Medial Migration of Intramedullary Intertrochanteric Fracture Fixation Devices

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Abstract
Intramedullary Intertrochanteric Nail Fixation Devices and Medial Migration of Their Femoral Neck Implants
George Mikhail
Glen Pierson, Synthes USA, Supervisor

Intertrochanteric fractures have been fixed for decades with side plates and sliding hip screws, and more recently, with intramedullary devices and sliding lag screws. The most common failure mode of all such implants is superior cutout of the implant due to varus collapse of the femoral head and neck over the implant. The major cause of this type of failure mode is believed to be osteopenic bone.

Another rarely reported failure mode, is the medial migration of the femoral neck implant along its axis through the femoral head into the acetabulum. In follow-up x-rays, the femoral neck implant is seen to migrate through the intramedullary nail, and out of the femoral head. In this failure mode, the femoral head and neck do not collapse or may have already collapsed as far as possible, but instead the implant migrates medially on its own. The failure is very rare with few reported incidents over many years of use and hundreds of thousands of fractures. Due to its rarity, this mode has not been sufficiently documented or studied, nor is the cause well understood. It is postulated that the failure could be due to a specific combination of the physiologic properties of the bone, fracture pattern, and implant design.

The purpose of this research is to create a biomechanical test model that would reliably reproduce the medial migration phenomenon in a controlled lab setting. Once a robust model is achieved, various implant designs can be tested to determine if they effectively prevent this phenomenon from occurring. It is not our purpose to analyze or
predict the parameters that might induce medial migration. The event is rarely observed in the clinical setting. The parameters that may be contributing to this phenomenon are numerous, difficult to clinically assess, and there are not enough clinical cases to study. However if an implant is to be designed that would eliminate the capability for medial migration it must be tested. This project sets out to create a robust test model that can reliably be used to test designs claiming to fix the problem.

During the course of the study we came across situations that may provide insight into other failure modes. Our test construct design iterations sometimes displayed other failures that were not studied before, including the femoral head collapsing along the axis of the blade, but the blade itself not sliding as it is designed. We also discovered that two-screw devices are more prone to the “Z-effect,” which is another form of medial migration. This correlated to the fact that the “Z-effect” was commonly reported in the literature with two-screw devices while medial migration was almost never reported due to its very low occurrence rate.

The research did successfully create a biomechanical model that recreated the phenomenon of medial migration and can be used to test potential fixes to prevent medial migration. Without a biomechanical test model, all fixes are only theoretical and cannot be proven until thousands of cases have been performed because of the rarity of the failure. We hope that this work can be used to further improve implant designs reducing the number of revision surgeries needed after initial hip fixation.
Purpose and Summary of Specific Aims
The purpose of this research is to create a biomechanical test model that would reliably reproduce the medial migration phenomenon in a controlled lab setting. Once a robust model is achieved, current implant designs can be tested to determine if they effectively prevent this phenomenon from occurring. Additionally, new designs attempting to prevent this failure mode can be tested to prove their efficacy.

Specific Aim 1
The first goal of this project is to develop a mechanical test model to simulate and recreate the phenomenon of medial migration of the intertrochanteric nail fixation device. This model will be entirely composed of metal and plastic components to allow full control of all variables of the test.

Specific Aim 2
The second goal is to validate the model as biomechanically accurate, by placing the actual neck implants into foam blocks that simulate the cancellous bone of the femoral head instead of the plastic. For the construct to be considered valid, traditional varus collapse of the femoral head model should be observed.

Specific Aim 3
The third goal of this project is to evaluate various implants from different manufacturers on our validated biomechanical test model to determine if any implant designs inherently prevent this phenomenon from occurring.

If all these aims are achieved, this test model can be used later to evaluate implant concepts that are specifically designed to prevent this motion, since it seems that this failure is not only due to physiologic parameters, but a combination of physiologic conditions and mechanical design of the implant.
Chapter 1: Introduction

1.1 Hip Fracture Introduction

Hip fractures are a growing trend especially among the baby boomer generation occurring at a rate of 250,000 per year and are expected to grow to 500,000 per year by the year 2040. Approximately half of those are intertrochanteric fractures, often occurring in the elderly after a simple fall [1]. These proximal femur fractures can be identified under the classification system setup by the AO/OTA, which differentiate the different fracture types for easy identification. In the AO/OTA classification system, the first number designates the bone involved. For example, the humerus is designated by the number 1, the forearm is designated by the number 2, the femur is designated a 3, and the tibia is designated a 4. The second number typically designates which third of the bone is involved. A “1” indicates a proximal third fracture, a “2” indicates a shaft fracture, and a “3” indicates a distal third fracture. Therefore a proximal femur fracture is described as a “31” fracture. Additionally, in the proximal femur, a further breakdown of the fracture is designated. A 31-A fracture is an extracapsular fracture involving the trochanteric region, a 31-B fracture is extracapsular, involving the femoral neck, and a 31-C fracture is intracapsular involving the femoral head. Each of those are further broken down based on stability or severity of the fracture. The implants discussed in this project are used with 31-A(1-3) type fractures as shown in the picture below.

Figure 1. AO Classification of Intertrochanteric Fractures.
1.2 Intertrochanteric Plate Fixation Devices

There has been an evolution of fixation methods for the intertrochanteric or pertrochanteric fractures, classified as 31-A fractures. Early fixation methods often included an angle blade plate device like the Jewett Nail [Figure 2] which consisted of a side plate that was screwed to the lateral side of the femur and a blade that was hammered into the femoral head. The side plate and blade were all one piece, making the procedure technically challenging. These early blades were not cannulated, so the surgeon had to determine the appropriate neck angle and anteversion of the head and then chisel a path for the blade matching the angle of the implant. If the fracture was not properly reduced before chiseling the path, or if the neck angle or anteversion of the chiseled path was not correct, the fracture could often be malreduced. Valgus malreductions create an angle between the femoral shaft and the axis of the femoral neck that is larger than it originally was. This type of malreduction, aside from not matching the anatomic geometry, often leaves a gap between the two main bony fragments around the level of the lesser trochanter. A gap in this condition causes three problems. First, if the gap is too large, the bone may not heal at all. Second, lack of bony support around the level of the lesser trochanter puts more stress on the implant. The implants are designed to share the load with the bone until the bone starts healing, but with no bony contact, the implant carries the entire load for a longer period of time, and might therefore fail. Third, the loads on the femur are directed toward the lesser trochanter and without bony contact between the medial and lateral fragments, the bone in the femoral head takes all of the load during weight bearing. The majority of the patients who present with hip fractures are elderly patients with osteopoenic bone. The femoral head
might not be able to support the implant and might fall into varus, collapsing around the implant, causing the blade to stick out of the femoral head. Varus collapse in the proximal femur occurs when the angle between the femoral neck and the femoral shaft becomes smaller than it originally was, either due to a malreduction or due to implant failure, or cutout of the implant through the femoral head because of poor bone quality.

![Figure 2. 130º Angle Blade Plate](image1.png) ![Figure 3. Dynamic Hip Screw](image2.png)

The next major evolution in hip fixation was commonly called either the Dynamic Hip Screw (DHS) or Compression Hip Screw (CHS). This implant was composed of two pieces, a lag screw that went up into the femoral head, and a side plate with a barrel that engaged the lag screw and then screwed into the shaft of the femur. This made the technique much less technically demanding for at least two reasons. First, the lag screw was cannulated. Therefore a small guide wire, usually around 2.5mm in diameter, could be placed into the femoral head through an alignment jig, determining the placement of
the lag screw. If the guide wire is placed incorrectly, it can be easily corrected without removing much bone before the implant has been inserted. Once the guide wire is satisfactorily placed, a cannulated drill bit is placed over the guide wire to drill through the femoral head. A tap can then follow the drill bit if desired and then the lag screw can be inserted. Finally, the barrel of the side plate is placed around the shaft of the lag screw and the plate is brought down to the bone and screwed to the femoral shaft. The lag screw can freely slide through the barrel of the side plate, permitting bony contact between the medial and lateral segments upon weight bearing, allowing the bone and implant to share the load.

The sliding hip screw construct offered advantages to its predecessor, the angle blade plate, because it was less technically challenging to use and allowed for controlled collapse of the. While the technique was easier, there were still complications due to the inherent design of the lag screw and side plate. A study found that stable fractures collapsed along the axis of the lag screw about 5.3mm but unstable fractures slid about 15.7mm [2]. Other studies found that excessive sliding was the major reason for fixation failure. One of those studies characterized sliding of more than 15mm to a higher prevalence of failure of the fixation. Another study claimed that medialization of the femoral shaft by more than one-third of the diameter of the femur led to a sevenfold increase in loss of the fixation. In addition, an increase in hip pain was also associated with excessive sliding [3, 4, 5]. Additionally, on a fairly skinny or regular sized person, if the shaft of the lag screw protrudes beyond the plate in excess of 15mm, the patient might feel further discomfort.
1.3 Intramedullary Intertrochanteric Fixation Devices

Years after the dynamic hip screw became the gold standard for intertrochanteric fracture fixation, intramedullary implants were developed to treat these fractures as the next step in the evolution of hip fixation. These intramedullary nails provided some theoretical advantages as well as clinical advantages to the sliding hip screw. Biomechanically, intramedullary devices have a decreased lever arm from the point of fixation of the lag screw with the nail to the load of the hip force vector, reducing the stresses on the construct. Studies also show that all things being equal, an intertrochanteric fixation procedure using an intramedullary device generally requires less operating room time and has less blood loss than the same procedure with a compression hip screw [1, 6, 8, 9]. This is sometimes attributed to the fact that these surgeries usually require smaller incisions than for a DHS.

However an intramedullary device helps solve some of the stability issues seen with the side plate. An intramedullary device provides an early buttress to the medial bone which would make contact with the nail itself in the canal reducing the propensity for excessive sliding as shown in Figure 4 and Figure 5.
Reverse oblique fractures, 31-A3 fractures, were also biomechanically more stable with an intramedullary nail. These fractures still originated above the level of the lesser trochanter, classifying it as an intertrochanteric fracture, but the fracture line was proximal on the medial side and distal toward the lateral side, the opposite of most intertrochanteric fractures which often ran from the greater trochanter to the lesser trochanter. These were unstable fractures when treated with a DHS. While regular trochanteric fractures could rely on the bony contact of the medial segment on the lateral bone segment for support, these fractures only relied on the strength of the cortex screws holding the side plate to the bone to resist the hip forces. Since these fractures often occurred within the elderly population screw pullout strength may be even weaker. Here again, the intramedullary nail provides a buttress in the middle of the canal for the medial fragment to support it against the loads on the femoral head as shown in the pictures.
below [Figure 6 and Figure 7]. A study comparing the use of an intramedullary nail with a 95° screw plate for transverse intertrochanteric fractures found that of the 39 patients included in the study, those treated with an IM device had shorter operative times, fewer blood transfusions and shorter hospital stays. The authors also found that seven of the nineteen patients treated with the plate experienced implant failure or non-union, where only one of the twenty fractures treated with a nail did not continue to healing [6].

These hip fracture fixation nails were often offered in two size categories. Short nails spanned from the tip of the greater trochanter to around the isthmus of the femur (approximately 170mm-240mm in length depending on manufacturer), and were meant to be used for stable intertrochanteric fractures. Long nails ranged from around 300mm to 460mm (exact lengths varied by manufacturer) which were meant to span the entire length of the femur for unstable intertrochanteric fractures, or combined intertrochanteric fracture and shaft fractures. One of the complications of the first generation short nails
involved femoral shaft fractures that occurred around the level of the distal locking screw(s) close to the tip of the nail [7]. These nails often had one or two distal locking screws which were placed through one or two locking holes in the nail appropriately sized for the locking screw. As the femoral head was loaded, the nail would be loaded toward varus. That load would be transferred to the distal locking screw and ultimately to the bone. The bone contained a stress riser because of the screw hole and this was often the cause of these shaft fractures when they occurred at the tip of the short nails. Later generations of intramedullary nails replaced the distal locking hole with a slot, allowing the nail to slightly toggle in the canal until the tip of the nail could rest on the lateral wall of the cortex, sharing the load with the bone instead of concentrating it through the screw. This design was later adapted by most manufacturers to help alleviate this problem.
1.4 Hip Fixation and Superior Cut-Out

The failure more commonly encountered among all modes of intertrochanteric fracture fixation, whether intramedullary or extramedullary, is superior cutout of the lag screw through the femoral head. This is when the femoral head falls into varus and the femoral neck implant cuts out superiorly through the femoral head. This failure can be caused by surgical technique or may be a result of the biology of the patient. Studies have found an ideal location to place the femoral neck implant to reduce cut-out rates. Kawaguchi et.al. found that none of the times where the femoral neck implant was placed

<table>
<thead>
<tr>
<th>Figure 8. Fracture at Tip of Short Nails</th>
<th>Figure 9. Screw Slot to Reduce Fracture at Tip of Short Nails</th>
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<tr>
<td>Fractures sometimes occurred at the distal end of these short nail due to stress risers in the bone at the level of the locking screw due to the forces wanting the nail to toggle.</td>
<td>Later generation nails allowed the nail to toggle in the canal until the tip of the nail made contact with the lateral wall, sharing the load and reducing the stress on the distal locking screw.</td>
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less than 5mm of the subchondral bone cut-out but shallow insertion of the lag screw in
the AP view and a large deviation in the lateral view were significantly related to the
increased incidence of cutout of the lag screw [10]. Baumgaertner calculated an ideal tip-
apex distance as shown in [Figure 10 and Figure 11] for placement of the lag screw to
reduce cut-out rates. He found that no implant with a tip-apex distance (TAD) of 25 or
less proceeded to cut-out. He also showed how many lag screws cut-out based on which
region of the femoral head the lag screw was implanted as shown in the figure below

![Figure 10. Calculating TAD Technique for calculating tip-apex distance (TAD) [11].](image1)

![Figure 11. Cut-Out Based on Insertion Region The distribution of lag screw cut-out per zone. The numerator is the total number of screws implanted in that zone. The denominator is the total number cut-out [11].](image2)

However, it is also accepted that in some cases the patient biology may be the
major cause of fixation failure, especially superior cut-out of the femoral neck element.
In highly osteopenic bone, the lag screw may have little bone purchase. In poor quality
bone, the implant may cut through the femoral head under normal weightbearing because
of the poor bone quality. In 2002 a new intramedullary device was introduced to reduce
cut out rates in more osteopenic or osteoporotic cases. Synthes introduced their trochanteric fixation nail (TFN) which used a helical blade in the femoral head instead of a lag screw. It was shown many years earlier in a study by Richards, et. al. that a Pugh sliding blade could withstand loads 70% greater than the dynamic hip screw before cut out [12]. The Pugh blade was a straight tri-flange blade which supported varus loads well, but did not have purchase like a screw and it was unable to achieve active compression intraoperatively with this blade. Also because of the lack of axial purchase it could slide out of the neck over time. The Synthes helical blade used with the TFN incorporated the best of both worlds. Its helical blade design was designed to remove no bone from the femoral head except the bone removed by the central guidewire. Instead, the blade was designed to be hammered into the femoral head and compress the cancellous bone around it. Not only did this save as much of the original bone as possible but created a more dense layer of bone around the implant. The helical design also captured bone in its helical flutes, giving the blade an axial grip in the bone and allowing active intraoperative compression. It can also be seen that the blade occupies a smaller area in the femoral head than a lag screw. The largest advantage of the blade is its cross-section with a broad paddle-like footprint, increasing the surface area in the direction resistant to varus loads, reducing the stress on the bone and dramatically increasing its cutout resistance. The four flutes provide rotational control of the femoral head around the implant axis, previously impossible to achieve with a lag screw without inserting a second element into the femoral head.
Biomechanical studies performed in sawbone and cadavers confirmed the advantages of a helical blade. A study funded by Synthes performed by Legacy Labs in Portland Oregon [13] compared a Stryker Gamma Nail lag screw, a Synthes DHS lag screw, and a Synthes TFN helical blade in polyurethane foam blocks under fatigue loads in an unstable pertrochanteric fracture model. The TFN helical blade showed a ten-fold...
increase in resistance to cutout over the lag screw as shown in the graph below. This study also found an increased resistance to rotational loads of the helical blade compared to lag screws, which can especially be induced when implants are not ideally placed along the same axis as the femoral neck. Another study funded by Zimmer [14] compared the cutout resistance of the Zimmer ITST with a lag screw versus the Synthes TFN with a helical blade in cadaveric bone. That study confirmed the results found in the earlier studies of the Pugh blade and the TFN helical blade finding “significantly more permanent inferior femoral head displacement in the ITST samples compared to the TFN samples.”

Figure 15. Cut-Out Rate Comparison, Helical Blade vs Lag Screw
1.5 Z-Effect
Some intramedullary intertrochanteric fracture fixation devices were designed to have two screws inserted into the femoral head to control rotation of the femoral head. This implant design displayed a failure mode termed the “Z-effect” in the literature and was specific to implants that had two screws in the femoral head implanted through an intramedullary nail. It was seen both with intertrochanteric nails that had a larger lag screw and a smaller anti-rotation pin in the femoral head, or recon nails with two equally sized screws in the head used to fix femoral neck fractures. These failures involved one of the two screws migrating medially through the femoral head along its axis, which was called the Z-effect. Sometimes one of the two screws would migrate laterally out of the bone instead and this was termed in the literature the reverse Z-effect. These failures have been documented in many papers, often seen with the Proximal Femoral Nail (PFN) [17, 18, 19, 20] but also documented to occur with the Russel Taylor Reconstruction Nail [21, 22].
Figure 17. Z-effect
Z-effect where the proximal screw migrate medially through the femoral head in both (a) an intertrochanteric fixation nail (PFN) and (b) a reconstruction nail (RT Nail) [21]

Figure 18. Reverse Z-effect
Reverse Z-effect where proximal screw migrates laterally out of the nail in both (a) an intertrochanteric fixation nail (PFN) and (b) a reconstruction nail (RT Nail) [21]
The phenomenon is not well understood. A study by Eric Strauss [21] attempted to biomechanically understand it, although there were many limitations to the study.

1.6 Medial Migration

More recently another, much more rare failure was also observed. At the time of this study, only one case study was found [23] that documented this failure. The percentage of cases in which medial migration happened could not be quantified because of the rarity of its occurrence. This failure was a medial migration of a single femoral neck implant through the femoral head, where the neck implant travelled along its own axis through the nail and the femoral head sometimes into the acetabulum. Nobody understood this failure and no attempt to study it was made. The case study reported by Mark Tauber [23] called this failure “the rarest of the rare complications.” This failure mode seems to be a result of physiologic parameters including local bone densities through the femoral head and neck region, fracture patterns, and implant design. Even though the failures are rare, it seems feasible that a mechanical solution could be obtained to prevent the occurrence. Therefore if a design is capable of preventing the phenomenon it should be pursued to prevent the typically elderly people with intertrochanteric fractures from undergoing secondary surgery or a total hip replacement if it is unnecessary. Some companies have tried to design implants to resist this motion, but have been unsuccessful.
Before attempting to create a solution for this failure it is important to try to understand the mechanism of the failure, or at least to try to replicate the failure in the lab with a test model in which varying designs can be tested. The purpose of this research is to create a biomechanical test model that would reliably reproduce the medial migration phenomenon in a controlled lab setting. Once a robust model is achieved, various implant designs can be tested to determine if they effectively prevent this phenomenon from occurring. It is not our purpose to analyze or predict the parameters that might induce medial migration. The event is rarely observed in the clinical setting. The parameters that may be contributing to this phenomenon are numerous, difficult to clinically assess, and there are not enough clinical cases to study. However if an implant is to be designed that would eliminate the capability for medial migration it must be tested. This project sets out to create a robust test model that can reliably be used to test designs claiming to fix the problem.
Chapter 2: Specific Aim #1 – Mechanical Test Construct

The first goal of this project is to develop a mechanical test model to simulate and recreate the phenomenon of medial migration of the intertrochanteric nail fixation device.

Mechanical testing of intramedullary intertrochanteric fixation devices commonly consisted of analyzing the two known failure modes of intramedullary devices used in fixing intertrochanteric fractures. The first test typically performed is a standard fatigue failure of the implant construct. This test is often performed by most manufacturers of these devices in order to prove that their devices are at least as strong as the implants currently used for the same fracture. Fatigue testing entails holding the distal portion of the nail firmly in place while the femoral neck implant is cyclically loaded until the construct catastrophically fails.

The second failure mode more recently studied concerned what is clinically characterized as “cut-out,” which occurs when the femoral head, typically osteopenic, falls into a varus collapse due to the poor bone quality and the neck implant cuts out of the femoral head superiorly as a result. Cutout testing can be performed by testing the neck implant alone, placing it into a foam head which simulates cancellous bone, or actual cadaveric femoral heads. The lateral end of the neck implant is then held firmly, as in a vice, while the foam head is loaded until the implant cuts out of the foam head. In each of these two biomechanical tests the implants are securely anchored to control the test [13].
2.1 Hypothesis

In contrast to the above mentioned failures, medial migration is a result of many confluent factors and is believed at least requires motion of the nail, neck implant, and the femoral head, which is not a condition that was previously tested. The basic hypothesis is that medial migration is caused by a “jacking” action of the femoral neck implant created when the nail toggles in the canal as a result of the loading and unloading of the femoral head during activities like walking. It is believed that during loading and unloading cycles, the nail toggles medially and laterally, advancing the femoral neck implant much like a caulk gun. Often the lesser trochanter is broken so there is no medial buttress for the fracture. The lack of a bony medial buttress below the axis of the neck implant, allows this toggling motion to occur. Also, bone resorption is usually seen at the lateral cortex around the location of the femoral neck implant, which both indicates and allows toggling.
These are not the only conditions that create a situation favoring medial migration, else these failures would be much more common. Other varying physiologic unknowns play a seemingly large role, one of which involved local bone quality in the femoral neck and head. The majority of the patients undergoing these hip surgeries
generally have osteopenic bone, which contributes to superior cutout of the neck implant if a failure occurs. However, varying bone densities in different locales throughout the head and neck are believed to play a role in this medial migration phenomenon. For example, it is thought when the nail toggles laterally due to loading, the femoral neck implant could be lightly bound in the nail due to friction between the nail and neck implant and therefore cut medially into the femoral head, possibly only a few microns. Then because of a source of friction between the neck implant and the femoral head, the implant in the femoral head is held in its advanced position as the load is relieved from the femoral head and the nail toggles to its original. Otherwise, if there was no friction between the implant and the femoral head, the neck implant would toggle back with the nail, as there is some friction still between the nail and neck implant. This motion, repeated many times can advance the blade through the femoral head. Essentially, high friction between the neck implant and nail causes the implants to bind together during loading. As long as the friction between the nail and neck implant is higher than the resistance to neck implant advancing medially, the implant can cut medially into the femoral head. During unloading, as the friction between nail and neck implant is reduced, if it drops to a level lower than the friction between the neck implant and the bone, the neck implant is held in its new position and the nail returns.

However, other conditions need to exist for medial migration to occur. There must be sufficient bone resorption in the lateral cortex around the neck implant, otherwise, a tight fit between the implant and the bone would prevent toggling of the implants. The bone quality of the femoral head must also be high enough in certain locations to resist varus collapse of the femoral head, otherwise multiple load cycles
would result instead in superior cutout of the implant. However, the bone quality medial to the implant must be low in order to be overcome by the friction between the neck implant and the nail. Finally, there must be a specific amount of friction between the femoral head and the neck implant. Too much friction would not allow the neck implant to migrate medially and too little friction would not hold the neck implant in its new place in the femoral head as the nail toggles laterally and the implant would also return to its original position with the nail.

2.2 Test Objective
In this first phase, we will attempt to create a biomechanical test model that can replicate this motion. This model can then be used to test new nail designs that are intended to prevent this effect. In order to design an implant that does not allow for medial migration, this phenomenon must first be recreated in a test model so that the fix can also be tested in the same model. Otherwise, any fixes designed will only be theoretical and cannot be actually verified. The testing will be conducted on the Synthes Trochanteric Fixation Nail (TFN). This experiment will also test our null hypothesis by preventing toggling of the nail to determine if medial migration still occurs.

2.3 Phase I
2.3.1 Materials and Methods
Phase I of this specific aim is the first attempt to create a test model and involves designing the appropriate fixtures needed to replicate this effect of medial migration. The implant used in this part of the study is a Titanium Trochanteric Fixation Nail (TFN) produced by Synthes. The nail is 170mm long and has a 6º proximal bend. The proximal diameter of the nail is Ø17mm and the distal diameter of the nail tested is Ø11mm. There
is a 130° angle between the axis of the distal shaft of the nail and the axis of the Ø11mm oblique hole in the proximal end of the nail through which the neck implant is placed, commonly referred to as the neck/shaft angle.

Throughout the rest of this study, anatomic descriptions of location will be used in describing the fixture as the different parts of the fixture mimic the anatomy. The term medial will be used to describe anything that is toward the midline of the body, while lateral is away from the midline. For example, the delrin head described later which is used to mimic the femoral head would be medial to the rest of the fixture [Figure 21]. The term distal refers to the direction toward the foot, while proximal refers the direction toward the head.

An aluminum fixture was created to hold the TFN for testing and to simulate the intramedullary canal. It is a long rectangular block with a longitudinal, Ø15mm, hole through the center. A Ø17mm hole is drilled at a 6° angle to the axis of the Ø15mm hole to match the opening made during surgery for the implant at the proximal diameter of the implant. The TFN is normally fixed distally with a Ø5mm screw placed through the distal slot at an angle. A Ø5mm hole is drilled through the aluminum block at the appropriate location and angle to match the location of the locking screw used with the TFN, allowing a Ø5mm pin to hold the nail in its proper resting position. The diameter of the helical blade placed through the nail and into the femoral head is Ø11mm. Therefore a hole larger than Ø11mm is drilled in the lateral wall of the nail fixture to mimic bone resorption around the neck implant which allows nail toggle. Finally, an angled cut is made on the medial wall of the nail fixture to mimic an intertrochanteric fracture. This cut must not cross the space where the proximal portion of the nail would
sit to allow for the plate described next to be affixed to the fixture. Again, the entire construct is clearly illustrated in Figure 21.

Across the face of the cut on the fixture, a plate is attached that has an area cut out for the femoral neck implant. Between the backside of this plate and the nail that is in the aluminum block, a 3/8” thick piece of 70A durometer rubber elastomer is placed to simulate the elastic properties of the nail/bone interface which allow the nail to return toward its original position as the load is reduced.

In order create controlled conditions resistant to superior cutout, the femoral head was simulated with a delrin head with an axial hole providing a slip fit to the implant. Since medial migration is sensitive to the friction conditions in the femoral head as described above, the variability of those conditions was controlled by removing the fluted portion of the helical blade and replacing it with a round shaft of the same diameter. Otherwise the edges of the helical blade would cut into the delrin, creating high and unknown friction conditions. Perpendicular to the axis of this hole in the delrin head, another hole is drilled and tapped. The thread is reinforced with a stainless steel helicoil insert, so the plastic threads do not deform when stressed. Through the tapped hole, a small delrin cylinder is dropped and captured with a set screw. The set screw is tightened to a set torque driving down on the delrin bushing creating a frictional force on the modified helical blade. This creates a controllable mechanism of creating the friction seen by the neck implant in the delrin femoral head. The back end of the delrin head is rounded as shown in the Figure 21. When the head is loaded, it is expected to pivot around the rounded back end.
The construct is then placed on a tilt table and tilted to 19°. Since the nail has a 130° neck-shaft angle, this places the loading vector at 149° which is the physiologic loading vector [13]. The actuator on the MTS machine is fixtured with a block that has a conical cut out to capture the delrin head. Between this block and the axial actuator is a thrust bearing which transfers the axial load to the delrin head at all times but allows the block to move freely in the plane perpendicular to the actuator, following the head as it pivots around its axis and travels as shown in Figure 22 and Figure 23.
The construct is then cyclically loaded with a sinusoidal load pattern at a rate of 2 Hz. Various loads were used with the maximum loads ranging from 400 N to 1200 N and the minimum loads ranging from 10 N to 80 N. The torque on the set screw creating the friction was also tightened to torques ranging from 0.25 N-m to 1.5 N-m.

2.3.2 Results and Conclusions of Phase I

This biomechanical construct did not exhibit any indication that the neck implant was migrating medially under any combination of loading conditions or torques applied. The construct upon initial loading, appeared to toggle with the first cycle, compressing the elastomer, but no further motion was observed in the entire construct and no migration occurred. Upon complete removal of the load, the nail, neck implant and delrin head seemed stuck in the loaded position, and the elastomer was still compressed.
The construct had to be freed with a light tap in order allow the nail to return to its original location.

The recurrence of this incident throughout this phase of the study with various load and friction combinations, led us to believe that something was wrong with our initial setup and not with our range of loads and torque values. We theorized that during initial loading, the nail toggled as expected, increasing the angle of the “V” shaped gap between the neck implant and the cover plate. However, the delrin head did not merely roll as expected, but instead was pushed along the axis of the neck implant, squeezing into the increased “V” gap made due to the blade toggling medially. This caused the delrin head to become lodged further down between the neck implant and the cover plate, preventing the nail from toggling back to its original position when the load was relieved. For this reason, the construct needed to be tapped free after loading. See Figure 24.
Therefore, this construct is not suitable for medial migration. However, this discovery is still worth noting as it may relate to other clinical situations where the neck implants do not slide laterally as they are expected, nor migrate forward, but the head seems to collapse axially along the implant. Since this is also a clinically observed condition, this might actually be an important discovery in itself. This observation lends itself to the hypothesis that this condition might occur if the bone of the femoral neck also wedges itself in the same V-shaped gap between the shaft and neck axis. However more
research would be required to understand how this would work and what role local bone
density would play. The bone would somehow need to be strong enough to become
wedged but still crumble, allowing collapse where the two bony fragments meet. If the
bone quality is poor enough to crumble it may not be strong enough to wedge between
the nail and neck. Further study would be required if this condition is to be further
understood.

This failure led us to then design a new “toggle joint” to create a condition
suitable for medial migration. This design is described in phase II below.

2.4 Phase II
2.4.1 Materials and Methods
The same aluminum nail fixture is used as described in phase I. A new pivot
plate was designed with multiple v-grooves across the width of the plate at various
heights, with the same elastomer between the nail and the back of this new pivot plate. A
new delrin head was designed with an angled cut to match the angle of the “fracture” cut
such that the face of the pivot plate and the back face of the delrin head would be parallel
as shown in the picture below. The delrin head would still have the cross hole for the
delrin bushing and the set screw. Between the delrin head and the pivot plate is a
stainless steel pivot pin captured in one of the grooves in the plate.
The new fixture is again placed in the same MTS machine on a tilt table such that the vertical force vector is at a 149° angle to the shaft of the nail as in phase I. A sinusoidal load was again applied at a rate of 2Hz. The same range of loads on the head and torques on the set screw were also applied as in phase I. In addition, the tests were run with the pivot pin in the various groove locations along the pivot plate. Pictures below show the actual test setup on the machine. After this range of tests was completed, appropriate conditions from this range were chosen, and repeatability of the migration was ensured by testing the construct multiple times under the same conditions.

The null hypothesis was then tested to check the validity of the theory which stated that toggling of the nail was needed for medial migration to occur. This was tested
by removing the elastomer from between the pivot plate and the nail. The pivot plate had a thread tapped through at the location where the elastomer was. A set screw was then threaded through the pivot plate to engage the nail and prevent it from toggling under load. This setup was tested at a range of loads with the maximum load ranging from the ideal load determined from the elastomer test up to a maximum of 1200N to ensure a robust test.

![Figure 26. Photo of Phase II Construct on MTS Machine](image)

2.4.2 Results and Conclusion of Phase II

With this new setup, medial migration was observed under multiple loading conditions of the range applied above. Within a few hundred cycles a migration of over 10mm occurred. At high set screw torques creating high friction on the neck implant and low loads on the femoral head, no migration was readily observed. At intermediate loads and set screw torques, migration was observed. As expected, this demonstrated part of the delicate balance between the friction in the head on the implant and the loading conditions. Since the purpose of this study however was not to characterize migration
rates because they are influenced by physiologic factors beyond our current capabilities of measurement, we did not pursue further study of different combinations of loads and torque values. We also found that the neck implants only showed evidence of migration when the pivot pins were placed in a location below the axis of the neck implant. Also, we were able to prove that toggling of the entire construct was needed for migration to occur. When the elastomer was removed and replaced with a set screw, preventing nail motion, no medial migration of the neck implant was observed.

2.5 Discussion
We now have a working model where the phenomenon of medial migration of femoral neck implants can be replicated. It was shown in these experiments that for the femoral neck implant to travel medially, the nail must toggle.

It may seem that one simple fix would be to design a stiff system removing the ability for the nail to toggle inside the canal. However this fix is neither simple nor correct and creates other physiologic failures. One has to consider the compliance of the bone and implant and the fact that it is being placed in a broken bone. Keeping the nail immobile is probably not feasible. Additionally, creating a very stiff construct is also not desirable. One of the earlier intramedullary hip fixation nails was Stryker’s Gamma Nail. The short Gamma nail initially had two distal locking holes for cross locking screws as shown in Figure 27. As the nail was loaded during physical activity, the stress was transferred through those two distal locking screws to the bone as the nail was trying to toggle. This sometimes caused fractures in the bone which began through one of the screw holes due to the stress riser in the bone as shown in Figure 27b. Future generations of all short cephalomedullary nails including the Gamma nail replaced their locking holes
with slots that allowed short nails to toggle and rest on the lateral cortex, thereby sharing the loads between the nail and the bone. This successfully reduced the incidence of fractures of the bone at the level of the distal locking screw in the short nail.

Figure 27. Toggling Needed for Short Cephalomedullary Nails
(a) Note the two locking screw holes
(b) Fractures occurred through the stress riser created by the locking screws as the stress was transferred to the screws
(c) Future nails were designed with a slot, allowing the nail to toggle and rest on the lateral cortex, relieving the stress and reducing the fractures.

We chose to continue further phases of the testing with a sinusoidal load cycle where the minimum load was 40 N, the maximum load was 800 N, and the torque setting on the set screw in the femoral head was 0.5 N-m. Although the actual load on the hip has been studied during various physical activities and can be approximated to be two and a half times body weight during a normal gait cycle for example [24, 25], it is important to keep in mind that these chosen loads are not representative of physiologic load on the implant during physical activity since the actual load on the implant is not
simply determined. The load on the implant is not simply equal to the joint reaction force since the joint reaction force is distributed between the bony fragments contacting each other, the neck implant, the nail, and the rest of the bone. How much of the load is actually transferred to the implant depends highly again upon bone quality, implant geometry, and the reduction of the fracture.
Chapter 3: Specific Aim #2 – Construct Validation in Foam Model

The second goal is to validate the model as biomechanically accurate, by placing the actual neck implants into foam blocks that simulate the cancellous bone of the femoral head instead of the plastic. For the construct to be considered valid, traditional varus collapse of the femoral head model should be observed.

Since we have replicated medial migration in a simplified model we would like to now test the model by replacing the delrin head with a head made of polyurethane foam often used to represent cancellous bone structure. This foam was also used in the cutout study performed by Sommers, et. al. [13]. Although we would like to see the test construct achieve medial migration with the foam heads, this will not likely occur since the foam heads are of uniform density. However the goal is to validate the construct by showing that it would achieve varus collapse, which is the expected failure mode for these foam constructs.

3.1 Hypothesis

Medial migration in the foam heads is not expected. Although, for the first time, a toggling construct is tested, the foam head does not have varying densities. The foam head used is of uniform density, which when tested to failure is expected to demonstrate varus collapse. If medial migration does occur in this model, it would be expected to occur at a much higher rate clinically.
3.2 Test Objective
The objective of this test is to examine the results when testing the construct developed in specific aim #1 with a foam head instead of the delrin head. We want to validate the model by showing that it responds to constant cyclic loading with a failure mode that is clinically observed. If the construct does not exhibit the expected varus collapse under loading it may have to be redesigned to provide the desired response. A redesign would then require a retest of the methodology performed during specific aim 1.

3.3 Phase I
3.3.1 Materials and Methods
The aluminum tube, nail, cover plate, 130° nail, and elastomer from the earlier testing will be used. A new femoral head will be developed for this test. A foam head will be machined into a shape resembling the delrin head. The foam, however, can crumble under the loading actuator, so in order to distribute the load evenly through the head and not crumble the section in contact with the actuator, the foam head will be encapsulated in a two piece stainless steel shell that is 5mm thick, composed of a shell and a back plate capturing the foam head in the shell. The construct will look like the one in Figure 28.

The foam used is a cellular rigid closed cell polyurethane foam purchased from Sawbones Worldwide, A Division of Pacific Research Laboratories, Inc., (www.sawbones.com ). Two types of foam were used which are summarized in the table below. The foam does not have the mechanical properties of typical cancellous bone but is commonly used by industry in mechanical tests where a simulated cancellous bone material is required. It was also used in the testing performed at Legacy Labs on various femoral neck implants where cutout was simulated [13].
Table 1. Mechanical Properties of Cellular Rigid Closed Cell Polyurethane Foam

<table>
<thead>
<tr>
<th>Density (pcf)</th>
<th>Cell Size (g/cc)</th>
<th>Compressive Strength (MPa)</th>
<th>Modulus (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>0.16</td>
<td>0.5-2.0</td>
<td>2.3</td>
</tr>
<tr>
<td>12.5</td>
<td>0.2</td>
<td>0.5-1.5</td>
<td>3.9</td>
</tr>
</tbody>
</table>

All of the foam heads were prepared with two flats, one each of the anterior and one on the posterior side of the head matching flats on the inside of the metal shell. This was to prevent any rotation of the foam head inside shell. A helical blade, which is the femoral neck implant used with the TFN, 120mm in length, was then inserted on center into the foam head to a depth 7mm from the apex of the head. Pre-drilling was necessary before putting the blade into the 12.5 pcf foam. They were drilled with the provided Ø6.0mm/Ø10.0mm stepped drill bit which stops 5mm short of the final depth of the helical blade. It is a stepped drill bit which makes a Ø6mm hole for the length of the fluted section of the blade, matching the core diameter of the fluted section of the blade, then tapers up to a 10mm diameter, preparing an appropriate hole for the body of the blade.
The foam heads were sturdily fixtured and the helical blade was hammered in with the proper starting orientation to attain the desired final orientation and depth in the foam head model. Helical blades were inserted into 10 pcf foam heads, half of which were predrilled with the stepped drill bit and half of which were not predrilled. As stated earlier, the 12.5 pcf foam heads were always predrilled since they were too dense to insert the blade without predrilling.

The entire fixture then was placed on the tilt table at an angle of 19° as before and loaded with a sinusoidal load pattern with a minimum load of 40N and a maximum load of 800N at a frequency of 2Hz, according to what was determined to be acceptable in phase 1 of the research. If medial migration of the helical blade occurred under any of the tested conditions, then again the null hypothesis would be tested, replacing the
elastomer with a set screw, which would remove the nail toggle from the system. The expected result of this would be varus collapse of the foam femoral head.

### 3.3.2 Results and Conclusion of Phase I

Neither of the expected results were achieved during this part of the experimentation. It was expected that this model which provided us with medial migration when testing with a delrin head would exhibit one of the failure modes observed clinically. Instead, in every configuration of foam head/blade combination, a valgus rotation of the femoral head resulted, opposite of the expected varus rotation as shown in Figure 29. This condition is not documented to be an observed clinical failure of any of the existing cephalomedullary implants. Therefore, this biomechanical construct with the delrin head is not valid for testing implants.

The construct must be redesigned and validated with results matching those clinically demonstrated. We believe that the relatively vertical fracture pattern in the construct combined with the pin between the two segments allowed the head to roll backward more freely. As the loading force is transferred through the pivot pin, the reaction forces normal and parallel to the face of the fracture now sitting at 25° to the vertical (19° of the tilt table plus the 6° fracture angle) have a larger component in a vector parallel to the face of the fracture. Subsequently, the head traveled in that direction. Also, our model had a gap between the two segments which normally does not exist clinically. Often, as soon as the patient begins weight bearing, any gap that may have existed between the lateral and medial segments disappears as the medial segment collapses. In fact, medial migration is almost always seen after some initial collapse.
A new test fixture must be designed and tested according the testing outlined in this section. Then, if it proves to be a valid model, it must be tested per specific aim #1 to check if the new model can still mimic medial migration.

3.4 Phase II

3.4.1 Materials and Methods

A new fixture was designed to resist vertical sliding of the femoral head and remove the gap between the segments. The same aluminum tube and nails will be used. The grooved cover plate however will be replaced with a new plate that changes the
angle of the fracture between the two segments and provides a place to hold pins to allow
for rotation, yet make contact with the femoral head segment, removing the gap. Both
parts of the femoral head shell will also be modified. The back end of the shell will not
have an angled cut to match the angle of the fracture, but will instead be cut
perpendicular to its axis. This is not critical to the test but it is easier to design the back
cover plate of the shell with different angles than to create entire shells with different
angles. The back plate of the femoral head component will have an angled cut to match
the angle of the simulated fracture. Instead of a 6° fracture angle which is almost
vertical, the new fracture angle will be 45 degrees. This is accomplished by making a
plate that has a 20° face that is placed on the fracture surface, making a total fracture
angle of 26°. When the fixture is placed on the tilt table at an additional 19°, the sum
becomes 45°. This plate also has pockets to hold pins for the head to pivot around. Then
the back plate for the head fixture will have a cut 14° to the plane perpendicular to the
axis of the blade, creating a plane which mates with the cover plate of the aluminum tube.

It is hoped that by creating a 45° reaction angle and removing the gap between the
fixture cover plate and the head back plate, a torque is induced around the pivot pins
instead of the sliding action which caused the head to roll backward previously. The rest
of the testing would then be completed as before, with the same sinusoidal loading curve
at a frequency of 2Hz.

Again, foam heads of both the 10 pcf and 12.5 pcf densities will be tested. The
12.5 pcf foam heads will always be predrilled with the 6.0mm/10.0mm stepped drill bit
as described earlier before inserting the blade to a depth 7mm from the apex of the head.
Half of the 10 pcf foam heads will also be predrilled, while the other half will not be predrilled like the testing during phase I.

If this new construct with the foam head successfully demonstrates the typical varus rotation of the femoral head around the neck implant, but not medial migration, then the construct must be tested with a delrin head according to the protocol developed in the first specific aim, to determine if this model can be consistently used to recreate medial migration. A delrin head shaped like the current foam head will be made to fit
inside the stainless steel shell, with the same anti-rotation flats as the foam head. The helical blade will again be replaced by a smooth shaft, as was done throughout the testing for the first specific aim, with a minimal slip fit in the delrin head. A hole perpendicular to the axis of the neck implant will house the delrin friction plug. A tapped hole in the stainless steel shell (two can be seen in the picture above) matching the location of the hole in the delrin head will hold the set screw used to create the frictional hold on the implant as described in the first test performed in this research. The delrin head model will then be tested in the same manner as the established test protocol. The fixture will be placed on the tilt table at 19° and the head will be loaded with a sinusoidal load pattern, with a minimum load of 40N and a maximum load of 800N at a frequency of 2Hz. The friction on the smooth neck implant will be again maintained by tightening the set screw on the delrin plug to a torque of 0.5 N-m.

3.4.2 Results and Conclusion of Phase II

Changing the reaction angle and removing the gap between the segments created the desired result in the foam heads. Both densities tested, whether predrilled or not proceeded to a varus failure of the head around the implant without any noticeable medialization of the neck implant. The varus collapse is a positive indication that the test construct is valid.

The subsequent set of tests which replaced the foam heads and helical blades with the delrin heads and smooth shafts also resulted in the desired medialization of the neck implant as before. It was important to validate the new construct in the delrin head in order to ensure that by making the stainless steel head shell and aluminum cover plate
contact each other we did not introduce any factors that would have caused the head to wedge itself as we previously experienced.

We were unable to attain a medialization of the femoral neck implant through the foam head, but successfully demonstrated it in the delrin heads, strengthening our beliefs about the complexity of interactions needed for this phenomenon. It is our belief that medialization of the neck implant is highly related to varying densities of bone within the femoral head and neck, resisting varus cutout (dense bone superior to the blade), allowing medialization (low density bone medial to the blade), and maintaining a frictional grip on the blade, possibly somewhere in the femoral neck. These conditions, along with a fracture pattern with a pivot point below the axis of the implant, bone resorption of the lateral cortex around the shaft of the neck implant, and a toggle and return action of the nail in the canal all seem to be necessary combinations for medial migration to occur.

We can now, after all of the testing performed thus far, conclude that we have a valid and robust model that can reproduce medial migration in an intramedullary intertrochanteric fixation device. We have shown in the introduction that although rare, this failure occurs with all such devices, whether they use one neck implant or two, and whether those neck implants are screws or helical blades. The last part of this research is to analyze some of the current fixation devices from various manufacturers by testing them in this fixture to determine if they have any features that purposefully or accidentally work to reduce the frequency of this failure.
Chapter 4: Specific Aim #3 – Testing Other Implant Designs For Medial Migration

The third goal of this project is to evaluate various implants from different manufacturers on our validated biomechanical test model to determine if any implant designs inherently prevent this phenomenon from occurring.

In this phase, various implants from different manufacturers are tested in our model to understand if some of the different designs purposefully or accidentally influence the implant’s ability to migrate medially. We plan on testing five different trochanteric fixation devices: (1) Synthes’ Trochanteric Fixation Nail (TFN), (2) Synthes’ Proximal Femoral Nail (PFN), (3) Synthes’ PFN-A, (4) Stryker’s Gamma3, and (5) Smith & Nephew’s Intramedullary Hip Screw (IMHS). The Synthes TFN will represent a titanium construct, the Synthes PFN will represent two screw devices, the Synthes PFN-A will represent a neck implant with shaft that is not completely circular, the Stryker Gamma3 will represent a screw device with a claimed lower frictional coating, and the Smith & Nephew IMHS will represent a device where the lag screw is placed through a sleeve in the nail. Note that the PFN and PFN-A are only available in Europe.

It is evident that some of the manufacturers are aware of the issue and have tried to design implants that reduce its ability to happen, but have not been wholly successful. For example, Stryker’s original Gamma lag screw had 4 axial grooves along the shaft which engaged with a set screw to control rotation of the screw after final seating. The next generation Gamma3 lag screw tapered the 4 axial grooves. They advertise that the grooves are ramped along the axis of the screw, and when engaged with the nose of the set screw to control rotation, the lag screw can collapse freely in the lateral direction, but
cannot move medially since the set screw will bite into the groove as it gets shallower as shown in Figure 31. This is only minimally effective however because we have seen in most cases of medial migration brought to our attention, as also shown in the sequence of pictures in Figure 33, the implant first collapses laterally first before cutting out medially. If the fracture collapses a distance of 10-15mm, then it can in this situation move medially that same 10-15mm before it returns to its original position and runs into the set screw again. If, for example, the tip of the neck implant is correctly positioned about 5mm from the apex of the head, then it can protrude outside the femoral head by at least 5-10 mm. This has continued to occur with the Gamma3 as evidenced by the complaints log at the FDA [15].

**Figure 31. Stryker Ineffective Attempt to Prevent Medial Migration**
Highlighted in red is the angled groove and the contact it would make with the internal set screw as it moves medially.

**Figure 32. Limiting Overall Migration**
Note the circled collar added to the screw which does not allow the neck implant to completely disengage from the nail in the case of medial migration.

Most of the other manufacturers have also attempted to limit the overall migration distance by placing positive stops on their neck implants such that if they do travel medially, they stop at some point and do not migrate completely out of the nail and cause
damage to the internal organs such as the bladder. For example, the Synthes PFN and the DePuy Ace Trochanteric Nail, both of which are two-screw devices which incur a higher failure due to the “Z-effect,” added collars to the back ends of their lag screws after incidents where screws migrated completely through the nail. All of the implants mentioned have an automatic positive stop except for the Stryker Gamma nailing systems and the Zimmer Intertroch/Subtroch Nail (ITST). The ITST uses a similar set screw engaging technique as the Gamma, but the grooves are not angled. If the surgeon engages the grooves with the set screw then at the end of the groove a positive stop is encountered, but if the surgeon does not engage the lag screw as they sometimes choose not to do, then no positive stop is encountered.
An image taken at the end of the surgery showing the end of the blade close to the lateral cortex of the femur

A follow up image taken a few weeks later shows collapse of 10-15mm. For reference it seems that the blade collapsed at least a distance equal to the diameter of the neck implant, which is 11mm.

A follow up image taken approximately 2 months after initial implantation shows migration of the implant.

| Figure 33. Series of Images Showing the Initial Implantation, Subsequent Collapse, and Medial Migration |

4.1 Construct Setup

4.1.1 Nail Construct

The test construct will be similar to the one developed and validated, only slightly modified to accommodate the various implants. The aluminum tube simulating the femoral canal will be longer and will have multiple distal locking holes to match the locations of the locking holes of the different nails. It will have the same features as the previous one including the 6° fracture cut and the large cut out laterally simulating a resorbed lateral cortex around the implant. The appropriate nail is placed in the fixture and held in place distally with a pin the same size as the diameter of the screw normally used to lock it. For all the nails, a 5mm pin is used because a 5.0mm screw is used for
distal locking except for the IMHS which will use two 4.5mm pins to match the two 4.5mm screws typically used with the nail. The distal locking holes are positioned in the fixture such that the top of each nail lines up with the top of the fixture. The medial side of the aluminum fixture will use the same pivot plate developed in specific aim #2 phase II. The pivot plate can be placed in either of two locations such that the axis of the pivot pins is 32mm or 37mm from the top of the aluminum fixture. All of the nail constructs will be tested at both locations except for the PFN which only be tested in the top position because it will not fit in the lower location around this nail. Between the nail and the pivot plate, the same 70A durometer elastomer, 3/8” thick, is placed to simulate the elastic properties of the nail/bone interface, thus allowing the nail to return toward its original position as the load is reduced. Again each implant construct will also be subsequently tested in a condition where it is not allowed to toggle by replacing the elastomer with a set screw, to verify the null hypothesis.
4.1.2 Femoral Head Construct

Individual delrin femoral heads will be made for each varying diameter neck implant to allow for a minimal slip fit between the implant and the delrin head with a clearance of approximately Ø0.1mm. See Appendix 1 for the drawings with the exact dimensions for each of the delrin heads and the other fixtures. The head will also have a hole perpendicular to the axis of the implant hole that houses the friction delrin bushing
which is 8mm in diameter. The delrin heads will be made to fit inside the same stainless steel shell used earlier with the two anti-rotation flats. The heads have a length of 53mm and an outer diameter of Ø45mm. The steel shell will also have tapped holes that line up with the holes in the head for the delrin friction bushing. A set screw is threaded through the metal shell on top of the friction bushing to 0.5N-m of torque, creating a consistent frictional force on the neck implant inside the delrin head.

Lag screws and helical blades are also modified, cutting off the threaded portion or helical blade portion and replacing them with a smooth shaft matching the outer diameter of each implant. This allows consistent control of the friction on the implant inside the delrin femoral head. The crests of the threads and edges of the flutes otherwise would cut into the inside of the delrin head and introduce additional unknown and uncontrolled frictional variables that can also resist the desired motion. The length of the lag screw is not critical as long as the same length screw is inserted. These implants were modified to be 115mm long overall to allow them to fit in the fixture, except for the superior screw on the PFN. That was made to be 107mm long as it is supposed to be shorter than the distal screw. A hole was also tapped at the apex of the shell which allowed for a setup tool to be inserted. The neck implant would then be inserted until it made contact with the setup tool before the friction bushing is engaged, ensuring that all implants are inserted to the same 15mm depth from the inside of the metal shell. Also, since the PFN is a two screw device, the delrin head and steel shell are modified such that friction bushings engage both lag screws during the testing.
It is important to note any necessary orientation of the neck implant in the delrin head before tightening the set screw. For example, the TFN has an anterior flat which engages with an anti-rotation locking mechanism in the nail that should be properly oriented. The Gamma3 lag screw has the grooves mentioned earlier that engage with the set screw. We are assuming that the lag screw has already collapsed 15mm and therefore the set screw may only minimally engage the groove, allowing it to migrate medially 15mm. Due to length requirements of the neck implants, the grooves were not long enough to be engaged so we did not engage the set screw given that we were not worried about rotation in this construct. The other implant for which orientation was important for the test is the IMHS lag screw. The lag screw is designed to fit through a sleeve which has two internal flats that engage flats on the screw to prevent rotation. Clinically, the orientation of those flats is not relevant. For this test the flats must be oriented such that they face proximally and distally. Otherwise, the delrin bushing which engages the
anterior side of the implant will first engage the fully round portion of the screw, but as the screw migrates, the bushing will slip onto the flats and lose its hold.

Figure 36. Flats on IMHS Lag Screw

4.1.3 LVDT Attachment
In order to quantify the medialization, we will also attach a linear variable displacement transducer (LVDT) to the blades to measure the amount of migration experienced over a certain number of load cycles. The LVDT used was from Omega Engineering, Inc., model number LD310-10. Since the femoral neck implants were all cannulated to begin with, we kept them cannulated after the modifications we made to them. We then fed a flexible 1mm multifilament cable with a stop through the neck implant to be attached to the LVDT via an adaptor. In order to measure the relative motion of the blade to the nail, we had to attach the LVDT to the nail. Fixtures were made specific to each nail. Each nail had a different sized notch proximally to allow for the respective manufacturers’ insertion handles, with mating tangs, to connect to the nail and provide rotational control to the user. We made connection barrels with the
appropriate mating tangs to connect to each nail. The barrels were coupled with an arm which clamped the LVDT in line with the neck implant. Holding the LVDT arm and the connection barrel to the nail was a connecting screw with the corresponding thread appropriate for each nail.

![Diagram](image)

**Figure 37. Final Construct Used for Testing the Various Implants**

### 4.1.4 List of Implants

**Gamma3 Construct (5 of each)**

- **Nail:** Ø11mm x 180mm x 130°  
  p/n: 3130-1180S
- **Lag Screw:** Ø10.5mm x 95mm  
  p/n: 3060-0095S – modified as described above
**IMHS Construct (5 of each)**

Nail: Ø12mm x 210mm x 130°  
p/n: HN3012
Sleeve                               
p/n: HN1200
Set Screw                             
p/n: HN1202
Lag Screw: p/n: 12-1178 – modified as described above

**TFN Construct (5 of each)**

Nail: Ø11mm x 170mm x 130°  
p/n: 456.318
Blade: Modified as described above

**PFN Construct (5 of each)**

Nail: Ø11mm x 240mm x 130°  
p/n: 473.231
Lag Screw  
p/n: 473.120  Modified as described above
Hip Pin  
p/n: 439.095  Modified as described above, but overall length was 107mm

**PFN-A Construct (5 of each)**

Nail: Ø10mm x 240mm x 130°  
p/n: 472.265
Helical Blade: Blade portion replaced with smooth shaft as described below.

4.2 Procedure

The LVDT has to be calibrated before use. It is connected to a signal conditioner, also from Omega Engineering, Inc., model number LDX-3A. The signal conditioner feeds an analog input into the TestStar IIIm controller. The LVDT is held in its compressed state and the readings are tared. Then it is extended to 3mm, 6mm, and 9mm and the readings in volts are recorded. This is repeated three times. A best fit curve then is calculated and used to convert the subsequent computer readings to actual linear displacement of the neck implant.

Five nails of each of the five implants are to be tested. Each construct will be tested three times, once with the axis of the pivot pins 32mm from the top of the aluminum construct, and again at 37mm from the top. The third trial will replace the elastomer with a set screw clamping the nail from moving, ensuring that if medial
migration is exhibited, nail toggle is still a major contributing factor as we first hypothesized. For the third trial, the pivot plate should be placed in whichever location showed the quickest lateralization of the implant. This amounts to 75 total trials: 5 different types of nails x 5 nails of each type x 3 trials each = 75.

Each nail is placed in the construct as described above. Modified neck implants are appropriately positioned in the head construct clamped down with a set screw on a delrin bushing tightened to 0.5 N-m, and the cable is fed through the cannulation. The LVDT is connected, ensuring its arm is not fully extended or fully collapsed but can move in either direction recording either medial migration or lateral collapse, and then the entire construct is placed on a tilt table at 19°. A sinusoidal load is applied from 40N-800N at a frequency of 2Hz. The test is set to stop after the LVDT has recorded 9mm of medial migration, or after 5,000 cycles have passed, whichever comes first.

4.3 Results and Discussion

From the LVDT calibration shown in Table 2 below, the test was stopped when the signal conditioner output -3 volts, which corresponded to 9mm of displacement, or after 5,000 cycles were reached.

<table>
<thead>
<tr>
<th>Distance (mm)</th>
<th>LVDT Calibration Readings (V)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trial 1</td>
<td>Trial 2</td>
</tr>
<tr>
<td>3</td>
<td>-1.05</td>
<td>-1.00</td>
</tr>
<tr>
<td>6</td>
<td>-2.05</td>
<td>-2.01</td>
</tr>
<tr>
<td>9</td>
<td>-3.00</td>
<td>-2.98</td>
</tr>
</tbody>
</table>

None of the implants from any manufacturer demonstrated the ability to restrict medial migration. With a few exceptions, most of the implants all failed with
approximately the same number of cycles, without a large influence of the location of the pivot pins, as long as it was situated distal to the axis of the neck implant. The results are summarized in the table below and are shown broken down at each of the two pivot points.

<table>
<thead>
<tr>
<th>Nail</th>
<th>Pivot Location</th>
<th>Average Cycles to 9mm Displacement</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>TFN</td>
<td>32mm</td>
<td>318</td>
<td>3 nails ran out to 5,000 cycles. One with 6.6mm and another with 3.54mm of migration. The third showed no migration. These values were not factored into the average cycles result</td>
</tr>
<tr>
<td></td>
<td>37mm</td>
<td>518</td>
<td>3 nails ran out. One with 1.08mm of migration. The other two showed no migration. These values were not factored into the average cycles result</td>
</tr>
<tr>
<td>PFN-A</td>
<td>32mm</td>
<td>136</td>
<td>1 nail ran out with 4.35mm of migration. This was not factored into the average cycles result</td>
</tr>
<tr>
<td></td>
<td>37mm</td>
<td>N/A</td>
<td>Fixture did not allow for testing</td>
</tr>
<tr>
<td>PFN</td>
<td>32mm</td>
<td>136</td>
<td></td>
</tr>
<tr>
<td></td>
<td>37mm</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Gamma3</td>
<td>32mm</td>
<td>204</td>
<td></td>
</tr>
<tr>
<td></td>
<td>37mm</td>
<td>174</td>
<td></td>
</tr>
<tr>
<td>IMHS</td>
<td>32mm</td>
<td>59</td>
<td></td>
</tr>
<tr>
<td></td>
<td>37mm</td>
<td>95</td>
<td></td>
</tr>
</tbody>
</table>

Three of the Synthes TFN’s and one Synthes PFN-A completed 5000 cycles before they reached 9mm of migration. These data points were not included in the table shown above, although the full results are available in Table 4 found at the end of this section. They were not included because the reason they stopped migrating is unknown, but it is not due to a design feature that inhibited migration, as evidenced by the other cases that did migrate. In fact, of the TFN nails that stopped migrating, two began to medialize and then stopped and the same three that did not migrate the full 9mm at the first pivot point were the same ones that also did not migrate during the second test. This may be due to wear, a burr that developed during the test that prevented migration after
some time, or other characteristics including surface finish of the implants or tolerance between the hole in the nail and the outer diameter of the neck implant. However the most important thing to note is that each type of nail did exhibit medial migration characteristics and none of the implants had a design that inherently prevented medial migration.

An unexpected phenomenon occurred with the third trial of this phase of the testing. When the elastomer was replaced with a set screw that prevented the nail from toggling completely, none of the implants showed any indication of medial migration, except for the PFN. The PFN, a two-screw device, however continued to show migration of the inferior femoral neck element every time, with an average of 552 cycles to complete 9 mm of migration. The proximal femoral neck element, although not connected to an LVDT did not visually appear to migrate during these tests.

An additional trial was performed duplicating this one in every way, except that the superior femoral neck implant was removed from the test construct. This time, no migration was found. The additional neck element must have a secondary effect increasing the proclivity for these implants to migrate. This may begin to explain why the “Z-effect” was so commonly reported in the literature for two-screw devices like the PFN and the Depuy Ace Trochanteric nail and other recon nails and given the name “Z-effect,” but almost never reported for any of the other implants. It could be that the thinner, proximal screw, acts like the elastomer, providing a repelling force that returns the minimal deflection of the lag screw. This is not yet well understood but is a considerable discovery that supports the clinical observations that two-screw devices
have a higher chance of medial migration, also called the “Z-effect” under the right conditions.
### Table 4. Detailed Results of Medial Migration Testing Per Implant

<table>
<thead>
<tr>
<th>Implant</th>
<th>Elastomer - 1st pivot Cycles</th>
<th>Elastomer - 2nd Pivot Cycles</th>
<th>Set Screw (2-Screw) Cycles</th>
<th>Set Screw (1-Screw) Cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Travel (mm)</td>
<td>Travel (mm)</td>
<td>Travel (mm)</td>
<td>Travel (mm)</td>
</tr>
<tr>
<td>PFN 1</td>
<td>145</td>
<td>9</td>
<td>416</td>
<td>9</td>
</tr>
<tr>
<td>PFN 2</td>
<td>116</td>
<td>9</td>
<td>745</td>
<td>9</td>
</tr>
<tr>
<td>PFN 3</td>
<td>130</td>
<td>9</td>
<td>547</td>
<td>9</td>
</tr>
<tr>
<td>PFN 4</td>
<td>120</td>
<td>9</td>
<td>336</td>
<td>9</td>
</tr>
<tr>
<td>PFN 5</td>
<td>170</td>
<td>9</td>
<td>714</td>
<td>9</td>
</tr>
<tr>
<td>TFN 1</td>
<td>82</td>
<td>9</td>
<td>53</td>
<td>9</td>
</tr>
<tr>
<td>TFN 2</td>
<td>5000</td>
<td>6.6</td>
<td>5000</td>
<td>0</td>
</tr>
<tr>
<td>TFN 3</td>
<td>5000</td>
<td>0</td>
<td>5000</td>
<td>0</td>
</tr>
<tr>
<td>TFN 4</td>
<td>5000</td>
<td>3.54</td>
<td>5000</td>
<td>0</td>
</tr>
<tr>
<td>TFN 5</td>
<td>554</td>
<td>9</td>
<td>465</td>
<td>9</td>
</tr>
<tr>
<td>PFN-A 1</td>
<td>47</td>
<td>9</td>
<td>69</td>
<td>9</td>
</tr>
<tr>
<td>PFN-A 2</td>
<td>61</td>
<td>9</td>
<td>62</td>
<td>9</td>
</tr>
<tr>
<td>PFN-A 3</td>
<td>65</td>
<td>9</td>
<td>77</td>
<td>9</td>
</tr>
<tr>
<td>PFN-A 4</td>
<td>313</td>
<td>9</td>
<td>5000</td>
<td>4.35</td>
</tr>
<tr>
<td>PFN-A 5</td>
<td>194</td>
<td>9</td>
<td>222</td>
<td>9</td>
</tr>
<tr>
<td>Gamma3 1</td>
<td>317</td>
<td>9</td>
<td>194</td>
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<td>Gamma3 2</td>
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<td>9</td>
<td>215</td>
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<td>Gamma3 5</td>
<td>257</td>
<td>9</td>
<td>198</td>
<td>9</td>
</tr>
<tr>
<td>IMHS 1</td>
<td>64</td>
<td>9</td>
<td>168</td>
<td>9</td>
</tr>
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<td>IMHS 2</td>
<td>50</td>
<td>9</td>
<td>54</td>
<td>9</td>
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<td>IMHS 3</td>
<td>67</td>
<td>9</td>
<td>96</td>
<td>9</td>
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<td>IMHS 4</td>
<td>64</td>
<td>9</td>
<td>78</td>
<td>9</td>
</tr>
<tr>
<td>IMHS 5</td>
<td>49</td>
<td>9</td>
<td>58</td>
<td>9</td>
</tr>
</tbody>
</table>

*Fixture broke, testing was stopped - most likely would have runout also*
Chapter 5: Final Conclusion/Future Research

This study proved to be very challenging, but even our initial failures provided us with insight to other clinical occurrences of intramedullary hip fixation constructs. Many things were learned or accidentally discovered during the progress of this study. In the first phase we accidentally discovered a possible explanation for instances where the femoral head collapsed along the axis of the neck implant but the neck implant itself does not collapse along its axis with the bone as it was expected. It might possibly be due to bone wedging into the “V” shape between the nail and the neck implant during the collapse that prevents the neck implant from further sliding.

We also stumbled on a different mechanism that seems involved in creating the “Z-effect,” which is particular to two-screw devices used to fix the same fractures. These failures are clinically observed at higher rates and were reported more frequently in the literature. The fact that the PFN implants migrated when they were not allowed to toggle helps validate our test model, and hints that another mechanism is involved in this failure specific to two-screw devices. We did not study this event further because it was not the purpose of this study. We believed that our resources were better utilized understanding, and later fixing, medial migration for single screw devices because they are used by most manufacturers. With the rising number of intertrochanteric fractures amongst a population that is living longer, we would like to eliminate, if possible, this failure mode, reducing the number of secondary surgeries needed, especially for the elderly.

It is very difficult to predict whether medial migration will occur by looking at the implant and fracture pattern. We did outline certain conditions that we thought to be critical in allowing medial migration. The major factor included a missing lesser
trochanter which removes the medial buttress support allowing much of the toggle. Evidence of toggling after the fact can be seen sometimes by a lucency of the lateral cortex around the neck implant. However that is where visible signs end. Most intertrochanteric or pertrochanteric fractures involve a missing medial buttress and so we know that this is not the only condition needed. The rest of the conditions that we believe to be necessary are not visible to the naked eye or easily measured by other means. Per the testing, the other factor that seems to affect medial migration is the local bone density within different areas of the femoral head and neck. The bone proximal to the implant should be resistant to superior cutout, and the bone in other areas that contact the neck implant should create a frictional hold on the implant less than the friction between the nail and neck element during loading, but higher than that during unloading. As the implants of different manufacturers have different surface finishes the friction needed can vary from implant to implant. The rarity of the occurrence also makes it difficult to study clinically.

The purpose of our test was not to be able to predict the behavior but to develop a test model that could replicate the phenomenon in order give us a way to test potential fixes. We believe that after all of the testing that was done we have successfully developed a test model.

The challenge now lies in creating a device that can resist this failure because, although rare, is a rather severe failure. If gone unnoticed the neck implant can pierce the acetabulum and depending on its progress pose a risk of piercing the bladder. Measures have been taken by most device manufacturers to limit the total overall migration of the implant to prevent them from going so far that they migrate out of the nail completely.
None are successful in preventing medial migration. Some work has begun in this effort, although our initial attempts were unsuccessful. We had designed a mechanism that deployed a lever arm that engaged the top surface of the neck implant at an acute angle. The concept was to create a frictional lock with the implant, preventing medial motion, but still allow it to slide freely laterally as shown in Figure 38. We tried the concept, with varying angles between the arm and the implant, and tried varying the contact between the two, from line contact, to point contact and variations in between. When handling the prototypes by hand, pushing on the implant by hand or even banging it on the table did not move it medially. However, as soon as we placed it in the test fixture, the implant migrated medially as if our locking mechanism was not even there. While the frictional lock prevented macromotion of the blade, it did not prevent smaller motion as the blade moved slightly forward (on the order of a few hundred microns) before locking up. That micromotion was enough. It only took the implant moving forward microns each cycle that after hundred of cycles the result was the same. It seems that any future work cannot rely on frictional interference to prevent the event.
Also, it seemed that although at least some manufacturers are aware of the phenomenon, nobody has an implant that is immune to medial migration. It is unknown whether any time is being dedicated to researching a fix. This project took us over two years of constant experimenting and redesign before reaching a valid test model. Fixing the problem is equally as challenging because of the limited amount of space that exists inside the nail to fit a mechanism flexible enough to allow sliding, but sturdy enough to prevent migration and not allow micromotion. The device also needs to be out of the way during insertion of the neck implant since it is inserted in the same direction as the direction of the motion we want to prevent.
While there is still plenty of work left to do, we believe the most challenging part of the project is complete. We have a better understanding of medial migration and have developed a reliable test model that can now be used to test future designs aimed at minimizing or if possible preventing the failure from occurring completely. Ultimately, the goal is to improve the quality of life of individuals. Even though the failure is not common, the people undergoing these surgeries are our grandmothers, sisters, fathers. Every time an elderly person goes under the knife, the risk of decreasing the quality of life increases, along with the risk of complications. Hopefully, this research will lead to future work improving these implants.
List of References


15. Medical device reporting can be found at: http://www.fda.gov/cdrh/mdr/index.html
Samples of supposed medial migration reported to FDA can be found at the following sites. Note some of the descriptions are vague enough that they may not be medial migration but instead superior cut-out where the head fell into varus and the implant was sticking out into the acetabulum.

a. Stryker Gamma:

b. Stryker Gamma3:

c. Depuy Ace:

d. Zimmer ITST:

e. Synthes TFN:


NOTES:
1. BREAK ALL SHARP EDGES, 0.3mm MAXIMUM.
2. HEAT TREAT PER ES0052. H900.
3. BEAD BLAST PER ES0135.
4. ELECTROPOLISH.

SYNTHES USA PAOLI
TFN, TEST HEAD SHELL ANGLE
1:1
NOTES:
1. BREAK ALL SHARP EDGES 0.3mm, MAXIMUM.
2. MEDIUM STRAIGHT KNURL, 90DP.
3. HEAT TREAT PER EG0052, H900.
4. BEAD BLAST PER EG0135.
5. ELECTROPOLISH.
NOTES:
1. BREAK ALL SHARP EDGES, 0.3mm MAXIMUM.
2. HEAT TREAT PER ES0052, H900.
3. BEAD BLAST PER ES0135.
4. ELECTROPOLISH.
NOTES:
1. HOLES ONLY THROUGH ONE SIDE.

- Fitted Head

<table>
<thead>
<tr>
<th>Fitted Head</th>
<th>Delrin</th>
</tr>
</thead>
<tbody>
<tr>
<td>TFN Test</td>
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</tr>
<tr>
<td>I:1</td>
<td></td>
</tr>
</tbody>
</table>

SYNTHES USA PAOLI

NOTES:
1. HOLES ONLY THROUGH ONE SIDE.

- Fitted Head

<table>
<thead>
<tr>
<th>Fitted Head</th>
<th>Delrin</th>
</tr>
</thead>
<tbody>
<tr>
<td>TFN Test</td>
<td></td>
</tr>
<tr>
<td>I:1</td>
<td></td>
</tr>
</tbody>
</table>

SYNTHES USA PAOLI
### NOTES:
1. HOLES ONLY THROUGH ONE SIDE.

<table>
<thead>
<tr>
<th>Fitted Head</th>
<th>Delrin</th>
<th>TFN Test, Delrin, Head, PFM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheet Number</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Dimensions:**

- **Ø8.2 ± .0.2**
- **4x**
- **53**

**Notes:**
1. HOLES ONLY THROUGH ONE SIDE.
NOTES:
1. MODIFY GIVEN GAMMA3 SCREW BY CUTTING OFF THREADS AND CHANGE FRONT END AS SHOWN.
NOTES:
1. MODIFY GIVEN PFN SCREW BY CUTTING OFF THREADS AND CHANGE FRONT END AS SHOWN.
2. REMOVE FLANGE AT BACK END OF SCREW ALSO. IT CAN BE CUT OFF OR TURNED DOWN, WHICHEVER IS EASIER.
1. SHOT PEEIN PER ES0054.
2. ANODIZE PER ES0063, TI-101 (GOLD).

NOTES:
1. HEAT TREAT PER ES0052, H900.
2. BEAD BLAST PER ES0035.
3. ELECTROPOLISH.
4. ETCH "PFN", "PFN-A", & "TFN" AS SHOWN. HEIGHT: 2mm.
5. PASSIVATE AFTER ETCH PER ES0057.
NOTES:
1. HEAT TREAT PER ES0052, H900.
2. BEAD BLAST PER ES0135.
3. ELECTROPOLISH.
4. ETCH "TFN" AS SHOWN, HEIGHT: 2mm.
5. PASSIVATE AFTER ETCH PER ES0057.
80

NOTES:
1. HEAT TREAT PER ES0052, H900.
2. BEAD BLAST PER ES0135.
3. ELECTROPOLISH.
4. ETCH "GAMMA3" AS SHOWN, HEIGHT: 2mm.
5. PASSIVATE AFTER ETCH PER ES0057.