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Finite Element Analysis of Transverse Medial Malleolar Fracture Fixation

Ruchi Chande
Virginia Commonwealth University

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FINITE ELEMENT ANALYSIS OF
TRANSVERSE MEDIAL MALLEOLAR FRACTURE FIXATION

A Thesis submitted in partial fulfillment of the requirements for the degree of Master of Science at Virginia Commonwealth University.

by

RUCHI DILIP CHANDE
Bachelor of Science, University of California, Berkeley, 2006
Master of Science, Virginia Commonwealth University, 2012

Director: Jennifer S. Wayne, Ph.D.
Professor, Biomedical Engineering

Virginia Commonwealth University
Richmond, Virginia
May 2012
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Abstract

FINITE ELEMENT ANALYSIS OF TRANSVERSE MEDIAL MALLEOLAR FRACTURE FIXATION

By Ruchi D. Chande, B.S.

A Thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Biomedical Engineering at Virginia Commonwealth University.

Virginia Commonwealth University, 2012

Major Director: Jennifer S. Wayne, Ph.D.
Professor, Biomedical Engineering and Orthopaedic Surgery
Director, Orthopaedic Research Laboratory

Injury to the medial malleolus, the distal end of the tibia and one of the bones comprising the ankle joint, can occur in various loading scenarios. Open reduction/internal fixation (ORIF) to reattach the malleolar fragment to the proximal tibia can be achieved via various devices, however small fragments are particularly challenging to treat. In this study, computational finite element analysis (FEA) was utilized to investigate the fixation of transverse medial malleolar fractures by two cancellous screws or by a new fixation device, the Medial Malleolar Sled™. Cadaveric testing assessed the performance of the two constructs in both tension and torsion. Following experimentation, the cadaveric study was modeled in SolidWorks and analyzed via FEA to validate the model against the experimental results. Overall, stress analysis was indicative of areas of relatively higher stress concentrations that correlated with failure locations in the experiment. Such results speak to the predictive nature of the tension and torsion models created in the study, and to the general utility of computational modeling for the study of biomechanical systems.
CHAPTER 1 Introduction

1.1 Ankle Anatomy

When observing the anatomy of the ankle, the joint’s importance to stable movement becomes clear. Together with articulations of the foot, the intact ankle sustains mobility by adapting to the various forces incurred during weight-bearing activities and restricting excessive motions via its mortise shape [1]. The ankle joint, also referred to as a mortise joint, is comprised of the talar dome and the distal ends of the tibia and fibula [2]. The tibial plafond, which is an articular face of the distal tibia, is oriented approximately perpendicular to the tibia’s long axis, while the most distal projection of the tibia—the medial malleolus—is concave and aligned with the medial portion of the talus [3]. Similar to the medial malleolus, the lateral malleolus is the most distal projection of the fibula. Together, the plafond and malleoli create the arch that articulates over the talar dome [2]. Just below the talus lies the calcaneus, and anterior to the talus lies the navicular. While the calcaneus and navicular are not considered part of the ankle joint [4], rather they belong to the hindfoot and midfoot, respectively [5], they are mentioned here due to their roles in the current study, which will be further elucidated when discussing the deltoid ligament and later in the experimental methodologies.
As this study focuses on the medial malleolus, a closer examination of the distal tibia was made, and two projections were noted. The more distal of the two is the anterior colliculus, while the second projection is known as the posterior colliculus. The two colliculi are separated by the intercollicular groove [3]. These three sites, along with the talus, navicular, and calcaneus, serve as attachment surfaces for medial ligaments [4–8].

Although numerous ligaments traverse the ankle joint, only the deltoid ligament will be highlighted here because of its significance to the study. The fan-shaped deltoid ligament
originates from the medial malleolus and inserts on three bones of the ankle complex and foot [4–9]. It is separated into the deep and superficial deltoid, each with further subdivisions: deep and superficial anterior tibiotalar, deep and superficial posterior tibiotalar, tibionavicular, and tibiocalcaneal. Per McGlamry, the deep deltoid is stronger than the superficial, and the deep posterior tibiotalar and the tibiocalcaneal are the strongest of each component, respectively [9].

It is important to note here that, although deep and superficial designations exist, each band was looked at as a whole during the course of the study, and so the deltoid was considered to have four “parts” rather than two, each with subdivisions. In line with this, the origin and insertion of the deltoid is described for the four individual bands. The anterior tibiotalar band originates from the anterior colliculus of the medial malleolus and inserts onto the talar neck, while the posterior tibiotalar originates from the posterior colliculus and intercollicular groove proximally and inserts onto the posteromedial portion of the talus distally. The tibionavicular attaches to the anterior colliculus and intercollicular groove proximally and to the dorsal surface of the navicular distally. Finally, the tibiocalcaneal band inserts proximally on the anterior colliculus and the intercollicular groove and distally on the sustentaculum tali, which is a medial projection of the calcaneus [4–9]. Functionally, the intact deltoid ligament acts to limit motion when the foot is plantarflexed, abducted, or externally rotated [10]. If forces experienced during these types of motion exceed the strength of the deltoid, or even the bone, medial injury may occur.

1.2 Injury Modes

Medial malleolar fractures can occur in a variety of scenarios and are typically described by one of two classification systems: Lauge-Hansen or Danis-Weber. Per the Lauge-Hansen system, medial malleolar damage occurs first in pronation, while damage to the medial malleolus
is secondary to that of the lateral structures in supination injuries. The two-word naming convention utilized by the Lauge-Hansen system describes first the position of the foot followed by the direction of the applied force. The second classification method, the Danis-Weber system, includes three (3) injury mechanisms (A, B, and C), which are based on fibular damage [11–13]. Table 1 illustrates the various injury states described by each system with a focus on those modes resulting in medial malleolar damage.

<table>
<thead>
<tr>
<th>Classification System</th>
<th>Injury Mechanism</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lauge – Hansen</td>
<td>Supination – Adduction</td>
<td>Force causes foot to be simultaneously raised and turned toward the body's midline. Talus is forced into MM resulting in vertical fracture of MM.</td>
</tr>
<tr>
<td></td>
<td>Supination – External Rotation</td>
<td>Force causes foot to be raised and rotated axially away from body’s midline. Large forces result in avulsion fractures of MM as medial structures are placed in tension.</td>
</tr>
<tr>
<td></td>
<td>Pronation – Abduction</td>
<td>Foot is depressed beyond neutral position and turned away from body’s midline. Tension on MM causes fracture at distal tibia.</td>
</tr>
<tr>
<td></td>
<td>Pronation – External Rotation</td>
<td>Depressed foot is axially rotated outward. Avulsion of MM is inferred from literature and illustrations.</td>
</tr>
<tr>
<td></td>
<td>Vertical Loading*</td>
<td>Talus is forced into distal tibia and can result in MM fractures.</td>
</tr>
<tr>
<td>Danis – Weber</td>
<td>Type A Fracture</td>
<td>Fracture of fibula below tibial plafond results in vertical or oblique fracture of MM.</td>
</tr>
<tr>
<td></td>
<td>Type B Fracture</td>
<td>External rotation resulting in spiral or oblique fibular fracture and subsequent damage to medial structures.</td>
</tr>
</tbody>
</table>

**Table 1:** Medial malleolar injury can be described by either of two classification systems. Only those injury mechanisms resulting in medial malleolar damage are given above. *This category was later added to the Lauge-Hansen classification system. (neutral position = position of foot during walking stance; MM = medial malleolus [13])
Aside from the injury mechanisms described in Table 1, injury scenarios are also possible in calcaneal varus/valgus motion and axial rotation. The subtalar joint, which is comprised of the calcaneus and talus, exhibits triplanar motion. This triplanar motion—described as dorsiflexion/plantarflexion, adduction/abduction, and inversion (varus)/eversion (valgus)—is accomplished by the calcaneus in non-weight-bearing circumstances. Upon weight-bearing, however, these motions must be carried out by the talus as the weight of the body prevents the calcaneus from doing so. For example, the calcaneus will invert (varus motion) and the talus will abduct and dorsiflex during supination. In pronation, the calcaneus will evert (valgus motion) while the talus will adduct and plantarflex [2]. From this example, one can assume that supination would subject the medial structures to tensile forces as the talus and tibia are “pulled” apart. If great enough, the tension could lead to avulsion fractures of the medial malleolus. Similarly, one can infer that malleolar fractures could result from pronation as compression of the medial structures would drive the talus into the tibia.

Comparable fracture mechanisms can be deduced from axial rotation. For example, when axial rotation occurs away from the midline of the body and the foot is planted, the talus is forced to dorsiflex within the mortise [2]. Again, one could infer that an adequate rotational force directed laterally could result in tension of the medial structures and subsequent fracture of the malleolus. While external rotation could result in tension, internal axial rotation could result in compression, followed by fracture, due to the medial malleolus running into the talus.

1.3 Surgical Repair and Complications

Surgical repair of the above types of fractures can be achieved in both open and closed procedures and may involve implanting hardware to stabilize the fracture [13-14]. With regard
to hardware, devices including cancellous screws, K-wires, tension bands, plates, or a combination of these are used to fix the medial malleolus [1,13,15]. Complications such as nonunion and malunion can occur but are rare in the ankle joint [13,14]. Nonunion is usually the result of an avulsion fracture that is treated closed and has displacement of the fracture, remnants of soft tissue within the fracture site, or shear forces due to pulling of the deltoid ligament [13]. In comparison, malunion is more common. Such complication is usually the result of a fracture treated either open or closed in which the deltoid pulls on the fractured fragment. If left uncorrected, a permanent elongation can result. Additionally, failure of a fixation device to properly support a fractured bone, support at a single point only, or undetected comminution resulting in rotation or shortening of the malleolus can all result in incomplete healing [13].

1.4 Previous Studies, Medial Malleolar Fracture Fixation

To further elaborate on the hardware previously mentioned, several biomechanical studies that were consulted during the current investigation are presented here. The first of the studies consulted was conducted by Rovinsky et al. and tested the pullout strength, resistance to shearing and insertion time for partially threaded cancellous screws, threaded K-wires, and smooth K-wires. (NOTE: Although insertion time was evaluated during the Rovinsky investigation, the focus in the current discussion will be kept on the biomechanical aspects of the study.) Because a larger number of cadaveric specimens would have been necessary to capture small differences in pullout strength (due to the varying qualities of the samples), the authors chose to use polyurethane foam in three densities to represent bone during their experimental studies. Each device was embedded in foam at three different insertion depths and a tensile load was applied via a servohydraulic test apparatus. As two millimeters of displacement indicated
loss of fixation, the peak force within these first two millimeters was recorded as the pullout strength [15].

Following pullout strength studies, offset axial testing was conducted on cadaveric tibia to determine each device’s resistance to shearing. An osteotomy at the distal tibia was created, which simulated a Weber A type fracture (similar to a supination – adduction fracture in the Lauge-Hansen classification system), and then the medial malleolus was fixed using each of the three devices previously mentioned. A compressive load was applied seventeen degrees off the long axis of the tibia at the fixed fracture. This same loading was also applied to intact tibia as these represented control samples [15].

Rovinsky et al. concluded that the partially threaded cancellous screws had the highest pullout strength followed by the threaded K-wires and lastly the smooth K-wires; however, the percent difference in strength between the screws and threaded K-wires decreased as bone density and insertion depth increased. In general, pullout strength increased with increasing bone density regardless of the fixation method used. Finally, offset axial testing resulted in failure modes such as bending and tensile pullout; however, no significant differences were noted among the devices’ mechanical performances [15].

A second study conducted by Johnson and Fallat examined relative and actual strength of K-wire tension banding and cancellous screws. Soft tissue had been dissected away from each of ten lower extremities (paired legs from five cadavers) starting at the midshaft down to just above the ankle; tissues and ligamentous constraints of the ankle were left intact. A transverse medial malleolar fracture was created in each specimen and fixed by either cancellous screws or K-wires. An upward vertical force was applied to simulate eversion loading of the foot and an
avulsion fracture of the medial malleolus. Fracture distraction proceeded through four millimeters of displacement (with the exception of one specimen whose deltoid ligament and joint capsule failed sooner); a displacement of two millimeters was considered loss of fixation. The results of this study showed that the K-wires performed better than the cancellous screws, and the failure mode involved only pullout rather than any breakage. The authors concluded that K-wires were a better option than cancellous screws for fixing avulsion fractures, and they also recommended K-wires in fracture cases involving a small fragment or osteoporotic bone [3].

Two other studies cited among the literature evaluated fixation of vertical fractures [16,17]. The first of these, conducted by Dumigan et al., compared four fixation methods involving either plates or screws. Osteotomies were performed on tibia saw bone models, and both offset axial and offset transverse loading were applied. Offset axial testing, which represented a supination-adduction injury, was performed on inverted tibia models with loading applied seventeen degrees off the longitudinal axis of the bone. Offset transverse loading, a representation of an external rotation injury, was carried out by laying the tibia perpendicular to the applied loading and rotating it outward by thirty degrees. As in the cases of the investigations mentioned previously, the authors, here, also used two millimeters of distraction as an indication of lost fixation. Of the two plate and two screw methods used for fixation, the final outcome supported the use of correctly applied neutralization plates to stabilize vertical fractures of the distal tibia [16].

Similar to the Dumigan study, Toolan et al. also examined plate and screw configurations to determine the constructs’ resistance to displacement. A preload of no more than five Newtons was applied to the specimens prior to testing, and both offset axial and offset transverse testing
were performed in a similar manner as described for the Dumigan study. Force-displacement data was recorded during testing, and resistance to displacement was measured as the slope of the force-displacement curve, while failure was noted as the maximum force obtained prior to a noticeable decrease. Following testing, each fixation device was visually inspected and radiographed. In this study, the authors concluded that the use of antiglide plates was not superior to lag screws. Furthermore, lag screws inserted perpendicularly to the fracture performed best. Finally, before turning attention to the next study, it is important to note here that Toolan et al. made a disclaimer regarding their transverse test methodology. While the experimental set up met the authors’ needs with regard to objectives, it did not represent a “true” external rotation since the test set up placed an oblique bending moment on the samples [17].

A final study compared cancellous screws, K-wires, and tension banding in cadaveric tibia specimens. Ostrum et al. conducted both clinical and experimental testing; however, the mechanical testing will be the focus of this literature review. Each of six cadaveric lower extremities was fixed to a test apparatus and a pronation moment was applied to the foot. Force versus displacement data was recorded for each intact tibia, and these samples’ stiffnesses were considered the control. This same data was also recorded for each specimen following osteotomy and fracture fixation. Due to the limited number of specimens, however, each specimen was subsequently fixed with the different devices. The percent stiffness (compared to the intact specimen) of each fixation device was compared and data was normalized to the control displacements. As in the case of the previously mentioned study by Johnson and Fallat, Ostrum et al. also concluded that tension banding was beneficial in certain injury instances, particularly those involving comminuted fractures or osteoporotic bone [18].
1.5 Fixation Devices and Choice of Loading

Per the literature cited above, tension banding and cancellous screws are two viable options for fixing medial malleolar fractures. While mechanical evidence suggests that tension banding is indicated in certain scenarios [3,18,19], its use by clinicians at Virginia Commonwealth University (VCU) is not preferred. In general, the most commonly used method for repair of medial malleolar fractures is fixation via screws [18,20].

In this particular research, further investigation into medial malleolar fixation was conducted and consisted of both experimental and computational testing. As malunion and nonunion are rare among ankle fractures, the goal of the experimental study was not to determine if a device was suitable for fracture repair, but rather it was to compare performances of different fixation options. The Medial Malleolar Sled™ (TriMed, Inc., Valencia, CA), a relatively newer construct intended for malleolar fractures, is a low profile device that offers a way to fix a single, horizontal fragment broken off or avulsed just inferior to the tibial plafond (Figure 3). It is suitable for such larger fragments (as opposed to comminuted fractures) with fracture lines that are (near) horizontal and not too far proximal along the tibia due to its design. Specifically, the Sled™ is a single-piece tension band [21] that provides two-point fixation via two metal prongs inserted into the distal fragment and terminating in the proximal tibia. The remainder of the “sled” wraps around the fragment and proximal tibia. A washer rests on the sled just proximal to the fracture line, and the entire device is secured via two fully threaded screws that are inserted into the proximal tibia. The construct’s rigid design offers resistance to both tensile and torsional loading in an attempt to prevent separation of the fragment from the proximal tibia [21].
As previously mentioned, the Sled™ is optimal for tensile and torsional loading [21]; therefore, a second device was chosen to compare against the Sled™ in these scenarios. Alongside the Sled™, cancellous screws were evaluated (Figure 3). Two-screw fixation was chosen for comparison in part due to its wide use among clinicians. Additionally, it was chosen over tension banding due to the latter construct’s less rigid characteristics and inability to resist rotational forces applied to the medial malleolus during torsional loading. Furthermore, screw fixation was considered a better option over a plate. Although its stiff construct would provide resistance in both tension and torsion, the plate was bypassed as a comparison group due to the size of the malleolar fragment.

1.6 Finite Element and its Application to the Ankle Joint

While the experimental study sought to compare fixation devices, an additional goal of this ankle investigation was to perform a computational analysis. In the current study, finite element analysis (FEA) was applied to a three-dimensional computer model of the ankle joint in order to determine the forces and displacement experienced by the bone. More specifically, FEA
was applied to determine the mechanical performance of the given fracture fixation devices (i.e. Sled™ and cancellous screws), and these results were compared to the data determined experimentally. In general, FEA is a useful tool for solving various types of complex engineering problems. “Complex” may refer to the geometry of a problem, boundary conditions, or even the presence of dissimilar material properties. To solve such a problem, the body to be analyzed is first discretized, or divided into smaller pieces known as finite elements, that approximate the original body’s shape. The applicable governing equations for the body are then applied to each element (often at the nodes) in order to determine the “quantity of interest” [22]. Finally, the elements are reassembled and the combination of their individual solutions provides an approximation for the solution of the body as a whole [22].

To further elaborate on how FEA is used, its application to the present study is given as an example. As previously mentioned, a performance comparison of two medial malleolar fracture fixation devices was performed. In this particular case, the forces seen by the bone, specifically at the fixed site, and the displacement of the malleolar fragment are of interest. FEA becomes a suitable option to determine these quantities especially due to the model’s complex geometry (i.e. bony geometry) and various components with differing material properties (e.g. trabecular bone, cortical bone, metal hardware). Via computer software, FEA is implemented by first creating a finite element mesh of the fixed ankle complex. A solution (i.e. stress distribution, force values, and displacement distribution) is then determined for the overall model after applying the displacements at each node along with the governing stress-strain equations [22,23]. As is demonstrated in the above example, FEA enables one to take a large, unruly
problem and break it down into several small approachable elements to yield an overall solution [22,23].

With regard to the ankle, finite element analyses have been utilized to determine contact stresses at the joint [24–26]. For example, one such study focused on articular cartilage found at the distal tibia. The authors examined contact stresses experienced by the articular cartilage as a result of “unstable motion,” whereby the unstable motion simulated a “malunited pilon fracture” [24]. A second study compared contact stresses between fracture-reduced and intact ankles [25], while the third study sought to experimentally validate a FEA ankle model of contact stresses [26]. In general, results of these models may aid in identifying degeneration of the joint and the onset of disease such as osteoarthritis [26].

In addition to the contact stress analyses, various studies have examined implant performance, not only in the ankle, but also in the scapula, femur, vertebrae, fibula, and tibia [27–32]. For the ankle, specifically, different configurations of two- and three-screw ankle arthrodesis were studied in order to determine the most stable construct [33]. Similar to the aforementioned studies, the current investigation uses FEA to compare two fracture fixation constructs and validate the FEA results against the experimental findings.

1.7 Study Objectives

Following determination of the loading scenarios and fixation devices, a computational model was built to simulate the experimental study. Thus, the overall goal of this study was to validate a computational model of medial malleolar fracture fixation against experimental testing. In order to accomplish this goal, the following objectives were achieved:
(1) Determined performance of two-screw fixation and the Medial Malleolar Sled™ in both tension and torsion via experimental testing;

(2) Established a computational model that simulated the experimental set up;

(3) Validated the computational model against the experimental results using solid modeling software coupled with a finite element program.
CHAPTER 2 Methods

2.1 Experimental Testing – Tension

Tensile testing, representing an abduction injury, was conducted on ten (10) paired cadaveric lower extremities. In order to maintain consistency with regard to fracture creation and fixation, as well as represent a clinical reduction, an orthopaedic resident prepared all specimens. Soft tissues, with the exception of the ankle joint ligaments and joint capsule, were dissected away in order to expose the distal tibia and fibula, as well as the navicular and calcaneus. The tibia and fibula were transected approximately twelve (12) centimeters above the level of the tibial plafond, and the forefoot anterior to the navicular was removed. Additionally, the posterior portion of the calcaneus was removed for the purpose of sample potting. A transverse medial malleolar fracture (simulating an avulsion fracture) was then created and subsequently anatomically reduced. Each ankle and its contralateral pair were fixed with either two partially threaded cannulated screws (Depuy Orthopaedics, Inc., Warsaw, IN) or the Medial Malleolar Sled™ (TriMed, Inc., Valencia, CA), the assignment of which was random. Fixation was aided by the use of fluoroscopy, which allowed visualization of device placement.

The ankle was then potted in two polyvinyl chloride (PVC) cups using polymethyl methacrylate (PMMA). Prior to adding PMMA into the PVC cups, neutral joint position was first visually determined and then physically held via two k-wires inserted (from tibia to talus) on the anterior and posterior sides of the joint. (NOTE: These wires were removed after mounting the specimen in the Instron and just prior to testing.) In order to maintain this position in the
PVC cups, two 1/8” diameter pins were drilled through the cups and specimen. One pin entered through the PVC and secured the navicular to the talus before exiting the PVC cup, while the second pin entered the PVC cup and fixed the calcaneus to the talus before exiting the opposite side. At the proximal end of the specimen, 1/8” pins were drilled through the PVC, tibia, and fibula. PMMA was then added to the proximal cup and allowed to cure for approximately thirty (30) minutes; this was repeated for the distal cup as well.

Finally, the potted specimen was mounted in an Instron 1321 Materials Testing apparatus (Instron Corp., Canton, MA) retrofitted with MTS TestStarII digital data acquisition and control (MTS Systems Corporation, Eden Prairie, MN). Prior to running the tensile test, two black glass beads were glued proximal to the fracture line and separated by a distance of approximately one (1) centimeter. A second set of beads was glued distal to the fracture line on the medial malleolar fragment, about 1.5 centimeters below the proximal beads. These two sets of beads would ultimately be useful for calculating fragment movement during testing. All remaining soft tissue other than the deltoid ligament was cut away, and the distal fibula was removed. In this way, the only means of transferring tension to the malleolar fragment was through the deltoid. A Panasonic PV-GS35 Digital Palmcorder (Panasonic Corporation of North America, Secaucus NJ) was set up approximately 28 centimeters away from the specimen (4x magnification, manual focus, with light on at highest setting) to record each tensile test, and a LED marked the start of each run. Additionally, the orthopaedic resident was allowed to mark observations throughout the test via button activation. Usually, this qualitative measure corresponded with when the resident felt that fracture distraction signified loss of fixation. Numerically, this value was set at two (2) millimeters of fracture distraction in accordance with other studies [3,15].
perturbation of one (1) millimeter per second was applied along the long axis of the tibia via the Instron, with maximum crosshead travel set to five (5) millimeters. Data output included force (Newtons)-displacement (millimeters) curves collected via the data acquisition system.

![Figure 4, Tensile Test Set Up: Photograph showing the medial view of a specimen, which is fixed with the Medial Malleolar Sled™, ready to be tested in tension.](image)

2.2 Experimental Testing – Torsion

Torsional specimens were dissected and fixed in the same manner as those tested in tension. Potting of the ankle joint was also identical to that of tensile samples. Proximally, the fibula was removed so that the tibia was centered in the proximal PVC cup. Again, 1/8” pins were used to fix the tibia shaft within the potting cup.

Just as with tensile specimens, beads were fixed to the medial malleolus both proximal and distal to the fracture line. As this test was meant to simulate an external rotation injury, distraction of the fracture could potentially occur in all three dimensions. As a result, the video camera was fixed to the Instron actuator approximately 10 centimeters away from the specimen, along with a mirror attached at a 45°, so that all motion and failure modes could be visualized (Figure 5). The rate of rotation was established at one (1) degree per second, with a range of
motion spanning -45° to 45 °. Again, the resident was able to mark via button activation any observations during testing. (Note: A second orthopaedic resident assisted during torsional testing.)

**Figure 5, Torsion Test Set Up:** Photograph illustrating torsion test setup. The camera and mirror are mounted to the Instron enabling both to track with the specimen as the test progresses.

### 2.3 Finite Element Modeling of the Experimental Test

Previous work conducted by Dr. Joseph Iaquinto included the use of a tibia model constructed from computed tomography (CT) scans, and this same tibia model was imported into SolidWorks (Dassault Systèmes, Concord, MA) for use in the current study [5]. Because the model was that of a full tibia, it was modified to represent the anatomy tested. After establishing a plane at the level of the tibial plafond, a second parallel plane was constructed twelve (12) centimeters proximally along the tibia. Using the SolidWorks “Extrude Cut” feature, the portion
of the tibia proximal to the transection plane was removed. The remaining tibia’s coordinate system was then oriented anatomically so that the tibia’s x, y, and z axes were normal to the sagittal, transverse, and coronal planes, respectively.

Following plane assignment, two bone layers were created to simulate both the trabecular and cortical layers. In order to create these two layers, two part files—cortical layer and trabecular-void layer—were generated. The base tibia model represented the cortical layer, while a scaled version of this same model was saved as a second part file and used to create the trabecular layer. The CT scan of the tibia model was referenced to determine the height of the trabecular layer within the cortical shell, and the scaled tibia was transected at this height. (Note: The height of the trabecular region was measured at approximately the center of the plafond on a coronal view, and spanned from the plafond to just below the start of the intramedullary canal. Although the proximal end of the trabecular layer does not reach a uniform height, i.e. it is not a flat surface within the cortical layer, it was represented as such for the ease of building the SolidWorks model.) To create a “void” region representative of the intramedullary canal within the bone, the most proximal surface of the cancellous layer was converted to a sketch. A second copy of this sketch was scaled and moved proximally to a height just past the height of the cortical model. A lofted feature was created between these two sketches and was coincident—but not merged—with the cancellous model.

The trabecular-void part was inserted into the cortical part file and aligned by mating coronal and sagittal planes, along with top surfaces of the void and cortical bone. Subtracting the trabecular-void layer from the solid cortical bone using the “Combine” function created a cortical shell. Using the “Combine” feature a second time, the trabecular-void layer was inserted
into the newly created cortical shell, and finally, the void was subtracted. By combining parts in this way, two distinct bone layers were created and each could be assigned separate material properties (Figure 6).

![Figure 6, Bone Layers](image)

**Figure 6, Bone Layers:** Coronal section depicting the tibia model with two bone layers. The inner trabecular layer was idealized to have a flat proximal surface. The cortical and trabecular layers were not merged in SolidWorks so that material properties could be assigned to each portion. The intramedullary canal was represented as a voided region above the trabecular layer.

Using a series of combine-subtract features, two threaded screw holes, entering through the medial malleolus and stopping within the cancellous bone, were constructed. A threaded screw component, which was modeled separately per product sheet [34] and measurements made on sample parts, was inserted into and subtracted from the two-layer model. This task was repeated to create the second screw hole.

Just as was done with the screws, the Medial Malleolar Sled™ was modeled via a series of combine-subtract features. All components of the Sled™ fixation device were modeled as individual components and then assembled onto the tibia model. The prongs of the Sled entered through the medial malleolus and terminated in cancellous bone, while the two Sled screws
entered through the proximal tibia into the cancellous bone. Once the components were positioned, their profiles were subtracted from the model.

Finally, following inclusion of the screw or sled profiles, the “Split” function in SolidWorks was used to create the transverse osteotomy. The plafond plane was selected as the reference geometry for the split, while the trabecular and cortical fragments were selected to create the medial malleolar fragment. (Note: Because the trabecular and cortical layers were combined but not merged, each represents an individual solid body. By creating planar splits, additional solid bodies are generated and may be selected to create new part files or deleted entirely.) Prior to deleting these fragment bodies from the tibia part file, each was saved as an individual part to be later combined as one fragment with two bone layers.

With respect to the torsion models, two additional features were added to the tibia part file. Two solid bodies resembling a box and a plate were mounted to the proximal end of the tibia. The proximal portion of the transected tibia was first removed using the “Cut-Extrude” feature in SolidWorks. A rectangular profile was then sketched at the proximal end of the remaining tibia and extruded to create a thin plate. A second extrusion of the rectangular sketch was then added to create a box on top of the thin plate. This latter feature was added so that it could be designated as a beam element in the finite element analysis. In this way, loading could be applied to the beam joints and torsion values would be provided as a direct output. The plate was incorporated so as to create a body to which both the beam and remaining tibia could be bonded. Without inclusion of this plate, the prescribed motion would not be translated to the tibia. In order to make the beam and bonding distinctions, the plate, box, and tibia were deliberately included as separate solid bodies rather than a single, merged body (Figure 7).
Figure 7, Torsion Model: Torsion models included additional solid bodies, specifically a box and plate, stacked on top of one another at the proximal end of the tibia. Inclusion of these bodies facilitated load application in Simulation.

It is important to mention that the order of the above tasks played an important role in developing a model that could be successfully meshed and analyzed in SolidWorks Simulation. Early assembly models of the tibia with fragment included addition of screw holes and screws (modeled as simple cylinders) at the assembly level. Although these assembly models meshed, simulation run time was long and produced nonsensical, zero-value results. It was later determined that defining screw holes (a component feature) at the assembly level created confusion within SolidWorks and produced inefficient analyses. Creating this feature as described above (i.e. at the part level) resulted in a few improvements. First, initial run time of these early models reduced from a day to approximately one hour. Second, more sensible non-zero stress values were obtained. Finally, an efficient means of creating and updating the screw
holes was determined. Creating these features within a single part document and then producing the fragment from this same part generated matching screw hole profiles in both the proximal tibia and fragment. Rather than updating two components independently, the necessary modeling was completed in a single file. These improvements allowed introduction of model complexities, such as the screw threads and head, which in turn allowed for a more accurate representation of the experimental set up.

Following creation of the proximal tibia and tibial fragment, both were inserted into an assembly file along with the two screws. Additionally, models of the talus, navicular, and calcaneus, which were previously developed by Dr. Joseph Iaquinto, were included in the assembly model. These bones served as insertion surfaces for the deltoid ligament, which was represented by several tension-only spring elements. Furthermore, all three bones were fixed in space to simulate the bones that were potted during experimentation. Similarly, a second assembly file was created in which the Sled™ device was utilized for fixation (Figure 8).
Figure 8, SolidWorks Models: Both of the above models represent a right leg with a fixed plafond-level fracture. Two-screw fixation is shown on the left, while fixation via the Medial Malleolar Sled™ is depicted on the right. The relevant ankle anatomy is also shown and includes the spring representation of the deltoid ligament (hidden on the right to highlight bony anatomy).

While all part and assembly tasks took place in SolidWorks, discretization and finite element analysis were executed in Simulation, an add-on to the SolidWorks suite. The model was assumed to be linear; and therefore, a linear static analysis was performed. Prior to meshing the assembly, material properties were assigned to each component per the literature (Appendix A) [35–38]. These properties included aged and osteoporotic bone data, which was representative of the experimental test group. Furthermore, two spring elements per each of the four deltoid bands were included in the model, and stiffness and pretension were assigned as per
the literature [39]. Origins and insertions of these ligament bands were based on anatomical texts and referenced literature.

Following ligament assignment, Simulation was used to identify contact sets among the proximal tibia, fragment, and both screws (or Sled components). (Note: As the talus, calcaneus, and navicular served only an anchoring function and did not physically interact with the rest of the assembly, it was unnecessary to include these bones in the identification of contact sets.) Two finite element models were created for each fixation construct based on the contact type. The first of the two models, subsequently referred to as the “bonded contacts model,” utilized a global bonded contact between all interfaces except for the fracture surface, which was under a no penetration surface-to-surface contact. The second version, denoted below as the “no penetration model,” included a global bonded condition between the bone layers and no penetration surface-to-surface contacts between the (1) hardware and bone surfaces and (2) at the fracture surface between the whole tibia and medial malleolar fragment. With respect to the Sled™ model, additional manual contacts were added between the Sled and screws and the washer and screws. These interfaces were included as bonded component contacts. Within the FEA software, a bonded interface indicates two surfaces that act as though they are rigidly connected, while a no penetration condition permits surfaces to slide and separate relative to each other [40–42].) Friction was not included in the model.

In addition to the fixed constraints applied to the talus, calcaneus, and navicular, prescribed motion was assigned to the proximal end of the tibia. In the tensile models, this prescribed motion was included as a displacement constraint on the proximal-most face of the tibia. To simulate actuator displacement, the proximal tibia was allowed to displace vertically
along the y-axis but was constrained in the x- and z-directions. In the torsion models, a two degree (~0.035 radians) axial rotation was applied to the proximal-most beam joint so as to simulate actuator rotation. Whereas the tensile models had three degrees of freedom, the torsion models had six degrees of freedom due to incorporation of the beam element. All motions were set to zero at the proximal joint with the exception of axial rotation and vertical displacement. The latter condition was included to account for vertical movement of the tibia due to running the Instron in load control mode. Finally, a curvature-based mesh with tetrahedral elements was applied to the entire tensile assembly, while curvature-based mixed mesh (tetrahedral and beam elements) was applied to the torsional assembly (Table 2). Analysis of the tensile and torsional models resulted in force and torque data, respectively, which were compared to experimental results. Stress and displacement data were also noted for the models.

<table>
<thead>
<tr>
<th>Table 2: Simulation Mesh Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tension</strong></td>
</tr>
<tr>
<td>Two-Screw</td>
</tr>
<tr>
<td>Bonded</td>
</tr>
<tr>
<td>Nodes</td>
</tr>
<tr>
<td>Elements</td>
</tr>
<tr>
<td>Minimum Element Size (mm)</td>
</tr>
<tr>
<td>Maximum Element Size (mm)</td>
</tr>
</tbody>
</table>

*Table 2:* Element size for a curvature based mesh and the resulting number of nodes and elements are given for each model. (Np = no penetration)
CHAPTER 3 Results

3.1 Tensile Study

Experimental results are presented as tensile force versus tibia (Instron actuator) displacement as well as force versus fragment (bead) displacement. Finite element findings are presented as force for construct displacement as well as in contour plots of 3D displacement and of von Mises stress. With respect to stress and displacement, the focus is mainly on the fragment and tibia proximal to it. Although maxima and minima for the assembly as a whole are reported, the primary interest lies in the response of the bones near the fracture site.

With regard to the finite element models, two variations were created for each fixation construct; and therefore, results are presented for each version. The first of the two models, subsequently referred to as the “bonded contacts model,” utilized bonded contacts everywhere but the fracture site, while the second, or “no penetration model,” used no penetration contacts at interfaces except between the bone layers.

3.1.1 Experimental Results, Two-Screw Fixation

During experimental testing, force and displacement in the direction of actuator (crosshead) motion (i.e. along the long axis of the tibia) were recorded via the materials testing equipment. Axial force was first compared against the actuator’s excursion. A second set of data, measured via optical tracking of beads glued onto the cadaveric specimen, compared axial force against relative fragment movement (Figure 9).
Figure 9, Force vs. Displacement, Two-Screw Fixation: The graphs above demonstrate the force versus (A) actuator and (B) fragment displacement recorded for ten matched cadaveric pairs fixed as a two-screw construct.
As model data was provided in the form of contour plots rather than continuous force versus displacement plots, a specific displacement—and the corresponding average force at that displacement—was chosen as a means to compare the model to the experiment. A small strain assumption was made; and therefore, a linear static model was used in all simulations. Actuator displacement, rather than fragment movement, was used for comparing the experiment and model since the applied loading was effected as a user-controlled input at the proximal tibia. At 1.00mm (SD = 0.004mm) of actuator displacement (equivalent to a bead displacement range of -0.05mm to 0.15mm), the mean force experienced by ten cadaveric ankles fixed via two-screws was 49.19N (SD = 20.895N).

With respect to failure modes, all but one specimen failed via screw pullout in the proximal tibia or through the fragment (Figure 10). In cases where the screw head traveled through the fragment, the fragment broke at the screw-bone interface. Nonuniform distraction was noted with separation usually occurring first at the anterior edge of the fracture.

![Figure 10, Tensile Failure Modes, Two-Screw Fixation](image)

**Figure 10, Tensile Failure Modes, Two-Screw Fixation:** (A) Failure via screw pullout (right specimen). (B) Failure via screw head pulling through and breaking fragment (right specimen).

### 3.1.2 Bonded Contacts Model, Two-Screw Fixation

The corresponding bonded two-screw model (n = 1) experienced 61.30N of axial force. This result fell within one standard deviation of the mean. Because each deltoïd band was
assigned a different stiffness and had different 3D orientation, the various bands resisted 1mm of proximal tibia displacement with varying force (Table 3).

### Table 3: Force by Deltoid Component, y-direction Bonded Contacts, Two-Screw Model

<table>
<thead>
<tr>
<th>Deltoid Component</th>
<th>Total Force (N)</th>
<th>Pretension (N)</th>
<th>Net Force (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATiTa - 1</td>
<td>8.09</td>
<td>6.26</td>
<td>1.83</td>
</tr>
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<td>ATiTa - 2</td>
<td>8.04</td>
<td>6.19</td>
<td>1.85</td>
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<tr>
<td>TiNa - 1</td>
<td>7.63</td>
<td>5.96</td>
<td>1.67</td>
</tr>
<tr>
<td>TiNa – 2</td>
<td>9.38</td>
<td>6.77</td>
<td>2.61</td>
</tr>
<tr>
<td>TiCa – 1</td>
<td>8.15</td>
<td>5.83</td>
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<td>TiCa – 2</td>
<td>7.72</td>
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<tr>
<td>PTiTa - 1</td>
<td>7.03</td>
<td>4.89</td>
<td>2.14</td>
</tr>
<tr>
<td>PTiTa - 2</td>
<td>5.25</td>
<td>3.89</td>
<td>1.36</td>
</tr>
</tbody>
</table>

Table 3: The above table shows the distribution of force among the four deltoid components (each broken into two bands, denoted by 1 or 2) of the bonded, two-screw model. The net force represents the amount of additional force experienced by each pretensioned band following displacement application. (ATiTa = Anterior Tibiotalar; TiNa = Tibionavicular; TiCa = Tibiocalcaneal; PTiTa = Posterior Tibiotalar)

Across the entire model (excluding the fixed calcaneus, navicular, and talus), the average, minimum, and maximum Von Mises stresses generated were 2.06MPa, 8.77e-6MPa, and 46.27MPa, respectively. The minimum was found at the anterolateral fracture surface, while the maximum was found along the anterior edge of the posterior screw hole. When components were examined individually, the medial malleolar fragment was found to have an average stress of 2.53MPa with a range of 8.78e-6 to 46.27MPa. The minimum and maximum stresses were found to be the same as those for the entire assembly. A maximum stress near the screw heads corresponded to those cadaveric specimen that failed due to the screw heads pulling through the fragment. The whole tibia developed an average stress of 1.42MPa, with a minimum stress of 0.011MPa and a maximum of 38.68MPa. (NOTE: Here, the “whole” tibia refers to the entire tibia excluding the fragment.) The minimum occurred at the proximal surface of the trabecular
bone, while the maximum, which was above the yield value (5.76MPa) of osteoporotic bone modeled, occurred just above and along the anterior screw (Figure 11). The maximum that developed along the screw within the model, along with the higher stress concentrations around the hardware, suggested a point of failure similar to that observed experimentally (i.e. a weakened screw-bone interface which resulted in screw pull-out).

![Figure 11, Max Stress in Tibia, Bonded Contacts, Two-Screw Model](image)

*Figure 11, Max Stress in Tibia, Bonded Contacts, Two-Screw Model:* Anterior section view depicting maximum stress in the tibia proximal to the fragment. This high stress location matches the failure region in experimental specimens that experienced screw pull-out.

With respect to axial displacement, the average displacement for the entire model (excluding the fixed bones of the ankle and foot) was 0.982mm. A minimum displacement of 0.887 was noted at the posterior screw head and a maximum of 1.043mm was observed along the lateral proximal tibia. Numerically, an average fracture distraction of 0.005mm was measured by probing the fracture surfaces and taking a difference between their average displacements; however, visually, no noticeable fracture distraction was seen (at this level of applied vertical force).
displacement) in the model. For the fragment alone, the average displacement was 0.936mm, with a minimum of 0.892mm and a maximum of 1.036mm. The minimum was observed on the medial surface of the fragment above and slightly anterior to the posterior screw hole. Just as with the model’s maximum value, the fragment’s maximum displacement was also found along its lateral side. As for the whole tibia, the average displacement was 0.990mm, with a range of 0.922mm to 1.043mm. The minimum was found on the fracture surface at the edge of the posterior screw hole.

3.1.3 No Penetration Model, Two-Screw Fixation

Compared to the bonded model, a lower force was generated in the no penetration model. At 1mm of applied displacement, the model (n = 1) resulted in 60.63N of force. This model value fell within one standard deviation of the experimental mean. As was the case with the bonded contacts model, forces in the deltoid structures were nonuniformly distributed in the no penetration model; however, the majority of bands exhibited lower forces than those in the bonded contacts model (Table 4).

<table>
<thead>
<tr>
<th>Deltoid Component</th>
<th>Total Force (N)</th>
<th>Pretension (N)</th>
<th>Net Force (N)</th>
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</table>

Table 4: The above table shows the distribution of force among the four deltoid components (each broken into two bands, denoted by 1 or 2) after additional “no penetration” contacts were applied to the model. (ATiTα = Anterior Tibiotalar; TiNa = Tibionaviculare; TiCa = Tibiocalcaneal; PTiTα = Posterior Tibiotalar)
The average Von Mises stress across the entire model, discounting the fixed bones, was 3.00MPa with a range of 5.37e-5 to 94.82MPa. The minimum stress was noted at the lateral side of the fragment within the trabecular layer as well as in the trabecular bone of the whole tibia, and the maximum value occurred along the anterior screw. When the fragment was independently examined, an average stress of 2.33MPa was recorded. A maximum stress of 84.26MPa was observed on the fracture surface at the interface of the trabecular and cortical bone layers. The next highest stresses were observed in the bone immediately adjacent to the screw heads (Figure 12) as well as at ligament origins. Although these values were below the yield strength of cortical bone modeled (102MPa), the area of stress concentration corresponded with the experimental observation that several specimens failed when the screw heads pulled through the malleolar fragment.

In the whole tibia, an average stress of 1.31MPa was noted, with a range of 0.02MPa to 24.26MPa. The minimum was observed in the trabecular bone near an anterior screw thread and the maximum occurred on the fracture surface at the trabecular-cortical interface. From the contour plot, the lateral fragment and screw hole edges along the fracture site had relatively higher stresses compared to the surrounding bone. High stresses around the screw-bone interfaces corresponded with experimental failure via screw pullout (Figure 13).
Figure 12, Stress Concentrations, Fragment, No Penetration, Two-Screw Model: Inferior view depicting modeled fragment. In general, high stresses were found in the bone near the screw holes and at the ligament origins.

Figure 13, Stress behind Fragment, No Penetration, Two-Screw Model: Antero-superior view of the fixed fragment depicting higher stresses just behind the fragment. A close examination of the model showed a slight distraction along the medial fracture site but not along the lateral side. In the model, this suggested that the lateral part of the fragment was being pushed into the whole tibia as the fracture site opened, which corresponded to the higher stresses.
With respect to the tibia assembly (excluding the fixed bones), an average of 0.990mm was recorded. The average fracture distraction in the model was 0.013mm. Upon examination of the contour plot of displacement in the y-direction, one millimeter of displacement was confirmed at the proximal tibia, while the maximum displacement was 1.043mm incurred by the lateral most portion of the fragment. 0.849mm at the posterior screw head was recorded as the minimum displacement (Figure 14).

![Figure 14, Max and Min Displacements, No Penetration, Two-Screw Model](image)

Across the entire fragment, the average displacement was 0.922mm with maximum and minimum displacements of 1.036mm and 0.856mm, respectively. This maximum was observed on the fracture surface at the lateral edge of the fragment. Just as with the fragment in the bonded contacts model, the minimum axial displacement occurred on the medial face of the
fragment just above and slightly anterior to the posterior screw hole. In the proximal tibia, the lateral side just proximal to the fracture exhibited the highest displacement. The minimum was found on the fracture surface adjacent to the lateral edge of the posterior screw hole (Figure 15). Experimental results showed less gapping at the posterior fracture in comparison to the anterior; and therefore, less movement would be expected on the posterior side of the modeled construct.

![Image: Figure 15, Max and Min Tibia Displacements, No Penetration, Two-Screw Model](image)

**Figure 15, Max and Min Tibia Displacements, No Penetration, Two-Screw Model:** The above image depicts a superior view of the right proximal tibia. The maximum displacement occurred at the lateral tibia, while the minimum was found on the fracture surface near the entry point of the posterior screw.

### 3.1.4 Experimental Results, Medial Malleolar Sled™ Fixation

Just as was done with the two-screw model, both force and displacement were observed during experimental testing of the Sled™ construct (Figure 16), and both bonded and no penetration models were run in Simulation. The average force observed for ten cadaveric ankles fixed with the Medial Malleolar Sled™ at a displacement of 1.00 mm (SD = 0.009 mm) (which matched a bead displacement range of -0.05mm, 0.20mm) was 43.61 N (SD = 16.500 N).
Failure occurred primarily due to the Sled™ prongs pulling through and breaking the fragment. One specimen failed because the screws cut through the proximal bone (Figure 17). As was the case with two-screw fixation, distraction was initially noted at the anterior edge of the fracture.

**Figure 16, Force vs. Displacement, Sled™ Fixation**: The plots above show the force versus (A) actuator excursion and (B) fragment displacement recorded for ten matched cadaveric pairs fixed by the Sled™ construct.
3.1.5 Bonded Contacts Model, Medial Malleolar Sled™ Fixation

The force acting at the proximal surface of the bonded tibia assembly (n = 1) was 61.64N, which was just outside one standard deviation of the experimental mean. Similar to the two-screw models, the total force was nonuniformly distributed among the deltoid bands (Table 5).

<table>
<thead>
<tr>
<th>Deltoid Component</th>
<th>Total Force (N)</th>
<th>Pretension (N)</th>
<th>Net Force (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATiT a - 1</td>
<td>8.11</td>
<td>6.26</td>
<td>1.75</td>
</tr>
<tr>
<td>ATiT a - 2</td>
<td>8.06</td>
<td>6.19</td>
<td>1.95</td>
</tr>
<tr>
<td>TiNa - 1</td>
<td>7.67</td>
<td>5.96</td>
<td>1.75</td>
</tr>
<tr>
<td>TiNa – 2</td>
<td>9.38</td>
<td>6.77</td>
<td>2.95</td>
</tr>
<tr>
<td>TiCa – 1</td>
<td>8.21</td>
<td>5.83</td>
<td>1.97</td>
</tr>
<tr>
<td>TiCa – 2</td>
<td>7.80</td>
<td>5.66</td>
<td>1.68</td>
</tr>
<tr>
<td>PTiT a - 1</td>
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<td>2.23</td>
</tr>
<tr>
<td>PTiT a - 2</td>
<td>5.28</td>
<td>3.89</td>
<td>1.39</td>
</tr>
</tbody>
</table>

Table 5: The distribution of force among the four deltoid components (each broken into two bands, denoted by 1 or 2) is represented above for the bonded condition. Again, the net force and pretension are shown. (ATiT a = Anterior Tibiotalar; TiNa = Tibionaviccular; TiCa = Tibiocalcaneal; PTiT a = Posterior Tibiotalar)

Regarding stress, the average Von Mises stress was 1.65MPa across the assembly. The maximum stress was 61.08MPa and occurred in the anterior Sled™ prong within the fragment.
When the fragment was examined alone, the average stress across the fragment body was 1.86MPa, with maximum and minimum stresses of 47.99MPa and 2.99e-6MPa, respectively. The maximum, which was above the yield strength of the osteoporotic trabecular bone modeled, occurred along the anterior Sled prong near the point of maximum assembly stress. This model observation corresponded with experimental results in that the bone near the Sled prongs constituted a point of failure in tested specimens. The minimum occurred at and below the anterolateral fracture surface. (This minimum also corresponded to the minimum found for the assembly.) The whole tibia experienced an average stress of 1.51MPa with a range of 6.61e-3MPa to 31.93MPa. The maximum occurred on the fracture surface at the interface of the posterior Sled™ prong and bone layers. (NOTE: This interface was a consequence of modeling where the angle of insertion of the Sled™ was dependent on the outer bone profile. The Sled™ profile was laid on top of and as close to the bone profile without overlapping the two components; however, Sled™ placement still resulted in the prong inserting at the intersection of the two bone layers.) In general, higher stresses radiated around and along the length of the prongs (Figure 18). The minimum stress was found within the trabecular bone near the end of the proximal Sled™ screw. The lowest stresses in the model were generally found along the periphery of the proximal screw hole. The observation of low stresses around the screws agreed with the experimental finding that most specimen exhibited failure due to the Sled™ slicing through the fragment rather than pullout of the screws.
Figure 18, Stress Concentrations along Hardware, Bonded Contacts, Sled™ Model: Anterior section view showing higher stresses radiating along the anterior Sled™ prong. (Deltoid bands, calcaneus, navicular, talus, and other Sled™ components not shown.)

Figure 19, Assembly Displacements, Bonded Contacts, Sled™ Model: The above image shows (A) the deformed, bonded Sled™ model following application of one millimeter of displacement (navicular, calcaneus, talus not shown) and (B) the maximum and minimum displacements experienced by the tibia and fixation construct.
The average displacement in the y-direction observed for the model was 0.982mm, with a maximum of 1.043mm occurring along the lateral proximal tibia. The minimum, 0.903mm, was found at the posterior Sled™ prong (Figure 19). Additionally, the average distraction noted at the fracture site was 0.004mm. Focusing solely on the fragment, the average displacement was 0.957mm. The maximum and minimum displacements were 1.036mm and 0.915mm, respectively. The given maximum occurred at the lateral side of the fragment, while the minimum was found on the medial surface at the posterior entry point of the Sled™. Regarding the whole tibia, an average displacement of 0.988mm was noted. As previously stated, the maximum was 1.043mm, while the minimum displacement was 0.918mm and was seen at the fracture surface just medial to the posterior Sled™ prong (Figure 20). Minimum displacements would be anticipated on the posterior side of the construct as experimental testing showed less gapping at the posterior side of the fracture compared to the anterior side.

![Figure 20, Max and Min Displacements, Bonded Contacts, Sled™ Model](image)

The above image shows the maximum and minimum displacements in the y-direction experienced by both the whole tibia and malleolar fragment. The maximum for each component occurred along the lateral side of the tibia, with the fragment’s maximum occurring specifically at the fracture line. Both minima were observed on the medial side, with the whole tibia’s minimum occurring at the fracture line and the fragment’s minimum appearing on the medial surface near the posterior hole. (Sled™ component, deltoid bands, navicular, calcaneus, talus not shown.)
3.1.6 No Penetration Model, Medial Malleolar Sled™ Fixation

Of the forty-four no penetration contact sets initially incorporated in the no penetration Sled™ model, only thirty-two were included as active, no penetration contact sets in the final model due to solving errors. This setup yielded a force value of 61.65N in the y-direction (n=1). Similar to the bonded model, the no penetration model also resulted in a force value just outside one standard deviation of the experimental mean. Force was distributed unevenly within the deltoid bands (Table 6).

<table>
<thead>
<tr>
<th>Deltoid Component</th>
<th>Total Force (N)</th>
<th>Pretension (N)</th>
<th>Net Force (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATiTa - 1</td>
<td>8.12</td>
<td>6.26</td>
<td>1.76</td>
</tr>
<tr>
<td>ATiTa - 2</td>
<td>8.05</td>
<td>6.19</td>
<td>1.96</td>
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<td>TiNa - 1</td>
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</tr>
<tr>
<td>TiNa – 2</td>
<td>9.38</td>
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<td>PTiTa - 1</td>
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<td>4.89</td>
<td>2.23</td>
</tr>
<tr>
<td>PTiTa - 2</td>
<td>5.28</td>
<td>3.89</td>
<td>1.39</td>
</tr>
</tbody>
</table>

Table 6: The distribution of force among the four deltoid components (each broken into two bands, denoted by 1 or 2) is represented above for the no penetration condition. With the exception of the anterior tibiotalar bands, the remaining deltoid bands generated the same net forces as they did in the bonded model. (ATiTa = Anterior Tibiotalar; TiNa = Tibionavicular; TiCa = Tibiocalcaneal; PTiTa = Posterior Tibiotalar)

With regard to stress, the average value across the assembly was 1.63MPa with a range of 4.93e-5MPa to 60.77MPa. Both the minimum and maximum occurred in the fragment, with the minimum stress located in the antero-lateral fragment and the maximum located immediately inferior to the fracture surface along the lateral wall (Figure 21). When focusing specifically on the fragment, the average stress was 2.29MPa with high stresses generally found along the
anterior Sled™ prong hole. This result corresponded with the experimental observation that specimens tended to distract and fail anteriorly.

The whole tibia exhibited an average stress of 1.43MPa with stress values ranging from 5.58e-3MPa to 40.07MPa. The maximum was observed along the postero-medial fracture surface, while the minimum was noted within the trabecular bone. Higher stresses were generally seen along the posterior Sled™ prong hole, while low values were observed throughout the trabecular bone. As the majority of specimen failed at the fragment due to the prongs slicing through it, low stresses elsewhere would be expected and so the latter model observation of low trabecular stresses was consistent with experiment.

The average displacement observed for the assembly (discounting the fixed bones) was 0.979mm. Just as was seen in all tension models, the no penetration Sled™ model also had a maximum displacement of 1.043mm at the lateral proximal tibia. The minimum value was
0.902mm and was found in the posterior Sled™ prong. The average fracture distraction was 0.001mm. Across the fragment, the average displacement was 0.954mm with a maximum of 1.037mm noted at the antero-lateral fragment. The minimum, 0.915mm, was observed at the posterior Sled™ prong. The whole tibia displaced an average of 0.987mm with a minimum displacement of 0.918mm observed at the fracture surface just medial to the posterior prong (Figure 22). Minimum displacements at the posterior side of the construct support experimental findings in that gapping, or opening angles, at the fracture site tended to favor the anterior side over the posterior side (i.e. minimum displacements would be expected along the posterior construct).

**Figure 22, Max and Min Displacements, Tibia, No Penetration, Sled™ Model:** The whole tibia, shown with its maximum and minimum displacements, exhibited the same value and location of maximum displacement as all other tension models. (Fragment, deltoid bands, navicular, calcaneus, talus not shown.)
3.2 Torsion Study

With respect to the torsion studies, experimental results are presented as axial torque for an internal tibia (Instron actuator) rotation. (Internal rotation of the tibia is equivalent to an external rotation of the foot relative to the tibia.) Similar to the tensile models, results for the torsion models are presented as torque values and contour plots of von Mises stress and displacement. Maximum and minimum stresses are given for each model as a whole, but as with tensile analyses, the focus of the results lies on the malleolar fragment and tibia proximal to the fracture. Displacement is presented as average displacement of the fragment and tibia fracture surfaces, as well as the difference between the two. Finally, results related to each construct are presented for both bonded and no penetration models.

3.2.1 Experimental Results, Two-Screw Fixation

During experimentation, torque was tracked against axial rotation (Figure 23). Similar to tensile results, torsion results from the finite element analysis were generated as contour plots rather than continuous torque-rotation plots. Therefore, a specific rotation and the torque at that rotation were chosen as a means of comparison between experimental and computational tests. Again, a small strain assumption was made and so a linear static model was used. Rotation referred to that of the actuator as this was a user-controlled input.
At 2.00 degrees of actuator rotation (SD = 0.012 degrees), the mean axial torque experienced by eleven cadaveric specimen fixed with the two-screw construct was 0.13N-m (SD = 0.060N-m). Failure modes included screw loosening within the bone and fracturing of the fragment as the posterior screw broke through the lateral fragment wall (Figure 24). One sample failed due to ligament rupture.

**Figure 23, Axial Torque vs. Rotation, Two-Screw Fixation:** The above curves represent axial torque versus rotation data obtained for eleven matched cadaveric specimens fixed with the two-screw construct.

**Figure 24, Torsion Failure Modes, Two-Screw Fixation:** (A) A superior view of the fracture surface on the proximal tibia shows evidence of screw loosening, which resulted in a “wind-shield wiper” effect within the bone (left specimen). (B) A lateral view shows the fractured fragment of a left specimen as the posterior screw broke through the lateral fragment wall.
3.2.2 Bonded Contacts Model, Two-Screw Fixation

Similar to the tensile models, the bonded torsion models included no penetration contacts at the fracture surface. Additionally, these models included two designated bonded contacts due to the inclusion of a beam element at the proximal end of the model. Since Simulation interpreted the modeled box as a beam, the beam had to be bonded to the plate, which in turn, was bonded to the remaining tibia. Thus, the bonded model for torsion simulations is defined as having the aforementioned contacts.

A torque value of 0.21N-m was recorded for the bonded, two-screw model (n = 1). This value was just outside one standard deviation of the experimental average. With regard to von Mises stress, the average, maximum, and minimum values in the assembly (including tibia, fragment, and hardware) were 1.16MPa, 117.53MPa, and 0 MPa. The maximum occurred at the interface between the box and plate while the minimum occurred within the trabecular region.

When observing the tibia independently, the average stress was 0.92MPa with a range of 0MPa to 117.50MPa. The minimum occurred at the postero-lateral tibia, while the maximum corresponded to that reported for the overall assembly. Near the hardware, a maximum of 14.09MPa was noted along the anterior screw hole in the trabecular bone (Figure 25). In general, higher stresses in the tibia immediately proximal to the fracture surface occurred along the screw-bone interfaces. As for the fragment, the average stress observed was 0.84MPa with a maximum and minimum of 23.11MPa and 3.72e-5MPa, respectively. The maximum was observed at the ligament insertion site, and the minimum was noted at the antero-lateral fragment. Near the hardware, a range of 0.4 to 11.6MPa was observed in and around the screw holes, with the maximum at the anterior screw hole (Figure 26). High stresses would be
expected at the screw holes because as the fragment tended to move with the foot (i.e. opposite the direction of tibial rotation) during the experiment, the anterior fragment tended to move anteriorly and laterally while the posterior fragment moved anteriorly and medially. Such motion would likely result in stress concentrations as a result of the screws pressing against the bone. Thus this model observation correlated with experimental findings.

**Figure 25, Stress Concentration near Hardware, Bonded Contacts, Two-Screw Model:** Near the hardware proximal to the fracture line, the maximum stress observed was along the length of the anterior screw as can be seen in the above posterior view.

**Figure 26, Stress Concentration near Hardware in Fragment, Bonded Contacts, Two-Screw Model:** Higher stress concentrations can be seen in and around the screw holes of the fragment (transverse section view looking down on fragment).
Displacement within this model (as well as the models yet to be discussed) was observed as average fracture movement in the x-, y-, and z-directions, or sagittal, transverse, and coronal planes, respectively (Table 7). Positive values for the fragment or tibia represented movement in the medial, anterior, or superior directions. Per the data, both fragment and tibia moved anteriorly and laterally, with the fragment moving more laterally than the tibia. An average fracture distraction, or gap, of 0.001mm was measured.

<table>
<thead>
<tr>
<th>Direction (Plane)</th>
<th>Fragment (mm)</th>
<th>Tibia (mm)</th>
<th>Relative Displacement (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>x- (sagittal)</td>
<td>-1.056</td>
<td>-1.048</td>
<td>0.008</td>
</tr>
<tr>
<td>y- (transverse)</td>
<td>0.057</td>
<td>0.058</td>
<td>0.001</td>
</tr>
<tr>
<td>z- (coronal)</td>
<td>0.961</td>
<td>0.961</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Table 7: The above table shows the average displacement (mm) in each plane exhibited by the fracture surface of both the fragment and tibia. Movement of the fragment relative to the tibia represents the difference between the two surfaces. Positive fragment or tibia values in the x-, y-, and z-directions denote movement in the medial, superior, and anterior directions, respectively.

3.2.3 No Penetration Model, Two-Screw Fixation

The no penetration model (n = 1) generated an axial torque of 0.18N-m, which was within one standard deviation of the experimental mean. In addition to torque, stress values were observed for the entire assembly (excluding the fixed talus, calcaneus, and navicular) and resulted in an average of 1.09MPa and a range from 0MPa to 97.56MPa. The maximum was observed at the interface between the beam element (i.e. box at proximal tibia) and plate. The minimum was noted at the antero-lateral fragment.

The tibia alone experienced an average stress of 0.43MPa, while its maximum coincided with the assembly maximum. A minimum stress of 0MPa was observed along the posterior tibia at the surface of the cortical layer. Bone of the tibia proximal to the fracture surface and surrounding the hardware was also examined. A local maximum of 2.30MPa occurred along the
anterior screw (Figure 27A). Simultaneously, the fragment exhibited an average stress of 1.28MPa, with a maximum of 48.18MPa that occurred in the bone along the neck of the anterior screw hole (Figure 27B). This corresponded with experimental failure in that higher stresses would be expected around the neck of the anterior screw as the fragment traveled with the foot. 3.94e-6MPa was recorded as a minimum and occurred in the antero-lateral fragment.

Figure 27, Stress Concentrations, Tibia and Fragment, No Penetration, Two-Screw Model: (A)Within the tibia (shown here in an anterior view) proximal to the fracture surface, the highest stress concentrations were noted at the anterior screw hole (white arrow). (B) A local maximum occurred near the neck of the anterior screw hole (inferior view of fragment).
With respect to displacement, average fracture movement was recorded (Table 8). Tibia and fragment movement in the anterior and lateral directions was greater in the no penetration model than the bonded model, as well as movement of the fragment relative to the tibia. Little gapping was observed at two degrees of rotation.

Table 8: Average Fracture Displacement, Relative Displacement
No Penetration Contacts, Two-Screw Model

<table>
<thead>
<tr>
<th>Direction</th>
<th>Fragment (mm)</th>
<th>Tibia (mm)</th>
<th>Relative Displacement (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>x- (sagittal)</td>
<td>-1.729</td>
<td>-1.708</td>
<td>0.021</td>
</tr>
<tr>
<td>y- (transverse)</td>
<td>-0.038</td>
<td>-0.039</td>
<td>0.001</td>
</tr>
<tr>
<td>z- (coronal)</td>
<td>1.173</td>
<td>1.155</td>
<td>0.018</td>
</tr>
</tbody>
</table>

Table 8: The above table shows the average displacement (mm) in each plane exhibited by the fracture surface of the fragment and tibia as well as the relative displacement. Positive values in the x-, y-, and z-directions denote movement of the fragment or tibia in the medial, superior, and anterior directions, respectively.

Figure 28, Displacements, No Penetration, Two-Screw Model: (A) Medial/lateral, (B) superior/inferior, and (C) anterior/posterior, movements are depicted above for the assembly. As was the case with the bonded model, the anterior colliculus exhibited the most anterior and lateral movement in the assembly.
3.2.4 Experimental Results, Medial Malleolar Sled™ Fixation

As with torsional testing of the two-screw construct, curves denoting torque versus actuator rotation were also obtained for specimens fixed with the Sled™ (Figure 29). At 2.00 degrees (SD = 0.011 degrees) of actuator rotation, the average axial torque exhibited by eleven specimen fixed with the Sled™ was 0.13N-m (SD = 0.075N-m). For these specimens, failure modes included screw loosening, bending of the Sled™ prongs, and fragment fracture at the insertion site of the prongs (Figure 30). One specimen, which was the matched pair of the two-screw specimen that failed via ligament rupture, also failed due to ligament breakage.

Figure 29, Axial Torque vs. Actuator Rotation, Sled™ Fixation: Axial torque versus angualr rotation is depicted above for eleven matched cadaveric ankles fixed with the Medial Malleolar Sled™.
3.2.5 Bonded Contacts Model, Medial Malleolar Sled™ Fixation

At two degrees of applied rotation, the bonded Sled™ assembly (n = 1) exhibited 0.11N-m of axial torque, which was within one standard deviation of the experimental mean. Additionally, the assembly generated average, maximum, and minimum stresses of 0.93MPa, 117.58MPa, and 0MPa, respectively. Like the two-screw torsion models, the assembly maximum occurred at the beam and plate interface. The minimum occurred at the proximal screw.

In the isolated tibia, the maximum corresponded with the assembly maximum, while an average of 0.99MPa was recorded. Nearer to the hardware, the maximum stress was 9.60MPa, which was found near the posterior Sled™ prong just proximal to the fracture surface. When considering the fragment alone, the average von Mises stress across the body was 0.73MPa, with a range of 1.05e-5MPa to 17.12MPa (Figure 32). The minimum was observed along the anterolateral fragment, while the maximum occurred within the trabecular bone along the anterior sled prong. This maximum did surpass yield. Observations of high stresses near the prongs in both the tibia and fragment were consistent with experimental findings. Because testing indicated that...
one mode of failure was breakage at the Sled™ prong insertion site, high stresses would be expected in this area.

Figure 31, Stress Concentration, Fragment, Bonded Contacts, Sled™ Model: This anterior section view depicts relatively higher stresses around the anterior Sled™ prong hole in comparison to the surrounding bone. This is indicative of a failure region, which corresponds to failure via fragment fracture at the prong insertion site. (Calcaneus, navicular, talus, and deltoid bands not shown.)

Following stress analysis, average fracture displacement was examined and revealed that the fragment moved anteriorly and laterally relative to the tibia. This was consistent with testing. Gapping (i.e. vertical fracture distraction) remained small as in the two-screw models.

Table 9: Average Fracture Displacement, Relative Displacement Bonded Contacts, Sled™ Model

<table>
<thead>
<tr>
<th>Direction (Plane)</th>
<th>Fragment (mm)</th>
<th>Tibia (mm)</th>
<th>Relative Displacement (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>x- (sagittal)</td>
<td>-1.590</td>
<td>-1.589</td>
<td>0.001</td>
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<tr>
<td>y- (transverse)</td>
<td>-0.113</td>
<td>-0.112</td>
<td>0.001</td>
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<tr>
<td>z- (coronal)</td>
<td>0.638</td>
<td>0.628</td>
<td>0.010</td>
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</tbody>
</table>

Table 9: Average fracture displacement for the bonded Sled™ model indicated overall anterior movement of the tibia-fragment construct. Gapping in axial direction and fragment-tibia overlap in the sagittal plane were small. (Average fragment and tibia movement were medial, superior, and anterior if positive in the x-, y-, and z-directions, respectively.)

3.2.6 No Penetration Model, Medial Malleolar Sled™ Fixation

Several iterations of the no penetration model were attempted and included various combinations of no penetration contacts; however, each iteration yielded an equilibrium error. Results were saved for the simulation up to the point of the error and these results are reported
here. The final model, discussed below, included those contacts in the bonded model as well as no penetration contacts between the Sled™ and the fragment.

A torque value of 0.11N-m was generated in this model (n = 1), which was within a standard deviation of the experimental mean. The whole assembly (excluding the fixed bones) generated an average stress of 1.51MPa. Stresses ranged from 0MPa to 115.64MPa, with the minimum and maximum occurring at the proximal screw within the trabecular bone and Sled™ prong, respectively.

For the tibia alone, an average of 1.06MPa was observed. Like the other torsion models, the maximum coincided with the overall assembly maximum. The location of the minimum was found in the trabecular region in the lateral portion of the bone. Furthermore, high stress concentrations were examined closer to the hardware. A value of 37.96MPa, which was greater than yield, was observed in the trabecular bone along the anterior prong (Figure 32).
Figure 32, Stress Concentrations Surrounding Hardware, No Penetration, Sled™ Model: This anterior cross section depicts a high stress concentration (A) at the bone along the Sled™ prong (cortical layer not shown) and (B) along the anterior prong within the fragment.

When the fragment was isolated, an average stress of 1.38MPa was recorded. Stresses ranged from 3.14e-4MPa to 87.76MPa. The minimum was located at the antero-lateral fragment and the maximum was observed at the bone along the anterior Sled™ prong interface. Again,
this latter observation correlated with experimental findings as this location was a reported failure region.

Compared to the tibial fracture surface, the fragment fracture surface slid more anteriorly (similar to experimental findings) and laterally, and an average fracture distraction of 0.012 millimeters was measured (Table 10).

<table>
<thead>
<tr>
<th>Direction (Plane)</th>
<th>Fragment (mm)</th>
<th>Tibia (mm)</th>
<th>Relative Displacement (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>x- (sagittal)</td>
<td>-1.576</td>
<td>-1.571</td>
<td>0.005</td>
</tr>
<tr>
<td>y- (transverse)</td>
<td>-0.121</td>
<td>-0.109</td>
<td>0.012</td>
</tr>
<tr>
<td>z- (coronal)</td>
<td>0.666</td>
<td>0.616</td>
<td>0.050</td>
</tr>
</tbody>
</table>

Table 10: The above table shows that the fragment moved anteriorly and laterally relative to the tibia. More gapping in the vertical direction compared to the other torsion models was demonstrated as well. Again, positive fragment and tibia values in the x-, y-, and z-directions denoted movement in the medial, superior, and anterior directions, respectively.
CHAPTER 4 Discussion

4.1 Model Set Up

4.1.1 Choice of Applied Loading

During tensile experimental tests, a vertical displacement was induced by applying a constant displacement rate of 1 millimeter per second to each specimen. Similarly, an axial rotation was induced during torsion testing by applying a constant angular rotation rate of 1 degree per second. These experimental conditions were simulated in the computational model by applying a specific displacement or rotation, which represented actuator motion, to the proximal tibia. Because a small strain assumption was made and static loading applied, one millimeter (for tensile studies) and two degrees (for torsion studies) were selected as the induced perturbations. All components were assumed to behave in the linear ranges of their stress-strain curves.

4.1.2 Contact Sets, Related Errors and Remedies

Initial tension models for both the two-screw and Sled™ constructs were created with no penetration contacts between all component interfaces; however, the result of these models was often an error stating that equilibrium had not been achieved. As a result of the error, another approach was used in which all contact sets aside from the no penetration sets at the fracture interface were suppressed. This effectively changed the suppressed contact sets to bonded contacts as the entire model was under Simulation’s default global bonded condition. The model was re-run and the Simulation analysis progressed to completion. Following a successful bonded run, contact conditions were unsuppressed a group at a time during subsequent iterations, with
each group being selected arbitrarily. The goal of unsuppressing contact sets in this manner was to gradually build up to a no penetration model with as many nonbonded contacts that would solve to completion.

With regard to the initial two-screw, tension models, once successful bonded and no penetration models were obtained, the two were compared. Ultimately, it was determined that the bonded condition resulted in a higher resultant force than the no penetration model, with the difference being approximately 15N. Because a bonded contact acts as though two surfaces are glued together, it is reasonable to expect that a higher resistance to tension would be generated in the model containing primarily bonded contacts. While the final no penetration model did not exhibit as drastic of a difference from the bonded model, the force in the no penetration model was slightly below that of the bonded model, thus upholding the trend noted in the initial models.

For the Sled™ assembly, the equilibrium error mentioned above was one of two errors observed for the no penetration tension model. Just as with the two-screw fixation, contact sets were suppressed and a bonded model was run in Simulation. Force values for the initial bonded models were approximately 101N. The second error was noticed as contact sets were gradually unsuppressed for the Sled™ assembly. While the resultant force decreased by only 15N in the two-screw model following the addition of no penetration contacts, it decreased sharply in the Sled™ model with total resultant values of various iterations ranging from approximately 8 to 18N. Upon closer examination of the deformed result, it was determined that, as the tibia displaced, the screw heads passed through the Sled and washer instead of resisting the motion of these latter components. As a result, little force was generated due to the applied loading.
In an attempt to remedy the issue of components passing through one another, additional contact sets were added between non-touching interfaces (i.e. screw head and washer, screw head and Sled). SolidWorks Simulation allows contact sets to be applied manually and automatically. When identifying contact sets automatically, the user may specify whether “touching faces” or “non-touching faces” should be examined. Prior to identification of interfering components, contacts sets were found automatically between touching faces only. By selecting two components for examination and prompting Simulation to identify interfaces within a specified gap, additional no penetration contacts were included between non-touching faces as well. Ultimately, while the aforementioned contact sets were included in the model and the issue of interfering components was eliminated, the final no penetration Sled model included some bonded sets due to the continuing equilibrium error.

While no penetration contacts had to be suppressed in order for the Sled™ tension model to run to completion, a similar run was not achieved in the torsion studies. Suppression of groups of contacts continued to yield an equilibrium error, and so, results were saved up to the point just prior to the error and reported. The no penetration sets included the bone and prong interfaces in the fragment, as well as the fracture surface. Because experimental results showed bending of the prongs or breaking of the fragment, it was determined that contacts allowing for such sliding or separation be included in the model. Furthermore, in an effort to prevent component interference in the model, additional contacts were added between the washer and screws, as well as the Sled™ and proximal screw.
4.1.3 Deltoid Ligament, Assignment of Material Properties

In order to assign material properties to the deltoid ligament, details of the experiment were used to make certain assumptions within the model. Because it was difficult to have an exact knowledge about the state of the deltoid during the experiment, matching experimental data was the most appropriate approach to correctly set up the computational model. Two factors were considered in the determination of total ligament strain at the start of the test. First, per Fung [43], soft tissues are often in a strained state within the body; and therefore, the assumption and application of in-situ strain (4%) was deemed applicable to this study. Secondly, it was reasonable to assume that the anatomic reduction contributed to the overall strain in the ligament. A loss of one millimeter of bone (thickness of the saw blade) in the transverse plane due to the creation of the simulated fracture effectively displaced the origin of the deltoid superiorly and presumably increased the strain in the ligament. Per the data presented in Funk et al. [39], force (pretension) and stiffness of each deltoid band were determined at the total calculated strain. (Note: Since the tibionaviculcar band was not included in the study conducted by Funk et al. [39], this band was assigned the same properties as those of the anterior tibiotalar band.)

In the initial tension models, the application of the aforementioned pretensions and stiffnesses yielded force values within two and three standard deviations of the experimental mean. In an attempt to bring these values closer to the mean, adjustments were made to the ligament properties. Various combinations of ligament stiffnesses and pretensions were input into the model; however, it was determined that a reduction in posterior tibiotalar stiffness and pretension yielded a resultant force within one standard deviation of the experimental mean.
In addition to bringing the model values closer to the experimental data, another observation was made that supported the decrease of posterior tibiotalar properties. During tensile testing, it was noted that fracture distraction was first observed on the anterior side of the fragment. One could assume that the resultant force in the anterior deltoid band was higher than that in the posterior band. The opposite was observed in the initial tensile model; however, as the posterior bands generated the highest resultant forces. Independent of the conflicting experimental and model behavior, high posterior tibiotalar resultant forces was reasonable since these bands were assigned the highest pretensions and stiffnesses of the deltoid bands. Because of this observation, any plan to adjust the ligament properties included only reduction with respect to the posterior tibiotalar bands. The remaining bands were left unchanged in the final model.

Within the torsion models, the above spring representation of the deltoid was maintained. However, no additional shear components were included in the models. This provides a possible explanation as to why less movement between the fragment and tibia were seen in all torsion models. Although such components were not included, resistance to torsion was still offered via the horizontal components of the spring pretension. Therefore, the model setup within this study was deemed an acceptable approximation of the experiment.

4.2 Bonded versus No Penetration Models

4.2.1 Tension Simulations

Unlike in the case of the two-screw construct where the force in the bonded tensile model exceeded that of the no penetration model, the bonded and no penetration Sled™ models generated similar forces (61.64N versus 61.65N, respectively). This is most likely due to the fact
that the no penetration model was run with some suppressed no penetration (i.e. bonded) contacts. The suppressed contacts were those between the Sled™ prong-bone and washer-Sled™ interfaces. Suppression of these contact sets, in particular the Sled™ prong-bone contacts, resulted in these interfaces falling under the “global bonded” condition. The only deltoid bands showing a difference in net force were those comprising the anterior tibiotalar band, and these differences were seen in the second decimal place.

In general, greater variation was observed between the bonded and no penetration models for the two-screw construct in comparison to the Sled™ assembly. For example, maximum stress due to the two-screw fixation in the no penetration model was slightly more than twice that found in the bonded model, whereas the maximum stress was similar (less than 0.5MPa difference) for the Sled™ models. Again, this is likely due to the suppression of some of the no penetration sets, particularly those at the Sled™ prong-bone interfaces. As previously mentioned, the majority of specimen fixed with the Sled™ failed via the prongs pulling through the distal fragment. While the no penetration prong-bone interfaces were left suppressed to allow the model to run, these were more likely to experience movement in comparison to the screw-bone interfaces. Therefore, it is reasonable that the results obtained from both bonded and no penetration models for the Sled™ construct were similar.

4.2.2 Torsion Simulations

For the Sled™ construct, no change in torque and an increase in average fracture displacement were noted for the no penetration model in comparison to the bonded model. A greater difference in relative displacement would be expected in the no penetration model as components of the bonded model have less freedom to move relative to one another. An added
reason as to why more motion was observed in the no penetration model has to do with the placement of bonded and no penetration contacts. For example, in the tibia proximal to the fracture, the screws and prongs were bonded to the bone. The fragment, on the other hand, only had no penetration contacts assigned between it and the prongs. As a result, the fragment had more freedom to move relative to the tibia thereby resulting in greater displacements. This is in contrast to the bonded model whose tibia and fragment moved more as a unit rather than independently of one another.

For the screw construct, decreased torque and greater relative displacements were noted for the no penetration model in comparison to the bonded model. Specifically, smaller differences in motion were recorded in all three anatomic planes in the bonded assemblies. As with the bonded Sled™ model, the fragment and tibia in the two-screw assembly appeared to move more like a single unit with small displacements. Again, this is likely a result of bonded interfaces throughout the assembly. The no penetration model allowed for more relative motion between interfaces (i.e. greater relative displacements), thus requiring less torque to achieve two degrees of rotation.

4.3 Two-Screw versus Medial Malleolar Sled™, Implications of Tensile Results

4.3.1 Average Fracture Distraction

When bonded and no penetration two-screw models were compared, average fracture distraction was greater in the no penetration model (0.013mm, no penetration versus 0.005mm, bonded). This observation was expected since the bonded model contained mostly bonded interfaces, such that relative movement between surfaces was not permitted. This result also implies that the assignment of no penetration contacts, rather than bonded contacts, is more
appropriate for the majority of interfaces since the ability of different components to slide or separate from one another is more representative of the experimental set up.

A comparison of the two constructs’ bonded models, as well as their no penetration models, revealed a lower average fracture distraction due to the Sled™. This is likely due to the “wrap-around” nature of the Sled™ design captured in the model. Whereas the two-screw construct merely grasps the fragment and proximal bone interiorly via the engagement of threads, the Sled™ engages the proximal bone interiorly via screw threads and exteriorly by wrapping around the fragment before hooking back into the bone. Per the computer models, a lower fracture distraction, along with a higher resistance to tension (i.e. higher resultant force at 1mm of applied displacement), suggests that the Sled™ is a stronger construct in tension in comparison to the two-screw fixation and is better able to maintain a “closed” fracture.

4.3.2 Displacement Observations

All tension models, irrespective of the fixation construct or type of model (i.e. bonded or no penetration), resulted in the same maximum vertical displacement (1.043mm). Furthermore, this displacement was found in the same location in all models, which was the lateral most side of the tibia. Because it serves as the origin of the deltoid, the medial malleolus experienced limited motion in comparison to the lateral tibia in the model. Therefore, as the proximal tibia was pulled in tension, the distal medial tibia resisted more than the distal lateral tibia. Also, it is suspected that the maxima of the models did not change due to the fact that the lateral tibia was far from the applied loading, fixation construct, and deltoid restraint. Because no external loading or constraints were affecting the lateral portion of the models, the lateral tibia showed consistent behavior across all models in response to the proximal applied loading.
Just as was seen among maximum displacements, a trend was observed for minimum displacements in the tension models as well. While the values were not identical, the locations were similar as all minima occurred in the posterior fixation hardware (i.e. posterior screw head in both two-screw models and posterior Sled™ prong in both Sled™ models). This corresponds with visual observations made at the time of testing. Gapping was usually first noted along the anterior side of the fragment, while the posterior side had relatively less movement. Thus, the finding that lowest displacements were observed in the posterior constructs of all models is reasonable.

When comparing no penetration models only, a lower average displacement was measured in the Sled™ assembly. This supports the earlier assertion that the Sled™ is better able to maintain a closed fracture in comparison to two-screw fixation. Again, this is likely due to the design of the Sled™ in the model. Unlike the two screw fixation which simply inserts through the fixed bones, the Sled™ inserts into and wraps around the fragment thereby improving the fragment’s ability to stay in contact with the proximal tibia.

**4.3.3 Stress Observations**

At one millimeter of applied vertical displacement, a higher average stress was noted in the two-screw model as compared to the Sled™ model. This suggested that the medial malleolus was under less duress due to the Sled™ construct than the two-screw fixation. Furthermore, this result alluded to a better long-term performance of the Sled™. Specifically, when examining no penetration models, both the average and maximum stresses generated in the two-screw assembly were over one and a half times that noted in the Sled™ assembly, thus predicting earlier bony failure in the former model rather than the latter. These model observations were
generally in line with the experimental observation that specimens fixed via Sled™ tended to fail at a higher force than those fixed with two-screws.

4.4 Two-Screw versus Medial Malleolar Sled™, Implications of Torsion Results

4.4.1 Average Fracture Displacement

With regard to gapping, the bonded models showed the screws having equal distraction. Magnitudes were likely small due to the presence of bonded contacts; little movement would be expected since the hardware was bonded to the bone both in the proximal tibia and fragment.

A difference was observed in gapping in the no penetration models, with the Sled™ exhibiting much higher gapping. This was opposite the trend noted during experimentation. A possible cause of this may have been the fit of the Sled™ profile against the bone. The Sled’s™ prongs are of the same length, and thus allow it to be used for both right and left ankle fixation. However, the colliculi do not protrude the same distance from the distal tibia (i.e. the posterior colliculus is shorter than the anterior) and so some space between hardware and bone may exist after fixation. This space is further exaggerated in the SolidWorks model as the Sled™ was designed as a rigid object. Whereas during experimentation the hardware could be installed such that it followed the bone profile as closely as possible, the Sled™ could not be “molded” around the bone of the SolidWorks model. Therefore, the bone and hardware did not sit flush against one another thereby leaving space within which the fragment could move.

Observations of anterior/posterior and medial/lateral movement were also noted. While the no penetration, two-screw model exhibited more anterior movement of the tibia and fragment in comparison to the Sled™ model, the relative motion between the two was greater in the no penetration Sled™ model. The first of these two observations correlated with experimental
findings in that, although no statistical difference was measured, a trend toward more anterior movement was noted among specimens fixed with screws. The no penetration models also showed greater lateral movement of the tibia and fragment when fixed with screws. This observation also matched experiment in that the Sled™ trended towards more medial movement than the screws. In general, the no penetration models exhibited a greater change in average displacements between the fragment and tibia in both the anterior/posterior and medial/lateral directions. More relative movement would be expected due to the presence of no penetration interfaces in these models.

4.4.2 Stress Observations

The designation of a beam at the proximal end of the tibia was deemed the most direct way to obtain torque outputs for the torsion simulations. As a result, the prescribed rotation was applied to the proximal most joint of the beam element. Because the tibia itself was hollow at the proximal end, the incorporation of a connecting body between the beam and tibia was necessary in order to transfer the applied loading. As a result of bonding these bodies together, a high stress concentration was generated at the interface in all four torsion models. These maximums were presented alongside specific stress values recorded near the hardware. In this way, model maximums did not convolute the effects of the fixation construct.

As for the bone nearer to the hardware, the highest stresses were found along bone-hardware interfaces in all models. In both the two-screw assemblies, relatively higher stresses were found near the screw holes. Specifically, area near posterior and anterior screw holes were locations identified in the bonded and no penetration models, respectively. In the case of posterior stresses, this observation correlated with an experimental failure mode of the posterior
screw breaking through the lateral wall of the malleolus. Anterior locations in the model likely resulted due to less twisting of the fragment relative to the tibia during simulation. Furthermore, stress concentrations in both the fragment and bone proximal to the fracture surface supports the experimental observation of screw loosening.

The Sled™ construct also exhibited local maxima along the bone-hardware interfaces. Relatively high stress concentrations were found in the bone adjacent to the prongs in both models, which matched failure via fragment breakage. The thinner diameter of the prongs, contrasted with the more robust size of the cancellous screws, likely make the Sled™ more vulnerable to deformation in torsion scenarios. This was evidenced both during simulations, in which higher torques were found in the two-screw assemblies in comparison to the Sled™ fixation, as well as during experimentation, which demonstrated failure via prong bending.
CHAPTER 5 Overall Discussion

5.1 Benefits and Limitations of Computational Modeling

Computational modeling can serve an important role in the study of the human body, and in particular, its joints. It affords many benefits to such study in that it is cost effective and efficient. Whereas obtaining cadaveric specimens can take time and may be costly in terms of how many specimens are necessary for a test, computational modeling allows a single investment in software that is capable of running multiple iterations of a given design scenario. Additionally, use of such modeling also reduces the amount of variability in a study as parameters can be changed one at a time without affecting the remaining model.

With respect to computational finite element analysis, the opportunity to replicate any host of loading scenarios, in a joint for example, provides an engineer the ability to preview the joint’s response to a given perturbation. Displacements and stresses as a result of some prescribed loading may be analyzed to determine the gross deformation of the joint under investigation. The ability to predict joint behavior, or that of any anatomic model, subsequently aids the clinician as well. A better understanding of the body’s mechanics via computational modeling may lead to improved or new treatments for various ailments.

While computational modeling has the aforementioned benefits, it is not without its limitations. Though cadaveric data is available to aid in the creation of an accurate anatomic model, some soft tissue data remains sparse in the literature thus making replication of material behavior more difficult. Additionally, anatomy may be idealized (e.g. representing ligaments with linear springs) or loading may be simplified (e.g. applying point loads rather than
distributed forces) for ease of implementation. Computational resources represent yet another factor that plays into the complexity of the model. For example, interface conditions within a finite element model may be approximated as bonded to decrease simulation run time. In any model, the complex anatomy must be balanced with practical considerations.

In this study, finite element analysis was used to model ankle fracture fixation in two loading scenarios. Transverse medial malleolar fractures were created on cadaveric specimens and subsequently fixed via two cancellous screws or the Medial Malleolar Sled™. Both pronation-abduction and pronation-external rotation loading scenarios were simulated by applying tension or torsion, respectively, to the specimens until failure. The details of the experiment and its resulting data were then used to create a finite element model in an attempt to simulate the fixation constructs’ performance.

5.2 Simulation Outputs, General Comments

As previously stated, a benefit of modeling is the ability to predict response. In this investigation, experimental testing simulated loading that the fragment construct could experience during the course of healing, as did the computational analyses. Though parameter magnitudes did not identically match between computational prediction and experimental values, simulation outputs were correlated with experimental observation as a means to predict behavior. For example, within all the models, average fracture displacement was examined in at least one direction; however, magnitudes for most models were approximately one order smaller than measured bead displacements. Generally speaking, the no penetration models achieved displacements on the order of hundredths of a millimeter, whereas the bonded models tended to have displacements of thousandths of a millimeter. This is most likely a result of interface
contacts as some were designated bonded and others were set to no penetration. Designation of
such contacts was dependent on matching the experimental setup as closely as possible while
still enabling the simulation to run per computational resources. Although magnitudes were
small, values were still useful for making comparisons between (1) constructs and (2) experiment
and simulation.

Resulting forces in the tension simulations were higher than the experimental averages
however, trends indicative of the experimental model were identified. For example, relatively
higher stress concentrations were noted in the bone surrounding the fixation hardware. As both
two-screw and Sled™ testing demonstrated failure via the hardware breaking from or through
the bone surrounding it, one may conclude that the tension models were representative of the
experiment.

Similar to the tension studies, stress concentrations generated in the torsion simulations
were examined in the bone near the hardware. Again, relatively higher stress concentrations
were observed around the hardware, which was suggestive of failure modes seen during
experimentation. Torques were similar to the experimental mean at the rotation simulated, thus
supporting the model’s predictive behavior.

5.3 Conclusion

Based on the observations made during this computational research, both benefits and
limitations of fixation via two screws and the Sled™ were considered in proposing design
improvements to reduce the occurrence of hardware pullout and/or bone trauma. For example, in
the case of weaker trabecular bone (i.e. osteoporotic such as that represented in this study),
hardware could be designed such that it relied on the stronger cortical bone for fixation. For
example, a pin or prong could be inserted into the fragment and anchor into the opposite cortex of the bone proximal to the injury. The anchoring could be accomplished by extending a specialized tip that flared outward and gripped the cortex. In this way, compression of the fracture surface would be achieved and pullout would be mitigated. Furthermore, as mentioned earlier during the discussion of malunion, a single point of fixation can result in inadequate support. Two-screw fixation and the Sled™ both included two-points of fixation in their design. Similarly, in the newly proposed design, at least two parallel pins would be inserted across the injury site. Pins utilizing a diameter within the range of the Sled™ prongs and cancellous screws would provide a suitable, robust construction in both tension and torsion, and accommodate varying fragment sizes. By utilizing the advantages of computational modeling, specifically the ability to determine displacement and stresses which cannot be seen during experimentation, new or improved devices and treatments may be developed to benefit clinicians and patients.

As this study demonstrated, computational modeling may be utilized as a means of foretelling behavior due to prescribed perturbation. In order to gain insight into a biomechanical system, for example, knowledge of cadaveric data and experimental setup is important so as to enable building of a representative computer model. Ideally, similar deformation responses are obtained and may facilitate prediction of live responses. In the current study, a fixed medial malleolar fracture was modeled as per the available anatomic and experimental data. While some outputs of the simulations differed from experiment, the models ultimately succeeded in predicting regions of bony failure observed during cadaveric testing.
References
References


[34] 2007, “TiMax 3.5/4.0 mm Cannulated Screw System.”


[37] “Surgical Fixation - TriMed: Ankle Fracture System: Medial Malleolar Sled.”

[38] “ASM Material Data Sheet.”


[40] “2011 SolidWorks Help - Types of Contact.”

[41] “Mixed Meshing in SolidWorks Simulation - Contact Sets (Part 3 of 5) by Brian Zias.”


APPENDIX A

SolidWorks Simulation Material Inputs [35-39]

<table>
<thead>
<tr>
<th>Material</th>
<th>Cortical Bone (Aged)</th>
<th>Trabecular Bone (Osteoporotic)</th>
<th>Titanium Screws</th>
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<tr>
<td>Young’s Modulus, $E$ (N/m$^2$)</td>
<td>1.85e10</td>
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<td>Poisson’s Ratio, $\nu$</td>
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<td>Density, $\rho$ (kg/m$^3$)</td>
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<td>Yield Strength, $\sigma_y$ (N/m$^2$)</td>
<td>1.02e8</td>
<td>5.76e6</td>
<td>8.80e8</td>
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Note: All Sled™ components were assigned “AISI 316 Annealed Stainless Steel Bar” from Simulation’s material library.

<table>
<thead>
<tr>
<th>Ligament Band</th>
<th>Anterior tibiotalar</th>
<th>Tibionaviculat</th>
<th>Tibiocalcaneal</th>
<th>Posterior tibiotalar</th>
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<tr>
<td>Stiffness (N/m)</td>
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<td>Pretension (N)</td>
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<td>10.47</td>
<td>6.12</td>
<td>6.78</td>
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</tbody>
</table>

Each of the four deltoid bands was represented by two springs in Simulation, for a total of eight springs. The above values represent the properties assigned to a single spring of that particular band.
VITA

Ruchi Dilip Chande was born in Syracuse, New York on February 28, 1984. Her family lived in various cities in the United States but spent most of their time in Southern California, primarily in the city of Brea. Ruchi graduated from Brea Olinda High School in 2002 and then attended the University of California, Berkeley where she received a Bachelor of Science in Mechanical Engineering in May 2006. During the three years following her graduation from UC Berkeley, she took a position at Medegen, Inc. (now part of Carefusion) where she contributed to tooling and product validations, design and development, and manufacturing process improvement. In July 2009 with the support of her coworkers at Medegen, Ruchi left to pursue her academic goals in Biomedical Engineering at Virginia Commonwealth University. Following completion of her studies, Ruchi plans to re-enter industry to pursue a career in product design or manufacturing.