A PHYSIOLOGICALLY ACCURATE MECHANICAL REPRESENTATION OF THE BONE-IMPLANT CONSTRUCT UNDER GAIT LOADS

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ABSTRACT

Intramedullary nailing is a widely accepted technique utilized in the treatment of femoral fractures. Design of such devices should be accomplished based on physiological constraints, and loading of the femur, simulating *in vivo* conditions to prevent bone refracture and implant failure after surgical operation. It has been shown in literature that, walking is the most frequent dynamic activity of a patient, which necessitates testing implants mainly under walking loading conditions. In the present study, the response of the implanted femur having femoral mid-fracture as well as the intact femur were investigated at the instance of maximum hip contact force of the gait cycle in a finite element environment. Displacement and strain distribution on both bone-implant construct and intact bone were presented. The results may lead to an accurate estimation of the implants mechanical behavior in design stage, and be used in fatigue based analyses.

Keywords: Biomedical implant, intramedullary nail, design performance, contact model, finite element method

YÜRÜME YÜKLERİ ALTINDA KEMİK İMPLANT YAPISININ DOĞRU MEKANİK TEMSİLİ

ÖZET

İntramedüler çivi uygulamaları uyluk kemiği kırıklarının tedavisinde sıklıkla tercih edilen bir tekniktir. Bu tip cihazların tasarımı yapılırken vücut içindeki fizyolojik durum (kemiğin maruz kaldığı sınır koşulları ve yükleme), kemiğin ve implantın kırılmasını önlemek için göz önünde bulundurulmalıdır. Yapılan bir araştırmada, yürüme eyleminin hastaların en sık yaptığı dinamik bir aktivite olduğu gösterilmiş olup, bu durum implantların temel olarak yürüme yükleri altında test edilmesini gerekli kılmaktadır. Bu çalışmada diafizyel bölgede kırık içeren intramedüler çivi takılmış bir uyluk kemiğinin yürüme yükleri altında (kalça temas kuvvetinin en yüksek olduğu anda) mekanik davranışı sonlu elemanlar ortamında incelenecektir. Kemik ve implant üzerindeki yer değiştirme, gerinim ve gerilme dağılımları sunulmaktadır. Sonuçlar, tasarım aşamasında mekanik davranışın gerçekçi olarak tahmin edilmesini sağlayacaktır ve çıktılar yorulma analizlerinde kullanilabilir.

Anahtar Kelimeler: Biyomedikal implant, intramedüler çivi, tasarım performans, kontak model, sonlu elemanlar yöntemi

1. INTRODUCTION

The role of intramedullary nails (IM nails) is to stabilize broken bone during fracture healing, while allowing load transmission across fracture site. Failures of such devices were reported in several studies, emphasizing locking pin failures especially due to excessive bending, bone refracture, and so on. Design of these mechanical devices is critical to prevent such complications, and therefore should be based on *in vivo* conditions, ie., physiological constraints, and loading of the bone. Morlock et al., [1] has reported frequency and duration of daily activities in patients after total hip arthroplasty. The most frequent patient activity was sitting (44.3% of the time), followed by standing (24.5%), walking (10.2%), lying (5.8%), and stair climbing (0.4%) on the average. Based on these results, walking is the primary dynamic activity of a patient, and also one of the worst case scenarios for hip joint loading [2]. According to the same study [2], implants should mainly be tested under walking, and stair climbing loading conditions.

The biomechanical response of human femur was investigated in many finite element studies with a large variety of boundary and loading conditions. However, most of these studies do not actually correspond to the physiological conditions which occur *in vivo*. The effect of boundary and loading conditions on the results obtained from femoral analysis [3, 4] showed that certain care should be allocated when simulating these conditions. In the study of Speirs et al., [3], constraints applied on the femoral head and distal condyles together with the addition of muscle forces were proved to represent more realistic conditions based on physiological deflections of the femur.

Several research studies – looking at the mechanical behavior of intact and implanted femur – exist in the literature. However a few studies [5-8] incorporate the gait cycle in their analyses. The way these studies were performed is far from physiological conditions, leading to misrepresentation of the *in vivo* mechanical behavior. The study of G.Cheung [5] included both experimental, and numerical work at four stages of gait – results are only valid after a complete bone union has occured –, however lacking physiological constraints on the femur. The study did not simulate femoral fractures. In the present study, the mechanical response of the implanted femur having a diaphyseal fracture as well as the intact femur will be investigated in a finite element environment at the instance of maximum hip contact force during the gait cycle. The effect of different boundary and loading conditions on the mechanical response of the models will be discussed. Mechanical behavior is illustrated based on the hip displacements and main principal strain profiles over the diaphyseal region. It is argued that the results portray an accurate representation of the implants' mechanical behavior in design stage, and be used in fatigue based analyses.

2. MATERIALS AND METHODS

In this study, standardized femur model [9] was used, and modeling was done in ADINA 8.7.5 [10]. A retrograde nail-bone construct with three interlocking pins – two of which were located at proximal, and one at the distal side – was created. A diaphyseal osteotomy, of 5 mm was performed in the mid-diaphysis to simulate a transverse fracture. The solid nail and pins had a diameter of 11 and 4.5 mm respectively.

2. 1 Finite Element Analysis

Finite element analysis (FEM) enables to examine the mechanical behavior of biomedical devices [5, 11]. When creating FEM of the consruct, several contact regions were considered which are shown in Fig.1. Tied contact was utilized at two contact interfaces, bone to pins (b/p), and nail to pins (n/p). The interaction between bone and nail (b/n) was such that frictionless sliding of the nail inside the canal was possible. The nail and pins were made of 316L grade steel. All materials were assumed to be isotopic and linearly elastic. Material properties are shown in Table 1. Tetrahedral and hexahedral elements were used to mesh the models. The maximum element lengths were 2, 1 and 1 mm for the bone, nail and pins respectively. Mesh refinements were applied at bone and nail holes. Bone-implant construct (BIC) was discretized by a total of 365811 elements (81933 nodes), and intact bone by about 134738 elements (30885 nodes). The meshed view of the construct is depicted in Fig. 1.

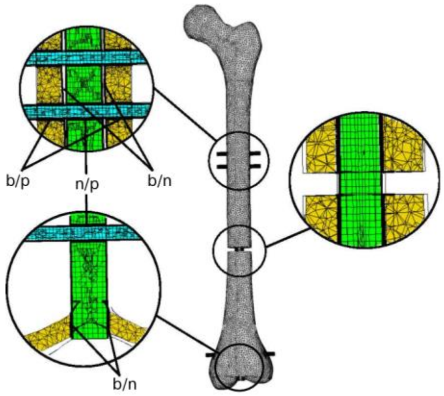

Figure 1: Meshed view of the bone-implant construct with section views of the contact regions, i.e., b/p: bone to pin, n/p: nail to pin and b/n: bone to nail.

Table 1: Mechanical properties of all the constituents of the bone-implant construct model.

Region	Elastic modulus, E (GPa)	Poisson's Ratio, ν
Nail (316L steel)	200	0.33
Bone (cortical)	17.4	0.25

2. 2 Boundary and Loading Conditions

The mechanical behavior of the femoral constructs highly depend on the boundary and loading conditions assigned in pre-clinical tests. It was shown that unrealistic constraints on the femur yielded excessive femoral deformations [3], which necessitated simulating *in vivo* conditions by more physiologically-based boundary conditions and loads. Applying realistic constraints on the intact bone – in contrast to previous studies in the literature, e.g., [8] –, the method was proved to be more physiological. Their results were supported by an *in vivo* study [12]. The aim of our study is, therefore to show the misrepresentation of the mechanical behavior of the constructs' which is caused by unrealistic boundary and loading conditions. We adapt the method proposed by Speirs et al., [3] to analyze the situation for the bone-implant construct, which will be compared with two other boundary and loading cases. In this study, loading and boundary conditions applied on the models are shown in Fig. 2.

In cases (*a*) and (*b*), femur was fully-constrained at its distal condyles as it was done in previous studies [8, 4]. However, in case (*c*), femur was only constrained at two points simulating a more realistic knee contact, reflecting a more physiologically accurate condition [3]. The hip joint – point C –, was only allowed to translate along an axis (local X axis defined at point C) towards the knee center. To prevent rigid body motion of the model, a node D, at the knee center was restricted in three translational degrees of freedom (x, y, z), and anterior-posterior (A-P) motion (y) of a point B, at the distal lateral epicondyle was constrained.

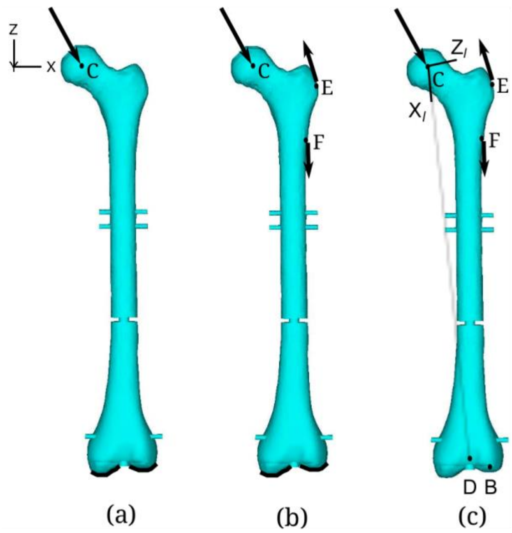

Figure 2: Boundary and loading conditions considered in this study: Case (a) consists of hip contact force with fixed boundary conditions on the distal condyles. Case (b) is the same as (a), including additional musle forces (abductor, tensor fascia latae and vastus lateralis). Case (*c*) corresponds to pyhsiological conditions with joint constraints.

Table 2: Load profile for loading bone-implant construct and intact bone [13]. Walking (BW=860 N)

Force (N)	x	y	z	Point
hip contact	464.4	282.1	-1971.1	C
abductor	-498.8	-37.0	743.9	E
tensor fascia latae, proximal part	-61.9	-99.8	113.5	E
tensor fascia latae, distal part	4.3	6.0	-163.4	E
vastus lateralis	7.7	-159.1	-798.9	F

When it comes to loading, case (*a*) utilizes only a hip contact force at point *C*, while loading of the construct and intact bone was conducted using additionaly reduced muscle loading together with the hip contact force [13], in cases (*b*) and (*c*). Instead of including all muscles and joint forces in the numeric models [3], some muscles were extracted which showed no or negligible effect during walking together with no joint forces. This loading model - comprising hip contact, abductor, tensor fascie latae (proximal and distal parts) and vastus lateralis forces - provided a realistic approximation of physiological loading conditions, and seems achievable in vitro test set-ups according to Heller et al., [13]. In all cases, maximum hip contact force of the gait cycle in walking was used for loading. The magnitude and point of applications of these loads were approximated for the standardized femur model, for a patient of 860 N body weight (BW), and given in Table 2. Note that load applied at point *E* is the resultant of the abductor and tensor fascia latae forces.

3. RESULTS

Deflected constructs in the medial (M) and anterior (A) views compared to undeflected shapes (green color) are shown in Fig. 3, for three boundary and loading cases. It is certain that the application of hip contact force alone produced significant bending in A-P and M-L planes resulting a total displacement magnitude above 6.5 mm at the femoral head (top). However, addition of muscle forces – abductor, tensor fascia latae and vastus lateralis – seems to prevent excessive bending caused by hip contact force (middle) lowering the deflection of the construct to a magnitude of nearly 5.8 mm in case (*b*). The situation even gets better when the joint constraints are present (see Fig. 2). In case (*c*), deflections are read of less than 2 mm in the shaft region.

Principal strain distributions along the A-P and M-L sides of the femur and nail are plotted in Fig. 4, for cases (*a*), (*b*) and (*c*) corresponding to loads and boundary conditions depicted in Fig. 2; while strain distributions only for the bone are plotted in the last row, corresponding to an intact bone. In this figure, black solid lines depict the strain distribution on the implanted femur, while red ones do on the nail. As seen from the figure, anterior and lateral sides are under tension, while posterior and medial sides go through compression, except case (*a*), where medial side is under tension. Localised strain effects are apparent where muscle loads are applied. At these regions, strains increase rapidly. Strains also increase in the bone at pin holes – where load transfer from bone to pins occur –, while decrease in the nail in all cases. It is not suprising that a peak value of strain in the nail is observed at the fracture site. Due to the fracture, the load is mainly carried by the nail. Around the fracture site, strains are lower in the bone compared to the nail, which is obviously due to the load transfer due to contact between bone and the nail. In general, medial and lateral strains on the bone cortex are higher than anterior and posterior sides. This is explained by the presence of the larger bending moments on the M-L plane compared to A-P plane.

Unfortunately, to the knowledge of the authors', there is no *in vivo* study of an implanted femur during walking. Therefore, numeric model of the bone-implant construct and intact bone corresponding to case(*c*) will be compared to the similar studies in the literature in discussion section. In this regard, strain distribution on the intact bone is depicted in the very bottom of Fig. 4 Cortical surface strains on the medial-lateral sides of the intact bone has a peak magnitude of 1500 $\mu\varepsilon$ while it is above 750 $\mu\varepsilon$ on the posterior side.

4. DISCUSSION

Pre-clinical testing of IM nails is critical to determine stability and performance targets for these devices. Understanding the *in vivo* conditions which these devices operate, carries a primary importance in this regard. However, there is still lack of consensus on the boundary and loading conditions to apply in these tests. According to Bergmann et al., [2], femoral implants should mainly be tested under walking and stair climbing loads, as these activities resulted in the most critical loading of the femur. This hypothesis is further supported by the work of Morlock et al., [1], which showed walking to be the most frequent dynamic activity of a total hip arthroplasty (THR) patient.

In the literature, several boundary and loading conditions were employed in many experimental tests [8, 4] and numerical models [14, 8, 3] in an attempt to investigate the mechanical behavior of the implanted or intact bone. Because there is no standart accepted procedure of applying boundary and loading conditions in these tests, results show huge variations. In this study, maximum principal strain distributions along the long axis of the intact bone presented in the very bottom of Fig. 4 (case (*c*)) showed resemblance with the results given by Duda et al., [14]. Their study included all thigh muscles of the gait with distal end of the bone was restricted at three points. Speirs et al., [3] presented maximum principal strains on the intact bone applying physiological constraints for a time of maximum hip contact force during the gait cycle. Strain distribution on the intact bone presented in the very bottom of Fig. 4 showed similar trends with [3] along all surfaces, however with magnitudes of approximately half of their results. Peak strains were seen in the subtrochanteric region along the medial-lateral sides, while it was in the mid-diaphysis along posterior-anterior surfaces in both study. The anterior surface strains were similarly the lowest among other sides. Remember that the study [3] included very complex loading comprising of joint contact forces (hip, knee and patella) and all muscles, contrary to the current study which utilized hip contact force plus some additional muscle forces (abductor, tensor fascia latae and vastus lateralis) proposed by Heller et al., [13]. Unfortunately, there is no information regarding the patella joint and muscle forces applied on the femur in the study [3]. The difference in the principal strain magnitudes, therefore is thought to be caused by this loading factor. Moreover, it has been reported that reduced muscle loading [13] can predict the *in vivo* hip contact force, Bergmann et al., [2] by approximately 7% during walking. However, the musculoskeletal loading conditions used in the study of Speirs et al., [3] was adapted from [15]. They already reported that their model can predict the *in vivo* hip contact forces by a mean of 12% during walking [15]. Including all muscles in an experiment set-up or finite element analysis is very complex which makes difficult controllability and reproducibility of the tests. From engineering point of view, we conclude that reduced musculoskeletal loading proposed by Heller et al., [13], and joint constraints [3] can be used to apply in femoral analysis.

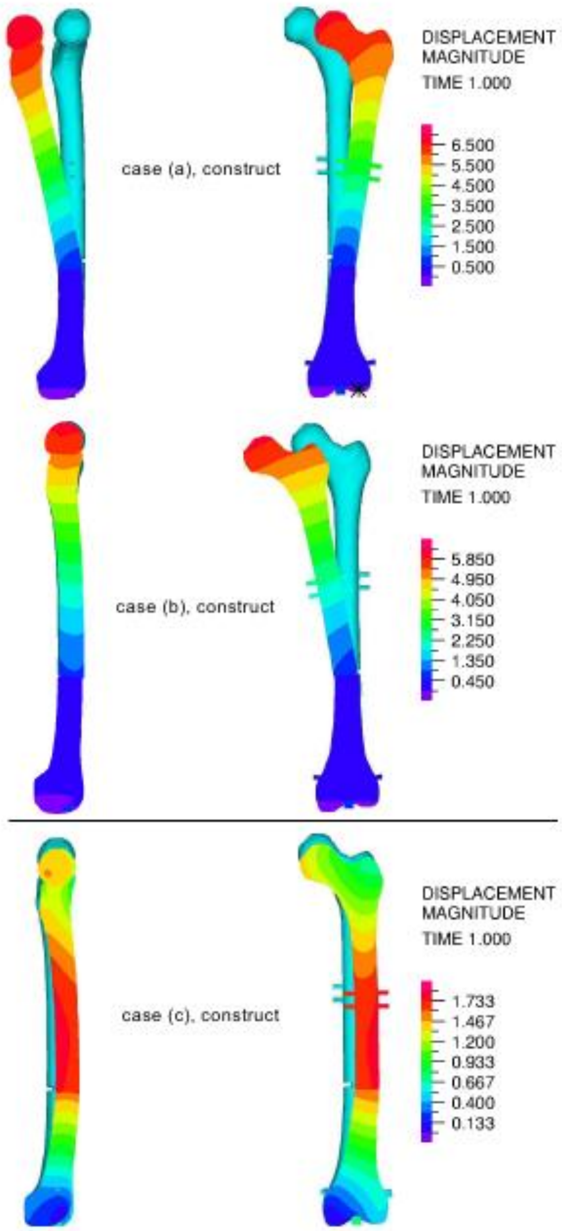

Figure 3: Displacement distribution on the bone-implant construct under walking loads for three boundary and loading cases in the medial (left) and anterior (right) views. Top: case (a), middle: case (b), and bottom: case (c). Displacements are exaggerated 10x for clarity.

A recent study [8] reported the results of stress and strain distribution within a standardized femur implanted with an intramedullary nail which can benefits of seperate antegrade and retrograde nailing systems. The study utilized two boundary and loading configurations, i.e., case (*a*) and case (*b*) as in the current study, but with a lower magnitude of 980 N. Roberto et al., [8] reported femoral head displacements for fractured femur to be about 2 mm and 55 mm corresponding to load cases (*a*) and (*b*) which are too high compared to the current study where a maximum of 6.5 mm and 5.9 mm has been reported respectively (see Fig. 3). Even though they used a lower Young's modulus of 10 GPa for cortical bone (17.4 GPa in the present study), their results are somehow very high considering that they used a lower load magnitude. They also presented longitudinal strains on the medial and lateral sides of the fractured bone corresponding to case (*a*) which are almost the same in magnitude and position to the present study. However, as they reported longitudinal strains (maximum principal strains are presented in the current study), any conclusion drawn from this comparison might be incorrect.

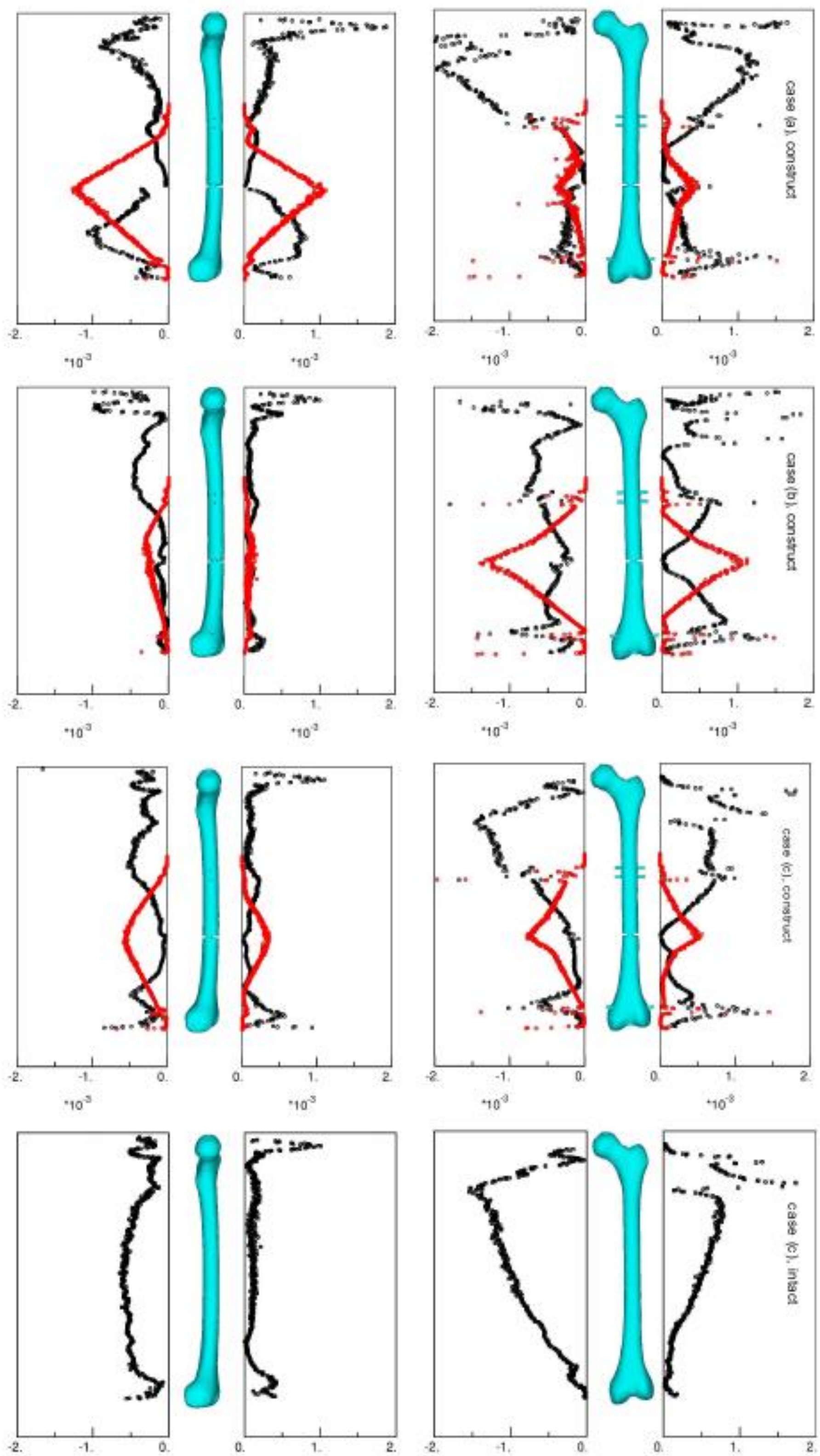

Figure 4: Main principal strain distribution on the cortex of the construct, on the nail and intact bone (lower most) under walking loads for three cases. Left: posterior and anterior sides, right: medial and lateral sides. Top: case (a), middle: case (b), and bottom: case(c).

The application of hip contact force alone were proved to be oversimplified loading situation, resulting in huge deflection of the femur by bending [4], and therefore unrealistic straining of the femur in a test set-up, in which horizantal movement of the femur head is constrained. This is readily seen from Fig. 4, where higher strain magnitudes are observed in the femur, in case (*a*) on the M-L and A-P sides compared to cases (*b*) and (*c*). In the same figure, strains are the highest in the nail on the M-L sides corresponding to the case (*b*). This is explained by the addition of muscle forces which lowered the A-P moments resulting a higher M-L moments (but in the opposite direction). At the fracture site, strains are higher in the nail which implies that most of the load is carried by the nail. The presence of joint constraints in case (*c*) acts to decrease this contact force, lowering the strains in the femur and nail on the M-L plane. The resulting principal strain distributions on the M-L and A-P sides of the implanted femur corresponding to case (*c*) look very similar to the distribution obtained on the intact bone. Among all cases, the most uniform principal strain distribution is obtained in case (*c*), which further proves that addition of mentioned muscles and joint constraints are necessary to simulate physiological conditions of the femur *in vivo*.

5. CONCLUSION

The finite element models of the bone-implant construct and intact bone presented in this study allowed to estimate the mechanical behaviors of the implants more accurately in design stage. The models were based on the physiological constraints and loading of the femur during walking activity, simulating *in vivo* conditions of the lower extremity. An experimental study is required to validate the results obtained in this study.

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