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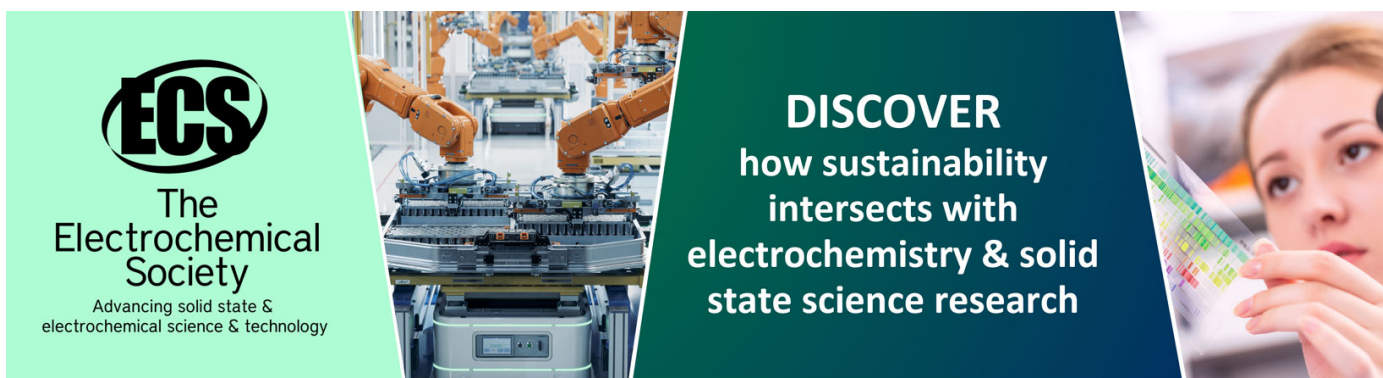
## Mechanical response of a human femoral diaphyseal stabilized fracture using implant plate

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# Mechanical response of a human femoral diaphyseal stabilized fracture using implant plate

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**Abstract.** The stabilization of a human femoral diaphyseal comminuted fracture using a fixation plate and screw system is analysed. A diaphyseal comminuted fracture represents a disruption in the medial femur with more than two bony fragments and bone loss. As a result of this, the osteosynthesis implant is subjected to a very high stress that could lead to its fracture, also the patient standing stability is affected due to higher slenderness of the lower limb. A procedure is proposed to simulate the surgery operation and the mechanical response of an in-vivo stabilized fracture. Stresses and displacements that occurred in the plate, fixation screws and bony fragments produced by the forces applied to the femoral head by the hip and to the diaphyseal cortex by tendons and muscles insertions during patient restoration are determined. Different fracture locations, cortical screws and fixation plates were analysed using the Finite Element Method which is configured to take into account heterogeneity and anisotropy of cortical and medullary bone. Recommendations about optimal implant design for the patient standing up stability and load bearing are concluded.

## 1. Introduction

The aim of this paper is to analyze different plates and screws combinations to stabilize a diaphyseal femur fracture, a 32-C3 diaphyseal femur fracture following the Müller AO Classification of Fractures—Long Bones [1], with a 30 mm gap between the upper and the lower part of the comminuted of this comminuted fracture, using the Finite Element Method. It was observed that the plate of several patients fractured unexpectedly several months after stabilization (See figures 1 and 2). This paper is intended to justify the phenomena and give criteria on patient stabilization procedures.

Three different fractured leg equivalent static load cases are of interest:  $0.23 \cdot BW$  vertical load exerted on the femur ( $BW$  is the body weight) for a patient using crutches carefully after operation (this is the maximum recommended, support on the fractured leg is prohibited),  $0.75 \cdot BW$  vertical load for a patient using crutches carelessly allowing partial standing on the fractured leg, and  $1.643 \cdot BW$  vertical load for the patient walking as normal (without crutches). This case is an extreme load case that should not happen in reality but it is of interest to estimate if the patient would suffer an injury or not.



Along with the forces due to the own weight of the patient on the femoral neck that is attached to the hip, forces due to the contraction of muscles attached to the femur should be considered. These muscles help the femur to support the weight of the patient and contract during walking, standing on one leg, climbing stairs and so on.

Unicortical and bicortical locking screws are used in different cases. The thread shape of the screws are not considered in this study. Several authors compare the screw thread effect on the simulation with that of considering the screw shaft and bone interaction as a bonded junction [2-4].



**Figure 1.** Plates and screws used to stabilize a 30mm long 32-C3 diaphyseal femur fracture. Upper (fractured) Lower (spare).



**Figure 2.** Fractured surface of the fractured plate shown in figure 1.

Normally, screws are not modelled as a helical 3D shape but as a 2D straight shape due to the complexity of the system and the high density mesh required to achieve realistic stresses on the plate and to get the highest stress on the neck of the screws zone. Bibliography about this point considers the high holding power of cortical screws (because of the very low thread pitch). Then the screw thread can be modelled as a smooth shaft and the screw-bone contact as a bonded junction. For the same reason the joint between the thread on the head of the screws and that on the hole of the plate can be modelled as a bonded junction too.

Implant plate fracture is initially motivated by fatigue during normal level walking of the patient. Shaat [5] has reported 316L stainless steel locking compression plate implants fatigue life based on femoral and tibial biomechanics during the gait.

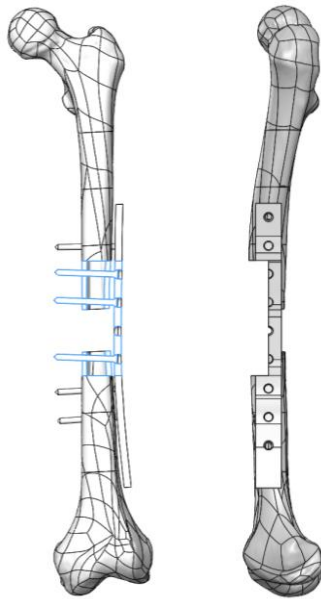
During decades several authors have reported information about geometry and mechanical response of the human femur both by experiments and biomechanics modelling. Internal forces and moments on the medial femur during level walking activities were calculated mainly by equilibrium considerations and thigh isolation of the knee (Shaat[5], Taylor[6]) or thigh isolation of the hip (Duda[7], Bergmann [8]).

Brand [9] presented a mathematical model for predicting lower extremity muscle and joint forces based upon several cadavers. Duda [7] calculated internal forces and moments of the femur during gait taking into account all thigh muscles, body weight and contact forces. Taylor [6] measured *in-vivo* the forces in the distal femur and the knee during normal level walking activity using a distal femoral replacement. Tung-Wu[10] and Schneider[11] performed experiments on patients using a proximal femoral prostheses implanted after tumor resection and an intramedullary nail, respectively. In-vivo axial forces were calculated during level walking activity.

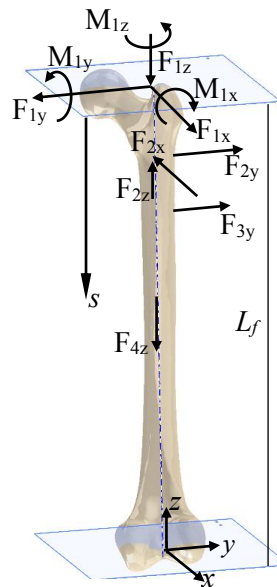
Seo[12] used the musculoskeletal simulation program Anybody Modeling System (Anybody Technology Inc. Denmark) and finite element analysis to calculate the stresses, strain and total deformation from a healthy male adult aged 29 (171cm height and 72kg weight) who walked normally.

## 2. The model

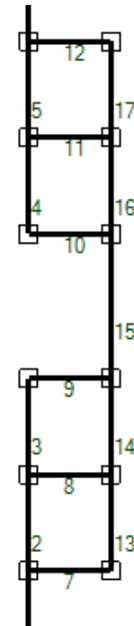
Let us first define the geometric model, materials properties and characteristics of the parts involved. The diaphysis (see figure 3) has an exterior layer of cortical type bone from 3 to 4 mm thick, whereas the bone interior is filled with trabecular or cancellous bone whose strength and holding power is about 10% that of the cortical bone [13] at the ends, and yellow bone marrow whose strength is null at the center. For simplicity, the 3D femur model includes only cortical bone material which occupies femur cortical bone space and occupied space by both yellow bone marrow and cancellous bone masses emptied. The cortical type screws used would stay in place due to the thread of the screw which is carving the cortical bone. Then the connection of the screws to the bone has been considered as a bonded junction.



**Figure 3.** Sectional view of stabilized femur using fixation plate and bi-cortical screws.



**Figure 4.** Schematic forces exerted on the left femur.



**Figure 5.** Truss bar model for stabilized femur using plate (13-17) and bi-cortical screws (7-12).

The femur shape was loaded from free internet library [14] and then scaled to get  $L_f = 404\text{mm}$  length which corresponds to a 25-26% of  $1.63\text{m}$ , the total height of a  $58.5\text{kg}$  weight patient. The femur geometry was modified to emptying the yellow bone marrow diaphyseal zone and complying with the above mentioned consideration about cancellous bone resistance (Figure 3). Diaphyseal ellipsoidal shape was minor axis  $20.7\text{mm}$  and major axis  $24.6\text{mm}$ . A procedure based in an artificial vision program is proposed to create the specific fractured femur geometry of a particular patient. A 3D finite element model can be built by scanning real human femur tomography images, subject the images to a number of filter processes and then apply a tool like “cover” of a drawing platform to build the 3D model.

The fixation plate studied (see figures 1 and 2) has threaded holes to lock the threaded screws head in, so it is a locking plate. During operation the traumatologist adapt the plate to the bone contour. Then, the plate is plastically deformed and bent to fit the approximate bone shape and then the gap between the bone and the plate is adjusted to a tolerance between  $1\text{mm}$  and  $2\text{mm}$  [2]. Similar process was followed to construct the 3D model from the bone and plate models (Figure 3). The deformed plate was constructed first using the Solidworks [15] sweep command to a directive curve which coincides with the nearest bone profile, separated  $2\text{mm}$  gap from the bone surface. The drill direction for every self-tapping screw is defined to be perpendicular to the directive curve. The cavity or similar

command is applied to define a non-gap assembly between the plate and the screws and the screws and the bone.

The plate model is designed to simulate different fixation configurations by varying the plate thickness, the screws separation and type (compatible bi-cortical and uni-cortical fixation screws are feasible). The bicortical screws are  $35\text{mm}$  long and have a  $4\text{mm}$  shaft diameter. The head shape is threaded and shown in figure 1 which is similar to that shown at *ISO 5835:1991*. On the other hand, the uni-cortical screws will have the same shape than that of the bi-corticals but only  $20\text{mm}$  length. Two different plate widths are tested,  $5.0\text{mm}$  and  $4.5\text{mm}$ , both  $200\text{mm}$  length and  $20\text{mm}$  separation between threaded consecutive holes.

According to bibliography bone can be modelled as an elastic anisotropic material  $120\text{MPa}$  yield strength. In this study, bone will be considered orthotropic,  $1850\text{ kg/m}^3$  density and elastic mechanical properties [16] according to Table 1.

**Table 1. Mechanical data for cortical type bone.**

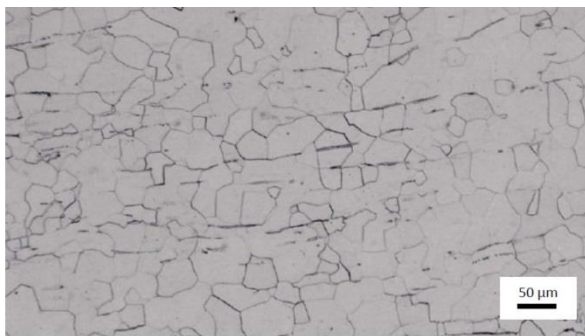
| Young Modulus (MPa) | Shear Modulus (MPa) | Poisson coefficient |
|---------------------|---------------------|---------------------|
| $^1E_1=16000$       | $^2G_{12}=3200$     | $\mu_{12}=0.30$     |
| $E_2=6880$          | $G_{23}=3600$       | $\mu_{23}=0.45$     |
| $E_3=6300$          | $G_{13}=3300$       | $\mu_{13}=0.30$     |

<sup>1</sup>Subscript 1 refers to dyaphyseal femur longitudinal axis

<sup>2</sup>Subscript 2 refers to tangential direction and subscript 3 to radial direction.

The fractured fixation plate was characterized by micro-hardness measurements  $310\text{-}330\text{ HV}0.2$  in longitudinal section and  $260\text{-}290\text{ HV}0.2$  in cross section, **SEM** (Scanning Electron Microscopy) and optic microscope test tube observation after Kroll's reactive attack (see figure 6) showing light acidity compatible with cold stretching fabrication process and grain size 6 ( $40\text{-}60\mu\text{m}$ ). The fixation plate was identified as commercially pure titanium *CP-Ti* in coarse grain condition which possesses an elastic limit  $\sigma_e=155\text{MPa}$ , endurance limit  $\sigma_{f7}=120\text{MPa}$  ( $10^7$  cycles),  $\sigma_{f4}=280\text{MPa}$  ( $1.5\cdot 10^4$  cycles), tensile strength  $\sigma_t=370\text{MPa}$  [17]. Typical elastic modulus and Poisson's ratio for *CP-Ti* are  $E=105\text{GPa}$  and  $\mu=0.3$ , respectively.

The locking screws were treated as *Ti 6Al-4V* titanium alloy which possess an elastic modulus  $E=104.8\text{GPa}$  and yield strength  $\sigma_e=827\text{MPa}$



**Figure 6.** Optic micrograph for the fractured plate test tube after Kroll's reactive attack showing light acidity and grain size 6.

Internal moments and forces in the human femur during normal level walking has been estimated by different researchers (Duda[7], Taylor[6], Bergmann[8], Shaat[5]). The maximum healthful femur stress and displacements depend mainly on the vertical load exerted instantaneously on the thigh during the gait cycle and section location. A wide spread of data was found due to the extreme complexity of boundary conditions and high number of muscles needed on biomechanics models and scarce number of experiments which results are not directly extrapolable due to the inherent

mechanical changes induced by the implants or prostheses in the thigh. This data is summarized in Table 2 below.

**Table 2.** Internal forces and moments exerted on femur. (*BW* is the body weight of the patient).

| Simulation<br>or Experiment<br>configuration                                         | $^1M_x$<br>$^2s=0$<br>[BWm] | $^1M_x$<br>$^2s=L_f$<br>[BWm] | $^1M_y$<br>$^2s=0$<br>[BWm] | $^1M_y$<br>$^2s=L_f$<br>[BWm] | $^1M_z$<br>$^2s=0$<br>[BWm] | $^1M_z$<br>$^2s=L_f$<br>[BWm] | $^1N$<br>$^2s=0$<br>[BW] | $^1N$<br>$^2s=L_f$<br>[BW] |
|--------------------------------------------------------------------------------------|-----------------------------|-------------------------------|-----------------------------|-------------------------------|-----------------------------|-------------------------------|--------------------------|----------------------------|
| Duda 10% gait cycle (Fig.4) All muscles                                              | 0.1300                      | 0.2600                        | 0.0011                      | 0.2800                        | 0.0055                      | 0.0022                        | 1.643                    | 1.429                      |
| Duda 10% gait cycle (Fig.5) All muscles                                              | 0.1645                      | 0.0188                        | 0.0090                      | 0.0380                        | 0.1108                      | 0.0386                        | 1.955                    | 1.610                      |
| Duda 20% gait cycle (Fig.5) All muscles                                              | 0.2250                      | 0.0375                        | 0.0190                      | 0.0190                        | 0.1060                      | 0.0386                        | 2.415                    | 2.070                      |
| Duda 10% gait cycle (Fig.4) Hip muscles                                              | 0.1300                      | 0.0011                        | 0.0011                      | 0.0022                        | 0.0055                      | 0.0055                        | 1.643                    | 1.643                      |
| Duda 10% gait cycle (Fig.4) Only glutei                                              | 0.1789                      | 0.0800                        | 0.0210                      | 0.1050                        | 0.0055                      | 0.0055                        | 1.643                    | 1.250                      |
| Duda 10% gait cycle. Only Hip contacts                                               | 0.1789                      | 0.2526                        | 0.0210                      | 0.2842                        | 0.0400                      | 0.0400                        | 1.643                    | 1.643                      |
| Bergmann (Hip implant Fig. 5 and 9)                                                  | 0.0470                      | -                             | 0.0080                      | -                             | 0.0133                      | -                             | 2.150                    | -                          |
| Taylor knee-femur implant at $s=0.5 \cdot L_f$                                       | -                           | 0.0718                        | -                           | 0.0350                        | -                           | 0.0115                        | -                        | 1.860                      |
| Tung-Wu intramedullary nail at $s=0.38 \cdot L_f$                                    | -                           | -                             | -                           | -                             | -                           | -                             | 2.200                    | -                          |
| Schneider intramedullary nail partial<br>weighting 250N at $s \approx 0.5 \cdot L_f$ | -                           | 0.0720                        | -                           | 0.0320                        | -                           | 0.0880                        | -                        | 1.320                      |

<sup>1</sup>*N* is the compression force. *M<sub>x</sub>*, *M<sub>y</sub>* and *M<sub>z</sub>* are the internal moments on the *x*, *y* and *z* axis respectively.

<sup>2</sup>*s* is the distance from the hip femur section to the specified section (See figure 4).

The forces exerted on the femur were calculated considering the internal forces and moments distribution due to body weight and contact forces at the hip and contact forces exerted on the diaphysis boundary by all thigh muscles at 10% gait cycle in normal level walking of the patient (Duda[7]). The gait cycle is between strike of the left leg and next heel strike of the same leg. The magnitude of forces modelled are summarized in table 3.

**Table 3.** Magnitude of forces exerted on the femur.

| Force    | Description                                                                                                                                                                    | Value <sup>1</sup> |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| $F_{1x}$ | Internal force at the femur head in <i>x</i> direction due to hip contact force and force exerted by gluteus maximus, gluteus medius, gluteus minimus and tensor fascia latae  | $0.786 \cdot BW$   |
| $F_{1y}$ | Internal force at the femur head in <i>y</i> direction due to hip contact force and force exerted by gluteus maximus, gluteus medius, gluteus minimus and tensor fascia latae  | $0.835 \cdot BW$   |
| $F_{1z}$ | Internal force at the femur head in <i>z</i> direction due to hip contact force and force exerted by gluteus maximus, gluteus medius, gluteus minimus and tensor fascia latae  | $1.643 \cdot BW$   |
| $M_{1x}$ | Internal moment at the femur head in <i>x</i> direction due to hip contact force and force exerted by gluteus maximus, gluteus medius, gluteus minimus and tensor fascia latae | $0.1300 \cdot BWm$ |
| $M_{1y}$ | Internal moment at the femur head in <i>y</i> direction due to hip contact force and force exerted by gluteus maximus, gluteus medius, gluteus minimus and tensor fascia latae | $0.0011 \cdot BWm$ |
| $M_{1z}$ | Internal moment at the femur head in <i>z</i> direction due to hip contact force and force exerted by gluteus maximus, gluteus medius, gluteus minimus and tensor fascia latae | $0.0055 \cdot BWm$ |
| $F_{2x}$ | Force exerted by psoas major, iliacus, piriformis, obturator, gemelli, popliteus, quadratus, pectineus and vastus lateralis at $s=0.15 \cdot L_f$ in <i>x</i> direction        | $0.926 \cdot BW$   |
| $F_{2y}$ | Force exerted by psoas major, iliacus, piriformis, obturator, gemelli, popliteus, quadratus, pectineus and vastus lateralis at $s=0.15 \cdot L_f$ in <i>y</i> direction        | $0.497 \cdot BW$   |
| $F_{2z}$ | Force exerted by psoas major, iliacus, piriformis, obturator, gemelli, popliteus, quadratus and pectineus and vastus lateralis at $s=0.15 \cdot L_f$ in <i>z</i> direction     | $0.572 \cdot BW$   |
| $F_{3y}$ | Force exerted by gluteus maximus, adductor brevis and biceps femoris breve at $s=0.35 \cdot L_f$ from femur head in <i>y</i> direction                                         | $0.1427 \cdot BW$  |
| $F_{4z}$ | Force exerted by adductor longus, biceps femoris breve, vastus medialis and vastus intermedius at $s=0.55 \cdot L_f$ from femur head in <i>z</i> direction                     | $0.3575 \cdot BW$  |

<sup>1</sup>Direction of forces and moments are shown in figure 4.

$F_{1y}$ ,  $F_{2x}$ ,  $F_{2y}$ ,  $F_{2z}$ ,  $F_{3y}$  and  $F_{4z}$  forces (figure 4) has been determined by equilibrium considerations from the  $x$ ,  $y$ ,  $z$  internal forces and  $x$ ,  $y$  internal moments diagrams of the femur shown by Duda [7].

Following previous screw-plate and screw-bone connections hypothesis, an equivalent 2D truss bar structure of the sane femur and stabilized femur (averaged 25mm diameter 4mm thickness and isotropic material with elastic modulus  $E=16GPa$  cortical bone) can be derived (see figure 5).

In addition, FEA simulations were performed in order to get estimates of the stress distribution on femur, plate and screws. FEA modelling was implemented in the SolidWorks platform using small displacement and small strain solver [15]. See figure 3. 76998 tetraedric elements compose a mesh with a minimum size of 2.8mm and maximum of 13.9mm on non-critical regions like those of the lower end of the femur. Various mesh densities and mesh control were simulated to confirm that the number of elements were enough so the displacement results will not vary significantly due to meshing.

Compatible stress calculations of the structural system shown in figure 4 demands that the tibio-femoral joint were considered a fixed joint and that the hip joint of the femoral head to the acetabulum of the hip were considered to move free. Femur displacements are measured with respect to the straight line connecting both deformed ends. These displacements can be estimated from the quarter of the fixed-free ends displacements considering similarity with the pinned ends bar deflections.

### 3. Results and discussion

Several stabilization configurations were performed varying the number and type of stabilization screws and fracture location using both 2D truss bar model and FEA model. The denomination of a particular configuration consists in six figures: first three figures for the type of screw used to thread in every hole of the three possible in the upper femur followed by another three figures for those of the lower femur holes. Any figure can be: **B** for a bicortical screw inserted in the hole, **U** for unicortical screw or “-” for free hole.

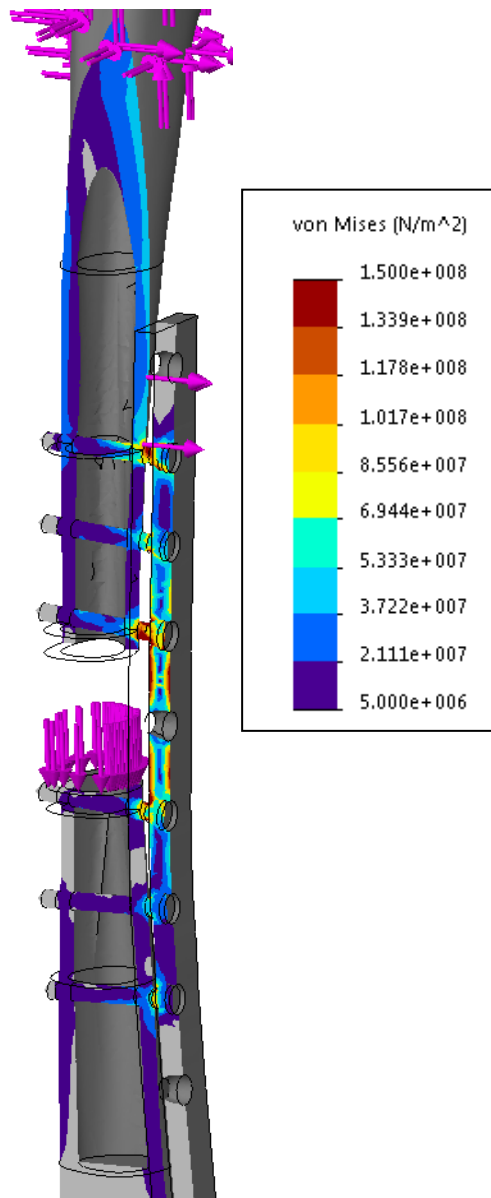
Table 4 below shows the femur, screws and plate maximum sectional normal stresses in the direction coincident with the longitudinal axis of the femur (this is a good estimate of Von Mises equivalent stress) and system maximum displacement (expressed as displacement resultant for the 2D truss bar).

**Table 4.** Data retrieved from 2D truss structure analysis ( $BW=650N$ )

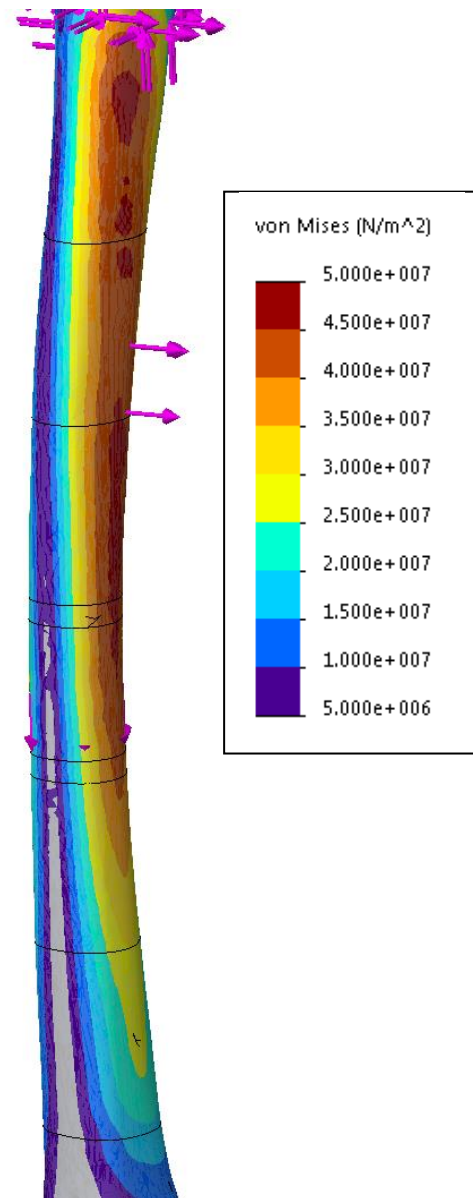
| Configuration                   | Width         | 0.230·BW load                 |             | 0.750·BW load                 |             | 1.643·BW load                 |                   |
|---------------------------------|---------------|-------------------------------|-------------|-------------------------------|-------------|-------------------------------|-------------------|
|                                 | Plate<br>(mm) | Plate/Screw/Bone Stress [MPa] | Displ. [mm] | Plate/Screw/Bone Stress [MPa] | Displ. [mm] | Plate/Screw/Bone Stress [MPa] | Displ. [mm]       |
| <b>BBBBBB</b> $s=0.39\cdot L_f$ | 5.0           | 53/189/8                      | 0.47        | 174/616/27                    | 1.54        | 380/1350/60                   | <sup>1</sup> 3.38 |
|                                 | 4.5           | 64/186/8                      | 0.92        | 210/607/27                    | 1.79        | 459/1330/60                   | 3.93              |
| <b>BBBBBB</b> $s=0.49\cdot L_f$ | 5.0           | 41/176/7                      | 0.45        | 133/575/23                    | 1.47        | 292/1260/51                   | 3.23              |
|                                 | 4.5           | 49/174/7                      | 0.86        | 159/566/23                    | 1.68        | 348/1240/51                   | 3.68              |
| <b>BBBBBB</b> $s=0.59\cdot L_f$ | 5.0           | 25/168/6                      | 0.36        | 82/548/18                     | 1.16        | 179/1200/40                   | 2.55              |
|                                 | 4.5           | 29/164/6                      | 0.39        | 96/534/18                     | 1.26        | 210/1170/40                   | 2.75              |
| <b>B-BB-B</b> $s=0.59\cdot L_f$ | 5.0           | 27/217/6                      | 0.38        | 89/707/20                     | 1.22        | 195/1550/43                   | 2.68              |
|                                 | 4.5           | 32/216/6                      | 0.41        | 105/703/20                    | 1.32        | 230/1540/43                   | 2.90              |
| <b>UBBBBU</b> $s=0.59\cdot L_f$ | 5.0           | 25/190/6                      | 0.47        | 82/621/20                     | 1.53        | 179/1360/43                   | 3.35              |
|                                 | 4.5           | 32/186/6                      | 0.49        | 103/607/20                    | 1.60        | 226/1330/43                   | 3.50              |
| <b>-BBBB-</b> $s=0.59\cdot L_f$ | 5.0           | 28/284/6                      | 0.61        | 91/927/20                     | 1.98        | 200/2030/43                   | 4.33              |
|                                 | 4.5           | 33/283/6                      | 0.62        | 109/922/20                    | 2.03        | 238/2020/43                   | 4.45              |
| <b>BBBBBB</b> $s=0.69\cdot L_f$ | 5.0           | 15/167/5                      | 0.30        | 49/543/16                     | 0.97        | 105/1190/36                   | 2.13              |
|                                 | 4.5           | 17/153/5                      | 0.30        | 56/498/16                     | 0.98        | 123/1090/36                   | 2.15              |
| No fractured femur              |               | 7                             |             | 22                            |             | 48                            | 1.83              |

<sup>1</sup>Figures in red means exceeded value with respect to that of healthful femur performance or component stress that exceeds its elastic limit.

If we focus on the plate stresses results, it must be observed that 2D structure analysis uses Strength of Materials formulas for bars to get the maximum sectional normal stress. In critical regions, the maximum stress could be, at least, 2.5 times that of the maximum normal stress shown in Table 4 due to stress concentration phenomena which could lead to very early plate fracture depending on the configuration. This would mean that only stresses below  $110\text{MPa}$  would be safe. This conducts to prohibit support on the damaged leg and only partial standing if the fracture location is farther than  $0.49 \cdot L_f$  from hip femur head.



**Figure 7.** FEA results. *BBBBBB* stabilized femur fractured at  $s=0.49 \cdot L_f$  subjected to  $1.643 \cdot BW$  Vertical load ( $BW=650\text{N}$ ).



**Figure 8.** FEA results. Sane femur subjected to  $1.643 \cdot BW$  Vertical load ( $BW=650\text{N}$ ).

The difference between  $5\text{mm}$  or  $4.5\text{mm}$  plate thickness results are more pronounced on the displacements results than on the stresses. Though  $5\text{mm}$  plate thickness is more up to reduce bending

stresses the centroid of its sections has to be separated an extra  $0.25\text{mm}$  from the femur increasing bending moments.

With respect to the current debate between making a fixation more or less rigid, several researchers conclude that a thinner plate make the bone support more stressed, the bone cures faster and prevents it for becoming atrophied due to Wolff's law [13]. Also, higher stresses near the screw holes of the bone can produce hypertrophy on those zones.

For some configurations, a small displacement small strain static simulation were performed according to the FEA model presented in previous paragraph. Solidworks platform [15] were used. The equivalent Von Mises stresses and magnitude of the maximum displacement were calculated. FEA results are shown in figures 7 and 8 for comparison of the same femur stresses with stabilized femur stresses. Good agreement was found with 2D Structural Analysis displacements but considerably higher stresses due to stress concentration in the critical regions. FEA analysis reveals that maximum overall stress appears in the nearest holes of the plate to its center (even free hole), in the gap fragment of the screws due to tangent force and in the holes practiced by the traumatologist on the femur fragments.

Though FEA analysis is a good tool for stress concentration problems it was found that it did not provide a good distribution of results if the mesh was increased in the critical regions, some convergence fault inherent to the method appears. Then, no quantitative information on stresses could be discussed and future research should be done on this point.

If we get back to table 4 and compare stresses and displacements for the three load cases, it is clear that the recommended use of crutches during patient restoration, even allowing partial standing, is safe for all the screws configurations except for **-BBBB-** configuration which would be the case of weak fixation of the screw on the plate or reduced femur fragment space. If we take into account repetitive load and unload which is the normal walking case, additional fatigue analysis will be essential to allow partial standing of the patient, the application of other configurations different to the safer **BBBBBB** configuration or the change for a best performance material or component dimensions.

With respect to fracture location proximity to femur head is more critical. With respect to the number of screws for fixing one femur fragment comparing **BBBBBB** with **B-BB-B** and **-BBBB-** reveals that three screws reduce the screw stresses considerably. If only two screws are possible it is preferred to locate them as far as possible (**B-BB-B** is preferred to **-BBBB-**, for example).

An alternative for a patient could walk without crutches, stresses results reveals that it is the screws the weak point of the system. This could be corrected increasing the screw diameter from  $4\text{mm}$  to  $4.5\text{mm}$  which is feasible but this need detailed analysis because this change affects the plate and bony fragments performance too.

#### 4. Conclusions and future work

The stabilization of a human femoral diaphyseal comminuted fracture using a fixation plate and screw system has been modelled and simulated. A number of typical patient habits during restoration like walking as normal or the carelessly use of crutches are considered. Different stabilization configurations were performed varying the number and type of stabilization screws and using FEA modelling implemented in the SolidWorks platform.

The deformation process similar to that of the traumatologist when adapting the plate to the bone contour during operation was simulated to get realistic 3D model of a stabilized femur.

It was found that the mechanical characteristics and stress concentration factors in the critical regions of the fixation plate compromises the restoration period without using crutches and even partial standing on the fractured leg of the patient if the fracture is located close to the femur hip head.

Unexpected fractures of an in-vivo implant plate were analyzed. The model and simulation performed is simple and accurate enough to justify why the plate of a patient could fracture unexpectedly after stabilization if good estimates of the stress concentration factors in the critical regions of the plate are available. Mechanical fatigue of a Titanium alloy fixation plate is compatible with fracture after four patient restoration months and clinical data.

The model and procedure presented in this investigation when applied to a sample of similar patients' fractures could be useful to generalize conclusions. This could reduce the number of surgery operations due to the fracture of the fixation plate. Furthermore, the methodology proposed in the paper can be considered as a useful tool for improving patient stabilization procedures.

More precise estimates of the fatigue life of fixation plates requires a more precise determination of the stress concentration factor in the critical regions observed in this paper.

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