MODELING THE ZIMMER FITMORE AND ML TAPER IMPLANTATION
PROCESS AND THEIR EFFECTS ON THE MEDIAL CORTEX

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ABSTRACT

Modeling the Zimmer Fitmore and ML Taper Implantation Process and Their Effects on the Medial Cortex

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With more young adults requiring total hip arthroplasties the need for bone saving implants becomes more important. The Zimmer Fitmore is a new bone saving implant that utilizes an implantation technique that reduces the damage to the muscle tissue allowing for patients to have a short recovery time as well as a new design that allows it to rest on the medial cortex. There has been anecdotal evidence that this device leads to early revision within six months of implantation due to failures occurring in the medial cortex. The main goal of this study was to computationally model the Zimmer Fitmore and compare it to the ML Taper to see if the failures are due to the design of the implant. The models were created using CT scans of the implants and the same implantation process was simulated for each. Two sizes for the cortical bone thickness, 4mm and 10mm, were used and contrasted with each other. The 10mm cortical thickness model showed that

the strains experienced by the Zimmer Fitmore femur were higher than that of the ML Taper. The 4mm model did not fully complete the simulation, but the results that were obtained showed an increased strain in Gruen zone 7. These results show that the design, not implantation method, could be to blame for the need for early revision when using the Zimmer Fitmore.

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1. Introduction

1.1 Purpose

The average age of patients in need of total hip arthroplasty (THA) are much younger than what they use to be 20 years ago.¹ Patients are showing a greater interest in shorter hospital stays as well as quicker rehabilitation times.² Quicker recovery times have been achieved with the emergence of minimally invasive surgery (MIS), which has been becoming more popular as a surgical technique for THA because it allows patients to return to their jobs in a timely manner.² In conjunction with MIS, bone saving implants have been designed to allow for more surgical options in the future if complications arise and the primary prosthetic hip needs to be replaced.

With a hip prosthesis expected lifespan around 10 to 15 years, people are outliving their implants making bone saving implants more popular.³ An example of a bone saving

implant is the resurfacing implant seen in Figure 1-1.

Figure 1-1 Resurfaced femur using an Articular Surface Replacement implant.

This type removes part of the femoral head and places a cap over it giving the shape needed to appropriately remain fixated in the femur. This results in an intact femoral neck allowing the patient to have multiple options to receive another implant.³ The Zimmer Fitmore is another type of bone saving implant that removes a portion of the femoral neck while preserving the greater trochanter.⁴

According to anecdotal evidence by a number of surgeons, the new design of the Zimmer Fitmore's broach and implantation method may cause complications that can lead to major risks such as femoral fractures. It is believed that these fractures can result in reoperation and early revision. The ML Taper is an older model of a bone-saving implant made by Zimmer, and is used as a control in this study. The ML Taper has a longer stem relative to the Zimmer Fitmore. Also the Zimmer Fitmore uses a triple taper design, which helps stabilize the press-fit implant where the ML Taper uses a tapered wedge.

The goal of this study is to identify if these complications are due to the design and implantation process of the Zimmer Fitmore using finite element analysis (FEA). The objectives of this study are to: (1) create a 3D model of both the Zimmer Fitmore and ML Taper, (2)

validate the femoral strains of the intact femur model with a previous study, (3) implement the prostheses into the femur model, (4) perform and validate the broach process of ten hammer strikes to analyze the stress and strain experienced during the implantation process at several Gruen zones, (5) compare the Zimmer Fitmore to the ML Taper using femur models with a 4mm or 10mm thickness of cortical bone.

1.2 Bone Structure

Bone is constantly changing its structure to adapt to its environment and physical conditions it sustains. Bone is comprised of water, collagen, hydroxyapatite mineral, proteoglycans, and noncollagenous proteins. There are two types of bone that can be differentiated by porosity or apparent density. The bone that lines the outer surface of most bone has low porosity and is known as cortical or compact bone as seen in Figure 1-2, and the high porosity or spongy bone is called trabecular bone as seen in Figure 1-3. The section within bone that has no mineralized aspects to it is known as the medullary canal; this part houses the marrow which is made up of blood vessels, nerves, and is the site where red blood cells as well as stem cells are formed.

Cortical bone's porosity typically ranges from 5-10% with an apparent density of approximately 1.9g/cm^3 .⁵ Looking at the structure of cortical bone in Figure 1-2, there are long tube-like columns running along the stress lines of the bone called osteons. Osteons are typically $200\mu\text{m}$ in diameter, 1cm long, and contain Haversian canals. They contain capillaries and nerves and serve as the structure that gives bone its stability. There are connecting tunnels that link osteons together known as Volkmann's canal which also contain capillaries. Surrounding the osteons are multiple layers of lamellae around $5\mu\text{m}$ thick with their orientation and structure similar to that of plywood.

Figure 1-2 Cortical bone and its components.⁶

Trabecular bone is on the opposite end of the porosity spectrum with a porosity of 75-95%. These are typically found in the vertebrae and at the ends of long bones for example the ulna, tibia, fibula, and femur (Figure 1-3). What makes trabecular bone so porous is that its structure

is made up of tiny struts called trabeculae. Trabeculae can appear to be random in orientation, but they arrange themselves to give support along stress lines that the bone experiences through everyday use. Each trabeculae are on average the same size of an osteon in diameter. However, in the older population or osteoporotic patients these struts become smaller due to loss of bone mass and increase their chances of fracture. Bone marrow is also found in the pores between trabeculae.

Figure 1-3 Trabecular bone⁶

Both types of bone have two different types of bone tissue: woven and lamellar. Woven tissue is a quick forming disorganized arrangement of bone. It is typically found at locations of fracture to quickly regain the structural integrity of that section of bone. Over time the second type of bone tissue is formed known as lamellar bone. This is a more organized bone that takes much longer to form. Lamellar bone forms layers called lamellae, which creates a complex structure of collagen fibers and minerals. Because it is more organized less bone is required to maintain the same level of support.

1.3 Bone Remodeling

Basic multicellular units (BMUs) are responsible for the remodeling of bone (Figure 1-4). BMUs are consisted of osteoclasts, multinucleated cells formed from monocytes to resorb bone, and osteoblasts, mononuclear cuboidal cells that differentiate from mesenchymal cells to produce bone. These two cells work together creating new Haversian canals to provide pathways for nutrients to be brought to the bone. When there is disuse or damage in the bone osteoclasts are activated. Over a three week period they demineralize bone with acid, dissolve collagen with enzymes, and resorb the bone. The osteoblasts then follow

the osteoclasts down the tunnel several days behind them adding new bone to the resorption space. As this is going on osteoblasts have the chance to become embedded into the bone matrix where they are turned into osteocytes.

Osteocytes are able to communicate with each other through small canals, and when these communications are inhibited it seems to trigger the BMUs. The whole process from osteoclasts being activated to the last osteoblast takes approximately 90 days to complete and every year about 10-15% of the bone in your body has been replaced with new bone.

Figure 1-4 Basic multicellular unit⁷

1.4 Fracture Mechanics

Bone can fail in two different ways: fast fracture and fatigue. Fast fracture occurs when stress levels exceed the failure or ultimate stress of the bone tissue. Situations where this arise can be through trauma or impact; for example, a common fast fracture occurs when elderly people fall on their hip. Stress fracture happens when the BMUs are not given enough time to repair damaged bone and cracks propagate to the point of fracture below the ultimate stress. Stress fractures typically occur in athletes and military recruits due to the heavy cyclic loading and unloading conditions their bones are subject to. Bone has a couple of precautionary attributes that help fight crack propagation, such as mineralization and the cement lines around osteons. Mineralization helps deter cracks from forming in the bone so when the crack reaches it the tip turns into a blunt point increasing the force required to propagate it. The cement lines work in the same fashion, but instead of attempting to stop the crack they redirect it in a nonthreatening direction by providing a path of least resistance. Figure 1-5 shows examples of different crack propagations: A) crack between lamella B) a crack propagates to the cement line of an

osteon C) the crack propagating around the cement line and
D) cracks that formed on the strut in trabecular bone.

Figure 1-5 Different types of crack propagations.⁶

The rate at which cracks propagate can lead to different types of fracture.⁶ Figure 1-6 shows what the microstructure of a pullout fracture looks like. This is a result of a slow propagating fracture.

Figure 1-6 Osteon pull-out.⁶

Figure 1-7 shows a transition from slow to fast crack propagation going from left to right. The left side is a representation of the pullout fracture while the right side the crack has entered fast fracture and results in shearing.

Figure 1-7 Osteon cleavage.⁶

More energy is required for pullout fracture to occur and it increases as the speed of the crack formation increases. However, once the crack enters shear fracture the amount of energy required to continue the crack propagation continuously decreases as the speed of the crack formation increases.

1.5 Hip Dysplasia

Hip Dysplasia is a condition where the acetabulum is in the wrong shape or the femur is in the wrong location. This can result in the need for a THA at a young age where a bone sparing implant can be useful.⁸ Figure 1-8 is a radiograph of a 19 year old girl who is suffering from hip dysplasia.

Figure 1-8 The right hip has early-stage dysplastic osteoarthritis and the left hip has advanced stage.⁸

This affects about 1% to 3% of all infants in the United States; medication can temporarily fix the issue, but surgery is the only long term solution.⁹ The onset of hip

dysplasia can occur from as early as birth until after years of life.

It is believed that during pregnancy the mother goes through hormonal changes that result in increased ligament looseness, which crosses over the placenta and the baby will experience lax ligaments. With the femur not resting appropriately within the acetabulum, the cartilage wears down at an accelerated rate due to the excess stress on the joint, which can cause the individual life-long pain. Because of this about 8% of the people who suffer from hip dysplasia also develop osteoarthritis later in life.

1.6 Osteoarthritis

Osteoarthritis affects an estimated 12.1% of the people in the United States making it the most common type of arthritis.¹⁰ Aside from hip dysplasia, factors that can lead to an increased risk of developing osteoarthritis are trauma and obesity. It can be characterized by damage to the articular cartilage, changes in marginal bone, and capsular thickening (Figure 1-9).¹¹

Figure 1-9 Both images are taken by x-rays. The first image is of a normal hip, and the second image is of a patient with osteoarthritis.¹²

About 40% of the people who show signs of osteoarthritis through a radiographic experience no symptoms while others may experience pain, stiffness, crepitus, and swelling. To prolong the need for joint surgery pharmacological treatment and lifestyle modifications, for example weight reduction and exercise, are alternative therapies that patients can choose from.

1.7 Direct Anterior Approach

To insert the femoral prosthesis during hip replacement surgery, the anterior approach was first used by Robert and Jean Judet in 1947 in conjunction with the use of an acrylic stem implant.¹³ They used Hueter's short anterior incision to gain access to the hip because it was

quick, simple, and hemorrhage free. For the same reasons why surgeons today use the anterior approach, their method allowed adequate exposure of the femur without damage to any major muscle. It also allowed the lateral cutaneous nerve of the thigh to be untouched.¹³

When the anterior approach was first introduced it received a lot of criticism due to the steep learning curve and failed implants. Surgeons believed the benefits from the new techniques (mainly cosmetic) did not outweigh the dangers associated with them.¹⁴ However, in recent years the method has become widely accepted as safe. Of the different methods, the anterior approach requires the surgeon to overcome a steep learning curve in order to perform the surgery effectively.¹⁵

Today's anterior approach places the patient in a supine position on a Hana table.⁴ The patient's feet are bound into leg spars which allows the surgeon to rotate the leg freely to gain better access to the femoral head at different points in the surgery. The initial incision is made 2cm posterior and 1cm distal to the anterior superior iliac spine (Figure 1-10). It is approximately 10cm in length, and the incision runs parallel to the tensor fasciae latae muscle.

Figure 1-10 Site of initial incision for the direct anterior approach to the hip⁴

With the tensor fascia latae muscle exposed, it is released from its superficial aponeurosis and the fatty tissue comes into view (Figure 1-11).

Figure 1-11 The tensor fascia latae muscle is released and the fatty tissue exposed.¹⁶

Beneath the layer of fatty tissue is the anterior capsule of the hip. To gain access to the femoral head and neck a capsulectomy is performed, which removes the capsule (Figures 1-12 & 1-13).

Figure 1-12 Anterior capsule of the hip¹⁶

Figure 1-13 Capsule is removed¹⁶

Once the femoral neck is exposed, it is dislocated (Figure 1-14) and an oscillating saw is used to separate it from the femoral shaft (Figure 1-15).

Figure 1-14 Dislocation of the femoral neck.¹⁶

Figure 1-15 Femoral head is separated from the shaft.¹⁶

A screw is put into the osteotomy of the head and it is removed.

Next the labrum and soft tissue in the acetabular fossa is removed using standard methods. The acetabulum must be shaped using a reamer so the acetabular shell can be fit appropriately. Positioning of the acetabular shell is verified and inserted. The femur is then broached and the prosthetic is implanted (Figure 1-16).

Figure 1-16 Broaching the femur.¹⁶

1.8 Zimmer Fitmore

The Zimmer Fitmore utilizes the anterior insertion method for implantation; however, the broaching process differs from other implants using this method. The Fitmore is designed to be a bone saving implant by resting on the medial cortex during the broach and implantation process as well as having a short-curved stem (Figure 1-17).⁴ The broaching process for the Fitmore differs from other hip

implants by having a single point of contact on the lateral cortex while the medial side remains in contact with the medial cortex of the femoral shaft.

Figure 1-17 Points of contact during implantation for the Zimmer Fitmore hip implant⁴

1.9 ML Taper

The ML Taper uses a tapered wedge fixation philosophy to maintain mediolateral stability.¹⁷ Made from titanium alloy it is designed to be a bone conserving implant. With a narrow neck it enables the patient to have a wider range of motion (Figure 1-18).¹⁷

Figure 1-18 ML Taper implant.¹⁷

1.10 Computer Models

Computer models analyzing the effects of hip implants on the femur using FEA allow for cheap and accurate structural analysis without the need of creating a physical apparatus. One of the first times this method was utilized was in the late 1980's by Huskies and Yoon.¹⁸ In the more recent years, Griza and Reis used FEA to investigate an uncemented hip stem failure.¹⁹ Chris Deuel and Trevor Hryce developed finite element models of the femur with various implants, looked at the effects of the implants on femoral stress, and analyzed the long term effects of alendronate

on bone mass preservation.^{20,21} In the current study the broaching process of the Zimmer Fitmore and the ML Taper implants will be analyzed using FEA to determine if the design of the Zimmer Fitmore and its implantation process may be responsible for the early revisions experienced with this implant.

2. Methods

Following on the work of Chris Deuel and Trevor Hryce, the femur model used was provided by Biomed Town²², which modeled the right femur with the soft tissue removed. SolidWorks was used to perform the osteotomy to remove the femoral head for insertion of the implants. To allow for easier boundary conditions for the simulation the adductor tubercle and everything distal to it were removed. It was then imported into the finite element software, ABAQUS, and meshed. A convergence study was performed to compare strains so an appropriate mesh density could be selected. A comparative experimental study²⁰ that analyzed the differences between hip resurfacing versus total hip arthroplasty was used to validate the femoral finite element model. The regions of interest for the Zimmer Fitmore and the ML Taper were defined by Gruen zones in Figure 2-1.

Figure 2-1 Shows the seven Gruen zones²³

For the Zimmer Fitmore and ML Taper two similar meshes were created from the native femur. The femur model for the Fitmore contained 21070 elements and 32560 nodes and the ML Taper's femur consisted of 20213 elements and 31589 nodes. Material properties associated with these models are cortical bone, trabecular bone, and the medullary canal.

The type of Zimmer Fitmore model used was the A2 with a titanium stem which consisted of a 31mm offset and 87mm stem length. The control was a titanium ML Taper 5 extended offset with an offset of 40mm and 109mm stem length.

One load case was applied to the broach of the implants to simulate the implantation. Each load was applied using the magnitude shaped in a bell curve over a 0.3 second period.²⁴ It takes approximately ten strikes²⁵ to get an implant completely into the femur. A 500g hammer²⁵ was used and an arm swing velocity of 8m/s (Figure 1-21).²⁶

Figure 2-2 Max hand velocity.²⁶

2.1. Model Creation: Implant

CT scans were performed at UC Davis in helical mode, with a slice thickness of 1.25mm and resolution of 0.98mm/pixel using LightSpeed QXi CT scanner (GE Healthcare, Milwaukee, WI). The CT scans were then imported into Mimics and a layered image of each implant was compiled. The dimensions of both implants were taken and applied to the models that were created in SolidWorks as well as a rough 3D model generated by Mimics (Figures 2-3 - 2-6).

Figure 2-3 Zimmer Fitmore Isometric View

Figure 2-4 Zimmer Fitmore Front View

Figure 2-5 ML Taper Isometric View

Figure 2-6 ML Taper Front View

The models were cross checked with images of both implants^{17,27} to insure accuracy of the dimensions obtained through Mimics. A broach was added to each implant that contained a one inch diameter strike pad. Both implants were then imported into ABAQUS as an IGS file for seeding and meshing. For the Zimmer Fitmore a general seed size of 25 was used in order to provide a count of 751 elements and 1483 nodes (Figure 2-7).

Figure 2-7 Zimmer Fitmore Broach Mesh

The ML Taper used a general seed size of 19. Some of the faces were too small to generate a proper mesh so these faces used a seed by number of 5 which provided a count of 1880 elements and 3431 nodes (Figure 2-8).

Figure 2-8 ML Taper Broach Mesh

The elements used in the implants were explicit quadratic tetrahedral (C3D10M) because they allow for accurate stress and strain analysis in a dynamic/explicit simulation.

2.2. Model Creation: Femur

The femur model was taken from the Biomed Town website.²² In SolidWorks, an osteotomy was performed on the

femur by removing the head with a 45 degree incision and the condyles were also removed (Figures 2-9 and 2-10).

Figure 2-9 3D femur model with the condyles removed

Figure 2-10 Femur model with the 45 degree angle incision removing the head

The femur was imported into ABAQUS as an IGS file at a scale of 1:1.1. The resultant length of the femur came out to be 440mm and a diameter of 24mm. The femur was cut so that the implants would fit as though it were the final broach used during implantation. This was done by positioning the tip of the stem at the origin of the coordinate system so there was a common reference point for both implants. The modified femur was then rotated and translated to be in the appropriate position relative to the implant. Once the femur was in place, the implant was subtracted from the femur leaving a cavity for the broach.

This was performed for both implants and cortical bone sizes with their respective femurs.

Figure 2-11 Cavity for the Zimmer Fitmore implant

Figure 2-12 Cavity for the ML Taper Implant

For the Zimmer Fitmore femur a general seed size of 5.7 was used which resulted in 21070 elements and 32560 nodes (Figure 2-11). The ML-Taper femur used a general seed size of 6 which resulted in 20213 elements and 31589 nodes (Figure 2-12). The element type used in the mesh was explicit quadratic tetrahedral: C3D10M.

2.3. Model Creation: Defining Properties

Table 2-1 shows the materials used as well as the properties associated with each material.

Table 2-1 Shows the different material properties used and their respective density, young's modulus, and poisson's ratio.^{5,6,28}

	Density (g/cm ³)	Young's Modulus (MPa)	Poisson's Ratio
Cortical Bone	1.9	17000	0.33
Trabecular Bone	0.4	1000	0.3
Medullary Canal	1.5E-4	0.1	0.3
Titanium	4.5	114000	0.32

Both the Zimmer Fitmore and ML Taper were simulated with material properties of titanium. The elements on the surface of the femur were defined as cortical bone. This was done by creating an element set and using the select elements by angle and defining the angle to be 20 degrees. Some surface elements were not selected due to the organic geometry so these were added manually by individually selecting the missing elements. This selection was hidden using the display group tool and the next layer of elements was added onto the selection which simulates approximately a 4mm thickness of cortical bone distal to the 45 degree angle cut made to remove the femoral head in the shaft of the femur. For the Zimmer Fitmore this resulted in

approximately 60% contact to the implant while the ML Taper experienced 50%. Another pair of femurs were created with a cortical bone thickness of 10mm around the implant in the shaft of the femur with a 100% contact to the implants. The remaining elements distal to the lesser trochanter were defined as the medullary canal and the remaining bone was defined as trabecular (Figure 2-13).

Figure 2-13 Highlighted is the elements for the medullary canal, and the surrounding elements on the medial and lateral side were defined as cortical bone.

By utilizing display groups, element properties were checked for accuracy.

2.4. Model Creation: Loading and Boundary Conditions

The simulation had the broach experience hammer strikes during the direct anterior implantation process. The hammer strike loading conditions were calculated based on three criteria: hammer weight, hand swing velocity, and contact time of the hammer to the broach. The mass of the hammer simulated was 500g²⁵ with a max velocity of 8m/s²⁶, which results in a concentrated load of 2000N for a single swing. For the contact time, the information gathered from the impact of a hammer onto concrete was used. This resulted in 300 micro seconds as the total impact time.²⁴ However, the force experienced over this time is shaped similar to that of a bell curve with the peak at 150 micro seconds.²⁴ To properly simulate this in ABAQUS a tabular amplitude was applied to the loading conditions. At time 0 and 300 micro seconds the amplitude is 0 and at 150 micro seconds the amplitude is set to 1. Each hammer swing was set 0.3 seconds apart from each other.

A total of eleven steps were used to simulate the implantation process. The first ten steps simulated the hammer strikes. A 2000N concentrated force was applied to the center of the broach with an amplitude to mimic an

impact force that occurs over 300 micro seconds. The rate of hammer strikes occurred once every 0.3 seconds.

The 11th step was introduced to allow the stress and strain of the simulation to formulate over 25 seconds. Without this step the simulation does not have enough time to propagate the stress and strain throughout the femur. This step had no additional loads.

The boundary condition used for the femur was a pinned constraint at the distal face. To define the contact between the broach and the femur a tie constraint was used. The faces of the implant that were in contact with the femur were selected as the master surface and the faces of the femur that were in contact with the implant were selected as the slave surface.

2.5. Model Convergence and Validation

Two convergence tests were performed to find the optimal number of elements as well as the minimum time for the 11th step of the simulation. Five mesh densities were used to determine the appropriate element count for the simulation (Figure 2-14).

Figure 2-14 Shows the micro strain experienced by a region on the femur at varying degrees of freedom.

Also, five durations of the 11th step were used to determine convergence as well as an optimal length (Figure 2-15). The simulations performed for each of these tests were a simple loading condition applied to the head of the broach. Over the first 25 seconds the stress continually increased as the stress developed with each additional strike. From 30 to 50 seconds the femur experienced reduced stress because the impact force from the hammer strikes had stopped. The cumulative stress from the hammer strikes converged at 25 to 30 seconds. It is expected to see a decline in stress due to no more loading being applied to the femur.

Figure 2-15 Shows the stress experienced at a specific node on the femur during the 11th step.

Validation was achieved by comparing experimental results of a study by Christopher Deuel at UC Davis²⁰ to the simulation results from the native femur in the current study. In his study the strains experienced by the fully intact cadaveric femora were measured when a load was applied to it at a 22 degree angle from vertical (Figure 2-16). Strains were measured using one three-element 45° stacked rosette strain gauge (model 060WR-350, Vishay Micro-Measurements, Raleigh, North Carolina) and three axial strain gauges (model 125UN-350, Vishay Micro-Measurements, Raleigh, North Carolina). They were attached to the femur by light sanding of the bone surface and using cyanoacrylate adhesive and a catalyst.

Figure 2-16 Shows the apparatus used to measure strain in the proximal femur.²⁰ Strain gauges were placed just below the anterior and posterior side of the lesser trochanter.²⁰ Deuel showed that three-dimensional finite element modeling was capable of

simulating the remodeling process in bone by comparing observed experimental data gathered from a human femur to a simulated model (Figure 2-17).

Figure 2-17 Shows the comparison of the native femur relative to the simulation performed in ABAQUS.

2.6. Model Implementation

Models were run using ABAQUS 6.10 on two custom built workstations each with Intel Core i7-950 3.06 GHz quad-core processors, ASUS P6x58D premium motherboards, and 12 GB RAM.

2.7. Post-Implantation

The eleven step simulation was performed following validation. The implantation process took approximately 3 seconds. Once completed, the true strains were examined

for both implants at Gruen zones 1, 2, 3, 5, 6, and 7. These regions of interest were compared with each other to determine if the design of the implant has an effect on strain during the broaching process with a 25 second 11th step. 25 seconds was used to save computational time because there was little change between a 25 second and 30 second 11th step. The ML Taper and Zimmer Fitmore 4mm cortical bone thickness model's 11th step ran for 0.25 seconds and 8 seconds, respectively, because the simulation were unable to reach the 25 second. The results were used because the 4mm model represents the cortical bone found in the femur better than the 10mm model. From the data obtained comparisons were made between the ML Taper and the Zimmer Fitmore at 25 seconds and 10mm thick cortical bone, the strains experienced by the ML Taper at 0.25 seconds with 4mm or 10mm thick cortical bone, the Zimmer Fitmore strains using 4mm or 10mm thick cortical bone at 0.25 seconds and 8 seconds, and compared the ML Taper and the Zimmer Fitmore strains with 4mm thick cortical bone at 0.25 seconds.

3. Results

3.1 Validation

The loading conditions in the simulation were set up to represent slow walking as described by McLeish and Charnley. This resulted in femoral strains of $-552\mu\epsilon$ and $609\mu\epsilon$ in the proximal medial and the proximal lateral region, respectively.

The model was validated by comparing these results to Christopher Deuel's data of a cadaveric femur in its native state seen in Figure 3-1. After the load was applied the resultant simulation strains were within one standard deviation of the experimental mean values.

Figure 3-1 Shows a comparison of the microstrain in the proximal medial (PM) and proximal lateral (PL) locations in a fully intact femur in ABAQUS and Christopher Deuel's native femur clinical data.

The values generated by the ABAQUS simulation are close to what is expected for strain. This enables us to use the femur model for the simulation of the implantation of the Zimmer Fitmore as well as the ML Taper with confidence.

3.2 Implantation

The 11th step of the simulation with the ML Taper and the 4mm cortical bone thickness ran for 0.25 seconds. The results displayed in Figure 3-2 are a comparison of the ML Taper models when the cortical bone thickness is 4mm or 10mm at 0.25 seconds. The model with the 4mm thick cortex experienced microstrains in Gruen zones 1, 2, 3 at 246µε,

455 $\mu\epsilon$, and 152 $\mu\epsilon$, respectively. In Gruen zones 5, 6, and 7 the microstrains were -173 $\mu\epsilon$, -249 $\mu\epsilon$, and -490 $\mu\epsilon$, respectively. With the 10mm thick cortical bone it is in complete contact with the implant and the original strains in the bone were reduced to 34.4% (GZ1), 20.1% (GZ2), 26.5% (GZ3), 44.5% (GZ5), 20.2% (GZ6), and 0.04% (GZ7).

Figure 3-2 Compares strains due to the effects of the cortical bone thickness on the femur with a ML Taper implant after 0.25 seconds of run time at Gruen zones 1, 2, 3, 5, 6, and 7.

The Zimmer Fitmore model that contained the larger medullary canal ran for 8 seconds. This model was simulated with a cortical bone thickness of 4mm. The results in Figure 3-3 display the effect of varying cortical thickness at 0.25 seconds. For the 4mm simulation the lateral side of the femur experienced microstrains of

202 $\mu\epsilon$, 434 $\mu\epsilon$, and 125 $\mu\epsilon$ at Gruen zones 1, 2, and 3, respectively. The medial side was -108 $\mu\epsilon$, -278 $\mu\epsilon$, and -624 $\mu\epsilon$ at Gruen zones 5, 6, and 7. When the cortical bone thickness was increased to 10mm the strains were less resulting in 22.8% (GZ1), 10.7% (GZ2), 42% (GZ3), 52% (GZ5), 10.8% (GZ6), and 5.6%(GZ7) of the original values.

Figure 3-3 Compares strains due to the effect of the cortical bone thickness on the femur with a Zimmer Fitmore implant. The model with a 4mm thick cortex has a greater magnitude of strain relative to the simulation performed with a thickness of 10mm after 0.25 seconds of run time.

The Zimmer Fitmore comparison of the effects of the cortical bone thickness at 8 seconds can be seen in Figure 3-4. The simulation that contained the 4mm thick cortical bone had microstrains of 838 $\mu\epsilon$, 1196 $\mu\epsilon$, and 1018 $\mu\epsilon$ at Gruen zones 1, 2, and 3, respectively. Whereas Gruen zones 5, 6, and 7 had microstrains at -1447 $\mu\epsilon$, -2183 $\mu\epsilon$, and -2160 $\mu\epsilon$,

respectively. For the simulation with cortical bone at 10mm thick the microstrains experienced were again lowered to 22.1% (GZ1), 16.4% (GZ2), 13.7% (GZ3), 15.5% (GZ5), 7.59% (GZ6), and 7.47% (GZ7).

Figure 3-4 Compares strains due to the effects of the cortical bone thickness on the femur with a Zimmer Fitmore implant. After 8 seconds of run time the 4mm cortical bone simulation has a consistent trend of increased strain relative to the simulation with 10mm thick cortical bone.

The results from the simulation with the 10mm thick cortical bone can be seen in Figure 3-5. For the ML Taper the resultant microstrains on the lateral side were 555 $\mu\epsilon$, 449 $\mu\epsilon$, and 559 $\mu\epsilon$ for Gruen zones 1, 2, and 3, respectively. For the medial side it was -566 $\mu\epsilon$, -497 $\mu\epsilon$, and -607 $\mu\epsilon$ for Gruen zones 5, 6, and 7. As for the Zimmer Fitmore, it experienced greater microstrains on the lateral

side with 1476 $\mu\epsilon$, 634 $\mu\epsilon$, and 1622 $\mu\epsilon$ in Gruen zones 1, 2, and 3, respectively. While on the medial side microstrains ranged from -930 $\mu\epsilon$ to -1721 $\mu\epsilon$.

Figure 3-5 Compares the ML Taper to the Zimmer Fitmore strain after 25 seconds of run time at Gruen zones 1, 2, 3, 5, 6, and 7 with 10mm thick cortical bone.

The ML Taper and Zimmer Fitmore are compared at 0.25 seconds with the 4mm cortical bone thickness in Figure 3-6. At Gruen zones 1, 2, 3, and 5 the Zimmer Fitmore experienced less strain compared to the ML Taper. For Gruen zones 6 and 7 the Zimmer Fitmore showed a slight increase in strain.

Figure 3-6 Compares the ML Taper and the Zimmer Fitmore with the 4mm thick cortical bone present and a run time of 0.25 seconds.

4. Discussion

Surgeons and implants have started to use the Direct Anterior Approach for THAs. This method has been known to reduce recovery time by limiting the damage done to muscle surrounding the femur. The Zimmer Fitmore utilizes this method but has been anecdotally associated with early revision within six months postoperatively due to failure in the medial cortex. The ML Taper was used to compare to the Fitmore because they are both made by Zimmer and it has been known to be an effective implant. The comparison was done by creating 3-D models of the implants and using them to create finite element models to analyze femoral strain. The implantation process was then simulated and the simple model showed an increased strain for all Gruen zones in the Zimmer Fitmore. The final model ran for an abbreviated time, and the results of that simulation initially showed an increased strain in Gruen zones 1, 2, 3, and 5 for the ML Taper while in Gruen zones 6 and 7 the Fitmore had an increased strain.

The simple model which was performed used a cortical bone thickness of 10mm. The strain experienced by the femur that used the Zimmer Fitmore was much higher relative to the ML Taper femur. Figure 4-1 shows the percent change

between the Zimmer Fitmore and ML Taper that ranged from 141.1% at Gruen zone 2 to as high as 304% at Gruen zone 5.

Figure 4-1 Looks at the percent difference in strain between the Zimmer Fitmore and the ML Taper with a cortical bone thickness of 10mm.

Because both simulations used the same implantation method the results of the simple model imply that the difference in strains could be linked with the design of the implant rather than the method of implantation.

The same model for the femur was used for the more anatomically correct simulation using a cortical bone thickness of 4mm. The implant was moved so that it was in the appropriate location within the femur. This simulation took substantially longer to run, over 7 days of clock time relative to the simple model's 20 hours, and would crash or

fail to move onto the next iteration. For the ML Taper the simulation would stop 0.25 seconds (simulation time not real time) into the 11th step. Convergence happens at 25 seconds therefore the values obtained were not an accurate representation of the true strain experienced by the femur. The Zimmer Fitmore ran until the 8th second of the 11th step and would continue to analyze that iteration until a kill command was issued. Similar to that of the ML Taper, the convergence occurs at 25 seconds so the values obtained by this simulation were not an accurate representation of the true strain experienced by the femur.

Taking a look at the ML Taper, there is a large increase in strain when comparing the effects of the cortical bone thickness at 0.25 seconds. The percent increase in strain between the simulation with a bone thickness of 10mm to the simulation that had 4mm ranged from 225% at Gruen zone 5 to 2244% at Gruen zone 7 as seen in Figure 4-2.

Figure 4-2 Shows how the ML Taper is affected by the varying size of cortical bone thickness.

The Zimmer Fitmore experienced similar trends when comparing the effects of the cortical bone thickness at 0.25 seconds as well as at 8 seconds. Figure 4-3 shows the percent increase in strain between the two simulations at 0.25 seconds ranged from 192% at Gruen zone 5 to 1707% at Gruen zone 7 and the increase for the simulations that took place at 8 seconds exhibited a low of 453% at Gruen zone 1 and a high of 1338% at Gruen zone 7.

Figure 4-3 Shows the Zimmer Fitmore and the effects the cortical bone thickness has on the percent change in strain at 0.25 and 8 seconds.

Dr. Carter tested the strain range of adult cortical bone by using the femoral mid-diaphyses of two male and two female subjects.²⁹ His results showed that the yield strain was around 0.0068 while the ultimate strain was closer to 0.0157. It was also observed that fatigue loading strain from -0.003 to +0.003 was subject to failure after 2147 loading cycles. Comparing the 0.25 second data the Zimmer Fitmore appears to have lower strains relative to the ML Taper. The strains that both implants experience however do not seem to suggest that there would be any form of early failure except in Gruen zone 7 where it experienced

strains that exceed -0.003 however at a reduced loading cycle.

There were some limitations associated with the femur model. The location of the cortical bone, medullary canal, and trabecular bone were selected by hand based upon the known characteristics of each. Also, the material definitions of the cortical and trabecular bone did not use anisotropic properties. The simulation itself only simulated the last broach size during the implantation process. Normally there are several broach sizes to gradually increase the size of the cavity to fit the final implant. Also, the accuracy of the load applied to the broach during the hammer strikes performed by the doctor was calculated using three different sources.

There is no reason to believe that these limitations would cause the simulation to be grossly inaccurate. A larger source of error may have stemmed from the material properties associated with the implant, medullary canal, and cortical bone. This can be seen by looking at the simulation that had the cortical bone with a thickness of 10mm. This simulation had 100% contact with the implant and the simulation completed whereas the simulation that contained the bone thickness of 4mm failed. This can occur

in the simulation due to elements experiencing distortion in the medullary canal from the titanium and cortical bone compressing it.

Future experiments involving the effects of the Zimmer Fitmore design on the femur during implantation might want to look at the damage levels of the bone six months postoperative. Furthermore, there are multiple sizes for the Zimmer Fitmore as well as the ML Taper. Simulations could be performed to see if the size of the stem has an effect on the strains experienced in the femur. It would also be interesting to include the entire broaching process in the simulation. For this the impact force of the hammer hitting the broach should be examined further to increase the accuracy of the simulation. The current study uses three different sources to estimate the load the broach would experience during implantation. An alternative would be to have an orthopaedic surgeon strike a force sensor to get a more accurate reading.

This study demonstrated that a 3-D model of the Zimmer Fitmore and ML Taper can be created using CT scans and that they could be implemented in a FEA simulation using ABAQUS. The results from this simulation showed the design of the Zimmer Fitmore can be responsible for high strains in the

medial cortex during the implantation process, specifically Gruen zone 7, to the point where early revision may be required.

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