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The Design of Patient-Specific Implants to Treat Bone Cancer

By

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of the requirements for
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ABSTRACT

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Advisor: Glenn Sanders

Benign and malignant tumors often arise in bone due to metastasizing cancer. Thirty years ago limbs affected by tumors were treated with amputation, now with new technology, limb-saving surgery is used most of the time; however, these surgical methods have limitations. Research shows a trend of using allografts and metallic implants to fill the bone gap once the tumor is resected. In some cases sections up to one third of the femur can be removed, sometimes disrupting the joint. There are many problems such as the integration and risk of failure in these implants. A more patient specific approach can be beneficial. It is important to create an implant that is optimally porous to promote osseointegration, bony ingrowth through the implant. While porosity is important, the implant must also sustain mechanical loading. We hypothesized that we can reduce the limitations of current bone cancer treatment methods by utilizing novel CAD and manufacturing technology to design a patient-specific orthopaedic implant.

Using a software program called Mimics, we transformed CT scan data of a patient's cancerous femur into a three-dimensional model. Using the 3D model, we resected the 15cm tumor through a "virtual surgery". A custom implant was designed to fill the bone gap and the overall porosity and pore size was optimized to withstand physiologic loading and promote osseointegration. The implant's stresses and strains will be tested using Finite Element Analysis (FEA) to confirm the mechanical properties. Once the design is optimized, a titanium (Ti6Al4V) implant will be created using Direct Metal Laser Sintering (DMLS), an additive manufacturing (rapid prototyping) technique. Additive manufacturing has recently started to appear in the medical device industry because of the capabilities to create intricate and complex structures and the cost-effectiveness. This process for creating patient-specific implants can greatly improve bone cancer patient's outcomes by minimizing the surgical resection, avoiding the resection of the (knee)

joint, and allowing for improved osseointegration. We also anticipate that bone health will be better maintained as the bone marrow will not be disrupted.

Introduction/Background

The American Cancer Society estimated about 2,890 diagnoses of bone and joint cancer in 2012 and about 1,410 deaths from these cancers¹. Until thirty years ago, amputation of the limb was common, but as medical technology advances, limb saving surgery has become a frequent option for the patient. The present treatment of bone cancer involves chemotherapy and resection of the tumor from the bone and/or soft tissue. Eighty to eighty-five percent of patients can be safely treated with resection and limb salvage². Many factors are present with limb saving surgery, such as the location and size of the tumor, and the type of implant that will be inserted after removal. Depending on the location and size of the tumor, patient-specific implants can be used to fill the bone gap after resection.

Two types of bone cancer are Osteosarcoma and Ewing's Sarcoma. Ewing's Sarcoma is most commonly found in children and young adults, which complicates the implant design because it needs to allow for the remaining growth of the patient. Ewing's Sarcoma is typical in the pelvis, femur, tibia, and humerus³. Osteosarcoma is typically located in end of the long bone. Osteosarcoma is more commonly found near the knee, which makes resection of the tumor more complicated because the margins of removal would include the joint⁴. This type of implant is more complex but also well documented in the medical field because of the frequency of the location.

Magnetic resonance imaging and CT scans of the tumor-affected area are important in order to establish the size and location of the tumor. The patient's specific case as to whether the cancer has spread and other factors are important when considering limb saving surgery. A wide margin of resection is typically removed to makes sure there are no cancerous cells left in the remaining bone or limb².

Bone is composed of hard, cortical bone and soft, spongy cancellous bone. The cortical bone is the outer layer which comprises 80% of the bone's mass. Cancellous bone is 20% of the bone's mass and has ten times more surface area than cortical bone¹. Surgeons use a particular terminology to classify different planes and parts of bones. Some of these anatomical terms are important to note as they may be used frequently in this report. The proximal end of the bone is the part closest to the center of the body. The distal end of bone is the part farthest away. Sections of the bone are classified as well, as shown in Figure 1 below⁵. The ends of the bone are called the epiphysis, the diaphysis is the middle segment of the bone and the metaphysis lies in between these two. Where the tumor lies in relation to these regions may affect treatment. For instance tumor removal in the distal end of the femur could be affected by the nearby knee joint, similarly for the proximal end of the femur with the hip joint. Therefore a more patient specific approach could combat these issues and avoid joint replacement.

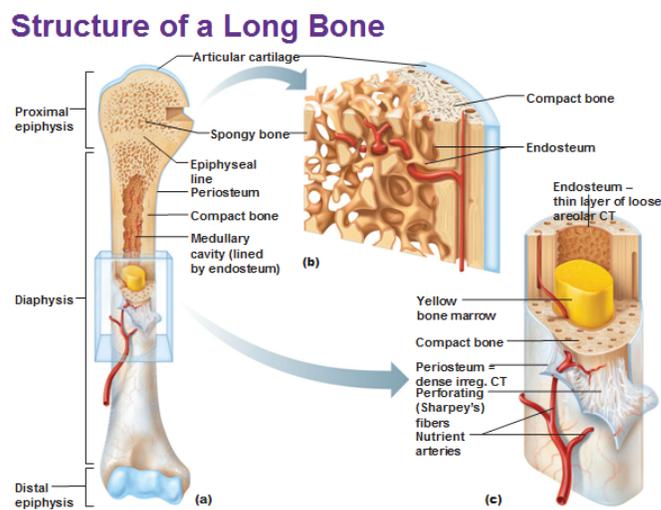


Figure 1. Structure of the long bone.

An important feature of the structure of the bone to note from Figure 1 is the spongy bone's porous nature and the medullary cavity. Bone is made up of Haversian and Volkmann's canals that run parallel and perpendicular, respectively, to allow for blood flow. The medullary cavity in the diaphysis of the bone also

contains important bone marrow and allows for blood and protein supply. Therefore when choosing a material to replace bone, it is optimal to not only replicate the material properties of bone but also features such as the medullary cavity and the porous nature of the trabecular (cancellous) bone to allow for bony ingrowth, osseointegration.

Various materials can be used for the custom implant such as metal, cadaveric allograft, a composite of bone and metal, and other bone substitute materials (i.e. hydroxyapatite). There are positives and negatives to the different types of materials that can be used, such as the “take” of the implant and the durability. It is important to weigh the pros and cons of each material. In limb salvaging surgery biological reconstruction, allografts are used as implants but these could experience complications such as graft resorption, fracture, and failure of fixation⁶. Figure 2 displays a distal femur allograft⁷. Metallic endoprostheses avoid graft problems but can experience fatigue, loosening, infection, etc. Figure 3 shows a metallic endoprosthesis used after tumor resection of the distal femur (due to the location of the tumor the knee joint was replaced as well)⁸.

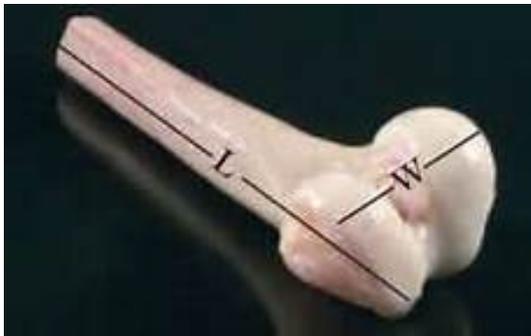


Figure 2. Allograft of distal femur.

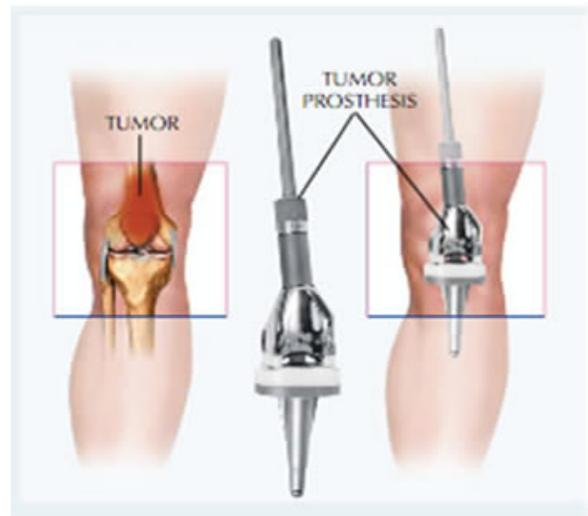


Figure 3. Metallic Endoprosthesis.

New biomaterials are being explored in which they avoid graft problems but can also withstand loading similar to bone. As limb saving surgery grows commonplace and the patient’s survival rates increase, it becomes important that

the implant material can withstand a longer period of loading with the ultimate goal of outlasting the life of the patient.

Recent studies have investigated hydroxapatite, a calcium phosphate, as a good synthetic bone substitute that interacts well with bone, possessing osteoconductive and osteointegrative traits. Hydroxapatite is unique, containing the porous structure similar to that of bone, while providing the same mechanical strength⁹. *The Journal of Bone and Joint Surgery* published an article in which the long-term effects of calcium hydroxapatite ceramic (CHA) implants, after benign tumor resection, were examined. CHA was found to be a good bone substitute, there was significant absorption in skeletally immature patients, new bone formation within the CHA and normal fracture healing¹⁰. Hydroxapatite is also used in the biomedical industry as a coating on implants to facilitate greater success of bone integration¹¹.

At a Musculoskeletal tumor society conference in Tampa in September of 2012, Paul Unwin described the use of additive layer manufacturing in creating limb salvage implants¹². Styrker orthopaedics developed a cobalt-based alloy implant fabricated using Direct Metal Laser Sintering – a type of 3D printer¹³. These examples prove the emergence of additive manufacturing methodology and the clinical relevance of this research and design trial. The methodology used in this project will test out promising fabrication techniques.



Figure 4. Knee replacement component fabricated using DMLS (3D printer).

A major goal of this project was to make sure the efforts made are beneficial to the medical field. The objective is to define the process of designing a patient-specific implant from initial CT scan to postoperative care. Utilizing computer software and finite element analysis (FEA), the effects of using titanium as the implant material can be predicted. Patient-specific implant research and design is growing and the methods found could hopefully be applied outside of tumor resection into other relevant fields.

Methods

Initial Cancerous Femur

The director of orthopaedic oncology surgery at Albany Medical center, Dr. DiCaprio has collaborated on this project. He has provided an anonymous patient's cancerous femur CT (computer tomography) scan data. This data was imported into Mimics, a medical image software tool by Materialise, to generate a 3D model of the femur. The CT scan includes muscles, ligaments and bone. In order to create a CAD model of the patient's femur a mask was created selecting both cortical and cancellous bone through a process called threshold. In order to distinguish the femur from the muscle surrounding, profile lines were drawn to show the Hounsfield units for the different elements in the scan. A threshold was created from these Hounsfield units to include the cortical and cancellous bone. Since it is possible to have included the proximal tibia or pieces of the muscle in this initial threshold – a new region of interest mask was generated by including points attached to the femur mask. The marrow cavity of the femur was filled in using a fill gap tool in Mimics for simplicity of the model. In addition to filling the bone cavity the number of surfaces of the model was reduced using the smoothing tool in Mimics. The CAD model of the cancerous femur was exported as STL.

Virtual Surgery

The CAD file of the cancerous femur was imported into 3-Matic, also a program by Materialise. 3-Matic is similar in function to SolidWorks but has more capabilities with medical anatomy models. Once the femur was imported into 3-Matic it was ready for a “virtual surgery”. Dr. DiCaprio communicated the dimensions he would cut for this particular patient and the cuts were made on the femur according to his notes: 8 cm down from the most proximal point of the greater trochanter and 14 cm from the distal end (knee cap). The 15 cm bone resection resulted in two segments of the femur. Using the Boolean Union tool, the two parts were “union-ed” together to create one part in 3-matic so that other tools such as loft and/or surface reconstruction could be used to fill the gap.

Implant Design

Once the tumor was removed from the CAD model, an implant was created to fill the bone resection. The remaining femur had two surfaces at each end of the cut that could be lofted together to form a new reconstructed surface for the implant. The surfaces of these pieces were deleted so that two contours were created around the border of each side of the resection. Four free curve guides lines were drawn from one contour to the other contour to help direct the reconstruction of the implant surface. The anatomical reconstruction tool was used to recreate a non-cancerous smooth implant surface in the bone gap. This resulted in a new hollow part that fit the contours of the bone resection.

Surface and Volume Meshing

The next step of the process was to make the implant porous. In 3-Matic the surface reconstruction tool only created a surface for the implant. It is important that this implant is porous and includes the medullary cavity. Therefore to export back into SolidWorks, the segments of the femur had to be meshed. Each segment was individually surface meshed using the auto re-mesh tools to get a desired fine

mesh with no bad triangles. A volume mesh was created from the surface meshes. The segments of the femur were then solid and exported into SolidWorks as solid bodies.

Implant Design: Porosity

The three pieces of the femur were successfully imported into SolidWorks as solid models: the (top) proximal femur, the (bottom) distal femur and the reconstructed smooth implant. The femur has a slight bend in the sagittal plane (anterior – posterior direction) therefore a lofted cut was made to represent this curve in the medullary cavity. Measurements of the placement of the canal were taken from the CT scan, toggling through the different scans (shown in Figure 5).

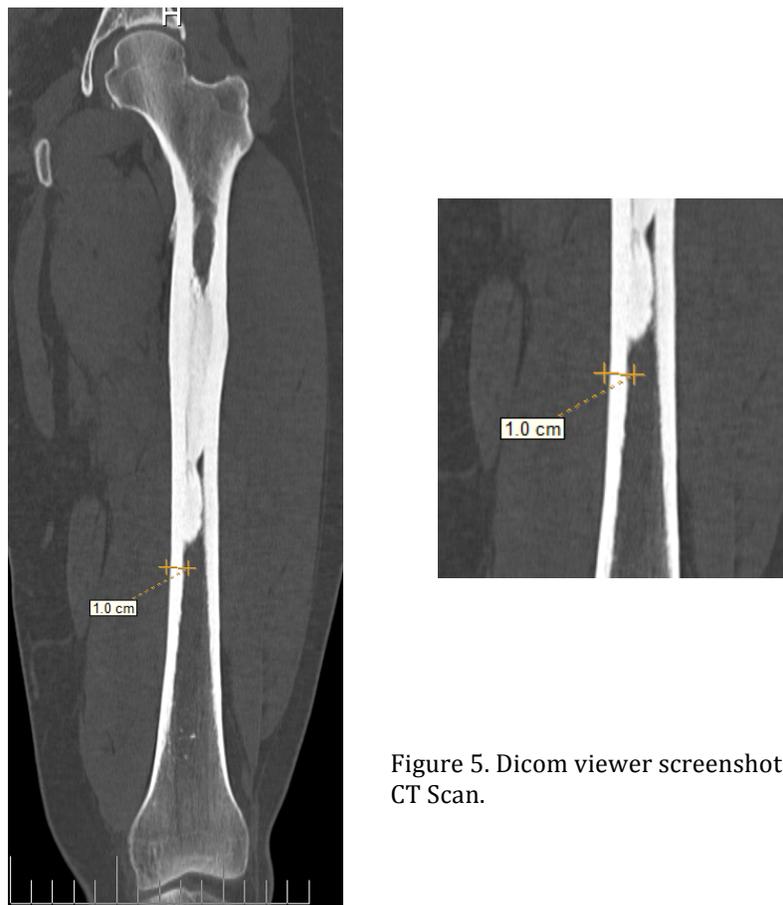


Figure 5. Dicom viewer screenshot of the CT Scan.

Since the imported implant body was not smooth and made up of many different surfaces, a separate cylinder was created with 2 mm holes, 2.5 mm apart around the implant. The holes were wrapped to the surface and cut in the radial direction into the surface. Using the combine feature in SolidWorks, a Boolean operation was performed to leave only the parts that intersected. This resulted in a reconstructed implant body with radial holes through to the medullary cavity. For optimization testing the pore size was altered to 1.5 mm (5 mm apart) and 1 mm (2 mm apart).

Finite Element Analysis

In SolidWorks assemblies of the proximal femur, the distal femur and the different implants were created, aligning and mating the ends of the segments precisely. Material properties of the bone (remaining femur) and the titanium implant were assigned. The proximal and distal portions of the femur were assumed to be all cortical bone (which is an assumption for simplicity since in reality cancellous bone, which possesses different properties, would be present). Cortical bone's Young's Modulus was found to be 18 GPA and 0.3 Poisson's ratio¹⁴. Titanium (Ti-6Al-4V) in SolidWorks had a Young's Modulus of 110 GPA and a Poisson's ratio of 0.3.

A rigid connection was enforced around the bone-implant interface with an overall global bonded contact (Figure 6a). According to literature the force on the femur acts along the axis running in between the intercondylar fossa to the femoral head¹⁴. Therefore a load was applied at this angle. Other FEA studies used body weight for standing and 2.5 times the body weight during gait¹⁴. The patient was assumed to weigh 160 lb. The condyles of the distal end of the femur were fixed as a boundary condition. The loading and boundary conditions applied is displayed in Figure 6b.

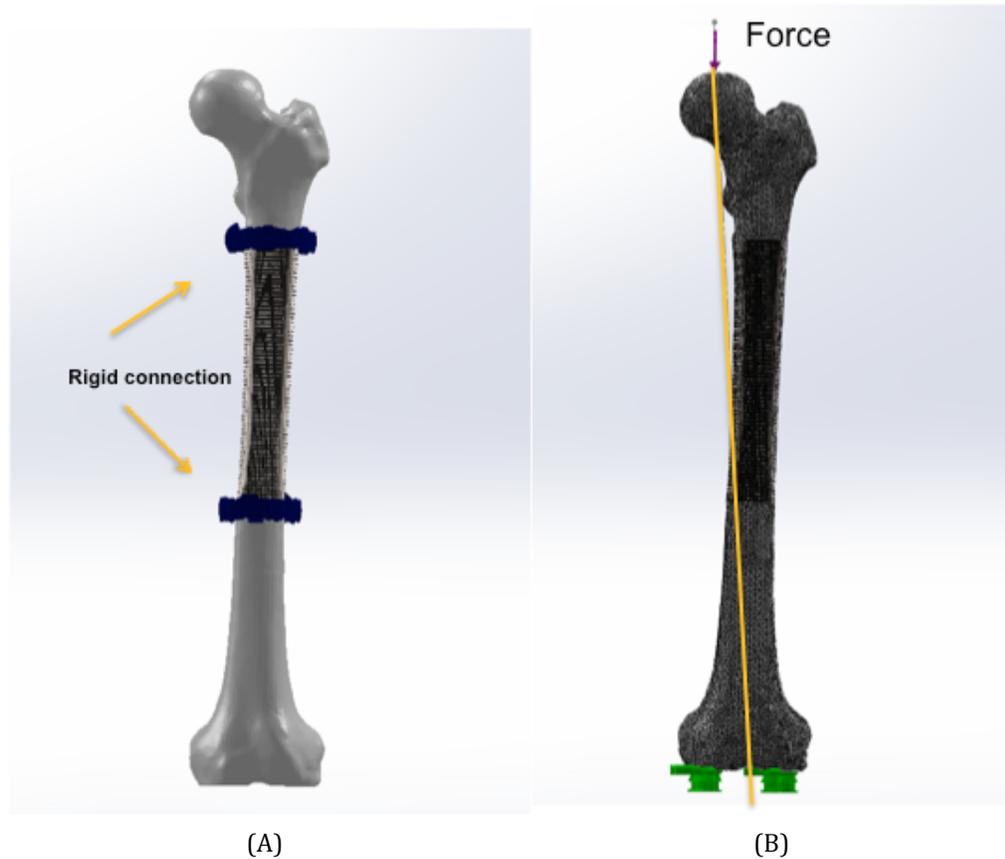


Figure 6. (A) FEA connection and bonding setup. (B) The FEA force axis and boundary conditions.

The assemblies of the different implants were meshed using circular elements. Once all the parts were meshed using a tetrahedral, incompatible mesh, the simulation was run. Two studies were done for each implant, one with a force of 712 N (standing) and one with 1780 N (walking). For comparison a solid titanium implant with 0% porosity (medullary cavity included) also underwent the same FEA tests. Stress plots, factor of safety plots and other plots were examined. The results were probed for average, max and min values. The Factor of safety plot was created using an endurance limit of 600 MPa (to account for cyclic loading of the femur).

Finite element analysis is important in ascertaining the functionality of the implant. The optimal porosity was found by examining the results plots. The implant should sustain mechanical loading of the body while also allowing bony ingrowth.

Design of Bone Plate Attachment

A bone plate was constructed from the assembly to assist in implant attachment and load bearing at the implant bone interface. The plate was designed by creating a 3D sketch from a reference-points curve along a desired path. The resourceful feature of this bone plate design is the ability of the bone plate to contour to the femur since it was constructed from the femur's geometry. This plate would be best placed on the lateral side of the femur, the side in tension, to prevent stress shielding.

Future work in methodology

Additive Manufacturing

A prototype of the implant made out of plastic was created using the 3D printer in the mechanical engineering department. In the future once this implant design was confirmed mechanically sound and optimal for osseointegration, it would be fabricated using an additive manufacturing machine for metal. Additive manufacturing is building a part layer by layer. The Direct Metal Laser Sintering Machine (DMLS) will fit this purpose well since the implant contains an intricate structure and will be made out of titanium (Ti6Al4V), a biocompatible metal.

Experimental Testing

After the titanium implant is fabricated, experimental tests to simulate physiological loading would be beneficial to validate the FEA model. A Saw bone of a femur and Professor Bucinell's photogrammetry machine could be obtained to use for testing.

Results

Initial Cancerous CT Scan Data

The patient's CT scan data was imported into Mimics. An x-ray of the femur shows the tumor (abnormality – filled in intramedullary cavity) in the diaphysis of the left femur (Figure 7).

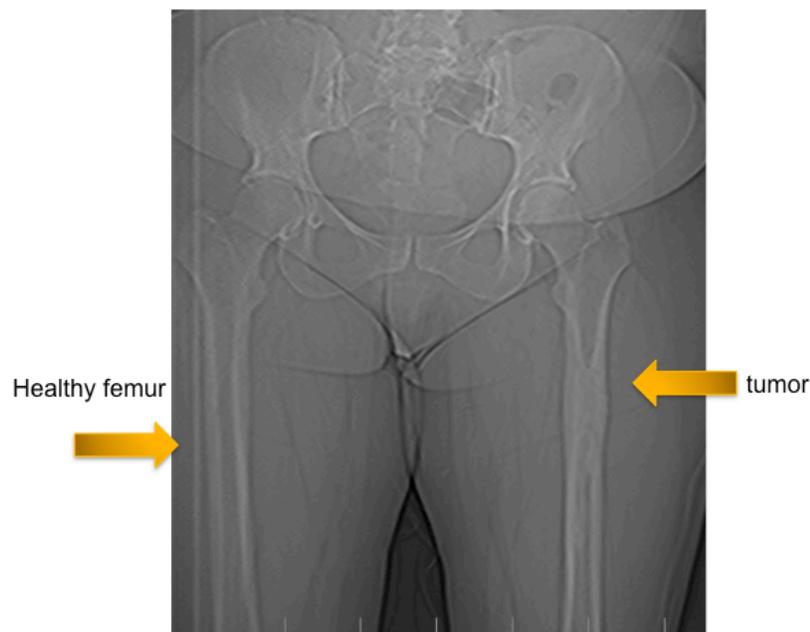


Figure 7. X-ray screenshot.

Figure 8 shows the thresholding process of drawing profile lines and separating the bone from the soft tissue. The lighter blue line shows the peak in Hounsfield units of bone. In the lighter green profile line the Hounsfield units graph peaks for the cortical bone and dips for the cancellous bone. From this profile line a threshold will be set to separate a mask at the desired minimum and maximum values (Fig. 9). An initial green mask (Fig. 9) was created by thresholding from 73 to 1762 Hounsfield units. A region of interest was created from this green mask to include just the femur, excluding the tibia and unintended muscle captured (Fig 10).

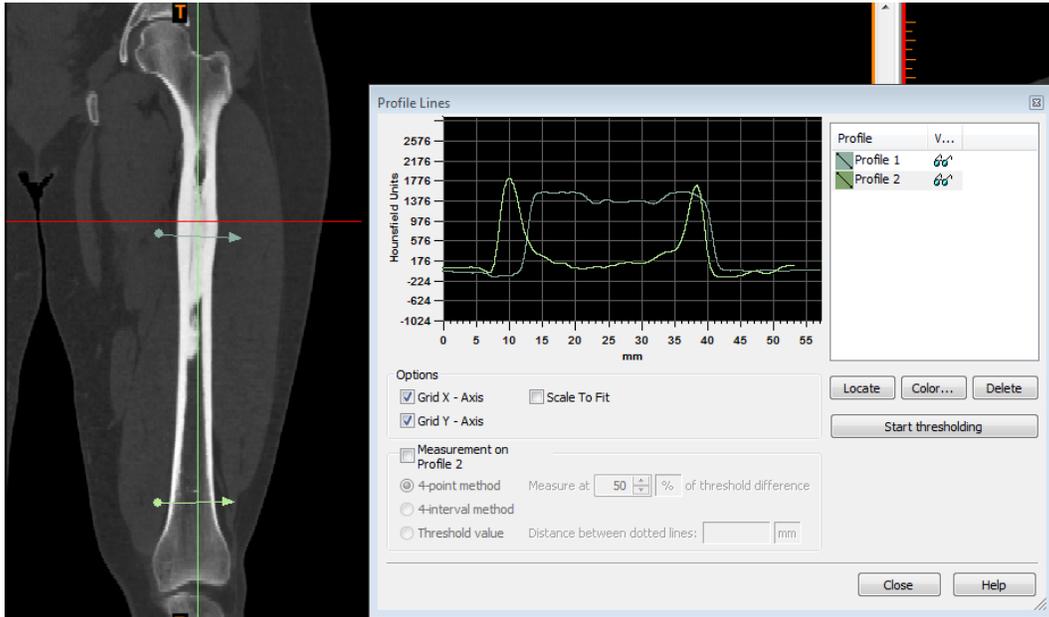


Figure 8. Cancerous femur CT Scan capture with profile lines shown.

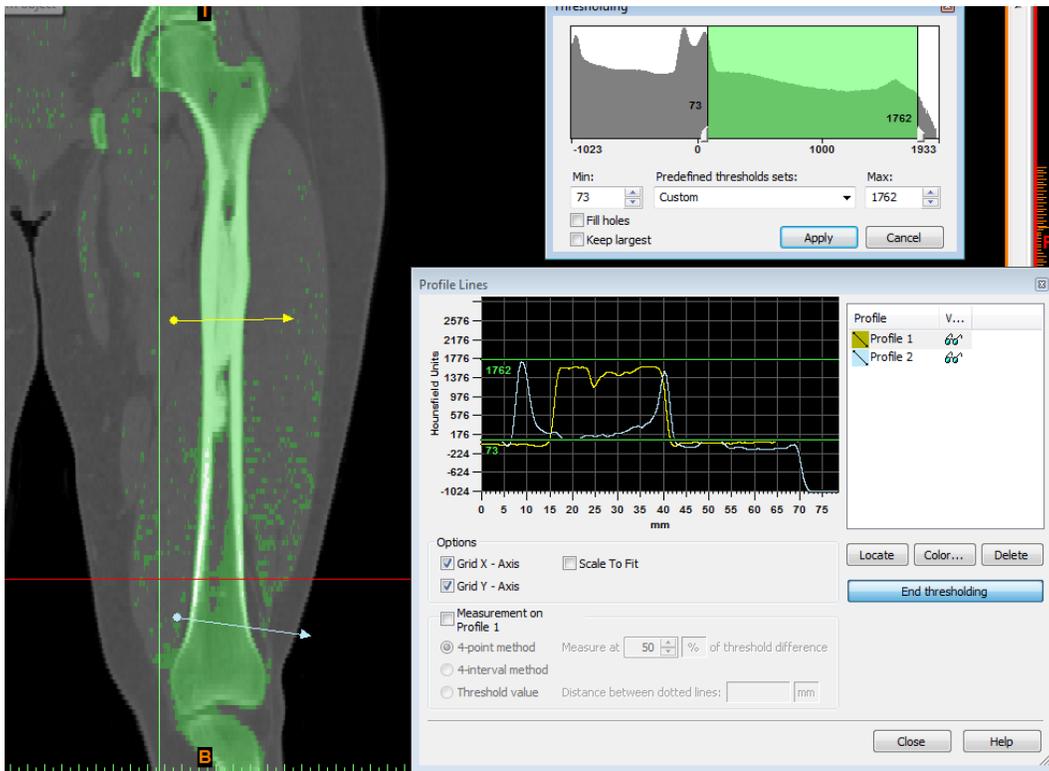


Figure 9. Mask showing threshold process.



Figure 10. Region of Interest from initial mask.

The pelvis was deleted from the mask for simplicity and the marrow cavity was filled. The model of the cancerous femur was successfully exported as an STL file.

Virtual Surgery

The CAD model of the femur had too many surfaces for SolidWorks to open as a solid model. Therefore it could only be opened as a graphics model as seen in Figure 11 below. A slight deformity can be seen in the model where the tumor is located.

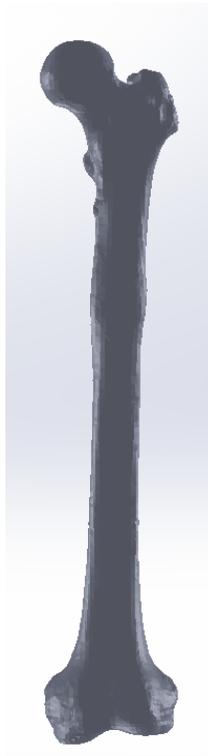


Figure 11. SolidWorks graphics model of patient's femur with cancerous tumor.

The model was imported into 3-Matic, which was able to handle the complex anatomy. According to Dr. DiCaprio's cut dimensions, the tumor was resected and the 15 cm bone gap is shown below (Figure 12).

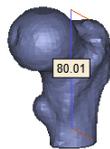


Figure 12. Tumor resection. (8cm from proximal, 14 cm from distal)

Implant Design

The surface reconstruction tool successfully recreated the femur surface. This validates the fit of the implant, since the reconstruction was based on the exact contours of the remaining femur. Figure 13 shows the reconstructed surface of the of the implant shape (smooth femur without tumor bulge). The section on the right in Figure 13 shows these are surfaces (hollow).

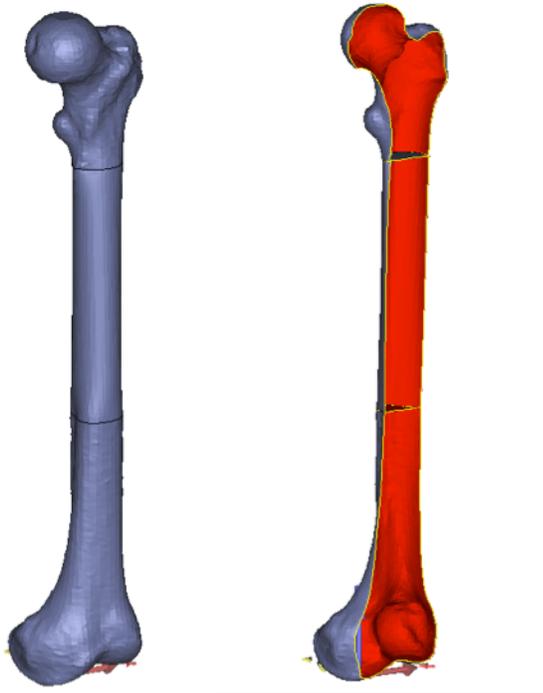


Figure 13. Implant shape from surface reconstruction

Surface and Volume Meshing

Figure 13 illustrates that the femur and implant parts in 3-Matic are just surfaces, therefore surface and volume meshing was done to make these solid entities. Figure 14a and 14b show the surface mesh and the volume mesh results, respectively. These parts were meshed individually and exported individually for import into SolidWorks. This was an important step because importing the femur and implant as solid bodies enabled them to be altered.

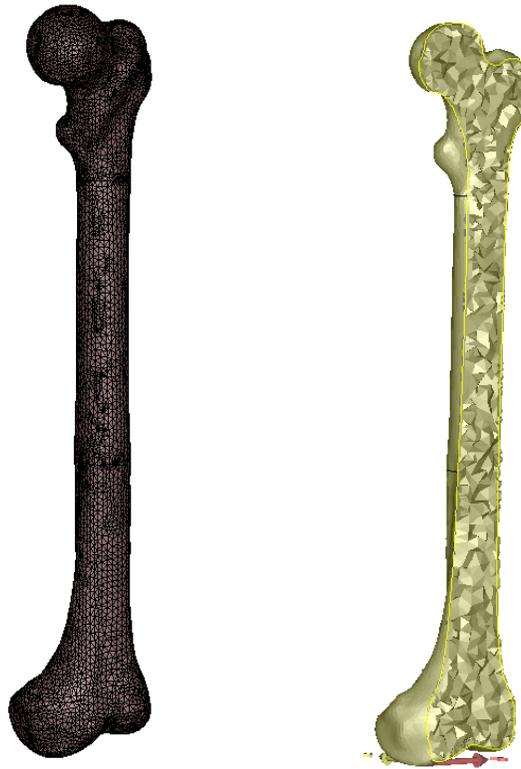


Figure 14. (A) Surface mesh. (B) Volume mesh (section view).

Implant Design: Porosity

The intramedullary cavity lofted cut is shown through a section view in Figure 15a. The next step of the implant design was to make this structure porous. Using the SolidWorks combine feature the smooth reconstructed implant (Fig. 15b) was intersected with a porous cylinder (Fig. 15c - transparent cylinder) to create a porous implant (Fig. 15d).

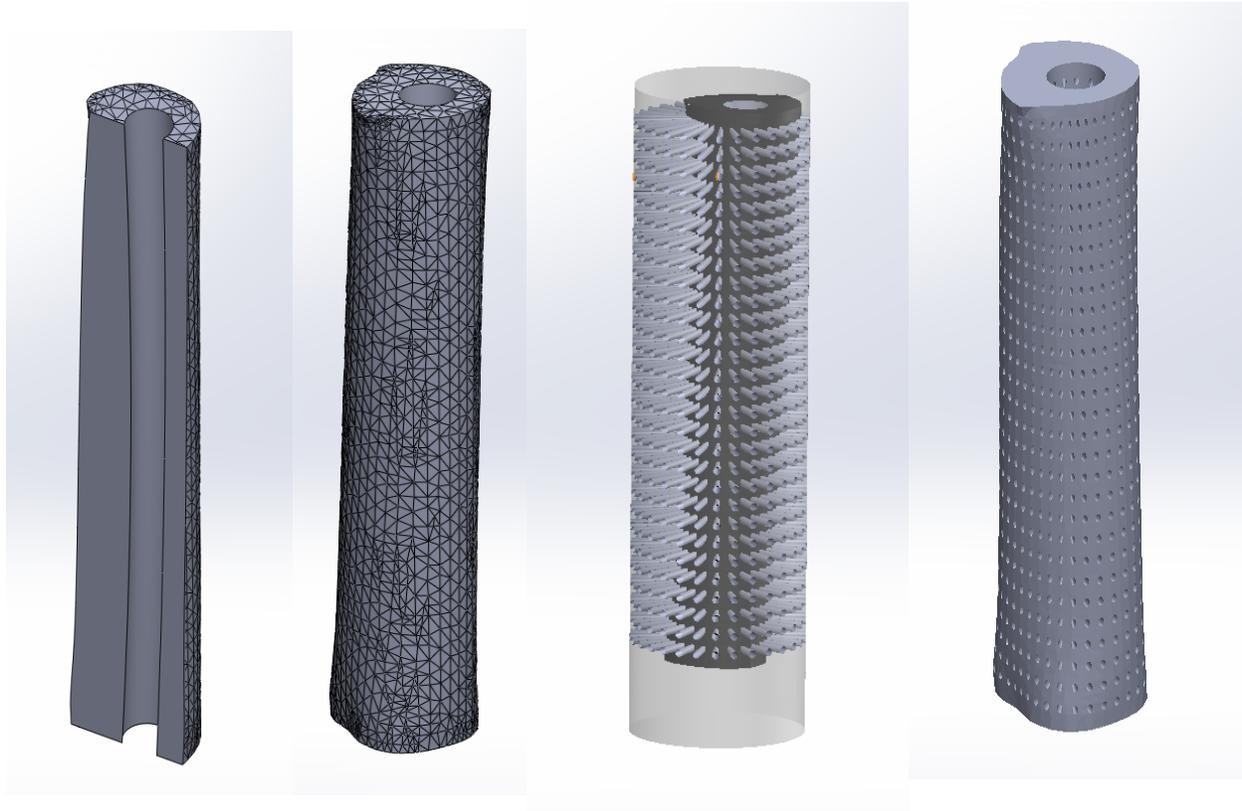


Figure 15. (A) Section view intramedullary cavity. (B) Reconstructed implant. (C) Boolean intersection operation (transparent cylinder). (D) Porous implant.

The same design process was replicated for all pore sizes: 2mm, 1.5 mm and 1 mm. Pictures of these implants and overall porosity values are presented in Figure 16 and Table 1.

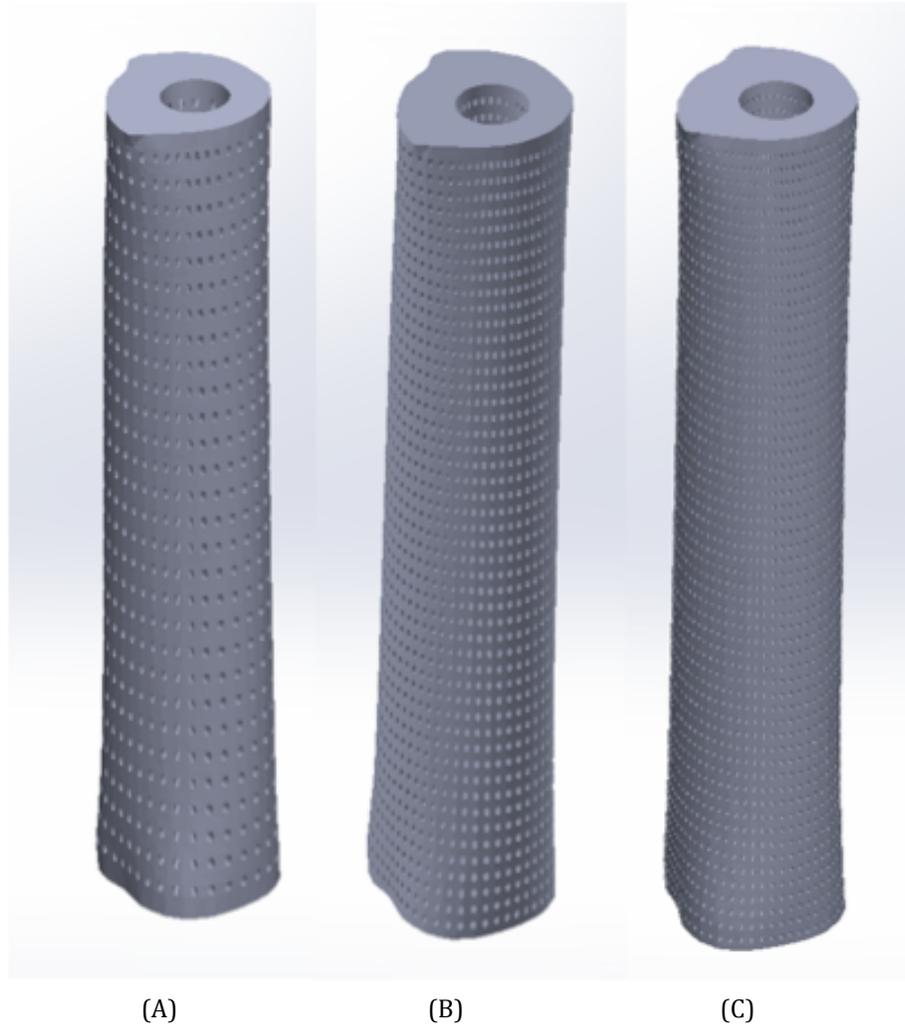


Figure 16. SolidWorks models of the implant designs. (A) 2mm. (B) 1.5mm. (C) 1mm.

Table 1. Implant designs porosities.

Implant	Porosity
2mm	13.7 %
1.5mm	23.4 %
1mm	14 %

Finite Element Analysis

Simulations for both loading during standing and walking were tested. Figure 17 shows an example of a stress plot for normal to the Y direction (up/down) for the 1 mm implant. From these diagrams it is clear to see the compression developed on the medial side and tension on the lateral side. Although the max values on these plots are very high, the average stresses occurring in the implant shown in Table 2 are at a reasonable value.

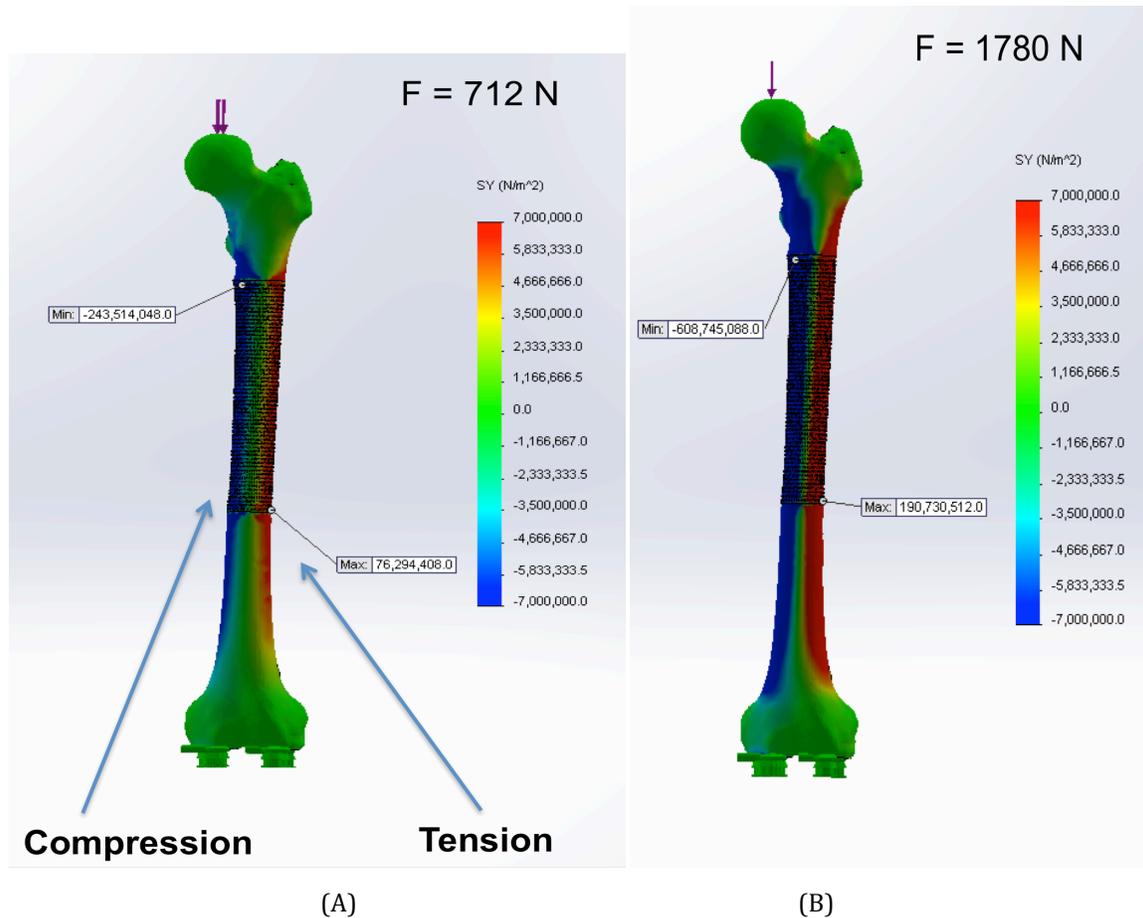


Figure 17. Stress (Normal to Y) for standing (A) and walking (B).

Table 2. FEA results of different implants during loading.

		F = 712 N (standing)			F = 1780 N (gait)		
Porosity		Avg von Mises (MPa)	Max von Mises (MPa)	Factor of Safety (avg)	Avg von Mises (MPa)	Max von Mises (MPa)	Factor of Safety (avg)
Solid Titanium	0%	4.98	66.5		12.4	166	
2 mm holes	13.7%	5.4	80	227	13.7	201	90.8
1.5 mm holes	23.4%	5.3	305	301	13.4	757	120
1 mm holes	14%	5.1	203	351	12.8	508	102

Figure 18 displays the von Mises plots for the 1 mm implant. A reoccurring theme with these stress plots is a stress concentration developed near the proximal bone-implant interface as seen by the maximum value location in Figure 18b. Although this value is 508 MPa, the average von Mises in the 1 mm implant is 5.1 MPa.

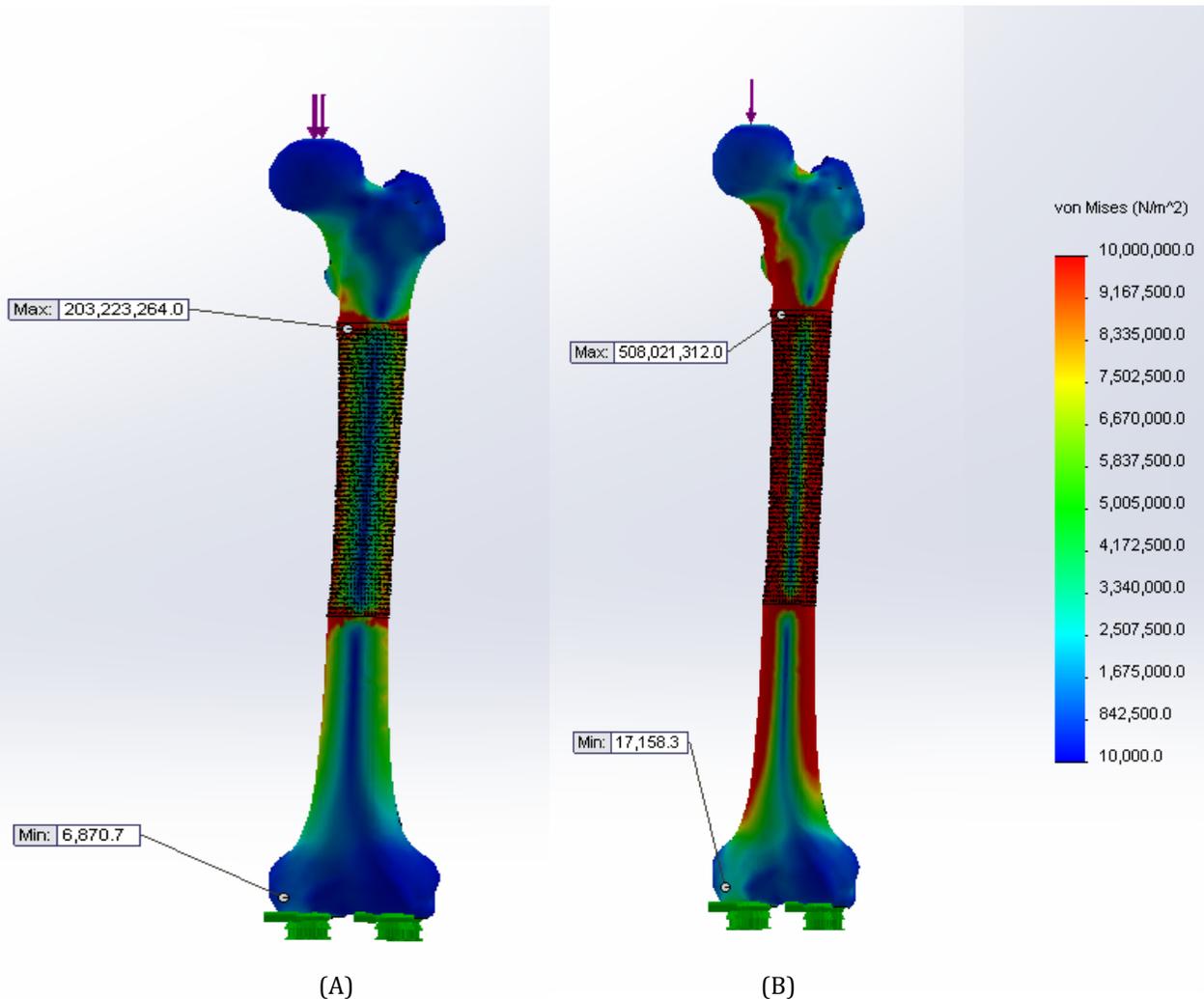


Figure 18. Von Mises stress plots. (A) Standing. (B) Walking.

Another important plot that was examined was the Factor of Safety plot. Since the femur is cyclically loaded daily (and not statically loaded) it is important to take the yield strength at fatigue strength. The FOS plots in Fig. 19 and the average values in Table 2 show that the implant will not fail. The lower values for FOS are located near the stress concentrations seen in Fig. 19 (same area as in Fig. 18). Except these values are uncharacteristic of the implant considering the average values for FOS in Table 2.

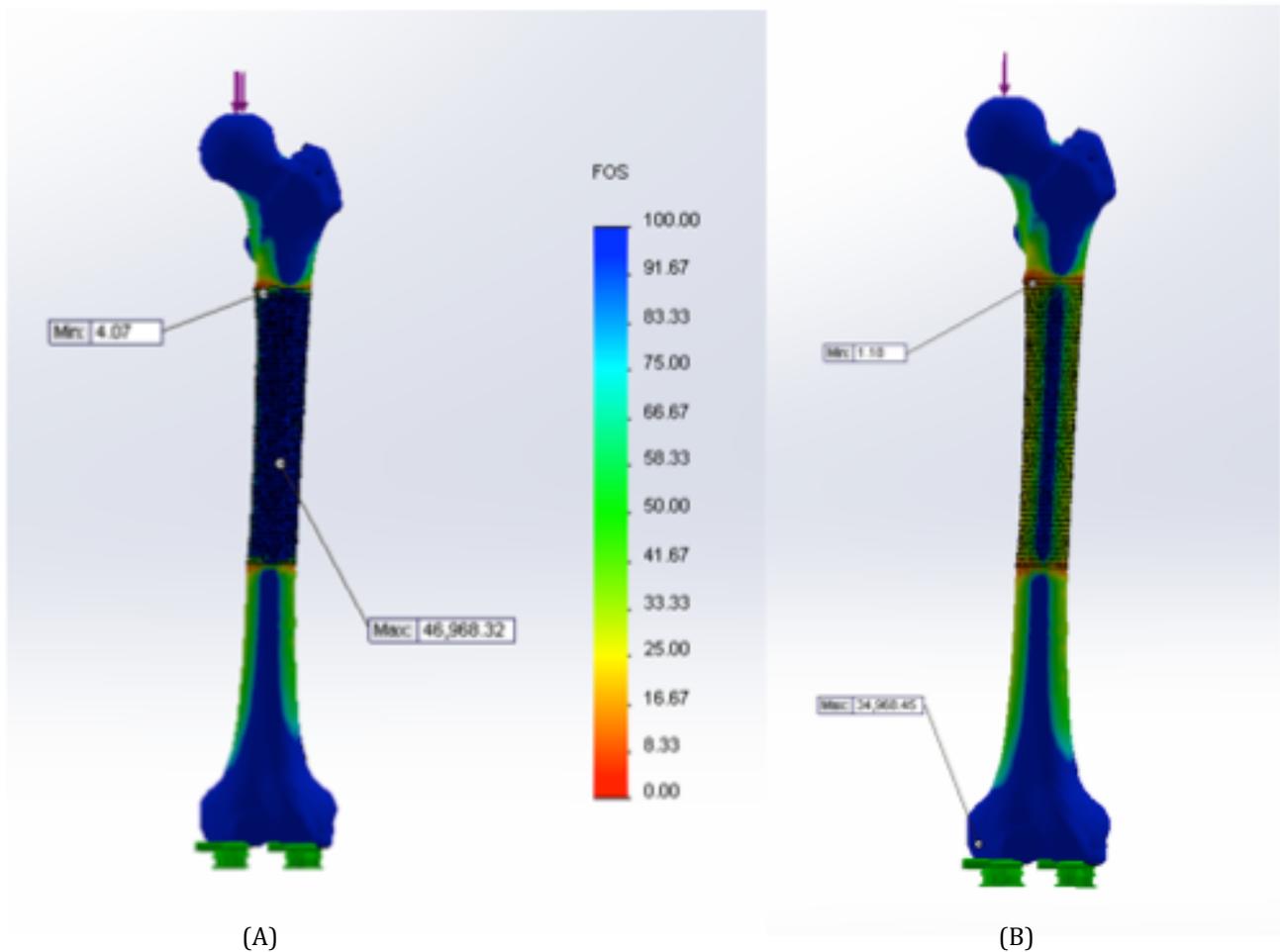


Figure 19. Factor of Safety Plots (A) Standing. (B) Walking.

Optimized Choice

Based on the results in FEA, the optimal implant choice is the 1mm implant. It will survive the mechanical loading of the body while also providing osseointegration. Figure 20 below shows the front, side and back view of the implant (rendered as titanium) within the femur. This displays the correct fit of the implant.

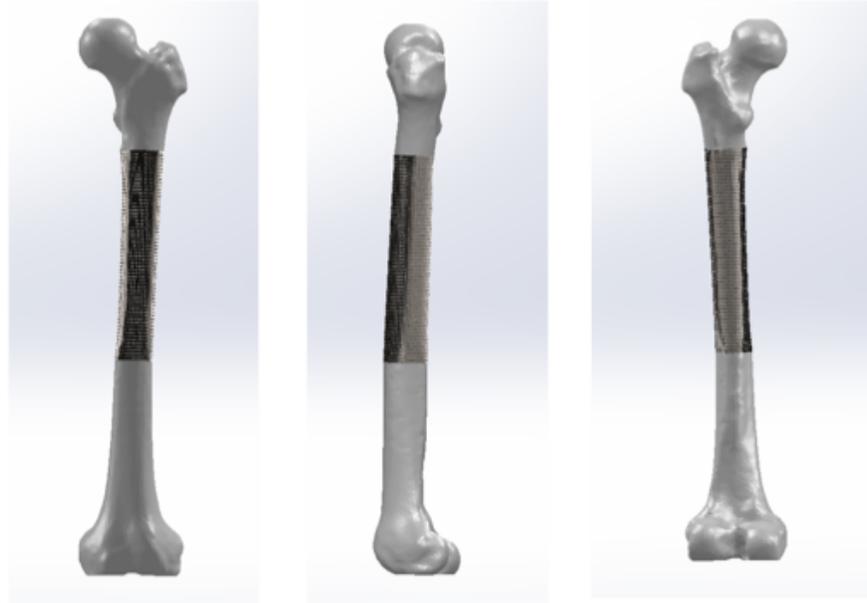


Figure 20. Implant and femur assembly: anterior, lateral and posterior view.

Bone Plate Design

Figure 21 displays the femur and implant assembly with the custom bone plate. This plate was extruded off of a 3D sketch fitted to the femur's curvature. The bone plate contours to the femur's geometry accurately.

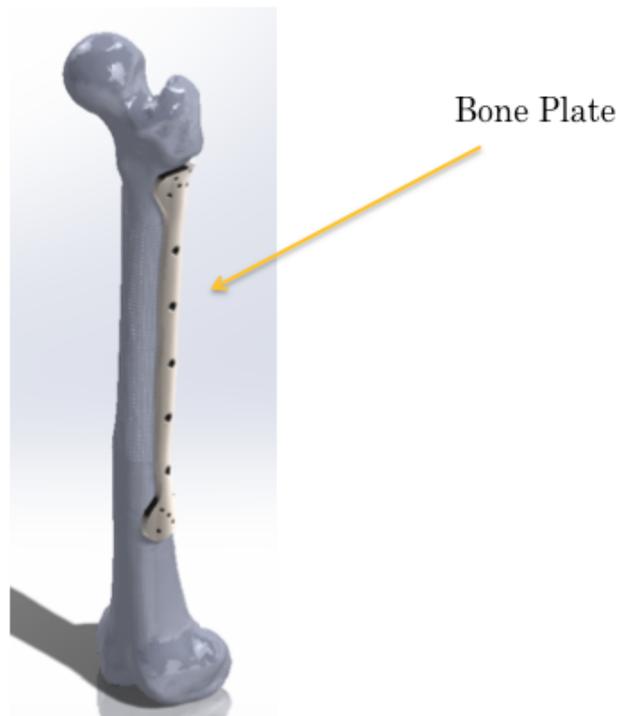


Figure 21. Femur and implant assembly with bone plate addition.

Additive Manufacturing

Figure 22 is a picture of the plastic prototype of the 1mm implant made using the mechanical engineering department 3D printer at Union College. The larger holes cut across the entire implant – these are for the bone plate attachment screws.

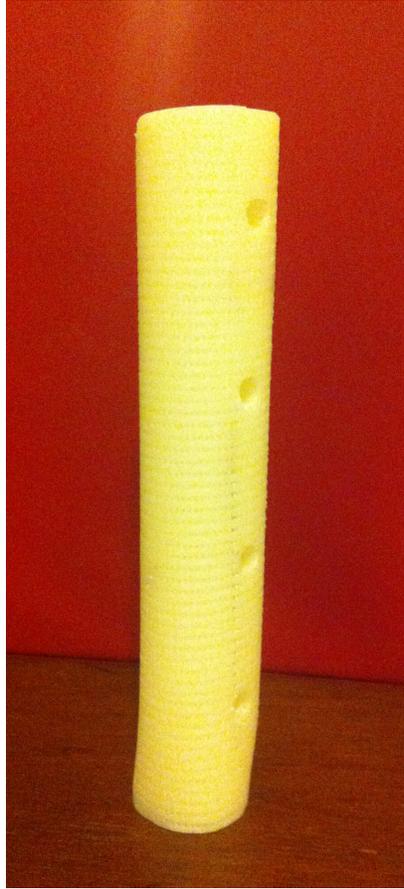


Figure 22. 1 mm plastic implant prototype fabricated by additive manufacturing.

Discussion

This project researched the design methodology of treating bone cancer through the use of medical imaging software and additive manufacturing. Through two terms implant designs were optimized through FEA testing in SolidWorks. An optimal implant design was chosen as it performed well under the FEA simulations and its pore size provided osseointegration. Further optimization could better this design such as adding axial pores for increased osseointegration and better loading.

The main aspects of the design were to sustain mechanical loading without provided too much strength as too induce stress shielding or surrounding bone atrophy. While mechanical properties were important, optimal porosity for osseointegration was also examined. The more bony ingrowth the better the blood supply to the distal femur and the possible eventual removal of the bone plate.

Many tasks were successfully done that could greatly help create patient-specific implants. With the use of medical imaging software from Materialise a patient's anatomy can be transformed into 3D models. This made simulating the tumor resection straightforward and accurate to Dr. DiCaprio's notes. In the 3-Matic program the surface/anatomical reconstruction tool was very useful in creating a smooth reconstructed surface for the implant. The implant will fit the dimensions of the patient precisely because it was created based on the specific contours of the patient's femur. The femur also has a slight bend to the anatomy and therefore the marrow cavity was aligned with the remaining femur using measurement tools in a dicom viewer. Similar to other implants such as in the hip, in which dimensions are taken from a 2D image, dimensions from the specific patient's anatomy are valuable for proper fitting.

FEA testing with the bone plate attached could also provide more answers to the reoccurring stress concentrations near the proximal implant-bone interface. Overall the implant experienced much lower average values for von Mises stresses and factor of safety values, which uphold its safety. Other assumptions were made in the FEA simulations such as the static load applied. Ideally a fatigue simulation would be beneficial to the research and whether the implant would fail. Better

approximation of the femur's material properties would also increase the validity since the bone was assumed to be all cortical. In the future, keeping or defining a separate cancellous bone area would be ideal since it possessing different properties.

Bone plates are typically placed on the side in tension to prevent stress shielding, which based on Figure 17, is the lateral side of the femur. In the femur and the implant the holes for the bone plate (as seen in Figure 22) cut all the way through. These screws would pass through two layers of cortical bone, which provides more stability.

Throughout the term there were many computer software issues. SolidWorks' inability to handle too many surfaces caused some of the design work to be done in 3-Matic. Creating meshes for export was necessary in order to import into SolidWorks as a solid model. Initially Abaqus was considered for the Finite Element Analysis program as it has very strong capabilities, except even with a 100,000-node limit there were too many nodes to run the simulations. SolidWorks did an adequate job meshing and running studies once the contacts and boundary conditions were sorted out. In order for the simulation to run the proximal femur, implant and distal femur portions were connected by a rigid connection otherwise there was too large of a displacement. A global bonded contact was also applied to keep the segments moving together under the load.

The FEA testing validated the functionality of the design on the computer and future work would include experimental testing of the implant within a saw bone. In reality in medicine the patient-specific implant approach would need further refinement to make it faster, such as better computer power and a set methodology defined. Under the pressure of time in the real world, the implant could not undergo extensive FEA testing and optimization, as the design should be created quick so that the implant can be fabricated and the patient can have the surgery as soon as possible.

3D printing is cost effective and time efficient and the fabrication of patient-specific implants through the use of additive manufacturing is an emerging industry in medicine and it will certainly grow in the next couple of years. Further research

will need to be done to make sure this type of manufacturing doesn't alter the material properties drastically.

This paper and project definitely shows the benefits of a patient-specific approach and its application to bone cancer treatment. It begins to lay down the groundwork of the process of patient-specific implant design, with an eventual goal of implementation into medical treatment upon further fine-tuning of the procedure.

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