DESIGNING A MECHANISM TO INHIBIT TALOCRURAL JOINT MOVEMENT TO FACILITATE THE LOCATION OF THE SUBTALAR JOINT AXIS

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ABSTRACT

The purpose of this honors thesis was to create a device that restricts the motion of the talocrural joint in the human ankle in order to determine the location of the subtalar joint axis. By locating this axis, an accurate analysis of the internal muscular moment about the subtalar joint can be performed. The ability to determine the subtalar axis can be crucial for the treatment of a number of foot and gait disorders, such as cerebral palsy, planovalgus, and cavovargus (club foot). Despite decades of research done on the subject, there is currently no effective non-invasive technique to determine the location of the axis, especially one that can be conveniently utilized in gait laboratories. This project builds upon these previous studies, using a technique known as the subtalar axis locator (SAL) approach to isolate and track subtalar joint movement. Months of investigation and design culminated in a device known as the Subtalar Axis Locator II, or SAL II. Preliminary testing has confirmed that the SAL II successfully utilizes verifiably accurate techniques to find the axis while meeting the design requirements necessary for the device to be practical in a clinical setting. Once the testing protocol has been approved by the Penn State Institutional Review Board, the device can be used to locate the subtalar joint axis in subjects and determine the internal moment at the joint.
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CHAPTER ONE

INTRODUCTION

1.1 Problem Overview

Gait disorders affect millions of Americans and have a substantial impact on mobility and quality of life for those afflicted. One of the most common is cerebral palsy, a condition caused by prenatal or early childhood damage to the cerebrum, the motor center of the brain. Cerebral palsy can take a number of forms, the most common of which is spastic diplegia. In subjects suffering from this condition, muscles in the lower half of the body spasm and tense without external stimulation, making walking and other forms of physical activity extremely difficult. Frequently, these contractions occur around the joints in the ankle, which makes foot movement challenging. This is especially debilitating given the fundamental importance of these joints to the act of walking. The significance of the ankle to human mobility lies in the freedom of motion it grants the foot. While walking, the foot rotates about the ankle, allowing the person to push off the ground much more effectively. Tension in the muscles that control these movements arising from cerebral palsy negates this flexibility. Often, only one or a few muscles are tensed, creating an imbalance across the foot.

The ankle is where the shank (lower shin) and foot meet and connects three bones. The tibia, commonly known as the shin bone, is the topmost of these. The calcaneus, also known as the heel bone, is the lowermost of the three, and is located in the tarsus of the foot. The talus is located between the tibia and calcaneus and is difficult to locate due to its inaccessibility and lack of noticeable landmarks. The ankle itself consists of two joints, the talocrural joint between the tibia and talus and the subtalar joint between the talus and calcaneus. Because the two joints both behave like hinges, the ankle can be approximated as a universal joint. Ankle motion is
usually thought of as simply pointing the foot up or down, called dorsiflexion and plantarflexion, respectively. This rotation occurs almost solely at the talocrural joint. However, because there are two joints, the ankle does not act as a simple hinge. Rather, it has a much broader range of motions. The foot can be twisted along its length, turning the sole of the foot towards (inversion) or away from (eversion) the other foot. The foot can also be rotated about the shank towards (adduction) or away from (abduction) the other foot. These movements can be combined to produce either supination (plantarflexion, inversion, and adduction) or pronation (dorsiflexion, eversion, and abduction). Unlike dorsiflexion and plantarflexion, the subtalar joint plays a significant role in each of these motions.

**Figure 1.1.1.** A lateral view of the ankle, showing the primary bones and ligaments (U.S. General Services Administration)
Subjects suffering from *spastic diplegia* often lack the ability to perform these ankle motions without great difficulty. In order to resolve the complications caused by this disorder, gait specialists must somehow neutralize the imbalance in the force exerted by the muscles upon the foot. Planovalgus and cavovarus, disorders in which the ankle bows outward or inward respectively, can severely curtail the ability to walk and require surgery to correct. In order to effectively treat any of these conditions, the physician must know the location of the two joints in the ankle, the talocrural and the subtalar. Without this information, it is impossible to determine the moment arms exerted on the foot and tibia by the ground reaction force. However, there is no simple and accurate way to locate the subtalar or talocrural axes. The reasons is that the talus is inaccessible and lacks boney landmarks that can easily be tracked. This inaccessibility makes placing markers on the talus to track movement very different on living subjects. A number of techniques have been used in the past to solve this dilemma, although none of them has successfully resolved all of the difficulties faced by researchers in identifying the subtalar axis.
1.2 Previous Work

The primary difficulty with treating these gait disorders lies in the tremendous variation in the location of the subtalar axis between subjects. Without knowing its orientation, it is impossible to determine the exact moments acting on the foot from the ground reaction force. The deviation angle of the axis, the horizontal orientation relative to the front-to-back midline of the foot, has been measured at angles ranging from $4^\circ$-$47^\circ$. The mean deviation angle is approximately $21^\circ$. The inclination angle, the vertical orientation relative to the midline of the foot, can lie between $20^\circ$-$68^\circ$. The mean inclination angle is approximately $40^\circ$ (Piazza, 2005). With such wildly divergent data, it is clear that each individual must be examined independently in order to determine the exact orientation of their subtalar joint axis.

The most direct means of identifying the subtalar axis in a given subject is to perform invasive surgery on their ankle and examine the movement of the bones with respect to one another or to simply insert pins into the skin to locate the major bones. This method was used in cadavers in early studies by Manter (1941), Root et al. (1966), and others. In vivo tests were later performed by Close et al. (1967) and Lundberg and Svensson (1993). While simple and very effective for use in cadavers, this technique is extremely undesirable for use in vivo given the inherent discomfort and potential risks of cutting into the subject’s ankle. Consequently, surgery should be considered a last resort method for locating the subtalar axis in living subjects.

Another method is the insertion of pins into the foot and ankle to locate the major bones, but again this method causes discomfort to the subject. Magnetic resonance imaging (MRI) can be used to accurately locate the subtalar axis; however, an MRI machine is quite expensive and not readily available in gait laboratories.
A more complex strategy is the optimization approach pioneered by van den Bogert et al. (1994). Essentially, it consists of approximating the human ankle as two perfect hinge joints and tracking the motion of the calcaneus with respect to the tibia by placing motion tracking markers on the shin and heel. By using a mathematical model and comparing the data to known parameters, it is theoretically possible to use this motion tracking data to locate the subtalar joint. The advantage of this system is it does not require invasive surgery and can be performed using motion tracking equipment already found in most gait laboratories.

While the original study achieved promising results, further studies by other researchers have failed to obtain the same level of success. This was analyzed by Lewis et al. (2006), who concluded that the range of motion in the human angle was not sufficient to locate two axes simultaneously. Furthermore, the talocrural and subtalar joints do not act as perfect hinge joints, which challenges the validity of the model used in the optimization approach. Unless this issue is resolved, it is mathematically impossible to determine with absolute certainty the location and orientation of a particular joint. One of the primary causes of this dilemma is a phenomenon called “kinematic crosstalk” in which movement in one joint or limb is confused with the movement of another. In the case of the subtalar joint, this is caused by the movement of the talus with respect to the tibia at the talocrural joint. Because isolation of the movement of the calcaneus with respect to the talus cannot be achieved, the exact location of the subtalar axis using the optimization method cannot be determined.

One solution to this problem is to immobilize the talocrural joint. If this can be accomplished, all calcaneal motion with respect to the tibia can be regarded as purely subtalar motion. The most straightforward way to do this is to coax the foot into dorsiflexion by applying an external force to the top face of the foot near the toes. External forces can then be applied to
the foot to induce subtalar motion while the movements of the tibia and calcaneus are tracked by a motion analysis system. This theory forms the basis to research done by Kirby (1987) and Lewis et al. (2007, 2009), which has established the plausibility and validity of this approach for finding the subtalar axis in an accurate and reliable manner. Their work culminated in a device known as the Subtalar Axis Locator (SAL I) which was capable of both incapacitating the talocrural joint and initiating subtalar joint movement. However, the nature of the device presented other challenges, namely the positioning of motion tracking cameras. While the data collected were within a reasonable error, the device itself was impractical in a clinical setting.

1.3 Project Overview

Since this project is the second generation of SAL, the original device was the obvious starting point. The new iteration, designated SAL II, would have to take advantage of the lessons learned, most importantly that immobilizing the talocrural joint would allow the researcher to isolate the subtalar joint. However, the design would have to resolve the obstacles that hindered the effectiveness of SAL I. These included the need to reposition the tracking cameras, the bulkiness of the device, and the overall complexity of the design due to the large number of distinct components and moving parts. With these constraints in mind, we begin the design process by brainstorming possible solutions to the problem. After considering multiple options, we decided to move forward with a “boot” device; that is, SAL II would be a relatively self-contained piece of equipment that fit around the subject’s leg.

Before we could fully design the device or build a prototype, we had to determine how we would track the motion of the calcaneus with respect to the tibia. Previously, four motion tracking markers were placed directly on the subject’s heel. While this arrangement functioned
well in static testing, the presence of a sizeable pad of fatty tissue on the bottom of the heel caused the markers to bulge and shift upon heel-strike during waking. To correct for this, we affixed the marker cluster to a hard plastic strip which was placed on the calcaneus. Preliminary testing demonstrated that this updated arrangement provided the necessary visibly and firmness without sacrificing mobility during gait. Once the design and fabrication of the device were complete, we were able to begin testing it using the motion capture system that was described earlier.

1.4 Project Objectives

The purpose of this research project is to create a device that restricts the motion of the talocrural joint in the human ankle in order to determine the location of the subtalar joint axis in vivo. By locating this axis, an accurate analysis of the ground reaction forces on the foot can be performed, and the moment this force creates in the foot can be calculated. There is currently no efficient way to determine the location of the subtalar axis, especially one that can be conveniently utilized in gait laboratories. One of the primary applications of this device would be to assist in the location of the subtalar joint axis in subjects with cerebral palsy who require foot or ankle surgery to improve their ability to walk. There are two main objectives to this project:

- The device must improve on or involve a redesign of the original Subtalar Axis Locator.

In order to meet this goal, the design must adequately resolve the problems outlined earlier. Namely, it must utilize the techniques established by Lewis et al. (2009) to find the subtalar axis by means of a simple, compact design, thereby eliminating the need to reposition the motion tracking cameras. This includes minimizing the number of moving
parts and not obscuring the cameras’ view of the markers placed on the tibia and calcaneus. Also, unlike SAL I, this incarnation is not being designed for use in an MRI, which increases the options for material selection and fabrication. Ultimately, the device must be safe for both the operator and the subject and must be reasonably easy to operate.

- The second generation of SAL must reliably locate the subtalar axis in a variety of subjects. This is essential if the device is to have a practical application in gait laboratories. SAL II must exhibit repeatability by yielding the same results with the same subjects during different testing sessions. Finally, testing must yield reasonable results that fall within an acceptable range of deviation, using the data obtained by earlier researchers as a guideline.

In order for SAL II to be considered a successful device, it must adequately accomplish these two objectives.
2.1 Anatomy of the Subtalar Joint

The human ankle is composed of two joints, the talocrural and the subtalar. Both are synovial joints, meaning the two bones are not directly connected but rather can move relatively freely with respect to one another. While the talocrural joint acts like a hinge, there is some disagreement among researchers as to whether the subtalar joint behaves like a hinge or screw joint. Some studies, such as the one conducted by Manter (1941) and Huson (1961) noted translation in addition to rotation. However, others, such as Hicks (1953) and Root et al. (1966), observed only minimal lateral movement. For the purposes of this and previous subtalar axis locator studies, the joint has been approximated as a hinge (Lewis et al., 2007). As with any dual-hinge system, the ankle complex can be modeled as a universal joint, turning it into a two degree-of-freedom system.

The orientation of the subtalar joint is most commonly defined in terms of inclination and deviation angles. The inclination angle refers to the axis’ orientation with respect to the horizontal plane. The subtalar axis always points upwards at the toes. The deviation angle refers to the axis’ orientation with respect to a vertical plane passing through the midline of the foot from the heel to the toes. The subtalar axis always points medially at the toes.

To fully understand the significance of the subtalar joint, we must understand the basic mechanics of the foot during walking. When pushing off the ground, the foot enters plantarflexion, in which the toes are pointed farther away from the tibia. Upon heel strike, the foot enters dorsiflexion, in which the toes are pointed upwards toward the tibia. Most of the movement during these actions is in the talocrural joint, with only slight rotation about the
subtalar axis. However, walking does involve approximately 10° of inversion/eversion about the subtalar joint. The primary function of the subtalar joint is to provide balance when walking over uneven surfaces (Hicks, 1953). As a result, disorders at this joint can severely impact a person’s ability to walk properly.

2.2 Attempts to Locate the Subtalar Joint Axis

2.2.1 Cadaver Testing

Before the advent of magnetic resonance imaging in the 1970s, attempts to locate the talocrural and subtalar axes relied on invasive procedures either in cadavers or living subjects (in vivo). While the human ankle has been studied to varying degrees for centuries, one of the earliest such attempts to pinpoint the axes was conducted by Manter (1941). He understood the significance of the subtalar joint to foot movement and tested cadavers to analyze ankle mechanics. In his tests, the calcaneus was immobilized, and long rods were inserted into the talus so that its movements could be tracked. Tracing the paths that the rods traversed produced concentric arcs, the center of which marked the location of the subtalar axis. From the 16 cadavers he tested, he measured inclination angles of 29°-47° with a mean of 42° and deviation angles of 8°-24° with a mean of 16°. Ultimately, it was determined that the subtalar joint exhibited behavior more like a screw than a hinge due to the presence of lateral movement when the bones were rotating about the axis. This somewhat unusual action, along with the shape of the joint, helps to explain the foot’s limited range of motion. The screws appeared to turn in opposite directions on the left and right foot, and this motion was most closely associated with pronation and supination.

Research into the nature and function of the subtalar joint was conducted by Hicks
To simulate the forces imparted by connective tissue, the muscles and tendons were left intact and attached to springs. One rod was connected to the talus and another to the calcaneus while the tibia was held in place. The rods were adjusted until they rotated about their long axis without lateral movement. Hicks concluded that the subtalar joint was essential for walking on uneven surfaces. Furthermore, little to no translation was observed in the cadaver specimens, meaning that the joint acted like a hinge, unlike what was observed by Manter. The location of the subtalar axis was not analyzed in this study.

Using a method comparable to Manter, Root et al. (1966) used rods to trace the movements of the calcaneus and talus with respect to each other. The 22 cadavers he tested had an average inclination angle of 41° (22°-55°) and deviation angle of 16° (8°-29°). Rather than acting like a screw as Manter concluded, it was determined that the subtalar joint behaved just like a hinge as almost no translation was measured.

Isman and Inman (1969) attempted to locate the axes in the ankle using anatomical landmarks as reference points. In particular, one factor they analyzed was the impact the shape of the articulation sites had on the rotation of the talocrural and subtalar joints. Inserting a wire into cartilage affixed to the calcaneus, the talus was pressed against it and rotated at the subtalar joint. The wire marked the tissue attached to the talus as the rotation occurred, and a compass was used to find the center of the arc it traced, pinpointing the axis. Testing the ankles of 46 specimens, the mean inclination angle measured was 41° (20°-68°) and the mean deviation angle was 23° (4°-47°). Interestingly, the average angles were nearly identical. This study produced a much larger variation in results than the previous two, possibly due to the large sample size used. Their studies also found that the subtalar joint acted like a hinge. Notably, they no viable means of locating the joint’s axis of rotation in living subjects was determined during the course of their
research, mainly due to substantial variation between subjects and the absence of skeletal landmarks. The importance of accurately locating the subtalar axis for the treatment of gait disorders was also noted.

2.2.2 In Vivo Testing

A number of methods for locating the subtalar joint in live subjects have also been examined. The primary purpose of such strategies is the location of the subtalar joint in persons suffering from gait disorders. Among the earliest in vivo experiments was one conducted by Close et al. (1967). Subjects were locally anesthetized and pins were inserted into their ankles to track the motions of the talus and calcaneus. They were asked to walk along a preset path, and their gaits were recorded via camera. The frames from each test were analyzed with respect to the position of each pin. The functional importance of the subtalar and talocrural joints was emphasized as Close et al. asserted that the articulations in the foot, namely the intertarsal and tarsometatarsal joints, had a negligible impact on foot mobility. It was determined that rotation of the leg while the foot remained fixed relied primarily on the subtalar joint. As a result, clinical procedures, such as bone blocks and arthrodesis, that limit the motion of the subtalar joint can more negatively impact mobility than previously thought. Supination and pronation were found to be caused primarily by subtalar rotation, while the talocrural and tarsal joints had minimal influence. The eight subjects he tested yielded an average inclination angle of 42 and an average deviation angle of 16. These values are almost identical to the results obtained by Manter (1941) and the other researchers studying cadavers.

Kirby (1987) investigated two distinct ways of locating the subtalar axis, the palpation technique and the range of motion technique. In the former, the subject sits or reclines while the
examiner places their thumb on the sole of the foot and presses firmly against the fifth metatarsal head. The foot is then rotated into pronation and supination while the examiner’s thumb locates points on the sole that do not experience rotation. The examiner’s thumb is moved laterally and medially to find multiple sites across the foot. These points are located along the subtalar axis, so by connecting them the deviation angle of the axis can be determined. In second technique, the examiner once again loads the fifth metatarsal head while moving the subtalar joint through its full range of motion. If applied properly, this method is useful as a screening tool for an abnormal subtalar axis in subjects with gait disorders. However, the accuracy of this method was never confirmed in vivo with the use of an MRI. Furthermore, the techniques involved require considerable expertise and practice to be consistent and effective. The number of variables inherent to these methods, such as where and how the load is applied, could produce significant variations between patients. This makes these techniques relatively impractical for widespread use in a clinical setting to achieve consistently accurate results.

2.2.3 Stereophotogrammetric Testing

Roentgen stereophotogrammetry is a procedure by which markers are tracked three dimensionally by using two or more cameras that capture x-rays. This produces a stereo effect similar to that created by the eyes to give depth perception. Van Langelaan (1983) was among the first to use this technique to locate the subtalar axis. Tantalum markers, which show up clearly in x-ray images, were inserted into the talus and calcaneus to follow their motion, and the tibia was loaded vertically. The subtalar joint was approached as a screw axis and analyzed for both lateral and rotational movement. However, little translation was measured, with an average of just 1.7 mm per test. The data were analyzed by decomposing the screw axis to identify the
axis of rotation in the subtalar joint. The ten cadavers van Langelaan studied yielded inclination angles of 41° (28°-55°) and deviation angles of 26° (7°-35°).

Lundberg and Svensson (1993) employed stereophotogrammetry to determine the orientations of the talocrural and subtalar axes in eight subjects. After applying local anesthesia, three 0.8 mm markers were imbedded into the talus, calcaneus, and navicular of each subject’s right foot. Each subject then stood on a platform and moved their foot and shank into a variety of positions while the motions were recorded on film. The results were then analyzed by a computer program utilizing rigid body kinematics. Supination produced the greatest amount of subtalar joint rotation, while dorsiflexion and plantarflexion produced the least. Talocrural rotation was larger than subtalar rotation in virtually every orientation. However, variation in axis orientation between subjects was substantially higher in the subtalar joint. The overall motion of the joint was found to be best approximated as a hinge with minimal translation, similar to what was observed by van Langelaan. Inclination angles of 29°-38° and deviation angles of 23°-37° were found.

Leardini et al. (2001) used stereophotogrammetric techniques to locate the subtalar axis and determine the overall mobility of the ankle at the joint. A rod was inserted into the calcaneus, while the tibia was held stationary. The rod was moved by hand to numerous orientations. Later, a rod connecting the tibia and talus was inserted to immobilize the talocrural joint. The motion of the bones was recorded by a stereophotogrammetric system with anatomical landmarks used as reference points. It was noted that the connective tissue adjacent to the talus and calcaneus resisted any motion within the subtalar joint, requiring the application of outside moments. This limited the degrees-of-freedom inherent to the ankle. The six cadavers tested yielded an average inclination angle of 53° (44°-61°) and deviation angle of 38°.
These values are significantly higher values than those of the tests previously discussed, further emphasizing the immense variation in the location of the subtalar axis between individuals.

2.2.4 The Optimization Approach

Theoretically, it is possible to construct a mathematical model that could simultaneously locate the subtalar and talocrural axes by measuring the movements of the tibia and the calcaneus. This was the foundation of the optimization approach utilized by van den Bogert et al. (1994). His model took the raw 3-D kinematic data and applied set parameters based on the structure of the ankle and lower leg documented by previous researchers. For his approach to work, he needed to approximate the talocrural and subtalar joints as ideal hinge joints in a three-segment system consisting of the tibia, the talus, and the calcaneus. Most importantly, he did not believe it was necessary to locate the inaccessible talus and track its movements during his tests. The method was tested on fourteen subjects and resulted in data that fit established values for the inclination and deviation of the subtalar axis. The repeatability of the method was only confirmed on one of the subjects, however. Without using an MRI or invasive techniques to confirm the accuracy of his findings, the validity of the optimization approach could not be determined with certainty.

The validity of this technique was tested by Lewis et al. (2006) on a computer simulation, a mechanical device, and cadaver specimens. Using a six degree-of-freedom mathematical optimization approach similar to van den Bogert et al., the locations of the ankle joints were determined by analyzing tibia-calcaneal motion. In computer simulations, a two-revolute model was utilized to optimize the initial inputs and locate the axes. A two-axis mechanical linkage
was similarly set up with ranges of motion comparable to the talocrural and subtalar joints. The movements of the linkages were recorded and optimized using the same algorithm. On the cadavers, the motions of the tibia, talus, and calcaneus were measured using markers inserted into the bone and a computerized motion analysis system. The foot was placed on a platform and remained stationary while the shank was moved through a variety of positions. Once again, the optimization method was applied to the data to locate the talocrural and subtalar axes. In both the computer model and the mechanical linkage, the optimization method was able to locate the axes of rotation within 1° to 5° of error. However, in the cadaver specimens, errors as large as 20° were measured. The results for the orientation of the subtalar axis were particularly inaccurate. In all three cases, the results were repeatable. One reason for the discrepancy between the mechanical and computer simulations and the cadavers is the limited range of motion of the foot at the ankle joints, particularly at the subtalar joint. In order to simultaneously determine two axes of rotation, a large range of movement is necessary. For small degrees of rotation, one universal joint orientation can behave almost identically to another orientation. The presence of screw translation may also affect the efficacy of the results. Consequently, the optimization approach is not viable as a means of reliably locating the subtalar axis.

2.2.5 Subtalar Axis Locator

A new approach to locating the subtalar axis was studied by Lewis et al. (2007). By inducing and maintaining dorsiflexion in the foot, it is possible to essentially immobilize the talocrural joint. If an external moment is then applied to the foot, the resultant motion will be almost entirely about the subtalar axis. This allows the researcher to track only the movements of the tibia and calcaneus, eliminating the need to know the exact position of the talus. To test
the validity of this technique, known as the subtalar axis locator (SAL), six cadaver feet were placed in a rig that pulled the forefoot toward the tibia and then rotated it into supination and pronation. Marker clusters were inserted into the talus and calcaneus, and their motion was recorded by motion analysis cameras. By analyzing the data using helical axis decomposition, Lewis et al. were able to deduce the location of the subtalar axis. Angular errors of under 5° and lateral errors of less than 5 mm were found, well within acceptable parameters based on the enormous variability in subtalar axis location between individuals.

Once the accuracy of subtalar axis location by talocrural restriction had been established in cadavers, the next step was to test its efficacy in vivo. Lewis et al. (2009) constructed a device known as SAL I that pulled the foot into dorsiflexion while applying a torque. Marker clusters were affixed to the skin on the calcaneus and tibia, and a video-based motion tracking system recorded their movement. Some of the 24 subjects were also tested in an MRI to obtain a benchmark against which to compare the data. The mean errors were found to be 6° and 2.5 mm, and talocrural rotation averaged 3.3°. While the rig produced reasonable and repeatable results, its large number of components and moving parts made it quite complicated and limited its mobility. Because it had to be designed for use in an MRI, bulky plastic parts were used in fabrication instead of smaller metal ones. This caused the rig to block the markers, removing them from the cameras’ fields of vision. As a result, the motion analysis camera had to be moved, severely handicapping SAL’s effectiveness in gait laboratories. The device had to be redesigned from the ground up for practical use in a clinical setting. However, the validity of the subtalar axis locator approach had been confirmed in vivo, setting the stage for the device designed over the course of this project.
2.2.6. Motion Analysis Systems

To fully comprehend the significance of SAL, it is helpful to understand how motion tracking systems work, specifically how the raw data on each marker location are used to determine the location of and moments about the subtalar joint axis. Before the trial begins, the computer analyzes the marker clusters and establishes a coordinate system for each (Lewis et al., 2006). In this case, three coordinate systems are created: a tibial \(X_T\), a calcaneal \(X_C\), and a ground reference frame \(X_G\). The axes for each system are based on the relative positions of the four markers that make up each cluster. At all times during testing, the locations of the tibia \(T_X\) and calcaneus \(C_X\) markers are known in their own reference frames. To find a helical axis that accurately represents the rotation of the ankle about the subtalar joint, the motion of the calcaneal markers must be determined in the tibial coordinate system. Therefore, in each frame, the location of the calcaneus cluster must be converted into tibial coordinates. This requires a 4x4 homogeneous transformation matrix \(T_{TC}\). While collecting data, the motion tracking software also records the locations of the tibia and calcaneus markers in the ground coordinate system \(T_G\) and \(C_G\). These values are necessary to compute the transformation matrix at a given frame \(i\).
using a least squares function (Challis, 1995):

\[
[T_{TC}^i] = \text{lsqRT}(T_G^i, C_G^i)
\]

However, \(T_{TC}\) varies with each frame, so the entire process must be repeated hundreds or even thousands of times. A displacement matrix (\(\Delta^{i+d/i}\)) is then used to convert the transformation matrix into a helical axis, where \(d\) represents another frame against which the marker locations in frame \(i\) are being compared (Spoor and Veldpaus, 1985):

\[
\Delta^{i+d/i} = [T_{TC}^{i+d/i}][T_{TC}^i]^{-1}
\]

\([\rho, u, \theta, t] = \text{helical}(\Delta^{i+d/i})\)

In the latter equation, \(\rho\) is a point along the helical axis, \(u\) is a unit vector along the axis, \(\theta\) is the amount of observed rotation about the axis between frames \(i\) and \(d\), and \(t\) is the amount of translation observed between the two frames. Note that if \(\theta\) is found to be less 5° for any pair of frames, that comparison is discarded due to the tendency of helical axis decomposition to be inaccurate for small rotations. Each comparison creates a helical axes to fit the data. Ultimately, all of these axes are compared, and the software creates a best-fit helical axis that most closely fits these axes. This represents the location of the subject’s subtalar joint axis.

Once the axis is located, the next step is to determine the moment about the joint from the ground reaction force (\(M_{STJ}\)). This value is important to calculate because it closely represents the moment about the subtalar joint from the muscles and connective tissue in the subject’s ankle. Whereas the subtalar axis is located during SAL testing, the moment is calculated based on the walking test. The positions of the calcaneus markers are recorded, as is the ground coordinate system. For each frame the subject is in contact with the force plate, the total ground reaction force and the center of pressure are also collected (GRF_G, COP_G). Based on the information gathered during the SAL tests, the location of the subtalar axis in calcaneal
coordinates is already known, as are a point “ρ” and a unit vector “u” along the axis. Using the same process of linear transformation, the point and unit vector are converted into the ground coordinate system (ρ_G, u_G). Now that the subtalar axis location and ground reaction force are known for each frame, the next step is to determine the effective radius (r_G):

\[ r_G = \rho_G - \text{COP}_G \]

Finally, the cross product of the effective radius and ground reaction force is taken, adding an addition dot product to include only the portion of the moment that acts along the subtalar axis:

\[ M_{STJ} = (r_G \times \text{GRF}_G) \cdot u_G \]

Because the mass of the foot is relatively low, it does not produce an inertial effect when it rotates. Thus, the calculated moment about the subtalar joint axis is representative of the moment exerted on the foot by the muscles and connective tissue of the ankle.

**Figure 2.2.2.** Helical axis decomposition of subtalar joint axis location
CHAPTER THREE
DESIGN AND METHODS

3.1 Design Specifications

Before design and fabrication of SAL II could begin, the basic requirements and constraints for the device had to be analyzed. These criteria are dependent upon the needs of the end users, which in this case are the gait laboratories that will use the device to locate the subtalar joint axis. Ultimately, eight primary design specifications were identified:

- **Accuracy:** Most importantly, the device must be capable of creating measurable, pure subtalar joint motion that can be recorded and analyzed. To this end, it must generate light dorsiflexion to immobilize the talocrural joint and apply side-to-side movement in the foot along the lines of action established by Lewis et al (2009). As with SAL I, the new iteration should apply approximately 5 lbs of force; enough to sufficiently prevent talocrural motion without causing pain or discomfort to the subject. The wagging force must be applied in a manner such that its line of action passes through the talocrural axis – otherwise talocrural movement may be induced. Since the exact location of this axis is unknown, the best approximation is to align the force vectors with the malleoli of the ankle. Since subjects’ subtalar axes will not be confirmed in an MRI, the absolute accuracy of the results cannot be verified. As a result, the data will be compared to existing values for the inclination and deviation angles of the subtalar joint axis to ensure they fall within an acceptable range. To maximize the likelihood of valid data, every effort must be made to replicate the processes validated by Lewis et al.

- **Repeatability:** The device must also produce repeatable results. If the variation between tests for a given subject is more than a degree or two, the device is clearly not functioning
as intended and the results would be discounted. In this case, each subject will be tested twice over the course of a few days to look for consistency of results. While challenging, the best way to encourage repeatability is to operate the device identically for each run and each subject. Consequently, the number of variables on the device should be minimized without hampering the accuracy.

- **Safety:** Like any apparatus that involves human interaction, it is essential that its operation in no way endangers the well-being of the subject or the operator. Because SAL II will not involve fast moving parts, high forces, or sharp objects, the risks are inherently low. However, this does not mean that safety and comfort can be ignored by the designer. All rough or sharp edges must be sanded down or covered, and moving parts should be created as to avoid injuring fingers or limbs even if used improperly. Finally, hygiene must be taken into account. Since many people will be placing their legs and feet into the device, it must be easy to sanitize between tests. NOTE: Because SAL II will not be operated inside an MRI, metal components may be used without creating a safety hazard.

- **Cost Effectiveness:** As with any product that is intended for distribution, it must be made as inexpensively as possible without sacrificing quality. This includes both the total cost of the materials and the time and skill required to fabricate it. Furthermore, time and budget constraints on this project severely limit the potential cost and complexity of the prototype. Based on SAL I, it is reasonable to assume that the device can be completed using relatively common and inexpensive materials, such as 6061 Aluminum or wood. Also of concern is the amount of time it takes to fully fabricate the prototype. Both of these factors underline the need for a simple device with as few parts as possible.
- **Compactness:** SAL II needs to be lightweight and easily portable. Mobility is essential so the device can be flexibly positioned as needed with respect to other laboratory equipment, especially the motion analysis cameras. As stated in the initial objectives, at least two cameras must have line of sight to each marker at all times. If it is too bulky, it may obscure the cameras’ view of the marker clusters on the calcaneus and tibia, a significant obstacle encountered while testing SAL I. Otherwise, the cameras would need to be moved to obtain a better view, a tedious and time-consuming process. Also, With storage space in laboratories at a premium, having a smaller device would be beneficial even when it is not in use.

- **Ease of Use:** Ideally, all items should be simple to operate with only minimal training, and SAL II is no exception. Every aspect of use, including assembly, set-up, operation, maintenance, and cleaning must be carefully considered. For example, will extremely specific tools, such as a particular Allen wrench, be needed to put it together or take it apart? Are any components difficult to access or replace? The most vital aspect is ease of operation. Inducing dorsiflexion and applying the wagging force to the foot should require as few steps as possible, preferably in a manner that requires little training for the operator. Once again, this includes eliminating the need to move the motion analysis cameras to collect data.

- **Durability:** To be a worthwhile investment for gait laboratories, the device must possess sufficient sturdiness and longevity to work properly for hundreds of uses with as little maintenance as possible, even if used improperly. A principal constituent of durability is simplicity – the fewer the parts, especially moving parts, the fewer the pieces that can break or malfunction. If the device needs more than rudimentary servicing between each
use, it begins to lose its effectiveness and therefore its appeal. Using common, inexpensive components reduces the complexity of finding replacement parts. Durability does come at a price however, since the strongest materials and mechanisms are generally more expensive and harder to fabricate.

- **Practicality:** Because our end users are gait laboratories nationwide, it is essential to design SAL II to conform to the environment in which it will be used. Proper operation cannot require the use of expensive or atypical equipment, such as an MRI or other imaging devices. Based on the fundamental principles behind the device, a digital motion tracking system is necessary to utilize the subtalar axis locator method. These systems are quite common however. In addition, the finished product must represent a professional medical device since it will be used on subjects.

All designs had to be considered and compared with these eight criteria in mind. To determine the relative importance of each requirement, they were run through an Analytic Hierarchy Process (AHP), shown in Figure 3.1.1. The process consists of assigning a relative weight for each specification using factors of 1, 3, 5, 7, and 9. For example, in this case accuracy was determined to be 7 times more significant than cost, so a 7 was placed in the “Accuracy” row in the “Compact” column. Conversely, 1/7 was placed in the “Compact” row under the “Accuracy” column, and so on. Ultimately, five tiers were established:

- **Tier 1:** Accuracy, Repeatability (Weight: 0.25)
- **Tier 2:** Safety, Practicality (Weight: 0.15)
- **Tier 3:** Ease of Use, Durability (Weight 0.08)
- **Tier 4:** Compactness (Weight 0.03)
- **Tier 5:** Cost Effectiveness (Weight 0.01)
Table 3.1.1. Analytic Hierarchy Process for the SAL II design specifications

3.2 Concept Generation

With the objectives defined and prioritized, the next step was to begin “brainstorming” to develop general conceptual ideas for the primary features. The preliminary design consideration was how to orient and position the subject and the device. SAL I testing was performed with the subject lying on their back on a table with the device situated around and above the leg. Problems with calcaneus marker visibility ultimately required that the motion tracking cameras be mounted on tripods close to the ground. Since this is unacceptable for SAL II, a new configuration was necessary. Several orientations were analyzed, including having the subject:

1) Stand with their leg down
2) Stand with their leg bent at the knee and pointing behind them
3) Lie on their stomach (prone)
4) Lie on their back (supine)

5) Sit down with their leg outstretched.

While cases 2 and 3 would greatly increase the visibility of the calcaneus markers, the tibia cluster would be nearly impossible to see without creating a complicated set of marker extensions. Designing a device to work while the subject is standing would be quite challenging, as would operating such a device, ruling out options 1 and 2. The remaining orientations, 4 and 5, would work, but the decision was ultimately made to proceed with the sitting position. This position simply requires the subject to sit down in any chair with their leg resting on a stool of some sort.

The next consideration was how to induce dorsiflexion in the subject’s foot. SAL I accomplished this by hanging a 2 kg weight from the rig, which was connected by a string to a foot plate. While very good at producing a constant tensile force, it required a complicated pulley system to work effectively, making the device bulky and hard to use. Simply taping or tying the foot back is by far the simplest way to induce dorsiflexion as it only requires a length of rope and something to which it can be attached. However, any movement in the foot plate could cause the rope to completely lose tension, allowing motion at the talocrural joint and rendering the entire test invalid. Without a scale or strain gauge connected to the rope, there would also be no way or determining the tension within the system at any moment in time. The best compromise between constant force and compactness was determined to be an elastic mechanism. Once the spring constant of the elastic material was calculated, it would act as its own strain gauge. Originally, the plan was to have one cord connecting the foot plate to the base plate. Concerns were raised that the wagging of the foot plate could cause the tension in the cord to decrease, which would cause the ankle to rotate about the talocrural axis. The solution was to
have an intermediate linkage between the two plates, with the elastic cord connected to a turnbuckle with eye bolts on either end. The turnbuckle would then be connected to the foot plate by a string, allowing the foot plate to rotate without loosening the elastic cord. When it was determined that a string or rope would cut into the subject’s foot and cause discomfort, the string was replaced by a strap.

Another major design consideration was how to apply the side-to-side force to the foot to produce inversion/eversion. SAL I produced this wagging motion with two strings attached to either side of the foot plate. The strings went through guide holes to a horizontal bar which was rotated towards and away from the subject’s foot by the operator. While effective, the rig was cumbersome and obscured the cameras’ views of the tibia markers. It also contained a substantial number of moving parts and connections, making it more difficult to fabricate and assemble. One solution was to create two arches, with one at each end of a plate. By connecting them at the top with a beam, a pulley system similar to a bicycle chain sprocket could be implemented. The pulley would be laid horizontally and rotate about a vertical axis when the operator turned a long handle. One continuous string would travel from the left side of the foot plate, around the back side of the pulley, and then connect to the right side of the foot plate. If the pulley had no teeth, though, the string could easily slip in any direction. To correct for this, the smooth pulley would be replaced by a sprocket, and the string would be broken into three segments – a central portion similar to a bike chain with string on either side. The front arch would contain numerous drilled guide holes so that the lines of action could be arranged to pass through the malleoli. Fabrication of the arch and pulley system proved to be far more complicated than originally anticipated however. The string-to-chain interface would also create a potential weak point in the system. Preliminary testing also revealed that the bulky rig posed a
high risk of obstructing the cameras. The arches were scraped in favor of using adjustable eye bolts as guide holes and cords with handles to produce the wagging motion. By connecting the cords horizontally and farther out on the foot plate, a larger moment could be applied, leading to the design of an outrigger extension for the foot plate. Finally, the original foot plate was found to be too wide and heavy. The much smaller and lighter foot plate from SAL I was reused with a slight modification, namely the addition of an outrigger extension.

Figure 3.2.1. Arch/pulley concept

The final design consideration was not related to the actual device. Rather, a new means of mounting the reflective markers to the subject was needed. Previously, markers were affixed directly to the skin on the lateral side of the calcaneus. However, the presence of a pad of fatty tissue located directly beneath and around the heel caused the markers to bulge upwards and
outwards upon heel strike during walking trials, hampering the accuracy of the results from these tests. A technique used by other researchers to attach the markers in each cluster to a piece of hard plastic. This plastic, known as Aquaplast (WFR/Aquaplast Corp.; Avondale, PA), becomes extremely flexible when heated but hardens upon cooling. Small strips of it can be molded into any desired shape, in this case the calcaneus and the shank. An inner lining of foam stuck to the plastic with double sided tape makes the apparatus more comfortable to wear, and the entire thing is attached to the subject with double-sided tape. This arrangement does not guarantee that the cluster will not shift upon heel strike, but it does guarantee that all four markers will move in unison. The first iteration for the calcaneus cluster consisted of a U-shaped piece of Aquaplast that fit around the calcaneus with a pad sticking outward and facing forward on the lateral side. Four 4 mm markers were arranged in a rectangular pattern on the pad. However, camera resolution was imprecise due to the close proximity and small size of the markers. Consequently, the pad was removed, and the markers were attached directly to the U-shaped piece. To further increase visibility, the 4 mm markers were replaced with 9 mm markers and applied to 2” threaded rods that were imbedded into the Aquaplast base. For the tibia, an existing cluster on an Aquaplast base was going to be used to save time on design and fabrication. However, the base was too long and interfered with the straps that held down the subject’s leg. This interference could cause the markers to shift during the SAL II trials, causing the results from the other trials, such as walking, to be inaccurate. The solution was to create a similar cluster with a significantly shorter base.

3.3 SAL II

The Subtalar Axis Locator II utilizes an elastic mechanism to apply a dorsiflexion force
and two cords attached to a foot plate apply the side-to-side, or wagging, force. The subject’s shank is fixed to a base plate via Velcro® straps at two locations so it does not shift during testing. This ¾”x12” pine base plate is covered with a block of memory foam, attached to the wood with adhesive glue (Gorilla Glue Co.; Cincinnati, OH), to increase comfort. A detachable piece of vinyl serves as a cover for the foam to facilitate cleaning.

Figure 3.3.1. SAL II attached to a subject’s leg
The foot plate is the same one used in the SAL I experiment and is made of a ¼” thick nylon sheet. Slots cut into the plate allow strapping of the subject’s foot, and a thin layer of foam, also covered in detachable vinyl, is attached in the center. A ½”x1”x 9” extension bar of white Delrin (DuPont Co.; Wilmington, DE) is bolted to the back side of the foot plate, and the cords that produce the wagging motion are tied to this bar. While not part of the original SAL I design, the extension acts an outrigger to increase the moment produced by the operator pulling on the cords. Another strap goes through slots in the foot plate near the subject’s toes and is attached to a turnbuckle, which is connected to a polyurethane cord. This cord has two markings on it which, when subjected to the 5 lbs of force necessary to induce dorsiflexion, are exactly 4” apart. The cord is connected by hooks to eye bolts extending from the rear of the base plate.
The elastic force is provided by the slightly stretched $\frac{7}{32}$” diameter polyurethane cord. To ensure that the tension in the cord remains constant even as the foot plate rocks back and forth, the turnbuckle and foot strap provide an addition degree of freedom to the system. In addition, the turnbuckle allows the operator to fine tune the length of the elastic system and
therefore the tensile force.

The wagging force is transmitted to the foot plate via the nylon cords connected to the outrigger. The cords run towards the subject’s shank but are redirected through two eye bolts at the front end of the base plate away from the subject. They continue past the foot to two handles. These handles are held by the operator, who alternately pulls each handle back. The nylon cords produce very little friction against the stainless steel eye bolts, and the tension created by the operator keeps the position of the cords stationary within the guide holes. The operator does not need to pull in the exact same direction with each motion, as the holes redirect the force along the primary lines of action. All moments applied to the foot need to pass through, or at least very close to, the talocrural axis for the joint to remain immobilized. This is accomplished by making the height of the eye bolts adjustable. By repositioning the nuts holding the bolt in place vertically, the location of the guide holes along the y-axis can be set such that the cord is aligned with the malleoli of the ankle.

Figure 3.3.5. Cords and handles that produce the wagging force
Figure 3.3.6. Adjustable eye bolts allow the cords to pass through the malleoli.

The device was fabricated primarily in the Penn State Learning Factory by the researcher. After cutting a piece of pine with a band saw to form the base plate, two deep notches were cut into each side for the leg straps. All rough edges were sanded, and ¼” holes were drilled in each corner on the top face. A coat of black lacquer spray paint was applied to the entire board. A memory foam pillow was cut down to size on the band saw and glued to the base plate. Black vinyl was cut and shaped to fit over the foam on the base plate and the foot plate. ¼”-20 carriage screws were placed inside the holes in the base plate and attached via washers and nuts. Eye bolts were affixed to each screw by means of ¼”-20 connectors.

Custom calcaneus and tibia marker clusters were created for the project. Both were made from Aquaplast, which was heated, cut to the appropriate shape, and molded to the researcher heel and shank respectively. For the calcaneus cluster, the markers were affixed to 2” long threaded rods that were imbedded into the plastic and arrayed at 60° increments around the base. On the shank cluster, the markers were attached directly to the Aquaplast.
While the ultimate successfulness of SAL II cannot be determined until full large-scale testing can be performed, a strong benchmark for the success of the design process is how well the device meets the eight original design objectives:

- **Accuracy**: As discussed earlier, the absolute accuracy of the measurements obtained by SAL II cannot be independently verified. However, the relative accuracy can be checked by ensuring that the device operates under the methodology established by Lewis et al. (2009). The polyurethane cords that produce the dorsiflexion force can be fine-tuned to
produce exactly the 5 lbs of tension that are needed to prevent mobility in the talocrural joint. With multiple cords of different lengths and a turnbuckle for fine-tuning, the elastic tensile force can be held constant between subjects regardless of their height/shank length. The adjustable-height eye bolts attached to the base plate allow the operator to align the lines of action for the side-to-side force with the lateral and medial malleoli. Because of their large range of motion along the y-axis (~ 4”), the guide holes can accommodate a wide variety of foot and shank sizes among subjects. X-axis positioning is facilitated by sliding the base plate towards or away from the foot plate. This flexibility is afforded by several pre-gauged lengths of elastic cord and a turnbuckle.

- **Repeatability:** The best way to promote consistent results is to establish a testing protocol with very specific instructions on the operation of the device and peripheral equipment. For example, the closest end of the base plate should be 14 cm from the beginning of the foot plate. By limiting the number of variables, the circumstances for each trial can be more easily replicated. Certain elements of SAL II also assist in maintaining consistency. The polyurethane cords are pre-gauged with marks that are exactly 4” when 5 lbs of tensile force are applied, providing a convenient way to ensure that the induced dorsiflexion is consistent between tests. The eye-bolt guide holes direct the wagging cords such that the operator can pull the handles in almost any direction without affecting the lines of action.

- **Safety:** Because it lacks fast moving parts or high loads, the safety risks associating with setting up and operating SAL II are low. The entire device weighs less than 8 lbs and is used at only a foot or two above the ground. The subject’s shank and foot rest on memory foam and are strapped to the plates by simple Velcro® strips, securing the leg in
the device without causing discomfort or hindering circulation. Detachable vinyl covers over the foam can be easily sanitized between tests and replaced when worn down. With the elastic cords pre-gauged, the operator should have no trouble checking that the dorsiflexion force does not exceed 5 lbs, and the turnbuckle allows for greater precision in adjusting the force. All sharps edges have been removed or sanded down, and the wooden base plate has been painted with black lacquer to prevent splinters.

- **Cost Effectiveness:** Excluding the foot plate, which was pre-fabricated for use during SAL I testing, the entire prototype cost $53.89 in materials (See Table 3.2.1). Total labor time required for fabrication was approximately 4 man-hours. With repeated construction, the assembly time would probably fall significantly. Switching from 6061-T4 aluminum to pine for the base plate was a tremendous cost-reducing decision, as an equivalent amount of aluminum would have cost almost $300, over 100 times as much as the wood. Furthermore, the time required to create the base plate would have been much higher due to the relative difficulty of machining aluminum compared to pine.
### Table 3.3.1. Bill of materials for SAL II

<table>
<thead>
<tr>
<th>Part</th>
<th>Cost per Unit</th>
<th>No. of Units</th>
<th>Total Cost</th>
</tr>
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<tbody>
<tr>
<td>7/32&quot; Polyurethane Cord</td>
<td>$0.36</td>
<td>5'</td>
<td>$1.80</td>
</tr>
<tr>
<td>7/32&quot; Adjustable Hooks</td>
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<td>10</td>
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</tr>
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<td>1/2&quot; x 1&quot; White Delrin</td>
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<td>9&quot;</td>
<td>$2.25</td>
</tr>
<tr>
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<td>1</td>
<td>$1.29</td>
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<tr>
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<td>$0.14</td>
<td>2</td>
<td>$0.28</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$53.89</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Compactness:** When disassembled, the entire prototype is less than 1 ft³ in volume and can readily be transported in a small bag. Its small size and light weight make it exceptionally mobile. By removing the arches and pulley system, there are no parts over the tibia cluster that may obscure the cameras’ view of the markers except for the small turnbuckle. The same holds true for the much smaller and lighter foot plate from SAL I. Preliminary conceptual testing indicated that this configuration presented no problems with respect to marker visibility.

- **Ease of Use:** Assembly, set-up, and operation of SAL II requires can be performed completely by hand. Set-up consists of attaching the correct length of elastic cord to the
turnbuckle and base plate, strapping the subject’s shank and foot to the device, fine-
tuning the tensile force using the turnbuckle, and adjusting the front eye bolts so that the
wagging cord is aligned with the medial and lateral malleoli. During testing, the only
action that the operator must take is to alternately pull the two handles to induce
inversion/eversion. The only responsibility of the subject is to remain still during the
trials. Changing the height of the guide holes consists simply of loosening or tightening
two bolts. To clean the device between subjects, the vinyl covers can be wiped down or
removed. As mentioned earlier, SAL II does not obstruct the motion cameras’ view of
the marker clusters, removing the need to reposition them for each trial.

- **Durability:** As illustrated in the bill of materials, the prototype is composited of only 17
constituent parts. Many of them are permanently attached to others, further simplifying
the design. The only moving parts are the turnbuckle, the wagging cords, and the
adjustable guide holes. The biggest risk comes from dropping the device; a high enough
fall could shatter the pine base plate. However, since it will only be about 20” off the
ground during testing, there is little risk of damage. All components are readily available
if repair or replacement is needed.

- **Practicality:** By conforming to the parameters established during SAL I testing (See
“Accuracy” section above), gait laboratories will not need access to an MRI to locate the
subtalar axis with our device. The only external equipment requirement to use SAL II is
a digital motion analysis system and software to process the data. Complete set-up takes
less than ten minutes, including making adjustments based on the anatomy of the subject.
Steps were taken to give the device a professional appearance, such as applying a black
lacquer finish and covering the foam on the foot and base plates with a vinyl cover. Also,
the ease with which the removable vinyl can be sanitized should keep the device looking and feeling clean after each use.

3.4 Testing Procedures

Before the subject arrives, the EVaRT motion analysis software must be initiated and the operator’s template loaded. Once the cameras are calibrated, SAL II can be set up on the force plates in the center of the laboratory. After recording the subject’s height, weight, transmalleolar width, medial malleolus height, and lateral malleolus height, the tibia and calcaneus marker clusters can be attached. Another reflective marker should be placed on the shank below the plastic base. The subject sits down in a chair next to the device and one of their legs is strapped into the base plate with closest end 14 cm from the bottom of the heel. Next, the foot plate is strapped on and a length of polyurethane cord attached to the turnbuckle based on the subject’s shank length. Once the elastic cord is hooked onto the rear eye bolts of the base plate, the turnbuckle can be fine-tuned to ensure that tension is exactly 5 lbs. Next, the height of the front eye bolts are adjusted while the wagging cords are taut so that the cords are aligned with the malleoli.

To establish a baseline marker pattern for the software, a static test must first be taken. Once completed, the full SAL testing can begin. The computer should be set to run a 10 second trial while the operator gently and alternately pulls the handles until stiff resistance from the subject’s ankle is felt. Care should be taken to ensure that the subject is adequately comfortable at all times. After repeating this twice more, the straps can be undone, and the subject can stand. NOTE: If at any time the marker clusters shift, fall off, or are hit, all previous data must be considered invalid and retaken.
The next step is to identify important anatomical landmarks for the computer. While the subject is standing in view of all cameras, the operator must use a 42.2 cm rod fitted with reflective markers to point to a number of locations and take a one second static recording. The anatomical landmarks that must be identified are the ankle joint center, lateral malleoli, medial malleoli, femur epicondyles, ASIS, and PSIS.

For the walking trials, the force plate must be turned on and must be reset after each run. The subject starts by standing approximately 20’ behind the force plate, and the operator sets the software to record for 5 seconds. When the cameras begin recording, the subject must walk forward 30’, crossing the force plate. For the test to be valid, at least one foot needs to make complete contact with the force plate, and the subject’s walking pattern cannot have been altered for any reason, including aiming for the sensor. The test must be run five times: three times at the subject’s usual walking pace, once at 80% of the normal pace, and once at 120% of the normal pace. Upon completion of these walking trials, the marker clusters can be removed and the tests are concluded. The vinyl covers for the foam on the foot plate and base plate should be properly sanitized. To analyze the data collected by the motion tracking software, it must be post-processed. In this case, the data file must be run through a number of MATLAB files before it is transformed into meaningful results.
CHAPTER FOUR

PRELIMINARY TESTING

4.1 Purpose of Testing

The application for testing on human subjects located in Appendix C was submitted to the Penn State Institutional Review Board (IRB) once prototype fabrication was complete. While waiting for approval, a number of tests had to be run to confirm that the device met the standards set forth in the design specifications and the project guidelines. Two main criteria were examined during the pilot runs:

- Can all the reflective markers be located by the motion analysis system during testing? (Accuracy, Repeatability, Compactness, Practicality)
- How much does the elastic dorsiflexion force vary while wagging the foot? (Accuracy, Repeatability)

Figure 4.1.1 Computer running the motion analysis software during testing
4.2 Tracking Marker Visibility

While some of the markers will not be seen by all cameras in every frame, it is essential that at least two cameras see each marker at all times. Otherwise, the software cannot determine the location of the marker in 3D space. For the purposes of this preliminary test, eight markers were used – four on the tibia and four on the calcaneus. The markers were arranged in the clusters illustrated earlier and attached to the subject. For the test to be considered successful, all eight markers had to be visible in the resting position, as well as in cases of extreme inversion and eversion. If these three conditions were met, it would be evident that the device would not obstruct the cameras’ views of the reflective markers during full-scale testing. The subject’s shank and foot were strapped in the device, and 5 lbs of elastic force were applied to the forefoot via the polyurethane cord. A static trial was taken with the subject’s foot in a neutral position to establish a baseline. All of the markers were clearly visible in this frame (see Figure 4.2.1.).
Next, the wagging cords were pulled so that the foot was inverted until the operator met stiff resistance. While the subject’s foot was held in this position, another static trial was taken. Again, all of the markers could be seen by at least two cameras (see Figure 4.2.2.).

Finally, the foot was pulled into extreme eversion and the entire process was repeated (see Figure...
4.2.3.

As illustrated by the above figures, all eight markers were visible in all three frames. Even when the foot was placed on the most extreme ends of its rotation about the subtalar joint axis, the device was designed and fabricated in a manner that did not obscure marker visibility. This feature alone indicates that SAL II is a significant improvement over the original device.

4.3 Analyzing the Elastic Force

In order to ensure that all movement recorded by the motion tracking system is purely subtalar, it is critical that the talocrural joint is immobilized. Since the primary source of this immobilization is the applied dorsiflexion load, the elastic force exerted by the polyurethane cord on the foot plate should vary as little as possible while the operator wags the subject’s foot. Testing this design aspect is not as straightforward as tracking marker visibility however. The best method for measuring the elastic force is to remove the marker clusters for the subject’s tibia and calcaneus and attach two markers onto the polyurethane cord directly over the 4” gauge lines. By tracking the distance between the markers at a resting position, extreme inversion, and extreme eversion, the value of the elastic force in each position can be determined. First, the
spring constant of the polyurethane cord had to be calculated. Applying 5 lbs of tensile force to the cord yielded a displacement of $\frac{5}{16}$". This translates into a spring constant of about 16 lbs/in. The next step was to record the distance between the markers while the foot was at rest with 5 lbs of tensile force applied, which was determined to be 3.95" (see Figure 4.3.1.). This indicates that the distance between the markers with no tension applied is 3.63".

![Figure 4.3.1. Elastic strain at the resting position](image1)

Next, the foot was pulled to the maximum possible inversion. The distance between the markers was recorded at 3.88". That means the dorsiflexion force was around 4 lbs, 20% lower than the initial force (see figure 4.3.2.).

![Figure 4.3.2. Elastic strain at maximum inversion](image2)
The same technique was applied while the foot was held at its point of maximum eversion. A distance of 4.01” was recorded between the two reflective markers, which indicates that the tensile force in the elastic cord was approximately 6 lbs, 20% higher than the initial force.

**Figure 4.3.3.** Elastic strain at maximum eversion

Based on the neutral position of the foot, the elastic force fluctuates by ±20%, and the change in length between inversion and eversion is about $\frac{1}{8}$”. Because there is currently no benchmark against which to compare these values, there is no way to ensure they are within acceptable parameters. This is due to the fact that the variation in dorsiflexion force during testing for SAL I was not recorded. While the data cannot be used to verify the accuracy of results obtained using SAL II, it can be used as a standard for further testing with the device. One way to reduce the variability in elastic force is to replace the $\frac{7}{32}$” polyurethane cord with one of a larger diameter.
CHAPTER FIVE
DISCUSSION

5.1 Project Summary

Only in-depth testing will confirm if SAL II ultimately fulfills all of its design objectives, but the results so far have been encouraging. SAL II avoids the problems associated with the optimization approach van den Bogert et al. (1994). As previously discussed, the foot does not possess a sufficient range of motion for the software to simultaneously derive the locations of the subtalar axis and the talocrural axis. The device takes advantage of the findings of Lewis et al. (2007) with regard to the subtalar axis locator method, namely that the talocrural joint can be largely immobilized by inducing dorsiflexion in the foot. If a side-to-side force is then applied to the foot, the resultant motion is almost entirely subtalar, removing the largest obstacle to the optimization approach. Since the validity of this approach has been largely confirmed in numerous subjects, one of the primary challenges to locating the subtalar joint has been eliminated.

The device also builds upon the lessons learned from SAL I to avoid the pitfalls the original device encountered. SAL I contained a large number of parts, making it somewhat challenging to assemble and operate properly. The rig necessary to apply the dorsiflexion force and wag the foot obstructed the cameras’ views of the marker cluster, meaning the cameras had to be moved before and after every test. The size, weight, and complexity of the rig also severely hampered its mobility. By compacting the design, the motion analysis cameras can easily track the reflective markers. Inducing dorsiflexion with an elastic mechanism instead of a hanging weight allows the operator to manually determine the tensile load, and the addition of an outrigger to the foot plate increases the moment applied to the foot. Attaching the marker
clusters to an Aquaplast base appears to have countered the effect of skin movement upon heel strike, as they are connected to a solid base above the fatty tissue under the calcaneus. SAL II is also significantly lighter, contains less parts, and is easier to operate, while utilizing the same principles that successfully produced pure subtalar motion in the original. As a result, it can be used in gait laboratories without requiring an MRI.

Preliminary testing indicates that SAL II sufficiently meets its initial design specifications, indicating that the project has successfully achieved its goals. The testing protocol has been submitted to the Penn State Institutional Review Board for approval, and a number of potential subjects have been identified. After pilot runs have been performed to ensure that the actual trials run smoothly, data collection can begin.

5.2 Potential Applications

As the first practical device for clinically locating the subtalar joint axis, the potential applications for SAL II are impressive. Since the principles on which it operates have already been validated as accurate and consistent in vivo, the next step is to begin full-scale testing of the device. Once the repeatability and general validity of the data collected is confirmed, the device, or various permutations of it, can be distributed to gait laboratories for use in locating the subtalar joint axis in patients suffering from gait disorders such as cerebral palsy, planovalgus, and cavovarus. The information obtained from SAL II tests, specifically the location of the subtalar axis and the moment from the ground reaction force, can be utilized by gait specialists to determine the best options for treatment. This data can also be extremely helpful in planning ankle surgery by giving medical personnel detailed information on each patients ankle mechanics. Subtalar axis moments and locations are also indispensable in treating ankle injuries.
as they provide valuable insight into the forces and stress present in the ankle joints.

5.3 Limitations and Improvements

Despite the effectiveness demonstrated by SAL II, several issues remain. Until multiple subjects are tested in the device, repeatability cannot be confirmed. Even then, the absolute accuracy of the results cannot be verified at this time. If use of this or an equivalent device is to become widespread in gait laboratories, verification must occur. Since the device contains metal in the handles and on the base plate in the form of eye bolts, it cannot be tested in the MRI for independent verification. Thus, it would be worthwhile to replace these metallic components with similar parts of a material such as plastic.

As with any mechanism operated by a human, a level of inconsistency is to be expected during testing. This could result from deviations in the wagging force applied to the foot plate, the angle at which the operator pulls the handles, the speed at which the handles are pulled, and the range of motion the foot travels through with each cycle. While SAL II was designed to reduce the effect these variables would have on the results, the cumulative impact of these variations cannot be discounted. Any future modifications to the design should take this into account. Ideally, the entire operation of the device during each trial could be automated, thereby removing the influence of a human operator on data collection. This does present substantial challenges in its own right however. The mechanism would most likely be incredibly complex and quite expensive, not to mention extremely difficult to fabricate. If these obstacles could be overcome, the potential benefits of automation certainly make this option worth considering.

Finally, the basic idea behind SAL, a combination of joint immobilization and induced movement, could be applied to other joints. Even though the situation in the ankle is rather
unique, other parts of the body with multiple joints in close proximity can be just as difficult to study, such as the foot and hand. Creating a device similar to SAL II that is applicable to these regions would give researchers a more complete understanding of human anatomy and kinematics.

5.4 Conclusion

By using the information gathered by other researchers and the lessons of the original Subtalar Axis Locator, we were able to determine the design elements required to create an accurate and practical device. Now that the underlying principles have been validated and a prototype has been constructed, we have the knowledge and the means to begin testing on subjects. It is hoped that SAL II will give researchers the ability to effectively and reliably locate the subtalar joint axis.


APPENDIX A
Testing Protocol

Prior to Subject Arriving
1. Log on to MA lab computer
2. Turn on Eagle motion analysis cameras
3. Turn on the EVaRT software
4. Load template file for SAL II testing
5. Perform static calibration of cameras
6. Perform dynamic calibration of cameras
7. Attach marker clusters to operator to ensure the software can ID them
8. Set up chair on force plate
9. Place SAL on force plate near chair
10. Ensure Informed Consent Form (ICF) is prepared

After Subject Arrives
Introduction
1. Ask screening questions
2. Describe basic premise and procedures of test
3. Answer any questions
4. Explain ICF and have subject sign
5. File ICF
6. Measure and record the following values for the subject:
   a. Height
   b. Weight
   c. Foot length
   d. Foot width
   e. Transmalleolar width
   f. Medial malleolus height
   g. Lateral malleolus height

SAL Test
7. Have subject remove their shoes and socks
8. Attach marker clusters to the following:
   a. Tibia
   b. Calcaneus
9. Attach one marker to the second metatarsal
10. Attach one marker below the tibia cluster
11. Have subject sit down and place leg in device
12. Securely strap foot to foot plate tightly
13. Securely strap leg to base plate tightly such that the end is 14 cm from the foot plate
14. Fine-tune turnbuckle until gauge lines on elastic cord are exactly 4” apart.
15. Measure gauging marks on cords to determine tensile load on foot
16. Determine axis which runs through center of subject’s malleoli
17. Adjust height of guide bolts on base plate so that wagging cords pass through this axis
18. Run cameras and ensure all markers are visible on monitor
19. Ensure all markers are correctly labeled in the program
20. Record a one second static trial with the foot in the neutral position
21. Run cameras and record while wagging foot at moderate speed for 10 seconds
22. Repeat Step 21 two more times, saving the data after each run (Save often!)
23. Remove straps from foot and shank
24. Have subject stand up
25. Put SAL aside
26. Remove chair and stool
   NOTE: If at any time the marker clusters shift, fall off, or are struck, all previous data must be considered invalid and retaken.

Standing Test
27. Have subject stand on force plate
28. Ensure all markers are visible on monitor
29. Ensure all markers are correctly labeled in the program
30. Using the 42.2 cm rod, mark the locations of the following:
   a. Ankle joint center
   b. Lateral malleoli
   c. Medial malleoli
   d. Femur epicondyles
   e. ASIS
   f. PSIS
31. Run the cameras and record a one second trial for each

Walking Test
32. Turn on force plate
33. Zero force plate
34. Have subject stand 20 feet behind the force plate
35. Run cameras and record a 5 second trial
36. Have subject walk 30 feet forward across force plate at normal walking pace
37. Ensure at least one foot makes complete contact with the plate
38. Ensure subject walks normally and in a straight line
39. Repeat Steps 34-38 twice more at normal pace
40. Repeat Steps 34-38 once with subject walking at 80% of normal pace
41. Repeat Steps 34-38 once with subject walking at 120% of normal pace

Conclusion
42. Remove marker clusters from subject
43. Debrief as necessary
44. Thank subject for their time

After Subject Leaves
1. Wipe down vinyl covers on SAL
2. Safely store SAL
3. Ensure all data are saved in proper folder
4. Turn off EVaRT software
5. Log off computer
APPENDIX B
Informed Consent Form

INFORMED CONSENT FORM FOR BIOMEDICAL RESEARCH
The Pennsylvania State University

Title of Project: Investigation of the Location of the Subtalar Joint Axis and Mechanics of the Subtalar Joint During Walking

(i) Principal Investigator: Stephen J. Piazza
(ii) Address: Biomechanics Lab
(iii) 29 Recreation Building
     Penn State University
     Phone: 814-865-3413
     Email: steve-piazza@psu.edu
(iv) Other Investigators: Gregory Witt

This is to certify that you, ______________________________, have been given the following information with respect to your participation as a volunteer in a program of investigation under the supervision of Dr. Stephen Piazza.

1. Purpose of the study:

   You are being asked to participate in a study being conducted in The Biomechanics Lab, which is a laboratory specializing in studies of posture and walking. The purpose of this study is to locate a joint in your foot called the subtalar joint and then measure how the ground applies force to your foot relative to this joint.

2. Procedures to be followed:

   Twenty-five healthy volunteers between the ages of 18-40 years of age will participate in this study. You and the other volunteers will have measurements of both your height and weight taken. Several round markers about the size of a marble attached to hard plastic shells will be applied with adhesive tape to the skin above your shinbone and heel-bone. The locations of these markers will be followed using special video cameras as your foot is rocked from side to side by pulling on strings attached to a small plate strapped to the bottom of your foot. These rocking motions will be applied to your foot three times.

   You will be asked to stand on a wooden platform for a few minutes while a metal rod with markers attached to it is used to point at several locations of interest on your legs.

   You will then be asked to stand on a force platform, which is a steel plate built into the floor, while barefoot for five seconds. You will perform five of these standing trials while cameras record the locations of the markers on your legs.

   You will then be asked to walk approximately thirty feet, starting about twenty feet behind the force plate, and do this five times while cameras record the locations of the markers on your legs. You may have to repeat these trials to ensure that one of your feet comes in contact with the force plate.
3. **Discomforts and risks:**

There are only minimal risks associated with this study. There are no known risks associated with the wearing of markers on the skin or with recording of your movements using the cameras. There is a slight risk that you may develop slight discomfort while your foot is rocked back and forth during the first part of the testing. If you should experience any discomfort during these trials, please inform the researcher and you will be given an opportunity to rest or discontinue the experiment. There is also a slight risk that you may lose your balance while standing on the wooden platform during the standing trials or while walking during the walking trials. The experimenter will assist you when you getting on and off of the platform and a stool will be placed within reach for you to steady yourself if necessary. All of these risks are extremely small, however, considering your age and health.

If you feel that you cannot or should not perform any of these tasks, you should not participate in this study.

4. a. **Benefits to me:**

There is no direct benefit to you for participating in this research.

b. **Potential benefits to society:**

This study will contribute to our understanding of foot mechanics and movement problems.

5. **Alternative procedures which could be utilized:**

The procedures described above were designed to give information about the location of a joint within the foot and ankle; although alternative methods exist for locating this joint, the approach that we are using is the least invasive and carries the lowest possible risk. You may choose not to participate in this research.

6. **Time duration of the procedures and study:**

Each of your two visits to the Biomechanics Lab will last approximately two hours maximum.

7. **Statement of confidentiality:**

All data collected in this experiment will remain confidential. The data will be located inside a locked file cabinet and on password-protected computers in the Biomechanics Laboratory and will remain under the supervision of Dr. Stephen Piazza. Only the investigator and his assistant will have access to the data.

Any identifiers, such as your name or personal information, will be kept separate from your actual data.
All records associated with your participation in the study will be subject to the usual confidentiality standards applicable to medical records, and in the event of any publication of this research, no personally identifiable information will be disclosed.

The Office of Human Research Protections in the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration (FDA), the Office for Research Protections at Penn State and the Biomedical Institutional Review Board may review records related to this project.

8. **Right to ask questions:**

   You have been given an opportunity to ask any questions you may have, and all such questions or inquiries have been answered to your satisfaction. You understand that if you have additional questions or concerns at any time, you may contact the investigators by calling Dr. Stephen Piazza at the Biomechanics Laboratory at (814) 865-3413.

   **If you have questions about your rights as a research participant, or you have concerns or general questions about the research, contact Penn State University’s Office for Research Protections at (814) 865-1775. You may also call this number if you cannot reach the research team or wish to talk to someone else.**

9. **Compensation:**

   You will not be compensated for your participation in this study.

10. **Injury Clause:**

    Medical care is available in the event of injury resulting from research but that neither financial compensation nor free medical treatment is provided. You are not waiving any rights that you may have against the University for injury resulting from negligence of the University or investigators.

11. **Voluntary participation:**

    Your decision to be in this research is voluntary. You can stop at any time. You do not have to answer any questions you do not want to answer. Refusal to take part in or withdrawing from this study will involve no penalty or loss of benefits you would receive otherwise.
This is to certify that I consent to and give permission for my participation as a volunteer in this program of investigation. I understand that I will receive a signed copy of this consent form. I have read this form, and understand the content of this consent form.

______________________________________________________
Participant Signature (must be 18 yrs or older)    Date

I, the undersigned, have defined and explained the studies involved to the above volunteer.

______________________________________________________
Investigator                                             Date
APPENDIX C
IRB Application

Institutional Review Board (IRB)
The Office for Research Protections
205 The 330 Building
University Park, PA 16802 | 814-865-1775 | ORProtections@psu.edu

Submitted by: Stephen Piazza
Date Submitted: March 10, 2010 05:01:47 PM
IRB#: 33546
PI: Stephen Piazza

Study Title

1>Study Title
Investigation of the Location of the Subtalar Joint Axis and Mechanics of the Subtalar Joint During Walking

2>Type of eSubmission
New

Home Department for Study

3>Department where research is being conducted or if a student study, the department overseeing this research study.
Kinesiology

Review Level

4>What level of review do you expect this research to need? NOTE: The final determination of the review level will be determined by the IRB Administrative Office.
Choose from one of the following:
- Expedited

5>Expedited Research Categories: Choose one or more of the following categories that apply to your research. You may choose more than one category but your research must meet one of the following categories to be considered for expedited review.

[X] Category 4 – Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
(Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

- Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant’s privacy.
  - Weighing or testing sensory acuity;
  - Magnetic resonance imaging;

- Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

**Basic Information: Association with Other Studies**

6> Is this research study associated with other IRB-approved studies, e.g., this study is an extension study of an ongoing study or this study will use data or tissue from another ongoing study?  
No

7> Where will this research study take place? Choose all that apply.  
[X] University Park

8> Specify the building, and room at University Park where this research study will take place. If not yet known, indicate as such.  
Biomechanics Laboratory, 29 Recreation Building, University Park

9> Does this research study involve any of the following centers?  
[X] None of these centers are involved in this study

10> Describe the facilities available to conduct the research for the duration of the study.  
All research will be conducted in the Biomechanics Laboratory in 29 Recreation Building.

In this Laboratory, there is an 8-camera video motion analysis system (Motion Analysis Corp.; Santa Rosa, CA). This system is used to track the locations of small markers affixed to the skin of test subjects. While video is the technology used, no images of subjects’ faces or bodies are recorded, only the locations of reflective markers.

In addition, there is a 30 m walkway fitted with two optoelectronic emitter/sensor pairs that can be used to determine the average speed of a subject walking on the walkway.
In the middle of the walkway are two force platforms (Kistler; Amherst, NY) that are steel plates rigidly mounted flush to the floor and instrumented with strain gauges so that the platforms may be used to record the force applied by the ground to the subjects' feet and the location of the point of application of that force.

11> Is this study being conducted as part of a class requirement? For additional information regarding the difference between a research study and a class requirement, see IRB Guideline IV, “Distinguishing Class-Related Pedagogical (Instructional) Assignments/Projects and Research Projects” located at http://www.research.psu.edu/orp/areas/humans/policies/guide4.asp.

No

Personnel
12> Personnel List

<table>
<thead>
<tr>
<th>PSU User ID</th>
<th>Name</th>
<th>Department Affiliation</th>
<th>Role in this study</th>
</tr>
</thead>
<tbody>
<tr>
<td>sjp12</td>
<td>Piazza, Stephen</td>
<td>Kinesiology</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>gsw5009</td>
<td>Witt, Gregory</td>
<td>Mechanical and Nuclear Engineering</td>
<td>Co-Investigator</td>
</tr>
</tbody>
</table>

• Role in this study  Principal Investigator
  First Name  Stephen  Middle Name  Last Name  Piazza  Credentials  PhD
  PSU User ID  sjp12  Email Address  steve-piazza@psu.edu  PSU Employment Status  Employed
  [X] Person should receive emails about this application

Mailing Address  29 Recreation Building
Address (Line 2)
Mail Code  City  University Park  State  Pennsylvania  ZIP Code  16802
Phone Number  814 865 3413  Fax number  Pager Number  Alternate Telephone
Department Affiliation  Kinesiology
Identify the procedures/techniques this person will perform (i.e. recruit participants, consent participants, administer the study): Stephen J. Piazza, Ph. D., is the PI and responsible for all aspects of the study. He will train graduate and undergraduate students in techniques of data collection. He will oversee recruitment, screening, and data collection. He will keep subject identifiers.

Describe the person's level of experience in performing the procedures/techniques described above: Stephen J. Piazza, Ph.D., is an Associate Professor of Kinesiology, Mechanical Engineering and Orthopedics &Rehabilitation. He has conducted biomechanical research in lower extremity joint mechanics for 17 years. He is familiar with all the equipment used for this research.

• Role in this study  Co-Investigator
  First Name  Gregory  Middle Name  Last Name  Witt  Credentials
  PSU User ID  gsw5009  Email Address  gsw5009@psu.edu  PSU Employment Status  Not Employed or Student
  [X] Person should receive emails about this application

Mailing Address  119 S. Burrowes St, Apt. 303
Address (Line 2)
Mail Code  City  State College  State  Pennsylvania  ZIP Code  16801
Phone Number  724-396-1775  Fax number  Pager Number  Alternate Telephone
Department Affiliation  Mechanical and Nuclear Engineering
Identify the procedures/techniques this person will perform (i.e. recruit participants, consent participants, administer the study): Gregory Witt will be responsible for collecting motion and ground reaction force data for each of the participants in the study and for analyzing that data.

Describe the person's level of experience in performing the procedures/techniques described above:
Gregory Witt is an undergraduate student in mechanical engineering who will be completing his honors thesis under the supervision of Dr. Piazza.

Funding Source

13> Is this research study funded? Funding could include the sponsor providing drugs or devices for the study.
No

NOTE: If the study is funded or funding is pending, submit a copy of the grant proposal or statement of work for review.

14> Does this research study involve prospectively providing treatment or therapy to participants?
No

Conflict of Interest

15> Do any of the investigator(s), key personnel, and/or their spouses or dependent children have a financial or business interest(s) as defined by PSU Policy RA20, “Individual Conflict of Interest,” associated with this research? NOTE: There is no de minimus in human participant research studies (i.e., all amount must be reported).
No

Purpose

16> Provide a description of the research that includes (1) the background, (2) purpose, and (3) a description of how the research will be conducted [methodology: step-by-step process of what participants will be asked to do]. DO NOT COPY AND PASTE THE METHODOLOGY SECTION FROM THE GRANT.

• Background/Rationale: Briefly provide the background information and rationale for performing the research study.
The subtalar joint is one of two joints in ankle and permits the foot to move from side to side. This movement, termed 'inversion-eversion', is critical for walking on uneven surfaces, and muscles that cross this joint must apply forces that enable the arch structure of the foot to maintained during movement. Subtalar joint motion occurs between the talus and calcaneus bones, but only the calcaneus (heel bone) may be tracked using markers placed on the skin. Because the talus cannot be tracked using skin markers, location of the subtalar joint axis using video-based motion analysis has not been successfully accomplished. Without knowledge of the subtalar joint axis, it is not possible to assess the actions of muscles that cross the joint and gain a complete understanding of subtalar joint mechanics.

• Purpose: Summarize the study's research question(s), aims or objectives [hypothesis].
The purpose of this study is to apply a novel and non-invasive technique for location of the
subtalar joint from an applied ankle motion in healthy young adults, and then to use this knowledge of the subjects’ subtalar joint locations to characterize their subject-specific subtalar joint loadings (i.e., how their muscles support loads across the subtalar joint) during walking. It is our hypothesis that the orientation of the subtalar joint axis will vary considerably across subjects and that this variation will substantially affect the measured muscular subtalar joint moments.

**Research Procedures involving Participants: Summarize the study’s procedures by providing a description of how the research will be conducted [i.e., methodology - a step-by-step process of what participants will be asked to do]. Numbering each step is highly recommended. DO NOT COPY & PASTE GRANT APPLICATION IN THIS RESPONSE.**

1. Participants will have measurements of both their height and weight taken, as well as the values of their foot length, foot width, transmalleolar width, medial malleolus height, and lateral malleolus height.

2. An non-invasive technique for the location of the subtalar axis will be applied. This technique involves the placement of 9 mm diameter reflective markers attached to hard plastic, using double-sided tape to adhere the markers to the skin. The clusters of 4 markers will be placed on the skin overlying the calcaneus, tibia, and femur. One marker will be placed on the head of the second metatarsal. The motions of these markers will be tracked using a video-based motion analysis system while the foot is rocked from side to side by pulling on two cables attached to a platform affixed to the foot using velcro straps. While this rocking motion is applied by the experimenter, the foot will be held in a slightly dorsiflexed position by a third cable that applies a constant load to the forefoot by means of an elastic band (approximately 3 lbs). Each subtalar joint motion trial will last approximately 10 seconds and three such trials will be performed.

3. Subjects will be asked to stand in view of the motion system cameras. The location of the ankle joint center, the lateral and medial malleoli, femur epicondyles, ASIS, and PSIS will be marked using a pointer made of a 42.2 cm rod fitted with three reflective markers. These locations will be recorded using the video-based motion analysis system.

4. Subjects will be asked to walk approximately thirty feet, starting about twenty feet behind the force plate. The participants will then walk across the force platform, making sure that one foot makes a complete contact with the platform. Care will be taken that the participants do not alter their walking patterns to target the platform with their feet. Five walking trials each will be recorded at three different speeds: the subject's preferred comfortable speed, then at a slow speed equal to 80% of the preferred speed and a fast speed equal to 120 of the preferred speed. Each trial will last five seconds.

5. Subjects will repeat the steps outlined in #2 - #4 above in order to assess repeatability of the measurement.

17>How long will participants be involved in this research study? Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

Participants will be asked to participate in one session of approximately two hours.

18>Briefly explain how you will have sufficient time to conduct and complete the research within the research period.

Setup and calibration of the motion analysis system will occur before the participants arrive to
save time. Once they arrive, we will go over the experimental procedures, give them an opportunity to ask questions, and have them sign informed consent forms. There should be more than enough time to carry out the procedures planned in less than 2 hours.

19> List criteria for inclusion of participants:
Healthy males and females age 18-40 years of age will participate in this study.

20> List criteria for exclusion of participants:
Subjects will be excluded from the study if they have a history of joint pain, problems with walking, or a recent lower extremity injury (such as a fracture or sprain) diagnosed in the last year.

Multi-Center Study

21> Is this a multi-center study (i.e., study will be conducted at other institutions each with its own principal investigator)?
No

Participant Numbers

22> Maximum number of participants/samples/records to be enrolled by PSU investigators. NOTE: Enter one number – not a range. This number should include the estimated number that will give consent but not qualify after screening or who will otherwise withdraw and not qualify for inclusion in the final data analysis. This number should be based on a statistical analysis, unless this is a pilot study, and must match the number of participants listed in the consent form.
25

23> Was a statistical/power analysis conducted to determine the adequate sample size?
Yes

Age Range of Participants

24> Age range (check all that apply):

[X] 18 - 25 years
[X] 26 - 40 years

Participant Information: Participant Categories

25> Choose all categories of participants who will be involved in this research study.

[X] Healthy volunteers
[X] Women of reproductive potential at the time of the research
26> You have indicated women of reproductive potential will be used as research participants in this study. Choose one of the following:

[X] The research poses no added risk associated with pregnancy and/or lactation

27> Will Penn State students be used as study participants in this research study?
   Yes

28> Will students be recruited from a Subject Pool?
   No

29> Will participants be currently enrolled in a course/class of any personnel listed on this application?
   No

30> Will participants be employees of any personnel listed on this application?
   Yes

31> Describe the steps taken to avoid coercion and undue influence.
   This is a low risk study and it will be made clear to students or staff that they are free to participate or not.

32> Does this research exclude any particular gender, ethnic or racial group, and/or a person based on sexual identity?
   No

33> Could some or all participants be vulnerable to coercion or undue influence due to special circumstances (do not include children, decisionally impaired, and prisoners in your answer)?
   No

**Recruitment**

34> Describe the specific steps to be used to identify and/or contact prospective participants, records and/or tissue. If applicable, also describe how you have access to lists or records of potential participants.
   Recruitment will take place within the Biomechanics Laboratory and the Department of Kinesiology, and by word of mouth. All potential participant recruits will be made aware that their participation would be voluntary.
35> Will recruitment materials be used to identify potential participants?  
No

36> Who will approach and/or respond to potential participants during recruitment?  
Dr. Piazza or Gregory Witt will mention the study to students and staff.

37> Explain how your recruitment methods and intended population will allow you access to the required number of participants needed for this study within the proposed recruitment period. 
There are many graduate and undergraduate students and staff within the Biomechanics Laboratory and Department of Kinesiology, so there will be more than enough possible participants. We have not had problems in the past when we have recruited for similar studies in this manner.

38> Before potential participants sign a consent document, are there any screening/eligibility questions that you need to directly ask the individual to determine whether he/she qualifies for enrollment in the study?  
[X] Yes

39> During screening/eligibility questions, will identifiable information about these individuals be recorded?  
No

40> Will investigators access medical charts and/or hospital/clinic databases for recruitment purposes?  
No

41> Will physicians/clinicians provide identifiable, subject information (e.g., name, telephone number, address) to investigators for recruitment purposes?  
No

42> Will researchers who are not involved in the care of potential participants review and/or use protected health information before a consent/authorization form is signed in the course of screening/recruiting for this research study (e.g., reviewing medical records in order to determine eligibility)?  
No

**Participant Consent/Assent**

43> When and where will participants be approached to obtain informed consent/assent [include the timing of obtaining consent in the response]? If participants could be non-English
speaking, illiterate, or have other special circumstances, describe the steps taken to minimize the possibility of coercion and undue influence.
Prior to testing, subjects will be verbally instructed as to the intent and protocol of the study. The subjects will be given a copy of the informed consent form and asked to read and sign it before participation will be allowed.

44> Who will be responsible for obtaining informed consent/assent from participants?
Dr. Piazza or Gregory Witt will review the protocol with the participant and obtain informed consent.

45> Do the people responsible for obtaining consent/assent speak the same language as the participants?
Yes

46> What type of consent/assent will be obtained? Choose all that apply.
[X] Signed consent – participants will sign the consent form

47> If multiple groups of participants are being utilized (i.e., teachers, parents, children, people over the age of 18, others), who will and will not sign the consent/assent form? Specify for each group of participants.
Multiple groups will not be used. Every participant will sign the informed consent form.

48> Participants are to receive a copy of the informed consent form with the IRB approval stamp/statement on it. Describe how participants will receive a copy of the informed consent form to keep for their records. If this is not possible, explain why not.
Participants will be given a copy of the informed consent form before testing begins.

Cost to Participants: Compensation

49> Will the participant bear any costs which are not part of standard of care?
No

50> Will individuals be offered compensation for their participation?
No

Data Collection Measures/Instruments

51> Choose any of the following data collection measures/instruments that will be used in this study. Submit all instruments, measures, interview questions, and/or focus group topics/questions for review.
[X] Physical Testing Measures (e.g., height, weight, body mass index, blood pressure)
[X] Other
52> Describe the ‘other’ data collection measures/instruments that will be used in this study.
See attached document for photos and illustrations.

Video-based motion analysis system: This is an Eagle system (Motion Analysis Corp.) that consists of eight video cameras and computer hardware and software that track the locations of spherical reflective markers in three dimensions.

NOTE: While the Eagle motion analysis system (Motion Analysis Corp.) uses video technology, recordings made using this system are only of the movement of the reflective markers worn by the subject; the computer determines marker locations and discards the rest of the video image data. Actual images of the subject are not recorded and thus the subject's identity is not recorded on video in any way.

Force platform (Kistler Instr. Corp.): This is an instrumented steel plate mounted flush to the floor that is used to measure forces applied to the foot by the floor, as well as the point of application of that force.

NOTE: The force plates register force through readings of strain made using strain gauges affixed to the supports of the plate. As such, there are no electrical connections to the plate itself that will be walked upon by the subjects.

The subtalar axis will be located from foot and ankle motions using a specially-designed device called the "Subtalar Axis Locator" (SAL) that is used to apply motions to the foot in a specific way. Please refer to the drawings in the attached equipment document. SAL operates in this way: the participant sits in a chair with his leg extended in front of him. The lower leg is held in place with some Velcro straps and a plastic plate is strapped to the bottom of the foot. An elastic band pulls the toes of the subject toward the hip with a force of about 3 lbs. in order to lock one of the ankle complex joints. The subject's foot is rocked from side to side by the experimenter, who applies forces to the foot plate via cables. The subtalar joint axis is located from the relative motion of the markers on the shin and the heel. A similar device has been used successfully in the past in the Biomechanics Laboratory and none of the 25 subjects tested reported discomfort of any kind.

53> Will participants be assigned to groups?
No

Drugs/Medical Devices/Other Substances

54> Does this research study involve the use of any of the following? Choose all that apply.

[X] None of the above will be used in this research study

Biological Specimens
55> Will biological specimens (including blood, urine and other human-derived samples) be used in this study?
   No

**Recordings - Audio, Video, Digital, Photographs**

56> Will any type of recordings (audio, video or digital) or photographs be made during this study?
   No

**Computer/Internet**

57> Will any data collection for this study be conducted on the Internet or via email (e.g. on-line surveys, observations of chat rooms or blogs, on-line interviews surveys via email)?
   No

58> Will a commercial service provider (i.e., SurveyMonkey, Psych Data, Zoomerang) be used to collect data or for data storage?
   No

**Risks: Potential for and Seriousness of**

59> List the potential discomforts and risks (physical, psychological, legal, social, or financial) AND describe the likelihood or seriousness of the discomforts/risks. For studies presenting no more than minimal risk, loss of confidentiality may be the main risk associated with the research.
   There is minimal risk associated with this study. While subjects of similar age and health status have not experienced any discomfort while their feet were moved back and forth, there is a slight risk that a participant could experience discomfort due to the operator-applied foot motion in the apparatus.

   There is a slight risk that a participant could trip while walking. This is a serious risk but the likelihood of this occurrence is extremely low for these young healthy participants walking across a walkway that is free of obstacles.

   There is a risk that the participant would experience some slight discomfort when the reflective markers are removed from the skin and the tape is pulled off, but the level of this discomfort should be minor and has been well tolerated by participants in similar studies in our laboratory.

60> Describe how the discomforts and risks will be minimized and/or how participants will be protected against potential discomforts/risks throughout the study (e.g., label research data/specimens with code numbers, screening to assure appropriate selection of participants, identify standard of care procedures, sound research design, safety monitoring and reporting).
   The walkway will be free of obstacles. The length of time of the testing while the foot is in the SAL apparatus will be kept to a minimum, with a maximum of thirty minutes.
Does this research involve greater than minimal risk to the participants?
No

Benefits to Participants

What are the potential benefits to the individual participants of the proposed research study? (If none, state “None.”) NOTE: Compensation cannot be considered a benefit.
There are no direct benefits to subjects for the participation.

What are the potential benefits to others from the proposed research study?
There is a benefit of increasing our knowledge of foot mechanics, which should lead to improved treatments for foot disorders.

Deception

Does this study involve giving false or misleading information to participants or withholding information from them such that their “informed” consent is in question?
No

Confidentiality

Describe the provisions made to maintain confidentiality of the data, including medical records and specimens. Choose all that apply.

[X] Password protected computer files
[X] Locked file cabinets
[X] Locked offices
[X] Identification coding system.

Describe the provisions made to protect the privacy interests of the participants and minimize intrusion.
Data will be stored on a Kinesiology Department computer account designated for this experiment alone. This account will have the usual access safeguards; namely, an account number and password. The principal investigator and any research assistants will have access to the collected data.

Paper data will be separated in binders. Collection sheets without names and just subject numbers will be kept separately from data, such as consent forms, which have subject names. All paper data is kept in the Biomechanics laboratory, which has very limited access to the public, in a locked file cabinet. The file cabinet sits in a hallway and it is always kept locked. The only persons with keys to this cabinet are investigators with current projects that involve human subjects.

Will the study data and/or specimens contain identifiable information?
No
68> Who will have access to the study data and/or specimens?
   The principal investigator and any research assistants involved will have access to the collected data.

69> Will identifiers be disclosed to a sponsor or collaborators at another institution?
   No

70> Will a record or list containing a code (i.e., code number, pseudonym) and participants identity be used in this study?
   No

71> What will happen to the data when the research has been completed? Choose one.
   [X] Destroyed after a number of years

72> Specify the number of years after which stored confidential data will be destroyed.
   3

73> Is information being collected for this research that could have adverse consequences for participants or damage their financial standing, employability, insurability or reputation?
   No

74> Will a “Certificate of Confidentiality” be obtained from the federal government?
   No

HIPAA (Health Insurance Portability and Accountability Act)

75> Will participant’s protected health information (PHI) be obtained for this study?
   No

Radiation

76> Will any participants be asked to undergo a diagnostic radiation procedure while enrolled in this study?
   No

Physical Activity

77> Will participants be required to engage in or perform any form of physical activity?
   Yes
Describe the nature and extent of the physical activity.
The extent of the activity is minor for these young healthy subjects: participants will be required to walk approximately 30 feet several times.

Will any type of electrical equipment other than audio headphones be attached to the participants (e.g., EMG, EKG, special glasses)?
Submit a letter regarding the most recent safety check of the x-ray equipment being used with the supporting documents for this application.
No

Document Upload
ICFS
Document 1001 Received 03/10/2010 16:59:12 - Adult Form Informed Consent Form

INSTRUMENTS
Document 1001 Received 03/10/2010 16:59:53 - Illustrations/Photos of Instruments and Apparatus

RECRUITMENT
Document 1001 Received 03/10/2010 17:00:19 - Recruitment Material Recruiting script
Document 1002 Received 03/10/2010 17:00:40 - Eligibility Screening Screening questions
VITA
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EDUCATION
Bachelor of Science in Mechanical Engineering, Spring 2010
The Pennsylvania State University, University Park
The Schreyer Honors College

EXPERIENCE
Penn State Biomechanics Laboratory            Sept. 2009 - Present
Research Assistant
• Researched methods to locate the subtalar joint axis in the human ankle for thesis

Engineering Intern, Nuclear Services
• Worked on AP1000 Integrated Head Package and Krško Simplified Head Package

U.S. Army Aberdeen Test Center                     May – July 2009
Engineering Technician Intern
• Supported weapons testing for the U.S. Army
• Performed reliability and accuracy tests on numerous small arms weapons systems

Bettis Atomic Power Laboratory                      May – Aug. 2008
Mechanical Engineering Intern
• Performed manual and computer-assisted stress analysis calculations on mechanical components
• Designed piping systems and performed flow pattern analysis to support an upgrade to a multi-billion dollar testing platform
• Performed technical reviews of detailed testing specifications and instrumentation calibration procedures

Systems Engineer
• Integrated the various subsystems of the NittanySat project with special focus on the payload subsystem
• Developed electrical and mechanical interfaces for the science payload

Annual CanSat Competition hosted by AAS and AIAA     Dec. 2006 – June 2007
Designer and Tester
• Designed payload survival system
- Integrated the payload with the rocket and launch systems

**SKILLS**
AutoCAD, SolidWorks, Pro/ENGINEER, Visual Studio, Visio, ANSYS, AFT Fathom, C++, MATLAB, DataStudio, Mathcad

**AWARDS**
- Schreyer Honors Academic Excellence Scholarship
- PHEAA SciTech Scholarship
- National Merit Scholarship
- Dean’s List every semester

**ACTIVITIES**
- Participated in the Penn State IFC/Panhellenic Dance Marathon, the world’s largest student-run philanthropy, through Springfield THON to raise money for the treatment of juvenile cancer
- Worked in the Penn State Student Space Programs Laboratory developing and integrating components of various satellites
- Organized and volunteered at charity events with Circle K