Healing of femoral fractures by the meaning of an innovative intramedullary nail

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ABSTRACT

In this paper, an innovative design of nail, conceived to heal fractures of long bones has been investigated. Its functioning is based essentially on sliding of conical surfaces located in a spindle and in a series of holding pins radially disposed around it. Spindle and holding pins are connected together by means of a sleeve. Medial and distal screws are not necessary. Rotational and longitudinal motions of the spindle are transformed in a radial expansion of the holding pins by the sliding of conical surfaces. A complete numerical FE model of an implanted femur was realized and analyzed by the mean of two loading configurations: LC1 by imposing a vertical load of 980 N, and LC2 by considering resultants of the muscle actions. Analyses confirmed results, in terms of mechanical performances, comparable with the others traditional systems of prosthesis.

1. Introduction

Generally, fractures are treated with a conservative approach, which involves the immobilization, by cast bandage. However, when it is necessary to stabilize the skeletal segments employing mechanical devices, applied because of a surgical intervention. Osteosynthesis is applied in the following cases:

- Whenever a conservative approach cannot guarantee satisfactory results,
- When the fracture requires immediate surgical repair,
- When the cast bandage treatment appears to be too long and cause of degeneration,
- When the cast bandage could limit autonomy or self-management of the patient.

Pseudarthrosis is defined as the non-union of a fracture within about six months after the traumatic event, and can occur in those areas where the correct blood supply is lacking. Some bones can be healed with a minimum treatment,¹ while other can be compromised by the trauma reducing both the internal vascularization of bone marrow (endosteal, vessels) and the external (periosteal) coming mostly with branches piercing the overlying muscles.² In most cases, the stabilization of long bone fractures can be obtained by introducing into the medullar canal a nails in order to obtain a good coverage with contact on the inner cortical and cancellous epiphyseal tissue. The Kuntscher nail enabled the early mobilization of a large number of diaphyseal fractures (initially only in the femur), by using the intramedullary nailing technique and an open section nail shaped as a clover. The nail

shape allows, after an appropriate reaming of the medullary canal, good internal adhesion ensuring excellent stability in flexion, while less stability is guaranteed for rotation and translation. The intramedullary nailing provides some significant advantages as a limited and economic instrumental equipment; a simple and fast surgical intervention; and it is easy to remove and minimally invasive. This technique is generally adopted to stabilize the fractures occurred on long skeletal segments. On the other hand, some compliance can arise, such as difficulty in medullary vascularization, mobilization of the patient, auxiliary fixation devices.

Around the holes, created inside the bone to insert the fixation screws, stress concentration effects represent the most danger consequences, especially in bending and torsion loading conditions.³ In this paper a new type of intramedullary nail designed for fractures occurring on long bones, has been investigated simulating its insertion in a fractured femur. This new nail allows minimizing all of the disadvantages associated with traditional osteosynthesis devices.^{4,5} Its peculiar geometry and functioning ensure a stable fixation of the bone stumps, reduce and simplify the nailing, and finally, it does not require any kind of screw to improve the fixing. Functioning of the nail is based essentially on sliding of conical surfaces located on the spindle and on the holding pins. The sliding transforms the rotational and longitudinal motion of the spindle in a radial expansion of the holding pins to protrude inside the bone of the intramedullary canal.

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Fig. 1. Technical drawing of the innovative nail.

2. Materials and methods

2.1. The new endomedullar prosthesis

A traditional intramedullary prosthesis generally consists of a nail adapted to be inserted inside the bone, and proximal and distal threaded screws transversely inserted into the nail to fix it. It is necessary to individuate the insertion points and to ensure proper placement of screws, by using X-rays, drilling meaty bones and tissue, and finally inserting all the screws, with considerable increase in time and possible complications. A wrong positioning of the stabilizing screws may result in needing of further corrective actions, and pathological states due to infections and wounds. The intramedullary nail of new conception proposed here, is able to solve or minimize this type of problems, being able to fix the broken bones with less invasive procedures. The nail consists of three main parts: a longitudinal outer cable sleeve, adapted to accommodate a central pin and the anchoring pins. When the central pin is screwed on the sleeve, the conical surfaces located on the pin slide on those belonging to the anchoring pins, transforming the roto-translational longitudinal motion of the pin in a radial displacement of the anchoring pins, housed inside the sleeve, see Fig. 1. By analyzing Fig. 1, it can be argued how central pin is threaded on the top (M5 * 10) and has 5 conical surfaces, 79° angled, at regular distances of 48 mm, which engage with twenty anchoring pins, arranged in four orthogonal series. This configuration ensures an excellent fastening of the nail in the intramedullary canal, allowing the stabilization of the bone stumps, by replacing contribution of medial and distal screws with anchoring pins. The insertion procedure of this implant involves the following steps:

- Cutting of tissue and uncovering the upper bound of the bone;
- Drilling and reaming of the intramedullary canal, with support of RX;
- Implant insertion;
- Adjustment and stabilization of the system by screwing the upper end of the nail.

2.2. FE modeling

A numerical model of the femur (15.324 elements and 1.744 nodes) was obtained by matching nuclear magnetic resonance (MRI) for soft tissues, and a computerized tomography (CT) for bones, carried on a normal adult patient. Bony material properties were distinguished in cortical and trabecular bones, and were assumed to be linear elastic, isotropic and homogeneous. A Young's modulus of 700 MPa was chosen for the trabecular bone, while for cortical bone a value of 17.000 MPa was selected.^{6,7} A mid-diaphysar fracture, classified as A2 type 1 according to the AO classification,⁸ with a gap size of 6 mm, was simulated on femur deleting and modifying local tetrahedral elements. Finally the insertion of our innovative nail was simulated by positioning the prosthesis inside the medullary cavity. The AISI 316L steel was selected to simulate the nail, by imposing linear elastic, isotropic and homogeneous properties, and with a Young's modulus of 210.000 MPa. Contact interfaces were imposed at the sleeve-holding pin-spindle surfaces and at the holding pin-bone contact areas, defining a penalty-based method with a weight factor and a coefficient of friction of 0.4. Two different loading conditions were analyzed: the first one, LC1 obtained by angling the femur at 12° in the frontal plane and 5° in the sagittal plane,⁹ imposing a vertical loads of 980 N and fixing the condilar area of the femur (200 nodes).

The second one, LC2 was realized loading the model with the

Table 1
Physiological loads components and application points on the femur.

Components of muscle and joint contact forces						X	Y	Z	P	
Components of muscle and joint contact forces						X	Y	Z	P
Hip contact	-32,8	+229,2	+54,0	P1	Hip contact	- 32,8	+ 229,2	+ 54,0	P1
	Intersegmental resultant	-12,8	+78,2	+8,1	P1	Intersegmental resultant	- 12,8	+ 78,2	+ 8,1	P1
	abductor	+4,3	-86,5	-58,0	P2	abductor	+ 4,3	- 86,5	- 58,0	P2
	Tensor fascia latae prox. part	+11,6	-13,2	-7,2	P2	Tensor fascia latae prox. part	+ 11,6	- 13,2	- 7,2	P2
	Tensor fascia latae dist. part	-0,7	+19,0	+0,5	P2	Tensor fascia latae dist. part	- 0,7	+ 19,0	+ 0,5	P2
	Vastus lateralis	+18,5	+92,9	+0,9	P3	Vastus lateralis	+ 18,5	+ 92,9	+ 0,9	P3

physiological muscle and joint contact forces aging on the femur, as reported in Table 1, by taking into account conditions adopted in literature.¹⁰ Non-linear finite element analyses were performed with Abaqus version 5.4 (Hibbitt, Karlsson and Sorensen, Inc., Pawtucket, RI) using the geometric nonlinearity and automatic time stepping options.

3. Results

3.1. FE analysis of the implanted nail

The complete FE model was tested applying two loading case configurations. The first one (LC1), was carried on by imposing a vertical (Y axis) load of 980 N and fixing 200 nodes at the base of the femur. Results show in Table 2 and Fig. 2, evidences displacements of 0,58 mm localized on the bone while on the nail values ranging around 0,45 mm, localized on the sleeve and spindle. The relative displacement can be assessed in 0.13 mm. The stress has been evaluated by equivalent von mises method reaching an average value of 60 MPa on the femur with peaks of 203 MPa reached on the contact points between nail and bone, in good agreement with benchmark. The stress on the nail is higher about 280 MPa of maximum equivalent von mises stress localized on the holding pins, while the spindle and the sleeve are subjected to a stress of about 230 MPa. The medium stress ranges around 200 MPa. The maximum equivalent elastic strain value is of about 3,26E-03 $\mu\text{mm/mm}$, localized on the bone. LC2 loading configuration takes into account all the muscular and ligament forces and produces more severe effects on the entire model in terms of displacements and stress, see Table 2 and Fig. 3. In particular, displacements on femur are of the order of 15,40 mm while on the nail values range around 15,00 mm, on the sleeve and on the spindle. As it is possible to notice the relative displacement, in this second case, reaches a value of 0,40 mm. The maximum equivalent von mises stress amount to about 513 MPa, on the holding pins of the nail, while a value of 210 MPa was found on the

femur, at the contact interface. A lower stress of about 460 MPa was found on the spindle on the sleeve. The medium values of stress range around 340 MPa. In this second loading configuration the maximum equivalent elastic strain found on femur, 2,11E-03 $\mu\text{mm/mm}$, is lower than 2,17E-03 $\mu\text{mm/mm}$ observed on the nail.

4. Discussion

The fracture of femur, the longest and most massive bone of the human body located in the thigh, is an event that can occur at any age. Shocks, violent trauma, or osteoporosis can cause a failure; despite femur is a very resistant bone. The femur is a particularly important bone; on it are inserted muscles indispensable to the movement. Femur is linked with the hip, constituting the coxofemoral articulation, and with patella and tibia, constituting articulation of the knee. The fracture can hit the femur in its central part, or more frequently in the elderly in the femoral head. In this paper, the behavior of a new type of intramedullary nail for fracture occurring in long bones has been investigated by means of a finite element code. This nail exploits the presence of expansible hardening pins to anchor itself to the bone without using any transversal or distal screw. It shows a mechanical behavior very similar to the others traditional intramedullary fixation systems. In particular, results show a stress of about 280 MPa, obtained on the innovative nail, comparable with values of 237 MPa obtained by Montanini et al.,¹¹ on a Gamma nail with a vertical load of 980 N. Displacements obtained on the innovative nail are approximately 0.58 mm, while Montanini et al. obtained a value of 0.32 mm. In a second paper Montanini et al.,¹⁰ by using a vertical load of 980 N on a S2TM femoral A/R system nail, have obtained stresses of approximately 220 MPa and a displacement of about 0,85 mm, see Table 3. Seral et al.,¹² following Verdonschot et al.¹³ applied a loading condition corresponding to the stance phase of the gait cycle to a fractured femur implanted with the standard Gamma[®] nail (Howmedica) and the proximal femoral nail (PFN[®], Stratec). Results confirmed displacements of the order of 0,49 mm on the gamma nail and 0.17 on the PFN nail. Stresses evaluated on the femur showed values of about 70 MPa, while both nails were stressed with about 500 MPa, localized on the lag screws. The comparison of previous results has the simple purpose of assessing whether the mechanical behavior of the innovative nail can be considered comparable with the ones offered by conventional systems of synthesis, as it appears evident how geometries, loading and fixing conditions are different. The analysis of the fractured femur has revealed a remarkable decreasing of stress, respect to the intact bone, with stresses value of 203 MPa for LC1 configuration, and 210 MPa for LC2. The predominant type of stress is a press-bending concentrated on the antero-lateral cortex of the tibia. The results show a good stability of the nail inside the bone, the load sharing between implant and bone by the hardening pins produces mutual displacements comparable with those obtained by traditional methods of fixing by proximal and distal

Table 2
Displacements, stresses and strains for LC1 and LC2.

	Displacement [mm]	Eq. V. Mises Stress [MPa]	Eq. Elastic Strain [$\mu\text{mm/mm}$]
LC1 [loading case with a 980 N vertical load]			
Femur	0,58	203	3,26E-03
Spindle	0,44	226	2,00E-03
Hardening pins	0,39	280	2,16E-03
Sleeve	0,45	230	1,94E-03
LC2 [Loading case with muscular and ligaments forces]			
Femur	15,40	210	2,11E-03
Spindle	14,86	461	1,97E-03
Hardening pins	14,14	513	2,17E-03
Sleeve	15,00	458	1,86E-03

Fig. 2. XXX.

screws. The prevalence of compressive strains at the postero-medial cortex and the stress shielding on the antero-lateral cortices of the tibia suggested a combined loading consisting of axial compression superimposed onto bending in the mid-sagittal plane. The LC2 configuration highlights, more sharply than LC1, also a torque component of stress due to the muscle forces acting in different directions. In this case, the stress distribution on the nail is characterized by three principal

components: bending, axial compression, and torsion. The fractured region obliges nail to face the higher portion of load principally due to a bending component. The presence of the sleeve helps to increase the total strength the nail. The axial compression does not produce dangerous effect on the nail because it remains under yield point. On the contrary, the torque acting on the bony fragment generated by the muscle forces component might produce relative motions between nail

Fig. 3. XXX.

Table 3

Comparison of results obtained by different authors.

	Displacement [mm]	Stress on femur [MPa]	Stress on nail [MPa]
Montanini et al. ¹¹			
LC1 – 980 N	0,34	262	237
LC2 – Muscle force	20,00	249	331
Montanini et al. ¹⁰			
LC1 – 980 N	1,80	51	236
LC2 – Muscle force	26,00	31	697
Seral et al. ¹² (Gamma nail)			
LC1 – Muscle force	0,49	72	520
Seral et al. ¹² (PFN nail)			
LC1 – Muscle force	0,17	70	500
current			
LC1 – 980 N	0,58	203	280
LC2 – Muscle force	15,40	210	513

and bone. Results confirm a relative displacement between nail and femur of about 0,4 mm. The analysis of the intact femur, under simplified loading conditions, allows investigation of the surface stress and strain distribution, even if a simplified loading overemphasized significantly bending stresses on the distal portion of the femur.^{14,15,16}

5. Conclusion

The main purpose of this paper was to provide prosthesis suitable for elderly patients, having problems to effort the surgical intervention and to face risks related to the removal of nail. The particular design allows obtaining numerous advantages in terms of pre and post-operative complications as the nail does not involve the use of transverse screws and therefore the surgical intervention is much simpler, less invasive, and more rapid. The innovative nail consists of three main components: the central pin, sleeve, and hardening pins. It works by the mean of conical surfaces obtained on the central pin and on the hardening pins, which produce a radial expansion of the hardening pins on the endomedullary canal, by screwing the central pin on the sleeve. It is important to note that an accidental shock produced on the hardening pins does not produce any rotation on the central pin. This is crucial aspect as it makes the mechanism loose by the bony reaction force exerted on the hardening pins. The radial displacement of the hardening pins can be reversible exclusively by unscrewing of the pin, making the expansion force directly proportional to the screwing torque. The results obtained confirm a good overall resistance of the

prosthesis in terms of mechanical performance and a good level of stability of the prosthesis within the canal. In conclusion, this type of nail appear to offer a good solution for elderly patients who could not bear compliance due to a complex surgery, such as the medial or distal screws are not necessary for this new nail, and perhaps do not have the need to remove the prostheses.

Conflict of interest

There is no conflict of interest.

References

1. Al-Yassari G, Langstaff RJ, Jones JWM. The AO/ASIF proximal femoral nail (PFN) for the treatment of unstable trochanteric femoral fracture. *Injury*. 2002;33(5):395–399.
2. Giannoudis PV, Papakostidis C, Roberts C. A review of the management of open fractures of the tibia and femur. *Bone Joint J*. 2006;88-B(3):281–289. <http://dx.doi.org/10.1302/0301-620X.88B3.16465>.
3. Taylor ME, Tanner KE, Freeman MAR, Yettram AL. Stress and strain distribution within the intact femur: compression or bending? *Med Eng Phys*. 1996;18(2):122–131.
4. Penzkofer J, Mendel T, Bauer C, Brehme K. Treatment results of pertrochanteric and subtrochanteric femoral fractures: a retrospective comparison of PFN and PFNA. *Der Unfallchirurg*. 2009;112(8):699–705.
5. Filardi V. Characterization of an innovative intramedullary nail for diaphyseal fractures of long bones. *Med Eng Phys*. 2017;1–9. <http://dx.doi.org/10.1016/j.medengphys.2017.08.002>.
6. Filardi V. Stress shielding in the bony chain of leg in presence of varus or valgus knee. *J Orthop*. 2014;2(2):102–110.
7. Filardi V. FE analysis of stress and displacements occurring in the bony chain of leg. *J Ortho*. 2014;157–165.
8. Bergmann G, Craichen F, Rohlmann A. Hip joint loading during walking and running measured in two patients. *J Biomech*. 1993;26:969–990.
9. Behrens BA, Nolte I, Wefstaedt P, Stukenborg-Colsman C, Bouguecha A. Numerical investigations on the strain-adaptive bone remodelling in the periprosthetic femur: influence of the boundary conditions. *Biomed Eng*. 2009. ;8<http://dx.doi.org/10.1186/1475-925x-8-7> Special section p1-9. 9p.
10. Montanini R, Filardi V. In vitro biomechanical evaluation of antegrade femoral nailing at early and late postoperative stages. *Med Eng Phys*. 2010;32(8):889–897.
11. Filardi V, Montanini R. Measurement of local strains induced into the femur by trochanteric Gamma nail implants with one or two distal screws. *Med Eng Phys*. 2007;29(1):38–47.
12. Seral B, García JM, Cegonino J, Doblaré M. Finite element study of intramedullary osteosynthesis in the treatment of trochanteric fractures of the hip: gamma and PFN. *Injury*. 2004;35(2):130–135.
13. Verdonschot N, Huiskes R. Acrylic cement creeps but does not allow much subsidence of femoral stems. *J Bone Joint Surg*. 1997;79:665–669.
14. Filardi V, Milardi D. Experimental strain analysis on the entire bony leg compared with FE analysis. *J Orthop*. 2017;14(1):115–122.
15. Filardi V. The healing stages of an intramedullary implanted tibia: a stress strain comparative analysis of the calcification process. *J Orthop*. 2015;12:51–61.
16. Anastasi G, Bramanti P, Di Bella P, Favaloro A, Trimarchi F, Magaouda L, et al. Volume rendering based on magnetic resonance imaging: advances in understanding the three dimensional anatomy of the human knee. *J Anat*. 2007:399–406.