Influence of gap size, screw configuration and nail materials in the stability of anterograde reamed intramedullary nail in femoral transverse fractures

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ABSTRACT

Femoral shaft fractures are among the most serious of the skeleton and present high morbidity and mortality in addition to important complications and consequences. So, the most appropriate treatment depending on the type of fracture and location level should be chosen.

A finite element model of the femur has been developed, analysing various types of fractures in the subtrochanteric and diaphyseal supracondylar area, with several gap sizes, stabilizing with a single combination of screws for the intramedullary nail. The mechanical strength of the nail against bending and compression efforts was studied comparing two materials for the nail: stainless-steel and titanium alloy

Beside the FE simulations, a clinical follow-up was realized, considering a sample of 55 patients, 24 males and 31 females, with mean age of 52.5 years. Localizations of fractures were 22 in the right femur and 33 in the left femur, respectively.

A good agreement between clinical results and the simulated fractures in terms of gap size was found. Non-comminuted fractures have a mean consolidation time of 4.1 months, which coincides with the appropriate mobility at fracture site obtained in the FE simulations, whereas comminuted fractures have a higher mean consolidation period estimated in 7.1 months, corresponding to the excessive mobility at fracture site obtained by means of FE simulations.

The obtained results between both nail materials (stainless steel and titanium alloy) show a higher mobility when using a titanium nails, which produce a higher rate of strains at the fracture site, amplitude of micromotions and bigger global movements compared to stainless steel nails. Steel nails provide stiffer osteosyntheses than the titanium nails.

In conclusion, the anterograde locked nail is particularly useful in the treatment of a wide range of supracondylar fractures with proximal extension into the femoral diaphysis.

Key terms: Intramedullary nail, Anterograde reamed nail, Femoral fracture, Gap analysis, Osteosynthesis, Finite element analysis.

INTRODUCTION

Femoral shaft fractures are among the most serious of the skeleton, characterized by high morbidity and mortality in addition to presenting important complications and consequences [1, 2]. Therefore, they must be treated being conscious of its complexity looking for the most appropriate treatment depending on the type of fracture and location level.

In the 1940s G Küntscher [3] introduced the intramedullary nailing (IM). In the 60's, tibial and femoral compression plates slowed the expansion of nailing. But, from the 70's, nailing has gradually become the first choice in the treatment of diaphyseal fractures of long bones. Since the 80's, many changes have been performed in order to improve results such as: design of the nails, morphology, materials, locking system and placement technique, allowing the locked intramedullary nails to become the standard of care for most femoral fractures.

Their indication has been extended to almost all femoral proximal and distal fractures: running from the lesser trochanter to the supracondylar area zones 2 (subtrochanteric) and 5 (supracondylar) of Wiss [4, 5]. It can be said that at present locked intramedullary nailing is the most suitable technique to treat femoral fractures. The advantages of IM nailing are: is a closed technique, preserves the hematoma in the focus of fracture, permits an easier extraction [5], exhibits a high rate of consolidation (98%) and a low percentage of infection (1%).

Although several improvements in IM nails have been developed, some complications remain as fatigue failure, non-union, bone-fracture and screw loosening. Reducing the stiffness of nail material can contribute to diminish stress-shielding and thus accelerate healing process [6]. When too flexible materials are used, some problems associated with load transfer such as loosening, malunion or poor-union appear [7, 8].

Controversial results about rigidity of the implant have been reported leaving optimum fixation stiffness as a pending issue [7].

The indications for anterograde intramedullary nailing are essentially extra-articular fractures, inclusive in the rare cases of bi- or trifocal fractures of the distal femur, where nailing is often the only therapy [9]. The biggest controversy about their indication lies on the fractures located on the distal third of the femur, which although infrequent present major difficulties for their treatment. The estimated frequency is 0.4% of all fractures and 3% of femoral fractures [10]. Different treatments have been proposed for this type of fracture: blade plate, dynamic compression plate, locking compression plate, anterograde nailing or retrograde nailing [9]. However, the anterograde nailing with the new implants offer multiple distal screw position options that allow articular reconstruction and sturdy fixation even in intra-articular fractures [11].

Despite the multiple designs, techniques and materials, the static locking intramedullary nail remains the reference treatment of femur fractures located between Zones 2 and 5 of Wiss [4, 12, 13]. The ultimate success depends on the treatment according to the characteristics of the fracture, the habits of the patient, associated lesions and the surgeon's experience with the used technique [9, 14]. The great diversity of types of diaphyseal fracture, according to their anatomical location and degree of comminution, makes it difficult on multiple occasions the choice of nailing and locking to ensure stability and to achieve fracture consolidation. Therefore multiple experimental works to study the biomechanical behavior of different type of nailing and locking them have been done.

In vivo animal experimentation on biomechanical behaviour of intramedullary femoral nails has a difficult extrapolation to humans due to anatomical differences and load conditions. Similarly, in vitro studies experiments on cadaveric bone or plastic bone models [15], can hardly be applied to humans, due to the differences between in vivo and in vitro behaviour. Those difficulties have led to the development of simulation models using the finite element method (FE). Analysis of osteosynthesis by means of a FE models enables the assessment of all critical parameters, such as maximum permissible load on the nail, local movements at the fracture site and stress concentrations around the locking screws.

Few studies have been published on experimental or computational models based on FE method applied to intramedullary nailing investigation of femoral shaft fractures. So, Regarding femoral nailing, Wang [16] analyzes the behaviour of short nails in the management of proximal femoral fractures, by comparing two fixation screws and studies the stiffness of the distal end in a posterior work [17]. Reference [18] studies a gamma nail design made in two different materials: titanium and stainless steel. Cheung performed a study on long nails [19] comparing FE simulation with experimental tests results, analyzing the differences in the relative stiffness between healthy and nailed femur. More recently, reference [20] analyzes the mechanical behaviour of a single screw with the use of two distal locking screws in a gamma locking nail. Chen studied distal femoral fractures managed with short nails by analyzing the differences in stiffness between the healthy and the nailed femur [21] . Fracture stability for flexible nails used in pediatrics was studied, modifying nail stiffness, in [22]. In [23] the influence of muscle forces on failure of distal nail holes and locking screws is studied. In [24] a combination of experimental and numerical methods is used to evaluate the stress distribution in an anterograde intramedullary nail. In [25, 26] a comparison between nails and locking plates in a metaphyseal wedge fracture in synthetic osteoporotic bone is executed. Static versus dynamic fixation techniques are compared in [27]. Finally, in [13] a comparison of strain magnitude and distribution resulting from two different entry points for anterograde nailing is performed.

WORK OBJECTIVES

The present study pretends to evaluate the stability of an IM Stryker femoral nail S2 (Stryker,Mahwah, NJ, USA). A FE model of the femur has been developed, analysing various types of fractures in the subtrochanteric and diaphyseal supracondylar area, stabilizing with one combination of screws, studying the mechanical strength of the nail against bending and compression efforts, to determine its maximum resistant capacity. Two materials were studied for the metallic nail: 316 LVM stainless-steel and Ti-6Al-4V alloy. A comparative analysis of the different types of osteosynthesis at different fractures was done, in order to verify the optimal solution in each case of those analyzed.

2.-MATERIALS & METHODS

2.1.-Modelling of the femur and implants

A three dimensional (3D) finite element model of the femur from 55 year old male donor was developed. Outer Geometry of the femur was obtained by means of 3D scanner Roland3D Roland® PICZA (Irvine, California) scanner, whereas a set of computed tomography (CT) of the donor's femur were treated using Mimics® Software (Materialise, Leuven). Once the inner interface between cortical and trabecular bone was determined, by means of an in-house algorithm material properties were assigned to the FE model in I-Deas [28], using the same workflow of a previous study [29].

The studied femoral nail Stryker S2™ (Stryker, Mahwah, NJ, USA) was 380 mm long, with a wall thickness of 2 mm and an outer diameter of 13 mm. This reamed anterograde nail uses locking screws of 5 mm of outer diameter, which were modelled as cylinders of the same diameter.

2.2.-Meshing and material properties

Nail surgery was reproduced in I-Deas in a virtual way, inserting the nail into the femur with the corresponding screws. Afterwards the assembly of the computer aided design (CAD) model was performed under surgeon supervision. Bone, nail and screws were meshed with linear tetrahedra. They were assumed for the bone linear elastic isotropic properties ($E_{Cortical}$=20000 MPa, ν=0.3; $E_{Trabecular}$=959 MPa, ν=0.3 [30], as reference), with variable values related with the processed CT images. The metallic nail was made of 316 LVM steel (E=192.36 GPa, ν=0.3) or Ti-6L-4V (E=113.76 GPa, ν=0.34) and metallic screws of 316 LVM steel, both assumed to be linear elastic isotropic.

A sensitivity analysis was performed to determine the minimal size mesh required for an accurate simulation. For this purpose, a mesh refinement was performed in order to achieve a convergence towards a minimum of the potential energy, both for the whole model and for each of its components, with a tolerance of 1% between consecutive meshes.

2.3.- Configurations used and contact modelling

All the considered fractures were modelled as transverse by means of an irregular surface developed to represent a closer geometry to the actual fracture. The effect of gap size remains unclear in the literature. So, the majority of the reviewed in vivo studies are referred to a gap size ranging from 0.6 to 6 mm [31, 32] whereas in FE simulation articles it ranged from 0.7 to 10 mm. [33, 34].

Thus, using this irregular fracture pattern, three different fracture gaps have been studied: 0.5 mm (considered as a non-comminuted fracture), 3 mm (as the most referenced value found in literature, representing a mid-value) and 20 mm as an example of comminuted fracture (Fig. 1). In addition to this, three localizations of the fracture were studied: proximal, medial and distal for each gap size. Only one combination of screws was studied: one oblique placed proximally and two transverse at the distal part. Table 1 summarizes the list of FE models simulated for the three gap sizes.

The study was focused on the immediately post-operative stage. Thus, the interaction at the fracture site does not take into account any biological healing process. Contact interaction was assumed between the outer surface of the nail and the inner cortex of the medullary canal of the femur (Fig. 2). Interaction between screws and cortical bone was considered to be bonded, whereas contact between screws a femoral nail was simulated. The selected friction values of bone/nail and nail/screws were 0.1 and 0.15, respectively, in accordance with literature [34-36]. Other similar studies modelled bone/nail interaction as frictionless, though [24, 37].

2.4.- Loads and boundary conditions

This study considered fully constrained conditions at the condyles and a load case associated with an accidental support of the leg at early post-operative (PO) stage (Fig. 3). This load was quantified to be about 25% the maximum gait load. According to Orthoload's database, the hip reaction force and abductor force (as the prime muscle group), referred to the 45% of gait, correspond to the maximum and most representative load [38]. Muscle attachments areas corresponding to abductor group muscle were determined mimicking anatomy atlas.

2.5.- Clinical follow-up

Beside the FE simulations, a clinical follow-up was realized, considering a sample of 55 patients, 24 males and 31 females, with mean age of 52.5 years, all of them treated with femoral nail Stryker S2^{TM}. Localizations of fractures were 32 in the right femur and 33 in the left femur. The statistic corresponding to fracture localization and fracture grade are included in Table 2. The comminute grade was measured according to the scale of Winquist/Hansen [39].

3.-RESULTS

The FE simulations allow obtaining the mobility results for the different cases analyzed. Figure 4 shows the deformed shape amplified (x25) and the vertical displacement maps corresponding to fractures non-comminuted (gap size 0.5 mm) and comminuted (gap size 20 mm).

In order to study relative micromotion at fracture site, pairs of homologue points at the fracture site were identified, as nodes that were opposed as shown in Fig. 5.

When analysing results, Perren's method [28] gives a threshold strain value of 10% beyond which fracture healing is expected to occur. This strain value is defined as the relative motion in fracture gap divided by the original fracture gap. Tables 3a and 3b shows the results associated to Perren method at the three fractures sites and gaps studied for steel and titanium nails, respectively. This reference parameter strongly depends on the fracture gap size. Thus, according to Table 3a healing condition is fulfilled for all the fractures of 3 and 20 mm (comminuted) and the medial and distal location for 0.5 mm gap size. On the other hand, Table 3b exhibit higher strains for titanium nail compared to steel one, as none of the 0.5 mm gap fractures verify the condition for callus formation. Thus this strain criterion should be considered with caution. Conversely according to micromotion results, this parameter is not valid for small fracture gaps as it gives strain values higher than 10% for proximal and medial fracture location.

Tables 4a and 4b show the maximum amplitude of micromotion between homologue points at the fracture site for steel and titanium nails, respectively. Table 4a shows that the most rigid behaviour belongs to diaphyseal fracture (40.69-66.43 μm) followed by medial one (51.96-73.39 μm) and proximal one (60.29-90.29 μm). Micromotion amplitude follows the same growing tendency with the increase of the gap for all the three fracture locations.

Table 4b show the same tendency for titanium at the three fracture locations observed previously: micromotions at diaphyseal fracture ranges from 62.02 to 123.71 μm, followed by medial one (ranging from 75.88 to 139.80 μm) and finally proximal one (varying from 93.07 to 140.83 μm). If the ratio of the amplitudes between both materials is calculated, a pitchfork of 1.46 to 2.00 is obtained which is within the range of the Young's modulus ratio for both materials (1.69).

Nevertheless, when evaluating the global stability reported in Table 5a and 5b, by measuring the displacement at head of the nail (insertion point at trochanter) the trend is reversed: proximal fracture is the most rigid, followed by medial fracture and distal fracture. This result can be explained in terms of a basic concept of mechanics. Figure 6 shows a scheme of lever arms between proximal and diaphyseal fractures. Lever arm is defined as de distance ("D" or "d") between de mid-plane of de fracture and the head of the femur. For a proximal fracture, the lever arm is much shorter than for the distal fracture. Consequently when applying the physiological loads at the head of the femur, the IM nail blocks the global movement of the femoral head "sooner" for the proximal fracture than for the diaphyseal one. According to gap size influence, there is a marked increase in the interfragmentary movement as well as global stability when the gap increases.

For steel nail, Table 5a values range from 1.33 mm (proximal fracture, 0.5 mm gap) to 2.01 mm (diaphyseal fracture, 20 mm. gap), whereas titanium nail yield to a higher rate of global movement as Table 4b reports: 1.62 mm (proximal fracture, 0.5 mm gap) to

3.14 mm (diaphyseal fracture, 20 mm gap). Calculating the ratio of the global movement between both materials a pitchfork of 1.22 to 1.56 is obtained.

With respect to the clinical follow-up, non-comminuted fractures have a mean consolidation time of 4.1 months, whereas comminuted fractures (grade 4 Winquist and Hansen) have a higher mean consolidation period estimated in 7.1 months. On the other hand, intermediate conminution grades lead to longer mean consolidation periods than non-comminuted fractures (4.9 months for grade 1 and 6.2 months for grade 2, respectively. Grade 3 was not finally considered because only one case was reported). So, the healing time increases inasmuch as the comminution grade is higher.

4.-DISCUSSION

Difficulties in vivo experimentation and the unreliability of in vitro models, has conditioned the development of simulation models by FE that allow studying different biological systems in both physiological and pathological conditions, and provide a quick and easy testing in different conditions difficult to achieve experimentally. However, they are still a very limited number of published papers which study the behaviour of intramedullary nails in the femur. The models developed in the present work allow the simulation of fracture in different locations, with different gap and different alternatives of nailing (material and different locking system), and determine whether the relative displacement at fracture site fall within acceptable limits, in order to achieve the fracture healing. The stability of the fracture is essential for the consolidation.

Fracture healing depends on general and local factors which may be modified by extrinsic conditions, such as biomechanics of fracture fixation [40]. The excess of movement at the fracture site adversely affects callus formation [32], resulting in lower blood vessels content, a greater presence of fibrocartilage and a lower bone formation [41, 42]. Therefore, relative displacements between bone fragments must be wide enough to promote bone formation according to "Wolff’s Law", without exceeding the threshold value which prevents callus formation [32]. We simulated different types of fractures located between Zones 2 and 5 of Wiss.

Although distal fracture (zone 5 of Wiss) is considered to be the most problematic area in terms of fracture stability, anterograde intramedullary nailing is a suitable option to provide stability at the fracture site [43]. It is important that the morphology of the fracture allows the screw to be place at least, at three centimetres of distance to the fracture site [48].

Anterograde interlocked intramedullary nails have been used successfully in the treatment of extra articular distal femoral fractures with 7 cm of intact distal femur or when a 7-cm fragment could be reconstructed with accessory lag screws or distal locking screws [44]. Large-diameter nails should be used to avoid fatigue fracture at the screw holes. When necessary, the intramedullary nail can be shortened to decrease the distance between the distal locking screw and the nail tip. The anterograde locked nail is particularly useful in the treatment of supracondylar fractures with proximal extension into the femoral diaphysis.

There is a good agreement between clinical results and the simulated fractures in terms of gap size. Thus, non-comminuted fractures have a mean consolidation time of 4.1 months, which coincides with the appropriate mobility at fracture site obtained in the FE simulations, whereas comminuted fractures (grade 4 Winquist and Hansen) have a higher mean consolidation period estimated in 7.1 months, corresponding to the excessive mobility at fracture site obtained by means of FE simulations.

On the order hand, the obtained values between both nail materials (Stainless steel and titanium alloy) show a higher mobility when using a titanium nails, which produce a higher rate of strains at the fracture site, amplitude of micromotions and bigger global movements compared to stainless steel nails. This tendency is related with the stiffness of both materials: steel nails provide stiffer osteosyntheses than the titanium nails.

The obtained results agree with previous experiences using anterograde intramedullary nails. So, anterograde interlocked intramedullary nails have been used successfully in a wide range of fracture types: in the treatment of extra articular distal femoral fractures with 7 cm of intact distal femur, or when a 7 cm fragment could be reconstructed with accessory lag screws or distal locking screws [44].

However, contraindications to anterograde nailing are a pre-existing proximal prosthesis or hardware, femoral deformity, obliteration of the intramedullary canal, and insufficient distal bone stock [43, 45].

5.-CONCLUSIONS

The FE models developed allow the simulation of fracture in different locations, with different gap and different alternatives of nailing, in accordance with the clinical cases included in the follow-up, and determine whether the relative displacement at fracture site fall within acceptable limits, in order to achieve the fracture healing.

There is a good agreement between clinical results and the simulated fractures in terms of gap size. Non-comminuted fractures have the minimum mean consolidation time, which coincides with the appropriate mobility at fracture site obtained in the FE simulations, whereas comminuted fractures have the higher mean consolidation period, corresponding to the excessive mobility at fracture site obtained by means of FE simulations. The healing time increases inasmuch as the comminution grade is higher.

In view of the correspondence between clinical follow-up and simulation results, it is clear that the biomechanical behaviour of the different osteosyntheses, without forget other biological and physiological factors, determines the appropriate fracture healing.

Considering the obtained results, it can be asserted that the anterograde locked nail is particularly useful in the treatment of a wide range of supracondylar fractures with proximal extension into the femoral diaphysis.

List of abbreviations used

IM: Intramedullary Nailing
FE: Finite Element
3D: Three-Dimensional
CT: Computed Tomography
CAD: Computed Aided Design
PO: Pos-operative

Authors' contributions

AH, JA and LG conceived the design of study. LG, SG, EI and SP conceived and developed the finite element models and carried out all the simulations. AH and JA realized the medical supervision of models. All authors participated in the drawing up of the manuscript, and read and approved the final manuscript.

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Competing interests

None declared

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Figure legends

Figure 1. Different kind of fractures with different gap sizes: 0.5 mm, 3 mm and 20 mm.

Figure 2. Interaction between nail and bone and between screws and nail

Figure 3. Boundary conditions

Figure 4. Deformed shape (x25) and vertical displacement maps corresponding to distal fractures: a) non-comminuted (gap size 0.5 mm); b) comminuted (gap size 20 mm).

Figure 5. Homologue points for micromotion processing: anterior and posterior view.

Figure 6. Comparative mechanical behaviour scheme between proximal and distal fractures (deformed shape x50)

Tables

Table 1. *List of FE models according screw combination*

Model	Proximal screws	Distal screws	Fracture location	***Gap size***	
1	Oblique (#1)	2 L/M screws (#2,3)	Proximal	0.5 mm.	
2			Medial	3.0 mm.	
3			Distal	20 mm.	

Table 2. *Statistics for the clinical follow-up*

Wiss zone	Cases	Conminution grade	Cases
2	7	None	29
3	11	1	9
4	22	2	9
5	15	3	1
		4	7
Total	55		55

Table 3a. Gap strain verification according to Perren [μm]. Nail made of 316 LVM.

PERREN METHOD			
# Model	% ε 0.5 mm.	% ε 3.0 mm.	% ε 20.0 mm.
Proximal	12.06	2.20	0.45
Medial	10.39	1.79	0.37
Distal	8.14	1.61	0.33

Table 3b. Gap strain verification according to Perren [μm]. Nail made of Ti-6Al-4V.

PERREN METHOD			
# Model	% ε 0.5 mm.	% ε 3.0 mm.	% ε 20.0 mm.
Proximal	18.61	3.34	0.70
Medial	15.18	3.59	0.70
Distal	12.40	3.06	0.62

Table 4a. Amplitude of axial micromotion [μm]. Nail made of 316 LVM.

Maximum amplitude of micromotion [μm]			
# Model	GAP 0.5 mm	GAP 3 mm	GAP 20 mm
Proximal	60.29	66.13	90.29
Medial	51.96	53.77	73.39
Distal	40.69	48.33	66.43

Table 4b. Amplitude of axial micromotion [μm]. Nail made of Ti-6Al-4V.

Maximum amplitude of micromotion [μm]			
# Model	GAP 0.5 mm.	GAP 3 mm.	GAP 20 mm.
Proximal	93.07	100.13	140.83
Medial	75.88	107.81	139.80
Distal	62.02	91.87	123.71

Table 5a. Global movement at the top of the nail [mm]. Nail made of 316 LVM.

Global movement of the top of nail [mm]			
# Model	GAP 0.5 mm.	GAP 3 mm.	GAP 20 mm.
Proximal	1.33	1.35	1.38
Medial	1.53	1.54	1.67
Distal	1.75	1.85	2.01

Table 5b. Global movement at the top of the nail [mm]. Nail made of Ti-6Al-4V.

Global movement of the top of nail [mm]			
# Model	GAP 0.5 mm.	GAP 3 mm.	GAP 20 mm.
Proximal	1.62	1.65	1.73
Medial	1.98	2.01	2.26
Distal	2.36	2.85	3.14

Figures

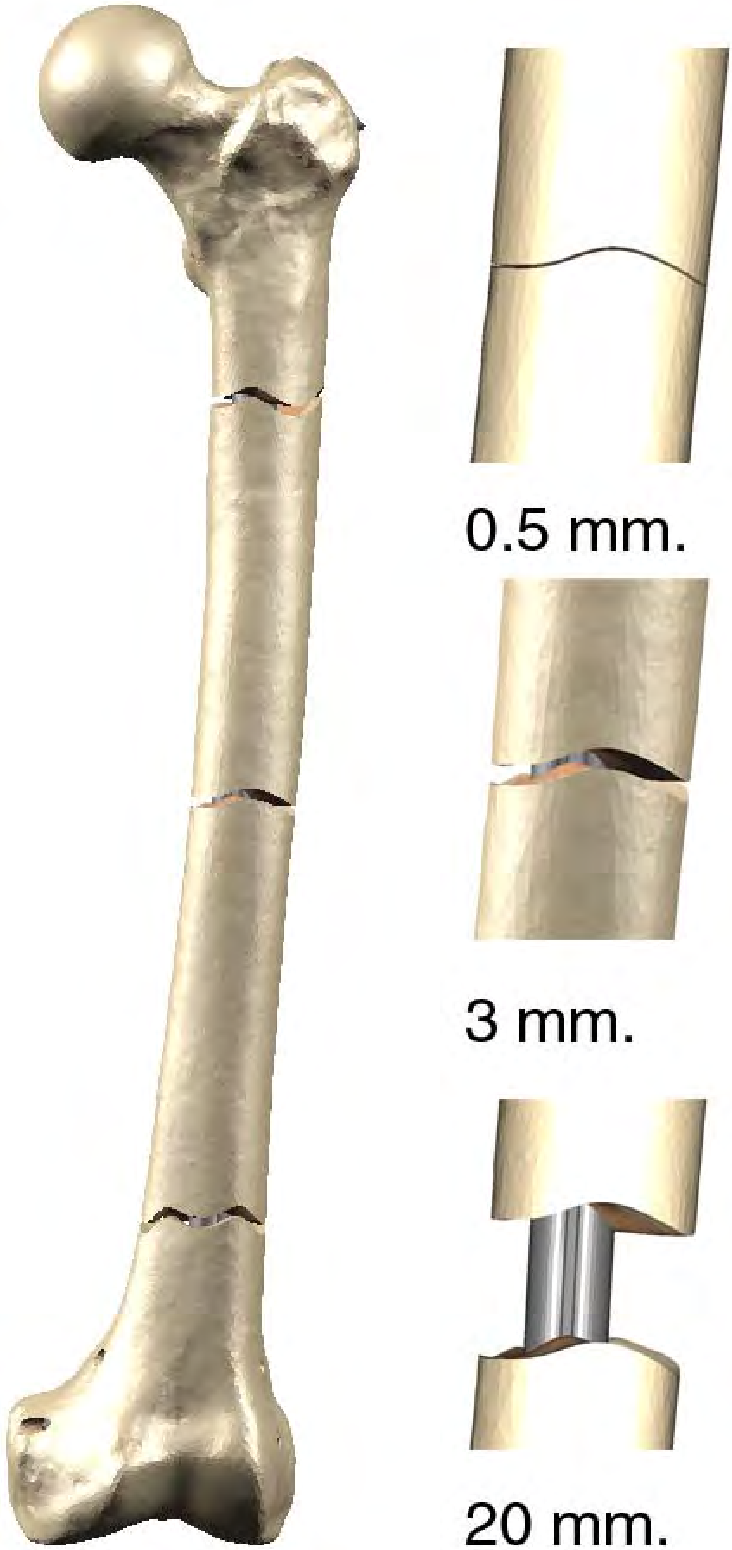


Figure 1. Different kind of fractures with different gap sizes: 0.5 mm, 3 mm and 20 mm.

Figure 2. Interaction between nail and bone and between screws and nail

Figure 3. Boundary conditions

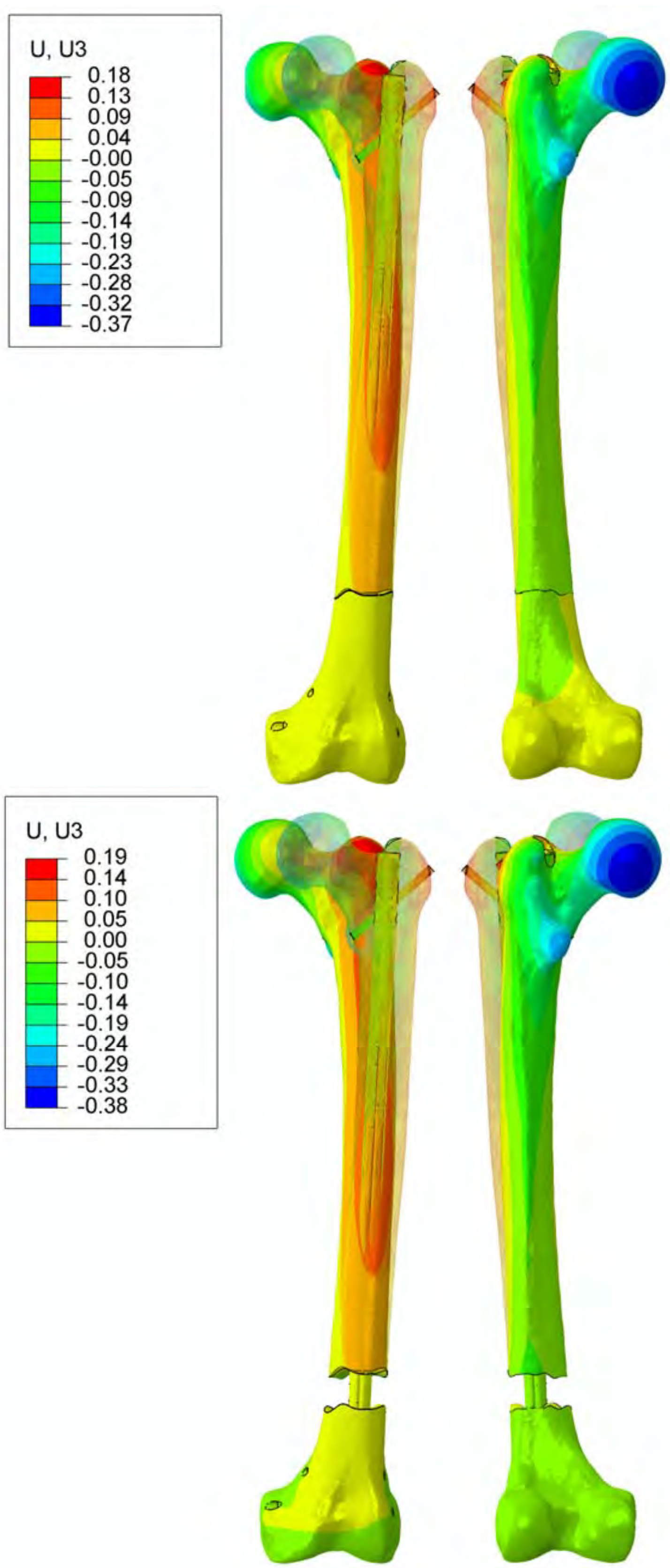
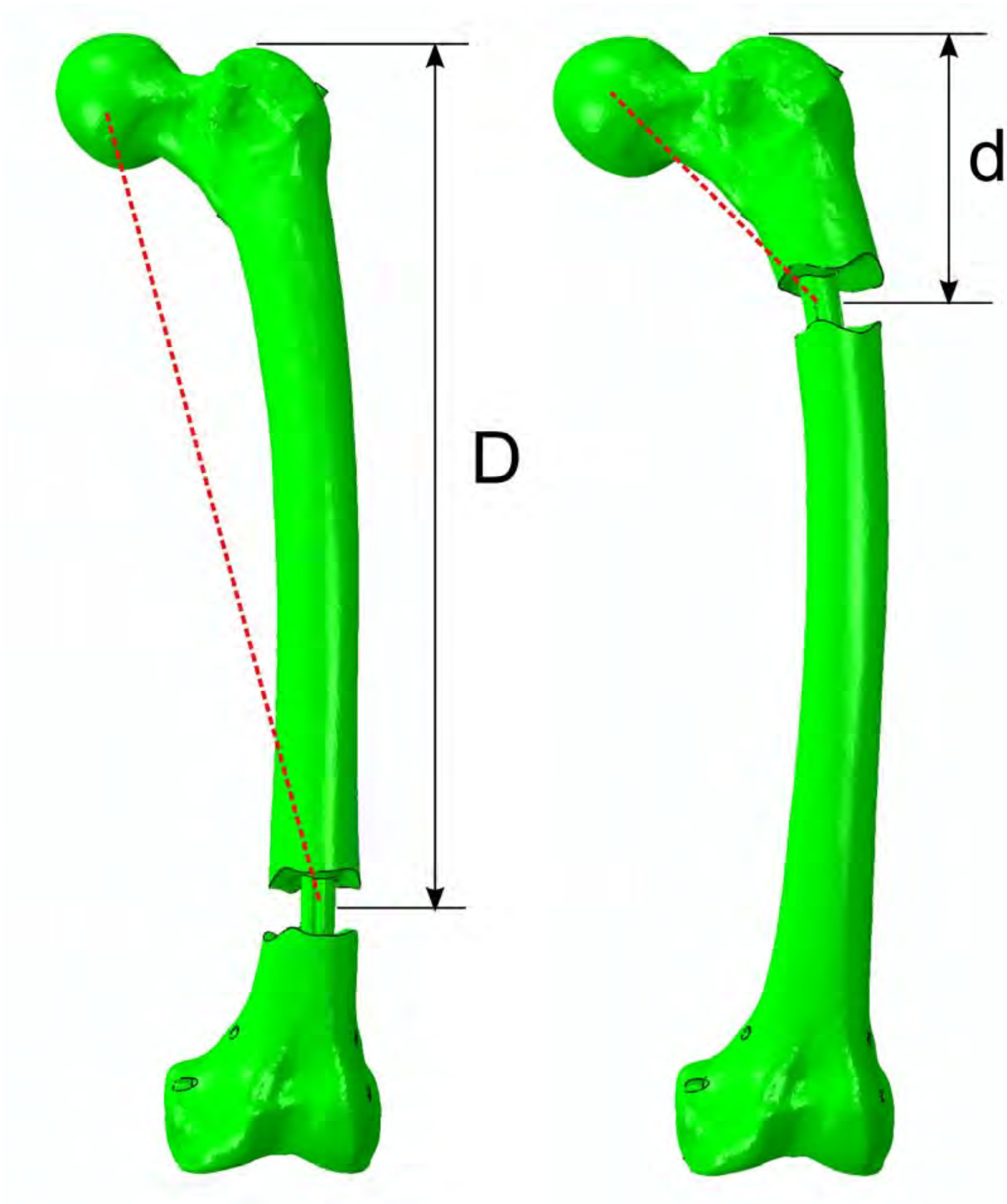


Figure 4. Deformed shape (x25) and vertical displacement maps corresponding to distal fractures: a) non-comminuted (gap size 0.5 mm); b) comminuted (gap size 20 mm)

Figure 5. Homologue points for micromotion processing: anterior and posterior view.



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574 **Figure 6.** Comparative mechanical behaviour scheme between proximal and distal fractures
575 (deformed shape x50)

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