



Design of a new tibial intramedullary nail

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Abstract

Aim of this work is designing a new intramedullary nail able to reduce the drawbacks of the distal locking, ensuring the axial stability, so enabling a speedy recovery of the fracture and a time-reduced immobilization of the limb.

During the first phases of the design process, the parametric CAD model has been carried out and, successively, several numerical analyses have been set up to verify the nail behaviour under the usual post-operation loading conditions.

In particular, non linear FEM analyses have been performed to define the right nail positioning, the average and maximum values of stress and contact pressure, and the stability of the joining by means of the new nail.

The obtained results have shown a not uniform contact pressure distribution at the nail-tibia interface due to the irregularity of the inner surfaces of the tibia.

Moreover, no longitudinal or rotational sliding has been observed during the numerical simulations, then demonstrating the effectiveness of the distal locking by the expansion of the flanges nail.

The new designed nail, besides simplifying the distal locking procedure and reducing the operation time, it is able to assure a reliable distal fixation and ensuring the stability of the system.

1 Introduction

Intramedullary nailing is currently the most common surgical technique for the fixation of tibia fractures requiring surgical treatment [1]. This surgical technique uses special nails for the treatment of the fractures [2]. It is largely used for the lower limbs fractures, especially in the diaphyseal tibial and femoral ones, when the fracture involves the region between the two epiphyses [3].

In particular, the locked intramedullary nailing technique uses nails with radial holes for its fixation, by screws, inside the bone. Two kind of fixing techniques are usually used: static and dynamic [4]. In static fixing, both ends of the nail are locked, both in the proximal and the distal part of the fractured bone. In dynamic fixing, instead, the nail is fixed by screws only at one end of the bone (proximal or distal depending on the location of the fracture); whereas the opposite extreme is free to slightly slide inside the bone [5].

The localization of the nail holes used for the distal fixing usually turns out to be quite difficult. The distal fixing procedures, in fact, is made manually, through a centering framework connected to a luminance amplifier that requires very long operating times and, consequently, a long exposure to ionizing radiation of the surgeon, medical staff and patient [6].

Moreover, many times, after some attempts and very long operation times, surgeons are forced to leave the nail unstable, so reducing the effectiveness of the intramedullary nailing technique.

To overcome these problems allowing a simpler use of this technique, a new intramedullary nail has been designed.

In particular, the new designed system allows to fix the nail in a very effective way, without any additional skin incisions so reducing the operation time.

2 The new “expansion nail”

Basing on the previous observations, it can be state that some of the most important requirements that must be met in the designing of a new intramedullary nail [7] are the following:

- the distal fixation of the intramedullary nail must be stable; this characteristic (in terms of torsional and sliding stability), in fact, ensures a fast and active mobilization of the injured limb, even with the possibility, in some cases, of an immediate full loading;
- the reduction of the radioscopical exposure time;
- the reduction of the surgical time;
- the possibility to use a guide-wire, that simplifies the insertion and centering operations of the nail inside the bone, (that can be achieved only using a holed nail to allow the wire longitudinal insertion);
- the nail must have an anatomic (ergonomic) shape that facilitates its insertion and extraction.

To achieve the objectives related to the improvement of the intramedullary osteosynthesis technique, basing on an idea of a previous work [8], a new intramedullary nail has been designed (figures 1-2).

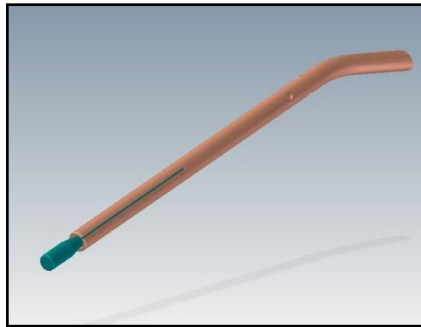


Fig.1 Nail - screw assembled.

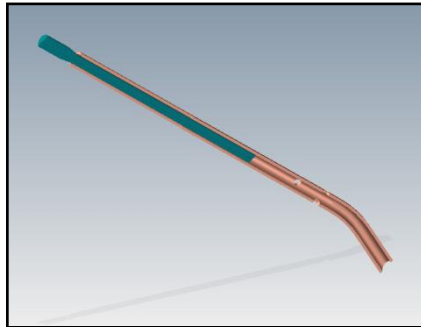


Fig.2 Axial section of the nail.

This is composed by the following elements:

- an ergonomic cylindrical body with an axial hole to allow the use of a guide-wire. The bottom side of the nail has four flanges, whose external surfaces are knurled to increase the friction with the inner surface of the tibia ensuring high sliding and torsion stability;
- a particular screw (whose lower end has a truncated cone shape) allowing the nail expansion (fig. 3); the upper end of the screw, instead, has a hexagonal shaped hole for the insertion of a flexible Allen key, of course also the screw has a hole to allow the use of the guide-wire.

2.1 Assembly and operating principle

Before to insert the nail, the tibia is bored (by a mill tool) in order to obtain a regular shape of its inner surface.

When the milling phase is completed, the nail is inserted in the tibia, using a particular aid-tool, similar to a handle. Once positioned, the nail must be fixed in the upper and the lower ends.

The proximal (upper) fixing is performed by radial screws, inserted through skin incisions and holes made on the bone .

In the standard nails, the same procedure is used for the distal fixation.

Through the new designed nail, instead, it is possible to fix the lower end without any skin incision or bone hole.

In fact, by using a flexible hexagonal torque key (a maximum torque value of about 20 Nm is needed to fix the nail in a young healthy bone) the screw is rotated until the flanges expand themselves. This expansion must assure the suitable values of the friction forces able to eliminate any sliding or rotation of the nail under the usual working loads but, also, should avoid any damage of the bone structure whose mechanical properties are highly variable according to species, age, etc...

Thanks to the expansion, in fact, the external surfaces of the nail get in contact with the internal surface of the tibia, producing the needed pressure to assure the stability of the distal locking.

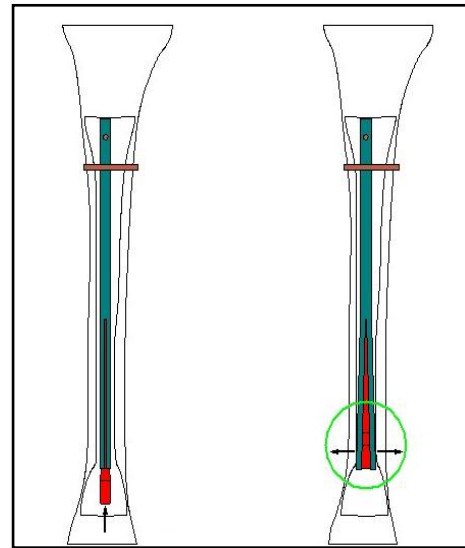


Fig.3 The new nail before (on the left) and after (on the right) the expansion

The following figures show the nail-screw assembly, positioned inside the bone at the end of the surgical treatment, before (fig.4) and after (fig.5) the expansion of the nail.



Fig.4 Nail before the expansion.

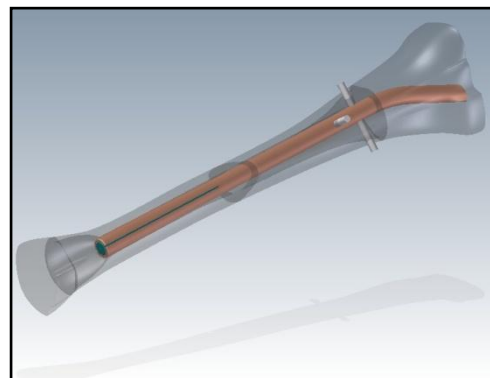


Fig.5 Nail after the expansion.

2.2 Material

The material used for the nail is the Ti6Al4V (90% Titanium, 6% Aluminum, 4% Vanadium) [9].

The Ti6Al4V titanium alloy is frequently used in several industrial sectors like aerospace, chemical, marine, automotive and, above all, for medical implants.

The Ti6Al4V is a very favourable material for medical implants thanks to its mechanical characteristics (e.g. good tensile strength and compression, good resistance to fatigue and corrosion) and, especially, its excellent biocompatibility level which represents an essential property for orthopaedic implants.

Table 1 shows the main mechanical properties of a common Ti6Al4V alloy, whose values also depend on the used processing and heat treatments.

Yield strength (MPa)	Ultimate strength (MPa)	Young modulus (GPa)	Poisson coefficient
760-895	1140	80-125	0.29-0.39

Tab.1 Mechanical properties of the Ti6Al4V.

3 FEM Analyses

To evaluate the performances of the new designed “expansion nail”, several simulations have been set up.

In particular, non linear FEM analyses were set up through the numeric code ANSYS, to define the right nail positioning inside the bone and to verify the distal locking and the nail behaviors in terms of resistance of the nail under the working loads to which the tibia is usually subjected after the surgery [10].

3.1 Set up of FEM models

The nail working simulation, after a preliminary pre-processing step in which the CAD and FEM models are set up, have been subdivided into the following simulation phases:

- expansion of the nail inside the bone;
- compression testing;
- torsion testing.

The bone model, created through computerised tomography images; is also available at the 3dcontentcentral web site (<http://www.3dcontentcentral.com/>), an online free CAD models library. After importing the models in ANSYS, all the materials have been defined for the different components. As said, for the nail and screw Ti6Al4V alloy was used; as regards the tibia, basing on previous works on the characterization [11], [12] and modeling [13] of the mechanical properties of a bone structure, the tibia has been considered as a material having a linear, elastic, orthotropic behavior, following the Hooke’s laws. During the FEM simulations the layered structure of the bone has been neglected by only considering the cortical bone. That because the trabecular bone structure has very low mechanical properties but, also, because most of the trabecular parts in the bone-screw (nail) interface is removed during the regularization drilling phase.

The following table shows the main mechanical properties of a bone material.

Main mechanical properties (GPa) of the cortical bone	
E ₁	6.91
E ₂	8.51
E ₃	18.4
G ₁₂	2.41
G ₁₃	4.91
G ₂₃	3.56
v ₁₂	0.49
v ₁₃	0.14
v ₂₃	0.12

Tab.2 Mechanical properties of tibia.

Finally, for the radial screws, used for the proximal locking, it was chosen a steel having the mechanical properties summarized in the table 3.

Young modulus (GPa)	Poisson coefficient
210	0.3

Tab.3 Mechanical properties of locking screws.

The following images show the meshed models of the nail, tibia and locking screws.

Solid elements with 10 nodes, with 3 degrees of freedom for each node, have been used for meshing the models.

Even if tetrahedral elements have been used, the quadratic formulation of the displacement function allows to obtain very accurate results even if irregular shapes (like the tibia) are simulated.

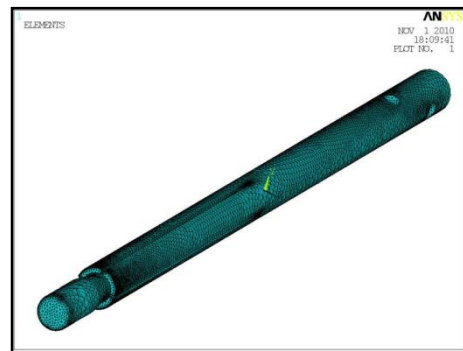


Fig.6 Mesh of the nail – screw assembly.

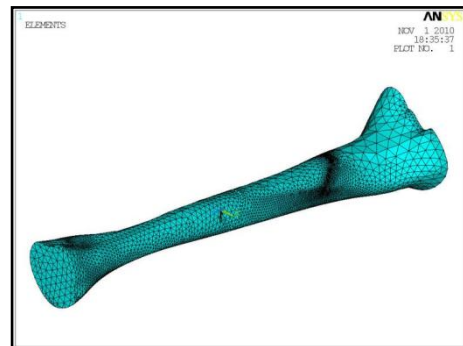


Fig.7 Mesh of the tibia.

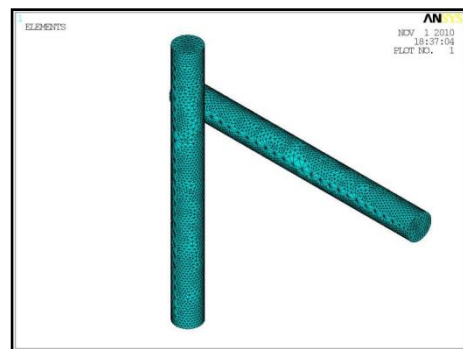


Fig.8 Mesh of the locking screws.

After meshing the models, the right material characteristics have been defined for every component and the contact surfaces have been identified. In particular, the following pairs of contact surfaces have been defined:

- Nail – Screw;
- Nail – Tibia;

- Nail – Locking screw;
- Tibia – Locking screw.

Finally, the boundary conditions, like displacements and rotations, have been imposed on the FEM models. This step was carried out carefully to simplify the assembly model but also assuring a correct simulation of the working conditions.

3.2 Expansion simulation

To simulate the expansion of the flanges, as a consequence of the screw movement, a z-axis displacement equal to 30 mm (corresponding to the total insertion of the screw inside the nail) has been imposed on the lower end surface of the screw.

Figure 9 shows the expansion of the nail according to the imposed boundary conditions. To obtain the shown (total) expansion, it has been calculated that a torque of about 20N/m must be applied to the screw.

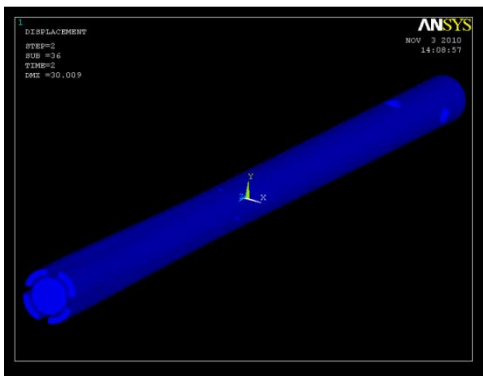


Fig.9 Expansion of intramedullary nail.

Due to the irregular internal shape of the tibia, the flanges displacements along the x and y directions are not symmetrical, as shown in Figures 10 and 11, because it is hampered by the internal part of the bone.

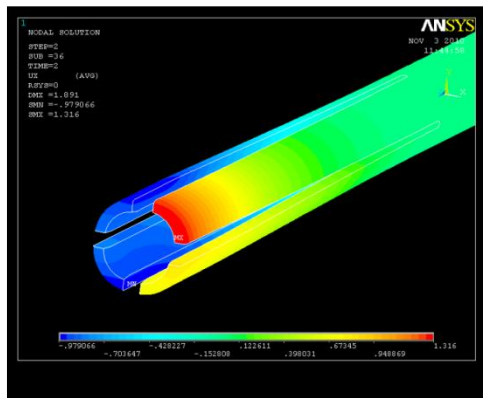


Fig.10 Displacements along the x-axis.

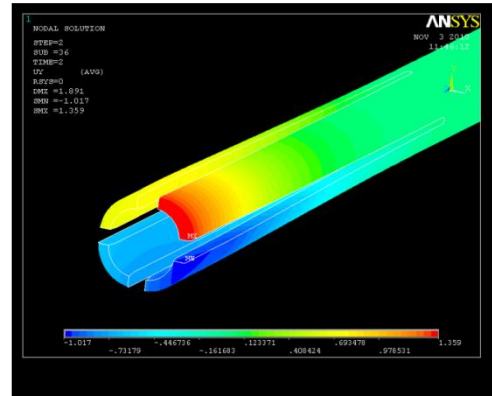


Fig.11 Displacements along the y-axis.

Moreover, even if reamed, the lower part of the inner surface of the bone has an asymmetrical shape, so causing a not uniform contact with the external surface of the nail.

For this reason, the pressure distribution generated between the nail and the screw and between the nail and the tibia is not uniform.

Despite this, the contact pressure distribution, even if irregularly distributed on the surface, is enough to guarantee the distal locking of the tibia, as verified in the subsequent tests of compression and torsion.

The maximum pressure value at the nail-bone interface is comparable with the one calculated in the contact between the screws (used for the proximal locking) and the bone.

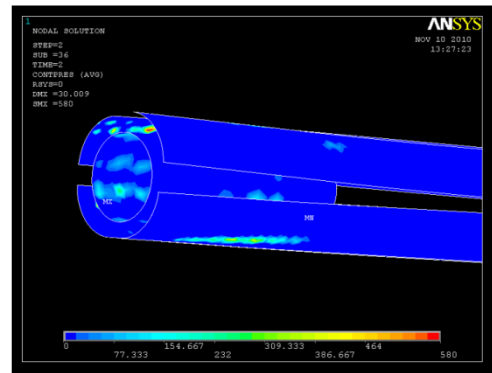


Fig.12 Contact pressure distribution.

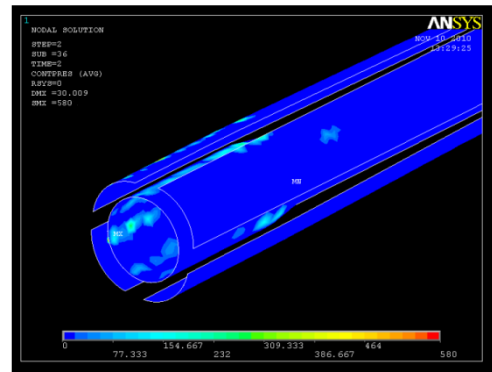


Fig.13 Contact pressure distribution.

3.3 Compression testing

After the expansion of the nail, the compression test has been carried out, to verify the stability of the distal locking as well as calculating the stress distribution on the nail components.

Of course, another objective is to verify the stresses distribution on the tibia, ensuring that the new nail is safe and does not cause, under the usual compression loads, any fractures of the tibia.

The compression test has been simulated by imposing on the nail-tibia assembly a 700 N compression load [14] (value equal to the weight of a patient of approximately 70 kg), that was applied on the upper surface of the tibia along the longitudinal axis.

Other boundaries conditions were applied on the lower surface part of the tibia by locking some displacement along the reference axes.

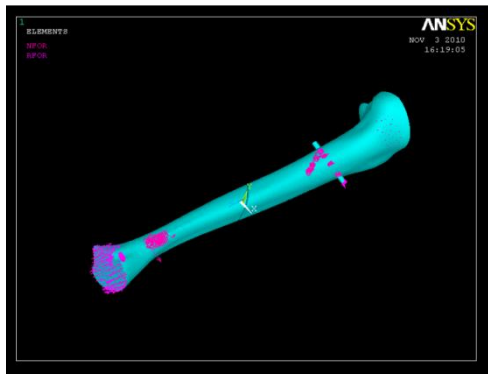


Fig.14 Reaction forces.

Figure 14 shows the reaction forces that are generated on the model following the application of compression load.

The distal reactions confirm the occurred contact between the nail and the tibia and the consequent distal locking.

As regards the contact pressure between the nail and the tibia, the distribution along the contact surface was almost unchanged, with a slight increase in term of maximum values.

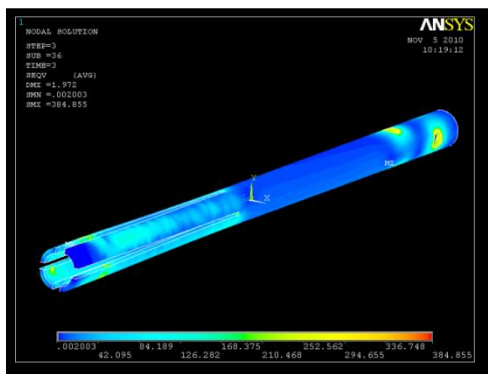


Fig.15 Von Mises stress on nail.

Figure 15 shows the stresses that are generated on the nail due to the compression load applied.

It is observed how the most stressed areas, as expected, are those corresponding to the proximal and distal locking. The values of stress are in the range 130-250 MPa, remaining, therefore, much lower than the yield strength (760-895 MPa) relative to the titanium alloy, Ti6Al4V, which is used for the nail.

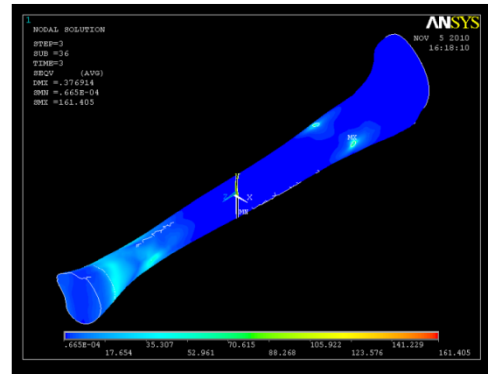


Fig.16 Von Mises stress on tibia.

As regards the tibia, in figure 16 can be observed that, also in this case, the most stressed regions are those far from the outbreak of the fracture. This confirms the efficacy of the expansion nail. The load, in fact, is transmitted through the proximal screws, from the bone to the nail, sparing the area affected by the fracture, and then is re-transmitted to the distal part of the cortical bone through the contact area with the nail.

The values of stress, obtained as result of the compression load, are included between 50 and 70 MPa, then largely admissible, because less than the ultimate strength of the cortical bone, which is about 150 MPa.

Finally, figure 17 shows the Von Mises stress distribution along the radial proximal locking screws.

Even for the screws, the obtained values (varying from 80 to 130 MPa) are largely lower the yield strength of the steel used for the screws.

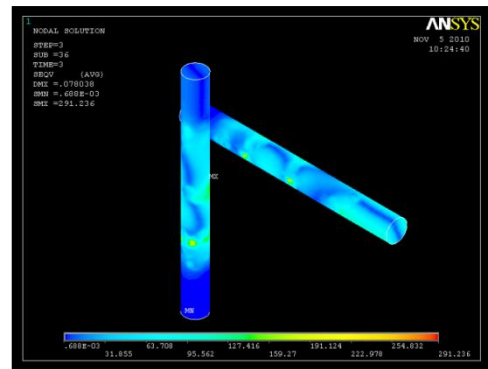


Fig.17 Von Mises stress on locking screws.

3.4 Torsional testing

As an additional testing of verification, was executed to evaluate the system behaviour under torsional load. In particular, it was simulated the machine used for the torsion testing. That was made using the device shown in figure 18, connected to the upper surface of the tibia, and blocking the lower face.

It has been considered a torque of 8 Nm, value used in many tests on long bones [14].

A pressure of 1.42 MPa was applied on the four faces of the device, in order to generate the required torque testing value.

Also in the torsion test the calculated values of contact pressure are similar to those obtained in the compression testing. The calculated tangential forces, due to the friction actions, are enough to avoid any rotation of the

nail, so ensuring a good distal locking and an optimal load transmission from the nail to the tibia.

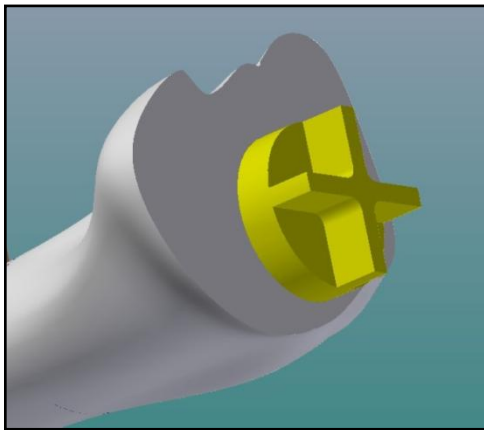


Fig.18 Device for torque transmission.

Unlike the compression test, the stress distribution on the nail slightly varies. Also in this case, however, the most stressed areas are those related to the proximal and distal locking parts, as shown in figure 19.

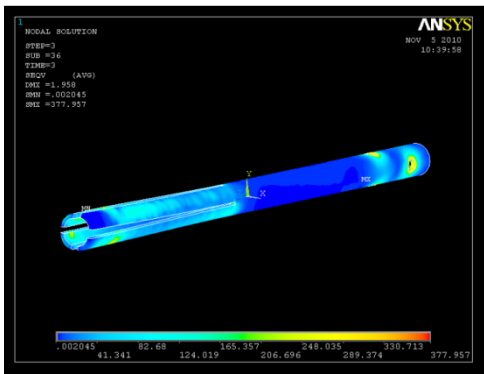


Fig.19 Von Mises stress on nail.

The stress values are very similar to those obtained from compression testing (varying from 130 to 280 MPa) and much smaller than the material yield strength. A slight stress values increasing has been noted in the areas close to the upper locking screw holes.

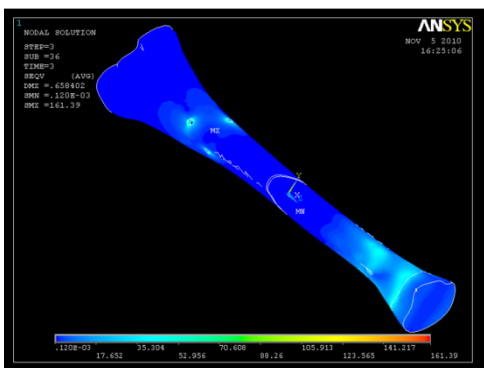


Fig.20 Von Mises stress on tibia.

The results obtained in the torsion test have given a further confirmation of the effectiveness of the expansion nail. In this case, in fact, the load is transmitted from the distal to the bottom part of the tibia (through the nail), without affecting the middle part of the fractured bone, which is fully unstressed (figure 20).

The stress values measured on the bone during the torsional test are included in the 50 - 70 MPa range, and then they are less than the ultimate strength of the cortical material.

Figure 21, finally, shows the stress distribution along the proximal locking screws; the resulting values are lower than the yield strength of the steel used for the screws.

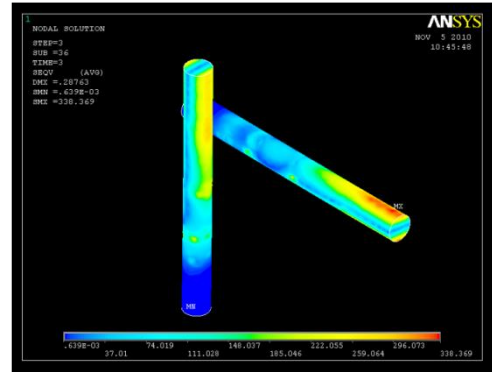


Fig.21 Von Mises stress on locking screws.

4 Conclusion

The present intramedullary expansion nail has been designed in order to satisfy, as best as possible, the primary requirements, which are the basis of a good intramedullary osteosynthesis treatment:

- a good distal locking, in order to ensure the axial stability of the system, allowing a rapid recovery of the fracture and an equally rapid recovery of the motor functions;
- a reduced radioscopical exposure time of the surgeon, medical staff and patient;
- easy insertion of the nail inside the bone and equally easy proximal and distal locking, in order to reduce the surgical times.

The contact pressures, obtained by compression and torsional tests, are able to ensure the stability of the system.

In fact, no longitudinal or rotational sliding has been noted during the numerical simulations; moreover, the most stressed areas, as noted, are those at the proximal and distal locking and the values of stress, although high, is much lower than the yield strength of the nail materials.

As regards the tibia, the most stressed parts are those far from the fracture, demonstrating the effectiveness of the distal locking by the expansion of the flanges nail.

Moreover, its application is less difficult than traditional nailed and this helps to reduce the surgery time.

For a complete design of the nail, then, could carry out further tests, simulating different load cycles (for example a walk, a run, etc...) and bending testing, and of course, to perform tests directly on the dry bones and patients, in order to compare the results with those obtained by numerical analysis and to estimate the fatigue behaviour of the assembly.

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