Healing of tibial comminuted fractures by the meaning of an innovative intramedullary nail

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ABSTRACT

In this paper, an innovative design of prosthesis, conceived to heal the comminuted fractures of long bones has been investigated. The proposed prosthesis consists of two shell valves hinged to each other by a central pin and bearing slits along the surface in such a way as to guarantee the exchange of body fluids and at the same time ensure the structural stability of the bone. Two screws then hold the two valves together. The operative technique for the introduction of this type of prosthesis for the decomposed fracture of long bones consists in the incision of the fracture site, introduction of the open shell prosthesis with reduction of the fracture and composition of the bone fragments, closure by means of fixing screws of the prosthesis shell, stitching open wound flaps. A complete numerical FE model of an implanted femur was analyzed, by considering a vertical load of 980 N. Analyses confirmed results, in terms of mechanical performances, comparable with the others traditional systems of prosthesis.

1. Introduction

A comminuted fracture is a break or splinter of the bone into more than two fragments. Since considerable force and energy is required to fragment bone, fractures of this degree occur after high-impact trauma such as in vehicular accidents. External fixation devices such as splints and casts are usually inadequate in treating this type of fracture. Repairing a comminuted fracture often requires open surgery to restructure the bone to normal anatomy. As mentioned, a comminuted fracture is an injury resulting to several pieces of broken bones. Depending on its severity, it can either be an open or closed fracture. An open one can lead to a complication since the internal tissues are exposed to the environment. An Infection is a common complication associated to open fractures. The comminuted fractures will only happen if a bone has received an extreme pressure. To be specific, a minor bone will have this kind of damage if it receives a pressure of about 9–13 pounds. Bigger bones, like the femur, are much stronger. A pressure of about 160 pounds is necessary to cause this injury. A bone may break into numerous pieces due to various causes, which are the following:

- **Accidents:** Most fractures happen due to an accident. However, comminuted fractures will only occur if the accident involves extreme pressure. The common accidents that can inflict a great amount of force are a car crash, falling from a high place, and a gunshot.

- **Age and Bone Disease:** Even though an extreme force is necessary to break a bone, it may still happen even with low pressure. One reason for this is brittle or weak bones. The common causes of the weakening of the bones are various medical conditions such as bone cancer, osteoporosis, osteosarcoma, and osteogenesis imperfecta. Another contributing factor of brittle bones is age. As a person grows older, bone deterioration may occur. For women, their bones will start to lose its minerals like calcium after menopause. This is also true for chronic smokers. A common remedy for this is to increase calcium intake.
- **Sports and Other Outdoor Activities:** Fractures will typically occur if a person does numerous sports and other outdoor activities. A common activity that may result in a comminuted fracture is cycling.

Compared to regular fractures, comminuted fractures will take longer to heal. Recovery will typically last for several months. The efficacy of statically locked intramedullary nails inserted after reaming for the treatment of fractures of the femoral shaft has been well established.¹ In comminuted fractures, the locking screws bear the transmitted load until the fracture has consolidated. Several authors have reported hardware failure, either through the distal screw-holes in the nail or of the distal locking screws, when fracture union was delayed or when full weight-bearing was initiated before callus formation.^{2,3}

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The standard protocol for postoperative rehabilitation at our institution calls for protected weight-bearing until evidence of early healing is noted on radiographs. These restrictions on weight-bearing are particularly confining to patients who have bilateral injuries and to those who have a fracture of the contralateral extremity or of an upper extremity that would preclude weight-bearing or walking with the use of crutches. Such restrictions would necessitate bed-to-chair transfers for a minimum of four to six weeks while the patient waited for early consolidation of the fracture, making self-care difficult and delaying rehabilitation and discharge from the hospital. Currently, the level of loading that leads to failure of the hardware in a fractured femur is unknown. Improvements in the design of the nails, including the elimination of welds and an increase in the amount of material in cross section, may have greatly improved the fatigue characteristics of these locking devices, distinguishing them from their predecessors. Failure of locking screws or nails used to stabilize fractures of the femoral shaft has been rare in our experience. Our clinical suspicion was that intramedullary nail systems of modern design could safely withstand immediate physiological loading without failure if the fracture united in a timely manner. Therefore, this two-part study was designed to determine the fatigue strength of eleven different configurations of locking nails and to use the data to form the basis of a prospective clinical study of immediate weight-bearing after treatment of fractures of the femoral shaft with a statically locked intramedullary nail. By thinking of the body in the anatomic position, fractures can be described by their location in the bone and how the parts are aligned and related to each other. Fractures are either displaced or non-displaced, meaning that they are adequately aligned or not. Some physicians suggest that all fractures have some displacement and prefer the term "minimally displaced". The description of the fracture, see Fig. 1, also includes the direction it takes within the bones:

- *Transverse: the fracture travels across the bone*
- *Oblique: the fracture occurs at an angle*
- *Spiral: –the fracture spirals or extends down the length of the bone*
- *Comminuted: the fracture has more than two parts and multiple fragments are present.*
- *Greenstick: In young children, the bones are not yet solid and when force is applied, it tends to bow and not break completely through. The term comes from a similar situation when trying to break a young branch off a tree.*
- *Open fracture: An open fracture describes the situation where the bone penetrates through the skin.*

The skin is very important in protecting the inside of the body from infection. If the skin overlying a broken bone is damaged, whether it is cut, torn or scraped, there is potential for bacteria from the outside world to invade the broken bone and cause an infection. Fractures are

classified as open (if the skin is damaged) or closed (if the skin is intact). An open fracture may require an orthopedic surgeon to wash out the fracture site to prevent **osteomyelitis** (bone infection). Depending upon circumstances, the type of fracture, the amount of contamination to the skin and **wound**, and the person's condition, this procedure may take place in the operating room.

Within the fixation system, high stresses and fatigue can lead to its technical failure. Compression, bending, and torsional tests have been performed to compare the stiffness and fatigue behavior of various interlocking nails,⁸ or implanted nails.⁹ Beside variations in mechanical conditions, a number of additional factors might have contributed significantly to the reported clinical outcome. The injury mechanisms are quite different in proximal (impact) versus distal fractures (torsion) of the tibia. This may result in differences in the clinical outcome.^{4,5} Additional injuries may considerably alter the long-term outcome for tibial fractures.⁶ In comminuted fractures, the locking screws bear the transmitted load until the fracture has consolidated. Several authors either have reported hardware failure, through the distal screw-holes in the nail or of the distal locking screws, when fracture union was delayed or when full weight bearing was initiated before callus formation. In this paper, a new type of prosthesis is suggested in order to treat the comminuted fractures able to align and maintain the position of the bony fragments and at the same time to ensure a certain mechanical resistance.

2. Materials and methods

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. The proposed prosthesis, see Fig. 2, consists of two shell valves hinged to each other by a central pin and bearing slits along the surface in such a way as to guarantee the exchange of body fluids and at the same time ensure the structural stability of the bone. Two screws then hold the two valves together. The operative technique for the introduction of this type of prosthesis for the decomposed fracture of long bones consists in the incision of the fracture site, introduction of the open shell prosthesis with reduction of the fracture and composition of the bone fragments, closure by means of fixing screws of the prosthesis shell, stitching open wound flaps. A numerical model of the tibia (28.854 elements and 8.754 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

Fig. 1. Different typology of bony fractures.

Fig. 2. a) Technical drawing of the shell prosthesis, b) loading condition of the implanted tibia with a comminuted fracture.

Fig. 3. Contour maps of displacements.

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.^{7–9} A comminuted mid-diaphysar fracture was simulated on the tibia deleting and modifying local tetrahedral elements and inserting the innovative prosthesis (3106 elements and 1325 nodes). The AISI 316L steel was selected, by imposing linear elastic, isotropic and

homogeneous properties, and with a Young's modulus of 210,000 MPa. Contact interfaces were imposed defining a penalty based method with a weight factor and a coefficient of friction of 0.4. The loading condition was simulated by angling the femur at 12° in the frontal plane and 5° in the sagittal plane¹⁰ imposing a vertical loads of 980 N and fixing the condylar area of the tibia (200 nodes). Non-linear finite element

Table 1

Displacements, Von Mises stresses, and elastic strain values at different tibial distances.

Tibial distance [mm]	Displacement [mm]	Eq. Von Mises stress on tibia [MPa]	Eq. Von Mises stress on the prosthesis [MPa]	Eq. Elastic strain [μmm/mm]
0	0	10		0.00E-022
5	0,37	35		2.10E-004
10	0,74	40	98	4.21E-004
15	1,11	98	77	6.31E-004
20	1,48	8	70	8.42E-004
25	1,85	7	75	1.01E-003
30	2,22	98	80	1.30E-003
35	2,59	50		1.68E-003
40	2,96	20		2.10E-003

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

A geometrical accurate 3D FE model of the human tibia was realized and successively implanted with an innovative shell prosthesis. A vertical (Z axis) load of 980 N was imposed at the top of the tibia while 200 nodes were fixed on its base. Results concerning analysis carried on the fractured tibia implanted with the innovative prosthesis shows maximum displacements of 2.96 mm, as depicted in Fig. 3, while the Equivalent Von Mises stress reaches values of 98 MPa, principally concentrated on the interface between the bony fragments and the shell prosthesis, see Table 1 and Fig. 4. The prevalence of compressive strains

at the postero-medial cortex and the stress shielding on the antero-lateral cortices of the tibia suggests a combined loading consisting of axial compression superimposed onto bending in the mid-sagittal plane. The maximum equivalent elastic strain value calculated was about 2.10×10^{-3} μmm/mm, see Fig. 5. The healthy tibia shows a typical mechanical behavior of the beam loaded on its top, the maximum values of stress are reached in the mid-diaphyseal area reaching the maximum deflection. Different behavior can be noticed on the implanted tibia where the presence of a comminuted fracture influences the trend of the stress vs. distance curve, causing a reset of the stress values in the fractured area, as depicted in Fig. 6, which is compensated by the presence of the shell prosthesis, as reported in Table 1. Only with sufficient bone contact, (i.e., friction between fragments and axial loading), the shear movement is reduced or avoided. A possible explanation for the negative effect of a large axial to shear ratio might be that fractures are hardly stabilized if they show a large amount of shear compared to compression. In conclusion, the presence of the prosthesis can ensure the continuity of the stress resistance along the structure and the bone is able to perform its physiological function ensuring coronal and sagittal alignment.

4. Discussion

A number of implant and surgical advances have been developed over the past two decades to improve implant durability and aid fracture reduction. Achieving and maintaining a good reduction is the most difficult aspect of nailing distal comminuted tibial fractures. In a clinical setting, the aim is to reduce large defects; this would lead to an unloading of the prosthesis and to compression of the fracture fragments. In all proximal and diaphyseal defect locations, considerable axial and shear interfragmentary strains were evident. Measurements

Fig. 4. Contour maps of Eq. Von Mises.

Fig. 5. Contour maps of Eq. elastic strain.

Fig. 6. Curves of Eq. Von Mises stress vs. tibial distance evaluated on the tibia and on the prosthesis.

on fracture gap movements in humans show strain values as large as 50% and more in external fixation. Compared with external fixation, a rigid medullary stability achieved through prosthesis avoids excessively large interfragmentary strains. Fractures are usually reduced or dynamized, this reduces the axial movement component dramatically but it does not necessarily reduce shear movements.

Filardi and Montanini,¹⁰ obtained values of 237 MPa on a Gamma

Table 2 Comparison in terms of stress and displacement among different authors.			
	Stress on bone [MPa]	Stress on nail [MPa]	Displacements [mm]
Montanini et al. 2010 ¹⁰ LC 980 [N]	51	236	1.80
Filardi 2015 ¹¹ LC 350 [N]	43	160	1.72
Gomez Benito 2007 ¹² LC 980 [N]	/	275	
Filardi 2018 ¹⁵ Expert nail LC 980 [N]	250	460	3.12
Filardi 2018 ¹⁵ Innovative nail LC 980 [N]	220	400	2.68
current	100	100	2.96

nail (Stryker Howmedica Osteonics Corp., Kiel, Germany) for the synthesis of intramedullary femoral fractures with a vertical load of 980 N. The higher values must be considered as the effect of the holding pins anchoring to the bone and the load acting at the top of the tibia, see Table 2. In literature Filardi¹¹ obtained a value of 160 MPa, on the nail body of an Expert Tibial Nail (DePuy Synthes[®]) loading the entire lower bony chain with a vertical force of 700 N. Superior screws were subjected to receive a stress of 36 MPa and a significant concentration of stress was detected on the bony area around the holes, while the three inferior screws resulted unloaded. A finite element analysis by

Gomez-Benito et al.¹² compared the biomechanical performance of reamed and unreamed tibial nails. They concluded that reamed nails were superior to unreamed nails in mid-diaphyseal and distal tibial fractures as lower stresses were transmitted to the locking screws, reducing the risk of screw failure. In distal tibial fractures, treated by the GrossKempf nail, the role of distal locking is not just to control length and rotation, but also stability in the coronal and sagittal planes. A clear stress concentration was always visible in the neighborhood of the insertion of the screws. In literature, different kind of prosthesis have been investigated and compared^{13,14} investigating the complete bony chain or single parts.^{8,15,16}

In another paper, Filardi¹⁷ compared two implanted tibias, by imposing a vertical load of 980 N.

Results concerning analysis carried on the fractured tibia implanted with the expert tibial nail show displacements of 4.26 mm localized on the bone, while a value of 3.12 mm was found on the nail and 0.75 and 0.58 mm were found around superior and inferior screws. The stress, evaluated by Equivalent Von Mises method, reached an average value of 90 MPa on the tibia, with peaks of 250 MPa on the contact points between nail and bone. The stress measured on the nail was higher, about 150 MPa of average stress, while the peak value was 460 MPa, mostly localized on the inferior holes. The maximum equivalent elastic strain value calculated was about $3.70E-03$ $\mu\text{m}/\text{mm}$. Stress on the screws was calculated in 136 MPa on the superior ones and 187 on the inferior ones. Analysis carried on the fractured tibia implanted with the innovative nail shows displacements of 2.87 mm localized on the bone, 2.68 mm on the nail. The stress, evaluated by Equivalent Von Mises method, reached an average value of 85 MPa on the tibia, with peaks of 220 MPa on the contact points between nail and bone. The average stress measured on the nail was about 180 MPa, with a peak value of 400 MPa, mostly localized on the holding pins. The maximum equivalent elastic strain value calculated was about $3.45E-03$ $\mu\text{m}/\text{mm}$, see Table 2. The obtained results must be interpreted by considering we have used a complete FE model taking into account the complete bony chain of the leg, much less rigid of a single constrained and implanted tibia. Unreamed nailing of the distal defect results in an extremely low axial and high shear strain between the fragments. Restrictions of this kind of approach are related principally to the simulation carried out. The model realized consisted of the nail and the bone without considering the entire human skeletal system and soft tissues. This kind of simplified simulation is easy to be reproduced by experimental test in laboratory. Material properties were assumed to be linear elastic, isotropic and homogeneous, but these assumptions don't replace exactly the real tissues constitution. Loading conditions were schematized as a loading system and a fixed constrain to the lower part of the tibia. The loading system can't really taking into account the interactions of the bone inside the leg with the other components (muscles, ligaments etc ...). The rigid constrain, obviously does not represent the real fixing configuration of the bone inside the bony chain.

5. Conclusion

The extended usage of unreamed tibial nailing resulted in reports of an increased rate of complications, especially for the distal portion of the tibia. Intramedullary nailing of a tibial fracture at any level has been associated with complications such as an increased risk of compartment syndrome, nail breaking and most commonly, chronic knee pain, which often persists beyond removal of the nail. The prosthesis here proposed consists of two shell valves hinged to each other by a central pin and bearing slits along the surface in such a way as to guarantee the exchange of body fluids and at the same time ensure the

structural stability of the bone. Two screws then hold the two valves together. The operative technique for the introduction of this type of prosthesis for the decomposed fracture of long bones consists in the incision of the fracture site, introduction of the open shell prosthesis with reduction of the fracture and composition of the bone fragments, closure by means of fixing screws of the prosthesis shell, stitching open wound flaps. 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. The comparison between the two typology of nail evidences a good overall resistance in terms of mechanical performance and a good level of stability within the canal. Performance of both nails are comparable in terms of maximum stress, displacements and equivalent elastic strain, but the innovative one offers the advantages deriving by its lack of any kind of distal or medial screw. This study represents only an initial step to investigate the mechanical behavior of the nail. It must be evidenced that this re-search presents same limitations. Only a single FE model was realized, material properties were imposed neglecting bony density topology and considering a simple mechanical elastic behavior.

References

1. Brumback R, Toal T, Murphy-Zane MD, Siobhan M, Novak V, et al. Immediate weight-bearing after treatment of a comminuted fracture of the femoral shaft with a statically locked intramedullary nail. *J Bone Joint Surg.* 1999;81(11):1538–1544.
2. Brumback RJ, Ellison PS, Poka A, Lakatos R, Bathon GH, Burgess AR. Intramedullary nailing of open fractures of the femoral shaft. *J Bone Joint Surg.* 1989;71(A):1324–1331.
3. Bucholz RW, Ross SE, Lawrence KL. Fatigue fracture of the interlocking nail in the treatment of fractures of the distal part of the femoral shaft. *J Bone Joint Surg.* 1987;69(A):1391–1399.
4. Grover J, Wiss DA. A prospective study of fractures of the femoral shaft treated with a static, intramedullary, interlocking nail comparing one versus two distal screws. *Orthop Clin N Am.* 1995;26:139–146.
5. Hajek PD, Bicknell HR, Bronson WE, Albright JA, Saha S. The use of one compared with two distal screws in the treatment of femoral shaft fractures with interlocking intramedullary nailing. A clinical and biomechanical analysis. *J Bone Joint Surg.* 1993;75(A):519–525.
6. Johnson KD, Tencer AF, Blumenthal S, August A, Johnston DW. Biomechanical performance of locked intramedullary nail systems in comminuted femoral shaft fractures. *Clin Orthop.* 1986;206:151–161.
7. Filardi V. Stress shielding in the bony chain of leg in presence of varus or valgus knee. *J Orthop.* 2014;2(2):102–110.
8. Filardi V. FE analysis of stress and displacements occurring in the bony chain of leg. *J Orthop.* 2014;157–165.
9. Filardi V, Milardi D. Experimental strain analysis on the entire bony leg compared with FE analysis. *J Orthop.* 2017;14(1):115–122.
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. The healing stages of an intramedullary implanted tibia: a stress strain comparative analysis of the calcification process. *J Orthop.* 2015;12:51–61.
12. Gomez-Benito MJ, Fornells P, Garcia-Aznar JM, et al. Computational comparison of reamed versus unreamed intramedullary tibial nails. *J Orthop Res.* 2007;25(2):191–200.
13. Filardi V. Healing of femoral fractures by the meaning of an innovative intramedullary nail. *J Orthop.* 2018;15(1):73–77.
14. Filardi V. Numerical comparison of two different tibial nails: expert tibial nail and innovative nail. *Int J Interact Des Manuf.* 2018:1–11.
15. Filardi V. Finite element analysis of the foot: stress and displacement shielding. *J Orthop.* 2018;15(4):974–979.
16. Filardi V. Flatfoot and normal foot a comparative analysis of the stress shielding. *J Orthop.* 2018;15(3):820–825.
17. Filardi V. Characterization of an innovative intramedullary nail for diaphyseal fractures of long bones. *Med Eng Phys.* 2017:1–9<https://doi.org/10.1016/j.medengphys.2017.08.002>.