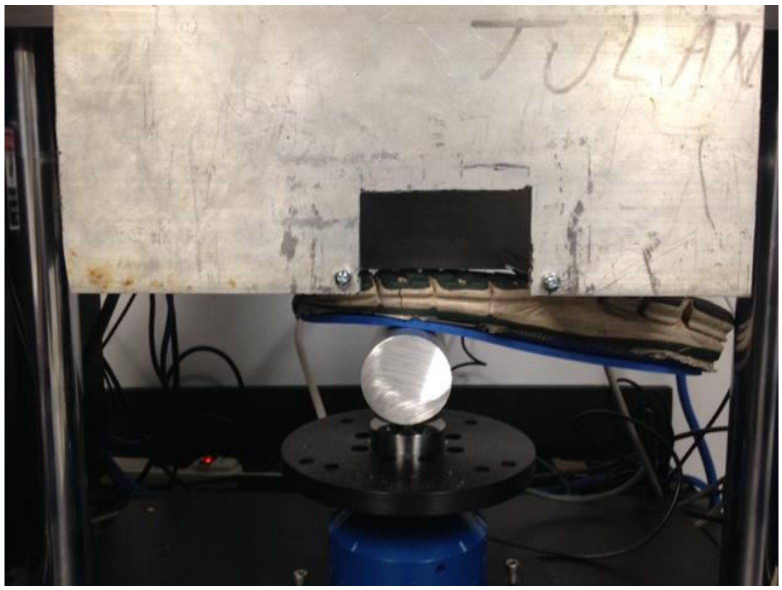

Figure 25: ***Shoe sole and orthotic before three-point bending***

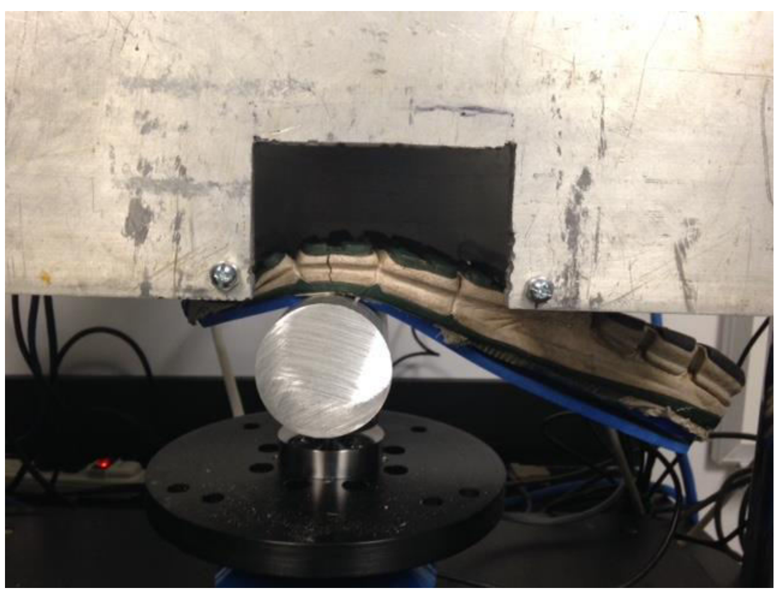

Figure 26: ***Shoe sole and orthotic after three-point bending***

For the thee-point bending, three trials were done on each thickness of insert with a constant displacement of 0.6”. This results in approximately 37° dorsiflexion. This displacement value was found using the arctangent equation and the lengths that are known. The plastic deformation was recorded for each test. One test sample at 1/32” thickness was then loaded nine more times to simulate cyclic loading. The forces and plastic deformation were recorded.

Figures 27 and 28 show the loaded beam-with-overhang testing apparatus. The beam-with-overhang testing used the same procedure as the three point bending test. Each thickness of insert had a 1” deflection applied. This created a 36° dorsiflexion angle which allowed comparison with the three-point bending test that deformed to approximately the same angle. This test was run three times with each thickness. A single 1/32” thickness spring insert was tested nine more times to record the changes after cycling.

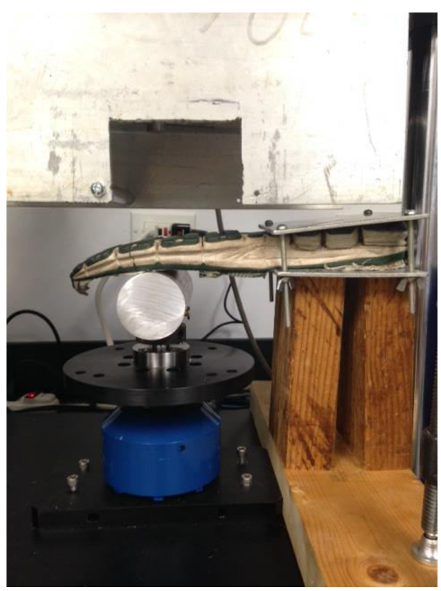

Figure 27: ***Shoe sole and orthotic before Beam-with-Overhang Bending***

Figure 28: ***Shoe sole and orthotic after Beam-with-Overhang Bending***

3.5 Analysis

For the computational model the y-displacement position over time was graphed. The maximum value and minimum value that followed the first local maximum position were recorded. The maximum y-displacement value along with the corresponding z-displacement were used to geometrically find the angle of dorsiflexion that corresponded with this displacement.

For the physical models the three trials per thickness on each testing setup were averaged and plotted on a position versus force graph. In both the three-point bending and the beam-with-overhang bending tests a third order polynomial was fit to the graph on each thickness size. This regression was used to create an extended clinical chart correlating weight with HR stage and maximum dorsiflexion angle. To analyze the cycling trials, during each of the ten consecutive runs the maximum force recorded during each trial was plotted. A linear regression was fit to the data. The R^2 values were also recorded to determine relevancy. After the standard deviation was calculated over the ten cycles the mean and the standard deviation were plotted on a bar graph.

CHAPTER 4: **RESULTS**

4.1 Mesh validation

To validate the mesh density of the computational model, Figure 29 shows a graph of the mesh size versus the deformation that occurred in the simplified finite element model. The data shows that the percent difference of the result between using a mesh size of 0.05 and 0.03 was only 1.4%. A mesh size of 0.05 was determined sufficiently small to both model the situation and run in a reasonable time. This mesh was fine enough to allow more than one mesh unit of thickness, an important consideration so that the different stresses can be measured on the top and the bottom.

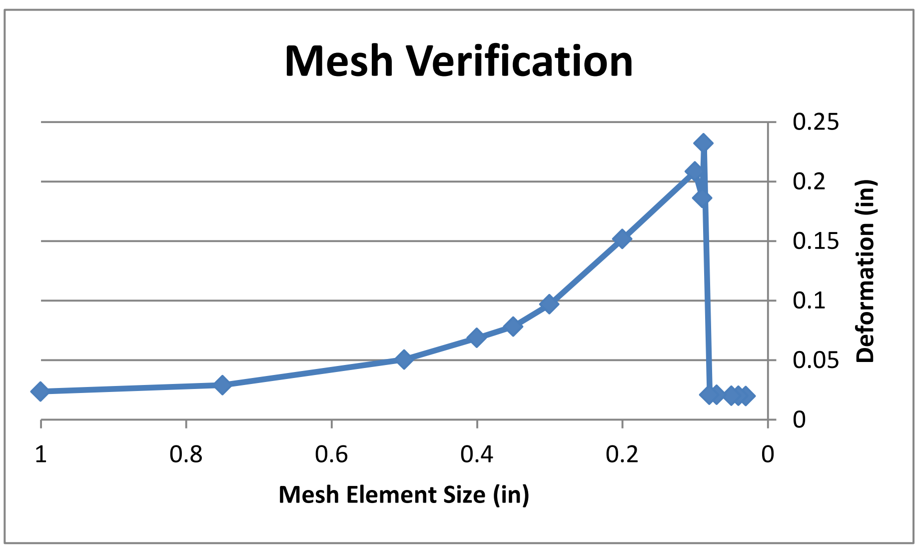

Figure 29: ***Deformation of simplified computational model with different mesh densities***

Figures 30 and 31 show the results of the simplified computational model. The colors represent the von Mises stresses felt while bending. The highest stress is felt in the elements that are the most red.

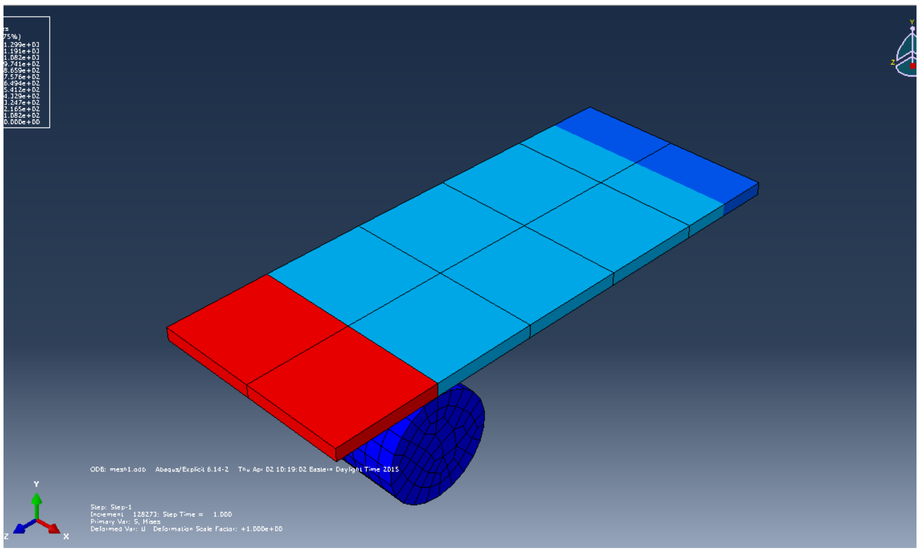

Figure 30: ***Deformed model with coarse mesh (size 1 in.)***

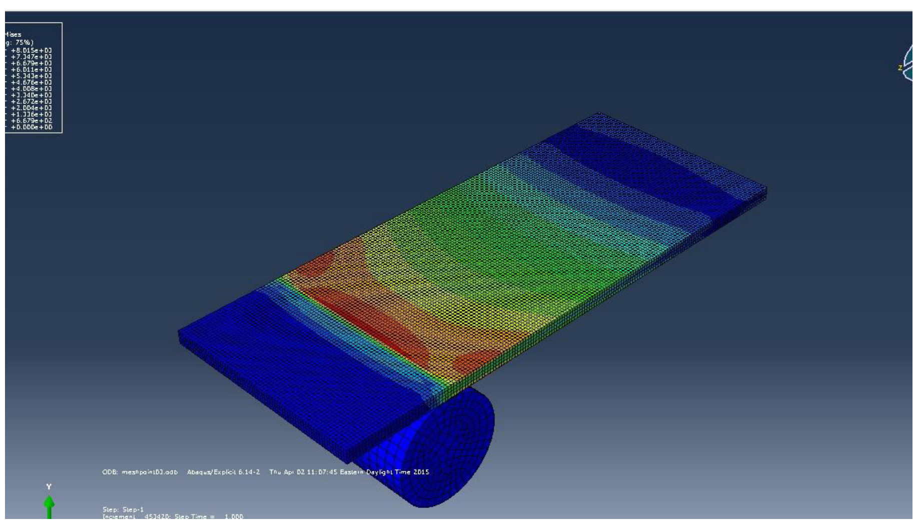

Figure 31: ***Deformed model with fine mesh (size 0.03 in.)***

4.2 Computational Modeling

Figures 32 and 33 show the results of the finite element simulation of the insert in bending. The more red the color is the higher the von Mises stress at that point. The points of highest stress are located at the points of bending.

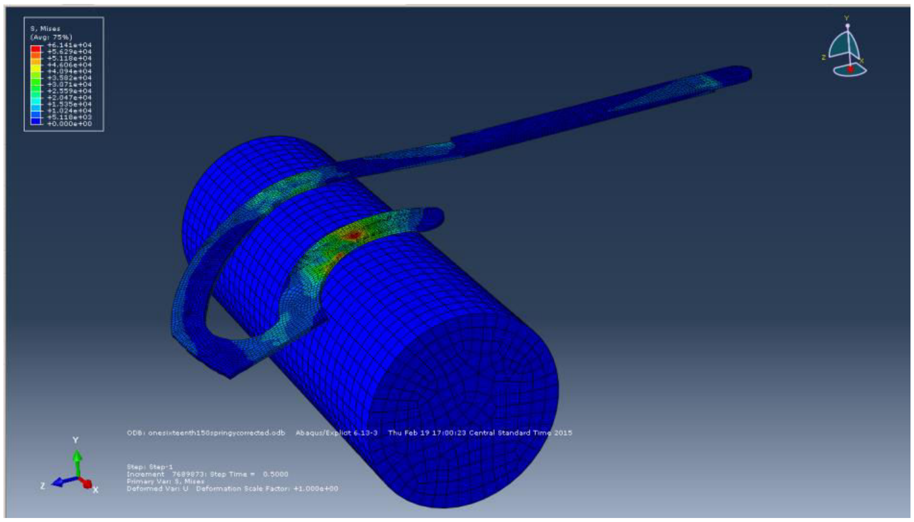

Figure 32: ***Deformed computational model after loading***

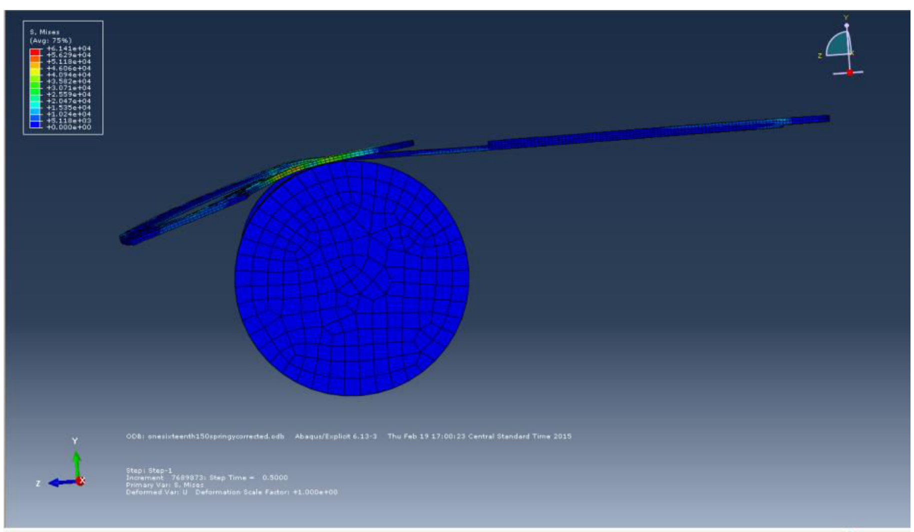

Figure 33: ***Side view of computational model after loading***

The model collected data over the course of 0.5 seconds. This allowed for two cycles of bending of the orthotic. Each orthotic thickness was loaded with 200 pounds of force. The first material tested was 304 stainless steel. The data collected can be seen in Figures 34, 35 and Table 7. Notice in Figure 34 that the thinnest insert thickness is displaced the farthest distance in the y-direction (2.1 in.), and the thickest insert is displaced the least distance in the y-direction (1.3 in.). Figure 35 translates the displacement values into degrees of dorsiflexion using the displacement in the y and z directions. The 1/8" thickness insert will allow only 29° of maximum dorsiflexion while the 1/32" thickness will allow almost 57° of dorsiflexion with 200 pounds of force. These values can be found in Table 7. Table 7 also shows the amount that the insert springs back after loading. None of the inserts return to less than one inch from their initial position.

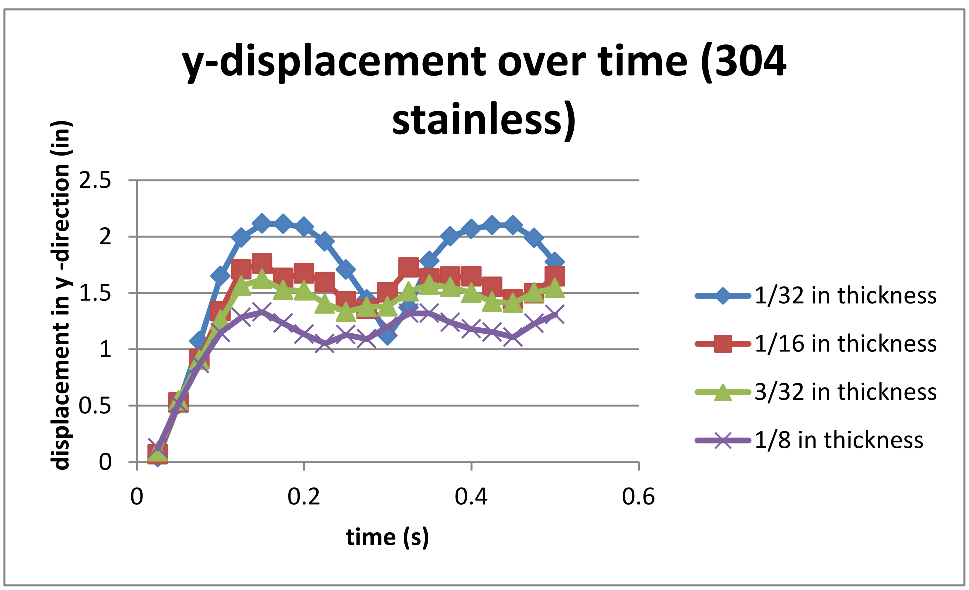

Figure 34: ***The y-displacement over time of the inserts in the computational model of 304 stainless steel***

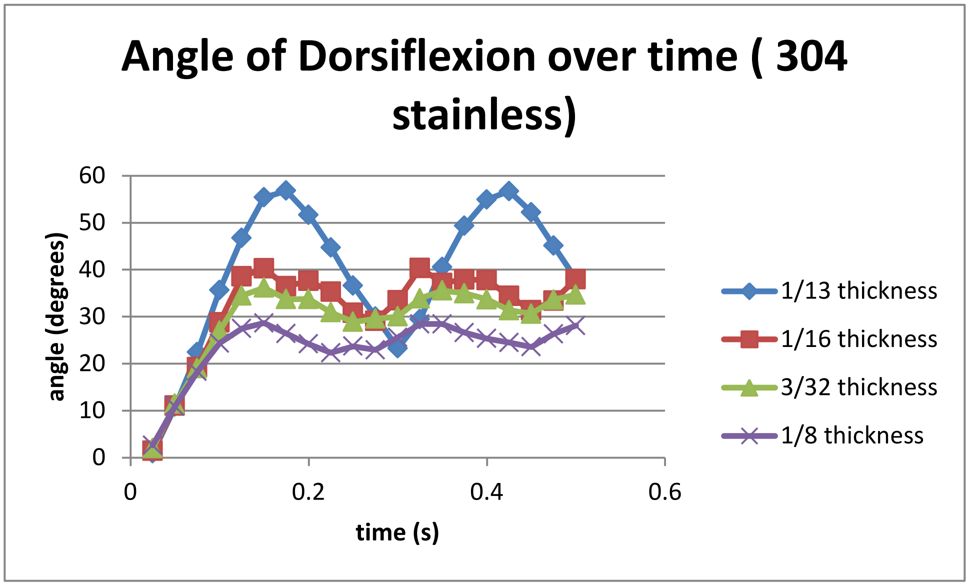

Figure 35: ***The angle of deflection over time for 304 stainless steel in the computational model***

	Max delta y (inches)	Min return displacement (inches)	Max angle dorsiflexion (degrees)	Min return angle (degrees)
1/32"	2.1	1.1	56.7	23.3
1/16"	1.8	1.4	40.3	29.1
1/32"	1.6	1.3	36.2	28.9
1/8"	1.3	1.1	28.6	22.9

Table 7: ***Data values from 304 stainless steel computational modeling (at 200 lb)***

The next material tested was 1095 carbon spring steel. These values can be seen in Figures 36, 37 and Table 8. The maximum angles of dorsiflexion range from 24°-56° when 200 pounds of force are applied. Each thickness returns to less than one inch from its starting position.

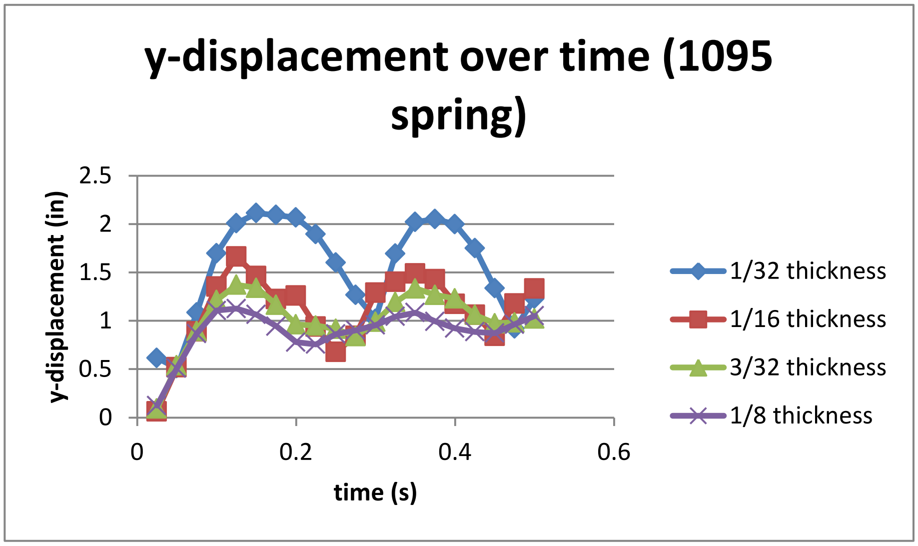

Figure 36: ***The y-displacement over time of the inserts in the computational model of 1095 spring steel***

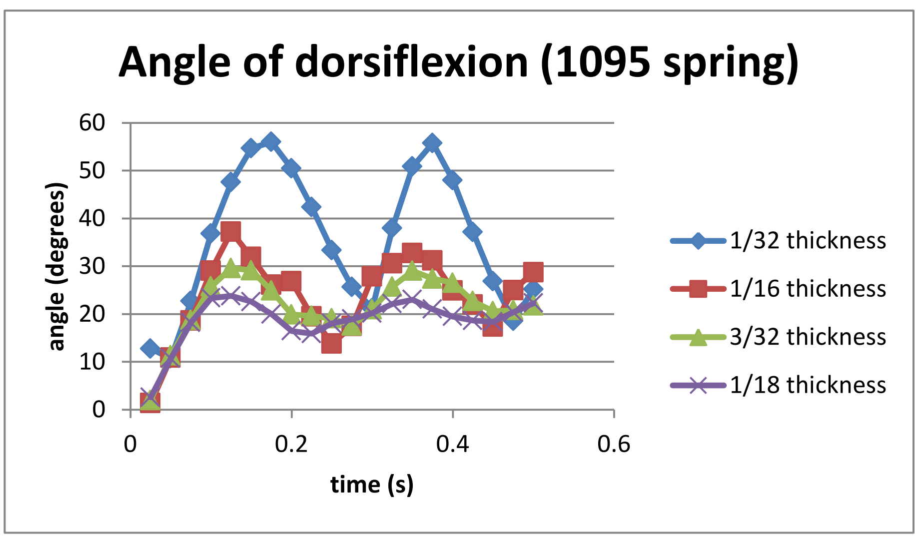

Figure 37: ***The angle of deflection over time for 1095 spring steel in the computational model***

	Max delta y (inches)	Min return displacement (inches)	Max angle dorsiflexion (degrees)	Min return angle (degrees)
1/32"	2.1	0.9	56.0	18.6
1/16"	1.7	0.7	37.2	13.8
1/32"	1.4	0.8	29.6	17.6
1/8"	1.1	0.8	23.8	15.9

Table 8: ***Data values from 1095 spring steel computational modeling (at 200 lb)***

Figures 38, 39 and Table 10 show the effect of applying different forces to the 1/16" thickness insert in the computational model. Aside from the 175lb load, there is a gradual increase of the maximum angle of dorsiflexion allowed as the force increases. However this trend is less apparent than the one seen in the previous figures. The 175 lb loading trial seems to be an outlier and does not follow the trend of the other applied force tests.

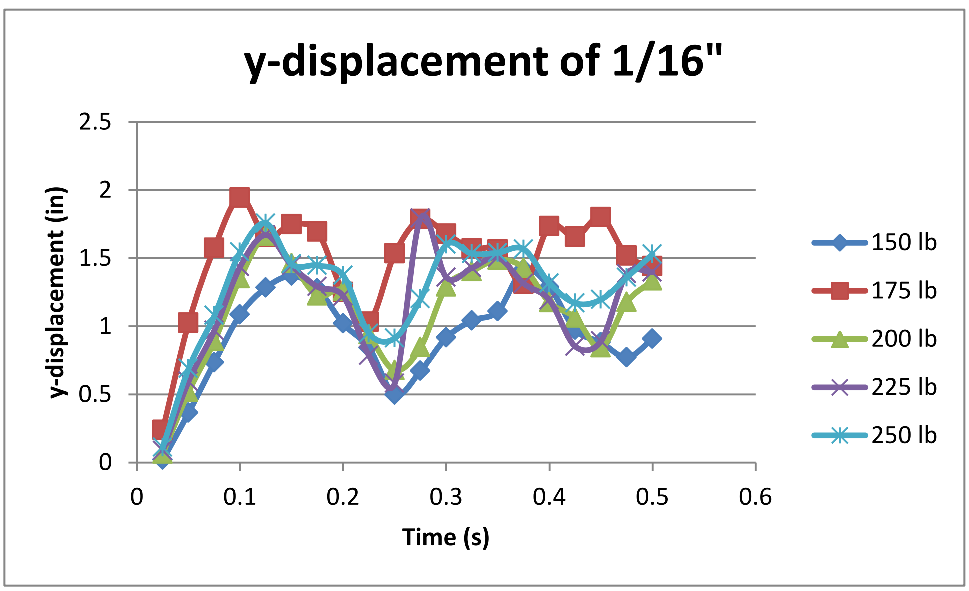

Figure 38: ***Effect of varying loads on y-displacement of 1/16" thickness insert in computational model***

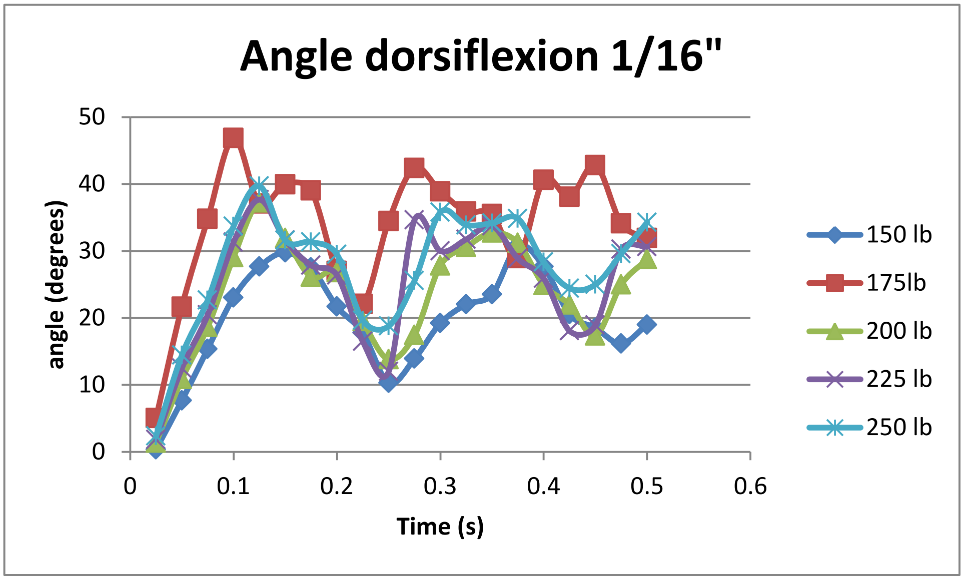

Figure 39: ***Effect of varying loads on the angle of dorsiflexion of 1/16" insert in computational model***

Weight (pounds)	*Max y-displace (inches)*	*Max return (inches)*	*Max angle (degrees)*	*Max return (degrees)*
150 lb	1.369	0.496	30.74	10.28
175 lb	1.944	1.032	46.869	22.067
200 lb	1.663	0.677	37.235	13.819
225 lb	1.793	0.581	37.664	11.981
250 lb	1.756	0.912	39.697	18.769

Table 9: ***Data extracted from Figure 38 (computational model varying forces)***

4.3 Orthotic testing

The physical prototype was then tested using an ADMET tabletop test stand with two different testing jigs. Figure 40 shows the initial trial run of the three-point bending test to prove that different loads can be seen for different thicknesses. This test was done using a deflection of one inch. This positive correlation encourages further testing.

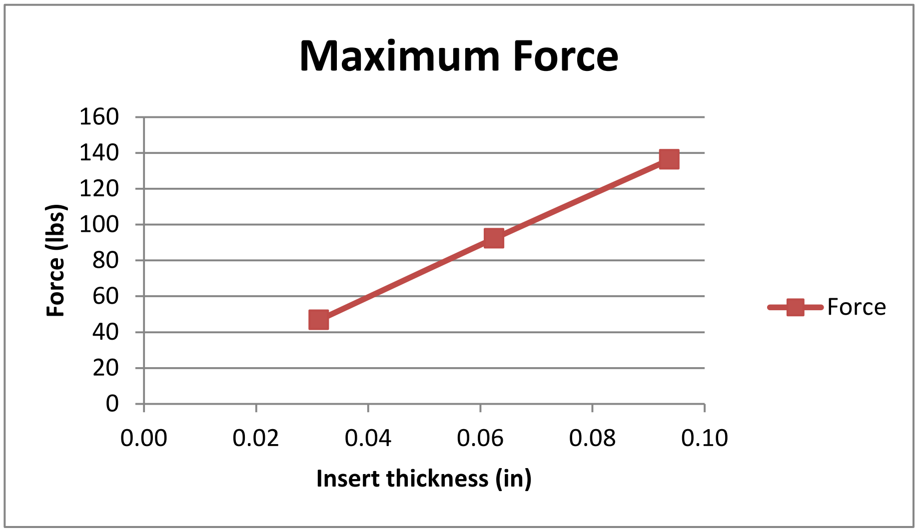

Figure 40: ***Force required to bend each insert thickness one inch during 3 point bending***

Figure 41 shows the plastic deformation of the insert after the three-point bending deflection of one inch. The plastic deformation at point b corresponds to the plastic deformation recorded from the finite element analysis, at the tip of the orthotic. Point a is the bend at the MTP joints.

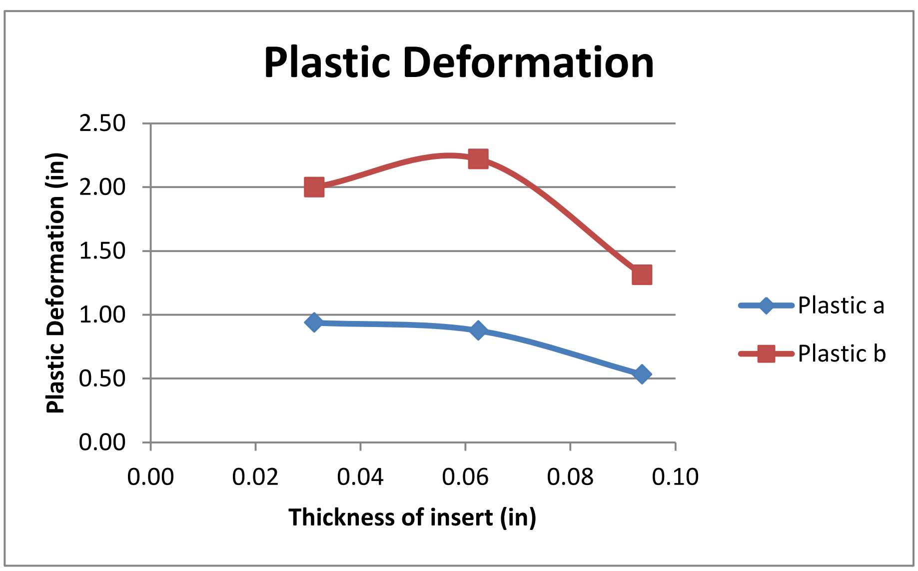

Figure 41: ***First trials three-point bending with 1” deflection***

Figure 42 presents the forces recorded as each insert thickness in the three point bending test reaches a displacement of 0.6 inches. Each of these tests were performed over the course of 35 seconds. This graph shows the average of the three trials for each insert thickness. For 1/16" thickness, this test tells us was approximately a 50 lb load is needed to bend to 37° dorsiflexion. A third order polynomial regression was fit to each thickness. This information was used to create the chart in Appendix B to determine the forces needed to reach larger angles of dorsiflexion.

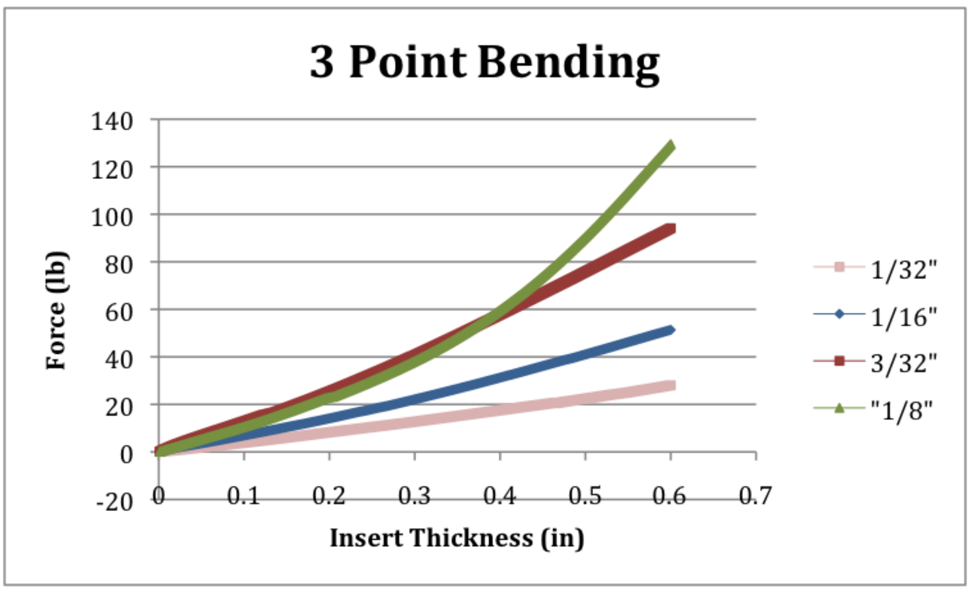

Figure 42: ***Three-point bending test data from 0.6" displacement***

Figure 43 demonstrates the same concept using the data collected from the modified beam-with-overhang tests. Each of these tests was performed over the course of seven seconds. The forces needed to reach a deflection of one inch are clearly visible and clearly different from each of the insert thicknesses. This model was also used to find third order regressions and create the charts in Appendix B and C.

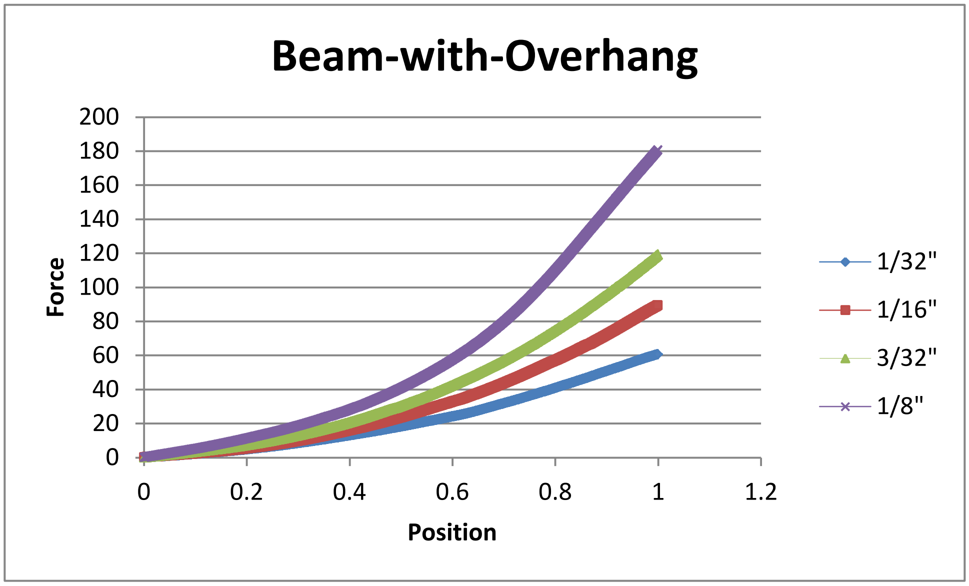

Figure 43: ***Beam-with-Overhang test data from 1" displacement***

Figures 44 and 45 compare the two physical testing methods. Each insert was tested approximately three times in each configuration and bent between 37°-36°. Figure 44 shows the average maximum force recorded by the load cell over the three trials at each thickness. We can see that the three point bending test needed significantly less force to reach the bending angle than the cantilever test needed.

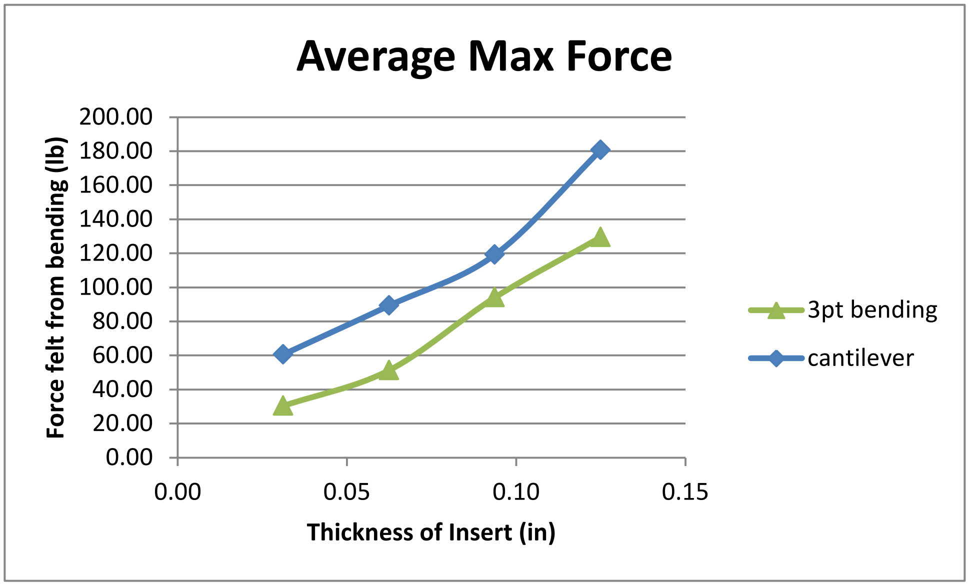

Figure 44: ***Average maximum force on each of the orthotic thicknesses comparing the two physical tests***

After the bending test the insert was measured at points a and b to determine the plastic deformation. Both tests showed similar plastic deformation at the same locations seen in Figure 45.

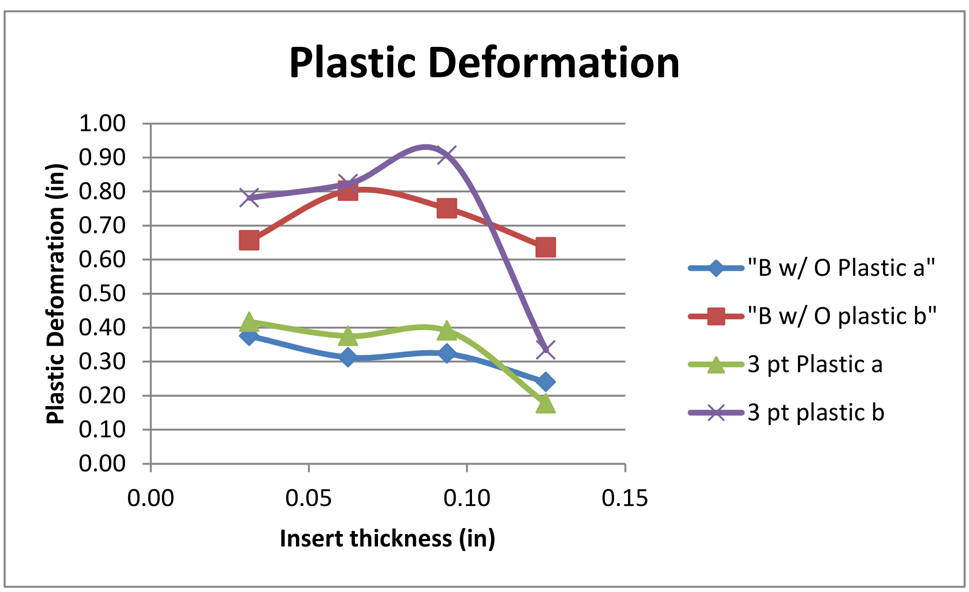

Figure 45: ***Plastic deformation at two points on the orthotic for both physical tests***

Figure 46 shows all three models of testing, and you can see that the beam-with-overhang test is much more closely modeled by the finite element analysis.

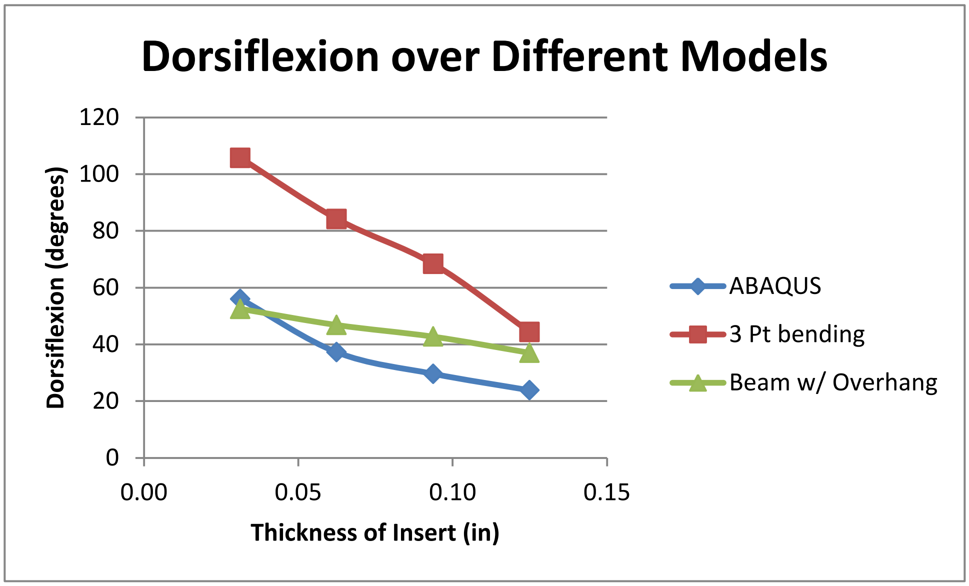

Figure 46: ***Angle of dorsiflexion over all three models (at 200 lb)***

However, when plotted alone (Figure 47) it is easier to see that the two tests are approximately 10 lb different on three out of the four testing thicknesses.

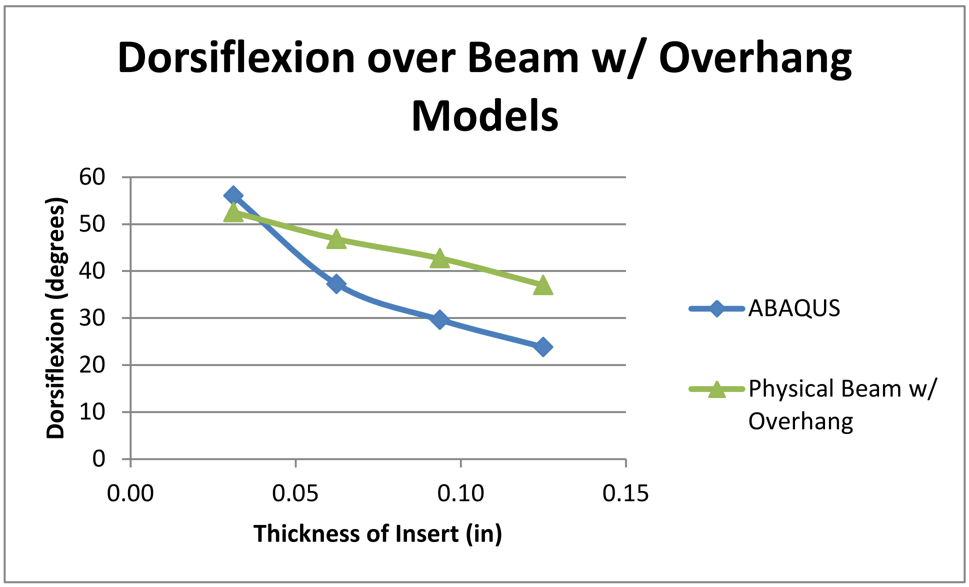

Figure 47: ***Angle of dorsiflexion over Abaqus and Beam-with-Overhang model (at 200 lb)***

4.4 Cycling

Figure 48 shows the forces recorded when the 1/32" thickness insert was cycled ten times to the 36-37° degree marker in the test. The regression lines are shown in both with a slightly negative slope on both tests.

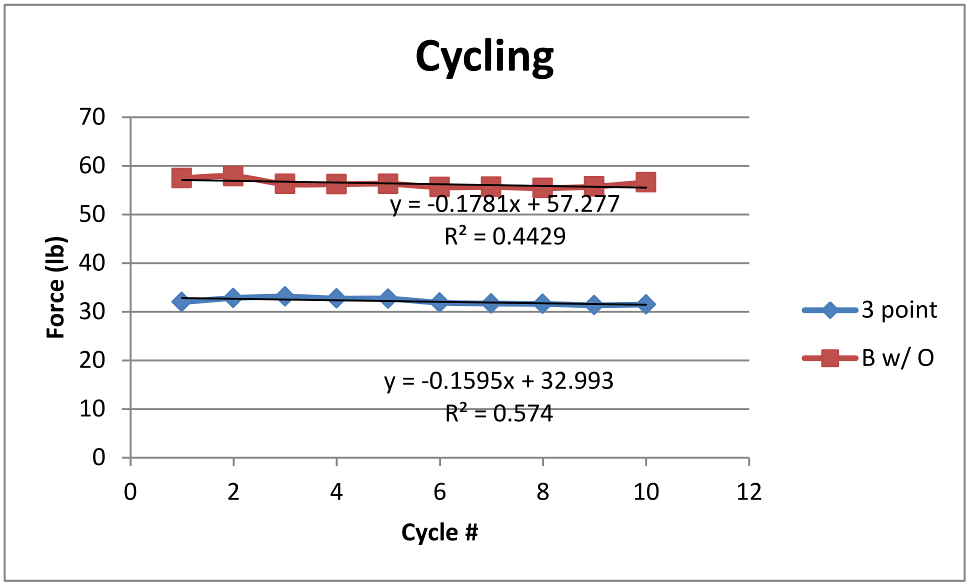

Figure 48: ***The force recorded over 10 cycles with the 1/32" thickness***

CHAPTER 5: **DISCUSSION**

5.1 Overview

This study created a clinician-adjustable, in-shoe orthotic to treat hallux rigidus. It is capable of specifically targeting stages of the condition and selectively limiting the angle of dorsiflexion available to the first MTP joint using the weight of the patient. Aside from this study, there is no known published work being done to give clinicians this kind of control over patients' gait. A computational and working prototype have been created that allow easy removal of the insert from the base part of the orthotic so that it can be exchanged for a different thickness. A finite element model in Abaqus was built that characterized the forces that would be applied to the orthotic. Several prototypes were tested on an ADMET tabletop stand to quantify the orthotics performance using a three point bending test and a modified beam-with-overhang test. Testing showed that the thicker inserts require more force to deflect to the same angle as the thinner inserts, and we saw that larger forces can deflect the same insert more that smaller forces. This suggested that there is a way to standardize the angle of dorsiflexion using an interchangeable orthotic and the weight of a subject. However, the magnitudes at which this correlation is seen vary with each testing method. Each of the tests done have presented a different magnitude of deflections for the inserts. Figures 46 and 47 appear to indicate that the finite element model and the beam-with-overhang testing yield similar results; however, at the thickest material (1/8”) there is a 43% difference in force. Additionally, the lowest amount of dorsiflexion offered to a 200 lb individual according to the beam-with-overhang test is 37°. This is not enough to be effective at treating late stage HR. However, this test does appear to be more accurate than the three-point bending test as it more closely approximates the virtual model.

5.2 Computational Model Discussion

Finite element models can be very powerful, allowing you to model a situation without taking the time or resources to create a prototype and do the actual physical testing; however, this type of analysis has limitations. The program is initially limited by the amount of information you provide. In this study elastic and plastic properties of the materials were provided along with the densities. It was modeled dynamically and all of the parts in the assembly were allowed to interact. The force was chosen to be applied in the negative y-direction with the entire area of the polyurethane “shoe sole” on the bending portion of the assembly coupled with the point where the load was being applied. This is not a perfect model of actual walking because all of the force is applied on the entire area at the same time. During walking the loading on the foot migrates from heel to toe and slightly laterally to medially finishing with toe off. This model attempts to take the toe off into consideration by placing the loading point off the centerline and more above where the great toe would experience the most force.

The setup of this loading is very similar to the beam loading below (Figure 49). The problem with this type of loading is that it is statistically indeterminate, so there is no simple way to calculate the deflection.

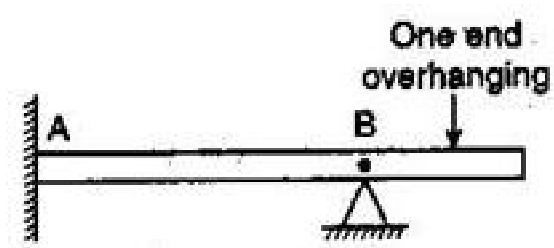

Figure 49: ***Beam-with-Overhang (Transtutors)***

Another issue with finite element modeling is that the simulation loading tends to model the material more stiffly than it behaves in real situations. This is due to the fact that rather than having infinitesimally small sections of the material experiencing loads the elements have finite lengths determined in the testing set up.

5.3 Physical Testing

The three-point bending test was first done on three different sized inserts with a deflection of one inch input into the machine. This first test was done to practice the testing method and prove that we were able to get different force values by using different insert thicknesses. The correlation appears almost linear. See Figure 40. Next the angle of bending was standardized for the three point bending and the beam-with-overhang testing. The graphs in Figures 42 and 43 confirm the relationship between thickness and bending force. In both testing set ups the thickest insert (1/8”) required the most force and the thinnest insert (1/32") required the least force to deflect to the 36°-37° angle. However, the magnitude varies between tests.

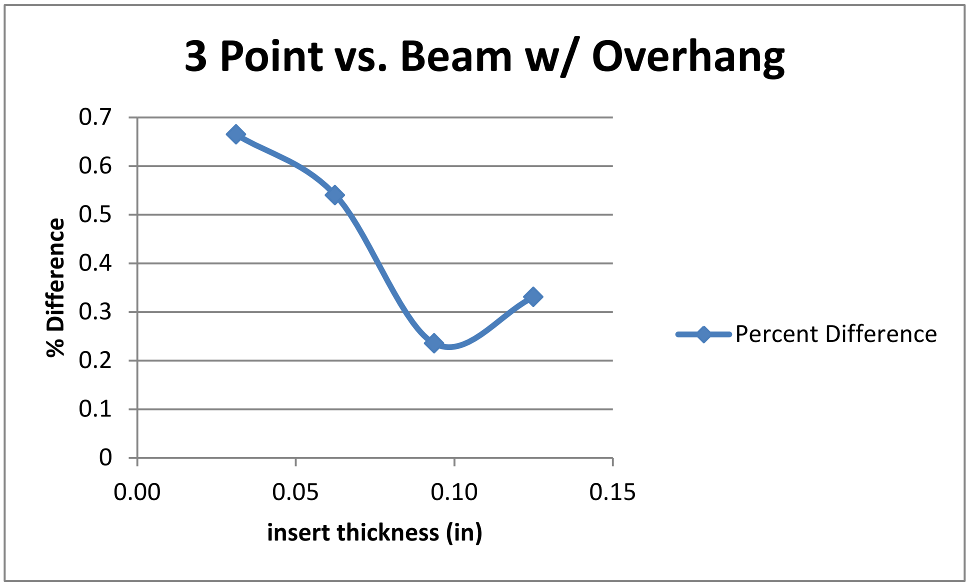

Figure 50: ***The percent difference for each sized insert between the 3 point and Beam-with-Overhang test to the same deflection angle (36-37°)***

Figure 50 shows us the percent difference in the amount of force needed to take the beam-with-overhang test and the three-point bending test to an angle of 36°-37°. There is a 66% difference at the thinnest insert. One potential explanation is the different length of the moment arms in the testing. The beam-with-overhang test is using only the one short side (~1.25") to create the entire angle that the three point bending test creates with that arm length and another twice as long lever arm (~2.5"). We see in Figure 45 that the computational model is much closer to the physical beam-with-overhang testing results. This makes sense because the testing set up is almost identical. The difference is in the loading. In the finite element model, the loading covers an area rather than a line load as it is loaded in the physical test stand. The area loading better demonstrates the forces that would be felt in the shoe.

5.4 Cycling

The test stand used in this study does not currently have the capabilities to do long term cycling tests. To address that issue, one of the inserts was taken through ten, consecutive cycles to see if the strength after cycling could be predicted. This data can be seen in Figure 48 and 51. In Figure 48, each of the lines was fit with a linear regression, and the slope of both lines was slightly negative. The beam-with-overhang set up cycling test has a slope of -0.1781 and an r^2 value of 0.44292. The three-point bending test has a slope of -0.1595 and an r^2 value of 0.57396. These negative slopes indicate a slight weakening of the insert over multiple loadings. After ten loading cycles this difference is only a few pounds but more information would have to be collected to determine how long the inserts would last before losing their ability to effectively restrict the range of motion. However, the r^2 values are low, so these regressions are not a very good fit of the data presented. In Figure 51, the average force over the ten loadings is shown with the standard deviation. The standard deviation calculated for the three-point bending cycling and the cantilever cycling were 0.637 and 0.810 respectively. This is small in comparison to the mean suggesting a minimal effect from cycling from our limited data.

Although the insert appears to at least be minimally affected by cycling, one observation during testing is that the base showed no signs of failure. It does not experience bending, but it is encouraging to see no deterioration at the insert pocket.

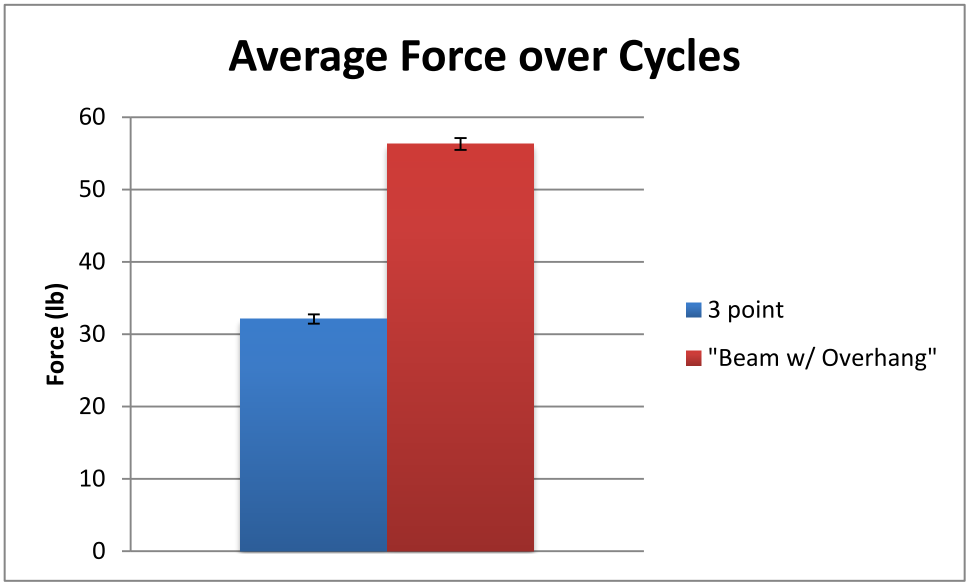

Figure 51: ***Average force over 10 cycles of loading of 1/32" insert***

5.5 Plastic Deformation

The physical prototypes were made out of 1095 spring steel rather than the 304 stainless steel because there was less plastic deformation after loading. This is due to higher yield strength. However, in the physical testing, each of the inserts saw significant plastic deformation. This could be in part because of the strain rate that was applied which will be discussed in the next section. In the test stand we are not able to apply the forces that would be coming from the toes after toe off. As seen in Figure 52, in the shoe there are forces (F_{Toe}) in the negative y-direction pushing on the orthotic from above, and there are reaction forces (F_{GRF}) in the positive y-direction. When F_{Toe} is added to the testing there should be less plastic deformation. Most feet do not have a completely flat plantar surface, so minor plastic deformation could be beneficial to positioning the toe in a more anatomical position.

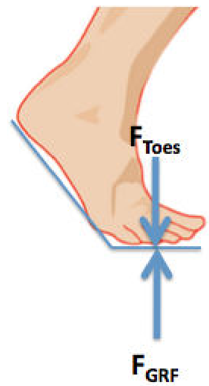

Figure 52: ***Forces on the insert***

5.6 Loading Rates

The gait cycle takes approximately one second from heel strike to toe off. This means that the orthotic would be experiencing approximately one bending cycle per second. Figure 53 shows the effect that the strain rate has on the stress in a steel object at room temperature. The yield strength and the ultimate tensile strength can be strongly influenced by the rate at which this material is loaded. This effect is magnified in higher temperatures, but we can see how the loading speed can vary these numbers by hundreds of MPa. The computational model ran about four times as fast as the orthotic would be loaded in a shoe. The ADMET testing machine used in this study was not able to load the bending tests at a rate that would approximate walking speeds. This may explain some of the differences between the finite element model and the physical testing. The three point bending tests were loaded once over the course of thirty-five seconds, and the cantilever tests were loaded once over the course of seven seconds. This is thirty-five times and seven times slower than natural gait respectively. Earlier work suggests that this would result in a lower yield point. (Wiesner and MacGillivray) Although this does not directly suggest that it would cause less deflection it does indicate that there may be less plastic deformation with faster loading times. Also it is reasonable to assume that there could be a change in the elastic modulus or other material properties that would further limit the deflection and allow this orthotic to target more stages of HR. This could suggest another reason why the beam-with-overhang test much more closely approximates the Abaqus model. The computational model is loaded twenty-eight times faster than this model, while it is loaded 140 times as fast as the three point bending test.

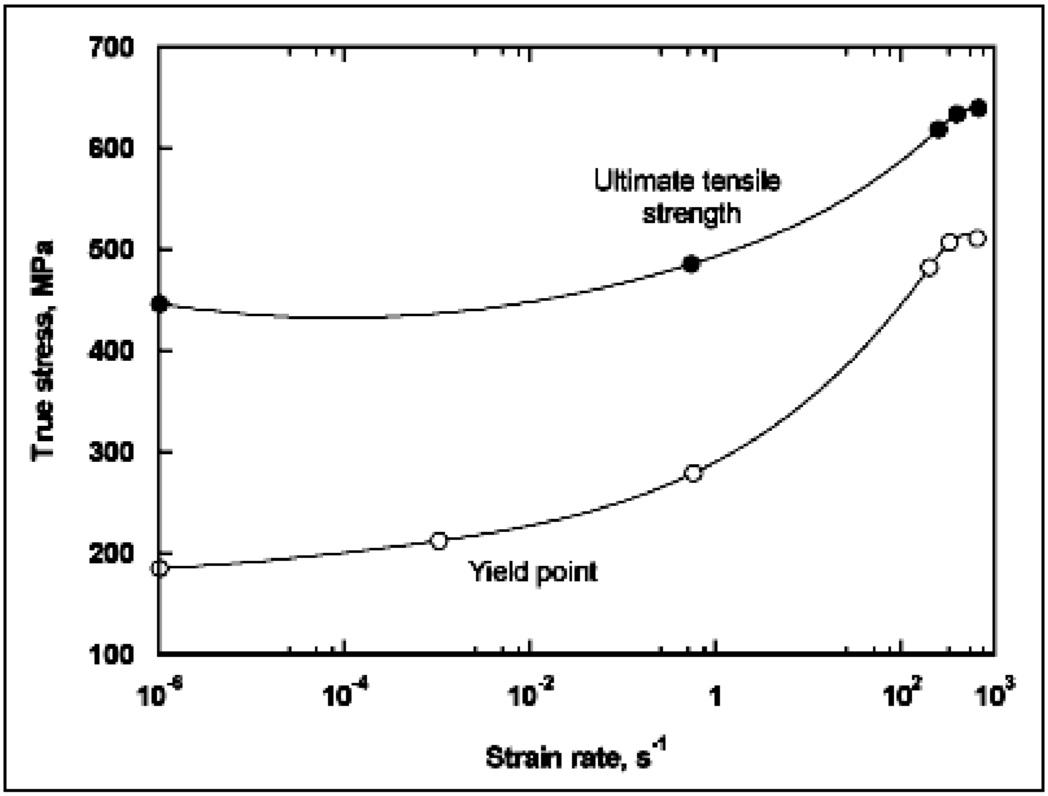

Figure 53: ***The variability of Yield Point and Ultimate Tensile Strength of steel due to strain rate at room temperature (Wiesner and MacGillivray)***

5.7 Manufacturing Considerations

To take the concept to market the orthotic design has to be easy to manufacture by an orthotist. The base should be very durable, comfortable, and last for an extended period of time, while the insert can be much more disposable because it is easy to replace. The orthotist must be able to make the base customizable to the patient while also retaining the interchangeable aspect of the insert. In the current design, the pocket for the insert can be removed from the rest of the base and molded into the bottom of a customized orthotic. It fits directly underneath the lateral arch of the foot, which is typically relatively flat. This would allow proper orientation of the insert. The base may have to be made slightly thicker than usual. The existing design should allow the orthotic to be no thicker than the ones currently on the market. For manufacturing efficiency, the inserts can be laser cut in bulk and any that are thicker than the base pocket can be cost-effectively machined down to fit. The thinner inserts are anticipated to be in higher demand based on the comfort in the shoe. They can easily be held in place by a foam plug, which can also be laser cut into the precise size and shape. Another benefit of the foam plug is that it attenuates or eliminates any noise created by the orthotic while walking.

5.8 Future Work

Although the current concept has shown that different loads and different thicknesses of inserts can selectively create different displacements, more work needs to be done to address different output values. Additional work is ongoing to determine better methods that are physiologically accurate and produce a refined clinical chart that uses these values to determine which sized orthotic insert should be used. See the first iteration in Appendix C. Future testing should include a machine that can create a faster loading rate that would be able to more closely simulate walking speeds. Proposed work also included clinical testing to measure the angle of dorsiflexion during gait.

Another step in the development of the product that is still needed is the sizing of the inserts. There should be a small, medium and large shape created so it could treat a wider range of foot sizes. Also, it would be beneficial to create more insert thicknesses once the chart values have been finalized.

5.9 Conclusions

The creation of an orthotic that has removable, variable-load inserts was demonstrated through multiple generations of prototypes. A provisional patent is filed for the current design. This project also demonstrated the feasibility of making a clinical chart from bending tests that indicates the appropriate insert used by specific patients. (Appendix C) Clinical input suggested the chart be easy to understand and use. More work must be done to finalize an accurate version of this chart; however, the data collected proves the validity of the concept by showing there is a significant difference in forces required to bend the inserts of different thicknesses. This is a promising new method of treatment for the field of podiatry and hallux rigidus.

APPENDIX A: Clinical Hallux Rigidus Patients' Foot Measurements

Patient	Width ball big	width ball	width heel	MT head to tip	MTP length	MTP width	MTP depth
HR1	9.2	8.9	5.5	4.8	2.7	2.5	2.2
HR2	10.5	9.7	4.5?	4.5	3	2.9	2
HR3	11	9.8	5.5?	5.9	3.7	2.8	2.2
HR4	9.7	8.7	5.4?	4.9	2.7	2.9	2
HR5	9.7	8.8	4.8	4.8	2.6	2.4	2.3
HR6	10		5.5	5.3	3	2.3	2.2
HR7	10.5	9.2	4.8	5	3.2	2.5	2.5
HR8	9.5	8.2	5.3	5.2	2.6	2.1	2.2
HR9	10.8	10	4.8	6.1	3.4	2.5	2.6
HR10	10.2	9.2	4.9	6	3.4	3.2	2.7
HR11	10.2	9.2	5?	5.1	2	2.7	2
HR12	11.2	10.2	5?	5.7	2.5	2.8	2.5
HR13	10.8	9.3	4.5	6.1	2.8	2.5	2.5
HR14	10.8	9.7	4.5	5.2	3.4	2.8	2.8
HR15	10.7	9.6	4	5	2.6	2.7	2.5
HR16	9.6	8.6	3.5	5.1	2.9	3	2.7
HR17	10.2	8.5	4	5.3	2.7	2.5	2.5
HR18	11.1	10.2	4.5	6.4	3.3	2.6	2.7
HR19	10.8	9.3	4.5	5.3	2.7	2.8	2.4
HR20	11	9.7	4.4	5.4	3.2	2.7	3.2
HR21	10.3	9.2	4.2	5.2	3.2	2.5	2.5
HR22	11.4	10.2	4.6	5.9	3.2	2.7	2.8
HR23	10.3	8.5	4	5.3	2.5	2.5	2.5
HR24	9		4	4.8	2.3	2.3	2.4
HR25	13	9.3	3.5	5.5	2.2	2.3	2.4
HR26	9.6	8.5	4	5.6	2.5	2.5	2.5
HR27	9.4	8.5	5	4.3	3.4	2	2
HR28	9.7	8.8	4.5	5	2.5	2.5	2
HR29	10.3	8.9	4.6	5.3	2.5	2.3	1.7
HR30	11	9.8	3.8	5.1	2.5	3.5	2.3

Mean	10.38333333	9.232142857	4.468	5.303333333	2.84	2.61	2.393333333
Stand Dev	0.809036606	0.588188412	0.545985348	0.490238037	0.420672696	0.3111159	0.311761772
Median	10.3	9.2	4.5	5.25	2.7	2.5	2.45
inches mean	4.087926509	3.634701912	1.759055118	2.087926509	1.118110236	1.027559055	0.942257218

APPENDIX B: Data from Regressions Based on the three-point bending and Beam with Overhang Tests

3 Point						
Inches	Angle	Stage	1/32" (lb)	1/16" (lb)	3/32" (lb)	1/8" (lb)
0.025	1.63	3 or 4	0.87	2.00	3.96	2.74
0.05	3.26	3 or 4	1.88	3.55	6.59	5.39
0.075	4.89	3 or 4	2.90	5.16	9.38	8.04
0.1	6.52	3 or 4	3.94	6.83	12.34	10.73
0.125	8.14	3 or 4	4.98	8.56	15.44	13.51
0.15	9.76	3 or 4	6.05	10.34	18.69	16.40
0.175	11.37	2	7.12	12.18	22.08	19.46
0.2	12.98	2	8.21	14.08	25.60	22.70
0.225	14.58	2	9.32	16.03	29.25	26.18
0.25	16.18	2	10.44	18.04	33.02	29.92
0.275	17.76	2	11.57	20.10	36.89	33.96
0.3	19.34	2	12.72	22.21	40.88	38.35
0.325	20.91	2	13.89	24.38	44.96	43.11
0.35	22.47	2	15.07	26.60	49.13	48.29
0.375	24.02	2	16.27	28.87	53.39	53.91
0.4	25.56	2	17.49	31.19	57.72	60.03
0.425	27.09	2	18.72	33.56	62.13	66.67
0.45	28.60	2	19.97	35.98	66.60	73.87
0.475	30.11	2	21.23	38.45	71.13	81.66
0.5	31.60	1	22.52	40.97	75.70	90.09
0.525	33.07	1	23.82	43.54	80.33	99.20
0.55	34.54	1	25.14	46.15	84.99	109.01
0.575	35.99	1	26.48	48.82	89.68	119.57
0.6	37.42	1	27.83	51.52	94.39	130.91
0.625	38.84	1	29.21	54.28	99.12	143.07
0.65	40.25	1	30.60	57.08	103.86	156.08
0.675	41.64	0	32.02	59.92	108.60	169.99
0.7	43.01	0	33.45	62.81	113.34	184.83
0.725	44.37	0	34.91	65.74	118.07	200.63
0.75	45.72	0	36.38	68.71	122.79	217.43
0.775	47.05	0	37.88	71.72	127.48	235.28
0.8	48.36	0	39.40	74.78	132.13	254.20
0.825	49.66	0	40.93	77.88	136.75	274.24
0.85	50.95	0	42.49	81.01	141.33	295.43
0.875	52.21	0	44.07	84.19	145.86	317.80
0.9	53.46	0	45.67	87.41	150.33	341.40
0.925	54.70	0	47.30	90.66	154.73	366.26
0.95	55.92	0	48.95	93.95	159.06	392.41
0.975	57.12	0	50.62	97.28	163.31	419.90
1	58.31	0	52.31	100.65	167.48	448.77
1.025	59.49	0	54.02	104.05	171.56	479.04
1.05	60.65	0	55.76	107.49	175.54	510.75

1.075	61.79	N/A	57.53	110.96	179.41	543.95
1.1	62.92	N/A	59.32	114.47	183.17	578.67
1.125	64.03	N/A	61.13	118.01	186.82	614.94
1.15	65.13	N/A	62.96	121.58	190.33	652.80
1.175	66.21	N/A	64.82	125.19	193.72	692.30
1.2	67.28	N/A	66.71	128.83	196.96	733.46
1.225	68.33	N/A	68.62	132.50	200.06	776.32
1.25	69.37	N/A	70.56	136.20	203.01	820.92
1.275	70.40	N/A	72.52	139.93	205.80	867.30
1.3	71.41	N/A	74.51	143.69	208.42	915.49
1.325	72.40	N/A	76.53	147.48	210.87	965.53
1.35	73.39	N/A	78.57	151.29	213.14	1017.46
1.375	74.36	N/A	80.64	155.14	215.22	1071.32
1.4	75.31	N/A	82.74	159.01	217.11	1127.13
B-w-O						
Inches	**Angle**	**Stage**	**1/32" (lb)**	**1/16" (lb)**	**3/32" (lb)**	**1/8" (lb)**
			r^2=0.99984	*r^2=0.99997*	*r^2=0.99999*	*r^2=0.99957*
0.025	1.05	3 or 4	0.53	0.53	0.98	1.70
0.05	2.10	3 or 4	1.02	0.98	1.64	2.84
0.075	3.15	3 or 4	1.54	1.50	2.37	4.02
0.1	4.20	3 or 4	2.11	2.09	3.18	5.23
0.125	5.25	3 or 4	2.73	2.77	4.07	6.51
0.15	6.29	3 or 4	3.39	3.51	5.06	7.85
0.175	7.32	3 or 4	4.10	4.34	6.13	9.27
0.2	8.36	3 or 4	4.85	5.25	7.30	10.79
0.225	9.38	3 or 4	5.66	6.25	8.57	12.41
0.25	10.40	3 or 4	6.51	7.33	9.94	14.16
0.275	11.42	2	7.42	8.49	11.42	16.04
0.3	12.43	2	8.38	9.75	13.02	18.06
0.325	13.43	2	9.39	11.10	14.73	20.24
0.35	14.42	2	10.46	12.54	16.56	22.59
0.375	15.40	2	11.59	14.08	18.51	25.13
0.4	16.37	2	12.77	15.72	20.59	27.86
0.425	17.34	2	14.01	17.46	22.81	30.80
0.45	18.29	2	15.32	19.29	25.16	33.96
0.475	19.23	2	16.68	21.23	27.65	37.36
0.5	20.17	2	18.11	23.28	30.29	41.01
0.525	21.09	2	19.60	25.44	33.07	44.92
0.55	22.00	2	21.15	27.70	36.01	49.09
0.575	22.90	2	22.77	30.08	39.10	53.56
0.6	23.78	2	24.46	32.57	42.36	58.32
0.625	24.66	2	26.22	35.17	45.78	63.40
0.65	25.52	2	28.05	37.89	49.37	68.80
0.675	26.37	2	29.94	40.74	53.13	74.53
0.7	27.21	2	31.92	43.70	57.07	80.62

0.725	28.04	2	33.96	46.79	61.19	87.07
0.75	28.85	2	36.08	50.00	65.50	93.89
0.775	29.65	2	38.27	53.34	69.99	101.10
0.8	30.44	2	40.54	56.81	74.68	108.72
0.825	31.21	1	42.89	60.41	79.57	116.74
0.85	31.98	1	45.32	64.15	84.66	125.19
0.875	32.73	1	47.83	68.02	89.95	134.09
0.9	33.47	1	50.42	72.02	95.45	143.43
0.925	34.19	1	53.10	76.17	101.17	153.24
0.95	34.91	1	55.85	80.46	107.11	163.52
0.975	35.61	1	58.70	84.89	113.26	174.30
1	36.30	1	61.63	89.47	119.65	185.57
1.025	36.97	1	64.65	94.19	126.26	197.37
1.05	37.64	1	67.75	99.07	133.11	209.69
1.075	38.29	1	70.95	104.09	140.19	222.55
1.1	38.94	1	74.24	109.27	147.52	235.97
1.125	39.57	1	77.62	114.61	155.09	249.95
1.15	40.19	1	81.10	120.10	162.92	264.51
1.175	40.79	0	84.67	125.75	171.00	279.67
1.2	41.39	0	88.34	131.56	179.34	295.43
1.225	41.98	0	92.10	137.54	187.94	311.81
1.25	42.56	0	95.96	143.68	196.80	328.82
1.275	43.12	0	99.93	149.99	205.94	346.47
1.3	43.68	0	103.99	156.46	215.36	364.78
1.325	44.22	0	108.16	163.11	225.05	383.75
1.35	44.76	0	112.43	169.93	235.02	403.41
1.375	45.28	0	116.80	176.93	245.29	423.76
1.4	45.80	0	121.28	184.11	255.84	444.82
1.425	46.31	0	125.87	191.46	266.69	466.60
1.45	46.80	0	130.57	198.99	277.84	489.11
1.475	47.29	0	135.37	206.71	289.29	512.37
1.5	47.77	0	140.29	214.61	301.05	536.39
1.525	48.24	0	145.32	222.70	313.12	561.17
1.55	48.70	0	150.46	230.98	325.50	586.74
1.575	49.16	0	155.71	239.45	338.21	613.11
1.6	49.60	0	161.09	248.12	351.24	640.29
1.625	50.04	0	166.57	256.97	364.60	668.28
1.65	50.47	0	172.18	266.03	378.29	697.12
1.675	50.89	0	177.90	275.28	392.31	726.80
1.7	51.31	0	183.75	284.74	406.68	757.34
1.725	51.72	0	189.72	294.40	421.39	788.75
1.75	52.12	0	195.81	304.26	436.44	821.05
1.775	52.51	0	202.02	314.33	451.85	854.25
1.8	52.90	0	208.36	324.61	467.62	888.36
1.825	53.28	0	214.82	335.10	483.75	923.39
1.85	53.65	0	221.42	345.81	500.24	959.36
1.875	54.02	0	228.14	356.72	517.10	996.28

1.9	54.38	0	234.99	367.86	534.33	1034.16
1.925	54.73	0	241.97	379.21	551.94	1073.02
1.95	55.08	0	249.09	390.79	569.93	1112.86
1.975	55.42	0	256.34	402.59	588.31	1153.71
2	55.75	0	263.72	414.61	607.07	1195.57
2.25	58.82	0	345.23	547.65	816.99	1672.71
2.5	61.43	0	441.55	705.36	1070.29	2265.24
2.75	63.66	N/A	553.88	889.73	1371.03	2985.92
3	65.59	N/A	683.42	1102.75	1723.29	3847.52

APPENDIX C: Clinical Chart for Choosing Insert Thickness for Hallux Rigidus Patients

Weight *Pounds*	**1/32"** *degrees*	**1/16"** *degrees*	**3/32"** *degrees*	**1/8"** *degrees*
70	38	33	29	26
80	40	34	30	27
90	41	36	33	28
100	43	37	34	30
110	44	39	35	31
120	45	40	36	32
130	47	41	37	32
140	48	42	38	33
150	49	43	39	34
160	50	44	40	35
170	50	45	41	35
180	51	46	42	36
190	52	46	42	37
200	53	47	43	37
210	53	47	43	38
220	54	48	44	38
Grade 0	Grade 1	Grade 2	Grade 3	Grade 4

APENDEX D: Institutional Review Board Approval for Human Subject Testing

IRBNet Board Document Published

REPLY REPLY ALL FORWARD ...

Lucia La Salle <no-reply@irbnet.org>

Thu 2/26/2015 10:40 AM

Inbox

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To: Dancisak, Michael J; Turlington, Callie F;

Please note that Tulane University Biomedical IRB has published the following Board Document on IRBNet:

Project Title: [648102-2] HR orthotic project
Principal Investigator: Callie Turlington

Submission Type: Revision
Date Submitted: January 14, 2015

Document Type: Approval Letter
Document Description: Approval Letter
Publish Date: February 26, 2015

Should you have any questions you may contact Lucia La Salle at llasalle@tulane.edu.

Thank you,
The IRBNet Support Team

www.irbnet.org

IRB 1 of 4

Tulane University
Human Research Protection Program

10/22/14

TO: Tulane University Human Research Protection Program

RE: HR Orthotic Project

***Please complete all information requested in the brackets. If that information is not applicable, please delete.**

PRINCIPAL INVESTIGATOR: Callie Turlington

STUDY COORDINATOR(S) (if applicable): N/A

Enclosed please find the following documents for a/an Expedited Review Submission:

1. Cover Sheet
2. CITI Training of all Investigators
3. Online Application Part I
4. Application Part II
5. Supplement G
6. Protocol
7. Questionnaire/ Survey
8. Consent Form
9. Letter of Support from second location
10. Recruitment Material (Flyer)
11. PI CV
12. Emergency Evacuation Card

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

HUMAN RESEARCH CURRICULUM COMPLETION REPORT

Printed on 05/20/2014

LEARNER	Callie Turlington (ID: 4161566)
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EMAIL	cturling@tulane.edu
INSTITUTION	Tulane University
EXPIRATION DATE	05/19/2018

GROUP 1.BIOMEDICAL RESEARCH INVESTIGATORS AND KEY PERSONNEL.

COURSE/STAGE:	Basic Course/1
PASSED ON:	05/20/2014
REFERENCE ID:	12997320

REQUIRED MODULES	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives	05/16/14	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research	05/16/14	4/5 (80%)
Introduction	05/16/14	No Quiz
Students in Research	05/16/14	7/10 (70%)
History and Ethics of Human Subjects Research	05/20/14	4/7 (57%)
Basic Institutional Review Board (IRB) Regulations and Review Process	05/19/14	5/5 (100%)
Informed Consent	05/19/14	3/4 (75%)
Social and Behavioral Research (SBR) for Biomedical Researchers	05/19/14	3/4 (75%)
Records-Based Research	05/19/14	2/2 (100%)
Genetic Research in Human Populations	05/19/14	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	05/19/14	3/4 (75%)
Vulnerable Subjects - Research Involving Prisoners	05/19/14	4/4 (100%)
Vulnerable Subjects - Research Involving Children	05/19/14	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates	05/20/14	3/3 (100%)
FDA-Regulated Research	05/20/14	4/5 (80%)
Research and HIPAA Privacy Protections	05/20/14	2/5 (40%)
Vulnerable Subjects - Research Involving Workers/Employees	05/20/14	4/4 (100%)
Hot Topics	05/20/14	No Quiz
Conflicts of Interest in Research Involving Human Subjects	05/20/14	5/5 (100%)
Tulane University Module	05/20/14	No Quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Progam course site is unethical, and may be considered research misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Program Course Coordinator

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report
Printed on 1/10/2013

Learner: Michael Dancisak (username: Micman)
Institution: Tulane University
Contact Information Tulane University
Center for Anatomical and Movement Sciences
500 Lindy Boggs
New Orleans, LA 70118
Phone: 504-865-5301
Email: dancisak@tulane.edu

Group 1.Biomedical Research Investigators and Key Personnel.:

Stage 1. Basic Course Passed on 01/10/13 (Ref # 990446)

Required Modules	Date Completed	Score
Students in Research	08/22/12	7/10 (70%)
Avoiding Group Harms: U.S. Research Perspectives	08/21/12	2/3 (67%)
Unanticipated Problems and Reporting Requirements in Biomedical Research	08/21/12	5/6 (83%)
Introduction	04/20/07	no quiz
History and Ethical Principles	08/22/12	5/6 (83%)
Basic Institutional Review Board (IRB) Regulations and Review Process	09/18/12	5/5 (100%)
Informed Consent	09/18/12	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	09/20/12	3/4 (75%)
Records-Based Research	09/20/12	2/2 (100%)
Genetic Research in Human Populations	09/20/12	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	09/26/12	4/4 (100%)
Vulnerable Subjects - Research Involving Prisoners	09/27/12	3/4 (75%)
Vulnerable Subjects - Research Involving Children	01/09/13	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates	01/09/13	2/3 (67%)
FDA-Regulated Research	01/09/13	4/5 (80%)
Human Subjects Research at the VA	01/10/13	2/3 (67%)
Research and HIPAA Privacy Protections	01/10/13	4/5 (80%)
Vulnerable Subjects - Research Involving Workers/Employees	01/10/13	3/4 (75%)
Hot Topics	01/10/13	no quiz
Conflicts of Interest in Research Involving Human Subjects	01/10/13	4/5 (80%)
Tulane University Module	01/10/13	no quiz

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Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report
Printed on 12/14/2012

Learner: Lauren Jensen (username: ljensen27)
Institution: Tulane University
Contact Information 2823 Soniat
2823 Soniat
NEW ORLEANS, Louisiana [LA] 70115 USA
Department: Aging Studies
Phone: 5047153887
Email: ljensen2@tulane.edu

Group 1.Biomedical Research Investigators and Key Personnel.:

Stage 1. Basic Course Passed on 12/14/12 (Ref # 9331124)

Required Modules	Date Completed	Score
Avoiding Group Harms: U.S. Research Perspectives	08/07/12	1/3 (33%)
Unanticipated Problems and Reporting Requirements in Biomedical Research	12/14/12	4/6 (67%)
Introduction	08/07/12	no quiz
Students in Research	08/07/12	9/10 (90%)
History and Ethical Principles	08/07/12	6/6 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	08/08/12	5/5 (100%)
Informed Consent	08/08/12	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	08/08/12	3/4 (75%)
Records-Based Research	08/08/12	2/2 (100%)
Genetic Research in Human Populations	08/08/12	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	08/09/12	4/4 (100%)
Vulnerable Subjects - Research Involving Prisoners	08/09/12	3/4 (75%)
Vulnerable Subjects - Research Involving Children	08/09/12	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates	08/09/12	3/3 (100%)
FDA-Regulated Research	08/20/12	4/5 (80%)
Human Subjects Research at the VA	08/20/12	2/3 (67%)
Research and HIPAA Privacy Protections	08/20/12	4/5 (80%)

Vulnerable Subjects - Research Involving Workers/Employees	08/20/12	4/4 (100%)
Hot Topics	08/20/12	no quiz
Conflicts of Interest in Research Involving Human Subjects	08/20/12	5/5 (100%)
Tulane University Module	08/20/12	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

HUMAN RESEARCH CURRICULUM COMPLETION REPORT

Printed on 11/23/2014

LEARNER	Leon Shingledecker (ID: 4514313)
PHONE	504-888-9403
EMAIL	drbreeze2004@yahoo.com
INSTITUTION	Tulane University
EXPIRATION DATE	11/22/2018

GROUP 1.BIOMEDICAL RESEARCH INVESTIGATORS AND KEY PERSONNEL.

COURSE/STAGE:	Basic Course/1
PASSED ON:	11/23/2014
REFERENCE ID:	14639156

REQUIRED MODULES	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives	11/12/14	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research	11/12/14	4/5 (80%)
Introduction	11/21/14	No Quiz
Students in Research	11/22/14	10/10 (100%)
History and Ethics of Human Subjects Research	11/22/14	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	11/22/14	5/5 (100%)
Informed Consent	11/22/14	4/4 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers	11/22/14	4/4 (100%)
Records-Based Research	11/23/14	2/2 (100%)
Genetic Research in Human Populations	11/23/14	2/2 (100%)
Populations in Research Requiring Additional Considerations and/or Protections	11/23/14	5/5 (100%)
Vulnerable Subjects - Research Involving Prisoners	11/23/14	4/4 (100%)
Vulnerable Subjects - Research Involving Children	11/23/14	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates	11/23/14	3/3 (100%)
FDA-Regulated Research	11/23/14	5/5 (100%)
Research and HIPAA Privacy Protections	11/23/14	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees	11/23/14	4/4 (100%)
Hot Topics	11/23/14	No Quiz
Conflicts of Interest in Research Involving Human Subjects	11/23/14	5/5 (100%)
Tulane University Module	11/23/14	No Quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Program course site is unethical, and may be considered research misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Program Course Coordinator

Study Title: HR Orthotic Project

1. **Study aim, background, and design**

   Hallux rigidus is a common great toe condition in people over the age of fifty. It is characterized by pain and limited range of motion of the first metatarsophalangeal (MTP) joint (McMaster 82-87) that hinges the big toe to the rest of the foot. Symptoms usually begin between the ages of thirty and sixty. (American Academy of Orthopedic Surgeons) The aim of this study is to create an adjustable spring orthotic that will be able to selectively limit the amount of dorsiflexion during walking and reduce the pressure felt under the foot, effectively protecting the affected joint.

   The plantar pressure will be recorded while walking using both the new and the current most common type of hallux rigidus orthotic on the market, Morton's extension. Each subject will be fitted with one of the orthotics (Morton's extension or the adjustable spring) and asked to walk around to get used to the new feel. They will then answer a survey about their feelings on the comfort. Next, the subjects will walk down a designated 20 ft walkway while data is collected on their plantar pressure. This will be done three times. The process will be completed with the other orthotic after the first is finished. The data will be analyzed by finding the peak and the average plantar pressure under the first MTP joint for each trial. These will then be averaged over the three trials taken in the same orthotic. Average results will be compared to the same subjects averages with the opposite orthotic. An average will also be taken over all of the subjects with each orthotic to compare the difference of the entire group. The range of the differences between each patient will be checked for consistency.
   ! ! ! ! ! !

2. **Subject Population**

   Typically symptoms do not start before the age of thirty, but any individuals over the age of eighteen will be recruited. We do not want to exclude any potential participants that are affected by the condition. Non-English speakers will be excluded because we do not have the resources to obtain informed consent from these potential participants. Also we will only be recruiting people in independent living to ensure that they are able to safely and effectively follow protocol.

   Fifteen subjects Will be recruited from a local podiatric clinic. Recruiting will be done mostly from the office of Dr. Leon Shingledecker, a local podiatrist. Flyers will be mailed or distributed in the office informing patients of the study and asking if they would be willing to participate.

3. **Procedure**

   The entire time that the patient must spend with us should take no more than an hour and a half over two sessions. The data collection will occur between the hours of 8AM and 5PM. The subjects will be fitted for their orthotics at the clinic of Dr. Leon G. Shingledecker, DPM,and the data will be recorded at the Center for Anatomical and Movement Sciences at Tulane.

   During the first session:

When the subjects arrive at the clinic they will first fill out a basic questionnaire about age, weight, and general problems with hallux rigidus while reading about their role in the experiment and have their responsibilities explained. [<10 minutes]
After giving their informed consent, the subjects will be fitted by the physician in two different orthotic styles (Morton's extension and the new orthotic). [<20 minutes]

During the second session:
One orthotic will be inserted into the shoe with in-shoe plantar pressure measuring devices. [<10 minutes]
The participants will walk around in the fitted orthotic for 10 minutes. [10 minutes]
At the end of that time, the participants will fill out another quick survey rating their comfort and making any other comments. [<5 minutes}
They will then be instructed to walk down a 20ft walkway while their plantar pressures are recorded. [2 minutes]
This walk will be repeated three times. [5 minutes]
The subject will then be fitted with the other orthotic with the plantar pressure measuring system.
The participants will again walk around for 10 minutes to acclimate to the orthotic.
The entire original procedure will be completed again.

4. Risks

The risks are very minimal for this study. If the orthotic is not in fact able to reduce the plantar pressure of the patient, temporary pain could occur from the excess pressure. The effects would be very temporary due to the small amount of time that the orthotics are in use and the lack of vigorous activity conducted. There is also the risk of minor skin irritation from having a new shape in the shoe. Also since there is no social stigma the risk of harm to the patient due to privacy breach is not detrimental to the subjects' reputation. However the information will be kept safely locked in the Center for Anatomical and Movement Sciences lab. Subject data will also be identifiable only by subject number.

5. Benefits

If this research is successful, it could benefit the entire hallux rigidus community in the future by providing another treatment option. It would allow the patient and the physician to both give input on the optimal amount of restricted range of motion needed.

6. Remuneration

There will be no payment for participation in this research study.

7. Academic or Extra Credit

N/A

8. Costs

Subject will be required to pay for transportation to the research location.

9. Alternatives

The subjects are currently being treated for the condition so they are aware of the other orthotic options. There are also surgical treatments including cheilectomies to remove bone spurs from the joint. (Muscarella and Hetherington 313-325; Harisboure et al. ; Nawoczenski) Arthroplasty is another option. It is the replacement or remodeling of a joint surface which can sometimes result in an unstable joint. (Taranow, Moutsatson, and Cooper 713-28, ix-x) Arthrodesis is the removal of the joint by fusing the bone together which can be effective at reducing pain but can negatively affect other joints in the future. (Nawoczenski ; Harisboure et al. ; Muscarella and Hetherington 313-325)

10. Consent process and documentation

The consent form will be submitted with the rest of the application. When the subjects arrive for their first visit they will be given the consent form and asked to look over it. When they are finished the PI will ask them if they have any questions and if not ask them to sign and date their consent. The PI will be sure to inform them that they are free to stop at any time.

11. Qualifications of the investigators

The PI is a biomedical engineering master's student that has volunteered her time tutoring and teaching swim lessons so she is practiced giving instructions and ensuring that they are followed correctly.

Dr. Michael Dansicak is in the population that we are studying. He also a Senior Professor of the Practice at Tulane and the Director of the Center for Anatomical and Movement Sciences. including This puts him in charge of the cadaver lab so he has experience with following strict protocol so as not to disrespect any of the people that donated their bodies to science.

Lauren Jensen is a PHD student in the aging program at Tulane. She obtained her bachelor's degree in biomedical engineering from George Washington University and has already completed two IRBs for her PHD.

Dr. Leon Shingledecker is a Tulane faculty member and a practicing podiatric surgeon and wound care specialist.

12. References

American Academy of Orthopedic Surgeons. "Stiff Big Toe (Hallux Rigidus)." September 2012 2012.Web.

Harisboure, A., et al. "**The Valenti Technique in the Treatment of Hallux Rigidus.**

." *Pubmed* 3.95 (2009)Print.

McMaster, M. J. "The Pathogenesis of Hallux Rigidus." *The Journal of bone and joint surgery.British volume* 60.1 (1978): 82-7. Print.

Muscarella, Vincent, and Vincent J. Hetherington. "Hallux Limitus and Hallux Rigidus." *Textbook of Hallux Valgus and Forefoot Surgery.* Ed. Vincent J. Hetherington. Independence, Ohio: , 2000. 313-325. Print.

Nawoczenski, D. A. "Nonoperative and Operative Intervention for Hallux Rigidus." *Pubmed* 12.29 (1999)Print.

Taranow, W. S., M. J. Moutsatson, and J. M. Cooper. "Contemporary Approaches to Stage II and III Hallux Rigidus: The Role of Metallic Hemiarthroplasty of the Proximal Phalanx." *Foot and ankle clinics* 10.4 (2005): 713,28, ix-x. Print.

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Basic Information Survey

!

Subject!Number:!________________________!

Date:!____________________________________!

!

Age:!_________________________________!

Height:!_____________________________!

Weight:!______________________________!

Other!Preexisting!Conditions!Relating!to!the!Foot!or!Lower!Leg!(Not!including!hallux!rigidus!or!limitus):!

____

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!

Orthotic(Questionnaire(

!

How!comfortable!is!the!orthotic!you!are!wearing!on!a!scale!of!1610!with!1!being!very! painful!and!10!being!extremely!comfortable?!

!

!

Do!you!have!any!more!comments!about!how!the!orthotic!feels!in!your!shoe?!

!

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!

!

For(researchers(use(only:(

Date:!________________________!

!

Subject!Identification!Number:!!____!

!

Orthotic!Type:!____!

!

Other!Comments:!

!

!

!

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Tulane University Human Research Protection Office
Biomedical IRB Consent Form for Participation in a Research Study
HR Orthotic Project

Principal Investigator: Callie Turlington
Study Title: HR Orthotic Project
Performance Sites: Center for Anatomical Movement Sciences and Houma Blvd Medical Plaza I (Dr. Leon G. Shingledecker, DPM)

The following informed consent is required by Tulane University for any research study conducted by investigators at the University. This study has been reviewed by the University's Institutional Review Board for Human Subjects.

Introduction

You are invited to participate in a research study to investigate a new orthotic to treat hallux rigidus or limitus. You are being asked to participate because you have been treated for symptoms associated with or diagnosed with hallux rigidus or limitus.

No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document if applicable.

There will be a total of fifteen participants in this study and you will not be contacted in the future.

Disclosure of Potential Conflict of Interest

The investigator in this study is interested in the knowledge to be gained from this study and in your well-being. You are under no obligation to participate in any research study offered to you.

Why is this study being done?

We are conducting this research study to try to find a better way to treat hallux rigidus with an orthotic that is easily adjustable by a doctor in the office. The orthotic is also anticipated to reduce the pressure under the affected joint to increase comfort.

In this study we are gathering information on the comfort of the insert and measuring the pressure under the foot while you are walking.

What are the study procedures? What will I be asked to do?

If you agree to take part in this study, you will answer a basic questionnaire about height and weight and be fitted with an orthotic by Dr. Leon G. Shingledecker, DPM at the clinic on Houma Boulevard in Medical Plaza I. We will then schedule a time that you can come to the Tulane Center for Anatomical Movement Sciences for testing. Upon arrival at the second visit, you will put on an orthotic and insole that has testing sensors and will be asked to walk around to get used to the fit. After you are adjusted to the new fit you will rate the comfort of the orthotic on a scale from 1-10 with 10 being very comfortable and 1 being very uncomfortable. There will also be space for you to leave any other comments you have. You will then walk down a short walkway at your typical walking pace while we measure and record the pressures under your foot. This procedure will then be repeated with a different orthotic. One orthotic will be the one being studied and the other will be a type currently used in the clinic. We will not tell you which one is which until after you have completed the entire process. It should take no more than an hour and a half total time for both visits.

What alternatives are there?

As you may know there are already orthotics on the market. There are also surgical treatments including cheilectomies to remove bone spurs from the joint. Arthroplasty is another option. It is the replacement or remodeling of a joint surface, which can sometimes result in an unstable joint. Arthrodesis is the removal of the joint by fusing the bone together, which can be effective at reducing pain but can negatively affect other joints in the future.

What are the risks or inconveniences of the study?

Since this is a newly designed orthotic comfort has not been proven. Blisters are possible while walking with either orthotic.

The data obtained from your participation will be kept in a locked lab, and it will be stored under your subject number rather than your name. This reduces the risk of your data being identified. Since this document is signed by you, it will be kept in a separate location from data identified by your subject number.

What are the benefits of the study?

If the new orthotic is successful it would offer another treatment option for Hallux Rigidus patients and allow doctors to adjust the orthotics stiffness in the clinic and reduce the pressure on the injured joint.

Will I receive payment for participation?

You will not receive compensation for your participation in this study.

Subject Initials:_____ ___

Are there costs to participate?

You will be responsible for transportation to and from the testing facilities. The participation will cost approximately an hour over the course of your two visits, but you will not be responsible for covering any monetary costs. A parking pass will be provided for the second visit.

How will my personal information be protected?

Your personal information will not be used for any data recording and your information will be kept in a secure location in the Center for Anatomical Movement Sciences at Tulane University. The information will only be identified by subject number. The data will be kept for one year after completion of the study and will only be accessible by the investigators.

At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

You should also know that the Tulane University Human Research Protection Office and the Biomedical Institutional Review Board (IRB) may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

Who do I contact if I have questions about the study?

Take as much time as you like before you make a decision to participate in this study. We will be happy to answer any question you have about this study. If you have further questions about this study, want to voice concerns or complaints about the research or if you have a research-related problem, you may contact the principal investigator, Callie Turlington or Dr. Michael Dancisak (504)247-1881. If you would like to discuss your rights as a research participant, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Tulane University Human Research Protection Office at 504-988-2665 or email at irbmain@tulane.edu.

Permission for Future use:

Tulane University Human Research Protection Office
Biomedical IRB Consent Form for Participation in a Research Study
HR Orthotic Project

Future students working in the CAMS lab may need to use this data for future research projects. Please check the space below if you are willing to allow further use of the data collected.

________ Yes, I agree to allow further use of my data past this project.

Documentation of Consent:

I have read this form and decided that I will participate in the research project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

____ ___ __________
Subject Date

____ _____________
Person Obtaining Consent Date

I am unable to read but this consent document has been read and explained to me by ___________________ (name of reader). I volunteer to participate in this research.

____ _____________
Subject Date

________________________________ ____________ _____________
Witness Date

____ _____________
Person Obtaining Consent Date

____ _____________
Principal Investigator Signature Date

Subject Initials:_____ ___

Leon G. Shingledecker, D.P.M., FACFAS
Board Certified Podiatric Surgeon
Board Certified Wound Care Specialist

December 03, 2014

To Whom It May Concern:

Dr. Shingledecker has agreed to work with Callie Turlington and Dr. Michael Dancisak on the Hallux Rigidus orthotic treatment. Dr. Shingledecker has Hallux Rigidus patients that would be appropriate for testing and will allow recruitment from his office. The original screenings and fittings of the fifteen subjects can be done in his office after informed consent is obtained.

Kim Kleiber

Kimberly Kleiber

3901 Houma Blvd.
Suite 204
Metairie, LA 70006
Phone: (504) 888-9403
Fax: (504) 888-2895

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!

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Needed:!

Subjects!for!insole!testing!

Eligibility!criteria:!

Ages!18+!

Independent!Living!

Diagnosed!with!Hallux!Rigidus!or!Limitus!

English!fluency!

Study:!

Tulane!University!Center!for!Anatomical!Movement!Sciences!is! researching!a!new!orthotic!design!that!targets!Hallux!Rigidus!and! Limitus!and!a!new!easily!adjustable!treatment!system!

If!interested:!

!Contact!Callie!Turlington!!

(504)2470881!

cturling@tulane.edu!

IN THE EVENT OF AN EMERGENCY, CONTACT:

Callie Turlington

24-hour # - (910)385-6758

cturling@tulane.edu

IN THE EVENT OF AN EMERGENCY, CONTACT:

Callie Turlington

24-hour # - (910)385-6758

[Email address]

IN THE EVENT OF AN EMERGENCY, CONTACT:

Callie Turlington

24-hour # - (910)385-6758

cturling@tulane.edu

IN THE EVENT OF AN EMERGENCY, CONTACT:

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24-hour # - (910)385-6758

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cturling@tulane.edu

IN THE EVENT OF AN EMERGENCY, CONTACT:

Callie Turlington

24-hour # - (910)385-6758

cturling@tulane.edu

Principal Investigator: ___Callie Turlington___

Study #: _648102-1__ Participant #: ________

If you are having trouble contacting
your study physician during an
emergency/evacuation, call:
Tulane University's
Human Research Protection Office
1-866-655-0014

Principal Investigator: ____ Callie Turlington _____

Study #: _648102-1__ Participant #: ________

If you are having trouble contacting
your study physician during an
emergency/evacuation, call:
Tulane University's
Human Research Protection Office
1-866-655-0014

Principal Investigator: __ Callie Turlington _____

Study #: _648102-1__ Participant #: ________

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Principal Investigator: ___ Callie Turlington _____

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1-866-655-0014

Principal Investigator: __ Callie Turlington __

Study #: _648102-1__ Participant #: ________

If you are having trouble contacting
your study physician during an
emergency/evacuation, call:
Tulane University's
Human Research Protection Office
1-866-655-0014

Principal Investigator: ____ Callie Turlington ___

Study #: _648102-1__ Participant #: ________

If you are having trouble contacting
your study physician during an
emergency/evacuation, call:
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1-866-655-0014

Principal Investigator: ___ Callie Turlington ___

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Biography

Callie Turlington was born in the small town of Clinton, North Carolina on February 1st, 1992 to Lisa and Bill Turlington. She is the oldest of three with a brother, Festus, age 21, and a sister, Lillie, age 19. She lived in Clinton until high school when she moved to Durham to attend the North Carolina School of Science and Mathematics. Callie came to New Orleans in 2010 to run cross country for Tulane and pursue her undergraduate degree in biomedical engineering. She chose to continue her education at Tulane by pursuing her master's degree in the same field. She hopes to go on to work in the medical device industry after graduation.