# BIOMECHANICAL INVESTIGATION OF A NEW HYBRID COMPOSITE MATERIAL FOR USE IN INTRAMEDULLARY NAILING IN FEMORAL SHAFT FRACTURES

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## Abstract

*Intramedullary (IM) nails are the primary choice for treating long bone fractures. Yet, there are still complications following IM nail surgery including non-union, delayed union, and fracture of the bone or the implant. Reducing the stiffness of the nail while maintaining sufficient stability seems to be the ideal solution to overcome the abovementioned complications. The aim of this study was twofold: first to develop a new hybrid concept for IM nails made of Carbon fibres (CF)/flax/epoxy in order to reduce stress shielding, and second, to assess the mechanical performance of this new implant in terms of fracture stability and load sharing using a comprehensive non-linear finite element (FE) model. The proposed model considers several mechanical factors in nine fracture configurations at immediately post-operative (PO) stage of healing. The results showed that the hybrid composite IM nail can provide preferred mechanical environment for healing by increasing the average normal force at the fracture site by approximately 320N ($p<0.05$), and the mean stress in the vicinity of fracture by 2.11MPa ($p<0.05$) at 45% gait cycle, while 0.39mm ($p<0.05$) increase in the fragments' shear movement were observed. This study demonstrated the effectiveness of the proposed composite material particularly in transverse shaft fractures. The findings could help bioengineers to better understand the biomechanics of fracture healing, and aid in the design of effective implants.*

## 1. Introduction

Intramedullary (IM) nails are used as internal fracture fixation tools to treat diaphyseal fractures in long bones. They are implanted within the IM canal and fixed by interlocked screws to stabilise the bone fragments during the healing process. Despite all the advancements in IM nail design used for treating femoral diaphyseal fractures, complications remain such as failure of the nail or screws, delayed union, non-union, and bone refracture [1]. In virtually all femoral shaft fractures, the definitive treatment protocol is to implant an anterograde, reamed, locked IM nail [2]. Such placement of nails can facilitate transfer of the load and stress through both the fractured femur and/or the nail itself. Titanium (Ti) alloys commonly used in manufacturing IM nails, provide appropriate stability at fracture site.

However, their high rigidity causes the nail to bear the majority of the load once implanted, shielding the bone from the stress it would naturally experience [3]. The reduction of the mechanical stress on the femur results in bone resorption at the vicinity of the implant over time which is referred to as stress shielding [4]. This condition makes the bone prone to refracture.

It was shown in *in-vivo* studies that reducing the stiffness of the implants accelerates the healing process and enhances the quality of the callus [5, 6]. However, implants that are too flexible have shown poor fixation and subsequent complications, such as malunion or non-union [7-9]. Conflicting results in studies that have investigated the effect of fixation rigidity on fracture healing leave the question of optimum fixation rigidity unsolved [2, 8]. Ideally, the fixation implant should counter bending, torsion, and shear stress adequately, while countering compressive stress fractionally [10].

The current IM nails made of Ti absorb between 70-74% of total axial force during the stance phase and 91% during the swing phase of gait [3], shielding the fracture from compressive loads and resulting in bone resorption in post healing stages. In an isotropic material which is the choice in IM nails, axial, bending, and torsional stiffnesses could not be altered without directly affecting one another. Fibre reinforced composites have been recently used in biomedical implants because of their high strength, low rigidity, and corrosion and fatigue resistance [11]. Most importantly, they have the possibility to be tailored and adapted based on specific requirements through changing the arrangement or volume fraction of the fibres [12]. The use of a hybrid composite material provides even greater customizability, particularly in altering the stiffness in different directions to facilitate an optimal mechanical environment for fracture healing [13].

Any effort to improve fracture healing and to reduce stress shielding in current IM nailing techniques requires a good understanding of the biomechanics of fracture fixation and fracture healing in long bones.

The purpose of this study, therefore, was to develop a hybrid composite (carbon fibre(CF)/flax/epoxy) material for IM nails and to assess its mechanical performance by using a comprehensive finite element model capable of capturing dominant mechanical factors involved in fracture healing. It was hypothesized that this would result in a more desirable condition for healing, as it would provide sufficient stability and reproduce the strain distribution of an intact femur in the healed bone through increasing of the load transferred to the bone. This would subsequently encourage bone regrowth and prevent bone degradation.

## 2. Finite element analysis

### *2.1. Computer-aided design (CAD) model*

A three dimensional (3D) model of a large left fourth-generation composite femur (model 3406, sawbones, Vashon, WA) was employed, which was developed and validated in previous studies [14]. The geometry of a 420mm Stryker T2 femoral nail (Stryker, Mahwah, NJ) was obtained by reverse engineering. The nail was modeled as a shell to ensure it would be capable of being used as a composite laminate later in simulations. Assemblage of the nail and bone was completed in SolidWorks (Dassualt Systèmes, Concord, MA) based on the manufacturer-provided instructions.

### *2.2. Gait loads and boundary conditions*

The present study employed a comprehensive load case that was presented by [15]. It included contributions from five major muscles and the hip joint force at 45% gait cycle. The muscle attachment points obtained by [15] and scaled for use on the 3rd generation composite femur by [3] were employed, as there is no geometrical difference between the 3rd generation and 4th generation composite femurs.

### *2.3. Meshing and material properties*

The assembled CAD model was imported into ANSYS Workbench (ANSYS Inc., Canonsburg, PA) to generate a FE model. Synthetic bone was assumed to be isotropic with linear elastic properties (Table1) as reported by the manufacturer and employed in previous studies [16-18]. Tetrahedral 10-noded elements, with three degrees of freedom at each node, were utilized to mesh solid bodies [19, 20]. The IM nail was meshed with 4-noded elements having six degrees of freedom at each node. This type of element has the capability of modeling thin to moderately-thick shell structures as well as composite shells or sandwich structures. The metallic IM nail was made of a Ti-6AL-4V and was assigned a 3.2*mm* thickness. This model involved a sandwich structure made of a 12-layer flax/epoxy core spanned by 2 CF/epoxy thin layers at the inner and outer surfaces (16 layers in total), with a unidirectional fibre orientation parallel to the nail axis. Each laminae was assumed to have a thickness of 0.2*mm*. This configuration has been recently shown to be a promising candidate for use in fracture fixation implants in long bones by providing efficient load sharing, and proper stability [13, 21]. The convergence of mesh refinement was checked with the "relevance" option in ANSYS Workbench with a value of -100 indicating a very coarse mesh and 100 corresponding to an extremely fine mesh. A set of simulations showed that a value of 75 will result in convergence, and thus further increasing the relevance will not change the strain values by more than 1%.

| **Composite** | | | | | | **Ti-6AL-4V** | | **Bone** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Flax/epoxy*** | | | **Carbon/epoxy*** | | | | | **Cortical** | | **Trabecular** | |
| **E (GPa)** | **G (GPa)** | **ν** | **E (GPa)** | **G (GPa)** | **ν** | **E (GPa)** | **ν** | **E (GPa)** | **ν** | **E (GPa)** | **ν** |
| $E_x$=35 | $G_{xy}$=5 | $\nu_{xy}$=0.3 | $E_x$=121 | $G_{xy}$=4.7 | $\nu_{xy}$=0.27 | 113.8 | 0.342 | 16.7 | 0.26 | 0.155 | 0.3 |
| $E_y$=2 | $G_{xz}$=5 | $\nu_{xz}$=0.3 | $E_y$=8.6 | $G_{xy}$=4.7 | $\nu_{xz}$=0.27 | - | - | - | - | - | - |
| $E_z$=2 | - | $\nu_{yz}$=0.4 | $E_z$=8.6 | - | $\nu_{yz}$=0.4 | - | - | - | - | - | - |

Table 1. Linear elastic isotropic (Ti-6AL-4V, cortical, and trabecular bone) and transversely isotropic Flax/epoxy and Carbon/epoxy) material properties used in the current study.* The layers were made of unidirectional (UD) prepreg flax and carbon sheets, with X-axis considered as reference axis for fiber orientation.

### *2.4. Configurations used and contact modeling*

Three fracture locations (i.e. proximal, midshaft, and distal) with three fracture angles in each (9 configurations in total) were investigated. For the angled fractures, proximal medial to distal lateral (PMDL) and proximal lateral to distal medial (PLDM) fractures were considered.

The screw threads were not modeled and the contact between the bone and the screws was assumed to be bonded [3]. The bone and the nail were assumed to have nonlinear frictionless contact in which an initial gap would be allowed and the surfaces might come into contact during the simulation. The same type of contact was assumed for the fracture surfaces to account for sliding, separation, and force transmission between fracture fragments.

### *2.5. Output parameters*

The output parameters include compressive normal force, and shear movement at fracture site and bone mean stress around the fracture.

### *2.6. Statistical analysis*

Consideration of all possible combinations of the fracture angles and locations led to a total of 9 data sets, which cover almost all transverse femoral shaft fractures. Using SPSS (SPSS Inc., Chicago, IL) the significance of the changes in the parameters (with the use of new material) was analyzed using a paired-samples T-test, with a P value less than 0.05 deemed as significant.

## 3. Results

### *3.1. FE results*

Figure 1 shows stress distribution in a typical fracture configuration that was fixed with Ti and composite IM nails. Compressive normal forces and the mean value of the von-Mises stress in the bone at the vicinity of the fracture increased ($p<0.005$) by 319.23N and 2.11MPa respectively when the composite IM nail is used instead of the Ti IM nail (Figure 2a-b). The shear movement between fracture surfaces, as illustrated in Figure 2c, was found to increase ($p<0.005$) by an average of 0.39mm.

### *3.2. Verification of FE results with the previous studies*

For the finite element results to be reliable, it is essential that they are verified against experimental data for at least one load case. The results were compared to similar studies in the literature [20, 22]. Strain values at five different locations were obtained for Ti nail and compared to the measurements performed by [22]. To mimic their experimental test setup, an axial load of 580N was applied on the femoral head and the bone was assigned the material properties of a 3rd generation composite femur. A good correlation (R2=0.926) was found between the strain values obtained from the current FE model and those that were experimentally measured (Table 2). The obtained stiffness (1378.8N/mm) also compared favourably with that reported by the prior investigation for retrograde IM nail implantation in synthetic femurs (1168.8N/mm) [22], and with that reported for intact synthetic femurs (1290±30N/mm) [20].

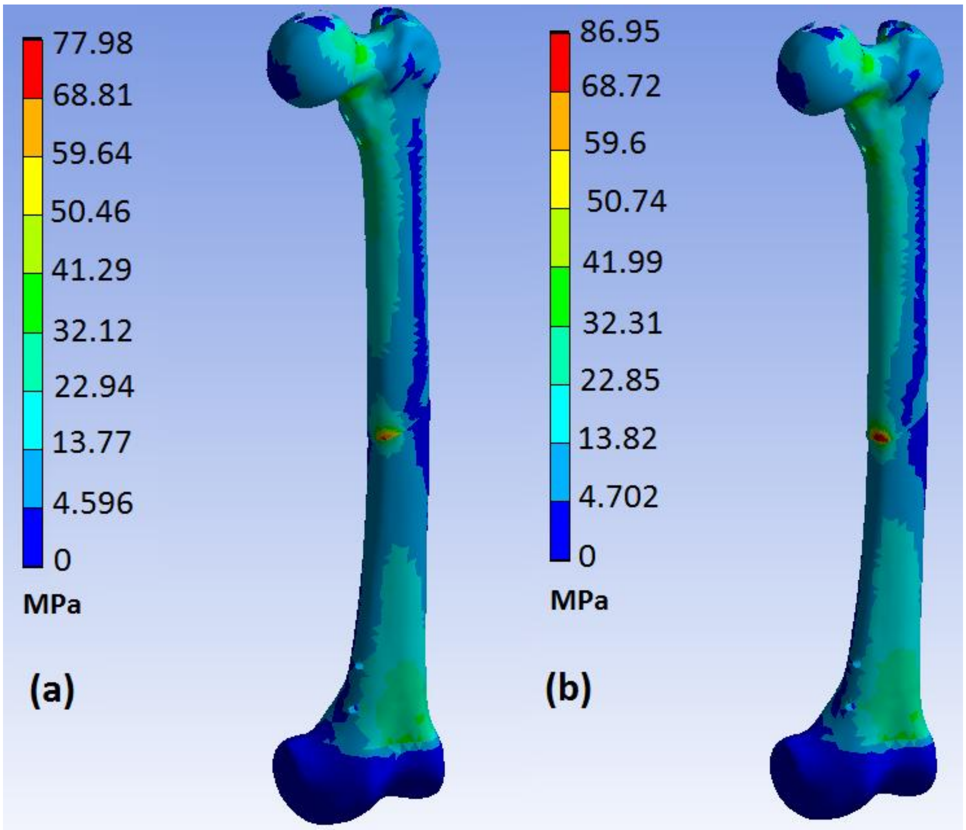


**Figure 1.** A typical graph of the von-Mises stress in the bone after the implantation of a) Ti and b) CF/flax/epoxy IM nail. Note the higher stress levels in the bone implanted with the composite IM nail.

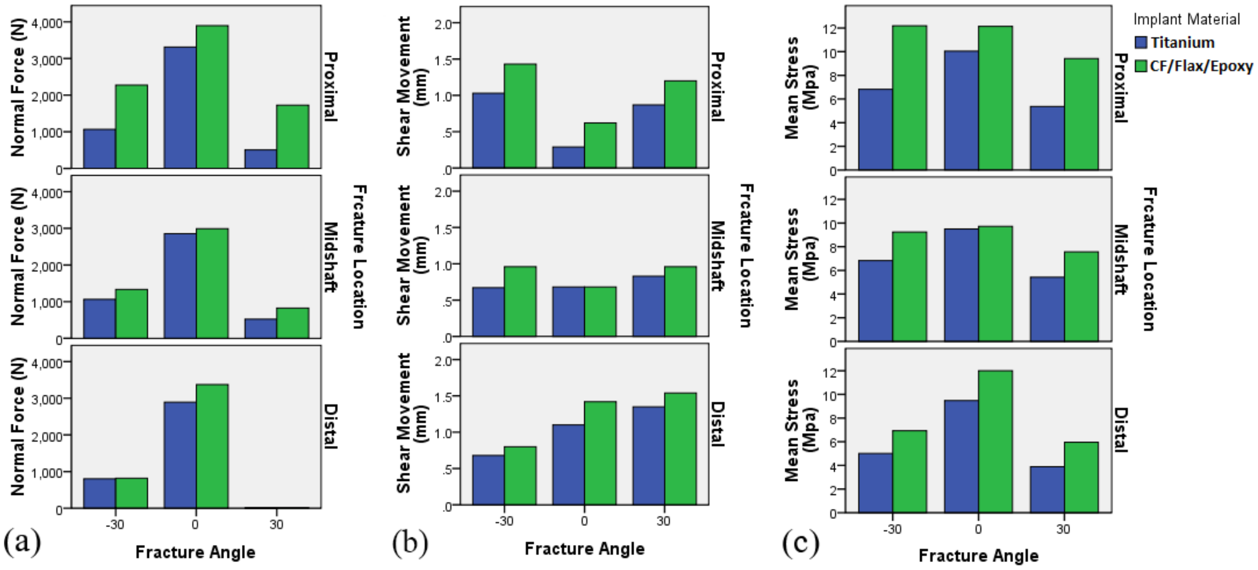


**Figure 2.** Normal force (a), shear movement (b), and mean von-Mises stress (c) at the fracture site for various fracture angles and locations throughout the femoral shaft. As for the fracture angle, 0 represents a transverse, -30° represents a PLDM, and 30° represents a PMDL angled fracture.

| | **Current study** | **Bougherara et al. [22]** |
|---|---|---|
| ***L1 Strain*** | 817 | 856 |
| ***L2 Stain*** | 708 | 904 |
| ***L3 Stain*** | 531 | 647 |
| ***L4 Stain*** | 441 | 470 |
| ***L5 Stain*** | 300 | 309 |
| **$R^2$** | 0.926 | |
| **Axial stiffness (N/mm)** | 1378.8 | 1168.8 |

**Table 2**. Results showing *axial stiffness* and *microstrain* values at different locations of the structure. L1-L5 refers to location 1-5 as reported by [22].

## 4. Discussion

Reducing the stiffness of the fixation could favourably increase the load levels at the fracture site, but it may also compromise the stability of the fracture by increasing the unfavourable (e.g. shear) interfragmentary movements which are detrimental to fracture healing [23]. Therefore, controversies remain regarding the optimal fixation rigidity [8]. One school of thought, referred to as selective stress shielding, suggest that the implant shields the detrimental stresses on the bone while allowing transfer of adequate amounts of beneficial stress (such as compressive stress) [10]. It is nearly impossible to reduce the axial stiffness of conventional Ti nails while still keeping them rigid enough in bending and torsion as the axial and bending stiffnesses are both dependent on the elastic moduli of the metal. Use of the proposed hybrid composite IM nail provides the possibility to reduce the axial stiffness with fewer reductions in the bending and torsional stiffnesses.

Among all the numerical studies that have investigated the biomechanics of IM nailing in femoral shaft fractures, very few have studied the presence of fracture [24] and still fewer considered different fracture locations and angles. This study employs a comprehensive FE model to compare the performance of a CF/flax/epoxy and a Ti IM nail used for treating femoral shaft fractures, with consideration of the important mechanical factors in fracture healing.

### *4.1. Clinical implications of the results*

As reported in in-vivo studies, loading the fracture in the axial direction appears to boost callus formation and provide higher mechanical stiffness while decreased loading slows fracture healing [7]. The increase found in compressive force at the fracture site (19.9%) as well as the stress levels in the vicinity of the fracture (28.7%) yield an increase in the portion of loads carried by the bone and suggest that healing is improved with use of the composite IM nail. This is in agreement with previous studies that found increased loading levels on the bone with the use of less stiff materials [3]. However, one must bear in mind that shear movement between the fragments should be considered at the same time, as it could degrade fracture healing, even in the presence of sufficient axial loading [23]. The current results showed a 36.2% (0.39mm) increase in the shear movements of the fragments with the use of a composite nail. However, this small shear movement could be tolerated and do not considerably delay healing [25] found abundant callus formation and proper healing with initial shear movements of 2-4mm in three tibial shaft fractures.

### *4.2. Limitations and conclusion*

There are some limitations that should be recognised in this study. Firstly, fracture healing is a complex process that is affected by diverse factors most of which are not mechanical, and the current computational models fail to precisely simulate *in-vivo* phenomena. As a result, the direct application of the current results in clinical cases may not be possible prior to *in-vivo* tests. However, the current model overcomes several shortcomings of previous ones by considering more realistic boundary conditions and the mechanical factors involved in fracture healing. This may allow simulation of the fracture healing process and development of more efficient fracture fixation devices. Secondly, linear isotropic material properties were assumed for the bone, while nonlinearity, anisotropy, and viscoelasticity might be more characteristic of the mechanical behaviour of real bones. However, previous FE comparisons of synthetic femurs with human cadaveric femurs suggest that linear material behaviour is a reasonable approximation for real femurs [3, 20].

Despite the mentioned limitations, the current work provides a precise numerical model to assess fracture fixation stability. Based on the findings of this study, the CF/flax/epoxy composite material may be an alternative to Ti as a material of choice for manufacturing IM devices. In contrast to Ti nails, load sharing in the CF/flax/epoxy case allowed the host femur to carry most of the loads, thereby encouraging bone regrowth, and preventing bone degradation by minimizing stress shielding. In addition, using a CF/flax/epoxy IM nail in femoral shaft fractures may enhance healing by increasing the compressive normal force at fracture fragments, and by increasing the stress at the vicinity of the fracture.

## 5. References

[1] M. Braten, T. Terjesen and I. Rossvoll. Femoral shaft fractures treated by intramedullary nailing. A follow-up study focusing on problems related to the method. Injury, 26 (6): 379-383, 1995.

[2] B. D. Browner. Skeletal Trauma: Basic Science, Management, and Reconstruction. (v. 1): 2009.

[3] G. Cheung, P. Zalzal, M. Bhandari, J. K. Spelt and M. Papini. Finite element analysis of a femoral retrograde intramedullary nail subject to gait loading. Medical Engineering & Physics, 26 (2): 93-108, 2004.

[4] J. Wolff, P. Maquet and R. Furlong. The Law of Bone Remodelling. 1986.

[5] M. Sha, Z. Guo, J. Fu, J. Li, C. F. Yuan, L. Shi and S. J. Li. The effects of nail rigidity on fracture healing in rats with osteoporosis. Acta Orthop, 80 (1): 135-138, 2009.

[6] S. E. Utvag and O. Reikeras. Effects of nail rigidity on fracture healing. Strength and mineralisation in rat femoral bone. Arch Orthop Trauma Surg, 118 (1-2): 7-13, 1998.

[7] T. Terjesen and K. Apalset. The influence of different degrees of stiffness of fixation plates on experimental bone healing. J Orthop Res, 6 (2): 293-299, 1988.

[8] D. R. Epari, J. P. Kassi, H. Schell and G. N. Duda. Timely fracture-healing requires optimization of axial fixation stability. J Bone Joint Surg Am, 89 (7): 1575-1585, 2007.

[9] J. Kenwright and A. E. Goodship. Controlled mechanical stimulation in the treatment of tibial fractures. Clin Orthop Relat Res, (241): 36-47, 1989.

[10] D. G. Poitout. Biomechanics and Biomaterials in Orthopedics. 2004.
[11] V. P. Mantripragada, B. Lecka-Czernik, N. A. Ebraheim and A. C. Jayasuriya. An overview of recent advances in designing orthopedic and craniofacial implants. J Biomed Mater Res A, 101 (11): 3349-3364, 2013.
[12] S. C. Cifuentes, E. Frutos, J. L. González-Carrasco, M. Muñoz, M. Multigner, J. Chao, R. Benavente and M. Lieblich. Novel PLLA/magnesium composite for orthopedic applications: A proof of concept. Materials Letters, 74 (0): 239-242, 2012.
[13] Z. S. Bagheri, I. El Sawi, E. H. Schemitsch, R. Zdero and H. Bougherara. Biomechanical properties of an advanced new carbon/flax/epoxy composite material for bone plate applications. J Mech Behav Biomed Mater, 20 398-406, 2013.
[14] H. Ebrahimi, M. Rabinovich, V. Vuleta, D. Zalcman, S. Shah, A. Dubov, K. Roy, F. S. Siddiqui, H. S. E, H. Bougherara and R. Zdero. Biomechanical properties of an intact, injured, repaired, and healed femur: an experimental and computational study. J Mech Behav Biomed Mater, 16 121-135, 2012.
[15] G. N. Duda, M. Heller, J. Albinger, O. Schulz, E. Schneider and L. Claes. Influence of muscle forces on femoral strain distribution. Journal of Biomechanics, 31 (9): 841-846, 1998.
[16] A. D. Heiner. Structural properties of fourth-generation composite femurs and tibias. Journal of Biomechanics, 41 (15): 3282-3284, 2008.
[17] M. P. Gardner, A. C. M. Chong, A. G. Pollock and P. H. Wooley. Mechanical evaluation of large-size fourth-generation composite femur and tibia models. Annals of Biomedical Engineering, 38 (3): 613-620, 2010.
[18] L. Grassi, S. P. Väänänen, S. Amin Yavari, H. Weinans, J. S. Jurvelin, A. A. Zadpoor and H. Isaksson. Experimental validation of finite element model for proximal composite femur using optical measurements. J Mech Behav Biomed Mater, 21 86-94, 2013.
[19] M. Viceconti, L. Bellingeri, L. Cristofolini and A. Toni. A comparative study on different methods of automatic mesh generation of human femurs. Med Eng Phys, 20 (1): 1-10, 1998.
[20] M. Papini, R. Zdero, E. H. Schemitsch and P. Zalzal. The biomechanics of human femurs in axial and torsional loading: comparison of finite element analysis, human cadaveric femurs, and synthetic femurs. J Biomech Eng, 129 (1): 12-19, 2007.
[21] K. Charlet, J. P. Jernot, M. Gomina and L. Bizet. Mechanical properties of flax fibers and of the derived unidirectional composites. Journal of Composite Materials, 44 2887–2896 2010.
[22] H. Bougherara, R. Zdero, M. Miric, S. Shah, M. Hardisty, P. Zalzal and E. H. Schemitsch. The biomechanics of the T2 femoral nailing system: a comparison of synthetic femurs withfinite element analysis. Proc Inst Mech Eng H, 223 (3): 303-314, 2009.
[23] P. Augat, J. Burger, S. Schorlemmer, T. Henke, M. Peraus and L. Claes. Shear movement at the fracture site delays healing in a diaphyseal fracture model. Journal of Orthopaedic Research, 21 (6): 1011-1017, 2003.
[24] R. Montanini and V. Filardi. In vitro biomechanical evaluation of antegrade femoral nailing at early and late postoperative stages. Medical Engineering & Physics, 32 (8): 889-897, 2010.
[25] C. A. Rockwood, R. W. Bucholz, D. P. Green, C. M. Court-Brown, J. D. Heckman and P. Tornetta. Rockwood and Green's Fractures in Adults. (v. 1): 2010.
[26] H. T. Aro, H. T. Wahner and E. Y. Chao. Healing patterns of transverse and oblique osteotomies in the canine tibia under external fixation. J Orthop Trauma, 5 (3): 351-364, 1991.