Personalisation of Implants:

Design and Simulate Patient Specific Fixation Plate for Proximal Humerus Fracture –.

Project by

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Abstract

In this study we designed and simulated a rigid fixation plate for proximal humerus fracture using patient scan dataset. Patient CT scan data was used to create a patient specific fixation plate using medical segmentation and CAD software ImageSim from VOLMO LTD(UK). Segmented models of full bone and bone fragments were exported as STL models from ImageSim. These STL models were imported into TSV software and fixation plate was designed using various features available inside the software environment. After designing the new plate, all the components bone , fragments, plate and screws were assembled and complete volume mesh was generated. Finite element software from Ansys was used to run static simulation under various loading condition. The result from these simulation helped us to optimise the plate and screw placements to minimize screw loosening, plate fixation failure & help quick healing and rehabilitation.

Background

Fractures of the proximal humerus are common, accounting for 5% of all fractures [1]. These fractures tend to occur in older patients who are osteoporotic. The most common mechanism for these fractures is a fall on the outstretched hand from a standing height. In younger patients, high-energy trauma is the cause of injury. Displaced fractures require reconstruction, because if left untreated will have a high likelihood of producing limited function. The most common definition of displacement is 1 cm between fragments or 45° of angulation between fracture fragments. The parts that most commonly produce these fragments are the humeral head, the greater and lesser tuberosities, and the surgical neck. The fracture pattern can be complex and difficult to assess adequately with plain x-rays, so a CT scan may be required to better understand the severity of the fracture.

Selection of proper surgical candidates and fixation techniques depends on the accurate assessment of the fracture. In order to classify the fracture, the fracture site with respect to the bony landmarks were identified. The fracture site, in this patient , is at the surgical neck and between the greater tubercle and head of the humerus, breaking the proximal humerus into three fragments. We can organize the fracture into three main groups based on the fracture location which was on the articular surface, greater tuberosity, surgical neck and diaphysis. The surgical neck has fractures and there is a presence of slight displacement. The shaft of the humerus has separated at the surgical neck and the Greater Tubercle has a fracture. The humeral head has a fracture along the anatomical neck.

Operative fixation is the preferred treatment. The choice of fixation depends on the surgeon's experience and skill, available implants, and equipment. However, the functional demands of the patients, the presence of comorbidities and the ability to undergo nonoperative treatment should also be taken into considerations. The decision for surgery should also include the functional demands of the patients, the presence of comorbidities and the ability to undergo operative treatment. Nonoperative treatment tends to have unsatisfactory results. Screw number can greatly affect the stability of the implant. Having a customized shape implant reduces interfragmentary movement and makes a better fit.

The proximal humerus is a particularly difficult structure to image, since the scapula floats on the chest wall and the humerus can rotate freely on the glenoid. Appropriate treatment of proximal humerus fractures, then, depends on an understanding of anatomy, accurate imaging techniques, and proper classification of the fracture type.

In this case , the fracture looks like a Proximal Type C fracture according to OA classification described as – Complete articular. The articular surface is involved, metaphyseal fracture completely separates the articular component from the diaphysis. It is simple articular, simple metaphyseal, multifragmentary, with slight displacement. The preferred treatment could be a plate fixation that has maximal mechanical stability.

Introduction

The incidence of a proximal humerus fractures is the third most common osteoporotic fracture type observed in patients and seems to have been increased in recent years. The incidence of a proximal humeral fracture occurring increases with age exponentially and also shows a seasonal variation that favour the winter months. [1] Proximal humerus fractures are the seventh most frequent fractures in adults and that older women are more prone to it.

It is well reported in the literature that the use of screw and plate fixations is becoming more prevalent due to the these devices being mechanically superior and also show better results when compared to non-operative procedures that attempt to heal such fractures.

Currently, however, there seems to be a lack of such devices that can promise a low failure rates , better locking and compressive forces. A study conducted by[2] to identify the specific complications of locking plate fixations of the proximal humerus fractures point out that out of the seventy-three patients studied with conventional plate fixations, eleven patients needed a second surgery and that 18 patients were lost for follow-up after six months caused due to partial necrosis of the humeral head. Screw cut outs and reductions in the quality of greater tuberosity were seen. The conclusion of this study was that even though screw plate fixations provide more secure fracture fixations, the complication rates are too high.

It is due to these disadvantages that developing fixation plates that can be considered as optimal and effective for displaced fractures in patients is important. However currently there is no solution available that produce fixation plates / implants that have biomechanical properties equivalent to the original tissue [3]. The continuous increase of man's life span, and the growing confidence in using artificial materials inside the human body necessities introducing more effective prosthesis and implant materials.

In this study we try to address this issue by design and simulation of fracture fixation plate using patient specific medical scan data. It is well reported in the literature that patient specific device design significantly minimise the screw-displacement and provide better stability[5]. The fixation plate design and simulations were iterated in the real bone environment until we achieve required stress distribution that would increase the life of the implant and prevent bone resorption.

The benefits of this approach is that the final design of fixation plate is patient-specific that can greatly improve the healing of fractures and probability rates of the success is high. The goal is to ensure the complete and best healing occurs while considering the multitude of biomechanical factors including the degree of interfragmentary movements the non-homogeneity of the density of human bone and the unique yet similar bone shape.

Finite element method and optimization technique were used to reach the required implant design. The finite element method (FEM) was first introduced to the field of orthopaedic biomechanics in the early 1970s to evaluate stresses in human bones[6]. Today, it is one of the most reliable simulation tools for evaluating wear, fatigue, crack propagation, and so forth, and is used in many types of preoperative testing.

Problem and Current surgical procedure.

To ensure that complete and optimal healing occur it is important to consider a multitude of biomechanical factors including the degree of interfragmentary movements the non-homogeneity of the density of human bone and the unique yet similar bone shape.

Surgeons base their decisions based on experience however this may not be the best way to approach every situation and may lead to implant failure.

A viable treatment technique for this case is an ORIF (Open Reduction Internal Fixation) Surgical Procedure. This is a surgical procedure to fix a severe bone fracture, or break. “Open reduction” means surgery is needed to realign the bone fracture into the normal position. “Internal fixation” refers to the steel rods, screws, or plates used to keep the bone fracture stable in order to heal the right way and to help prevent infection.

Methodology -

The method used in this study was to obtain CT scan data of the fracture area in the patient that required the implant. The ImageSim software was then used to segment the data using image processing algorithms to form a mask and capturing the required area/volume of interest. Segmentation was performed to detect the bones and hard tissue ranges and then generating a three-dimensional model from the image data. This three-dimensional model was then used as a reference to create the implant. In the next sections we describe all the steps done for complete model

Segmentation –

Computed tomography data of a patient suffering from a proximal humeral fracture was used. The CT file was then processed through the Imagism software that used each slice of the scan to create a three-dimensional model of the fractured bone. Basic image processing techniques were used to obtained the best quality and most accurate model. The total number of slices were 256. Image processing was done on the CT scan. An anisotropic gradient filter was applied for smoothing. The masks that differentiated the bone from the rest of the scans were identified using thresholds and connected threshold filters. The masks were merged using the Boolean OR operations. Figure 1 shows the CT scan data views in Imagism, in axial, coronal and sagittal views.. Figure 2 shows the mask being created during the image processing technique and figure 3 shows the complete mask and model of the fractured proximal humerus.

Model Assembly and Meshing.

The fracture pieces were then aligned and assembled in the software TSV-Pre (VOLMO supplied software) to create an assembled model depicting the position in which the bone fragments would heal in (fracture reduction), trying the replicate what the original bone would have looked like.

It is very important to avoid intraarticular screw placement ,screws that penetrate the humeral head may significantly damage the glenoid cartilage. Primary penetration occurs when the screws are initially placed. Secondary penetration is the result of subsequent fracture collapse. Drilling into the joint increases the risk of screws becoming intraarticular.

New Implant Design –

The device design was developed based on the Philos Proximal Humeral Internal Locking System. The implant and screws were modelled in SolidWorks. Stainless steel was the chosen material to be worked with.

The implant was then designed to fit the exact shape of the bone in order to minimize gaps between the implant and the bone. Optimal positions for the screws were then determined then placed into the implant model. The implant model and the humeral bone model were then assembled and finite element analysis was performed to test the load constraints of the implant.

The plate fixation is designed to be attached to the humeral shaft with a bicortical small fragment 3.5 mm screw inserted through. The correct plate position was determined to be about 5-8 mm distal to the top of the greater tuberosity, aligned properly along the axis of the humeral shaft and slightly posterior to the bicipital grove (2-4 mm).

The possible pitfalls were also kept in mind while positioning the plate. The bicipital tendon and the ascending branch of the anterior humeral circumflex artery are at risk if the plate is positioned too close to the bicipital groove. A plate positioned too proximal carries two risks, the plate can impinge the acromion and the most proximal screws might penetrate or fail to securely engage the humeral head

The result was a proximal humerus fixation plate that has a natural articular surface and a bone-implant interface that more evenly distributes the load on the bone surfaces. The thickness of the implant can be varied based on the needs of the patient and the constraints presented by their weight and lifestyle.

Finite Element Analysis -

Since the introduction of FEM to orthopaedic biomechanics, there have been rapid advances in computer processing speeds, the finite element and other numerical methods, understanding of mechanical properties of soft and hard tissues and their modelling, and image-processing techniques. The constraints measured and evaluated were the number of screws, the move of the fragments against each other, the distance between the plate and the bone and the material properties of the bone, plate and screws.

To test the hypothesis that the patient-specific implant would distribute stress more evenly a finite element mesh, finite element analysis was performed. Remeshing algorithms were used to reduce the amount of computational time.

Finite element analysis was conducted using Ansys . Axial, bending and torsional loads were applied separately on one end of the bone while the other was fixed, as seen in Figure 10. The other method was to keep the bone flat an apply force on the top surface of the plate and lastly, constraints were placed on the top and force was applied to the lower end of the bone, thus trying the replicate the moving of the arm. The displacement of the fracture was determined using Ansys to calculate the amount of deformation that occurred on one bone fragment relative to the other. An approximate 35%

decrease in stiffness was seen in each loading case. This was calculated using the initial and final axial and torsional stiffness for the model design with a steel plate with an average 3.5 mm thickness.

Materials and Methods

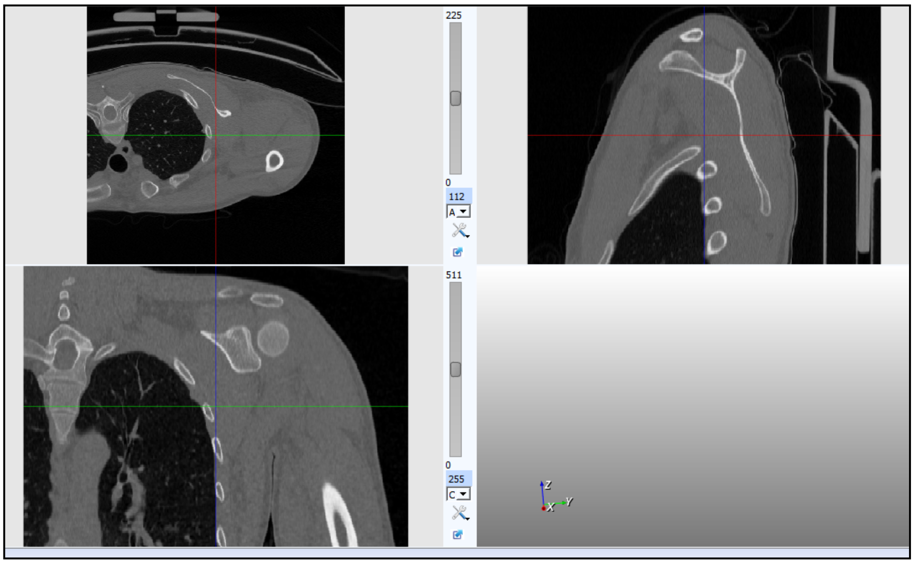

Figure 1: CT Scan data imported in ImageSim

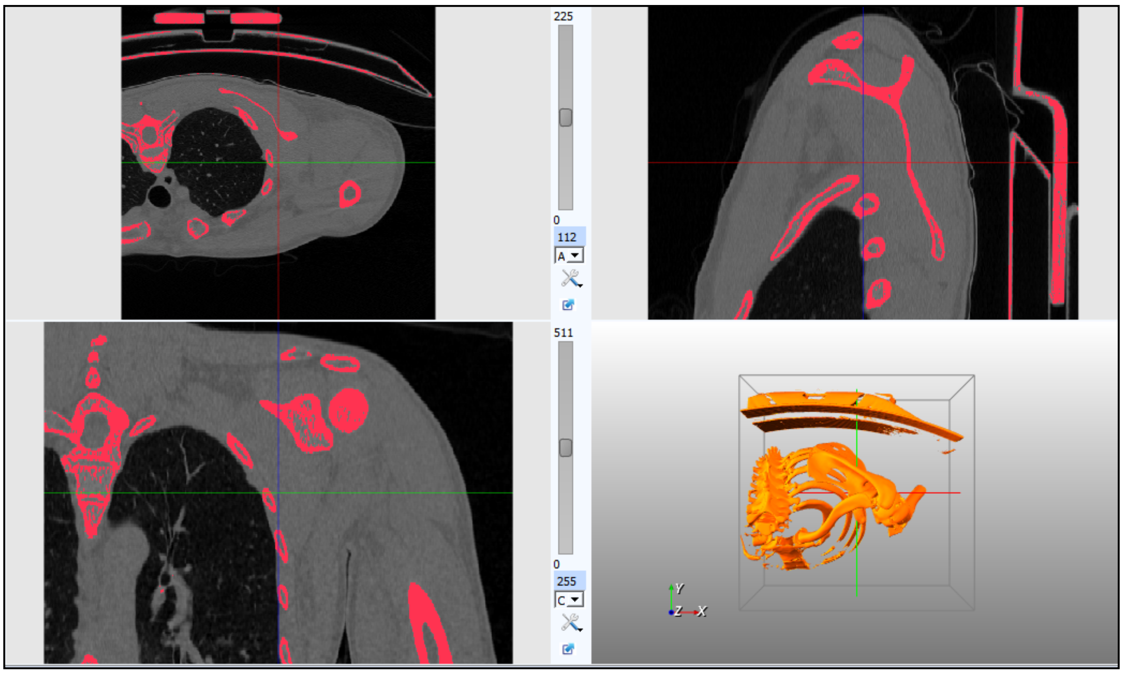

Figure 2: Slice by Slice Mask Created by ImageSim

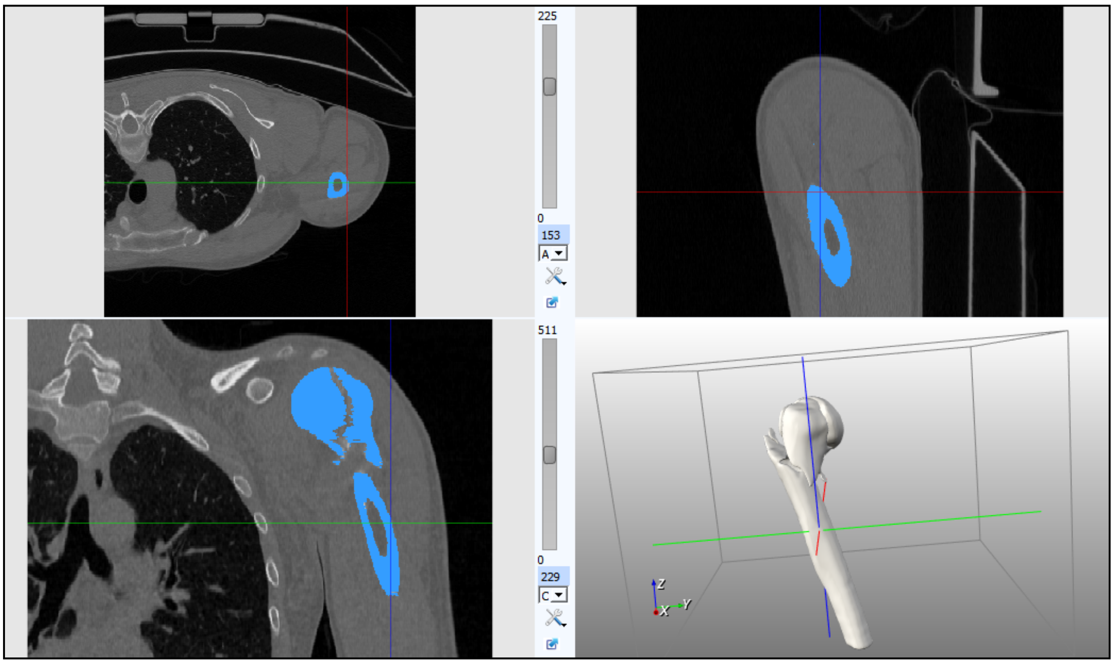

Figure 3: Mask and Model After Completing the Image Processing

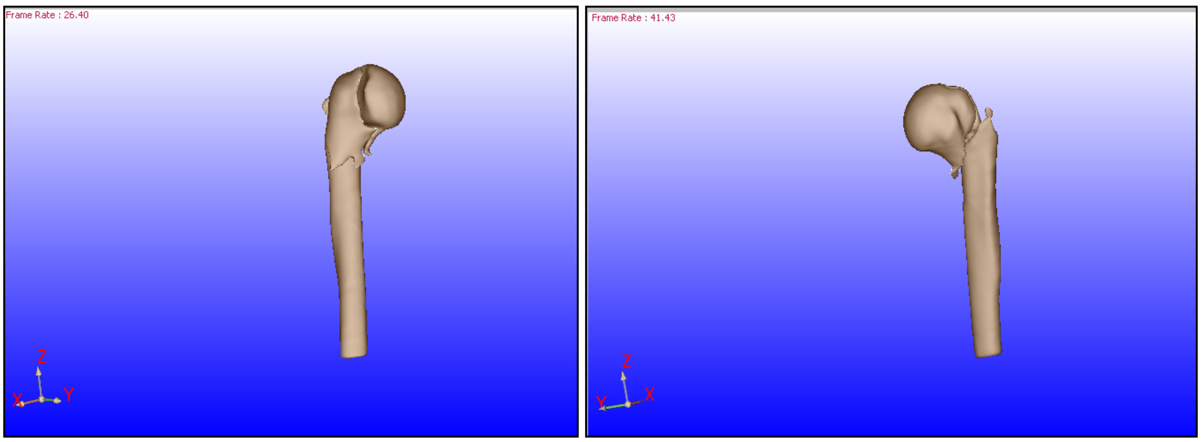

Figure 4: Imported STL model in TSV

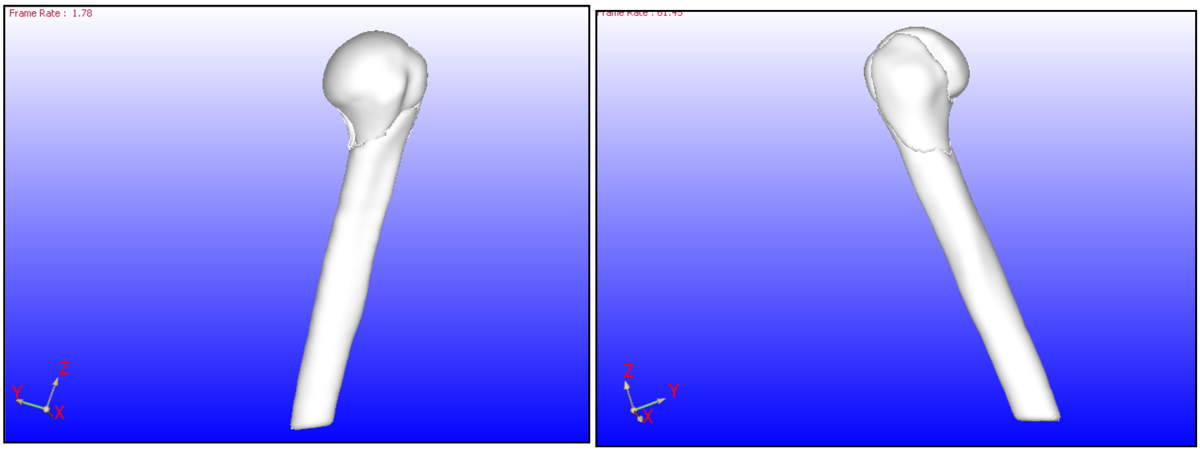

Figure 5: Consolidated Model of the Bone on TSV

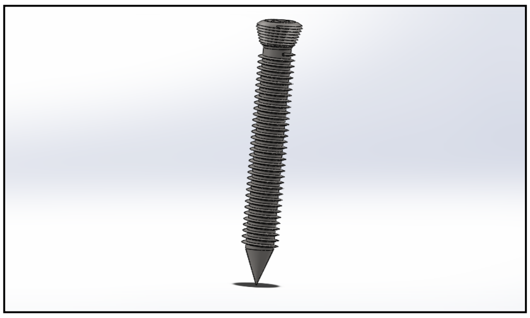

Figure 6: Locking head 3.5 mm screw generated on SolidWorks

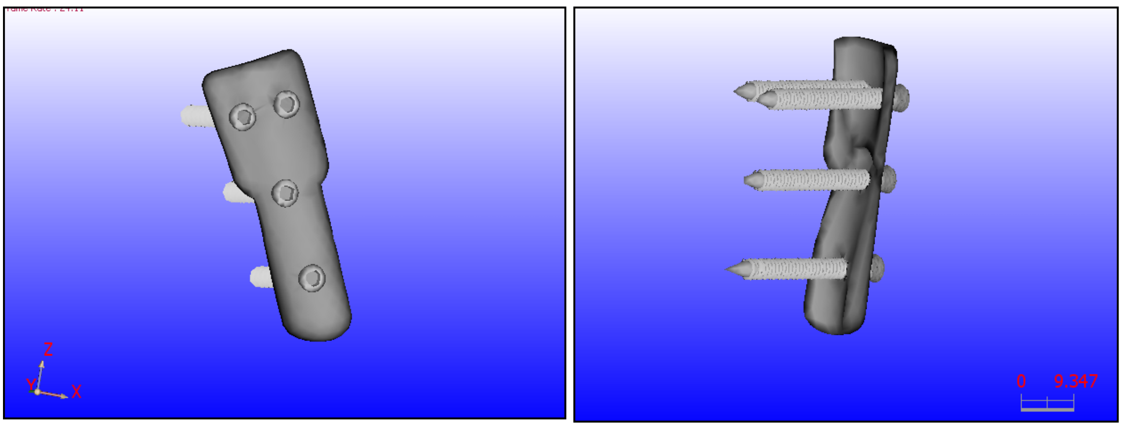

Figure 7: Completed Plate Fixation with Screws Positioned

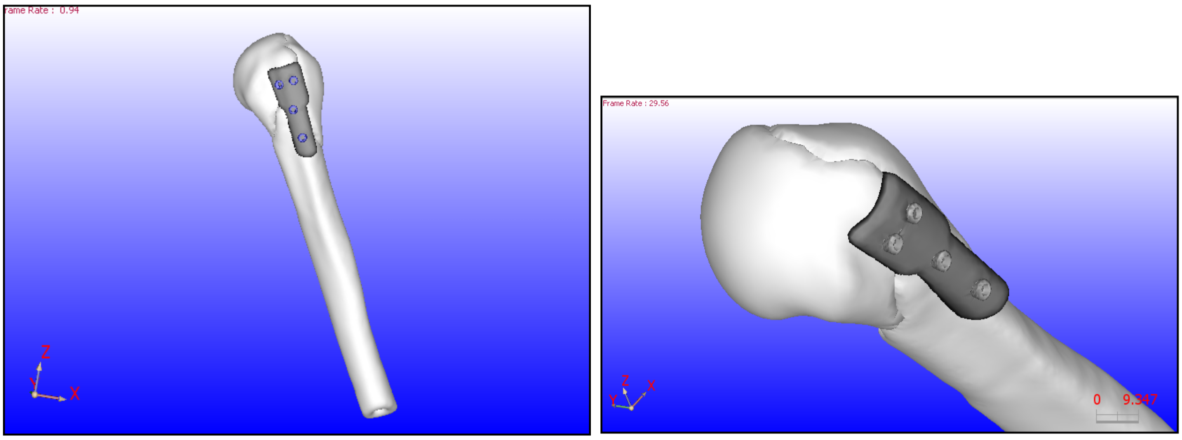

Figure 8: Combined model of the bone and the implant and screws

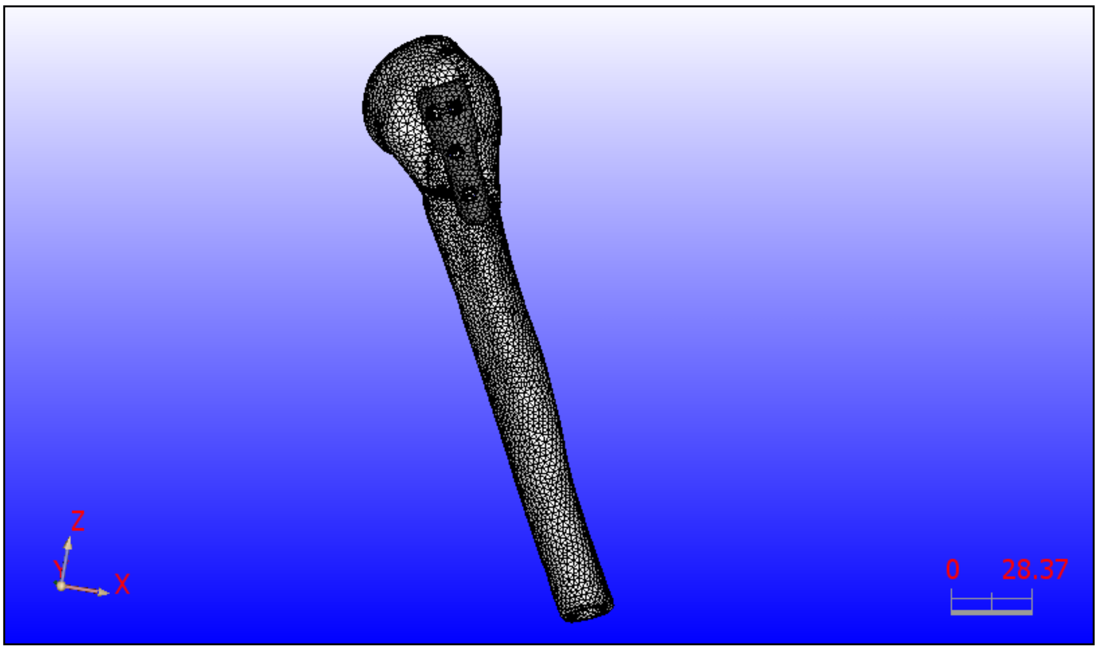

Figure 9: Tetragonal Mesh of the bone and implant model

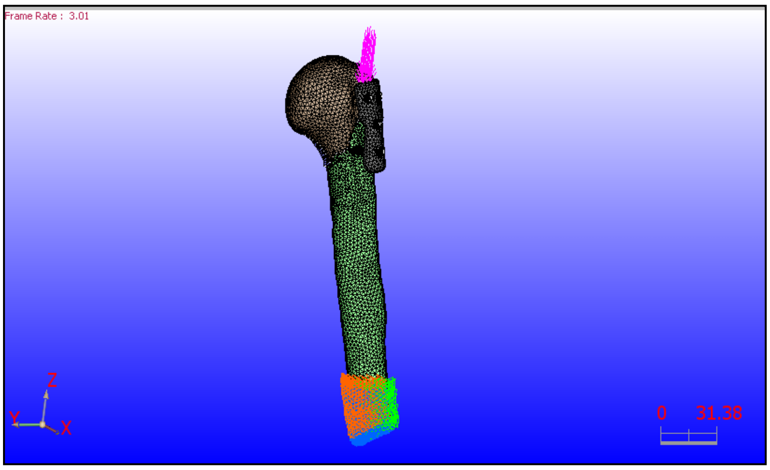

Figure 10: FEM done on the implant and bone model to test stability and stress resistance

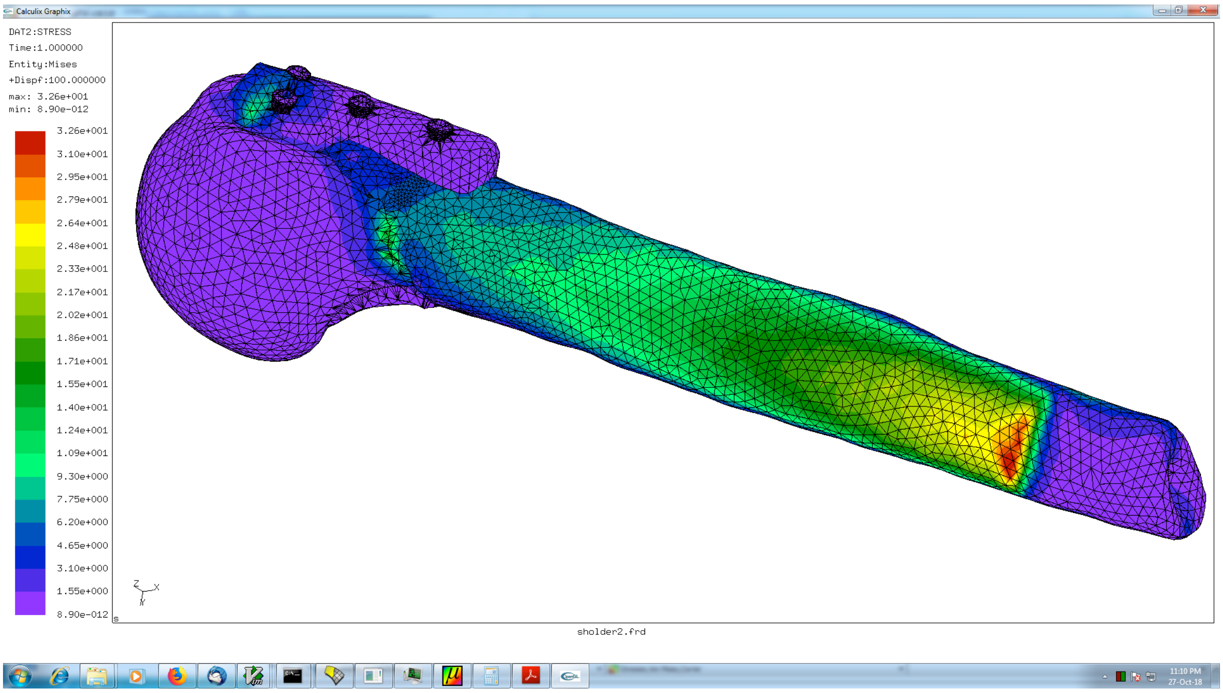

Figure 11: Stress distribution

Conclusions and Results

Patient specific locking-plate constructs exhibited significantly less loosening than blade-plate constructs for torsional loading. The proposed design shows a more even stress distribution on the bone-implant interface surface, which will reduce the uneven bone remodelling that can lead to premature loosening.

The proposed custom humeral component design has the following advantages compared with a conventional humeral component. Stress distribution showed that the risk of premature loosening might be reduced. As the bone-implant interface can accommodate anatomical abnormalities at the distal femur, the need for surgical interventions and fitting of filler components is reduced. The stability and longevity of the implant are greatly improved.

The primary disadvantages are the time and cost required for the design. It is recognized that the proposed custom implant system is not for every patient but can be applied to younger patients and those who have a more active lifestyle and will therefore depend on the implant for a long time. It is anticipated that custom-designed implants will increase the longevity and that the added cost can be justified for these younger, more active patients.

Future Improvements that could be automatic bone fragment placement, in our case the consolidation of the bone fragments were done manually, and lining up the shards of the fracture was difficult and time consuming and not completely accurate, in the future a 3-D puzzle solution software can be used for better results.

References

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