A BIOMODELING INVESTIGATION OF BRACING ON CLUBFOOT CHILDREN TREATED BY THE METHOD OF PONSETI

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ABSTRACT

ANDREW J. DIMEO, SR.: A Biomodeling Investigation of Bracing on Clubfoot Children Treated by the Method of Ponseti
(Under the direction of David S. Lalush and Edward Grant)

Congenital *talipes equinovarus* (clubfoot) is a complex deformity occurring in otherwise normal children. It presents in utero bilaterally or unilaterally with the affected feet turned inward. Clubfoot is the most common congenital musculoskeletal birth defect, with an annual worldwide occurrence of 150,000-200,000.

Regardless of treatment, whether surgical or conservative, clubfoot has a stubborn tendency to relapse, thus requiring post-correction bracing. While newborn treatment lasts weeks, brace wear is often maintained to five years of age. To date, there are no investigations specifically focused on clubfoot bracing from an engineering perspective.

This dissertation applies engineering principles to the condition; concluding that surrogate biomodeling is an accurate and repeatable method to investigate clubfoot bracing. Results show standard-of-care brace parameters (external rotation, width, and dorsiflexion) impact muscle-tendon tension. Increasing external rotation from 0-80 degrees results in a range of tension increase of 12%-18% in the gastrocnemius medial head, 22%-26% in the lateral head, 10%-16% in the soleus, and 0%-13% in the tibialis posterior.

The range of tension increase when decreasing brace width from 4-inches greater to 4-inches less than shoulder width is 11%-29% for the medial head, 10%-28% for the lateral head, 4%-25% for the soleus, and 8%-18% for the tibialis posterior.
The range of tension increase when increasing brace dorsiflexion from 0-30 degrees is 27%-44% for the medial head, 24%-50% for the lateral head, 19%-32% for the soleus, and 13%-23% for the tibialis posterior.

Comparing brace options, such as articulating and standard-of-care braces, produces unique tension characteristics. The results indicate that external rotation and width parameters serve to enable the dorsiflexion parameter. The standard-of-care is the only investigated-brace containing all three parameters. Limitations in effectiveness are observed for brace options that do not have all three parameters, such as the articulating brace, with no ability to set dorsiflexion.

It is concluded that surrogate biomodeling is an effective method to evaluate wide ranging brace options, and may potentially be used to assist in future clubfoot brace development. The surrogate biomodel may be used to impact patient care by tuning brace parameters to maximize benefit and minimize over-correction.
This dissertation is dedicated to my family for all of your patience, support, and inspiration; and to the late John Kelly and Elroy Bonerz, whose generosity will never be forgotten
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In the spirit of the saying, “it takes a village,” I can say that this dissertation, “took an international effort.” First and foremost, I thank my family for all of their patience, support, and inspiration. My wife, Jennifer has been generous, kind, an excellent cook for a very hungry researcher, and dissertation editor in chief. She has been the best mother children can have. It is my daughter, Virginia, whom in many ways sent me on this journey. She is my comic relief on stressful days, my entertainer, dancer, singer, and brick-wall soccer player. Andrew Jr. is the inspiration for this research, he’s a kid that wants to figure it all out, and of course the best companion for shooting some baskets or playing catch with. I also want to acknowledge the rest of my family, including parents Anna and John; brother and sister-in-law Anthony and Kim and their children Danielle, Nick, and Grace; sister and brother-in-law Daria and Bob and their children Alek and Olyvia; and the best in-laws a son-in-law can ask for, Mike and Susan. I cannot leave out my Aunt Marie, Uncle George, and cousins; and of course those that laid the foundation for who I am today: my late grandparents, Pop George and Grandma Jenny DeTitta; and Grandpa Al and Grandma Mary DiMeo.

This work could not have been completed without the support of my dissertation committee, David Lalush, Eddie Grant, Jose Morcuende, Ola Harrysson, and Denis Marcellin-Little. Their guidance in the art of conducting academic research, technical and clinical assistance, and access to resources were invaluable. I don’t like to single out any one person, but I cannot get past this paragraph without pointing out that I have been working under the direction of David Lalush since the fall of 1998. He has served as my Masters Thesis principal investigator and research chair, academic advisor, advisor to one of my entrepreneurial ventures, a career guide, and teaching mentor over the past eleven years.

There are several current and former students who contributed to this dissertation. Tabitha Staniszewski, Matt Penny, and Eric Rush helped develop a first generation proof of concept surrogate biomodel. Richard Daniels, with the support of his employer, Applied Technologies, did an extensive amount of solid modeling to help produce the current surrogate biomodel. I currently have the pleasure of working with Jessica Thomas, my undergraduate research assistant. She served as a second investigator in data collection and is working on the development of a soft-tissue covering for the surrogate.

Over the course of this work, I have had the great opportunity to receive feedback and guidance from thought leaders in both clubfoot and biomedical engineering. It has been the distinct honor to work directly with the inventor of the Ponseti method of treatment, Dr. Ignacio Ponseti. He, alongside Dr. Morcuende, has served as physician and surgeon to my son who was born with a severe case of clubfoot. Knowing that little Andrew is receiving the best healthcare available, while collaborating academically with the leading researchers and innovators in the field, is something for which I am most grateful. I often say that I
would easily trade not completing my dissertation for a son born without the clubfoot deformity. Nature, however, is something that I cannot control, and therefore it is a blessing to work on meaningful research with the support of Dr. Ponseti.

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<td>4D</td>
<td>Four-Dimensional</td>
</tr>
<tr>
<td>ABS</td>
<td>Acrylonitrile butadiene styrene (copolymer)</td>
</tr>
<tr>
<td>AFO</td>
<td>Ankle-Foot Orthosis</td>
</tr>
<tr>
<td>Avg</td>
<td>Average (statistical mean)</td>
</tr>
<tr>
<td>BME</td>
<td>Biomedical Engineering</td>
</tr>
<tr>
<td>Brace</td>
<td>Foot abduction splint, brace, bar, or orthosis</td>
</tr>
<tr>
<td>CAD</td>
<td>Computer Aided Design</td>
</tr>
<tr>
<td>Clubfoot</td>
<td>Congenital talipes equinovarus</td>
</tr>
<tr>
<td>CT</td>
<td>X-Ray Computed Tomography</td>
</tr>
<tr>
<td>DVRT</td>
<td>Differential Variable Reluctance Transducer</td>
</tr>
<tr>
<td>FAB</td>
<td>Foot Abduction Brace or Foot Abduction Bar</td>
</tr>
<tr>
<td>FAO</td>
<td>Foot Abduction Orthosis</td>
</tr>
<tr>
<td>FDM</td>
<td>Fused Deposition Modeling (rapid prototyping technology)</td>
</tr>
<tr>
<td>FE</td>
<td>Finite Element</td>
</tr>
<tr>
<td>FEA</td>
<td>Finite Element Analysis</td>
</tr>
<tr>
<td>FOR</td>
<td>Frame of Reference</td>
</tr>
<tr>
<td>Gel</td>
<td>Gelatin</td>
</tr>
<tr>
<td>KAFO</td>
<td>Knee-Ankle-Foot Orthosis</td>
</tr>
<tr>
<td>LVDT</td>
<td>Linear Variable Displacement Transducer</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>N/A</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>NCSU</td>
<td>North Carolina State University</td>
</tr>
<tr>
<td>PC</td>
<td>Personal Computer</td>
</tr>
<tr>
<td>RP</td>
<td>Rapid Prototyping</td>
</tr>
<tr>
<td>SLA</td>
<td>Stereolithography (rapid prototyping technology)</td>
</tr>
<tr>
<td>STL</td>
<td>File format native to the stereolithography CAD software created by 3D Systems (Valencia, California, USA)</td>
</tr>
<tr>
<td>SLS</td>
<td>Selective Laser Sintering (rapid prototyping technology)</td>
</tr>
<tr>
<td>UNC</td>
<td>The University of North Carolina at Chapel Hill</td>
</tr>
</tbody>
</table>
1 INTRODUCTION

Congenital *talipes equinovarus*, commonly referred to as clubfoot, is a complex deformity that occurs in an otherwise normal child. It presents in utero bilaterally or unilaterally with the affected feet completely turned inward. Clubfoot is the seventh most common congenital birth defect, and the first most common musculoskeletal birth defect, occurring in about 150,000-200,000 babies each year worldwide. In addition to its congenital presentation, clubfoot can also accompany such disorders as Spina Bifida and Arthrogryposis [1]. Despite extensive research, the etiopathogenesis of clubfoot remains unknown. Etiopathogenesis is discussed in detail later in this chapter.

Regardless of the method of treatment, whether surgical or conservative, clubfoot has a stubborn tendency to relapse. Nearly all forms of treatment prescribe bracing to prevent relapse. While surgical and conservative treatments can last weeks after birth, brace wear is often maintained until a child is between three and five years of age [2].

A survey of the literature reveals extensive research over the last fifty years concerning the pathology of clubfoot and surgical versus conservative treatment of clubfoot.
In contrast, while bracing is a topic that appears across such a survey, there are no investigations specifically focused on clubfoot bracing from an engineering perspective.

One significant outcome of this research is the development of a clubfoot brace test method and apparatus (the surrogate biomodel) that provides accurate and repeatable results. For example, the results of this testing can be compared to the braces currently considered the standard-of-care (Mitchell and Markell, see section on brace construction). Such testing provides useful clinical information. For example, there are many alternatives to the standard-of-care brace and many adjustments that can be made to all braces, including parameters such as brace width, abduction angle, and dorsiflexion angle. An alternative brace configuration is one that allows motion (such as the Dobbs Bar™ articulating brace, see section on brace construction). This research provides information on how the standard-of-care and alternative braces stretch measured muscle-tendon systems, and how changing the parameters of each brace will affect that stretching.

The specific aims of this research are to:

1) Build a surrogate biomodel of human pediatric lower extremity anatomy. A physical model of a pediatric musculoskeletal system was constructed for the purpose of taking repeatable and reliable measurements of force in muscle-tendon systems. The proposed hypothesis is that a surrogate biomodel shows minimal variance due to measurement error when conducting at least two tests with equal design.

The biomodel was built to simulate that of an average five-year-old human featuring the complete lower anatomy, including skeletal structure, major muscle-tendons, ligament, and soft-tissue (future work). Specifics on construction of the surrogate biomodel are discussed in detail in the Methods section of this dissertation.
2) Compare various clubfoot brace configurations within one brace type. Clubfoot braces can be constructed with various degrees of freedom, including width between shoes, angle of dorsiflexion, and angle of abduction. The proposed hypothesis is that a change in surrogate biomodel muscle-tendon force is expected when these degrees of freedom are varied within one brace type.

3) Compare different brace types. There are several clubfoot brace options (described in the Methods section). The proposed hypothesis is that a change in surrogate biomodel muscle-tendon force is expected when comparing the various brace options.
2  BACKGROUND – CLUBFOOT

2.1  Anatomy and Motions of the Foot

The foot is a complex structure consisting of 26 bones with multiple joints and ligaments [3]. Understanding of the skeletal structure, joints, and motions is important as a foundation to the discussion of clubfoot.

The skeletal anatomy of the foot (figure 2.1a) is comprised of the hindfoot (talus and calcaneus), the midfoot (navicular, cuboid, and cuneiforms), and the forefoot (metatarsals and phalanges). There are several joints in the foot, but those primarily important to this research include the ankle joint (a.k.a. tibiotalar or talocrural) and subtalar joint (a.k.a. talocalcaneal). These joints are shown as a finite model in figure 2.1b. The subtalar joint is between the talus and calcaneus (heel-bone) and the ankle joint is between the tibia and talus (see figure 2.1c).

Figure 2.1a: The skeletal anatomy of the foot; illustration by Lawless ARTery
In the normal state, variable degrees of motion occur at each joint, and all in different planes. The ankle joint primarily moves in plantarflexion (equinus) and dorsiflexion (calcaneus). The subtalar joint is oriented oblique to the axis of ankle joint motion and is primarily responsible for inversion and eversion. These motions are however coupled and complex, and will be explained in further detail in the Kinematics section below.

Figure 2.1b: From [4], illustrates the ankle (ANK), subtalar (ST), and metatarsophalangeal (MTP) joints as ideal revolute joints

Figure 2.1c: Rendition of the ankle and subtalar joints, shown respectively between the tibia and talus, and the talus and calcaneus; illustration by Lawless ARTery
Clubfoot is explained well by its clinical name, *talipes equinovarus*, where:

- *Talipes* refers to a congenital deformity in which the foot is twisted out of shape or position
- *Equinus* (Plantarflexion) is the position of increased angle between the foot and the leg, as when standing on toes
- *Varus*, meaning bent inward; denotes a deformity in which the angle of the anatomy is toward the midline of the body

![Equinus and Varus](image)

*Figure 2.1d: Equinus and varus components of clubfoot; illustration by Lawless ARTery*

The foot moves in all three planes, and can be described much like the roll, pitch, and yaw motions of an airplane, see *figure 2.1e* below. For the foot, these motions are as follows:

- Abduction/Adduction (a.k.a. External/Internal Rotation)
  - Described by toes pointing out and pointing in, respectively, while the feet are flat on the floor, standing in an upright position; like the ‘yaw’ of an airplane
- Inversion/Eversion (sometimes referred to as Varus/Valgus)
  - Described by the sole facing the midline of the body and facing away from the midline, respectively; like the ‘roll’ of an airplane
• Plantarflexion/Dorsiflexion (a.k.a. Equinus/Calcaneus and Extension/Flexion)
  o Described by toes pointing up and toes pointing down, respectively; like the ‘pitch’ of an airplane

Figure 2.1e: Rotation axes of the foot compared to that of the roll, pitch, and yaw of an airplane; illustration by Lawless ARTery

It is noted that the author considers Varus/Valgus to be a deformity toward or away from the midline of the body respectively, whereas Inversion/Eversion is a normal motion of the foot. However, the terms Varus/Valgus are sometimes used to describe a position (rather than a deformity) that is similar to the resulting motions of Inversion/Eversion.

The foot naturally moves in a rotation about the ankle and subtalar joints in all three of these directions simultaneously. These motions, clinically described as supination and pronation are described in the section on Kinematics below. A detailed list of definitions, including additional figures and further explanation of motions of the foot can be found in the glossary in Appendix D on page 147.
2.2 Kinematics

Two joints define gross motion between the lower leg and foot: the ankle joint and subtalar (or talocalcaneal) joint. The ankle joint consists of the articulation between the tibia and talus. The subtalar joint consists of the articulation between the talus and calcaneus. In the early literature, the ankle and subtalar joints were modeled as ideal revolute joints, each having a single rotational degree of freedom [5]. In those studies, the ankle joint was assumed to perform rotations resulting in dorsiflexion and plantarflexion, whereas the subtalar joint was assumed to perform rotations resulting in inversion and eversion.

Although the kinematics of clubfoot has been described accurately as early as 1892 [6, 7], the three-dimensional kinematics of the foot in general were not commonplace in the literature until nearly a century later. Siegler’s publication, in 1988 on “The Three-Dimensional Kinematics…of the Human Ankle and Subtalar Joints,” is part of a shift in the literature from single rotations of ideal joints to kinematic coupling and complex joint models [5].

In Siegler’s 1988 publication, he noted the following observations during his analysis of kinematic coupling of the ankle and subtalar joints:

- As the calcaneus internally rotates (adducts) about the subtalar joint, it is plantarflexed and inverted about the ankle joint. The resulting clinical motion is called supination.
- When the calcaneus externally rotates (abducts) about the subtalar joint, it is dorsiflexed and everted about the ankle joint. The resulting clinical motion is called pronation.
In addition, Siegler found that the range of motion of the “foot-shank complex” in any direction was larger than that of either the ankle or subtalar joints’ individual maximum range of motion. He concluded that this was, “obviously due to the fact that motion of the foot-shank complex is the result of rotation at both the ankle and the subtalar joint.” Note that detailed range of motion data is included in the Foot Joints and Range of Motion section below.

Critical to Siegler’s conclusion was the finding that neither the ankle nor subtalar joint could be considered ideal hinge joints. He concludes that, “The range of motion of neither of these joints is confined to rotations about a single fixed axis but rotations in all three directions are present at both joints.” He does conclude, however, that the ankle joint has a higher contribution to dorsiflexion and plantarflexion than the subtalar joint, and that the subtalar joint has a higher contribution to inversion and eversion movements. The total contribution of the ankle and subtalar joints to internal and external rotation is approximately equal until the extreme range of motion, at which point the subtalar joint has a larger contribution.

Siegler’s paper is focused on the gross motions of the foot. However, the kinematics of the foot are still more detailed and can be described by the anatomy of the foot as is done by Huson [8]. Huson notes that the distal part of the foot, comprised of the metatarsal and phalangeal chains, can move in dorsal or plantar directions almost independently with a distally increasing freedom. However, in the proximal part of the foot, Huson describes a “closed kinematic chain” describing the relationship between the talar head and the anterior part of the calcaneus supporting it. Huson’s work is extensive, detailing the kinematic chains of the most distal part of the foot to a global view that includes the lower leg as a kinematic
chain affecting foot motion. Huson’s work has descriptions of motion based on joint surfaces and loading, on ligament fibers creating constraint and nonconstraint mechanisms, and includes mechanical-based physical models of the foot. A relevant summary of Huson’s work is also found in Ponseti’s book [2].

A basic understanding of the work by Siegler and the work by Huson is important when considering the kinematics of clubfoot. Ponseti developed his manipulative method of treatment for clubfoot based on his understanding of the normal anatomy of the subtalar joint [2]. This view is lucidly described by Lamm and Herzenberg, “(Ponseti) views the clubfoot deformity as exaggerated position of the ankle and subtalar joint forefoot in maximum varus, equinus (plantarflexion), and inversion. Undoing the positions means reversing the direction of the subtalar and ankle joints in maximum valgus, dorsiflexion, and eversion” [9].

Ponseti’s maneuver is based on taking advantage of the natural movements of the subtalar and ankle joints. When attempting to correct a supinated forefoot, often clinicians will begin casting by holding the hindfoot in one hand to stabilize it and then forcibly pronate the supinated forefoot with the other hand. Ponseti recognized this approach was incorrect because it increases the cavus deformity and locks the midtarsal joint, preventing correction of the heel varus and internal rotation deformities [6, 9].

As discussed above, the subtalar joint is not fixed on an axis, instead the axis moves relative to ankle rotation, thus generating complex and continuously changing positions [5, 9]. The Ponseti method is effective because it takes advantage of the complex kinematics of the subtalar and ankle joints. Therefore correction of clubfoot is accomplished by abducting the forefoot while simultaneously blocking the talus. This maneuver brings the position of
the foot through the normal kinematics of the subtalar joint from supination (adduction, inversion, and flexion) to pronation (abduction, eversion, and extension) [9].

Even with a better understanding of the complex nature of the subtalar and ankle joint describing foot motion, models in the current literature are still employing a fixed-axis representation of the motion. This is typically done to simplify the model. One such interactive graphics-based model of the lower extremity defines the ankle, subtalar, and metatarsophalangeal joints as revolute joints. They do, however, show the ankle and subtalar joints rotating at oblique angles, such that they can contribute to dorsiflexion/plantarflexion and inversion/eversion [4]. The interpretation is that this is a tradeoff for which simplification of the model is gained while translation of the axes and the full range of motion of the dual-joint complex is reduced. These tradeoffs are of particular importance to this research that is utilizing a constructed surrogate biomodel. In a survey of the literature with respect to modeling and/or examining the kinematics of unaffected feet and clubfoot (usually after correction), the complex nature of the ankle and subtalar joints was not considered [4, 10, 11, 12]. See table 2.2 for a summary of these investigations.

<table>
<thead>
<tr>
<th>Investigation</th>
<th>Method</th>
<th>Ankle Joint Model</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The kinematics of the lower extremity were defined by modeling the hip, knee, ankle, subtalar, and metatarsophalangeal joints</td>
<td>Interactive graphics based modeling</td>
<td>The ankle and subtalar joints were modeled as revolute joints at oblique angles</td>
<td>[4]</td>
</tr>
<tr>
<td>Kinematic 4-segment rigid body model to investigate foot and ankle kinematics</td>
<td>Video motion analysis</td>
<td>Rigid body segments were connected by revolute joints</td>
<td>[10]</td>
</tr>
<tr>
<td>Effects of foot inturning on knee dynamics in children with surgically treated clubfoot</td>
<td>Three-dimensional gait analysis</td>
<td>Not reported</td>
<td>[11]</td>
</tr>
<tr>
<td>Measurement of lower extremity kinematics during level walking</td>
<td>Computer aided video motion analysis</td>
<td>At each joint, flexion/extension was assumed as the first rotation, abduction/adduction took place next in sequence about a rotated axis, and internal/external rotation last about a third rotated axis</td>
<td>[12]</td>
</tr>
</tbody>
</table>

Table 2.2: Summary of kinematic investigations involving the ankle joint
2.2.1 Foot Joints and Range of Motion

Reliable data on range of motion in the joints of the foot is sparse, especially when considering pediatric data. In general, range of motion literature falls in two camps: that which is measured in the clinic and that which is studied kinematically. In addition, the motions of the foot also fall in two categories. In one, each joint is considered responsible for a rotation in any one direction (such as dorsiflexion/plantarflexion about the ankle joint). The second category is explained as complex kinematic chains of the foot, in which each joint contributes only partially to rotation in any one direction. Adding to the complexity and reliability of such data are measurement techniques, such as measuring with the knee flexed versus in full extension.

As recently as 2005, Martin and McPoil wrote a literature review on the reliability of ankle range of motion measurements using a goniometer. Their literature search found only 11 articles through February 2004. Based on this review, Martin and McPoil concluded that measurements taken from one rater to another were not consistent. Most works cited were focused on dorsiflexion, and ranges were reported from 8 to 25 degrees [13].

A similar review of the literature was conducted by Rome and published in 1996 [14]. Rome focused on the sources of variability in ankle joint dorsiflexion measurements. The sources of error that Rome cited include the following:

- Measurement taken with the knee flexed at 90 degrees versus taken with the knee held in full extension
- Position of the subject may influence measurement, such as supine (most common), seated, or prone
• Whether or not the subtalar joint is in the neutral position (neither inverted nor everted) when taking measurements about the ankle joint;
  - Such work showed that maximum ankle dorsiflexion occurs with the subtalar joint in a pronated position (explained by the complex kinematics of these joints).
• Whether or not the measurements are taken using active or passive methods
• Tester variability, as reported by Martin and McPoil [13]
• Subject variability considering aspects such as gender, age, and physiology;
  - Ankle joint dorsiflexion has been shown to decrease with age (age range of 29-39 through to years 70-89).
• Variability in the test equipment used, such as goniometer (universal, plastic, disc, or biplane), photography, tractograph, and infrared sensors

Rome cited six articles reporting dorsiflexion at the ankle. Among the six articles, subject age ranged from 18 to 66 years, and mean dorsiflexion ranged from 8 to 26 degrees. Rome reports that potential error in the measurements is as much as 10 degrees [14].

One paper was found on pediatric ankle joint range of motion by Evans and Scutter, published in 2006. They report that, “measures of ankle joint dorsiflexion in children are highly variable among examiners.” They did report, however, that gastrocnemius range of motion is more reliable than soleus range of motion.

Evans and Scutter assessed range of motion as an indicator of muscle length, specifically the length of the gastrocnemius with the knee extended, and of the soleus with the knee flexed [15]. They note the complexity of the kinematics when stating the following:
“Anatomically, the joints that contribute to ankle range of motion are those formed by the articulations of the tibia, fibula, and talus, usually referred to as the ‘ankle mortise.’ Clinically, however, there may be range-of-motion contributions from the rearfoot tarsal joints, i.e., the subtalar joint and the calcaneocuboid and talonavicular joints...Because these joints cannot be clinically isolated and because this is a constant reality for the examination of all subjects, this is an accepted situation.”

It is worth noting that research addressing the reliability of range of motion in children with clubfoot was not found. Evans and Scutter point out that research does exist for children with spastic cerebral palsy (such as [16]), but that, “there is a dearth of such investigation in healthy children.” Their study was performed by three examiners with 11 to 15 years of experience on 29 children ranging from 4 to 6 years. Results were highly variable among the examiners. They reported dorsiflexion measurements ranging from 5 to 10 degrees with a maximum standard deviation of 2.5 degrees [15].

This dorsiflexion range of motion reported by Evans and Scutter is small when compared to that reported by Martin and McPoil, and Rome, and is in contrast to the notion that range of motion decreases with increasing age. This contrast is possibly due to the sources of variability already discussed.

As sparse as the literature is on the reliability of foot joint range of motion, what does exist is primarily focused on the ankle joint. One reference on the reliability of the subtalar joint range of motion measurements was performed by Freeman et al. and published in 2007 [17]. In this paper, twelve volunteer subjects ages 20 to 40 years were evaluated by two testers with one hour of training using a Phillips Biometer™. The results roughly showed subtalar joint inversion in the range of 20 degrees and eversion to be in the range of 10
degrees. Unlike the studies referenced here citing poor reliability between raters, Freeman does show good reliability when using the Phillips Biometer\textsuperscript{TM}. However, based on the lack of additional references, it is difficult to assess reliability in range of motion measurements in and of itself [17].

The difficulty in obtaining reliable and repeatable foot joint range of motion data lies in the complex kinematics of the foot. The kinematics of these joints leads to the discrepancy of range of motion measurements taken with a goniometer, which are usually higher than those taken based on X-Ray. This concept is best described by Siegler in his kinematics study of the ankle and subtalar joints. He clearly shows that these joints are coupled and that the range of motion of the foot in any direction is greater than that of either the ankle joint or subtalar joint alone [5]. This kinematic coupling is likely a cause of variability in joint range of motion measurements between raters.

Nonetheless, it is critical to this research to establish a realistic kinematic and clinical range of motion for the surrogate biomodel to be constructed. One method for choosing range of motion in the biomodel proposed in this research is to use a clubfoot classification system, such as those by Pirani or Diméglio. The Diméglio clubfoot classification system is particularly interesting because it measures severity based on angular positions of the foot. In this system, four parameters are assessed by applying a gentle corrective force and scoring the amount of deformity from 1 to 4 points, 1 being normal and 4 being severe clubfoot [18].

<table>
<thead>
<tr>
<th>Points</th>
<th>Degrees</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-20 to 0</td>
</tr>
<tr>
<td>2</td>
<td>0 to 20</td>
</tr>
<tr>
<td>3</td>
<td>20 to 45</td>
</tr>
<tr>
<td>4</td>
<td>45 to 90</td>
</tr>
</tbody>
</table>

Table 2.2.1a: Diméglio clubfoot classification system scale, with 1 being normal and 4 being severe clubfoot, applied to the four parameters in figure 2.2.1
The four parameters are as follows (shown in figure 2.2.1 below):

- Sagittal Plane Evaluation of Equinus (Plantarflexion)
- Sagittal Plane Evaluation of Varus
- Horizontal Plane Evaluation of Derotation of the Calcaneopedal Block
- Horizontal Plane Evaluation of Forefoot Adduction Relative to Hindfoot

Figure 2.2.1: From [18], the four Diméglio parameters, clockwise from the top left, Equinus, Varus, Derotation of the Calcaneopedal Block, and Forefoot Adduction Relative to Hindfoot

A review of the literature with respect to treatment and follow-up of clubfoot is also helpful in understanding the range of joint motion. In addition, this type of review gives insight to the relevance of clinical measures considered important to clubfoot, as does the classification scale.
The following table provides data from Laaveg and Ponseti [19], Herzenberg et al. [20], Cooper and Dietz [21], and Alvarez et al. [22]. Differences in age and measurement techniques are likely sources of variability among these values. An additional source not discussed in the reliability discussion above is treatment method. While all values in the table for clubfoot are reported as treated by the method of Ponseti, there is still significant opportunity for variation to be introduced by treatment method. It is again worth noting that no reliability data for clubfoot range of motion was found in the literature.

<table>
<thead>
<tr>
<th>Author/Reference</th>
<th>Ankle Dorsiflexion</th>
<th>Plantar Flexion</th>
<th>Varus-Valgus Motion of the Heel</th>
<th>Inversion-Eversion of Fore Part of Foot</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>deg(std.dev.)</td>
<td>deg(std.dev.)</td>
<td>deg(std.dev.)</td>
<td>deg(std.dev.)</td>
</tr>
<tr>
<td>Laaveg and Ponseti, 1980 [19]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal Feet</td>
<td>31(9)</td>
<td>Not Reported</td>
<td>39(7)</td>
<td>65(10)</td>
</tr>
<tr>
<td>All Clubfoot</td>
<td>13(9)</td>
<td>Not Reported</td>
<td>27(9)</td>
<td>52(16)</td>
</tr>
<tr>
<td>Clubfoot treated with plaster casts only</td>
<td>16(10)</td>
<td>Not Reported</td>
<td>31(6)</td>
<td>60(14)</td>
</tr>
<tr>
<td>Clubfoot treated with plaster cast and tenotomy</td>
<td>16(9)</td>
<td>Not Reported</td>
<td>30(7)</td>
<td>51(15)</td>
</tr>
<tr>
<td>Clubfoot treated with anterior tibial tendon transfer</td>
<td>9(6)</td>
<td>Not Reported</td>
<td>23(9)</td>
<td>45(15)</td>
</tr>
<tr>
<td>Herzenberg et al., 2002 [20]</td>
<td>32 (range 10-45)</td>
<td>Not Reported</td>
<td>Not Reported</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Cooper and Dietz 30 year follow up, 1995 [21]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal Feet (Passive)</td>
<td>11(12)</td>
<td>52(9)</td>
<td>Not Reported</td>
<td>E: 15(9) I: 34(11)</td>
</tr>
<tr>
<td>Normal Feet (Active)</td>
<td>6(10)</td>
<td>51(9)</td>
<td>Not Reported</td>
<td>E: 14(8) I: 34(10)</td>
</tr>
<tr>
<td>Clubfeet (Passive)</td>
<td>9(7)</td>
<td>42(12)</td>
<td>Not Reported</td>
<td>E: 13(8) I: 21(11)</td>
</tr>
<tr>
<td>Clubfeet (Active)</td>
<td>neg 4(8)</td>
<td>39(11)</td>
<td>Not Reported</td>
<td>E: 10(7) I: 17(11)</td>
</tr>
<tr>
<td>Alvarez et al., 2005 (Ponseti Method w/ BFX-A in place of tenotomy) [22]</td>
<td>1 month post BFX-A w/ knee in Flex 33(12) &amp; Externel 25(11)</td>
<td>Not Reported</td>
<td>Not Reported</td>
<td>Not Reported</td>
</tr>
</tbody>
</table>

Table 2.2.1b: Literature survey of foot range-of-motion measurements

Based on this current assessment of kinematics and range of motion, it is important to build a surrogate biomodel that includes a foot with at least two kinematically coupled joints, specifically that of the ankle joint and subtalar joint. The foot should model all of the motions seen in the clinic: dorsiflexion/plantarflexion, varus/valgus motion of the heel, inversion/eversion of the forepart of the foot, the combined motions of supination/pronation, and abduction/adduction.
Due to the complex nature of human foot range of motion, kinematics, and the added complication of clubfoot, the decided plan for the ankle/foot model used in the surrogate is a scaled reproduction of a training model used by Ponseti in [6].

2.3 Etiopathogenesis

As recent as 2005, Burajapanitkit and Leelasamran state that the “etiopathogenesis of congenital talipes equinovarus remains mysterious” [23]. The reported causes for clubfoot are fairly consistent (however not all in agreement) throughout the literature, suggesting many possibilities; including genetic inheritance, cell defects, vascular disruptions, soft-tissue factors, deformation from intrauterine factors, developmental arrest, myogenic factors, and skeletal, neural, and muscular anomalies [23 - 27].

As early as 1929, Max Bohm concluded that the majority of clubfoot cases were due to an “arrest of development” of the embryo, suggesting that the clubfoot is “analogous to the early physiologic embryonic form of the foot” [28]. Farrell, Summers, Dallaire, et al. agree with Bohm, stating in their 1999 publication that during embryonic growth, “there is a period when the foot is in a position resembling club foot” [24].

This position is clearly opposed by Ponseti, who states in his book that such an embryonic state, “does not exist.” Ponseti goes on to say that, “the severe medial displacement of the navicular is not seen at any stage of the development of a normal embryo” [2].

One area of similarity between the Farrell paper and Ponseti’s book is a suggestion of the onset of clubfoot during fetal development. Farrell et al. hypothesize that susceptibility to clubfoot might increase during a, “critical point in embryological development in the 11th to 12th weeks. Ponseti observes, citing many others’ observations as well, “that an apparently
normal foot of an 11-week-old fetus turns into a clubfoot at 14 weeks” [23, 24]. The literature suggests a multitude of theories, detailed below:

- Burajapanitkit and Leelasamran suggest a possible cause (or effect) of clubfoot to be an, “increase in the intracompartmental pressure of the posterior compartment of the leg with club foot.” They go on to question whether prolonged abnormal fetal positioning can cause such pressure elevation [23].

- Farrell et al. suggest a “vascular event or a physical restriction” as possible causes for clubfoot [24].

- Sano et al. state that there is, “strong evidence that localized soft-tissue contraction is involved in the pathogenesis of club foot,” and that soft-tissue cells may contribute to recurrence [25].

- Muir et al. suggest that there is a “genetic predisposition” and a “vascular deficiency” as possible causes [26].

- Loren et al. suggest a “fundamental neuromyogenic influence in clubfoot etiopathogenesis” [29].

- Dietz et al. note that most of the reported results are contradicted between multiple sources with the exception of disproportionate type I fiber population found in posterior and medial muscle groups, suggesting, “an abnormality of the neural stimulus” [27].

- Ippolito and Ponseti have speculated that, “genetically induced retraction of muscle-tendon units and of soft-tissues in the leg may be an important factor in the causation of the club foot” [30].
Ponseti states that, “the clubfoot deformity seems to be induced by an unknown dysfunction in the territory subtended by the posterior tibial nerve below the knee.” He further describes a decrease in growth in the structures innervated by this nerve, an excess of collagen synthesis in the Achilles and posterior tibial tendons, and in the medial and posterior tarsal ligaments [2].

While the works cited here are but a fraction of the available research, it is apparent that additional research is required to more fully understand the etiology of clubfoot.

2.4 Treatment Methods

There are two major categories of clubfoot treatment, surgical correction methods and conservative correction methods. A method common in the past, but less so now is that of forceful manipulation. The research reported here is based on the conservative method of Ponseti. Surgical methods are considered outside the scope of this work and will not be discussed. Below is an overview of conservative methods, including a detailed review of the Ponseti method. The method of Kite is also discussed because of the historical significance to current conservative methods.

The underlying principle of conservative treatment of clubfoot, such as the French and Ponseti methods, is that of gentle and repeated manipulations of the clubfoot toward a more normal shaped foot. Clubfoot, or more specifically, congenital talipes equinovarus, is a complex deformity that includes components in three dimensions, including equinus (plantarflexion), varus, adductus, and cavus [31]. The Kite and Ponseti methods both rely on manipulations followed by casting. The French method consists of daily physical therapy, use of a continuous passive motion machine, and taping.
2.4.1 Kite Method

The Kite Method of treating clubfoot was developed in response to the stiffness and pain associated with the historically popular methods of extensive surgical release and forceful manipulation [32]. Indeed, Kite’s description of the method he was taught is motivation alone to pursue more conservative treatment. Kite stated, “I was taught to use force to correct a clubfoot . . . with a triangular wooden block covered with leather . . . and the lateral border of the foot would be placed on the edge of this block, and considerable pressure would be put on the forefoot and heel, as the foot was forced a number of times against the edge of this block” [33]. Examples of forceful manipulation are shown in the figures below.
Figure 2.4.1a: Phelps’ machine for the forcible correction of clubfoot, circa 19th century, from [34]

Figure 2.4.1b: Thomas Wrench for the correction of clubfoot, circa 19th century from [34]
Figure 2.4.1c: The “nut-cracker” described by Denis Browne in 1934 to be used when feet were too stiff to be corrected by hand [35]

Kite’s technique consisted of grasping and distracting the forefoot with one hand while holding the heel from the back with the other hand. After elongating the foot, the thumb is placed laterally, pushing the talus in a medial direction. The medially placed index finger pushed the navicular in the lateral direction. The heel was everted as the forefoot was abducted. This manipulation was followed by applying a plaster cast to below the knee [32].

The Kite method corrects each component of clubfoot individually. After applying the plaster cast to the clubfoot, Kite would flatten the sole of the foot by setting it on a glass plate, thus correcting the cavus. He instructed not to push up and out on the forefoot in order to prevent cavus from recurring. He instructed to not twist the foot out on the ankle to avoid foot pronation and breach in the midfoot. Kite recommends getting all corrections by abducting the foot at the midtarsal joint when the thumb is pressed on the lateral side close to the calcaneocuboid joint [2].

Kite’s method required an average of 20.4 months in casts. After completing the casts, Kite recommended a Phelps night splint be applied to prevent relapse [32].
2.4.2 Ponseti Method

In contrast to Kite’s method, Ponseti suggests that the clubfoot deformity should be corrected simultaneously, with exception of equinus, which is corrected last. The simultaneous correction is considered critical by Ponseti due to the fact that the heel varus and foot supination occur primarily in the tarsus, and because the tarsal joints are mechanically interrelated. Ponseti notes that Kite’s method blocked the abduction of the calcaneus and interfered with the correction of the heel varus. In the Ponseti method, the cavus is corrected as the foot is abducted with the forefoot in supination. This correction brings the forefoot and the hindfoot into proper alignment. The adduction is corrected when the supinated foot is abducted while counterpressure is applied against the lateral aspect of the head of the talus. The lateral aspect of the head of the talus will be covered by the navicular. As the foot is further abducted, supination decreases until it is plantigrade. Simultaneously, heel varus is corrected as the calcaneus abducts together with the cuboid [2, 36].

Figure 2.4.2a: The thumb is placed on the head of the talus and the index finger is positioned behind the lateral malleolus to initiate the clubfoot correction; Note that no counterpressure should be applied at the calcaneocuboid joint; illustration by Lawless ARTery
Figure 2.4.2b: The cavus is corrected as the foot is abducted with the forefoot in supination; this correction brings the forefoot and the hindfoot into proper alignment; Note that the foot is never pronated; illustration by Lawless ARTery

Figure 2.4.2c: The adduction is corrected when the supinated foot is abducted while couterpressure is applied against the lateral aspect of the head of the talus; illustration by Lawless ARTery

Figure 2.4.2d: The lateral aspect of the head of the talus will be covered by the navicular; illustration by Lawless ARTery
Figure 2.4.2e: As the foot is further abducted, supination decreases until it is plantigrade; Note that no counterpressure is applied at the calcaneocuboid joint; illustration by Lawless ARTery

Figure 2.4.2f: Simultaneously, heel varus is corrected as the calcaneus abducts together with the cuboid; illustration by Lawless ARTery

The corrections described above are obtained during two to three minutes of gentle manipulations that are then immobilized by applying a toe-to-groin plaster cast, with the knee at 90-degrees of flexion. The casts are typically worn for 4 to 7 days. This process is repeated typically no more than ten castings (usually 5 or 6 cast changes) until the cavus, foot adduction and heel varus are corrected. The foot is then dorsiflexed at the ankle to correct the equinus. A tenotomy of the Achilles tendon is often performed to complete the correction. The foot is then immobilized in the last toe-to-groin plaster cast for three weeks in 70-degrees of abduction and 20-degrees of ankle dorsiflexion. When treating a newborn, this total procedure generally takes about 6 weeks [2, 32, 36].
The Ponseti method specifically calls for a foot abduction brace with shoes holding the feet in the same position as the last casts, full time for three months or until the child begins to walk. The brace may be worn for 4 to 5 years at night and naptime to prevent a relapse [2, 36].

The method, however, has been drastically improving over time. This improvement is claimed to be from realizing, in part, the necessity to hyperabduct the foot [37]. In 1980, Laaveg followed 104 clubfeet. Thirteen required only manipulation and plaster casts, 42 included lengthening of the Achilles tendon, and 49 were treated with tendon transfers [2, 19]. Currently, the Ponseti method has claims that posteromedial and lateral release is avoided in 98% of the cases when treatment is started shortly after birth [37].

Herzenberg et al. reported the results of treatment of 34 clubfeet using the method of Ponseti. The study resulted in only 1 of the 34 clubfeet (3%) requiring posteromedial release. A percutaneous Achilles tenotomy was performed in 31 (91%) of the 34 feet [20].

In 2003, Colburn and Williams published an evaluation of the Ponseti Method that followed 34 infants with 57 clubfeet. Results showed 54 of 57 clubfeet successfully corrected without requiring posteromedial release, and that only 2 patients (3 clubfeet) required extensive surgical correction [38].

In 2004 Morcuende et al. reported a study of 256 clubfeet treated between 1991 and 2001. Clubfoot correction was achieved in 98% of the patients, with only 4 patients requiring extensive corrective surgery [37].

Success rates for the Ponseti method of treatment are now prevalent worldwide. Table 2.4.2 is a collection of 14 peer reviewed journal articles published between 2002 and 2008. The results represent a combined total of 1268 clubfeet resulting in an average
correction of 97%. These results include the application of the treatment in the United States, India, England, Germany, Israel, Malawi, Turkey, and France. In addition, clinicians and/or technicians with varying levels of training performed the treatment: from orthopaedic surgeons to physical therapists to basic caregivers.

<table>
<thead>
<tr>
<th>Country</th>
<th>Author</th>
<th>Clubfeet</th>
<th>Correction</th>
<th>Year</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>Gupta, et al.</td>
<td>154</td>
<td>100%</td>
<td>2008</td>
<td>[39]</td>
</tr>
<tr>
<td>England</td>
<td>Shack &amp; Eastwood</td>
<td>40</td>
<td>98%</td>
<td>2006</td>
<td>[40]</td>
</tr>
<tr>
<td>Germany</td>
<td>Radler, et al.</td>
<td>87</td>
<td>93%</td>
<td>2006</td>
<td>[41]</td>
</tr>
<tr>
<td>Israel</td>
<td>Bor, et al.</td>
<td>36</td>
<td>97%</td>
<td>2006</td>
<td>[42]</td>
</tr>
<tr>
<td>USA</td>
<td>Abdelgawad, et al.</td>
<td>137</td>
<td>93%</td>
<td>2007</td>
<td>[43]</td>
</tr>
<tr>
<td>Malawi</td>
<td>Tindall, et al.</td>
<td>100</td>
<td>98%</td>
<td>2005</td>
<td>[44]</td>
</tr>
<tr>
<td>USA</td>
<td>Morcuende, et al.</td>
<td>319</td>
<td>99%</td>
<td>2005</td>
<td>[45]</td>
</tr>
<tr>
<td>Israel</td>
<td>Segev, et al.</td>
<td>48</td>
<td>94%</td>
<td>2005</td>
<td>[46]</td>
</tr>
<tr>
<td>USA</td>
<td>Dobbs, et al.</td>
<td>86</td>
<td>100%</td>
<td>2004</td>
<td>[47]</td>
</tr>
<tr>
<td>USA</td>
<td>Colburn and Williams</td>
<td>57</td>
<td>95%</td>
<td>2003</td>
<td>[38]</td>
</tr>
<tr>
<td>USA</td>
<td>Lehman et al.</td>
<td>87</td>
<td>92%</td>
<td>2003</td>
<td>[48]</td>
</tr>
<tr>
<td>Turkey</td>
<td>Goksan</td>
<td>44</td>
<td>95%</td>
<td>2002</td>
<td>[49]</td>
</tr>
<tr>
<td>France</td>
<td>Chotel, et al.</td>
<td>39</td>
<td>95%</td>
<td>2002</td>
<td>[50]</td>
</tr>
<tr>
<td>USA</td>
<td>Herzenberg, et al.</td>
<td>34</td>
<td>94%</td>
<td>2002</td>
<td>[20]</td>
</tr>
</tbody>
</table>

Table 2.4.2: Ponseti results worldwide

2.4.3 French Method

In the French Method, therapists perform manipulative stretching followed by taping of the leg and foot to a splint. Use of a continuous passive motion machine is also described by Charles, Canavese, and Diméglio [51]. In this method, the physiotherapy softens the tissues making the foot more compliant. The French method is typically described as a lengthy and expensive treatment option [31, 36].

Developed in the 1970’s by Masse and Bensahel, the French Method is also referred to as the Functional Method and sometimes as the Montpellier Method. The method involves daily manipulations of the clubfoot, stimulation of the muscles, and temporary
immobilization of the foot with strapping. The daily treatments are typically continued for two months and then gradually reduced to three sessions per week for an additional six months. After six months, taping is continued until the children are walking. Night splinting is typical for an additional two to three years. The French Method requires considerable time, expertise of the physical therapist, and significant family compliance [32, 51].

In the 1990’s, continuous passive motion was developed specifically for use with the French Method of treating clubfoot. After the daily manipulations and strapping, the feet are taped to a flat plate on the machine. The machine is used during the first 12 weeks of treatment, supplying continuous motion to the functional axes of the hindfoot. It is recommended for 18 hours/day for the first month and 10 hours/day for the remaining weeks [32].

Charles et al. noted in 2006 that the conservative treatment of clubfoot has changed considerably in the last two decades, claiming a rate of only 20% requiring surgery [51]. A more detailed breakdown is provided by Richards et al., reporting in 2005 that a study of 142 clubfeet treated by the French Method resulted in 42% needing no surgery, 9% needing a heelcord tenotomy, 29% needing posterior releases, and 20% needing comprehensive posteromedial releases [52].

Results for the French Method have continuously been getting better since 1990 when Bensahel reported good results in 163 of 338 clubfeet (48%) [53]. With the addition of the continuous passive motion machine, Diméglio reported that 74% of 201 feet did not require surgery in a period from 1991 to 1997 [32]. A recent publication by Richards et al., in 2008, reported an initial correction rate of 95% for the French functional method. Relapses did
occur in 29% of the feet that had been successfully treated, all of which required surgical intervention [54].

2.5 Long term results of surgical vs. conservative treatment

In his book, Ponseti notes that, “a painless, well-aligned foot with good function is far better than a foot with perfectly aligned bones...but with reduced range of motion owing to scaring, muscle weakness, and pain” [2]. Cooper and Dietz go into extensive detail discussing why results based on radiographic information as well as range of motion and other anatomical measurements are not good indicators of successful treatment [21].

In a long term follow-up of clubfoot patients treated with the surgical method of extensive soft-tissue release, Dobbs et al. evaluated forty-five patients. Using multiple quality of life measurements, Dobbs found significant impairment of physical function in patients treated with extensive soft-tissue release. The poor results were attributed to elevated osteoarthritis, ankle stiffness, and gastrocnemius weakness [55].

Dobbs et al. found, “moderate-to-severe osteoarthritic changes in 56%,” of patients treated surgically compared to only mild degenerative changes in 35% of patients treated with the Ponseti method [21, 55].

On one scale, Dobbs et al. found that clubfoot patients treated with extensive surgery rated their physical well being at a level equivalent or worse than patients with end-stage kidney disease, congestive heart failure, or cervical spine pain [55].

In addition, Dobbs et al. found a, “correlation between the extent of the soft-tissue release and the degree of functional impairment” [55].
In contrast, Cooper and Dietz found that patients treated by the method of Ponseti had long-term results comparable to individuals who did not have any congenital deformity of the foot [21].

2.6 Clubfoot Relapse

Regardless of treatment mode, whether surgical or conservative, the clubfoot has a stubborn tendency to relapse. As early as 1895, Walsham and Hughes stated in [34], “When the foot has been rectified…by the employment of…manipulative, mechanical and operative treatment, further mechanical after-treatment is, as a rule, necessary to prevent a relapse.”

Sano et al. suggest that soft-tissue contracture may be a cause for clubfoot relapse. The authors state that “cells from the medial soft tissue of club feet have many myofibroblastic characteristics and that some recurrences after soft-tissue release could be attributed to the continued presence of cytocontractile elements” [25].

Neuromyogenic factors may be at the root cause of relapse. Loren et al. suggest that, “clinical recurrence may be anticipated,” and they recommend, “ankle-foot orthosis to potentially minimize or delay equinovarus recurrence” [29]. Handelsman and Badalamente agree, suggesting that the underlying neurogenic disorder is at the root of a constant tendency to relapse. They likewise suggest, “prolonged night splint usage to counteract the out-of-balance forces,” once correction is achieved [56].

While the etiology of clubfoot is still unknown, it is apparent that, “relapses are caused by the same pathology that initiated the deformity” [2].

A relapse is usually first noticed when there is a presentation of slight equinus and varus deformity of the heel. Relapse of the cavus and forefoot adduction deformities are
rare. In most cases correction can be obtained with serial casting followed by lengthening of the Achilles tendon [2, 57].

Noncompliance of bracing is considered to be the primary factor in allowing the clubfoot deformity to relapse [37, 43, 47, 58]. In Ponseti’s first 20 years of treating patients, relapse rates of approximately 50% are reported [2, 57]. In recent years, the importance of bracing has been emphasized with families, and relapse rates are found to be much lower in compliant children (7%), compared to noncompliant children (78%) [57].

In the 2004 study of 256 clubfeet by Morcuende et al., a relapse rate of 11% was reported. The study stated that, “Relapses were unrelated to age at presentation, previous unsuccessful treatment, or severity of the deformity.” The only common denominator reported among the patients was noncompliance with the brace [37]. In the same year, Dobbs et al., reported similar findings, stating that, “Noncompliance was the factor most related to the risk of recurrence” as well as, “Parental educational level (highschool education or less)” [47]. With the patient sample size (fifty-one consecutive infants), no significant relationship was found between clubfoot relapse and gender, race, parental marital status, source of medical insurance, or parental income [47]. Dobbs et al. also found no relationship with relapse and clubfoot severity, age of patient when first treated, or whether the patient received previous treatment [47]. Of the fifty-one infants investigated, it was reported that the “families of twenty-one infants (41%)” had not complied with the use of the brace [47].

A summary of the literature with respect to relapse and brace compliance is provided in table 2.6 below.
Table 2.6: A summary of the literature showing rate of clubfoot deformity recurrence as a function of bracewear non-compliance

<table>
<thead>
<tr>
<th>Number of Patients</th>
<th>Percent non-compliant</th>
<th>Rate of recurrence (non-compliant)</th>
<th>Rate of recurrence (compliant)</th>
<th>non-compliant definition</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>51</td>
<td>41%</td>
<td>31%</td>
<td>0%</td>
<td>0%</td>
<td>[96]</td>
</tr>
<tr>
<td>92</td>
<td>42%</td>
<td>68%</td>
<td>3%</td>
<td>0%</td>
<td>[97]</td>
</tr>
<tr>
<td>8</td>
<td>63%</td>
<td>60%</td>
<td>N/A</td>
<td>&lt;50%</td>
<td>[98]</td>
</tr>
<tr>
<td>251</td>
<td>61%</td>
<td>34%*</td>
<td>9%*</td>
<td>&lt;75%</td>
<td>[99]</td>
</tr>
<tr>
<td>65</td>
<td>34%</td>
<td>37%</td>
<td>4%</td>
<td>&lt;100%</td>
<td>[105]</td>
</tr>
<tr>
<td>45</td>
<td>38%</td>
<td>60%</td>
<td>16%</td>
<td>&lt;100%</td>
<td>[105]</td>
</tr>
</tbody>
</table>

*Reported as fair and poor results, as opposed to specific percent recurrence

2.6.1 Historical Perspective on Bracing with Respect to Relapse

The 1895 publication by Walsham and Hughes on the deformities of the foot provides an early account of bracing for the prevention of clubfoot relapse [34]. In this book, the authors divide bracing into two categories, (1) instruments for use during the night, and (2) instruments for use during the day. They further breakdown the daytime bracing options into three subsets, including (a) instruments for holding the foot in a restored position, (b) those that, in addition to (a), are designed to overcome the tendency for the whole limb to roll inwards, and (c) those that have the purpose of further improving a partially corrected clubfoot.

Figure 2.6.1a is an example of a category (1) brace for use at night. This brace was intended for the recently corrected clubfoot. The authors of [34] state a tendency for the weight of bedclothes to press back the foot to a deformed position. The brace depicted in Figure 2.6.1a consists of a calf-piece for the back and outer side of the calf, and a foot-piece, bent at right angles and turned up on the inner side to prevent the foot from rolling inwards. An oval hole is placed opposite the internal malleolus to prevent pressure at this spot. This splint was softly padded and covered with leather, the foot being held in place with bandage.
Figure 2.6.1a: Tin rectangular varus night-shoe; from [34]

*Figure 2.6.1b* shows examples of category (2), subset (a) as described by the authors of [34] for holding the foot in a restored position. The authors of [34] suggest using such an apparatus only after varus has been completely overcome and dorsiflexion of 30-degrees is achieved.

![Diagram of boot with inside leg-iron and varus T-strap](image)

*Figure 2.6.1b*: Boot with inside leg-iron and varus T-strap (left) and boot with inside and outside leg-irons and varus T-strap (right); from [34]

*Figure 2.6.1c* shows examples of category (2), subset (b) as described by the authors of [34] for not only the maintenance of corrected clubfoot, but to also control inversion of the limb. The authors of [34] state that after clubfoot correction, children beginning to walk still have their toes pointing inwards. They suggest that this may be due to the laxity of the ligaments of the knee-joint, allowing the tibia to roll inwards on the femur, or, more often, from the whole lower limb rolling in at the hip joint due to a “faulty direction of the neck of the femur.”
Figure 2.6.1c: From left to right: Walking apparatus with outer iron carried to pelvic girdle with T-strap on outer side; Mathieu’s apparatus for producing eversion of the limb; Meusel’s apparatus for correcting the inversion of the foot and leg after clubfoot correction; all from [34]

Also included in this category from [34] is Sayre’s appliance for correcting inversion of bilateral clubfoot, shown in figure 2.6.1d. This is the only brace depicted in this nineteenth century book that resembles the standard-of-care bracing used today.

Figure 2.6.1d: Sayre’s appliance for correcting inversion in bilateral clubfoot [34]

Figure 2.6.1e shows examples of category (2), subset (c) as described by the authors of [34] for having the purpose of further improving a partially corrected clubfoot. They further divide these braces into two categories, (i) those that retain the foot in a corrected position and for further correcting the equinus (plantarflexion); and (ii) those for continuing the eversion as well as dorsiflexion of the foot. They are shown in Figure 2.6.1e together,
due to their similarity. Note that each employs a strategy (belt, spring, cable, etc.) for holding the foot in dorsiflexion, while some include additional leg irons for achieving eversion.

The braces most commonly used today employ a connecting bar and are often referred to as a ‘Denis Browne Bar’ or ‘Denis Browne Splint’ regardless of manufacturer or setup specifications. These braces are likely an evolution and adaptation of that described by Denis Browne in his 1934 publication, “Talipes Equino-Varus” [35]. Here Browne states that maintaining the clubfoot correction “can be obtained by connecting the feet horizontally at the desired angles to the Sagittal plane.” He describes, “the desired angles,” to be external rotations of 20-degrees for unaffected feet and up to 90-degrees for clubfeet. His original brace included an L-shaped bracket to hold the foot, “bending up one side to clear the external malleolus and bear against the outer side of the leg.” The foot is also described by Browne to be held in significant dorsiflexion, connected to the bar via “sticking-plaster” for babies, and open-toe straight last boots for walking children.

In 1952, in The British Encyclopaedia of Medical Practice, Browne describes a “night-splint” or “calcaneus splint” in greater detail [60]. The splint, he states, “consists of a
central grip around the ankle, from which there runs forward an open-ended shoe to hold the foot, and upwards 2 struts to hold a band below the knee.” The front part of the shoe can be pulled upwards by a strap to the upper band, bringing the foot into calcaneus. Varus or valgus was adjusted by rotation of a lever through which a strap passed. Browne believed that equinus was the most common factor in all foot deformities, and that, “there is at present no other splint that will counter it.” He concludes in [60], stating that, “If necessary, the feet can be turned outwards as well as held in calcaneo-valgus position by connecting the feet together with a jointed bar of metal.”

In a correspondence written in the *British Medical Journal* in 1956, Browne claimed difficulty in getting his work on the splint published due to the opposition of orthopaedic surgeons [61]. He states in this correspondence that, “The splint was first described in the U.S.A. with the lateral lever cut down to useless proportions, and from thence copied into various English textbooks.” Browne was clearly upset by the modifications; stating that, “Before improving a technique, first find out what it actually is and how it developed.” He also states, “If the originator is still available, get his opinion on the modifications before publishing it.”

In the 1997 book, *Atlas of Orthoses and Assistive Devices*, a figure is shown under a section on clubfoot correction with the following caption, “Eleven-month-old child in reverse last shoes and Denis-Browne bar after bilateral clubfoot repair. The combination (of shoes and bar) helps maintain external rotation, the corrected abducted position, and prevents turning in of the feet.” The figure from [62] is shown in figure 2.6.1f below:
The brace from [62] shown above is similar to that of the current standard-of-care brace. The standard-of-care brace and additional modern day clubfoot bracing is discussed in detail in the methods of this dissertation, below, under the heading of brace construction.
3 BACKGROUND – SURROGATE BIOMODELING

Anatomical modeling has many uses in the commercial sector. Such modeling is particularly well suited for medical applications. This modeling is seen in areas such as visualization, special effects, user interface development, gaming, interactive virtual environments, medical device development, medical device and implant placement, diagnostic assistance, preoperative planning and practice, and clinical education [63, 64, 65].

3.1 Digital Simulation

Digital simulation for medical applications was first based on the techniques from virtual reality. Concepts of navigation and immersion were applied to three-dimensional anatomical space. These techniques considered only the geometric kinematics of the anatomy and were typically well applied in the area of education and training. Delingette describes in [66] three generations of medical simulation. The first generation simulators considered only the anatomy, such as shape, surface, volume, and morphology. Second generation simulators can model the physical interaction of anatomical structures. These later simulators were also able to model kinematic coupling and muscle deformation. Second generation simulators considered the physics of modeling, including deformation, temperature, state of matter, and forces. A third generation of simulators is being developed to model the functional nature of human organs. These simulators attempt to model physiology, such as cell activity and pathology. In Delingette’s survey, he discusses the advantages and challenges of simulators attempting to combine all three generations.
The accuracy of a simulation is improved when it attempts to correctly represent deformation of real tissue. As a result, it is important to have quantitative knowledge of actual biomechanical behavior. Mathematical models have been developed to simulate such behavior, such as the linear elastic model for soft-tissue. This simple model of elastic deformation follows Hooke’s law, having a linear stress/strain relationship. For most materials, this linear model works only for small displacements. Larger displacements require more complex models such as Mooney-Rivlin, which has a nonlinear stress/strain relationship [66].

In practice, there are a number of different deformable models, such as those applied to soft-tissue simulations. These include surface models, volume models, spring models, and finite element models.

Surface models require less computation because they have less vertices than volume models representing the same shape. However, most biomechanical models are complex, and require volumetric models that can take into account physical inhomogeneities. Surface models have been shown to be applicable in vessel simulations, including liquid and gas pressure simulations and surface tensions.

Spring models are a set of points linked by springs and dampers. These models have been used for simulating the elasticity of soft-tissue. Of particular interest is that spring model stiffness can be derived from the intensity of voxels in a CT-scan, with the assumption that tissue density is proportional to stiffness. This reasoning was used to determine Young’s modulus of bones from CT scans [66, 67].

Finite element models are widely used in industry and academia, and are also based on surfaces and volumes. Finite element models define shapes by a basic set of elements
including triangles, quadrilaterals, and so on. The main limitation associated with FE models is computational time. Some medical simulation requires the ability to simulate the cutting of soft-tissue or other anatomical structures. FE is not well suited for simulation of cutting tissue [66]. FE is particularly well suited for studying the deformation of tissue and for visualization.

There are additional deformable models. For example, the modeling of very soft objects can be attained by collision detection computation of surfaces defined by potential fields. Others include modal analysis and extended free-form deformations. Free form deformation is a method of fitting a standard shape to an object based on multiple images taken from various directions [68].

One application of simulation is for the improvement of medical imaging equipment and image processing techniques. In this field, the anatomical model is referred to as a “phantom” that can represent both subject anatomy and physiological function. There are currently two classes of digital phantoms as well as physical phantoms. The digital phantoms are either voxel-based (from specific patient data) or mathematical in foundation.

Voxelized phantoms have the benefit of providing realistic, patient-specific simulations. However, these phantoms are constrained to a single resolution and fixed anatomical structure. Only simple scaling and interpolation functions can be used to alter the phantom, which are limited in flexibility as well as diminishing quality of the phantom.

Historically, mathematical phantoms were based on simple geometry and thus easily manipulated. However, these phantoms are limited in that they do not accurately model anatomic structure. Recent work is, “aimed at computer phantoms that are flexible while maintaining an accurate representation of anatomy and physiology” [69]. An example of
such a phantom is the 4D NCAT phantom based on imaging data and using non-uniform rational B-splines to model organ shapes [69].

Realistic deformation can be critical to any anatomic model. Some methods of soft-tissue deformation affected by underlying skeletal structure include Skeletal Subspace Deformation, finite element methods, and methods based on anatomy using bones and pseudo-muscles. Bone shape and skin surface can be obtained simultaneously with medical imaging. Using several views and “poses,” the center of rotation for each joint can be estimated [63]. When obtaining image data from a medical source, such as CT, a common method for converting the voxels into surfaces is via the marching cubes algorithm [63].

3.2 Physical Models

Thus far, this background has primarily been focused only on anatomical models in a digital environment, with the exception of a brief mention to physical phantoms for medical imaging. A model of the anatomy is commonly referred to as a ‘biomodel,’ and a physical model as a ‘surrogate biomodel.’ These are often based on digital image data and/or anthropometric data. The ability to develop patient-specific biomodels is particularly valuable for the development of new medical devices. Surrogate biomodels can help clinicians and product development engineers to accurately assess spatial relationships of the internal anatomy and medical devices [64].

One method to develop patient-specific surrogate biomodels is using rapid prototyping (RP) technology. A common procedure is to download an image dataset, such as X-Ray Computed Tomography (CT), to a personal computer. A program, such as Mimics (Materialise, Leuven, Belgium), can be used to import the dataset, stack the images into a 3D representation, and allow for thresholding to segment specific anatomic structures. Data can
be exported directly from Mimics to an STL file, an industry standard for rapid prototyping. In some cases, additional manipulation to the model can be made with a CAD package or an application such as Magics RP, also by Materialise. Several RP technologies can be used to produce rigid or flexible parts of varying strength of material and geometric accuracy. More details on RP methods and materials can be found in Appendix B of this dissertation.

In general, RP is defined as the fabrication of physical models from computer-generated 3D surface models. The virtual model is broken down into thin slices. The RP machine then builds the physical model one layer at a time replicating the virtual model. It is most common for biomodels to be built from image data from X-Ray CT and MRI image modalities and from anthropometric data.

A standard literature search using the terms, “medical rapid prototyping,” reveals that most medical applications of RP are focused on head and neck, oral, and craniomaxillofacial surgery. There are a few citations for vascular applications [70]. Literature is particularly sparse for other medical applications, but some other examples include surgical planning and patient-specific implants in both humans and animals.

There are certain advantages to surrogate biomodels over traditional virtual models. The display of a 3D object on a 2D screen does not provide a complete understanding of a patient’s anatomy. Physical models are particularly attractive because they give the opportunity to hold the model in the hand and view it in a natural environment. This provides a direct and intuitive understanding of especially complex anatomic details [71].
3.3 Comparison of Surrogate Biomodeling versus Digital Modeling

To address the complex nature of clubfoot, the complexity of the foot itself, and the physical interaction with a brace; this research uses the concept of a physical biomodel to perform an effective investigation.

In a current survey of the literature, J.W. Fernandez and M.G. Pandy are leading researchers in the area of modeling dynamic musculoskeletal function in humans. They point out key difficulties in understanding dynamic loading conditions [72]:

- The inability to measure bone movements accurately *in vivo*;
  - Conventional methods employ video-based motion capture technology to track markers attached to the body.

- The inability to monitor muscle and bone loading non-invasively in living subjects;
  - The number of muscles and ligaments crossing any joint is greater than the number of degrees of freedom, thus the forces developed by the muscles and ligaments cannot be determined uniquely.
  - Computational advances have enabled simulations of movement performed on large-scale anatomical models of the body, however models used to study whole body movement still use over simplified models of the joints.

- The inability to model musculoskeletal anatomy accurately on a subject-specific basis
  
  Fernandez and Pandy, “approach these challenges by proposing a hierarchical rigid-body and finite-element (FE) modeling framework using anatomically based subject-specific models.” Their paper cited here, details subject-specific musculoskeletal computer models, computational methods for simulating movement, and methods to integrate computer modeling, imaging, and *in vivo* experiments to assess musculoskeletal function [72].
Such FE modeling is seen across the literature in areas such as biomechanical evaluations of orthotic treatment [73] and impact studies, such as with crash test dummies [74]. Indeed, medical imaging is advancing such FE models by giving new methods for acquisition of data from living subjects, in contrast to the material properties previously derived from cadaveric specimens. Accuracy of FE models now includes the detail of anatomic structures in three dimensions, thus increasing their accuracy and utility [75].

Lohfeld expands the definition of biomodel to include a “virtual biomodel” and “computational biomodel” [65]. The definitions of each are intuitive. Ultimately, the research of this dissertation, in future work, will investigate clubfoot bracing from perspectives that include all three forms of biomodels (virtual, computational, and surrogate), as each can be used as a validation tool for the next. However, the scope, timeline, and budget of the present work limit such an expansive investigation.

The natural progression of this research began with the development of a virtual biomodel based on anthropometric and patient-specific data. The critical decision was whether to further develop that virtual biomodel into a computational model or a physical one to investigate the biomechanics. Since physical models are typically the validation tools for computational models, the emphasis was to first establish a baseline in the physical realm prior to future computational investigations. A main objective of such a surrogate biomodel is to perform testing on actual braces, which has been done in the past on cadaveric models [76]. The main advantage of the surrogate biomodel is that it provides an opportunity to perform evaluations that can provide accurate and reliable results that are repeatable over a wide range of brace options. France et al. demonstrated such testing on a surrogate model based on cadaver molds [77].
4 METHODS

4.1 Preliminary Studies and Data

The foundation of this research is a case study of a patient with severe clubfoot detected prior to birth. A study of the options to correct the clubfoot deformity was studied. One of the treatment options identified was that of Dr. Ignacio Ponseti, the University of Iowa, Iowa City [2]. The clubfoot correction technique he developed in the 1950s, known as the Ponseti Method, is a conservative treatment option that uses a series of casts followed by a brace. This method of treatment is discussed in detail in the introduction to this dissertation.

The Department of Orthopaedics and Rehabilitation at the University of Iowa hosts an annual international symposium on clubfoot. This symposium served as the location for a clinical needs assessment to develop a problem definition based on a driving question, “What clubfoot problem has not been studied from an engineering perspective?”

In addition to attending the conference talks, individual feedback sessions were performed with some of the clinical researchers. By the end of the symposium, possible research topics were narrowed down to three top prospects, including:

- Biomechanics Computer Modeling to study the effects of clubfoot bracing
- A physical model with user feedback for training of the Ponseti manipulative technique
- A study of different brace options
A common theme throughout the entire symposium was the fact that there was no study on the effects of bracing from an engineering perspective. Of the ideas above, a combination of all three was ultimately settled upon, to build a physical mechanical model with feedback to study the effects of bracing and to compare different brace options and configurations.

4.1.1 Proof of Concept Biomodel

The original plan to build the surrogate biomedical included using patient-specific three-dimensional image data as the source for a model built using rapid prototyping technology (see Appendix B). This process would include:

- 3D medical image data acquisition of a pediatric subject by X-Ray CT
- Data import and conversion to a surface model with commercially available Mimics software (Materialise, Leuven, Belgium)
- Custom features added to the surface model, such as articulating ball and socket joints, and attachment points for ligaments and tendons via computer aided design (CAD) software package SolidWorks (SolidWorks, Concord, MA)
- The final edited model is exported to an industry standard STL file for production with Steriolithography (SLA) using a custom nickel-plated ceramic resin that can be tuned to closely match material properties of bone of a three-year-old subject (see Appendix B)

A plan to build a proof of concept biomodel via the above method was scheduled for the Spring of 2007 with the collaboration of the NCSU Industrial and Systems Engineering biomodeling course. Obtaining the pediatric X-Ray CT image data proved to be a major hurdle. Collaborators at NCSU, UNC Chapel Hill, Duke University, and University of Iowa
in addition to research institutions across the nation and world were contacted to see if such data existed. This thorough search included data maintained by the American College of Radiology. The data needed to include the entire lower anatomy, including the ankles and feet. It was apparent after several months of searching, that the research project could not rely on data so difficult to find. Secondary steps were put into place with local area clinicians to possibly obtain such data on a cadaver. To the date of this print, no such data has been obtained.

As a backup plan for the biomodeling course, the decision was made to use the National Library of Medicine’s Visible Human Project® image data. Using anthropometric information, this data was scaled down to match the age of an average three-year-old subject. Time and material constraints limited the build process to the following steps:

- 3D medical image data acquisition of the Visible Human Project®
- Data import and conversion to a surface model with commercially available Mimics software (Materialise, Leuven, Belgium)
- Model scaling to a three-year-old subject with commercially available Magics software (Materialise, Leuven, Belgium)
- The final edited model was exported to an industry standard STL file for production with Fused Deposition Modeling (FDM) using a common ABS resin
Below are images of the resulting model, held together with simple hooks and bands at anatomically correct positions:

Figure 4.1.1a: Proof of concept surrogate biomodel

Figure 4.1.1b: Proof of concept surrogate biomodel (close-up left foot)

Figure 4.1.1c: Proof of concept surrogate biomodel (front view)
Several lessons were learned from the build of the proof of concept model, including the following:

- The dissertation research could not rely on pediatric patient-specific image data
- Anatomic skeletal image data is not a good representation of joint range of motion;
  - Either post processing with CAD or an alternative approach needed to be considered.
- Scaling (alone) of adult data is not representative of pediatric data;
  - Additional post processing and utilizing available patient-specific data (albeit incomplete) needed to be considered.

4.2 Surrogate Biomodel Literature Search

Based on the proof of concept results, a literature search was focused on finding alternative methods to building a surrogate biomodel. During that search, the work of France et al. was found. They demonstrated such testing on a surrogate model based on cadaver molds [9]. After contacting several of the authors of [9], communication was established with an engineer at Breg, Inc (Vista, CA) who had collaborated with France and who continues to work in the area of surrogate biomodels.
This search helped define the resulting plan to build a surrogate biomodel with anthropometric data as described above. An image of a modern surrogate biomodel at Breg, Inc. is pictured below:

Figure 4.2: Example Surrogate Biomodel (image supplied by Breg, Inc.)

4.3 Surrogate Biomodel Construction Overview

Commercially available clubfoot braces, including the standard-of-care brace according to Ponseti [2], are placed on a surrogate pediatric biomodel instrumented to measure force in muscle-tendon systems of the lower anatomy.

In order to perform tests that are accurate and repeatable, the surrogate pediatric biomodel was developed while considering the surrogate limb for knee brace impact testing designed by France et al. twenty years ago [77]. There are many differences, including advancements (such as scaling and mobility) and shortcomings due to budget and time constraints. However, many of the principles developed by France et al. were employed.
The surrogate biomodel was also built with the capacity for upgrades and advances to be included in future work, such as including the use of modern sensors and pneumatic and/or air muscles. Currently underway (also for future work) is a ballistic gel and/or silicone covering that will mimic soft-tissue.

The surrogate was developed to represent the anatomy of an average five-year-old human subject that can imitate normal biomechanical characteristics, including joint articulation, kinematics, and dynamics. The biomodel’s components include a skeleton, articulating joints, muscle-tendon systems, ligaments, and soft-tissue (currently underway for future work). Muscle-tendons and ligaments were inserted and connected at anatomically correct origins, the details of which are explained below. A comprehensive list of the anatomy modeled is below, followed by the details of the surrogate construction.

**Skeletal Structures:**

- Pelvis
- Femur
- Tibia/Fibula
- Foot

**Articulating Joints:**

- Hip
- Knee
- Ankle (tibiotalar)
- Subtalar (talocalcaneal)
Muscle-Tendon Systems (*included in data analysis):

- Gluteus Medius
- Semimembranosus
- Biceps Femoris Long Head
- Biceps Femoris Short Head
- Rectus Femoris
- Adductor Longus
- Pectineus
- Gastrocnemius Medial Head*
- Gastrocnemius Lateral Head*
- Soleus*
- Tibialis Posterior*
- Tibialis Anterior*
- Peroneus Longus*

Major Ligaments to constrain motion include:

- Knee Ligaments constrained by hinge joints
- Patellar Ligament modeled with extension springs
- Ankle Ligaments (deltoid, plantar calcaneonavicular, posterior calcaneofibular, and syndesmosis) modeled with flexible cord emulating a scaled version of the Ponseti Training Model [6]
The model that France et al. developed employed Teflon coated cables used to represent ligaments and muscle-tendon systems. At one end of the cable attachment, a load cell and compression spring assembly consisting of a strong and weak spring were placed in series. Such an arrangement can appropriately simulate tension and elongation characteristics of ligaments and tendons according to France et al [77]. This setup also allows for pre-tensioning of the system [78].

Optimization and/or alternatives to that method were considered. The use of small extension springs and miniature turnbuckles were used to obtain the ability to preload the model while at the same time achieving a scaled down (average five-year-old) and mobile surrogate.

The biomodel was designed such that it can readily be improved for future work. Examples of improvements that the model is capable of being updated with include: joints instrumented for angular measurements; the use of accelerometers to capture accurate, real-time data in three-dimensions; potentiometer, linear variable displacement transducers (LVDT), and electromagnetic 3D positioning; pneumatic muscles with embedded feedback systems; and other alternative methods to remotely measure force and displacement of the muscle-tendons.

A covering of ballistic gel and/or silicone, to be manufactured in future work, will be used to enclose the instrumented skeleton and designed to mimic characteristics of soft-tissue. The soft-tissue-like covering will be easily removed to access the underlying instrumentation. It is ideal to have such a soft-tissue covering from the feet to the upper thighs, primarily as an anatomically-correct attachment for various brace options. Such a
soft-tissue covering will also be beneficial for future work such as passive motion studies. This soft-tissue manufacturing process is currently underway.

Rapid prototyping (RP) technology has been employed to build the skeletal components of the surrogate biomodel. Refer to Appendix B for more information on RP technology and material options.

4.3.1 Detailed Construction Steps

• 3D medical image data of the Ponseti training model was acquired utilizing X-Ray CT [6] (MD Orthopaedics, Inc., Wayland, IA).

  Figure 4.3.1a: The Ponseti Training Model [6]; Figure 4.3.1b: The training model segmented; Figure 4.3.1c: The X-Ray CT scan of the training model

• The National Library of Medicine’s Visible Human Project® image data was acquired to model the pelvis, femur, and tibia/fibula.

• Both sets of image data were imported and converted to CAD surface models utilizing commercially available software (Mimics by Materialise, Leuven, Belgium).

• The surface models were then scaled to the size of an average five-year-old human subject using Mimics;
  
  o The size of the surrogate biomodel was determined from anthropometric data (See table 4.3.1, determined from [79], and figure 4.3.1d).
Table 4.3.1: Anthropometric Data including a 50% female at 15 years consistent with patient data of the Ponseti Training Model, and a 50% average five-year-old human used for the current surrogate biomodel [6, 79]

<table>
<thead>
<tr>
<th>Measurement (inch)</th>
<th>50% female 15 years</th>
<th>50% female 6 years</th>
<th>50% female 3 years</th>
<th>50% female 5 years</th>
<th>50% male 5 years</th>
<th>50% avg 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot Width</td>
<td>3.5</td>
<td>2.5</td>
<td>2.2</td>
<td>2.4</td>
<td>2.5</td>
<td>2.4</td>
</tr>
<tr>
<td>Foot Length</td>
<td>9.4</td>
<td>7.0</td>
<td>5.9</td>
<td>6.7</td>
<td>6.8</td>
<td>6.8</td>
</tr>
<tr>
<td>Tibia/Fibula</td>
<td>15.3</td>
<td>10.0</td>
<td>6.7</td>
<td>8.7</td>
<td>8.3</td>
<td>8.5</td>
</tr>
<tr>
<td>Femur</td>
<td>16.5</td>
<td>11.3</td>
<td>10.0</td>
<td>11.0</td>
<td>11.1</td>
<td>11.1</td>
</tr>
<tr>
<td>Bi-iliac distance</td>
<td>10.7</td>
<td>7.3</td>
<td>6.4</td>
<td>7.0</td>
<td>6.9</td>
<td>7.0</td>
</tr>
<tr>
<td>Biacromial distance</td>
<td>14.0</td>
<td>10.0</td>
<td>9.0</td>
<td>9.6</td>
<td>9.7</td>
<td>9.7</td>
</tr>
</tbody>
</table>

- Custom features were added to/modified on the surface models using Mimics, including:
  - Ball and socket joint at the femur/hip interface designed considering a standard replacement joint.
  - Hinge joint at the knee designed to fit a standard 5/16-inch nut and bolt set.
  - Addition of a patella to the femur.
o Merging of the Ponseti Training Model Tibia/Fibula (bottom half) with the Visible Human Tibia/Fibula (top half).

![Merging operations of the Ponseti and Visible Human CAD models, including orientation fitting (left), joining of the tibia/fibula (bottom right), and smoothing after the merge (top right)](image)

Figure 4.3.1i: Merging operations of the Ponseti and Visible Human CAD models, including orientation fitting (left), joining of the tibia/fibula (bottom right), and smoothing after the merge (top right)

- Mirroring the left and right halves of the model.

![Mirroring of the individual bones of the left and right foot from the Ponseti CAD surface models](image)

Figure 4.3.1j: Mirroring of the individual bones of the left and right foot from the Ponseti CAD surface models

- Building up the center of the Pelvis for added strength.

- The final edited biomodel components were exported to an industry-standard STL file for production using Fused Deposition Modeling (FDM) with a Dimension SST 1200es (Stratasys, Eden Prairie, MN) using an extra strength ABS plastic resin (See P430 ABSplus in Appendix B).
• The Femur and Tibia/Fibula (both right and left) were attached using the nut/bolt combination specified above.

• The bones of the foot were attached with elastic cord emulating the Ponseti Training Model.

• The feet were attached to the Tibia/Fibula by both elastic cord and a miniature extension spring and cable combination described in the muscle-tendon construction section below.

• The femur hip sockets are held in place from the muscle-tendon systems, all of which were constructed using the materials described muscle-tendon construction section.
4.3.1.1 Muscle-Tendon Construction

The muscle-tendon systems detailed above (and the patellar ligament) were instrumented with a spring and cable combination that included miniature turnbuckles and/or cable ties to achieve a desired preload. The cables were attached to the biomodel by small eyehooks. The following components were used:

- Stainless steel cables, internally lubricated and coated with nylon, .044 inch outside diameter with 7x7 construction with hand made loop ends using loop/sleeve fittings (Carl Stahl Sava Industries, Inc., Riverdale, New Jersey)
- Miniature Precision Turnbuckles (Carl Stahl)
- Precision Extension Spring constructed of Zinc-Plated Steel Music Wire (McMaster-Carr Supply Company, Princeton, New Jersey)
  - The specifications in table 4.3.1.1 are met by the American Society for Testing and Materials (ASTM) B633
  - The spring constant was verified by experimentation and is shown in figure 4.3.1.1, note that the springs have a perfect linear response to four significant figures, with an R-squared of 1.000
- Other standard components such as split rings and cable ties were used

<table>
<thead>
<tr>
<th>Overall Length</th>
<th>1.044”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length Inside Ends</td>
<td>1.000”</td>
</tr>
<tr>
<td>Outside Diameter</td>
<td>3/16”</td>
</tr>
<tr>
<td>Outside Diameter Tolerance</td>
<td>+.003&quot;/-0.005”</td>
</tr>
<tr>
<td>Wire Diameter</td>
<td>.022”</td>
</tr>
<tr>
<td>Load</td>
<td>2.45 lbs.</td>
</tr>
<tr>
<td>Deflexion at Load</td>
<td>1.000”</td>
</tr>
<tr>
<td>Deflexion at Load Tolerance</td>
<td>±10%</td>
</tr>
<tr>
<td>Rate</td>
<td>2.4 lbs./inch</td>
</tr>
<tr>
<td>Rate Tolerance</td>
<td>±10%</td>
</tr>
<tr>
<td>Initial Tension</td>
<td>.25 lbs.</td>
</tr>
<tr>
<td>Initial Tension Tolerance</td>
<td>±15%</td>
</tr>
</tbody>
</table>

Table 4.3.1.1: Spring specifications
4.3.1.2 Muscle-Tendon Attachment Points

The open-source software to create and analyze dynamic simulations of movement, developed by Scott Delp, et al., was used to determine muscle-tendon attachment points for the surrogate biomodel [80]. This software, OpenSim, was used to first position the existing lower anatomy simulation model in a pose similar to that of the desired final surrogate biomodel pose (left side images in figure 4.3.1.2). Note that foot angles are not as severe in the OpenSim model as they are in the surrogate biomodel (right side images of figure 4.3.1.2). The limited range of foot motion is due to OpenSim’s representation of the ankle and subtalar joints as ideal revolute joints, as discussed in section 2.2. The fact that graphics-based biomodeling does not realistically model the complex kinematics of the foot is one justification for choosing surrogate biomodeling as the methodology for this investigation. Future work may include developing a version of an OpenSim model that accurately models the foot, thus the justification for emulating the OpenSim attachment points on the current surrogate.

The muscle-tendon units as described in the construction overview above are shown in the OpenSim model. The attachment points for each muscle-tendon system were determined from OpenSim, and then marked on the corresponding surface of the surrogate.
biomodel. Figure 4.3.1.2 shows front, back, and side views for both the OpenSim model and the surrogate biomodel.

![Figure 4.3.1.2: OpenSim screen captures (front, back, and side views) in the pose used to determine muscle-tendon attachment points [80] with the corresponding views from the actual surrogate](image)

4.4 Brace Construction

4.4.1 Standard-of-Care Brace

A standard-of-care brace constructed according to the method of Ponseti is utilized throughout this dissertation [2]. This method calls for a bar with shoes attached at the ends of the bar set at 70-degrees of external rotation and up to 20-degrees of dorsiflexion (based on the maximum achieved after Achilles tendon tenotomy). The length of the bar should be equal to the width of the shoulder (anthropometric data is used to determine the shoulder with of the surrogate and can be found in table 4.3.1).

The specific standard-of-care brace utilized in this dissertation is the “Ponseti” brace (MD Orthopaedics, Wayland, IA). This brace is consistent with the specifications from the Ponseti method, with the exception of dorsiflexion angle, which was found to be 10 degrees when measured out of the box (as opposed to maximum achieved following Achilles tendon...
tenotomy). Attached to the bar are orthopaedic shoes that can be separated by a quick release mechanism. During this dissertation, the orthopaedic shoes are considered part of the surrogate biomodel due to the limitation of not yet having a soft-tissue covering to provide a repeatable attachment surface. In addition, leaving the orthopaedic shoe as part of the surrogate removes a degree of variation from the analysis that could be introduced by different shoes.

![Figure 4.4.1: The standard-of-care “Ponseti” brace and orthopaedic shoe by MD Orthopaedics](image)

### 4.4.2 Additional Brace Configurations

Two alternative brace styles are examined during the course of this dissertation, an articulating brace and an ankle-foot orthosis (AFO) style brace. The specific articulating brace used in this dissertation is the Dobbs Bar™ by D-Bar Enterprises, LLC (Webster Groves, MO). There are several shoe and AFO options that can attach to the Dobbs Bar™. In this dissertation, only the orthopaedic shoe supplied by MD Orthopaedics is used. The setup for the articulating brace used throughout this dissertation is shown in figure 4.4.2a. Note that external rotation and width of the articulating brace are adjustable parameters, as is the case for the standard-of-care brace. However, the articulating brace cannot be adjusted to a fixed dorsiflexion position, unlike the standard-of-care brace.
The third AFO-style brace used in this research is a leg attachment that is fixed to the orthopaedic shoe by MD Orthopaedics. The AFO-style brace maintains each foot in dorsiflexion independently, and has no connecting bar. With no bar, AFOs do not have the ability to have a set width nor external rotation, as can be done with the standard-of-care brace. The setup for the AFO used throughout this dissertation is shown in figure 4.4.2b.

Future research is planned to study as many brace options and configurations as possible to compile a significant database of bracing. Some braces may be unknown to the author at this time, or may not yet be developed. The following is a detailed list of existing braces known to the author planned for future work:
• Markell/Fillauer Brace, see figure 4.4.2c;
  
  o This brace is built according to specific guidelines and materials used by American Prosthetics and Orthotics at the University of Iowa Hospitals and Clinics (Iowa City, IA), the shop used by Ponseti.
  
  o The bar, including footplates to attach to shoes and necessary hardware, is sourced from Fillauer LLC (Chattanooga, TN).
  
  o The shoes are straight last, sourced from M. J. Markell Shoe Co. (Yonkers, NY).

![Figure 4.4.2c: The Fillauer/Markell bar/shoe combination](image)

• Uganda, Steenbeek designed a brace [81]

• The Wheaton™ Bracing System (KAFO), Wheaton Brace Co. (Carol Stream, IL) shown in figure 4.4.2d

![Figure 4.4.2d: Wheaton™ Bracing System (KAFO); from [62]](image)
• Flexible modification of the classic Denis Browne bar, with an attachment to standard straight last shoes developed by Action Orthopedic Company (Los Angeles, CA) [59];
  o The brace consists of straight last shoes connected to a flexible 1/8 inch thick polypropylene bar with the ankles in 10 to 15 degrees dorsiflexion, as shown in figure 4.4.2e on the left.
  o The shoes are attached to the bar via bolts placed through holes in the polypropylene.
  o The patients have the ability to momentarily plantarflex their ankles due to the bar’s flexibility; and then they quickly return to the original dorsiflexed position; this is shown in figure 4.4.2e on the right.

Figure 4.4.2e: Flexible modification of the Denis Browne bar by Action Orthopedic Company; on the left in the standard dorsiflexed position, and on the right momentarily being plantarflexed by the patient; from [59]

4.5 Research and Design Methods

Foot abduction splints (braces) for clubfoot are subject to testing on a surrogate pediatric biomodel instrumented to measure force in muscle-tendon systems of the lower anatomy, primarily that of the Achilles tendon. The objective of this research is to compare existing braces and brace configurations to the standard-of-care brace/configuration as prescribed by Ponseti [2]. No assumption of safety or efficacy is made with respect to the standard-of-care brace or any other brace options.
4.5.1 Experimental Design

The design of experiments used for this dissertation was developed specifically to address the proposed hypotheses detailed in the specific aims. The tests have been designed to observe changes in muscle-tendon force when braces are applied to the surrogate biomodel. Components of variance include:

- Brace variance
  - Variance between at least two of the same braces set up the same way

- Investigator variance, including:
  - Parameter variance;
    - Variance of setting up (at least twice) the brace parameters, such as brace width, external rotation, and dorsiflexion angle.
  - User variance;
    - Variance between different users (at least two) setting up and applying the same brace.
  - Measurement variance;
    - Variance between different investigators (at least two) recording spring length and joint angles & coordinates.

- Biomodel variance
  - Variance between surrogate biomodels with multiple variables, including:
    - Source of patient data.
    - Biomodel scale/age.
    - Construction materials and methods.
These components of variance are expected to be small, and considered normal measurement error. Replication is important, and therefore multiples (at least two) of the same brace and investigator were used. A limitation of this dissertation is that biomodel variance is not being considered due to the construction of one biomodel based on one set of combined and scaled patient data.

4.5.2 Test Methods

The protocols in this section were developed to investigate the specific aims, and are therefore broken down by each of the three hypotheses. Note that all of the testing was performed on the surrogate biomodel fixed at the pelvis in a frame of reference. Details on the frame of reference are provided in the glossary in Appendix D on page 147.

First Hypothesis: A surrogate biomodel shows minimal variance due to measurement error when conducting tests with equal design

Test 1: Force introduced by equal braces

The purpose of this test is to establish whether or not the approach of surrogate biomodeling is an accurate and repeatable method to investigate clubfoot bracing.

- Place the model in a supine position with the knees at 20 to 30 degrees of flexion consistent with clinical protocol for examining passive dorsiflexion \[82\];
  - This position is achieved by applying an initial preload to the muscle-tendons as described in the construction details above.

- Record the spring length (force), hip, knee, and ankle rotations, and joint coordinates prior to applying the brace;
  - Note: Shoes are part of the biomodel in this set-up, not part of the brace.
• A list of springs included in the data analysis is provided in the Surrogate Biomodel Construction Overview.

• The glossary in Appendix D on page 147 contains a list of all parameters recorded throughout experimentation.

• Apply the brace to the model using standard manufacturing and clinical specifications;
  - 70 degrees external rotation, shoes shoulder-width apart, and 10 to 20 degrees of dorsiflexion for the standard-of-care brace.

• After the brace is applied and the system is allowed to reach equilibrium, record spring length, and joint angles and coordinates.

• Remove the brace and allow the system to reach equilibrium.

• Record spring length and joint angle.

• Repeat the entire sequence at least two times (and repeat as necessary based on data analysis), repeating:
  - At least two of the same brace.
  - At least two set-ups/applications/measurements per brace.
  - At least two investigators setting-up, applying, and measuring.
Second Hypothesis: A change in surrogate biomodel muscle-tendon force is expected when degrees of freedom are varied within one brace type

Test 2: Force introduced by changing brace parameters

The purpose of this test is to investigate whether or not changing brace parameters such as width, external rotation, and dorsiflexion angle significantly impact muscle-tendon force. The outcome of this test will include a characterization of force vs. parameter.

• Place the model in a supine position with the knees at 20 to 30 degrees of flexion consistent with clinical protocol for examining passive dorsiflexion [82];
  o This position is achieved by applying an initial preload to the muscle-tendons as described in the construction details above.

• Record the spring length (force), joint angles, and joint coordinates prior to applying the brace;
  o A list of springs included in the data analysis is provided in the Surrogate Biomodel Construction Overview.
  o The glossary in Appendix D on page 147 contains a list of all parameters recorded throughout experimentation.

• Apply the brace multiple times to the model over a range of values for one parameter while keeping the other two parameters at clinical specifications as follows:
  o External rotation from 0 degrees to 80 degrees at 10 degree increments;
    ▪ See the example in figure D6 in Appendix D.
  o Brace width from 4 inches less than shoulder width to 4 inches greater than shoulder width at one-inch increments;
- Note, shoulder width is based on anthropometric data provided in table 4.3.1.
- See the example and instructions for brace width in figures D7 and D8 in Appendix D.
  - Dorsiflexion angle from 0 degrees to 30 degrees at 10 degree increments;
  - See the example in figure D9 in Appendix D.
- Record spring length and knee joint angles at each increment above
- Normalize the muscle-tendon data by the no brace condition

**Third Hypothesis:** A change in surrogate biomodel muscle-tendon force is expected when comparing the various brace options

**Test 3: Force introduced by different braces**

The purpose of this test is to investigate whether or not different braces significantly impact muscle-tendon force. Since the standard-of-care brace is being compared to an articulating brace and AFO-style brace, the surrogate biomodel will be forced through a small range of motion by bending the knees in opposition to each other (such as pedaling a bicycle)

- Place the model in a supine position with the knees at 20 to 30 degrees of flexion consistent with clinical protocol for examining passive dorsiflexion [82];
  - This position is achieved by applying an initial preload to the muscle-tendons as described in the construction details above.
- Record the spring length (force), joint angles, and joint coordinates prior to applying the brace;
A list of springs included in the data analysis is provided in the Surrogate Biomodel Construction Overview.

The glossary in Appendix D on page 147 contains a list of all parameters recorded throughout experimentation.

- Apply one brace type to the biomodel and then record spring length, joint angles, and joint coordinates
- Apply passive force to the model at the heel, translating the heel in the negative-X direction at one-inch increments, up to four inches;
  - See the example in figure D10 in Appendix D.
- Repeat with the opposite heel
- Repeat the protocol above for all three brace types and a no brace condition

### 4.5.3 Limitations

No claims of safety or efficacy in humans are made or implied as a result of this study with respect to the standard-of-care brace or alternative braces. The use of the surrogate pediatric biomodel is to quantify the human conditions at a best approximation and provide an opportunity for accurate, reliable, and repeatable test conditions. Actual human muscle loading and joint compression are variables that would affect patient-specific results. A significant limitation is the finite number of loading conditions simulated is not an accurate representation of dynamic movement in human subjects. The mechanical properties of all materials used in the biomodel are at best an approximation of the complex anatomical structures in humans. The biomodel itself is based on limited patient and anthropometric data that does not take into account the unique anatomies across a population. Factors such as brace application tightness, and user comfort are not considered.
A significant limitation to this research was a lack of resources, such that high-tech instruments to measure joint angle, position, and muscle-tendon force more accurately could not be utilized. Due to the fact that the methods used required hand measurements, such as springs for muscle-tendon simulation, development of a soft-tissue covering was moved to future work. The direct application of the brace to the skeletal structure is a limitation not consistent with normal clinical use.

Additional limitations arise from the single prone position in which the surrogate is placed throughout this investigation. This one position does not consider the complexities of a mobile human subject. In addition, the surrogate is currently not setup to perform certain movements, such as hip extension and internal/external rotations of the knee. Minimal isometric loading was investigated, including the use of a single spring constant over three unique preload conditions.

The loads induced in this investigation are not close to those of human subjects. This was done intentionally based on the requirement to obtain hand measurements with a digital caliper, rather than digitally reading from a load cell. In addition, the ABS resin utilized could not support such loads. Future work will consider the use of high strength materials, as discussed in Appendix B, in order to support more significant loads that better represent human subjects. As an example, the France load cell was rated at 6500 N [77]. This is consistent with the peak load of the Achilles tendon during walking, running, jumping, and hopping of approximately 2600 N, 5200 N, 3800 N, and 3000 N respectively [83, 84]. While these figures are for adults, it has also been shown that the ratio differences in tensile properties between child and adult are not large [74].
All of the translations of the surrogate biomodel during this dissertation are passive. This is a limitation due to the fact that human subjects perform voluntary motions. Muraoka et al. reported that the Achilles tendon torque in adult female and male during voluntary plantar flexion was measured at 2856±757 Nm and 4229±805 Nm, respectively [85]. A surrogate capable of simulating voluntary movement is a consideration for future work.

Passive torques are much lower than the voluntary torques cited in [85]. Table 4.5.3a is a literature search for studies involving the measurement of passive torque of dorsiflexion at the ankle. The range is wide, from as low as 1 Nm to as much as 40 Nm. The surrogate biomodel was measured to have a passive torque of ankle dorsiflexion that ranges from 1.34 Nm to 4.11 Nm, from 0-degrees to 15-degrees dorsiflexion. This is at the lower end of that shown in table 4.5.3a.

<table>
<thead>
<tr>
<th>Passive Torque (Nm)</th>
<th>Range of Motion (degrees)</th>
<th>Test Apparatus</th>
<th>Patient Population</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>.96 (1.25)</td>
<td>10 plantarflexion to maximum dorsiflexion</td>
<td>Biodes isokinetic dynamometer</td>
<td>15 male, 5 female, average age 44.1 (13.8)</td>
<td>[86]</td>
</tr>
<tr>
<td>12 to 16.8 (applied)</td>
<td>Not Reported</td>
<td>torque controlled measurement with spring balance</td>
<td>Nine people who had sustained traumatic closed head injuries and had limited dorsiflexion motion</td>
<td>[87]</td>
</tr>
<tr>
<td>4.94 (4.8) and 4.32 (1.02) for two tests</td>
<td>Peak at 0 (from 10 plantarflexion to 10 dorsiflexion)</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>20 healthy, male, volunteer subjects with mean age of 26.4 (4.2)</td>
<td>[88]</td>
</tr>
<tr>
<td>8.57 (7.57) and 7.59 (4.67) for two tests</td>
<td>Peak at 5 (from 10 plantarflexion to 10 dorsiflexion)</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>20 healthy, male, volunteer subjects with mean age of 26.4 (4.2)</td>
<td>[88]</td>
</tr>
<tr>
<td>8.57 (7.57) and 6.12 (4.67) for two tests</td>
<td>Peak at 10 (from 10 plantarflexion to 10 dorsiflexion)</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>20 healthy, male, volunteer subjects with mean age of 26.4 (4.2)</td>
<td>[88]</td>
</tr>
<tr>
<td>30.2 (2.3) before and 41.2 (2.0) after stretching</td>
<td>10 dorsiflexion</td>
<td>Leg holder with strain gauges</td>
<td>10 healthy young adults (6 men and 4 women)</td>
<td>[89]</td>
</tr>
<tr>
<td>21.68 (5.33)</td>
<td>25.83 (5.5) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>24 young women aged 20-39</td>
<td>[90]</td>
</tr>
<tr>
<td>17.66 (5.48)</td>
<td>22.78 (4.93) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>24 elderly aged women from 40-80</td>
<td>[91]</td>
</tr>
<tr>
<td>12.61 (5.98)</td>
<td>15.39 (5.78) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>33 older women aged 60-84</td>
<td>[90]</td>
</tr>
<tr>
<td>23.6 (5.0) maximum for slow stretch</td>
<td>24.1 (7.6) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>15 younger women without limited dorsiflexion range of motion, mean age of 23.9 years</td>
<td>[88]</td>
</tr>
<tr>
<td>30.2 (5.6) maximum for fast stretch</td>
<td>24.1 (7.6) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>15 older women with goniometric active dorsiflexion limited range of motion, mean age 78.1 years</td>
<td>[92]</td>
</tr>
<tr>
<td>7.9 (1.4) average for slow stretch</td>
<td>24.1 (7.6) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>15 younger women without limited dorsiflexion range of motion, mean age of 23.9 years</td>
<td>[88]</td>
</tr>
<tr>
<td>8.2 (1.4) average for fast stretch</td>
<td>24.1 (7.6) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>15 older women with goniometric active dorsiflexion limited range of motion, mean age 78.1 years</td>
<td>[92]</td>
</tr>
<tr>
<td>14.0 (4.3) maximum for slow stretch</td>
<td>8.8 (4.3) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>15 younger women without limited dorsiflexion range of motion, mean age of 23.9 years</td>
<td>[88]</td>
</tr>
<tr>
<td>15.6 (5.1) maximum for fast stretch</td>
<td>8.8 (4.3) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>15 older women with goniometric active dorsiflexion limited range of motion, mean age 78.1 years</td>
<td>[92]</td>
</tr>
<tr>
<td>8.5 (1.3) average for slow stretch</td>
<td>24.1 (7.6) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>15 younger women without limited dorsiflexion range of motion, mean age of 23.9 years</td>
<td>[88]</td>
</tr>
<tr>
<td>5.7 (1.5) average for fast stretch</td>
<td>24.1 (7.6) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>15 older women with goniometric active dorsiflexion limited range of motion, mean age 78.1 years</td>
<td>[92]</td>
</tr>
<tr>
<td>29.72 (12.3) maximum</td>
<td>29.72 (12.3) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>70 distance runners (aged 16-21 years)</td>
<td>[93]</td>
</tr>
<tr>
<td>22.14 (3.52) maximum</td>
<td>22.14 (3.52) maximum passive dorsiflexion</td>
<td>KIN-COM isokinetic dynamometer</td>
<td>16 untrained men (aged 22-28 years)</td>
<td>[94]</td>
</tr>
<tr>
<td>12.5 (3.1) at 10 dorsiflexion</td>
<td>computer controlled torque measurement system</td>
<td>18 adult brain injured subjects undergoing serial casting to correct ankle equinovarus deformity</td>
<td>Static-Stretch Group</td>
<td>[95]</td>
</tr>
<tr>
<td>17.99 (3.77)</td>
<td>28.76 (6.80) knee extended, 36.65 (9.17) knee flexed</td>
<td>81 healthy subjects randomized into 3 groups: a static-stretch group, a ballistic-stretch group, and a control group with a Biodes isokinetic dynamometer</td>
<td>Static-Stretch Group</td>
<td>[96]</td>
</tr>
<tr>
<td>17.99 (4.48)</td>
<td>28.06 (6.80) knee extended, 36.65 (9.17) knee flexed</td>
<td>81 healthy subjects randomized into 3 groups: a static-stretch group, a ballistic-stretch group, and a control group with a Biodes isokinetic dynamometer</td>
<td>Static-Stretch Group</td>
<td>[96]</td>
</tr>
<tr>
<td>17.12 (3.01)</td>
<td>28.00 (5.21) knee extended, 37.32 (6.68) knee flexed</td>
<td>81 healthy subjects randomized into 3 groups: a static-stretch group, a ballistic-stretch group, and a control group with a Biodes isokinetic dynamometer</td>
<td>Static-Stretch Group</td>
<td>[96]</td>
</tr>
</tbody>
</table>

Table 4.5.3a: Literature search for passive dorsiflexion torque in Nm
If the Achilles tendon passive stiffness is calculated from the three springs of the lateral head of the gastrocnemius, medial head of the gastrocnemius, and soleus all in parallel; that equates to 7.2 pounds/inch, or 1.261 N/mm. This is a fraction of the magnitude that is reported in [94], giving a range of passive stiffness from 46.04 N/mm to 59.42 N/mm. Passive torque is generally dependent on more than just the stiffness of one muscle-tendon group, but rather depends on the anatomy as a whole. Future work, including the addition of a soft-tissue simulant to the model is expected to impact the resulting measured passive torque for ankle dorsiflexion.

4.5.4 Resources and Facilities

Research, production, and testing has been performed at the facilities of the UNC/NCSU Joint Department of Biomedical Engineering including office and lab space at NCSU, such as the Biomechanics Lab and the Center for Robotics and Intelligent Machines.

Additional resources at the NCSU Department of Industrial and Systems Engineering have also been utilized, such as RP technology and specialized software to import and manipulate image data.

The following is a detailed list of resources used to produce the surrogate pediatric biomodel and to perform testing:

- A standard PC workstation with software Mimics and Magics from Materialise (Leuven, Belgium) and computer aided design (CAD) tool SolidWorks (Concord, MA) were used for data acquisition and post processing
- FDM RP technology was used to build the skeleton models at NCSU
- Molds and materials to construct the soft-tissue structure (future work) are utilizing the resources of NCSU ISE and BME
4.5.5 Surrogate Age Justification

The surrogate pediatric biomodel has been constructed to mimic an average five-year-old human. The most significant factor in choosing the model age was clinical relevance. Personal correspondence with leading clubfoot clinicians and researchers indicated that the most relevant age range when considering the effects of bracing would be a corrected patient that is walking. An age range of 18-months to five-years was initially considered, as five-years is the typical upper limit for brace wear for a patient treated as an infant.

Existing finite element data of the three-year-old model in the literature is promising for future work utilizing digital simulation [74]. However, the technical challenges of instrumenting such a small model were considered a technical risk not worth taking on a small budget and finite timeline, as is associated with dissertation research. The final decision to go with the five-year-old surrogate was due to the fact that the age is the standard pediatric age in the field of medical simulation. The surrogate biomodel produced here is considered a contribution to rehabilitation medical simulation, and as a result Gaumard Scientific (Miami, FL) donated the lower anatomy of a five-year-old simulator to the research. The model matched the anthropometric data compiled for the five-year-old age and was used for both reference points when building the skeletal model and is currently in use as a mold for construction of the soft-tissue structure. The five-year-old size has proven to be a size manageable for instrumentation.
5 RESULTS AND DISCUSSION

This section discusses the results from tests designed to investigate the three hypotheses stated in the test methods section above. The tests were specifically designed to examine these hypotheses. In turn, the hypotheses were written to be consistent with the original specific aims of this dissertation. These were first stated during the introduction section. For clarity, they will be stated again below, prior to their corresponding results section.

5.1 The First Hypothesis

The first hypothesis stated that a surrogate biomodel shows minimal variance due to measurement error when conducting tests with equal design. To prove this hypothesis, a test was designed to measure the force introduced to particular muscle-tendons of the lower anatomy from a resting position to a position after brace application. Measurement error was evaluated by looking at two sources of variance, brace variance and investigator variance.

*Figure 5.1a* shows graphically the spring lengths for the twelve muscle-tendons of interest in their initial resting position. Refer to the glossary in *Appendix D* on page 147 for a detailed explanation of terms used throughout the results and discussion. Note that the resting position for each spring is a unique preload. Throughout the entire investigation, three initial preloads were used, and referred to as A, B, and C. The tensions in preload-A are generally lower than the tensions in preload-C, with preload-B being a transition set.

*Figure 5.1b* shows the average resting length for each spring for each preload. It is important to note that, for example, left soleus and right soleus in preloads A, B, and C
represent 6 unique sets of data that will be described with abbreviations such as SOL, L, R, A, B, and C for soleus, left, right, preload-A, preload-B, and preload-C respectively. Again, refer to the glossary in Appendix D on page 147 for further details.

The data presented here supports the hypothesis that the surrogate biomodel shows minimal variance due to measurement error. In figure 5.1a, the error bars are one standard deviation from the mean. The coefficient of variation for each investigator ranged from a 1% to 6%.

![Resting Spring Lengths by Investigator for Preload A](image)

Figure 5.1a: Resting spring length data segmented by investigator

*Figure 5.1b* also shows standard deviation error bars, in this case for each preload set, A, B, and C. The coefficient of variation for each preload set ranged from 1% to 5%. These average resting lengths are used as normalization factors in data analysis for the second and third hypotheses. The spring lengths are generally shorter in preload-A, representing a lower initial tension, as compared to preload-C. Preload-B is a transition set between A and C. The only exception is the right tibialis posterior, for which preload-A was longer than preload-C. Note that due to Hooke’s Law, spring tension (force) is presented here as spring length because the linear relationship between the two. Hooke’s Law is

\[ F = -kX \]
where $F$ is the restoring force exerted by the spring, $k$ is the spring constant, and $X$ is the distance that the spring has been stretched or compressed from its equilibrium position. In addition, only relative changes or normalized changes are considered, eliminating the need to represent the data in units of force. The spring constant selected was to fulfill multiple requirements, including size of the biomodel, a stiffness that was capable of holding the biomodel in a static position, yet not so stiff as to limit motion. One criterion not capable of being achieved was anatomically-accurate muscle-tendon stiffness. Thus again eliminating the need to report data in terms of force as opposed to length.

Figure 5.1b: Average resting spring lengths for each spring preload set, A, B, and C

Figure 5.1c is a graphic representation of the spring lengths in preload-A segmented by two standard-of-care braces set-up and measured by two investigators. Error bars are standard deviations for each investigator and brace dataset. Such segmentation reduced sample sizes to as low as four data points, thus exaggerating measurement error. Even in this maximum segmentation scenario, the average coefficient of variation was 4%, with a range of 1% to 14%. When eliminating the segmentation, as shown in 5.1d, the standard deviations are reduced.
Figure 5.1c: Spring lengths after applying the standard-of-care brace for preload A, segmented by investigator and two equal braces.

Figure 5.1d: Spring lengths after applying the standard-of-care brace for preload A.

Figure 5.1e expands the view to include all three preload sets, A, B, and C. In this case error bars are standard deviations for each preload set. Coefficient of variation averaged 5%, 2%, and 2% for preloads A, B, and C respectively. In each case the minimum was 1%, with a maximum of 11%, 6%, and 3%, respectively.
The original intent of the first hypothesis was to only examine the no brace and standard-of-care brace conditions over time, looking at sources of variation. Additional data was collected under the same protocol for the articulating brace. Data was only collected for preloads A and C and is presented graphically in figure 5.1f. The error bars are standard deviations for each preload, A and C. The average coefficient of variation was 1% and 2%, and a maximum of 3% and 4% for A and C, respectively. While not segmented out, this data includes two investigators and two equivalent articulating braces, as was done with the standard-of-care brace.
The intent of the first hypothesis is to determine if surrogate biomodeling is a reliable and repeatable method to investigate clubfoot bracing. Only the right medial and lateral heads of the gastrocnemius, for preload-A for the standard-of-care brace, showed measurement error greater than 6% (10% and 11% respectively). In all other cases, for all preloads, muscle-tendons of interest, and for the standard and articulating braces; the coefficient of variation ranged between 1% and 6%. This result supports the first hypothesis, that a surrogate biomodel shows minimal variance due to measurement error. This hypothesis was proposed first specifically to lend credence to all further testing. These results do just that.

It is not surprising that the slightly higher measurement error took place during preload-A and on the gastrocnemius. Throughout experimentation, the investigators learned that gastrocnemius spring lengths were highly dependent on knee flexion. The no-brace normalization data collected during preload-A was allowed to have knee flexion anywhere between 20 and 30 degrees, as described in the test protocols, although as close to 25-degrees was always the goal. It is likely that the lower tension in preload-A resulted in larger variations between 20 to 30 degrees, while the higher preloads held the biomodel in a more firm static position.

5.2 The Second Hypothesis

The second hypotheses stated that a change in surrogate biomodel muscle-tendon force is expected when degrees of freedom are varied within one brace type. To investigate this hypothesis, a test was developed to measure force introduced by changing brace parameters, including external rotation, width, and dorsiflexion angle with the standard-of-care brace. The results provided below show support for the second hypothesis.
The intended data analysis for the results of this test was to first normalize the results by the preload resting lengths for each muscle-tendon spring. Once normalized, the results from the left and right sides of the biomodel, for the low preload condition (A) and high preload condition (C), would be averaged and displayed as a trend line with standard deviations as error. However, an unexpected result became apparent during data analysis that altered this approach. The normalized data sets consistently showed an increased impact of brace parameters on muscle-tendons with a lower preload. This was evident in both an increased magnitude and lesser evident in an increased slope.

As a result of this unexpected result, the data is presented as individual data points and lines for each muscle-tendon, for each side of the biomodel, and for each preload. The results may not be as smooth as averaged results; however, it is the author’s position that more significant information can be extracted from the data presented in this manner.

The clinical significance of this unexpected result is that, in practice, patients with hyperlaxity are often over-corrected, sometimes resulting in plantar valgus deformity, which is a shortening of the Achilles tendon. Clinical practice is to reduce brace external rotation from the prescribed 70 degrees to 20 degrees, and to reduce brace dorsiflexion from the prescribed 10 to 20 degrees to 0-degrees (based on conversation with Jose Morcuende, University of Iowa, Iowa City, IA, March 26, 2009).

*Figures 5.2a-c* show that for the medial head of the gastrocnemius, tension increases with respect to increasing external rotation, decreasing width, and increasing dorsiflexion angle. The impact of brace width appears to level off slightly at the 9.75-inch mark, which is the standard-of-care prescribed width for the surrogate biomodel (consistent with the surrogate’s anthropometric shoulder width). The data set consistently shows that for each
side of the surrogate (left and right), the lower preload (A) has a greater magnitude than the higher preload (C). The dorsiflexion parameter best shows the increasing slope for lower preload, in the resulting fan effect observed in the data. Note how the data at the 0-degree dorsiflexion parameter are more tightly packed than the 30-degree mark, where they spread out.

The percent change from parameter to parameter also varies, with external rotation having the least impact (ranges from about 15% to 20%), width having an increased impact (ranges from about 10% to 30%), and dorsiflexion having the greatest impact (ranging from 25% to nearly 50%). Kinematic data, presented in more detail below, show that biomodel dorsiflexion is impacted in a similar manner from brace external rotation, width, and dorsiflexion. It is the author’s interpretation of this data that changing external rotation and width of the brace impact brace dorsiflexion, and thus patient dorsiflexion. This point will be discussed further in the conclusion.

Note that all of the figures in this section have equal dimensions and scale, with each line on the horizontal axis representing 10% change in tension. This consistency was done to provide an objective representation of the data from one parameter to the next.
Figures 5.2a-c: Normalized tension vs. brace parameters of external rotation, width, and dorsiflexion in the standard-of-care brace for the medial head of the gastrocnemius.

Figures 5.2d-f show the results for the lateral head of the gastrocnemius. The results for the lateral head are similar to that of the medial head. An increase in tension is seen with increasing external rotation, decreasing width, and increasing dorsiflexion. A greater magnitude is seen in each side of the biomodel for the lower preload condition. A change of
slope is apparent in the width parameter at the 9.75-inch mark. A fan effect is particularly noticeable in the dorsiflexion parameter data.

The percent change from parameter to parameter also varies, consistent with the medial head data. External rotation has the least impact, width has an increased impact compared to external rotation, and dorsiflexion has the greatest overall impact.
Figure 5.2d-f: Normalized tension vs. brace parameters of external rotation, width, and dorsiflexion in the standard-of-care brace for the lateral head of the gastrocnemius.

Figures 5.2g-i are the results of the changing parameters for the soleus. The results for the soleus are generally consistent with those for the lateral and medial heads of the gastrocnemius. An increase in tension is seen with increasing external rotation, decreasing width, and increasing dorsiflexion. A greater magnitude is seen in each side of the biomodel.
for the lower preload condition in both external rotation and width parameters. This magnitude difference is not seen in the dorsiflexion data for the preloads of the left versus the preloads of the right. However, a clear difference is noted between the left and the right, with the left side being higher. A change of slope is apparent in the width parameter at the 9.75-inch mark, and the fan effect is most noticeable in the dorsiflexion parameter data.

The percent change from parameter to parameter also varies, consistent with the gastrocnemius data. External rotation has the least impact, width has an increased impact compared to external rotation, and dorsiflexion has the greatest overall impact.
Figure 5.2g-i: Normalized tension vs. brace parameters of external rotation, width, and dorsiflexion in the standard-of-care brace for the soleus

Figures 5.2j-l are the results of the changing parameters for the tibialis posterior. The results for the tibialis posterior are strikingly similar to that of the soleus. An increase in tension is seen with increasing external rotation, decreasing width, and increasing dorsiflexion. A greater magnitude is seen in each side of the biomodel for the lower preload
condition in both external rotation and width parameters. As with the soleus, this magnitude difference is not seen in the dorsiflexion data for the preloads of the left versus the preloads of the right. However, a clear difference is noted between the left and the right, with the left side being higher. A change of slope is apparent in the width parameter at the 9.75-inch mark, albeit not as pronounced as in the gastrocnemius heads and the soleus. Typically throughout, the fan effect is most apparent in the dorsiflexion parameter data.

The percent change from parameter to parameter varies consistently with that of the gastrocnemius heads and soleus. External rotation has the least impact, width has a slightly increased impact compared to external rotation, and dorsiflexion has the greatest overall impact.
Figures 5.2j-l: Normalized tension vs. brace parameters of external rotation, width, and dorsiflexion in the standard-of-care brace for the tibialis posterior.

Figures 5.2m-o and 5.2p-r are the results for the tibialis anterior and peroneus longus, respectively. With the coefficient of variations reported in the first hypothesis results, no claim can be stated about these two muscle-tendon systems changing tension with respect to
changing brace parameters. The data is consistently clustered around 1.000 on the vertical axis, suggesting no change.

Figure 5.2m-o: Normalized tension vs. brace parameters of external rotation, width, and dorsiflexion in the standard-of-care brace for the tibialis anterior
5.2.1 Kinematic Data

Throughout the test procedures, the surrogate biomodel was fixed at the pelvis in a frame of reference. Details regarding the frame of reference are provided in the glossary in Appendix D on page 147. Kinematic data was collected as described in the test protocols.
The X, Y, Z coordinates of the hip were fixed throughout experimentation and are not included in the graphical analysis. The fixed locations of the left and right hip are (2.00, 2.25, 2.75) and (2.00, -2.25, 2.75) respectively. The coordinates are provided as (X, Y, Z) and are in inch units accurate to 0.25 inch. Note that the biomodel was in a supine position with the origin of the frame of reference at the center of the pelvis. The right leg was in the (X, -Y, Z) quadrant while the left leg was in the (X, Y, Z) quadrant.

Kinematic data were measured by hand with a ruler and goniometer against the background of the frame of reference, which had markings in all directions at equal 1-inch spacing. Photographs were taken at each surrogate biomodel pose prior to collecting all data from two fixed positions for a Z-X planar view and a Z-Y planar view. A third oblique photograph was also taken to enhance overall perspective of the surrogate’s pose. The kinematic data presented throughout are the hand-recorded values taken during all of the preload A experiments. See the glossary in Appendix D on page 147 for example Z-X and Z-Y planar views.

*Figures 5.2.1a-c* show the knee joint locations with respect to the standard-of-care brace parameters of external rotation, width, and dorsiflexion. For all three parameters, the X-positions of the knees are stable. The Z-positions of the knees are stable for brace width and decrease slightly for increasing external rotation and dorsiflexion, indicating an extension of the knees. This is consistent with the data in *figures 5.2.1j-l*, which show a relatively stable knee flexion for brace width while increasing external rotation and brace dorsiflexion are shown extending the knees.

The Y-positions of the knees are slightly increasing with increasing external rotation, and more greatly increase with increasing brace width. The Y-position increase associated
with brace external rotation is likely due to the resulting external rotation of the hips, as demonstrated in *figure 5.2.1g*. Also note that as external rotation is decreasing, the knees are moving toward the centerline (X-axis), as the external rotation parameter of the brace changes from a dorsiflexion enabler to a hip-adduction enabler (due to the dorsiflexion bend in the brace’s connecting bar). This hip adduction with decreasing external rotation is also noted in *figure 5.2.1g*.

A decreasing brace width has a more significant impact by increasing the surrogate’s ankle dorsiflexion. This is shown in *figure 5.2.1k*. In *figure 5.2.1c*, the knees are seen to move toward the centerline as brace dorsiflexion increases. Therefore, whether due to brace width or brace dorsiflexion, an increase in surrogate dorsiflexion is consistent with the knees moving toward the centerline.
Figure 5.2.1a-c: Knee joint locations vs. brace parameters of external rotation, width, and dorsiflexion in the standard-of-care brace
Ankle joint locations as a function of brace parameters external rotation, width, and dorsiflexion are shown in figures 5.2.1d-f. No clinical significance is gleaned from this set of data. In general, the X, Y, and Z positions of the ankles are stable across all parameters. The only exception is brace width, in which case the ankles are moving away from the centerline of the X-axis, as expected.
Figure 5.2.1d-f: Ankle joint locations vs. brace parameters of external rotation, width, and dorsiflexion in the standard-of-care brace
In *figure 5.2.1g*, hip rotation is graphed as a function of brace external rotation. Increasing the external rotation of the brace from 0 to 80 degrees results in a nearly one to one relationship in increasing external rotation of the hip. It should be noted here that one limitation of the current surrogate biomodel is that it is not capable of internal and external rotations of the knee, nor is there a method to examine the stress due to torque at the knee. This result indicates that the capability to perform internal/external rotations of the knee and/or measure torque at the knees should be included in future versions of the surrogate.

That said, there are some visual and functional cues that the investigator can use to evaluate torque at the knee. The hinge joint at the knee has some play to allow for small rotations that can be observed visually. Throughout the data collection, no such observations were made to conclude that there was an excess of torque on the knee. In addition, excess torque on the knee would result in a binding of the hinge joint. Again, throughout the data collection, no such binding was noted.

This relationship between external rotation of the brace and external rotation of the hips supports the notion that the muscle-tendon stretching observed due to brace external rotation is due to the effectiveness of the brace dorsiflexion. The dorsiflexion angle in the brace is relative to the external rotation of the shoes. Hip flexion and abduction are also seen to increase with external rotation of the brace, albeit not nearly to the degree of the external rotation. Note that hip adduction with decreasing external rotation is recognized as a factor in moving the knees toward the centerline (X-axis) of the surrogate as discussed for *figure 5.2.1a*. 
In *figure 5.2.1h*, external rotation of the hips is stable across increasing brace widths. Increases of 10 to 20 degrees are observed in flexion and abduction with increasing width. The abduction is expected, simply due to the widening of the brace.

External rotation of the hip is also stable across brace dorsiflexion, as shown in *figure 5.2.1i*. A slight hip adduction and more significant extension are also observed. *Figure 5.2.1l* shows a significant extension of the knees as brace dorsiflexion increases. As previously mentioned, increasing the surrogate’s ankle dorsiflexion moves the knees toward the centerline (X-axis).

This is a clinically-relevant finding; that the knees of the surrogate are extending and moving toward the centerline. Such action on the knee may be, in part, cause for the knock-knee deformity that sometimes occurs in children with clubfoot (based on conversation with Jose Morcuende, University of Iowa, Iowa City, IA, March 26, 2009). It may be that poor results (such as rocker bottom) are caused by an over-correction of patient dorsiflexion due to too much bend in the bar (brace dorsiflexion) or too narrow of a brace width, and that too wide a bar can lead to knock-knee. Further evaluation of clinical results is needed to investigate this in more depth.
Figures 5.2.1g-i: Hip rotations vs. brace parameters of external rotation, width, and dorsiflexion in the standard-of-care brace

Figures 5.2.1j-l show the results for the knee and ankle rotations as a function of brace parameters. A slight, moderate, and significant extension of the knees is observed as a
function of decreasing width, increasing external rotation, and increasing dorsiflexion of the brace. All three observations are consistent with the notion that an increase in surrogate ankle dorsiflexion results in an extension of the knees. This is especially apparent on these three figures, as ankle dorsiflexion and knee flexion are plotted together. In all cases, as the dorsiflexion increases, the flexion decreases (or knee extends).

Particularly interesting is the ankle inversion/eversion. At rest, the ankles of the surrogate are inverted (not shown). Applying the standard-of-care brace results in a neutral position of inversion/eversion in all cases of brace external rotation, all cases of brace width, and from 10 to 20 degrees of dorsiflexion. At 0-degrees of brace dorsiflexion, the ankles are inverted, consistent with the surrogate at rest, while at 30-degrees, the ankles are everted. The everted ankles, at a state of hyper-dorsiflexion, are consistent with the rocker bottom deformity as discussed above.

Note also that the knee flexion is stable from 10 to 20 degrees of brace dorsiflexion, with an apparent under and over-correction occurring at 0 and 30 degrees. The current clinical standard-of-care is 10 to 20 degrees based on the maximum dorsiflexion achieved following the Ponseti correction maneuver.
Figure 5.2.1j-l: Knee and ankle rotations vs. brace parameters of external rotation, width, and dorsiflexion in the standard-of-care brace.
5.3 The Third Hypothesis

The third hypotheses stated that a change in surrogate biomodel muscle-tendon force is expected when comparing various brace options. To investigate this hypothesis, a test was developed to measure force introduced by different brace types, including the standard-of-care brace, an articulating brace, and an ankle-foot orthosis (AFO) style brace. The results provided below will show support for the third hypothesis.

It is important to note that no claims of safety or clinical efficacy are being made at any point during this dissertation. There are many brace options and parameters within each option. A limited set is investigated here. As just one example, this discussion includes but one type of articulating brace attached to the surrogate biomodel with one type of shoe. Clinical practice may include alternative shoes, such as AFOs, combined with articulating braces. A more accurate and efficient test apparatus will be discussed in future work with plans to perform testing on a much broader range of braces.

The first three figures, 5.3a though 5.3c include data that were collected during the experimentation for the first hypothesis, and not originally intended to be displayed in this manner. However, after going through data analysis, these figures provided information relevant to the third hypothesis. Shown in each figure is the percent change when applying the three brace types, standard-of-care, articulating, and AFO respectively, to the model in a resting position. The data is left to stand on its own for preloads A, B, and C, where applicable, and for the left and right sides of the biomodel (as they also represent unique preloads).

Based on what has been discussed to this point, it should not be surprising that bar charts show varying magnitudes of change for each preload condition. One would expect,
based on previous discussion, that the percent change will be typically greater for preload-A compared to that of preload-C, and that is indeed the case here.

Figure 5.3a shows the percent change after applying the standard-of-care brace to the surrogate biomodel at rest. Consistent with the results seen up to this point, the peroneus longus and tibialis anterior are centered around zero. For the other four muscle-tendon systems, based on the 6 preload conditions (left and right for A, B, and C), the biomodel shows consistent increases in tension from values between 4% and 28%. Note that only the standard-of-care brace includes data collection from the first hypothesis for all three preloads, including the transition preload-B.

![PERCENT CHANGE BY APPLYING STANDARD OF CARE BRACE](image)

Figure 5.3a: Percent change in muscle-tendon tension after applying the standard-of-care brace to the surrogate biomodel

The first hypothesis did not call for data collection of the articulating brace, but as discussed previously, data were collected at the time of experimentation and shown to be reliable for two investigators with two equivalent articulating braces. Those same data are presented here in figure 5.3b in this alternative format showing percent change. The percent
change for the articulating brace after being applied to the surrogate at rest is strikingly different from that of the standard-of-care brace. In this case, nearly all of the muscle-tendons are centered around zero percent change, with the exception of the lateral head of the gastrocnemius. In this case, the maximum change is less than 10%. The setup for the articulating brace during this dissertation does not allow for a dorsiflexion angle to be held in the brace. It is the author’s interpretation of the data to this point, that the parameters of width and external rotation are enabling the standard-of-care brace to deliver the intended dorsiflexion. Without the ability to set dorsiflexion in the articulating brace, there may be no benefit to the width and external rotation parameters. It is important to note that the second hypothesis was only performed on the standard-of-care brace. Future work should include such varying of brace parameters on the articulating brace.

![Figure 5.3b: Percent change in muscle-tendon tension after applying the articulating brace to the surrogate biomodel](image)

*Figure 5.3c* shows the percent change after applying the AFO-style brace to the surrogate biomodel at rest. This is a very limited data set and the only available data for the
AFO. While the AFO was intended to be tested to the same degree as the standard-of-care and the articulating braces, in practice, the surrogate biomodel in the current setup is not capable of obtaining quality data. Without the soft-tissue covering, intended in future work, there is no good way to attach the AFO above the ankle. Alternatively, a spacer was used behind the calf. In addition, direct length measurement from the springs was partially obstructed by the AFO, making the data collection difficult and results questionable. A future version of the surrogate biomodel with soft-tissue and muscle-tendons that allow remote measurement will provide better insight to AFO braces, and expand testing to include braces such as knee-ankle foot orthoses (KAFOs).

Nonetheless, the limited data is presented for discussion. The most striking observation, when compared to the standard-of-care brace, is the relaxation of the tibialis anterior. This muscle-tendon has been consistently unaffected throughout the dissertation with the exception of this case of relaxation after applying the AFO. Alternatively, the tibialis posterior is centered around zero percent change (as is the peroneus longus). The other three muscle-tendons of interest are seen to have consistent increases in stretch from 2% to 20% across the four preload conditions. There may be some significance, clinically, to the fact that the tibialis anterior is shown to relax when applying the AFO, as opposed to the tibialis posterior, which is seen to increase in tension when applying the standard-of-care brace. Further investigation is required to better understand what this clinical significance is, if any.
Figure 5.3c: Percent change in muscle-tendon tension after applying the AFO brace to the surrogate biomodel

The test developed for the third hypothesis including translating one leg of the surrogate biomodel from a braced, resting position through a four-inch translation. Data were collected at one-inch increments along the translation. The intention was to observe how the biomodel reacted to the translation with each brace type and to determine if a difference was apparent among the brace types. The AFO-style brace was intended to be included in this examination, however, based on the reasoning above, it was not tested. The results below include a standard-of-care brace condition, an articulating brace condition, and a no-brace condition. Note that the no-brace condition does include the shoes due to the fact that for the data collected in this dissertation, the shoes are considered part of the biomodel. In future versions of the biomodel that will include a soft-tissue covering, the shoes (or attachment points to the surrogate) will be considered part of the brace, not the biomodel.

Figures 5.3d, f show the results for both the ‘ON’ and ‘OFF’ sides of the biomodel, where ‘ON’ refers to the side of the biomodel that was forced through the translation. The
‘OFF’ side is best described as, along for the ride, due to the bar connecting the left and right feet for the standard-of-care and articulating braces. In the no-brace condition, the ‘OFF’ leg did not translate at all, and therefore, no data was collected.

The ‘OFF’ side is only shown in figures 5.3d, f as a demonstration of surrogate biomodel symmetry. Recall that the difference in a preload condition has shown consistent results in the magnitude of change, where the lower preload resulted in a more significant change, and vise-versa. In preload-A, the preloads of the left and right soleus are minimal when compared to the left and right tibialis posterior. So, one would expect to see a greater change in magnitude. Note that in figures 5.3d, f, both figures show a reaction to translation that is symmetrical. However, the results for the soleus are on top of each other, while the results for the tibialis posterior are shifted in magnitude.

These results support the data presented to this point for the first and second hypotheses, and that the left and right sides of the biomodel can be considered an additional preload condition. In order to eliminate distraction, the remainder of the results for the third hypothesis only show the ‘ON’ condition for four preload conditions (left and right sides of preloads A and C).
Figures 5.3d, f: Change in muscle-tendon tension due to the translation of one leg in the –X direction in one-inch increments for the soleus and tibialis posterior, respectively, with the standard-of-care brace; shown for both the “ON” and “OFF” legs as an example of surrogate biomodel symmetry.

Figures 5.3g-i show the change in tension of the medial head of the gastrocnemius over the four-inch translation. In all cases, the muscle-tendon is seen to relax. This is an expected result, as relaxation of the gastrocnemius occurs as the knees are flexing. An observation to note here is that in Preload-A, the muscle-tendons are nearly fully relaxed at the zero mark. Notice that in the no-brace condition, the load on the gastrocnemius is due to the preload alone. As the knee is bent (resulting from the translation), the springs quickly relax to an unloaded state and completely level off. In contrast, for Preload-C, the load, again entirely from the preload, is seen to continuously relax over the entire translation.
The results for the articulating brace condition are more similar to that of the no-brace condition, with the preload-A springs quickly relaxing and a similarly steep slope for preload-C. At the four-inch mark, note that the final resting loads of the medial head of the gastrocnemius is the same for the articulating brace and the no-brace condition. It is important to acknowledge that while the magnitude of the lines across the vertical axis are equal from graph to graph, the maximum and minimum magnitudes are different.

This is especially important when comparing the results of the standard-of-care brace to that of the no-brace condition. Here, the slope of the lines (which can be compared due to the equal scale between figures) are less steep than what is observed for the articulating brace and no-brace conditions. By the most relaxed point, at the four-inch mark, the preload-C results are a full 10% to 20% greater than what is seen for the articulating and no-brace conditions. The preload-A results are 5% and 10% greater for the standard-of-care compared to the articulating and no-brace conditions, again at the four-inch mark.
Figures 5.3g-i: Change in muscle-tendon tension due to the translation of one leg in the –X direction in one-inch increments for the medial head of the gastrocnemius with the standard-of-care brace, articulating brace, and no-brace, respectively.

*Figures 5.3j-l* show the results for the lateral head of the gastrocnemius over the four-inch translation with the standard-of-care, articulating, and no-brace conditions respectively. These results match closely with that seen for the medial head. This includes a quick
relaxation from preload to a resting load, for preload-A, and a more gradual relaxation for preload-C. The results for the no-brace condition match closely with the articulating brace condition. The slopes in both case move to relaxation rapidly, and both maximum relaxation results at the four-inch mark are nearly equal. The standard-of-care brace has a less-steep slope towards relaxation. At the maximum relaxation point of four-inches, the loads across the four preload conditions range up to 20% greater for the standard-of-care brace.
Figures 5.3j-l: Change in muscle-tendon tension due to the translation of one leg in the –X direction in one-inch increments for the lateral head of the gastrocnemius with the standard-of-care brace, articulating brace, and no-brace, respectively.

Figures 5.3m-o show the change in tension over the four-inch translation for the soleus. In this case, the tension of the soleus does not show any connection to translation for the no-brace condition as was seen in the medial and lateral heads of the gastrocnemius. For
all four preload conditions, the length of the soleus does not change when no-brace is worn. Results for the articulating brace are very similar to that of the no-brace condition, showing no change over the four-inch translation.

Results for the standard-of-care brace are clearly different, with a near 10% increase seen at the zero mark (surrogate at rest with the brace on). Here, the less tense preloads (left and right of preload-A) are seen to increase from about 10% to greater than 40% over the four-inch translation. It is worth noting that in figure 5.3c above, the ‘OFF’ leg of the soleus maintains 5% to 10% increase from zero to four inches of translation. The more tense preloads (left and right of preload-C) increase from near 10% to 23% and 28% for the right and left sides, respectively.
Figures 5.3m-o: Change in muscle-tendon tension due to the translation of one leg in the –X direction in one-inch increments for the soleus with the standard-of-care brace, articulating brace, and no-brace, respectively.

Figures 5.3p-r show the change in tension over translation for the tibialis posterior. These results are similar to what was seen in the soleus. The no-brace and articulating brace show little change over the four-inch translation. The standard-of-care brace, however, has increases from 20% to near 30% over the four preload conditions.
It is consistent with the results to this point that the left side of preload-A shows the greatest magnitude across the entire translation, starting at the zero-mark, due to its least-loaded resting position compared to the other three preloads.

Figures 5.3p-r: Change in muscle-tendon tension due to the translation of one leg in the –X direction in one-inch increments for the tibialis posterior with the standard-of-care brace, articulating brace, and no-brace, respectively
For the tibialis anterior, shown in *figures 5.3s-u*, little change is seen for all three brace conditions, over the entire translation. The standard-of-care brace slopes are particularly level, where the articulating brace and no-brace conditions show a slight relaxation over the range.
Figures 5.3s-u: Change in muscle-tendon tension due to the translation of one leg in the –X direction in one-inch increments for the tibialis anterior with the standard-of-care brace, articulating brace, and no-brace, respectively.

Figures 5.3v-x are the results for the peroneus longus over the translation. Here again, little change is occurring for all three brace conditions over the entire translation. In this case, the no-brace condition is particularly flat, while the standard-of-care brace shows a
slight increase in tension. In the articulating brace, just the left side of the biomodel is seen increasing over the translation. Based on the model’s symmetry, this is not an expected result. However, in the kinematic data below, *figures 5.3.1k-m* show a severely inverted left foot for the articulating brace condition. That kinematic inversion is consistent with a load on the peroneus longus. The left foot is also seen to be plantarflexed, as opposed to the dorsiflexion seen on the right side.

One possible explanation is that the surrogate biomodel is seeking to reach equilibrium. Since the left and right side are connected by a bar, yet allowed to freely rotate in dorsiflexion and plantarflexion, one leg will take on a large inversion and plantarflexion, while the other side maintains dorsiflexion.

Regardless, the third hypothesis is supported due to the varying responses of the biomodel to the different brace conditions.
Figures 5.3v-x: Change in muscle-tendon tension due to the translation of one leg in the –X direction in one-inch increments for the peroneus longus with the standard-of-care brace, articulating brace, and no-brace, respectively.
5.3.1 Kinematic Data

The kinematic data collected during the third hypothesis experimentation are presented in the figures of this section. The first figures of the third hypothesis for muscle-tendon response to translation were examples of surrogate biomodel symmetry. The same is done here at the beginning of the kinematic data section. Figure 5.3.1a shows the knee joint (X,Y,Z) coordinates for the standard-of-care brace over the four-inch translation for both the ‘ON’ and ‘OFF’ sides. This figure clearly demonstrates the symmetry of the surrogate. The remainder of the results below will show just the ‘ON’ side for the sake of clarity.

Figure 5.3.1a: Knee joint X,Y,Z coordinate locations due to the translation of one leg in the –X direction in one-inch increments with the standard-of-care brace; shown for both the “ON” and “OFF” legs as an example of surrogate biomodel symmetry

Figures 5.3.1b-d show the knee joint locations over translation for the three conditions; standard-of-care brace, articulating brace, and no-brace respectively. For all three brace conditions, the knee is shown to be translating in the negative-X and positive-Z directions, consistent with knee flexion caused by the imposed translation. For both the standard-of-care and articulating braces, the knees translate away from the centerline (the X-axis) with increasing translation from zero to four. In contrast, the knees are stable across that same translation in the no-brace condition. These results make sense due to the external
rotation of 70-degrees set in both the standard and articulating braces. As discussed during the second hypothesis, the external rotation of the brace results in an external rotation of the hips, therefore pointing the kneecaps outward. As the knees flex in the braced condition, they are translating back, up, and out (negative-X, positive-Z, and away from the X-axis).
Figures 5.3.1b-d: Knee joint X,Y,Z coordinate locations due to the translation of one leg in the –X direction in one-inch increments with the standard-of-care brace, articulating brace, and no-brace, respectively.
Angle joint location results are provided in figures 5.3.1e-g and are consistent over the three conditions. In all cases, the ankles are being pushed back in the negative-X direction as a result of the imposed translation. The Y and Z coordinates are stable along the four-inch translation.
Figures 5.3.1e-g: Ankle joint X,Y,Z coordinate locations due to the translation of one leg in the –X direction in one-inch increments with the standard-of-care brace, articulating brace, and no-brace, respectively.
Figures 5.3.1h-j are the results of hip rotation over translation. Hip flexion is noticed in all three conditions, consistent with the imposed translation and knee flexion. Hip abduction is seen in both the standard and articulating brace conditions, due to the external rotation of the brace and outward pointing knees discussed above. The no-brace condition actually shows a slight adduction of the hips from zero to four inches of translation.

The internal/external rotation varies across all three conditions. In the standard brace graph, a steady internal rotation is present. For the articulating brace, the hips seem to internally rotate over the first two inches, and then rotate back out over the last two inches. The no-brace condition shows a slight internal rotation followed by a leveling off. These internal/external rotations of the hip may not best describe what is happening anatomically due to the way they were measured. It is consistent with the experimental set-up to observe an internal rotation when an abducted hip is going into flexion, as the rod used to measure internal/external rotation moves with respect to the frame of reference. A more accurate indicator of internal/external rotation will need to be devised in a next generation surrogate biomodel. That said, the motion observed, while not anatomically descriptive, is consistent with the affects of the brace on the surrogate biomodel, and also supports the third hypothesis.
Figures 5.3.1h-j: Rotations of the hip due to the translation of one leg in the –X direction in one-inch increments with the standard-of-care brace, articulating brace, and no-brace, respectively.
Knee and ankle rotation results are provided in *figures 5.3.1k-m* below. Here, knee flexion is observed in all three conditions, consistent with the imposed translation. Ankle dorsiflexion is shown to increase over the four-inch translation for the standard-of-care brace. For the articulating brace, the right and left feet are roughly 10-degrees dorsiflexed and 10-degrees plantarflexed, respectively, and maintain those values across the entire translation.

At rest, the surrogate’s right foot is neutral (with respect to dorsiflexion and plantarflexion), while the left foot is plantarflexed at about 5-degrees. In the no-brace condition, the surrogate maintains those values across the entire four-inch translation. The neutral right foot, at rest, may explain why the biomodel tends to dorsiflex the right and plantarflex the left with the articulating brace on, as was also discussed for the results of the peroneus longus above.

Consistent throughout this investigation has been the neutral position of the foot with respect to inversion/eversion after applying the standard-of-care brace. The results of *figure 5.3.1k* further support this, and show that over the imposed four-inch translation, the ankle remains at neutral. For the articulating brace, both the left and right feet are inverted, with the left more severely inverted than the right. A slight inversion is also seen for the surrogate at rest, in a no-brace condition, and consistent along the translation when without brace.
Figures 5.3.1k-m: Rotations of the knee and ankle due to the translation of one leg in the –X direction in one-inch increments with the standard-of-care brace, articulating brace, and no-brace, respectively.
6 CONCLUSIONS AND FUTURE WORK

The goal of this research was to investigate the impact of bracing, from an engineering perspective, on children with clubfoot. The clinical significance is to better understand how brace types and brace parameters impact the load applied to muscle-tendon systems of the lower anatomy.

The research reported here is not intended to evaluate the safety or efficacy of the current brace options, but to validate the methodology of using a surrogate biomodel to investigate clubfoot bracing. As such, three hypotheses were proposed. The first hypothesis stated that a surrogate biomodel shows minimal variance due to measurement error when conducting tests with equal design. The intention of this hypothesis was to examine if using a surrogate biomodel approach would provide accurate and repeatable results. Multiple degrees of variance were considered, such as investigator and brace variance. Other variables were not considered due to resource constraints, e.g., comparing the results of more than one surrogate constructed from unique sets of patient data.

The first test resulted in measurement error between 1 and 6 percent, thus supporting the first hypothesis. While the surrogate biomodel used during this investigation proved to be a reliable test apparatus, it is clear that significant improvements can be made to increase accuracy and consistency in the results. These improvements could include: joints instrumented for angular measurements; the use of accelerometers to capture accurate, real-time data in three-dimensions; potentiometer, linear variable displacement transducers (LVDT), and electromagnetic 3D positioning; pneumatic muscles with embedded feedback
systems; and other alternative methods to remotely measure force and displacement of the muscle-tendons.

A covering to be manufactured with silicone or ballistic gel will be used to enclose the instrumented skeleton and designed to mimic characteristics of soft-tissue. The soft-tissue-like covering will be easily removed to access the underlying instrumentation. It is ideal to have such a soft-tissue covering from the feet to the upper thighs, primarily as an anatomically correct attachment for various brace options. Such a soft-tissue covering will also be beneficial for future work, such as passive motion studies. The development of the soft-tissue covering is currently underway with progress reported in Appendix A below.

Although significant improvements can be made and complexities added to the surrogate biomodel, the results presented support the first hypothesis. The experiment designed to test the first hypothesis resulted in small standard deviations and measurement error (1% to 6%), even with small datasets.

The second hypothesis stated that a change in surrogate biomodel muscle-tendon force is expected when degrees of freedom are varied within one brace type. To test this hypothesis, the three parameters (external rotation, width, and dorsiflexion) of the standard-of-care brace were varied independently. The results support the hypothesis, showing that for four of the six muscle-tendons investigated, a relationship existed between varying brace parameters and muscle-tendon tension. These results are summarized in Table 6a.

<table>
<thead>
<tr>
<th>Muscle-Tendon</th>
<th>Increasing External Rotation (over 80 degrees)</th>
<th>Decreasing Width (over 8 inches)</th>
<th>Increasing Dorsiflexion (over 30 degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDGAS</td>
<td>12% - 18%</td>
<td>11% - 29%</td>
<td>27% - 44%</td>
</tr>
<tr>
<td>LATGAS</td>
<td>22% - 26%</td>
<td>10% - 28%</td>
<td>24% - 50%</td>
</tr>
<tr>
<td>SOL</td>
<td>10% - 16%</td>
<td>4% - 25%</td>
<td>19% - 32%</td>
</tr>
<tr>
<td>TIBPOST</td>
<td>0% - 13%</td>
<td>8% - 18%</td>
<td>13% - 23%</td>
</tr>
</tbody>
</table>

Table 6a: Percent increase in muscle-tendon tension for each brace parameter for the standard-of-care brace; Values shown were calculated based on the trend-line slopes of the data shown in the results section; note that the range of values is due to the system preloads.
The major factor in increasing tension was due to the dorsiflexion parameter. Through the results and observations made during data collection, it is concluded that the external rotation and width parameters only serve to enable the dorsiflexion parameter. An example of this in the data is the slope change noticed in the width parameter, taking place at shoulder width. The clinical significance is that widths greater than shoulder width reduce the brace’s ability to maintain dorsiflexion, whereas widths much shorter than prescribed may over stretch the muscle-tendons. In the case of external rotation, observations clearly showed that at zero degrees, the brace had no impact on dorsiflexion, instead resulting in hip adduction. Externally rotating the brace resulted in increasing impact on dorsiflexion. Clinical significance is that future work may enable tuning a brace for maximum benefit (muscle-tendon stretch) while decreasing the detriment caused by over-correction or under-correction (such as the rocker bottom and knock-knee deformities).

*Figure 6a* demonstrates how a standard-of-care brace, when widened to more than shoulder width, allows for loss of dorsiflexion due to the increased hip abduction, thus increasing the angle between the legs. The increased hip abduction serves to negate the dorsiflexion angle in the bar. Below that, *figure 6b* demonstrates how a standard-of-care brace, when external rotation is set to zero, allows for the feet to fall into plantarflexion.

![Figure 6a: Examples of normal (left) and widened (right) widths for the standard-of-care brace; note how the widened bar allows loss of dorsiflexion due to the increased angle between the legs](image)
The third hypothesis stated that a change in surrogate biomodel muscle-tendon force is expected when comparing the various brace options. No claims of clinical safety and efficacy are made with respect to the three braces investigated, which include a standard-of-care brace, an articulating brace, and an AFO-style brace. The results of the data analysis support the third hypothesis, showing consistent results within one brace type, but varying results between different braces.

The clinical significance of the results, however, may have more to do with the notion discussed for the second hypothesis; the ability to develop a tuned brace in future work. In clinical practice an articulating brace may be prescribed in combination with an AFO (an AFO-style shoe connected via an articulating bar). That set-up was not utilized in this research, rather focusing on the impact of the connecting bar itself. As a result, an interesting observation can be gleaned from the results of the third hypothesis.
The articulating brace does not have the ability on its own to set dorsiflexion, as the articulation is achieved via a rotation about that parameter. The results showed that the articulating brace had little to no impact on muscle-tendon stretch. This is despite the fact that the brace was set at shoulder width and 70-degrees external rotation. Thus, it supports the notion discussed during the second hypothesis: that width and external rotation parameters of the standard-of-care brace only act to enable dorsiflexion, rather than delivering an outcome on their own. What impact this has in clinical practice is not known, nor surmised here.

Similarly, an AFO can have a set dorsiflexion parameter, but cannot have a width or external rotation parameter, and therefore may be missing these key enablers. Data for the AFO in this dissertation is limited, and no assumptions can be made regarding clinical impact. Future work on an advanced surrogate biomodel will include a detailed evaluation of AFO and KAFO style braces.

A second result of the third hypothesis that was not expected was the increase in stretch of the soleus and tibialis posterior for translations of the foot in the negative-X direction when wearing the standard-of-care brace. Note that the negative-X direction refers to a translation along the longitudinal axis from the inferior toward superior, thus flexing the knee. The medial and lateral heads of the gastrocnemius also showed a resistance to relaxing when wearing the standard-of-care brace compared to no-brace over the same translation. These results indicate that as a patient moves (such as a child laying supine and kicking legs), wearing the standard-of-care brace can increase the therapeutic affect.
All three hypotheses put forth were supported by the research conducted during this dissertation. The surrogate biomodel proved to be a reliable and repeatable method for investigation of clubfoot bracing, and is expected to only improve with advancement.

The three parameters of the standard-of-care brace were shown to have an impact on the stretch applied to key muscle-tendon systems involved in the clubfoot deformity. The results also indicated that the primary role of the standard-of-care brace is that of dorsiflexion, with brace-abduction and brace-width acting as enabling parameters to perform that dorsiflexion. It is particularly significant due to the fact that the general understanding is that brace-abduction is what is impacting clubfoot correction most significantly. This is apparent in a common name for the standard-of-care brace, often called a FAB for Foot Abduction Bar or Brace, or FAO, for Foot Abduction Orthosis. The Ponseti method itself has seen improvements over time due to increasing abduction, or hyperabducting the foot [37]. However, the results in this study from the articulating brace indicate that abduction alone has no impact. The results of this investigation suggest that a connecting bar with abducted feet can take advantage of the midline of the body and its symmetry to create the force necessary to enable dorsiflexion.

Additional results from this dissertation indicate that future work can be used to tune bracing parameters to maximize benefit and minimize over-correction. The surrogate biomodel may also be used to evaluate a wide range of brace options, comparing them to the standard-of-care. This work has the potential to assist in the development of future bracing options for children with clubfoot, and have a positive impact on clubfoot treatment.
APPENDIX A – SOFT-TISSUE PROGRESS

A soft-tissue covering for the surrogate biomodel is currently in the process of being developed. This section provides a brief description on this development process. The material used to be a soft-tissue simulant is also currently under consideration, with ballistic gel and/or silicone as options.

Historically, ballistic gelatin has been commonly used for the evaluation of firearms, hence the name. Ballistic gel is a good human soft-tissue simulant, as it has the approximate density and viscosity of living tissue. It lacks, however, the structure of normal human tissue, including fibrous muscle, internal organs, and fat. The primary disadvantage of ballistic gel is that it must be stored at cold temperatures, and that decomposition of the material begins in days [95]. Due to this decomposition, the covering would not be able to stay on the surrogate biomodel for long periods of time. As a result, silicone is being investigated further as a primary option.

Figures A1 through A5 provide a step-by-step breakdown of the current process by which the soft-tissue simulant is being manufactured. This process has included:

- Performing the Ponseti technique on the surrogate biomodel to correct the clubfoot deformity
  - This included first the protection of the surrogate biomodel by wrapping it in plastic
  - Casting the model using the same method and plaster cast material by Dr. Ponseti (Specialist, Extra Fast by BSN medical GmbH, Hamburg, Germany)
  - See figure A1
  - Removing the cast from the surrogate biomodel
o X-Ray CT scan of the plaster casts to define the inside dimensions of the soft-tissue covering
  ▪ See figures A2 and A3

o X-Ray CT Scan of a 5-year-old human simulation manikin (Gaumard Scientific, Miami, FL) to define the outside dimensions of the soft tissue covering
  ▪ Scan of the foot only shown in figure A4

o Solid model post processing to create a soft-tissue mold to which the simulation material will be poured, thus forming the covering to custom fit the surrogate
  ▪ Example post processing of the foot shown in figure A5

Figure A1: Plaster cast applied to the surrogate biomodel
Figure A2: X-Ray CT Scan preparation of the plaster cast after being removed from the surrogate
Figure A3: X-Ray CT Scan of the plaster cast with a cross-sectional view
This process and these figures represent preliminary work to develop a first-generation soft-tissue covering for the surrogate biomodel. This first-generation is planned to be made of silicone rubber and due to be completed in June, 2009. Isokinetic passive torque testing will be performed on the model with the soft-tissue applied at that time.
APPENDIX B – RAPID PROTOTYPING

This research utilized the capability of RP to produce components of the surrogate biomodel. Prior to selecting the appropriate RP technology and material, it is crucial to understand the mechanical properties that the biomodel is intended to mimic. Current and future work includes the construction of a surrogate biomodel with increasingly complex components. The current surrogate has an ABS plastic skeletal structure with spring and cable systems to model muscle-tendons. Near-term future work, currently underway will include the addition of ballistic gel or more likely a silicone rubber covering to represent soft-tissue. It is expected that a future generation surrogate biomodel will include a bone-like replica endoskeleton and joints, the ballistic gel soft-tissue exterior, and functional muscle-tendon systems and ligaments.

This appendix discusses RP technology and the ability for utilizing such technology to create bone-like structures. The structure of bone is complex and can be broken down into a hierarchy [96]. These include the macrostructure of cancellous and cortical bone, the microstructure of osteons and trabeculae (on the order of 10 – 500 µm), the sub-microstructure of lamellae (1 – 10 µm), the nanostructure of fibrillar collagen and embedded minerals (100 nm – 1 µm), and sub-nanostructure of molecular minerals, collagen, and non-collagenous organic proteins. This structure of bone, while organized, is irregular. The material of bone is heterogeneous and anisotropic [96, 97]. The nature of this research is on the macro scale, and therefore will focus specifically on the structural and material properties of cancellous and cortical bone.

Rho et al. define the structural properties of cancellous bone, “as the extrinsic properties of both trabeculae and pores.” He defines the material properties, “as the intrinsic
properties of the travecular struts only.” It is apparent that structural properties are important for the analysis of global stress, whereas material properties better characterize pathology. Rho cites that, “values for mechanical properties of (cortical) bone at the macrostructural level vary from one bone to another as well as within different regions of the same bone.” By contrast, cancellous bone shows less difference in mechanical properties from one bone to another. However cancellous mechanical properties do vary significantly around the periphery and along the length of a single bone [96]. It might be expected from this cursory overview that the inhomogeneous nature of bone may be difficult to reproduce accurately in a biomodel. However, important conclusions can be gleaned from the research. As an example, the anisotropic nature of bone defines that its mechanical properties are different when stressed in different directions. Indeed, modulus of elasticity is greatest when bone is loaded along its longitudinal axis [97]. Such anisotropic behavior is also found in RP models, where build orientation plays a critical role [98, 99].

In general, the mechanical properties of bone are difficult to characterize. A survey of the literature resulted in a wide range of Young’s modulus for both cortical bone (12 – 20 GPa) and cancellous bone (10 MPa – 23 GPa). The range of cancellous bone is particularly astonishing as it crosses three orders of magnitude.

One possibility considered for narrowing the window of mechanical property was to focus on the mechanical property of pediatric bone, as that is consistent with the nature of this research. However, the literature in this area is sparse. The work of Rauch and Schoenau was promising in that it characterized bone mineral density, considering both cortical and cancellous density. One example of interest was a model of bone development at the femoral midshaft from birth to six months. Analyzing the model reveals a makeup of
8% cancellous bone at birth and increasing to 31% at six months. However, data presented for cancellous and cortical bone mineral density were complex. Total and cortical densities are shown to decrease in the first months after birth and then increase into adulthood. Total density at age ten does not yet reach total birth density. In contrast, cancellous bone mineral density is shown to linearly increase from birth into adulthood. While interesting, this research provides only anecdotal information as it applies to RP technology and material selection.

One possibility is to obtain patient-specific CT data of a five-year-old subject. If such data existed, the details might help provide additional information necessary to make a final technology and material choice. As an example, intensity of voxels in a CT-scan is a measure of density. It has been shown that Young’s modulus of bones is proportional to density [100, 101]. In this manner, the image data itself, depending on resolution, may provide useful information regarding the ratio of cancellous and cortical bone, as well as the density, and thus elastic modulus.

It is apparent that a review of academic research might not provide a complete overview of technology and material selection for the production of replica bones. However, a patent search did reveal interesting insights to the problem.

Biermann *et al.* has developed a bone substitute for training and testing [102, 103]. In one patent, an instrumented model of the human torso is simulated with anatomic features including, “simulated bone having material properties similar to that of healthy human bone.” The patent also describes simulated tissue surrounding the bone as is planned for this research.
The bone substitute is claimed to have a look and feel, and cutting and drilling properties consistent with the properties of human bone. The model is comprised of an inner polymer foam core to mimic cancellous bone. Covering the core is an outer shell comprised of a polymer such as epoxy resin and particulate filler [103].

A description of the manufacturing process is also provided. The first step is to make a female mold from an original human bone (if using this technique while utilizing RP technology, an SLA bone produced from image data could alternatively be used). The bone substrate part is created from the female mold and reduced by a uniform thickness (this process could also be streamlined by image processing if using RP). A mold is created from the bone substitute part to replicate the inner core. The inner core is then molded from a foam polymer and suspended in the female mold. The outer shell is then formed by pouring or injecting the epoxy resin slurry into the female mold containing the suspended inner core [103].

While this method of producing a bone model appears to be very promising, it may be both over-engineered for this research, as well as non-ideal when considering the full scope of the project. As an example, the model developed here is required to have fully articulating joints. Being able to screw into the model as described by Biermann is of value for attaching artificial muscle-tendons, however, material finish may not be ideal for articulation, considering both friction and wear over time.

Indeed, it has been shown that bones made of steel are adequate for macro scale testing used in vehicle crash test dummies [102]. These steel bones can effectively simulate the gross deflection seen during a vehicle crash.
Throughout the course of this research, for the sake of comparison and material selection, material properties for bone as well as RP materials from selected processes have been consolidated in Table B1 below. The large range of elastic modulus of bone was challenging in and of itself. In addition, the entire group of materials first examined did not come close to matching the property of bone. It was for this reason that complex bone models were considered, such as those described by Biermann. However, it was this notion of crash test dummies that lead to RP as an option. One very good choice for future work will be the SLArmor process from FineLine Prototyping (Raleigh, NC, see [G] in Appendix C).

SLArmor has multiple characteristics that make it a promising material choice. The manufacturing process is SLA, a layered process that can mimic the anisotropic behavior of bone. SLArmor consists of a combination of ceramic-filled core coated with structural nickel-plating for strength. Such a coated/core combination mimics both the cancellous/cortical nature of bone as well as the Biermann-like model. Additional advantages of SLArmor include the precision and smooth surface finish of the SLA process, particularly useful for the biomodel’s articulating joints. The structural integrity of SLArmor should protect it from wear, allowing the model to be used over many iterations of articulation.

Material data is given for SLArmor over three options that include varying degrees of nickel plating (represented as percent metal volume). The 10% metal volume option is currently closest to the top end of the Young’s modulus given for bone. It is possible that actual patient image data may give a better indication of desired bone density, thus indicating a more targeted value for elastic modulus. There are also opportunities to tune the percent
metal volume to a custom value (verbal communication with Rob Connelly of FineLine on 6/3/07) that can approximate desired properties based on the patient data.

While ideal for a future model, the SLArmor process was not chosen for the current model due to the fact that drilling for attachment points of muscle-tendon would not be ideal. Cost of the SLArmor process was also prohibitive at this stage of research. Instead, an extra-strength ABS plastic was utilized and constructed with the Fused Deposition Modeling (FDM) RP technology (see P430 ABSplus in Table B1 below). This resin and process was chosen due to ease of fabrication and the material properties were ideal for drilling and attaching muscle-tendons. Details on the advantages and disadvantages of different RP technologies is provided in Table B2 below.

This appendix only contains information on the selection of bone simulation materials available with rapid prototyping. Future work will utilize ballistic gel and/or silicone to model soft-tissue. A detailed analysis of soft-tissue simulation materials is currently underway, and is explained briefly in Appendix A above.
### Table B1: Overview of bone and RP resin/process material properties

<table>
<thead>
<tr>
<th>Material</th>
<th>RP Technology</th>
<th>Flex Mod (MPa)</th>
<th>Tensile Strength (MPa)</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortical bone</td>
<td>N/A</td>
<td>12,000 - 17,000*</td>
<td>133</td>
<td>[97]</td>
</tr>
<tr>
<td>Cortical bone</td>
<td>N/A</td>
<td>14,000 - 20,000*</td>
<td>Not Reported</td>
<td>[96]</td>
</tr>
<tr>
<td>Cancellous bone</td>
<td>N/A</td>
<td>10 - 2000*</td>
<td>Not Reported</td>
<td>[97]</td>
</tr>
<tr>
<td>Cancellous bone</td>
<td>N/A</td>
<td>1,000 - 23,000*</td>
<td>Not Reported</td>
<td>[96]**</td>
</tr>
<tr>
<td>Cancellous bone</td>
<td>N/A</td>
<td>31 - 3,390*</td>
<td>Not Reported</td>
<td>[100]</td>
</tr>
<tr>
<td>ABS</td>
<td>FDM</td>
<td>971 - 1653*</td>
<td>8 - 16</td>
<td>[98]</td>
</tr>
<tr>
<td>STL Resin</td>
<td>SLA</td>
<td>2,200*</td>
<td>Not Reported</td>
<td>[104]</td>
</tr>
<tr>
<td>Duraform Polyamide</td>
<td>SLS</td>
<td>1,285</td>
<td>44</td>
<td>[105]</td>
</tr>
<tr>
<td>ProtoForm Composite</td>
<td>SLS</td>
<td>4,300</td>
<td>49</td>
<td>[106]</td>
</tr>
<tr>
<td>SL 7560</td>
<td>SLA</td>
<td>2,100 - 2,200 (2,600 - 2,700)*</td>
<td>54 - 56</td>
<td>[107]</td>
</tr>
<tr>
<td>Accura SI40</td>
<td>SLA</td>
<td>1,843 - 2003 (2338 - 3072)*</td>
<td>53 - 84</td>
<td>[107]</td>
</tr>
<tr>
<td>Duraform PA</td>
<td>SLS</td>
<td>1,104 - 1,150</td>
<td>41 - 49</td>
<td>[99]</td>
</tr>
<tr>
<td>SOMOS 201</td>
<td>SLS</td>
<td>13</td>
<td>Not Reported</td>
<td>[A]</td>
</tr>
<tr>
<td>Polyamide PA</td>
<td>SLS</td>
<td>1,110 - 1,370</td>
<td>42 - 48</td>
<td>[B]</td>
</tr>
<tr>
<td>Duraform PA</td>
<td>SLS</td>
<td>1,285</td>
<td>44</td>
<td>[A]</td>
</tr>
<tr>
<td>Duraform GF</td>
<td>SLS</td>
<td>3,300</td>
<td>38</td>
<td>[A]</td>
</tr>
<tr>
<td>Somos 9120</td>
<td>SLA</td>
<td>1,310 - 1,455 (1,227 - 1,462)*</td>
<td>30 - 32</td>
<td>[C]</td>
</tr>
<tr>
<td>WaterClear 10120</td>
<td>SLA</td>
<td>1,310 (1,710)*</td>
<td>26</td>
<td>[C]</td>
</tr>
<tr>
<td>RenShape SL 5510</td>
<td>SLA</td>
<td>3,054</td>
<td>77</td>
<td>[D]</td>
</tr>
<tr>
<td>RenShape SL 7560</td>
<td>SLA</td>
<td>2,400 - 2,600</td>
<td>42 - 62</td>
<td>[D]</td>
</tr>
<tr>
<td>ABS P400</td>
<td>FDM</td>
<td>2,618</td>
<td>34</td>
<td>[E]</td>
</tr>
<tr>
<td>ABS</td>
<td>FDM</td>
<td>1,834</td>
<td>22</td>
<td>[F]</td>
</tr>
<tr>
<td>P430 ABSplus***</td>
<td>FDM</td>
<td>2,250</td>
<td>37</td>
<td>[F]</td>
</tr>
<tr>
<td>Polycarbonate</td>
<td>FDM</td>
<td>2,137</td>
<td>52</td>
<td>[F]</td>
</tr>
<tr>
<td>Polycarbonate-ABS</td>
<td>FDM</td>
<td>1,863</td>
<td>35</td>
<td>[F]</td>
</tr>
<tr>
<td>Polycarbonate-ISO</td>
<td>FDM</td>
<td>2,193</td>
<td>52</td>
<td>[F]</td>
</tr>
<tr>
<td>Polyphenylsulfone</td>
<td>FDM</td>
<td>2,206</td>
<td>55</td>
<td>[F]</td>
</tr>
<tr>
<td>SLArmor 10%metal</td>
<td>SLA</td>
<td>28,000 (21,000)*</td>
<td>100</td>
<td>[G]</td>
</tr>
<tr>
<td>SLArmor 20%metal</td>
<td>SLA</td>
<td>44,000 (31,000)*</td>
<td>145</td>
<td>[G]</td>
</tr>
<tr>
<td>SLArmor 30%metal</td>
<td>SLA</td>
<td>54,000 (42,000)*</td>
<td>200</td>
<td>[G]</td>
</tr>
</tbody>
</table>

*Young’s Modulus, **Range of values represents twelve citations, ***ABS used to build surrogate biomodel; letter references shown in Appendix C

### Table B2: Rapid Prototyping Technology Comparison Chart

<table>
<thead>
<tr>
<th>RP Technology</th>
<th>Selective Laser Sintering (SLS)</th>
<th>Stereolithography (SLA)</th>
<th>Fused Deposition Modeling (FDM)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Powder based layer manufacturing process</td>
<td>Laser cured liquid photopolymer layer manufacturing process</td>
<td>Extrusion based layer manufacturing process</td>
</tr>
<tr>
<td><strong>Advantages</strong></td>
<td>Fully functional prototypes with high mechanical and thermal resistance</td>
<td>Very accurate; excellent surface finish; feature detail; materials including translucent and transparent</td>
<td>Strong &amp; rigid suitable for functional testing; cost effective; Dimensional stability; environmental resistance; Actual material similar to injection molded properties (ABS, PC)</td>
</tr>
<tr>
<td><strong>Disadvantages</strong></td>
<td>Rough, grainy, and porous surface finish and susceptibility to warp due to high shrink rate</td>
<td>Fragile; Sensitive to heat, moisture, and chemicals; Expensive</td>
<td>Ribbed appearance, Susceptible to snap and living hinge failures, layer thickness</td>
</tr>
<tr>
<td><strong>Typical Build Size</strong></td>
<td>340 x 340 x 560 mm</td>
<td>508 x 508 x 600 mm</td>
<td>203 x 203 x 305 mm</td>
</tr>
<tr>
<td><strong>Typical Feature Size</strong></td>
<td>No less than 1 mm</td>
<td>No less than 0.8 mm</td>
<td>No less than 0.8 mm</td>
</tr>
<tr>
<td><strong>Layer Thickness</strong></td>
<td>0.15 to 0.20 mm</td>
<td>0.127 mm</td>
<td>0.25 mm</td>
</tr>
</tbody>
</table>

Table B2: Rapid Prototyping Technology Comparison Chart
APPENDIX C – MATERIAL SPECIFICATION DATA REFERENCES


[D] RenShape, Basel, Switzerland, www.renshape.com


APPENDIX D – GLOSSARY

This glossary contains definitions for clinical language used throughout the dissertation. In addition, information is provided regarding motions of the foot and foot deformity. Abbreviations and explanations for all of the data collection parameters are contained in this section, and well as an overview of the frame of reference in which the data collection took place. Some examples of the experimental setups are also provided.

The following language is used to describe motions of the foot:

• Abduction/Adduction (a.k.a. External/Internal Rotation)
  o Described by toes pointing out and pointing in, respectively, while the feet are flat on the floor, standing in an upright position.

• Inversion/Eversion (sometimes referred to as Varus/Valgus)
  o Described by the sole facing the midline of the body and facing away from the midline, respectively.
  o Note, the author considers Varus/Valgus to be a deformity toward or away from the midline of the body, whereas Inversion/Eversion is a normal motion of the foot. However, sometimes Varus/Valgus is used to describe a “position” that is similar to the resulting motion of Inversion/Eversion.

• Plantarflexion/Dorsiflexion (a.k.a. Equinus/Calcaneus and Extension/Flexion)
  o Described by toes pointing up and toes pointing down, respectively.

• Supination/Pronation
  o Supination: the combination of plantarflexion, inversion, and adduction
  o Pronation: the combination of dorsiflexion, eversion and abduction
The following are used to describe deformities:

- Varus/Valgus
  - Varus: bent inward; denoting a deformity in which the angle of the anatomy is toward the midline of the body
  - Valgus: bent out, twisted; denoting a deformity in which the angle is away from the midline of the body

- Talipes
  - A congenital deformity in which the foot is twisted out of shape or position; it may be in dorsiflexion (t. calcaneus), in plantar flexion (t. equinus), abducted and everted (t. valgus or flatfoot), abducted and inverted (t. varus), or various combinations (t. calcaneovalgus, t. calcaneovarus, t. equinovalgus, or t. equinovarus)

Throughout experimentation, the surrogate biomodel was fixed at the pelvis in a frame of reference. The frame of reference was intended to provide a consistent and repeatable foundation for data to be collected. The intent was to also create the frame of reference to be consistent with both engineering and clinical terminology. Table D1 below was reproduced from [82], with additional columns added representing the corresponding engineering X, Y, Z coordinate terminology alongside the original clinical definitions.

<table>
<thead>
<tr>
<th>Plane</th>
<th>Description of Plane</th>
<th>Axis of Rotation</th>
<th>Description of Axis</th>
<th>Most Common Movement</th>
<th>Surrogate Biomodel Planes</th>
<th>Surrogate Biomodel Axes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frontal (coronal)</td>
<td>Divides body into anterior and posterior sections</td>
<td>Sagittal</td>
<td>Runs anterior/posterior</td>
<td>Abduction, adduction</td>
<td>X-Y Plane</td>
<td>Z-Axis</td>
</tr>
<tr>
<td>Sagittal</td>
<td>Divides body into right and left sections</td>
<td>Frontal (transverse)</td>
<td>Runs medial/lateral</td>
<td>Flexion, extension</td>
<td>X-Z Plane</td>
<td>Y-Axis</td>
</tr>
<tr>
<td>Transverse (horizontal)</td>
<td>Divides body into upper and lower sections</td>
<td>Longitudinal (vertical)</td>
<td>Runs superior/inferior</td>
<td>Internal rotation, external rotation</td>
<td>Y-Z Plane</td>
<td>X-Axis</td>
</tr>
</tbody>
</table>

Table D1: Planes and axes used to describe human movement along side the engineering X, Y, Z counterparts
The planes and axes listed in table D1 are shown in figures D2 and D3 below. The surrogate is resting on the X-Y plane at Z=0. The legs are resting in the positive-X direction, with the right leg in negative-Y and the left leg in positive-Y.

Figure D1: Clinical frame of reference from [82]

Figure D2: Surrogate biomodel in a corresponding frame of reference; note that the entire right leg is in the X, -Y, Z quadrant, while the left leg is in the X, Y, Z quadrant

Figure D3: A Z-X planar view of the surrogate biomodel (left) and a Z-Y planar view (right); note that the vertical brass rod seen in both the Z-X and Z-Y views is the X, Y origin, with the pelvis resting on Z=0

Different clinical terminology is used and defined throughout this dissertation. To avoid confusion, tables D2 and D3 below provide the specific terminology used throughout the data analysis.

<table>
<thead>
<tr>
<th>Movement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>Bending of a part so that the anterior surfaces come closer together</td>
</tr>
<tr>
<td>Extension</td>
<td>The straightening of a part, and movement is in the opposite direction to flexion</td>
</tr>
<tr>
<td>Abduction</td>
<td>Movement away from the midline of the body or body part</td>
</tr>
<tr>
<td>Adduction</td>
<td>Movement toward the midline of the body or body part</td>
</tr>
<tr>
<td>Internal (medial, inward) rotation</td>
<td>Turning of the anterior surface of a part towards the midline of the body</td>
</tr>
<tr>
<td>External (lateral, outward) rotation</td>
<td>Turning of the anterior surface of a part away from the midline of the body</td>
</tr>
</tbody>
</table>

Table D2: Specific description of anatomical movements used during the data analysis, from [82]
Table D3: Special movements referred to during the data analysis, from [82]

The data analysis contains an extensive set of parameters, each with an abbreviation used to simplify tables and charts. The set of tables below from \textit{D4} through \textit{D9} provide definitions for each of these parameters.

<table>
<thead>
<tr>
<th>Special Movements</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee Flexion</td>
<td>The posterior surfaces of the body come closer together</td>
</tr>
<tr>
<td>Ankle Flexion (dorsiflexion)</td>
<td>When the ventral surface of the foot is brought closer to the anterior aspect of the leg</td>
</tr>
<tr>
<td>Eversion of the foot</td>
<td>The sole of the foot is turned outward (away from the midline of the body)</td>
</tr>
<tr>
<td>Inversion of the foot</td>
<td>The sole of the foot is turned inward (toward the midline of the body)</td>
</tr>
</tbody>
</table>

Table D4: Abbreviations used for the muscle-tendons considered during the data analysis

<table>
<thead>
<tr>
<th>Label</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDGAS-R</td>
<td>Gastrocnemius Medial Head (right leg)</td>
</tr>
<tr>
<td>MEDGAS-L</td>
<td>Gastrocnemius Medial Head (left leg)</td>
</tr>
<tr>
<td>LATGAS-R</td>
<td>Gastrocnemius Lateral Head (right leg)</td>
</tr>
<tr>
<td>LATGAS-L</td>
<td>Gastrocnemius Lateral Head (left leg)</td>
</tr>
<tr>
<td>SOL-R</td>
<td>Soleus (right leg)</td>
</tr>
<tr>
<td>SOL-L</td>
<td>Soleus (left leg)</td>
</tr>
<tr>
<td>TIBPOST-R</td>
<td>Tibialis Posterior (right leg)</td>
</tr>
<tr>
<td>TIBPOST-L</td>
<td>Tibialis Posterior (left leg)</td>
</tr>
<tr>
<td>TIBANT-R</td>
<td>Tibialis Anterior (right leg)</td>
</tr>
<tr>
<td>TIBANT-L</td>
<td>Tibialis Anterior (left leg)</td>
</tr>
<tr>
<td>PERLONG-R</td>
<td>Peroneus Longus (right leg)</td>
</tr>
<tr>
<td>PERLONG-L</td>
<td>Peroneus Longus (left leg)</td>
</tr>
</tbody>
</table>

Table D5: Abbreviations used to denote the X, Y, and Z locations of the Hip, Knee, and Ankle

<table>
<thead>
<tr>
<th>Label</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIP-RX</td>
<td>X-Coordinate of the Right Hip</td>
</tr>
<tr>
<td>HIP-RY</td>
<td>Y-Coordinate of the Right Hip</td>
</tr>
<tr>
<td>HIP-RZ</td>
<td>Z-Coordinate of the Right Hip</td>
</tr>
<tr>
<td>HIP-LX</td>
<td>X-Coordinate of the Left Hip</td>
</tr>
<tr>
<td>HIP-LY</td>
<td>Y-Coordinate of the Left Hip</td>
</tr>
<tr>
<td>HIP-LZ</td>
<td>Z-Coordinate of the Left Hip</td>
</tr>
<tr>
<td>KN-RX</td>
<td>X-Coordinate of the Right Knee</td>
</tr>
<tr>
<td>KN-RY</td>
<td>Y-Coordinate of the Right Knee</td>
</tr>
<tr>
<td>KN-RZ</td>
<td>Z-Coordinate of the Right Knee</td>
</tr>
<tr>
<td>KN-LX</td>
<td>X-Coordinate of the Left Knee</td>
</tr>
<tr>
<td>KN-LY</td>
<td>Y-Coordinate of the Left Knee</td>
</tr>
<tr>
<td>KN-LZ</td>
<td>Z-Coordinate of the Left Knee</td>
</tr>
<tr>
<td>ANK-RX</td>
<td>X-Coordinate of the Right Ankle</td>
</tr>
<tr>
<td>ANK-RY</td>
<td>Y-Coordinate of the Right Ankle</td>
</tr>
<tr>
<td>ANK-RZ</td>
<td>Z-Coordinate of the Right Ankle</td>
</tr>
<tr>
<td>ANK-LX</td>
<td>X-Coordinate of the Left Ankle</td>
</tr>
<tr>
<td>ANK-LY</td>
<td>Y-Coordinate of the Left Ankle</td>
</tr>
<tr>
<td>ANK-LZ</td>
<td>Z-Coordinate of the Left Ankle</td>
</tr>
</tbody>
</table>
### Table D6: Abbreviations used to describe rotation of the hip

<table>
<thead>
<tr>
<th>Label</th>
<th>Definition</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIP-FLEX-R</td>
<td>Flexion of the right hip</td>
<td>Rotation about the Y-Axis from +X to +Z</td>
</tr>
<tr>
<td>HIP-EXT-R</td>
<td>Extension of the right hip</td>
<td>Rotation about the Y-Axis from +X to -Z (the apparatus is not set up for Hip Extension)</td>
</tr>
<tr>
<td>HIP-ABD-R</td>
<td>Abduction of the right hip</td>
<td>Rotation about the Z-Axis from +X to -Y (landmark is angle of the rectus femoris)</td>
</tr>
<tr>
<td>HIP-ADD-R</td>
<td>Adduction of the right hip</td>
<td>Rotation about the Z-Axis from +X to +Y (hip adduction reported as negative abduction)</td>
</tr>
<tr>
<td>HIP-IR-R</td>
<td>Internal rotation of the right hip</td>
<td>Rotation about the X-Axis from +Z to +Y (internal rotation reported as a negative external rotation)</td>
</tr>
<tr>
<td>HIP-ER-R</td>
<td>External rotation of the right hip</td>
<td>Rotation about the X-Axis from +Z to -Y</td>
</tr>
<tr>
<td>HIP-FLEX-L</td>
<td>Flexion of the left hip</td>
<td>Rotation about the Y-Axis from +X to +Z</td>
</tr>
<tr>
<td>HIP-EXT-L</td>
<td>Extension of the left hip</td>
<td>Rotation about the Y-Axis from +X to -Z (the apparatus is not set up for Hip Extension)</td>
</tr>
<tr>
<td>HIP-ABD-L</td>
<td>Abduction of the left hip</td>
<td>Rotation about the Z-Axis from +X to -Y (landmark is angle of the rectus femoris)</td>
</tr>
<tr>
<td>HIP-ADD-L</td>
<td>Adduction of the left hip</td>
<td>Rotation about the Z-Axis from +X to +Y (hip adduction reported as negative abduction)</td>
</tr>
<tr>
<td>HIP-IR-L</td>
<td>Internal rotation of the left hip</td>
<td>Rotation about the X-Axis from +Z to -Y (internal rotation reported as a negative external rotation)</td>
</tr>
<tr>
<td>HIP-ER-L</td>
<td>External rotation of the left hip</td>
<td>Rotation about the X-Axis from +Z to +Y</td>
</tr>
</tbody>
</table>

Note: Local hip frame of references have origins at the hip XYZ coordinates, and are parallel to the global frame.

### Table D7: Abbreviations used to describe rotation of the knee

<table>
<thead>
<tr>
<th>Label</th>
<th>Definition</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>KN-FLEX-R</td>
<td>Flexion of the right knee</td>
<td>Rotation about the Y-Axis closing the posterior surface</td>
</tr>
<tr>
<td>KN-EXT-R</td>
<td>Extension of the right knee</td>
<td>Rotation about the Y-Axis opening the posterior surface (static position will be measured as a flexion)</td>
</tr>
<tr>
<td>KN-IR-R</td>
<td>Internal rotation of the right knee</td>
<td>Rotation about the X-Axis from +Z to -Y (the apparatus is not set up for internal/external rotations)</td>
</tr>
<tr>
<td>KN-ER-R</td>
<td>External rotation of the right knee</td>
<td>Rotation about the X-Axis from +Z to +Y (the apparatus is not set up for internal/external rotations)</td>
</tr>
<tr>
<td>KN-FLEX-L</td>
<td>Flexion of the left knee</td>
<td>Rotation about the Y-Axis closing the posterior surface</td>
</tr>
<tr>
<td>KN-EXT-L</td>
<td>Extension of the left knee</td>
<td>Rotation about the Y-Axis opening the posterior surface (static position will be measured as a flexion)</td>
</tr>
<tr>
<td>KN-IR-L</td>
<td>Internal rotation of the left knee</td>
<td>Rotation about the X-Axis from +Z to +Y (the apparatus is not set up for internal/external rotations)</td>
</tr>
<tr>
<td>KN-ER-L</td>
<td>External rotation of the left knee</td>
<td>Rotation about the X-Axis from +Z to -Y (the apparatus is not set up for internal/external rotations)</td>
</tr>
</tbody>
</table>

Note: Local knee FORs have origins at the knee XYZ coordinates, and are oblique to the global frame.

### Table D8: Abbreviations used to describe rotation of the ankle

<table>
<thead>
<tr>
<th>Label</th>
<th>Definition</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANK-P-R</td>
<td>Plantarflexion of the right foot</td>
<td>Rotation about the Y-Axis from +Z to +X (plantarflexion reported as negative dorsiflexion)</td>
</tr>
<tr>
<td>ANK-D-R</td>
<td>Dorsiflexion of the right foot</td>
<td>Rotation about the Y-Axis from +Z to -X (dorsiflexion reported as negative plantarflexion)</td>
</tr>
<tr>
<td>ANK-INV-R</td>
<td>Inversion of the right foot</td>
<td>Rotation about the Z-Axis from +X to +Y (inversion reported as negative eversion)</td>
</tr>
<tr>
<td>ANK-EVF-R</td>
<td>Eversion of the right foot</td>
<td>Rotation about the Z-Axis from +X to -Y (eversion reported as negative inversion)</td>
</tr>
<tr>
<td>ANK-P-L</td>
<td>Plantarflexion of the left foot</td>
<td>Rotation about the Y-Axis from +Z to +X (plantarflexion reported as negative dorsiflexion)</td>
</tr>
<tr>
<td>ANK-D-L</td>
<td>Dorsiflexion of the left foot</td>
<td>Rotation about the Y-Axis from +Z to -X (dorsiflexion reported as negative plantarflexion)</td>
</tr>
<tr>
<td>ANK-INV-L</td>
<td>Inversion of the left foot</td>
<td>Rotation about the Z-Axis from +X to +Y (inversion reported as negative eversion)</td>
</tr>
<tr>
<td>ANK-EVF-L</td>
<td>Eversion of the left foot</td>
<td>Rotation about the Z-Axis from +X to -Y (eversion reported as negative inversion)</td>
</tr>
</tbody>
</table>

Note: Local ankle FORs have origins at the ankle XYZ coordinates, and are oblique to the global frame.

### Table D9: Abbreviations used to describe the three preload conditions used throughout the dissertation; note that by including the left and right sides of six muscle-tendons, there are a total of 36 unique preloads

<table>
<thead>
<tr>
<th>Label</th>
<th>Definition</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Preload A</td>
<td>Initial spring length (tension) applied to each muscle-tendon for a set of tests. Preloads on the left and right sides of the biomodel are not matching.</td>
</tr>
<tr>
<td>B</td>
<td>Preload B</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Preload C</td>
<td></td>
</tr>
</tbody>
</table>
The frame of reference was constructed with the intent to enhance reliable and repeatable measurements. The frame of reference was built utilizing an aluminum bolt-together framing system with 4-foot extrusions with a 1.5-inch square cross section. This framing system provided a secure structure for the frame of reference. Three planar surfaces were attached to the frame of reference utilizing Unframed Polypropylene Pegboard with holes equally spaced at 1-inch centers. The hole-spacing provided a consistent background to record kinematic data. A footplate was attached to the frame of reference on the X-Y planar surface. The footplate was constructed of 12x12-inch white Delrin sheets. The Delrin, which has very low friction, was an ideal surface to rest the surrogate’s feet, allowing the feet to come to an equilibrium position on their own, based on the surrogate’s preload and brace conditions. The Delrin was 3/16-inch thick. A base to secure the surrogate’s pelvis was custom made with a 3/16-inch thick platform, such that the surrogate’s position in the Z-direction was consistent throughout experimentation. The top surface of the Delrin and pelvis base were the specific Z=0 positions of the surrogate.

Figure D5 is showing CAD surface models of the pelvis base. Note the actual base and Delrin footplate in figure D6, showing an investigator collecting kinematic data from the surrogate.
The test developed for the second hypothesis called for changing the external rotation, width, and dorsiflexion parameters of the standard-of-care brace. Below are sequences of pictures taken and an example for each of these parameters. Note the Z-X, Z-Y, and oblique photographs were taken for every experimental pose throughout data collection. Only a sampling of these poses is represented here.
Figure D6: Sequence from the second hypothesis testing showing the external rotation increasing from 0-degrees to 70-degrees (testing was to 80 degrees, not shown)

Figure D7: Sequence from the second hypothesis testing showing the brace width increasing

Figure D8: Brace width is measured from center to center of the heel, denoted by the arrows pointing to the center screw; standard-of-care brace width is defined as the outside shoulder width of the patient
Testing of the third hypothesis called for translating one leg at a time of the surrogate biomodel in the negative-X direction, starting from a braced-resting position. This test was repeated for a no-brace condition, a standard-of-care brace condition, and an articulating brace condition. The figures below show a sampling of this data collection for just the right leg from positions -1 inch in X to -4 inches in X.
Figure D10: Sequence from the third hypothesis testing showing the right leg translating in the negative-X direction; the left, right, and middle columns are the no-brace, standard-of-care brace, and articulating brace conditions respectively.
REFERENCES


