Finite Element and Experimental Cortex Strains of the Intact and Implanted Tibia

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Finite Element (FE) models for the simulation of intact and implanted bone find their main purpose in accurately reproducing the associated mechanical behavior. FE models can be used for preclinical testing of joint replacement implants, where some biomechanical aspects are difficult, if not possible, to simulate and investigate in vitro. To predict mechanical failure or damage, the models should accurately predict stresses and strains. Commercially available synthetic femur models have been extensively used to validate finite element models, but despite the vast literature available on the characteristics of synthetic tibia, numerical and experimental validation of the intact and implant assemblies of tibia are very limited or lacking. In the current study, four FE models of synthetic tibia, intact and reconstructed, were compared against experimental bone strain data, and an overall agreement within 10% between experimental and FE strains was obtained. Finite element and experimental (strain gauge) models of intact and implanted synthetic tibia were validated based on the comparison of cortex bone strains. The study also includes the analysis carried out on standard tibial components with cemented and noncemented stems of the P.F.C Sigma Modular Knee System. The overall agreement within 10% previously established was achieved, indicating that FE models could be successfully validated. The obtained results include a statistical analysis where the root-mean-square-error values were always <10%. FE models can successfully reproduce bone strains under most relevant acting loads upon the condylar surface of the tibia. Moreover, FE models, once properly validated, can be used for preclinical testing of tibial knee replacement, including misalignment of the implants in the proximal tibia after surgery, simulation of long-term failure according to the damage accumulation failure scenario, and other related biomechanical aspects.
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Keywords: promixal tibia, knee prosthesis, synthetic tibia, finite element analysis, strain gauge measurements

1 Introduction

Using preclinical validation, the failure scenario in biomedical applications can be identified [1–4] and the specific requirements for the same can be verified using the experiments [1]. Biomedical aspects, such as micromovements and bone-implant interface stresses, are difficult to investigate and simulate using in vitro experiments; nevertheless, such phenomena become a lot easier to analyze when numerical models are used to simulate a specific scenario. Even though accurate quantitative results cannot be obtained mainly due to the lack of reliable biological data to feed the finite element analysis [5,6], the reliability of these numerical methods has been established for biomedical applications for predicting the implants performance.

Commercially available synthetic femurs have been extensively used to predict the performance of hip prostheses and are often used as cadaveric specimen replacement for experimental studies [7–18]. Synthetic tibias have also been used in some biomechanical analysis, and its mechanical validation was performed and documented by Cristofolini and Viceconti [19]. Despite the information available regarding synthetic tibia, the literature is lacking for the synthetic tibia with implant assemblies and further studies in what concerns this particular field of research are required. The validation of finite element (FE) and experimental specimens with implant assemblies assumes a great importance for the investigation of preclinical performance of tibial knee implants, where particular biomechanical aspects are difficult to study and cannot be reproduced or investigated in vitro.

In the current study, four FE models of synthetic tibia, intact and reconstructed, have been validated, relatively, to experimental bone strains. The objective was an overall agreement within 10% between experimental and FE strains.

2 Materials and Methods

2.1 Experiments. Four composite tibias (left model, No. 3302, Pacific Research Labs, Vashon Island, WA) were used in this study. A reference axis was marked on the outer cortical surface of each tibia for the reproducible alignment and positioning of the strain gauges [20,21]. The positions of the strain gauges were measured using a 3D coordinate measuring device (Mod. Maxim, Aberlink, UK) with a precision of 0.01 mm. Triaxial strain gauges (KFG-3-120-D17-11L3M2S, Kyowa Electronic Instruments Co., Ltd., Japan) were placed on the anterior-medial (AM), lateral (L), and posterior (P) sides of the cortex of the composite tibia at different levels to measure surface strains, as shown schematically in Fig. 1. The middle strain gauge ε_b was aligned with the vertical axis of the tibia, and the strain gauge data were acquired via a computer using Catman software (Hottinger Baldwin Messtechnik GmbH, Germany) by means of a data acquisition system Spider 8 (Hottinger Baldwin Messtechnik GmbH, Germany). Three tibial components of the P.F.C Sigma Modular Knee System (DePuy International, Inc., Johnson & Johnson, Warsaw, Indiana) were implanted into composite tibias, as shown in Fig. 2, by an experienced surgeon. The tibial component of the prostheses will be referred to in this paper as standard stem, cemented stem, and noncemented stem. Table 1 gives the description of the stems used in this study. The in vitro insertion procedure of the stems was performed according to the clinical protocol. CMW-1 (DePuy International, Inc., Johnson & Johnson, Warsaw, Indiana) bone cement was used in the case of the cemented stem, and the thickness of cement mantle was kept at 2 mm, measured from CT scans. The tibial plate was cemented with a cement mantle of 1.5 mm thickness.

Bone strains were initially measured under simple loading. The tibia was fixed at 0 deg adduction from its distal region using a stiff metallic device, shown in Fig. 2. The pneumatic load was applied vertically through a metallic sphere placed on the medial and lateral condyles, and a load cell (AEP TC4 1T, Modena, Italy) was used to control the applied forces. To ensure the repeatability of the results, each intact and reconstructed tibia was tested five times. The loading procedure was applied according to Finlay et al. [22] and is described in Table 2. The load stabilization time

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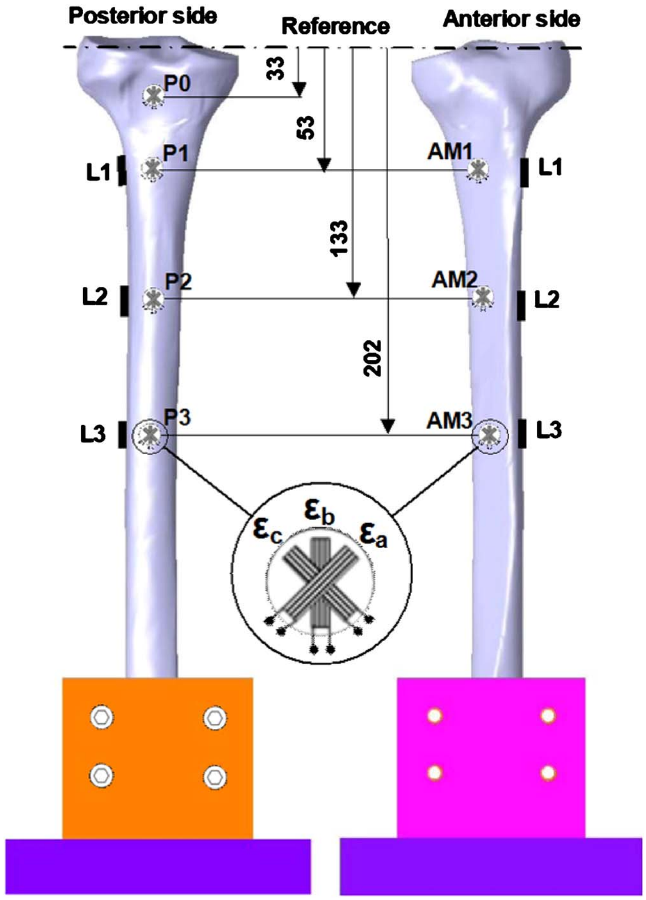


Fig. 1 Tibia with locations of strain gauges. Bone strains were measured with four gauges glued at the posterior (P0, P1, P2, and P3) and six gauges glued at the anterior-medial (AM1, AM2, and AM3) and lateral (L1, L2, and L3) sides of the tibia.

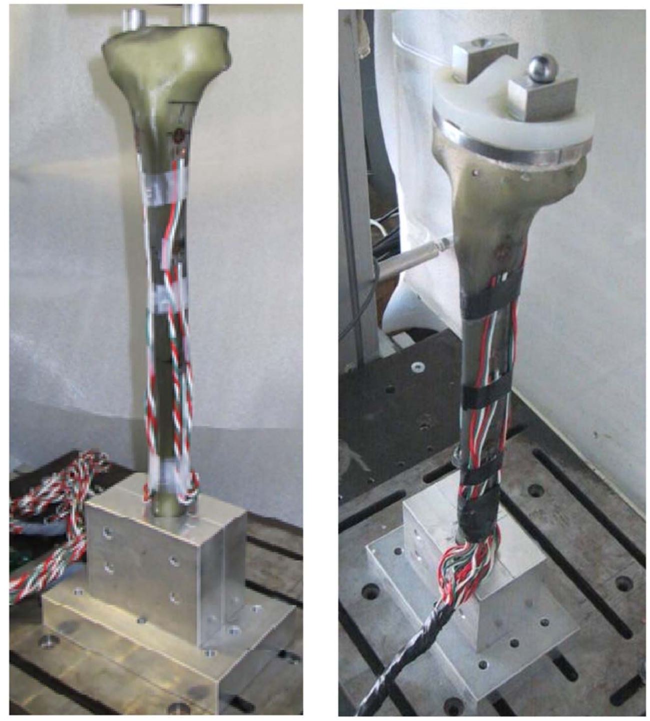


Fig. 2 Instrumented intact (left) and implanted (right) tibia

depends on the viscoelastic behavior of the composite tibias [23]. The experimental results are presented as the average of five loading conditions that were conducted at room temperature (20–22°C).

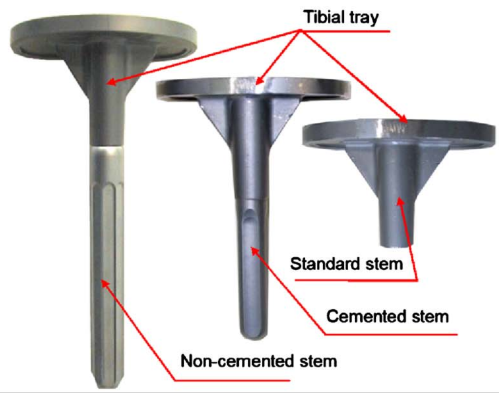
For each reconstruction, the load was applied separately on the medial and lateral condyles, where the applied loads were 1160 N and 870 N in medial and lateral condyles, respectively. The latter are the equivalent to three times the body weight (70 kg) distributed by 40% on the lateral condyle (870 N) and 60% on the medial condyle (1160 N) of the stance phase before toe-off [24,25]. The superimposition principle was applied to determine the experimental strains at desired loading condition (1160 N in medial condyle and 870 N in lateral condyle). The procedure was adapted to overcome some experimental problems encountered when trying to simultaneously simulate the loads on the tibia condyles, since Cristofolini and Viceconti [19] have referred large reproducibility errors detected in composite tibias due to misalignments and used a system of hinges and cross rails, allowing free deflections and rotations at the proximal extremity to apply axial loads.

2.2 Finite Element Analyses. To build the FE models, AP and ML radiographs and CT scans were made onto all in vitro reconstructions. The "standardized tibia," a 3D solid model made available in the public domain derived from a CT-scan dataset of a synthetic human tibia replica, was used as the reference geometry for the finite element analysis. The latter describes the endosteal and periosteal surface of the composite cortex. The material properties used are those referenced by the manufacturer (Table 3) [12]. The materials are assumed to be homogeneous, isotropic, and linear elastic, and the boundary conditions in FE models were defined to reproduce experimental setup. The tibial components were digitized with a 3D laser scanner device (Roland LPX 250) with a precision of 0.2 mm, and solid models were created with a CAD modeling package (Catia, Dassault Systèms, France). The exact position of the stem relative to the tibia was determined from the CT scans. A solid model for the cement mantle was created based on the cemented reconstruction, taking into account the size of the drill used and the cement mantle thickness. Automatic meshing of the models was done using FE meshing software HYPERMESH v6.0 (Altair Engineering, Troy, MI) and meshes were built from four-node linear tetrahedral, size 1.8 mm, with six degrees of freedom (DOF) per node. The number of elements and nodes of the meshes were chosen based on previous convergence studies and are presented in Table 4 and can be depicted from Fig. 3. For the convergence studies, the maximum displacements and equivalent strains at 32 positions (medial, lateral, anterior, and posterior sides) for the intact FE tibia model were assessed. The convergence rate for the displacements and equivalent strains for 125000 DOF was <0.2% and <5%, respectively.

Linear and nonlinear analyses were performed with MARC Research Analysis (Palo Alto, CA). For the nonlinear analysis (friction models), the contact between the implant-bone and cement bone was modeled using the node-to-surface algorithm. The coefficients of friction used in this study are 0.25 [26–28] and 0.3 [29–32] for the contact between implant and cement mantle, and the contact between implant and bone structures (cortical and cancellous), respectively. The Coulomb friction model was used in this study. For the linear analyses, all contacts between implant and others structures are simulated as being rigid bonded (bonded models). Linear regressions analysis was performed to determine the overall correlation between experimental and numerical results. This procedure is also used to find the influence of interface conditions implant bone and implant cement in maximum and minimum principal strains. The measured strain data were treated as dependent variables and FE strains as independent ones. A

Table 1 Characteristics of the standard, cemented, and noncemented proximal tibial components of the P.F.C. Sigma Modular Knee System used in the current study

Model	PFC Sigma Knee System	Stem	Cement
Standard stem	Tibial plate - Size 5 - Ti-6Al-4V 83mm ML - 55mm AP		CMW 1
Cemented Stem	Tibial plate - Size 5 - Ti-6Al-4V 83mm ML - 55mm AP	∅14mm x 115mm, Ti-6Al-4V	CMW 1
Non-Cemented Stem	Tibial plate - Size 5 - Ti-6Al-4V 83mm ML - 55mm AP	∅13mm x 60mm, Ti-6Al-4V	CMW 1



slope and R^2 close to 1, in combination with a small intercept, would indicate good agreement between FE and measured strains. If the intercepts were small, then slopes of 0.9 and 1.1 were considered to indicate differences between experimental and FE strains of −10% and +10%, respectively. An additional indicator of the overall absolute difference between FE and measured strains, the root-mean-square error (RMSE), was calculated and is defined as the square root of the average of the squared errors between FE and measured strains. The RMSE was expressed as a percentage (RMSE(%)) of the measured peak strain.

Table 2 Details of the test procedure utilized

Period	Description	Time
A	Conditioning	1 min
B	Unloading and relaxation	4 min
C	Strain gauges set to zero	15 s
D	Loading until test load at 60 N/s	
E	Load stabilization	4 min
F	Data collection	1 s
G	Unloading and relaxation	4 min
H	Residual strains collected	1 s
I	Loading intervals	20 min

Table 3 Material properties of intact and implanted tibia

	Material	Elastic modulus (GPa)	Poisson's ratio
Cancellous bone	Polyurethane foam	0.104	0.3
Cortical bone	Composite material	12.4	0.3
Tibial bone	Titanium	110	0.3
Stems	Titanium	110	0.3
Tibial tray	Polyethylene	0.5	0.3
Distal tip of the stem	Polyethylene	0.5	0.3
Cement	PMMA	2.28	0.3

3 Results

The standard deviation of the experimental strain data obtained from the five loading runs was <5% of the respective mean principal strain. This value was slightly higher for mean strains

Table 4 Number of nodes and elements of the FE models

	Elements	Nodes
Intact tibia	222,310	47,543
Standard implanted tibia	257,964	57,877
Noncemented stem	247,913	58,165
Cemented stem	263,450	60,825

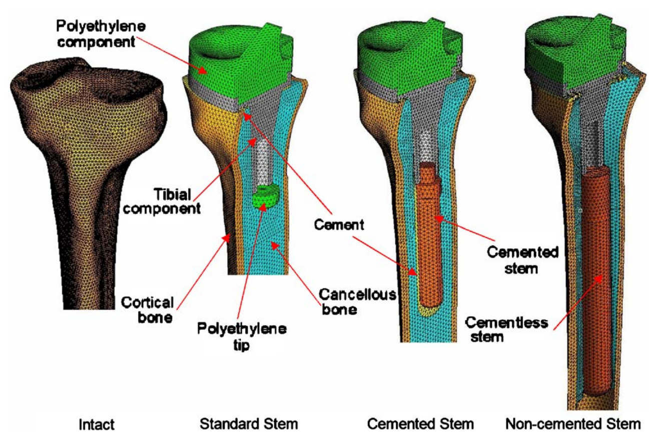


Fig. 3 FE models built and used to simulate the experiments: (*a*) FE model of a composite intact tibia, (*b*) FE model of a composite reconstruction with standard implant, (*c*) FE model of a composite reconstruction with cemented stem, and (*d*) FE model of a composite reconstruction with noncemented (press-fit) stem

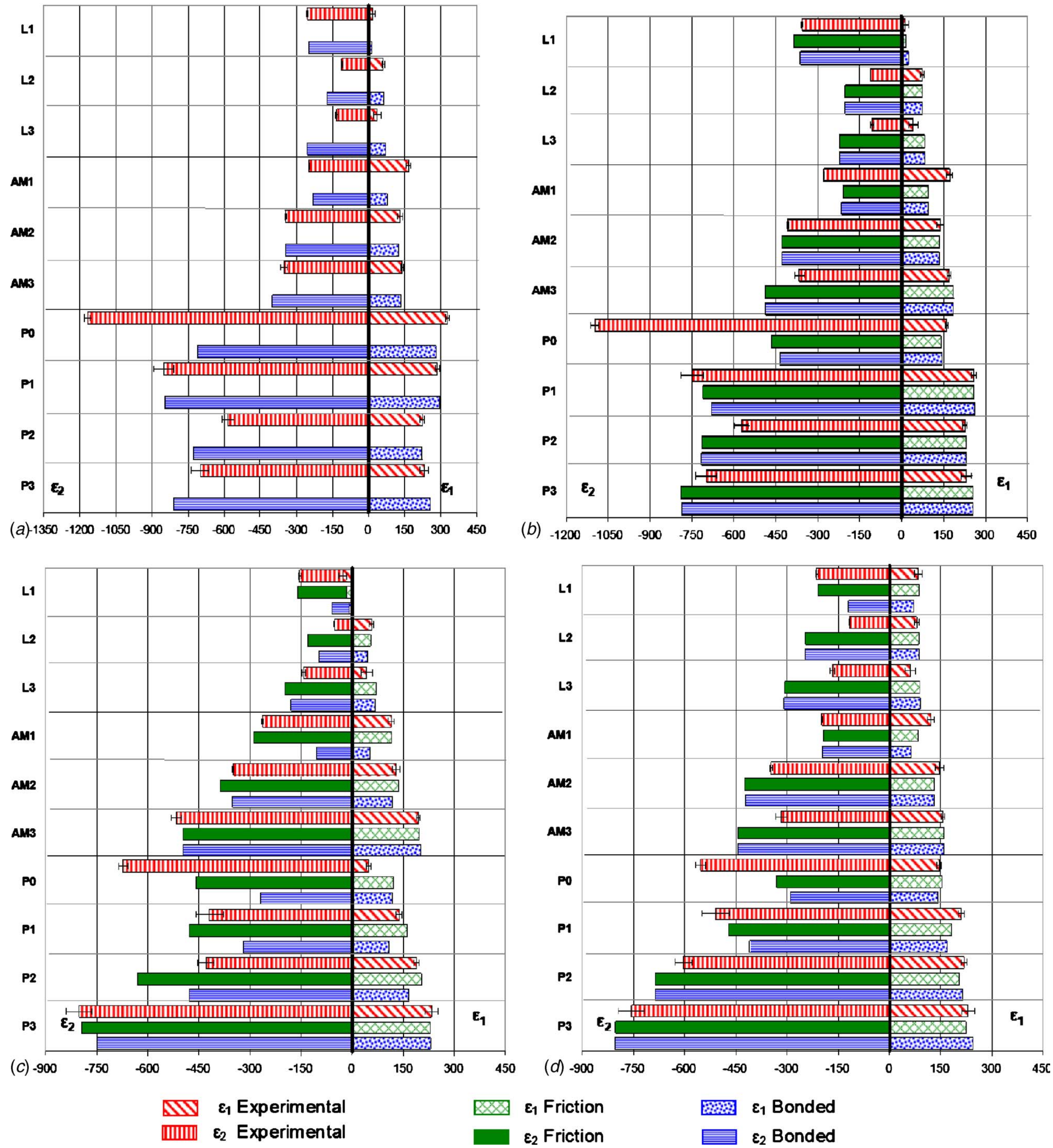


Fig. 4 Comparison of the FE and mean experimental principal strains for each gauge location for a vertical force applied on the medial (1160 N) and lateral (870 N) condyles (superimposition principal was used to determine the experimental strains): (*a*) intact tibia model, (*b*) reconstruction with standard implant, (*c*) reconstruction with noncemented stem, and (*d*) reconstruction with cemented stem. The gauge locations are named as defined in Fig. 1.

<80 μstrain and is in agreement with work by Heiner and Brown [7]. The direct comparison of FE strains and the experimental data are shown in Fig. 4 for each strain gauge. The quantitative analysis using linear regression was performed to determine the relation between them. The correlation coefficient, slope of the curve, interception, and RMSE values are presented in Table 5. Figure 5 shows the linear regression results between experimental strains and FE strains using friction and bonded models for intact femur model, reconstruction with standard implant, reconstruction with non-cemented stem, and reconstruction with cemented stem.

A close correspondence between measured and FE strains was obtained for the four analysed models (Fig. 4). Under simplified stance phase loading condition, most FE bone strains agreed within three times the standard deviation of the mean experimental strains. The exception refers to the gauge located at P0, for all models, where the differences between measured and experimen-

Table 5 Results of linear regression analysis, comparing FE and mean measured strains

Model	Interface	R2	Slope	Intercept (μ strain)	RMSE (μ strain)	RMSE (%)
Load on medial (1160 N) and lateral (870 N) condyles						
Intact	Bonded	0.91	1.03	7.69	33	4.0
Standard	Bonded	0.82	1.01	−6.80	36	3.5
Implant	Friction	0.83	1.00	−3.4	33	3.2
Noncemented	Bonded	0.89	1.08	−19.9	35	4.6
	Friction	0.94	0.95	−2.59	30	4.5
Cemented	Bonded	0.91	0.94	3.82	34	4.4
	Friction	0.94	0.94	9.24	29	3.6

tal bone strains exceed ten times the standard deviation of the measured strains. In addition to the strain magnitudes, the in-plane angles between the principal strain directions and the tibia long axis agreed well between the FE analyses and the experiments. The greatest deviation was observed for the proximal gauges, where the mean principal angles of the measured strains detain a deviation of 9 deg relatively to the numerical direction. For the intact tibia (Figs. 4(*a*) and 5(*a*)), the measured strains demonstrate a good agreement with FE strains. The slope of the regression line and correlation coefficient are 1.03 and 0.91, respectively. Additionally, the RMSE(%) value is 4%. The standard stem reconstructions show similar behavior to that of the intact tibia, and the results can be seen in Figs. 4(*b*) and 5(*b*). A better RMSE(%) value and slope were achieved with the friction model, 3.2% and 1.0, respectively. For the noncemented stem model (Figs. 4(*c*) and 5(*c*)), the most important difference between the friction and the bonded model was identified by the intercept value, which was 7.6 times greater for the bonded model (-19.9×10^{-6} m/m) than the one for the friction model (-2.59×10^{-6} m/m). The measured strains highlight better correlation values (R^2), slope, and the lowest RMSE(%) values for the friction model: 0.94%, 0.95%, and 4.5%, respectively. For the cemented stem reconstruction, the best correlation value, slope, and RMSE(%) was found for the friction model with 0.94%, 0.94%, and 3.6%, respectively. These values indicate a good correlation between the measured and the FE strains. It can therefore be said that a better agreement between the measured and FE strains was observed using FE friction models for reconstructed tibias.

4 Discussion

The purpose of this study was to validate four FE models of intact and implanted composite tibias joint reconstructions with standard tibial components, cemented, and noncemented stems of the P.F.C Sigma Modular Knee System. During the study, it was intended to obtain an overall agreement within 10%. Despite of localized deviations, numerical and mean measured strains agree well for all the models and loading conditions, considering a correct choice of interface conditions. The regression analyses produced slopes and R^2 values that are generally close to 1.0. To establish the latter, all slopes were within the range of 0.9–1.1 and the RMSE values were within 10%, indicating that the initial objective was achieved. The major differences between the experimental and numerical strains were found for all models at gauge located at P0 and can be explained by the local structural stiffness of the composite tibias. A similar effect was noticed by Cristofolini et al. [23] for proximal composite femurs (having more complex geometry) were the glass-fiber content of the cortex is relatively low, making it locally less stiff than expected. Heiner and Brown [7] also observed an identical difference for the third-generation composite femurs. Three tibias were sawed at the P0 level, and based on the cortex thickness measured, it was observed that the cortex thickness is slightly less than the one of the CAD model of the "standardized tibia."

A prerequisite for accurate FE models is a sufficient level of mesh refinement. In an earlier convergence study, a total of 125,000 nodal degrees of freedom (NDOFs) was found to be suf-

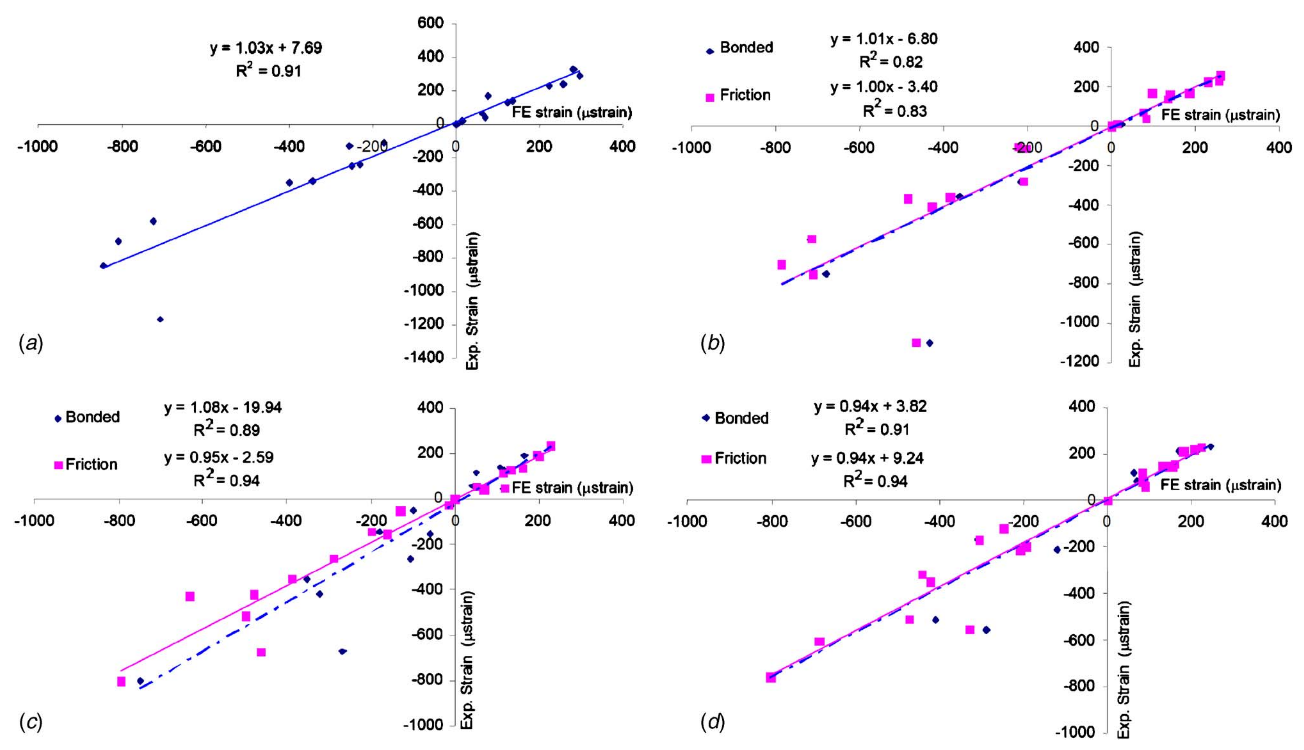


Fig. 5 The graphs show the linear regression results for the strains in (*a*) intact femur model, (*b*) reconstruction with standard implant, (*c*) reconstruction with noncemented stem, and (*d*) reconstruction with cemented stem

ficient for the FE models built from four-node linear tetrahedral elements, size 1.8, with six degrees of freedom per node, representing the entire intact tibia and reconstructed ones, guaranteeing the loading configurations used in the present study. Viceconti et al. [33] found that tetrahedral meshing yields the best results in cases where a solid model of bone is available, which is the case of the "standardized tibia" used in this study. Polgar et al. [34], in a comparative study between linear (four nodes) and quadratic (ten nodes) tetrahedral elements used to mesh a human femur, conclude that linear elements should be avoided and quadratic elements ought to be chosen whenever possible for the purpose of FE analysis on the human femur. The overall agreement between experimental and numerical strains in the tibia, obtained during this study, greatly contribute to proof that FE models of the proximal tibia based on linear tetrahedral elements are appropriate and minimize computational cost, since the results are strongly influenced by the nonlinear nature of the contact between the different components (implants, bone, and cement) coupled with large contact surfaces (tibial tray and noncemented stem).

The literature encounters several studies for FE model validation in what concerns intact and reconstructed proximal femurs involving the experimental bone surface strains in cadaveric and composite femurs [1,33,35–37]. The level of agreement was generally identical to the level reported here for the intact and reconstructed tibia. Experimental studies in cadaveric and composite tibias were carried out [19,22,38], but no comparison has been established between the experimental bone surface strains and the FE data obtained. Therefore, a direct comparison between the obtained results to other published data is not possible, since to the author's best knowledge no work has been published addressing this issue, in particular.

The bone strains predicted by the FE models depend on the material properties, and the mechanical behavior of the synthetic tibia are difficult to reproduce in FE analyses, due to the complex and inhomogeneous structure of the cortex. A previous study reported [17] found that, when considering bending loads, the mechanical properties of the cortex of the synthetic femur can be considered to be isotropic, instead of transversely isotropic, without much less accuracy. The loads applied on tibia models in the medial and lateral condyles generate mainly compression and bending loads in proximal tibia; therefore, during this study it was assumed a cortex completely isotropic with an elastic modulus of 12.4 GPa (Table 3). Furthermore, the bone strains predicted by FE models depend on the implant-bone interface and implant-cement interface conditions assumed. The results reported show that high correlations values (R^2) and the low RMSE values between numerical and experimental bone strains were obtained with friction considered at the implant-bone interface (μ=0.3) and implant-cement interface (μ=0.25), when compared to bonded interfaces, where the major difference was found for the noncemented stem model.

A first requirement for FE models to be used in preclinical tests is that they accurately reproduce the mechanical behavior of the reconstructed joint. The four models assessed in this study for total knee arthroplasty (TKA), representative of different designs (intact tibia, implanted tibia with and without stem) with diverse interface conditions (cemented stem versus noncemented stem) were successfully validated proving to be suitable for that specific purpose. It is therefore required to carry out the subsequent steps in order to guaranty its accurate usage, to simulate clinical errors, such as misalignment of the implants in the proximal tibia after surgery, and to simulate long-term failure according to a damage accumulation failure scenario. Additionally, in this study, a research protocol has been established that can be used for the validation of FE models of reconstructed proximal tibia for other research issues related to TKA.

Since it would also be interesting to obtain the strains more proximally in the condyles region, and since it is technically quite difficult to place strain rosettes in that region of the tibia without damaging them when performing the in vitro surgeries to implant the stems, the finite element model assumes an advantage relative to the experimental models, since it enables the assessment of the strains in this region. The study performed to validate the FE models was based on the comparison of periosteal bone strains to different interface-bonding conditions and, this issue may be one limitation of this study. A more effective validation with other parameters, such as prestress, nonlinear mechanical behavior of cortical and cancellous bone, and relative micromotion between bone and stem, can also be used for a more reliable FE model validation.

5 Conclusions

The study reported proved that FE models of intact tibia and implanted tibia with three different design components could reproduce experimental strains within an overall level agreement of 10%. The FE models correctly reproduced bone strains under most important loads, acting in the condylar surface of the tibia. For this reason, these FE models can adequately reproduce the mechanical behavior of the intact and reconstructions of tibia and are essential for the prediction of biomechanical changes of tibia with slight or considerable misalignment of the implant and long-term failure. This knowledge provides a good basis for further development of standardized FE preclinical test for knee replacements in tibia.

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