

Patient-specific finite element analysis of femurs with cemented hip implants

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Abstract

Background: Over 1.6 million hip replacements are performed annually in **Organisation for Economic Cooperation and Development** countries, half of which involve cemented implants. Quantitative computer tomography based finite element methods may be used to assess the change in strain field in a femur following such a hip replacement, and thus determine a patient-specific optimal implant. A combined experimental-computational study on fresh frozen human femurs with different cemented implants is documented, aimed at verifying and validating the methods.

Methods: Ex-vivo experiments on four fresh-frozen human femurs were conducted. Femurs were scanned, fractured in a stance position loading, and thereafter implanted with four different prostheses. All femurs were reloaded in stance positions at three different inclination angles while recording strains on bones' and prosthesis' surfaces. High-order FE models of the intact and implanted femurs were generated based on the computer tomography scans and X-ray radiographs. The models were virtually loaded mimicking the experimental conditions and FE results were compared to experimental observations.

Findings: Strains predicted by finite element analyses in all four femurs were in excellent correlation with experimental observations $FE = 1.01 \times EXP - 0.07$, $R^2 = 0.976$, independent of implant's type, loading angle and fracture location.

Interpretation: Computer tomography based finite element models can reliably determine strains on femur surface and on inserted implants at the contact with the cement. This allows to investigate suitable norms to rank implants for a patient-specific femur so to minimize

changes in strain patterns in the operated femur.

26 *Keywords:* Total hip arthroplasty, p-FEMs, Femur

27 **1. Introduction**

28 Total hip arthroplasty (THA) is a common procedure, with 1.6 million operations per-
29 formed annually in the OECD countries (Pabinger and Geissler, 2014). Cemented stems are
30 used in approximately half of the cases (Garellick et al., 2014; Havelin, 2016; Porter, 2016).
31 The metallic stem inserted into the femur changes its natural stress/strain distribution that
32 may lead to bone resorption that is detrimental to mechanical stability (Jayasuriya et al.,
33 2013; Stucinskas et al., 2012).

34 Implants are usually chosen based on patient's age and bone quality - cemented implants
35 are commonly preferred for older patients. Geometrical compatibility of implant and femur
36 is assured by 2D radiographs or preoperative 3D planning software. Biomechanical aspects
37 as to the strain/stress distribution in the implant-bone compound may prove to be useful in
38 choosing an optimal implant. Such a biomechanical insight is available nowadays by finite
39 element analyses (FEA) that may identify the implant that causes the least deviation in the
40 strain distribution compared to the strain distribution before fracture. Such FEA must first
41 be verified and experimentally validated (Standards, 2006; Henninger et al., 2010) in ex-vivo
42 studies and must demonstrate that the biomechanical response is independent of the type
43 of implant and direction of applied hip contact load. Since strains inside the bone at the
44 interface with the implant cannot be experimentally measured, strain measurements on the
45 implant's surface, being the closest to bone's inner tissue, should be addressed.

46 FEAs validation studies of implanted femurs were often performed on synthetic femurs
47 (Chen et al., 2013; Stolk et al., 2002; Chen et al., 2004) that do not well represent the
48 complexity of cadaveric femurs (Grant et al., 2007; Zdero et al., 2008). Only few studies
49 validated FEA by experiments on cadaveric femurs. Among these the pioneering study
50 performed three decades ago (Rohlmann et al., 1983) and a comprehensive validation study
51 performed on seven femurs with *cementless* implants Pettersen et al. (2009). In these studies
52 strains were not measured on the stem inside the femur and only one type of prosthesis was

53 investigated.

54 Patient-specific high order FEA of intact femurs, based on CT-scans (CTFEA) were
55 verified and double-blind validated in (Trabelsi et al., 2011), and a feasibility study to extend
56 these CTFEAs to a human femur with a cemented prosthesis was successfully completed in
57 (Yosibash et al., 2012). In this study one femur with one implant was studied, and difficulties
58 were encountered in determining the precise location of the implant in the bone and the
59 measurement of the friction load between actuator and implant's head.

60 To further verify and validate the CTFEA technology for the analysis of implanted fe-
61 murs we herein consider four femurs with four different cemented implants and present a
62 novel methodology to accurately determine implant's location. Friction forces in one of two
63 directions are eliminated by a new developed experimental jig.

64 We hypothesize that CTFEAs can reliably predict the mechanical response of a femur
65 with an implant for any femur or implant type, at various hip contact loads applied at
66 different angles. Validating this hypothesis while accounting on measurements performed
67 also inside the femur i.e. on the implant's surface, enhance the reliability of CTFEAs and
68 allows future research so to select an optimal patient specific implant.

69 **2. Methods**

70 Four fresh frozen femurs (National Disease Research Institute, Philadelphia, PA, USA)
71 were implanted with four different cemented prostheses. Donors and prosthesis details are
72 provided in Table 1. Experiments performed on the femurs in both intact and implanted
73 states were simulated by CTFEA and the predicted strains were compared to experimental
74 observations for validation purposes.

75 *2.1. Ex-vivo experiments*

76 All femurs were cleaned of excess fat and soft tissue, distally cut and imbedded 10 cm into
77 a steel cylinder using PMMA. The shaft was aligned with the cylinder axis and the head was
78 placed in the middle of cylinder's square base (see Fig.2). QCT scans were performed by a
79 Phillips Brilliance 64 CT scanner (Eindhoven, Netherlands) at 120 kVp while the femurs are

Table 1: Summary of donor data and prostheses used

Abbrev.	Donor						Prosthesis	
	Gender	Age (years)	Height [cm]	Weight [kg]	L/R	Death cause	Manufacturer	Model
FFM7R	Female	75	162	41	R	cervical cancer	Protec	LOT 2018 7.5 mm
FFB1R	Male	67	178	84	R	heart failure	Protec	LOT 2132 10 mm
FFB1L					L		Groupe Lepine	PAVI H015 0214
FFY	Male	20	185	68	L	drug overdose	Aesculap	ISONIC NK 082 s 8

Scanning parameters

Abbrev.	mAs	Slice thickness & spacing		Pixel size [mm]	medical center
		between slices [mm]			
FFM7R	250	1.25		0.195	Hadassah Ein Kerem
FFB1R	350	1		0.24	Barzilai
FFB1L	300	1		0.3125	Barzilai
FFY	250	1.25		0.336	Hadassah Ein Kerem

80 immersed in water with five K_2HPO_4 calibration phantoms. Uniaxial strain gauges (SGs)
81 (C2A-06-125 LW-350, Micro Measurements, Raleigh, USA) were bonded on femurs' surface.
82 Additional SGs were bonded to the prostheses prior to implantation. To protect SGs' leads
83 from tearing, the wires were attached to the implant using adhesive. SGs locations are shown
84 in Figure 1.

85 Loading experiments were performed using the jig shown in Fig. 2. The jig is free to
86 slide in the coronal plane implying zero horizontal force. It consists of a carriage (5) free
87 to slides on four low friction linear bearings and two fitting rail assemblies (*ThomsonTM*,
88 Radford, USA) (8). On the carriage, a platform (4) is fixated with two identical pins (6).
89 The platform has four holes to allow its inclination at various angles ($0^\circ, 7^\circ, 15^\circ$) representing
90 physiological loading positions (Bergmann et al., 2001). Load was applied by a Shimadzu
91 AG-IC machine (Shimadzu Corporation, Kyoto, Japan) trough a flat actuator pressed against
92 the femoral/implant's head. Forces were measured by a six-axes load cell (ATI Omega 191,
93 Apex, USA), located between the machine's bridge and actuator.

94 The femurs were anchored to the jig using four bolts at the cylinder's base (see Fig. 2) and
95 thereafter inclined laterally by tilting jig's platform (inclination plane is aligned with femur's

96 head center and shaft axis). All femurs were loaded to 1500 N at 5 $\frac{mm}{min}$ at 0°, 7° and 15°
97 loading configurations. The intact femurs FFB1L and FFB1R were loaded to fracture at 15°
98 inclination at 10 $\frac{mm}{min}$, prior to implantation. FFM7R was loaded to fracture in a past study
99 (Yosibash et al., 2014) and FFY was cut and implanted immediately after the CT scan, no
100 fracture loading was performed on it. Following fracture at the neck in FFB1R, FFB1L and
101 FFM7R and the cut of FFY, the prosthesis was implanted by an orthopedic surgeon. Figure 1
102 shows the four implanted femurs, the corresponding prostheses and the SGs locations. Figure
103 3 illustrates the experiments performed on FFB1R and FFB1L. Strains, displacements and
104 load were recorded using a Vishay system 7000 combined with StrainSmart software at a
105 sampling rate of 128 Hz.

106 Displacements were measured by linear displacement sensors (LDS) (Micro Measure-
107 ments, Raleigh, USA) The horizontal displacement was measured at the cylinder and vertical
108 was measured at the actuator. To examine femurs' linear elastic response, the strain vs. force
109 was plotted for each SG at each loading configuration. The slope was computed using linear
110 regression (typically between 800 N and 1200 N) and strain value at 1000 N loading was
111 determined from the slope. Each loading was repeated three times to confirm repeatability
112 and the average strain value was used. Same procedure was repeated for the displacements
113 measured by the LDS.

114 2.2. FE models

115 Femur's geometry and pointwise material properties were determined from the intact
116 femurs' CT scans following (Yosibash et al., 2007). Since CT scans of the implanted femurs
117 are distorted by the metallic prosthesis, they could not have been used for modeling. Instead,
118 the intact femurs' CTs were manipulated: femurs' models were "cut" at the neck and a CAD
119 model of the implant was virtually inserted (implant's CAD model was obtained by 3D laser
120 digitization prior to implantation).

121 The steel cylinder plays a key role in the recreation of the experimental conditions, because
122 it has a well defined geometry and configuration both in the experimental setting and in the
123 recreated model. The femur's orientation inside the cylinder defines the boundary conditions

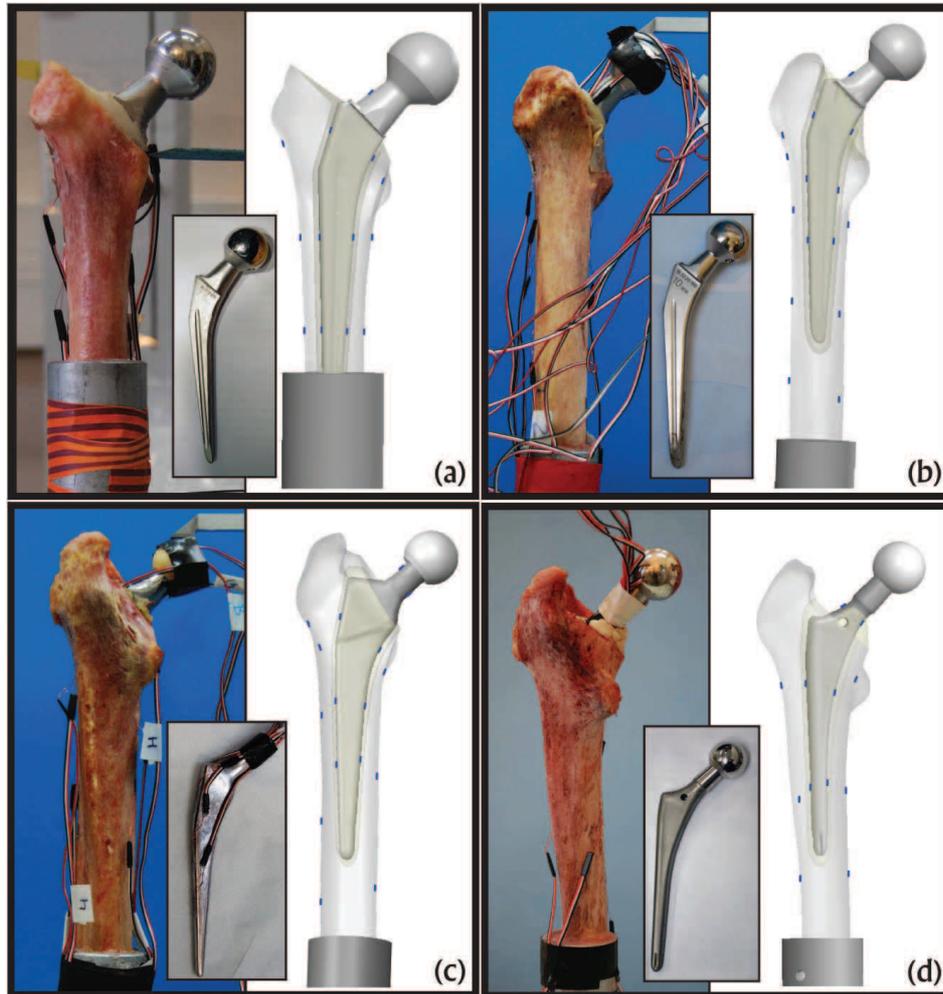


Figure 1: The four implanted femurs, corresponding prostheses and geometric models of cemented THA with SG locations. a) FFM7R b) FFB1R c) FFB1L d) FFY.

124 and loading directions.

125 Implanted femurs underwent X-ray radiographs along sagittal and coronal planes (parallel
 126 to the square cylinder base). These radiographs were imported into Solidworks (Dassault
 127 Systemes SolidWorks Corp, Waltham, USA) and placed onto the corresponding cylinder's
 128 planes. The radiographs were aligned with the cylinder and scaled to fit actual dimensions.
 129 Femur's CAD model was placed inside the cylinder, so it matches its projections on the two
 130 perpendicular radiographs. The implant was also positioned similarly. The entire algorithm
 131 is presented in Figure 4.

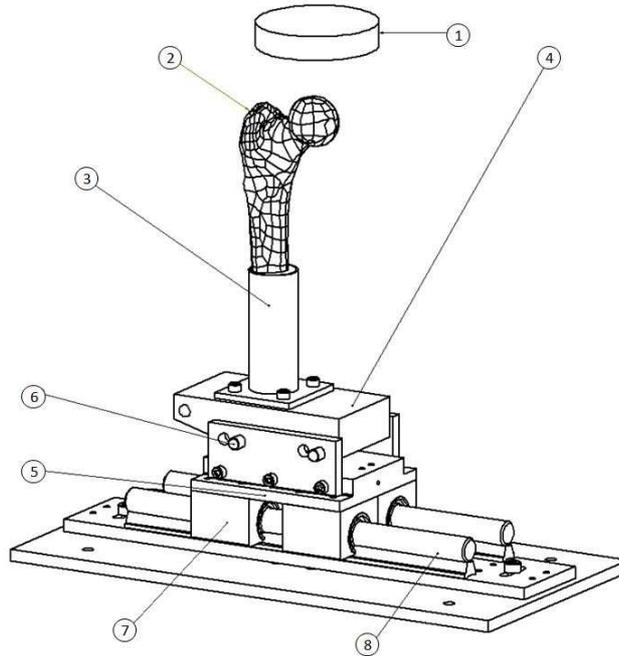


Figure 2: New jig (0° tilt). (1) Machine actuator (2) Fresh frozen bone (3) Steel cylinder (4) Platform (5) Carriage (6) Pins (7) Linear bearings (8) Rails.

132 Dimensions of the cement layer around the implant are invisible in the CT scan due
 133 to artifacts caused by the metallic implant, and are hardly visible in the X-ray images.
 134 The cement was assumed to have the same shape as the implant and to be homogenously
 135 distributed around it with an average thickness of 3 mm (Isaac et al., 2000). A scaled model
 136 of the implant was used to recreate cement's geometry as shown in Fig. 4. The remaining
 137 cement outside the femur was modelled based on radiographs and photographs. SG locations
 138 on the bone and implant were modelled based on geometrical length measurements. SGs
 139 exact orientation and horizontal positioning were assured based on photographs imported
 140 into Solidworks and aligned with the CAD model (see Fig. 4).

141 A sensitivity analysis that quantifies the influence on cement's thickness was performed
 142 by considering a FE model with the bone up to the implant (cement thickness layer was set
 143 to zero in the model). FE strains at the SG locations where compared between the two
 144 models (with and without a cement layer) and the absolute relative difference (relatively to
 145 the CTFE model with a cement layer) was computed.

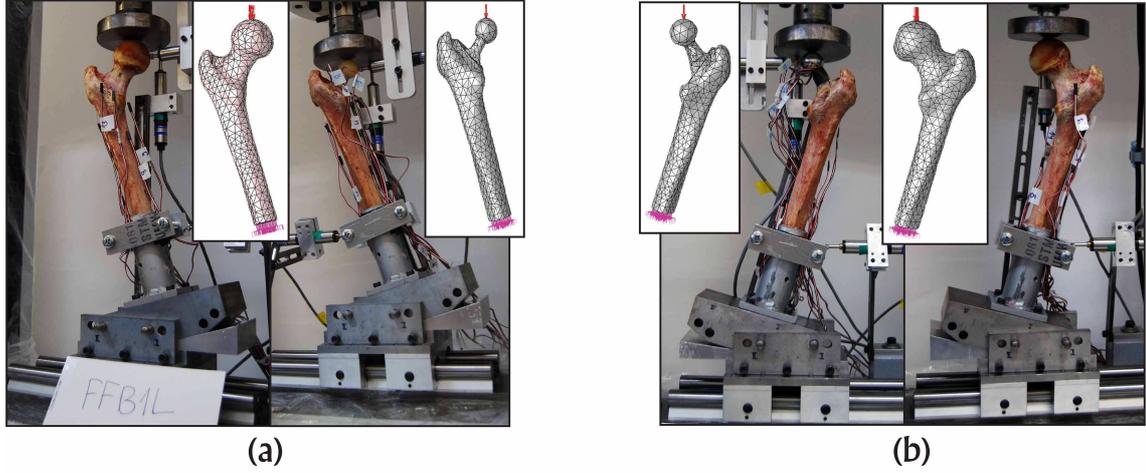


Figure 3: FFB1 loaded at 15° , Experiment and FE model: (a)FFB1L and FFB1L Imp (b)FFB1R and FFB1R Imp

146 2.3. CTFE analyses

147 A tetrahedral mesh was automatically generated resulting in 7500 to 10000 tetrahedrons
 148 for the implanted femurs (1.4-2.5 million degrees of freedom (DOF) at $p=8$) and about 4000
 149 elements for the intact femurs (about 1 million DOF at $p=8$).

150 Analysis of the QCT scan calibration phantoms' density and HUs resulted in:

$$\rho_{K_2HPO_4} = 10^{-3} (0.8 \cdot HU), \quad (1)$$

151 Ash density ρ_{ash} was determined based on $\rho_{K_2HPO_4}$ according to relations obtained in Faulkner
 152 et al. (1993) ($\rho_{K_2HPO_4}$ to ρ_{HA}) and Schileo et al. (2008) (ρ_{HA} to ρ_{ash}):

$$\rho_{ash} = (0.877 \times 1.15 \times \rho_{K_2HPO_4} + 0.08)[gr/cm^3] \quad (2)$$

153 Following (Yosibash et al., 2012, 2014), an inhomogeneous isotropic Hooke's model was used
 154 depending on ρ_{ash} :

$$E_{cort} = 10200 \cdot \rho_{ash}^{2.01} [MPa], \quad \rho_{ash} > 0.486 \quad (3)$$

$$E_{trab} = 2398 [MPa], \quad 0.3 < \rho_{ash} \leq 0.486$$

$$E_{trab} = 33900 \cdot \rho_{ash}^{2.2} [MPa], \quad \rho_{ash} \leq 0.3 \quad (4)$$

155 where E_{cort} and E_{trab} are Young's moduli for cortical and trabecular bone respectively.

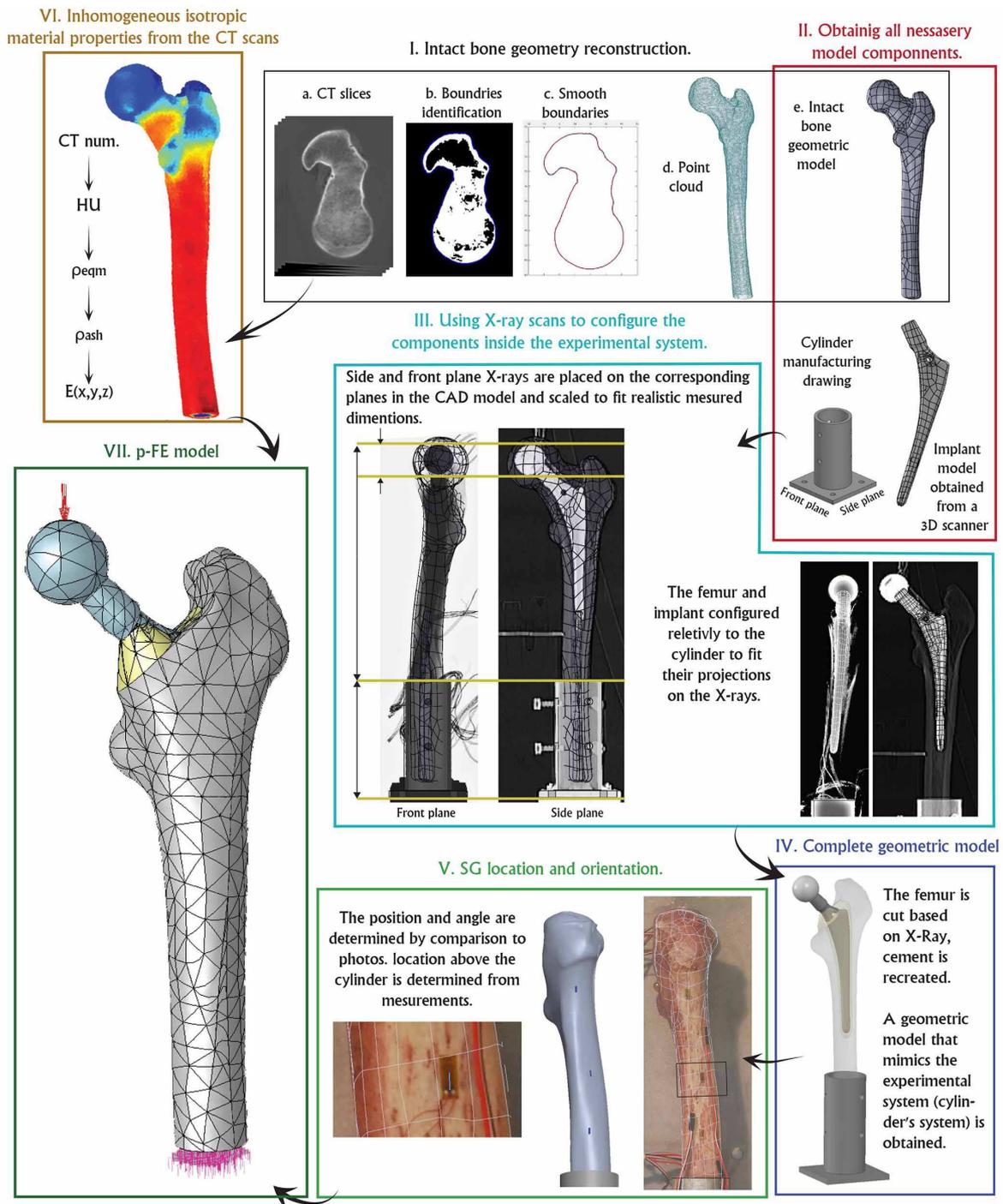


Figure 4: Construction algorithm of the CTFE model.

156 Poisson's ratio was taken as 0.3.

157 Material properties of the implants were found as follows: Density was calculated based

158 on the volume obtained from a 3D laser scan and their mass (7.85 *gr/cc* typical to stainless
159 steel). In addition, energy dispersive X-ray analysis (EDXA) was performed on one implant
160 showing a chemical composition of a high quality stainless steel: 22.19% Cr and 8.88% Ni.
161 Following these observations, mechanical properties typical to stainless steel were assigned
162 to the implant: $E_{Imp} = 200$ GPa, $\nu=0.3$.

163 Cement's Young modulus was determined by compression experiment conducted on cylin-
164 drical specimens created from same cement used during implantation, resulting in $E = 2.7$
165 GPa and $\nu=0.3$. In all CTFE models the implant was perfectly bonded to the cement that
166 was perfectly bonded to the bone.

167 A 1000N load was applied to head's surface at $0^\circ, 7^\circ$ and 15° . The direction of the load
168 and inclination plane were defined relatively to the upper cylindrical steel surface (cylinder
169 not included in the FE model). The femur was clamped at the distal end of the shaft. In the
170 experiment the distal shaft could slide laterally, while the head position remained constant
171 under the actuator. In the CTFE model we fully constrained the distal shaft and applied no
172 constrain on the head. These boundary conditions are equivalent.

173 Linear FE analyses were performed by increasing the polynomial degree (from 6 to 8)
174 using StressCheck software (ESRD, St. Louis, USA). Once ensuring that the error in energy
175 norm had converged, strain convergence was confirmed at the SG locations, and principal
176 strains were extracted and averaged along the length of each SG.

177 *2.4. Analysis of results*

178 Strains measured by the SGs were compared to the ones predicted by the CTFEA. Most
179 SGs were well aligned along the principal strain direction. Displacements were extracted and
180 averaged on the loading surface at the head.

181 To quantify the agreement, linear correlation (LC) and Bland-Altman (BA) plots (Bland
182 and Altman, 1986) were generated. The root-mean-square error (RMSE) was also calculated.
183 In BA plots the y-axis represents the difference in absolute principle strain values so that
184 positive values represent larger strains in experiment (stiffer CTFE model) whereas negative
185 values represent a "softer" CTFE model.

186 The yield load of the intact femurs FFB1L, FFB1R and FFM7R (yielding was noticed
187 before fracture) was measured and is provided in Appendix A in the Supplementary material.

188 To quantify the effect of the cement layer on the predicted SG strains, absolute relative
189 difference and RMSE between the fully cemented and zero cemented models was calculated:

$$RMSE = \sqrt{\frac{\sum_1^N (\varepsilon_{cemented} - \varepsilon_{noncemented})^2}{N}} \quad (5)$$

190 where N is the number of SG data available (number of SG times the number of loading
191 inclinations).

192 To quantify the change in the biomechanical conditions following the insertion of the
193 implant, Relative (*Rel*) and absolute (*Abs*) change in principal strains was calculated. The
194 calculation was performed at the implant's mid-plane, while addressing tensile strains at the
195 lateral side of the femur and compressive strains at the medial side. The computation was
196 performed using: (6-7):

$$Abs = |Intact_{\varepsilon_{1/3}}| - |Implant_{\varepsilon_{1/3}}| \quad \text{Absolute Diff} \quad (6)$$

$$Rel = \frac{Intact_{\varepsilon_{1/3}} - Implant_{\varepsilon_{1/3}}}{Intact_{\varepsilon_{1/3}}} \quad \text{Relative Diff} \quad (7)$$

197 where $Intact_{\varepsilon_{1/3}}$ and $Implant_{\varepsilon_{1/3}}$ are maximum principal strains before and after implanta-
198 tion.

199 3. Results

200 A linear response between load and measured strains was observed in the experiments
201 for all femurs at all inclination angles with a linear regression coefficient $R^2 > 0.99$. The
202 three repeated loads at all configuration showed high repeatability: strains typically varied
203 by 10-20 $\mu strain$ between repetitions.

204 All FE models were monitored so to ensure an error in energy norm below 6% at $p = 8$.
205 Strain converged to $\sim 1\%$ relative error between consecutive FEAs. Figure 5 shows the FE
206 mesh and principal strains on the four implanted femurs.

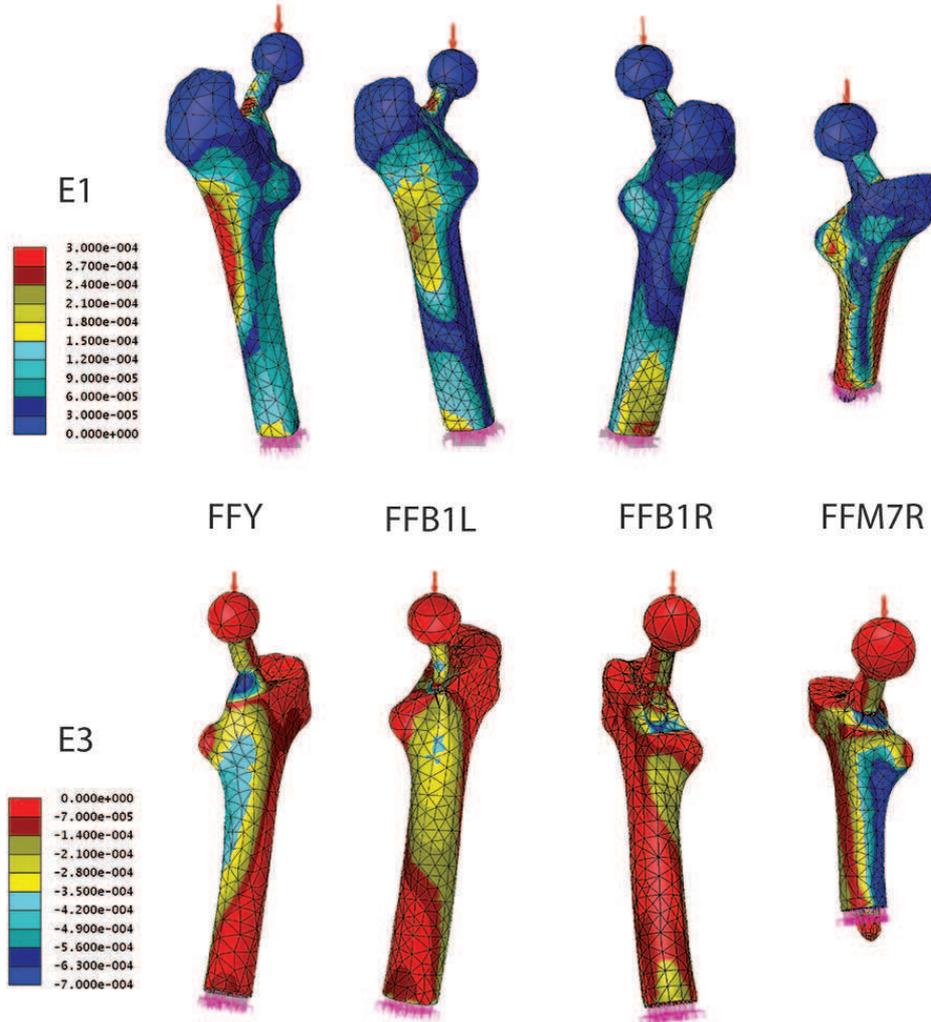


Figure 5: The four FE meshes for the implanted femurs (cement modelled) loaded at 15° and the maximum (top) and minimum (bottom) principal strains.

207 The linear correlation and RMSE between experiments and CTFEA is presented in equa-
 208 tion (8) for the two intact femurs and in equation (9) for the four implanted ones. The BA
 209 and LC plots are shown in Figure 6.

$$FE = 0.979 \times EXP - 5.44 \quad (R^2 = 0.987), \quad RMSE = 95 \quad [\mu strain] \quad (8)$$

210

$$FE = 1.01 \times EXP - 0.07 \quad (R^2 = 0.976), \quad RMSE = 84 \quad [\mu strain] \quad (9)$$

211 The LC obtained for each experiment separately is detailed in the following, plots and
 212 detailed results for each SG and every loading condition are summarized in Appendix B.

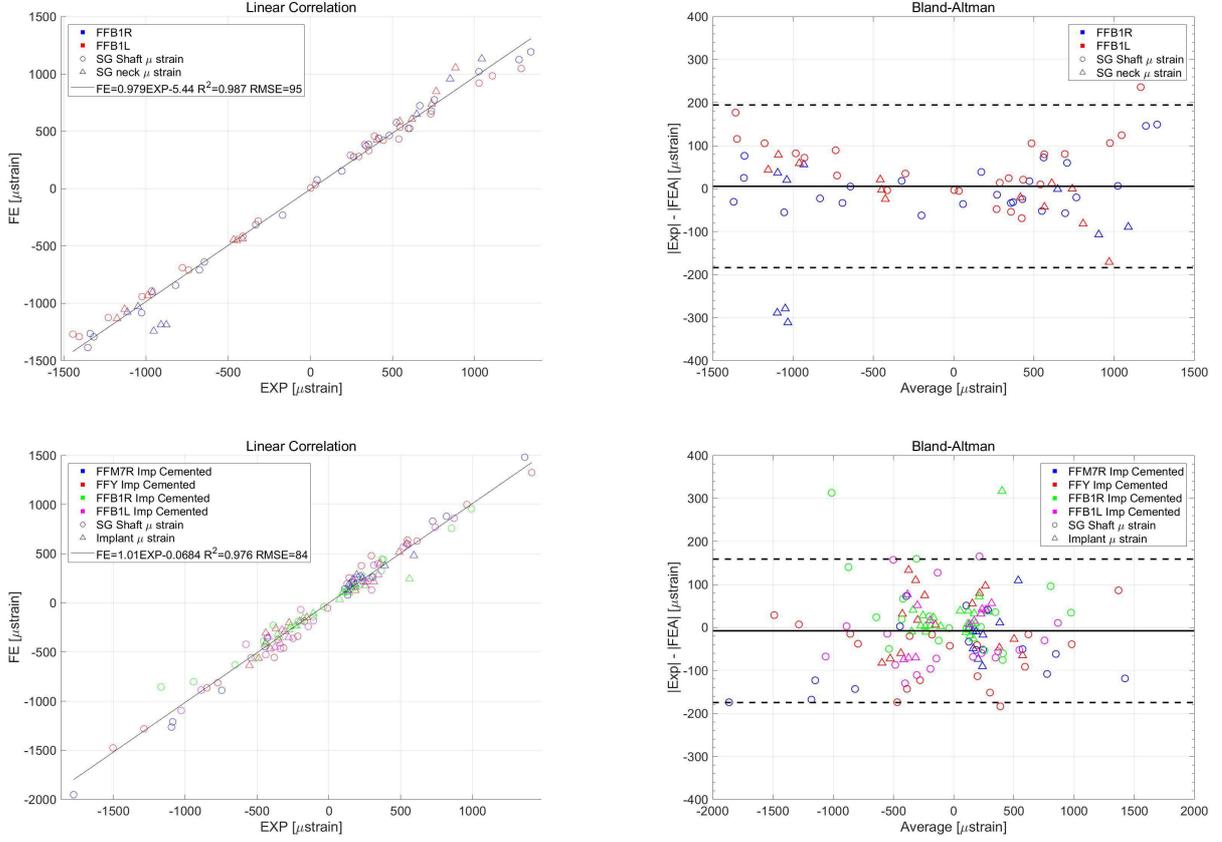


Figure 6: LC and BA plots including data of all intact (Top) and all implanted femurs (Bottom). All models include the cement.

213

$$FE [\mu \text{ strain}] = a \times EXP + b, \text{ where}$$

Femur	a	b	R^2
FFB1R	1.02	-25.2	0.987
FFB1L	0.935	13.6	0.993
FFM7R Imp	1.09	-4.56	0.994
FFB1R Imp	0.873	2.99	0.968
FFB1L Imp	1.02	-12.3	0.972
FFY Imp	1.02	2.02	0.981

214

The FE results for models with cement at the bone-implant interface were compared

215

to the ones without. A mean absolute difference of 4.2% and RMSE of 32.7 μ strain were

216

obtained accounting for all femurs and all locations. Analyzing implant and bone strains

217

separately, one obtains a difference of 2.4% (RMSE = 6.6 μ strain) for the implant strains

218 and 5.4% (RMSE = 42.6 μ strain) for bone strains. The linear correlation between the strains
219 in the cemented and non-cemented models resulted in a slope of 0.996, intersection of 6.39
220 and $R^2 = 0.975$

221 Figure 7 illustrates the relative and absolute differences in principal strains following
222 implant insertion for FFB1R at 7° loading, demonstrating a decrease in strains in almost all
areas.

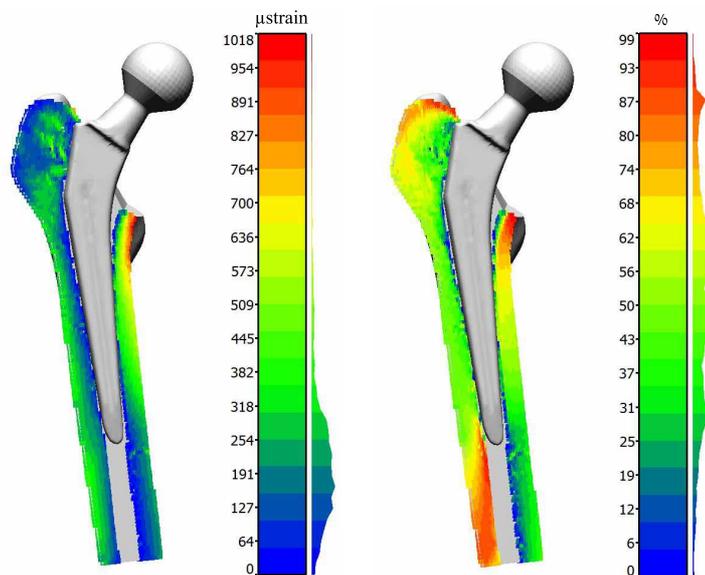


Figure 7: Strain shielding quantification for FFB1R at 7° loading using a simplified model which does not include the cement layer. Left: Absolute difference in principal strains (6). Right: Relative difference in principal strains (7).

223

224 4. Discussion

225 To the best of our knowledge, only a scarce number of studies presented verified and vali-
226 dated CTFE models of fresh-frozen human femurs with cemented prostheses. Herein methods
227 for the analysis of implanted femurs by high order FE methods were improved and validated
228 by ex-vivo experiments on four fresh frozen femurs with different prostheses. A construction
229 methodology to determine the prosthesis location within the femur was presented. An ex-
230 cellent correlation was obtained between experimental observations and FE predictions for
231 each of the implanted and intact femurs considering all three loading angles. The overall

232 agreement for all intact femurs was: $FE = 0.979 \times EXP - 5.44$, $R^2 = 0.976$ and for all
233 implanted ones was: $FE = 1.01 \times EXP - 0.07$, $R^2 = 0.976$. The slope values are close to
234 one and the intersection is close to zero. The RMSE between the experimental results and
235 the predicted values was less than $100 \mu\text{strain}$ while the strain values were $\pm 1500 \mu\text{strain}$. No
236 bias was observed In the BA plots (average error is close to zero) and the standard deviation
237 of the differences (random fluctuations) is small relatively to the measured/predicted values.

238 Validation is enhanced following our former study, where a single implanted femur was
239 used (Yosibash et al., 2012) and the lateral force has been assumed since it was not measured.
240 The improvements in the experimental system and the accurate CTFE model construction
241 in the current study improves the reliability of the predicted strains. The cohort of different
242 femurs and implants used for validation is also significantly increased (five in total), further
243 demonstrating that the model is femur/implant independent.

244 The cement modelling had negligible effect on the strains predicted at the SG locations,
245 attributed to the similarity in stiffness between the cement and the bone tissue. Both CTFE
246 models, with and without cement, were in good agreement with the experimental measure-
247 ments. This suggests that a simplified CTFE model, where the cement thickness is zero, may
248 be sufficient for experimental validation. Moreover, because the cement distribution cannot
249 be known preoperatively, such a simplified FE model may be a reasonable approximation and
250 might well serve for implant comparison and choice prior to implantation. Factors such as
251 implant's geometry and material are presumably much more dominant in their biomechanical
252 effect than the cement thickness - factors that will be verified in a future work.

253 Once patient specific CTFE models were shown to well predict the mechanical response
254 of both intact and implanted femurs (Yosibash et al., 2012; Trabelsi et al., 2011), these may
255 provide quantitative measures on the strain alteration due to the presence of an implant, i.e.
256 quantify strain-shielding. However, several different stress/strain-shielding measures exist:
257 some based on von Mises stresses (Yamako et al., 2014; Joshi et al., 2000; Pettersen et al.,
258 2009; Hirata et al., 2013), some based on von Mises strains (Pettersen et al., 2009), some
259 based on strain energy density (Yamako et al., 2014) and some based on the principal strains
260 (Cilla et al., 2017). In many cases these measures are computed on bone or implant surfaces

261 rather than inside the femur and changes between the intact and implanted configurations
262 are not quantified but qualitatively discussed.

263 Relative changes and absolute differences in principal strains between the intact implanted
264 femur was presented in Figure 7 for FFB1R at 7^0 loading. Similarly to Gruen zones (Gruen
265 et al., 1979) commonly used in clinical practice to qualitatively evaluate bone mineral density
266 (BMD) resorption, one may consider different volumes/areas as in Figure 7 to quantify the
267 strain shielding effects and minimize them by a proper implant. Herrera et al. (Herrera
268 et al., 2014) monitored patients after cemented prostheses (two kinds) and reported that
269 BMD decreased in all Gruen zones post prosthesis implantation (Fig. 4 in (Herrera et al.,
270 2014)). Jayasuriya et al. (Jayasuriya et al., 2013) reported on a decrease in BMD over the first
271 year with greatest loss of 14% in the proximal medial femur (Gruen zone 7). Stucinskas et
272 al. (Stucinskas et al., 2012) report on a significant decrease in cortical thicknesses in total hip
273 arthroplasty at all periprosthetic levels but less expressed distally. These clinical observations
274 are coherent with our FE predictions: one notices in Fig. 7 that maximum principal strain
275 decreased everywhere around the prosthesis.

276 The verified and validated (V&V) high order FE technique presented herein is a first
277 essential step to reliably address strain shielding by FEA. An appropriate norm to quantify
278 strain shielding has still to be determined and validated by comparison to clinical observa-
279 tions, which is a topic of future investigation.

280 There are two limitations of our study. Validation of CTFE results was performed on
281 the basis of a limited number of locations at which principal strains were measured. Vertical
282 measured displacements were consistently larger than CTFE predictions due to movement
283 of the distal part of femur's shaft placed within the PMMA. Future experiments will use
284 a digital image correlation system that will allow thousands of locations to be compared.
285 Linear and isotropic material properties were shown to be appropriate for FEA of intact
286 femurs (Trabelsi et al., 2011; Trabelsi and Yosibash, 2011). This assumption should be re-
287 evaluated for implanted femurs.

288 **5. Conclusions**

289 A high order CTFE model simulating the prosthesis location within the femur was pre-
290 sented and validated by experimentation. An excellent correlation of CTFE strains on femur's
291 and prosthesis' surfaces (inside the bone) to experimental observations was obtained for the
292 different femurs and implants examined. This allows the use of the validated CTFE models to
293 investigate strain-shielding effects in these locations within the bone that cannot be accessed
294 by any experimental measurement system. An appropriate norm to quantify strain shielding
295 has still to be determined and validated by comparison to clinical observations, which is a
296 topic of future investigation.

297 **Conflict of Interest**

298 YK and OL have no conflicts of interest. ZY has a financial interest in PerSimiO.

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403 **Appendix A. Yield load for the intact femurs**

404 The yield load of the intact femurs FFB1L, FFB1R and FFM7R (yielding was noticed
405 before fracture) was defined as the maximum recorded load before a deviation in the strain-
406 force slope occurs. In the FEA, the yield load was computed by the failure criterion based
407 on a linear elastic analysis and maximum principal strain on bone surface as documented in
408 (Yosibash et al., 2010). The yield load in stance position is the load resulting in a maximum
409 principal strain in tension equal to 7300 μ strain (Bayraktar et al., 2004).

410 FFB1L and FFB1R, loaded at 15°, experienced yielding at the neck at \sim 8100 N and
411 7600 N and brittle-like tensile fracture at 8600 and 8100 N respectively. The FEA predicted
412 yielding loads of 7100 to 7300 N. FFM7R was fractured in a previous study, experiencing
413 yielding at 4800 N and fractured at 5300 N whereas the FE predicted yielding was 3730
414 N (Table 6 in (Yosibash et al., 2014)). Force vs strain plot for all three fractured bones is
415 shown in Figure A.8. The presented strains were measured by the SGs closest to the fracture
416 initiation location.

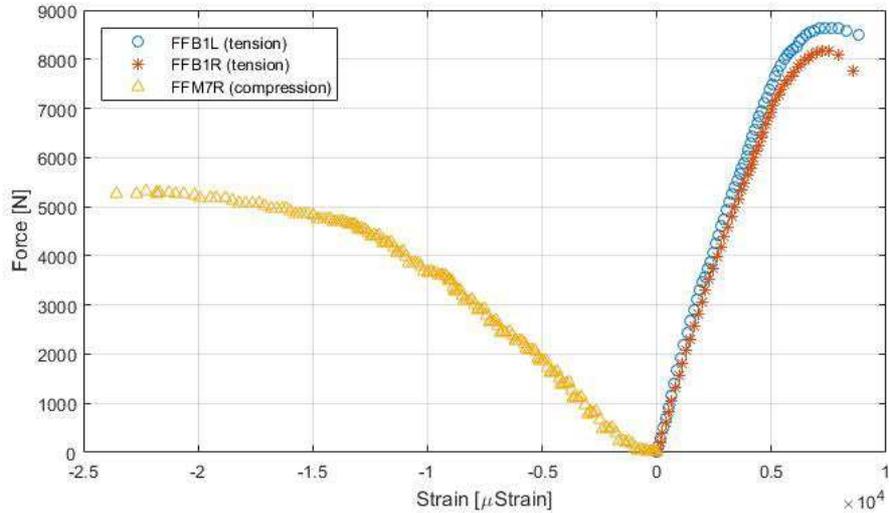


Figure A.8: Strains measured during fracture loading at the SG located closest to the fracture. Data for FFM7R was taken from (Yosibash et al., 2014)

417 The predicted yield load to fracture for the intact femurs FFB1L, FFB1R and FFM7R
 418 underestimated the experimental observation by 12.5%, 17% and 22%, respectively.

419 Appendix B. Experimental data and FE results

420 This appendix summarizes all measured strains and displacements and the corresponding
 421 QCT-FE results. Some of the SGs were damaged during prosthesis implantation so no data
 422 was recorded and some SGs were not bonded properly. These are marked blue and their
 423 data is discarded. Some SGs were bonded at neck's neutral axis and report on small strains,
 424 and in the FE analysis a very high sensitivity of the results to SG location in the FE model
 425 was noticed - these were also discarded and marked blue. We also discard displacements
 426 since the FE model does not represent the PMMA and cylindrical sleeve so measured and
 427 experimental displacements cannot be well simulated.

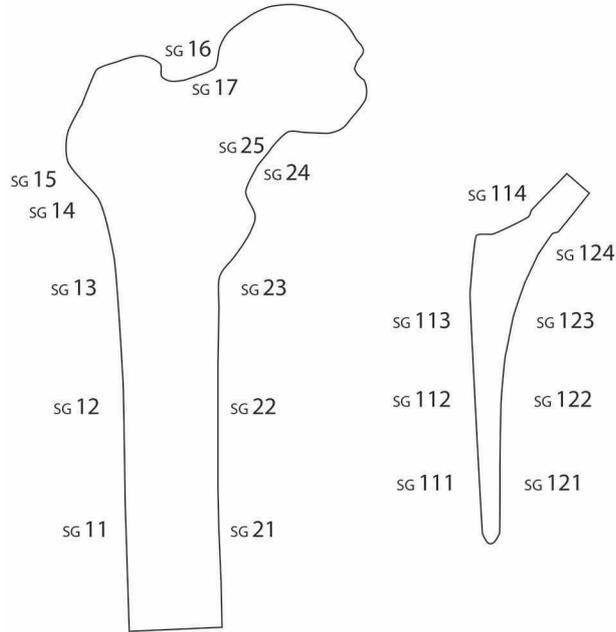


Figure B.9: Strain gauge notations for femurs and prostheses

Table B.2: FFM7R Imp: Experimental observations and FE results at 1000 N load.

	Strain [μ strain]													Disp [μ m]		
	SG 11	SG 12	SG 13	SG 21	SG 22	SG 23	SG 111	SG 112	SG 113	SG 114	SG 121	SG 122	SG 123	SG 124	Uz	Ux
0° loading																
Exp	1364	819	218	-1777	-1097	-81	-	592	194	181	-	-	-	-	-756	2040
FE	1483	881	270	-1952	-1265	-728	-	482	285	191	-	-	-	-	-420	1188
Diff %	-9	-8	-24	-10	-15	-802	-	18	-47	-6	-	-	-	44	42	
7° loading																
Exp	722	548	160	-1088	-746	-55	-	389	168	154	-	-	-	-376	1088	
FE	831	598	212	-1211	-889	-618	-	378	241	163	-	-	-	-218	793	
Diff %	-15	-9	-33	-11	-19	-1026	-	3	-44	-6	-	-	-	42	27	
15° loading																
Exp	131	305	109	-430	-446	-37	-	235	138	127	-	-	-	-152	-12	
FE	80	264	143	-357	-444	-489	-	252	187	128	-	-	-	-87	292	
Diff %	39	13	-30	17	1	-1210	-	-7	-35	-1	-	-	-	43	2446	

Table B.3: FFB1R Imp: Experimental observations and FE results at 1000 N load.

	Strain [μ strain]														Disp [μ m]	
	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	Uz	Ux
	11	12	13	14	21	22	23	111	112	113	115	121	122	123		
0° loading																
Experiment	993	854	380	39	-1169	-943	-654	301	561	151	189	-343	-357	-275	-494	2162
FE	958	758	440	235	-856	-803	-630	265	244	178	179	-353	-316	-271	-354	1437
Diff %	3	11	-16	-507	27	15	4	12	57	-17	5	-3	11	1	28	34
7° loading																
Experiment	227	365	228	27	-388	-454	-439	187	249	127	156	-225	-268	-236	-191	405
FE	226	329	282	179	-228	-388	-420	155	177	145	149	-235	-241	-233	-117	614
Diff %	0	10	-23	-565	41	15	4	17	29	-15	5	-5	10	1	39	-52
15° loading																
Experiment	-511	-109	105	24	370	-36	-215	74	141	97	122	-109	-179	-193	-202	849
FE	-561	-139	108	116	446	-38	-189	35	102	108	114	-106	-156	-188	-85	-304
Diff %	-10	-28	-3	-381	-20	-5	12	52	27	-12	7	2	13	2	58	136

Table B.4: FFB1L Imp: Experimental observations and FE results at 1000 N load.

	Strain [μ strain]														Disp [μ m]	
	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	Uz	Ux
	11	12	13	14	15	21	22	23	111	112	114	121	122	124		
0° loading																
Experiment	871	740	520	11	38	-1029	-890	-338	-	343	288	-	-421	-376	-279	1716
FE	861	770	572	171	192	-1096	-887	-468	-	287	247	-	-344	-451	-352	1275
Diff %	1	-4	-10	-1482	-404	-7	0	-38	-	16	14	-	18	-20	-26	26
7° loading																
Experiment	203	314	342	8	14	-440	-543	-250	-	258	243	-	-327	-339	-178	132
FE	263	384	398	147	137	-527	-558	-361	-	216	211	-	-275	-409	-140	675
Diff %	-29	-22	-16	-1822	-857	-20	-3	-44	-	16	13	-	16	-21	21	-412
15° loading																
Experiment	-579	-196	127	7	-6	297	-107	-144	-	133	178	-	-204	-280	-157	-750
FE	-421	-68	195	111	80	132	-179	-240	-	126	163	-	-187	-349	-61	-55
Diff %	27	65	-54	-1551	1484	56	-67	-67	-	6	8	-	8	-25	61	93

Table B.5: FFY Imp: Experimental observations and FE results at 1000 N load.

	Strain [μ strain]													Disp [μ m]	
	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	Uz	Ux
	11	12	13	21	22	23	111	112	113	121	122	123			
0° loading															
Experiment	1412	961	296	-1504	-1288	-381	-	313	540	-441	-440	-554	-985	1413	
FE	1326	1001	480	-1475	-1281	-555	-	216	605	-410	-307	-636	-644	2066	
Diff %	6	-4	-62	2	1	-46	-	31	-12	7	30	-15	35	-46	
7° loading															
Experiment	613	547	227	-775	-850	-315	-	256	489	-307	-370	-490	-404	1313	
FE	629	639	378	-813	-865	-458	-	176	516	-290	-260	-562	-273	1250	
Diff %	-3	-17	-67	-5	-2	-45	-	31	-6	6	30	-15	32	5	
15° loading															
Experiment	-171	174	142	-10	-355	-217	-	183	357	-154	-277	-408	-228	-162	
FE	-188	215	255	-53	-375	-340	-	128	404	-148	-203	-468	-93	238	
Diff %	-10	-24	-80	-428	-6	-57	-	30	-13	4	27	-15	59	247	

Table B.6: FFB1R (Intact): Experimental observations and FE results at 1000 N load. SG18 data was discarded because it is located at the highest point of the neck and the CT-scan slices above and below it are too far apart to contain the cortex. As a result the FE model at this point has no cortex properties and FE strain there is unrealistically large.

	Strain [μ strain]													Disp [μ m]	
	SG 11	SG 12	SG 13	SG 14	SG 15	SG 21	SG 22	SG 23	SG 16	SG 17	SG 18	SG 24	SG 25	Uz	Ux
0° loading															
Experiment	1342	1271	1026	666	416	-1340	-1318	-1354	1043	148	799	-1114	-953	-1008	-
FE	1193	1125	1020	723	441	-1264	-1293	-1385	1133	63	1525	-1077	-1242	-786	-
Diff %	11	11	1	-9	-6	6	2	-2	-9	57	-91	3	-30	22	-
7° loading															
Experiment	597	737	754	524	340	-645	-821	-1028	851	68	651	-1049	-909	-516	1538
FE	525	677	775	576	373	-640	-843	-1083	957	-47	1292	-1029	-1188	-407	1374
Diff %	12	8	-3	-10	-10	1	-3	-5	-13	169	-98	2	-31	21	11
15° loading															
Experiment	-169	192	481	355	263	41	-332	-675	647	-56	470	-961	-877	-307	93
FE	-231	153	464	386	278	77	-314	-709	648	-142	956	-905	-1188	-188	356
Diff %	-37	20	4	-9	-5	-88	5	-5	0	-154	-103	6	-36	39	-283

Table B.7: FFB1L (Intact): Experimental observations and FE results at 1000 N load.

	Strain [μ strain]													Disp [μ m]	
	SG 11	SG 12	SG 13	SG 15	SG 14	SG 21	SG 22	SG 23	SG 16	SG 17	SG 24	SG 25	SG 26	Uz	Ux
0° loading															
Experiment	1284	1108	1027	390	546	-1446	-1407	-1230	884	739	-1177	-467	-82	-995	2421
FE	1048	984	921	459	536	-1269	-1291	-1124	1054	739	-1133	-446	-165	-661	1986
Diff %	18	11	10	-18	2	12	8	9	-19	0	4	5	-101	34	18
7° loading															
Experiment	538	605	733	331	443	-779	-965	-1024	766	617	-1131	-447	-157	-524	1028
FE	433	525	653	385	423	-690	-893	-942	847	605	-1052	-450	-221	-346	1239
Diff %	20	13	11	-16	5	11	7	8	-11	2	7	-1	-41	34	-21
15° loading															
Experiment	-318	2	356	244	295	30	-412	-741	544	406	-990	-413	-244	-301	-89
FE	-283	5	331	292	281	36	-416	-711	587	426	-931	-437	-289	-191	305
Diff %	11	-167	7	-20	5	-18	-1	4	-8	-5	6	-6	-18	37	444

428 For the sensitivity analysis so to quantify the influence of the imprecise cement layer
429 thickness we compare the strain values obtained by FE models with the cement layer to FE
430 models in which the cement layer is zero (cement neglected).

Table B.8: FFM7R Imp: FE results for models with and without a cement layer. The values marked in red are untypical in their sensitivity to cement's presence (especially SG21).

	Strain [μ strain]										
	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG
	11	12	13	21	22	23	112	113	121	122	123
	0° loading										
Cemented	1483	881	270	-1952	-1265	-728	482	285	191	-440	-554
Non Cemented	1519	922	305	-1713	-1277	-757	494	284	193	-307	-636
	7° loading										
Cemented	831	598	212	-1211	-889	-618	378	241	163	-370	-490
Non Cemented	888	622	234	-1017	-870	-622	391	241	165	-260	-562
	15° loading										
Cemented	80	264	143	-357	-444	-489	252	187	128	-277	-408
Non Cemented	167	268	149	-203	-399	-471	268	188	130	-203	-468

Table B.9: FFB1R Imp: FE results for models with and without cement.

	Strain [μ strain]													
	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	SG	
	11	12	13	14	21	22	23	111	112	113	114	121	122	123
	0° loading													
Cemented	958	758	440	235	-856	-803	-630	265	244	178	179	-353	-316	-271
Non Cemented	959	730	429	247	-854	-812	-606	269	256	181	195	-348	-332	-278
	7° loading													
Cemented	226	329	282	179	-228	-388	-420	155	177	145	149	-235	-241	-233
Non Cemented	227	313	273	185	-227	-395	-405	154	188	149	162	-231	-253	-240
	15° loading													
Cemented	-561	-139	108	116	446	-38	-189	35	102	108	114	-106	-156	-188
Non Cemented	-560	-153	102	116	445	-31	-183	30	111	112	124	-101	-163	-194

Table B.10: FFB1L Imp: FE results for models with and without cement.

	Strain [μ strain]											
	SG 11	SG 12	SG 13	SG 14	SG 15	SG 21	SG 22	SG 23	SG 112	SG 114	SG 122	SG 124
	0° loading											
Cemented	861	770	572	171	192	-1096	-887	-468	287	247	-344	-451
Non Cemented	858	749	526	159	184	-1090	-875	-482	291	247	-332	-450
	7° loading											
Cemented	263	384	398	147	137	-527	-558	-361	216	211	-275	-409
Non Cemented	263	371	369	135	134	-528	-552	-373	215	210	-265	-407
	15° loading											
Cemented	-421	-68	195	111	80	132	-179	-240	126	163	-187	-349
Non Cemented	-423	-69	184	105	75	130	-174	-245	125	164	-183	-350

Table B.11: FFY Imp: FE results for models with and without cement.

	Strain [μ strain]										
	SG 11	SG 12	SG 13	SG 21	SG 22	SG 23	SG 112	SG 113	SG 121	SG 122	SG 123
	0° loading										
Cemented	1326	1001	480	-1475	-1281	-555	216	605	-410	-307	-636
Non Cemented	1335	1008	473	-1488	-1298	-548	220	603	-410	-302	-636
	7° loading										
Cemented	629	639	378	-813	-865	-458	176	516	-290	-260	-562
Non Cemented	632	643	372	-821	-878	-453	180	514	-289	-257	-563
	15° loading										
Cemented	-188	215	255	-53	-375	-340	128	404	-148	-203	-468
Non Cemented	-180	215	250	-44	-383	-336	130	403	-145	-201	-468

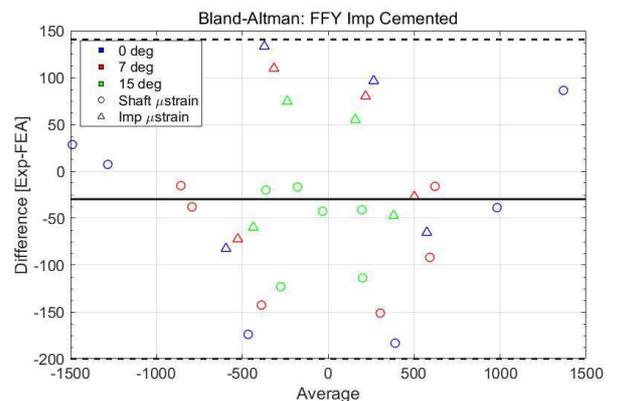
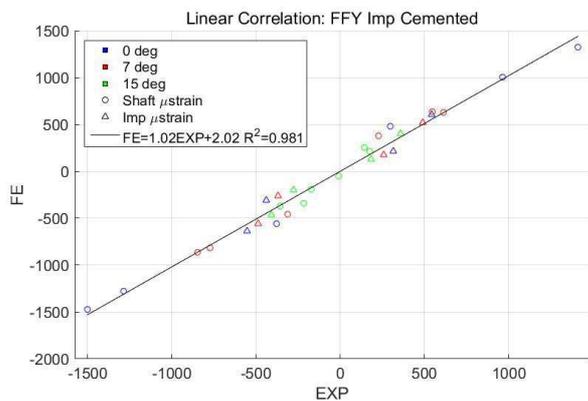
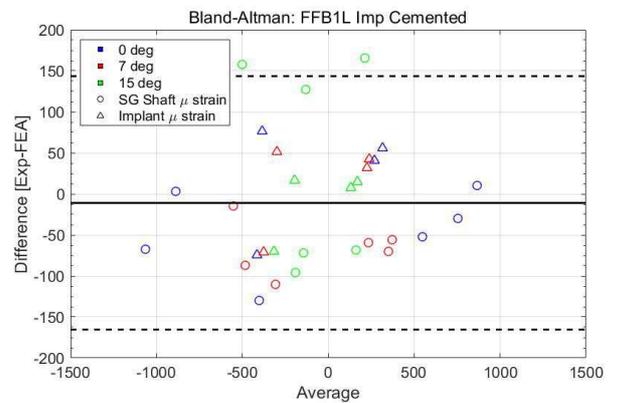
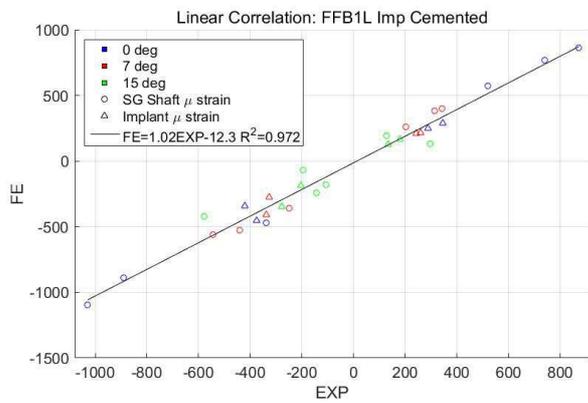
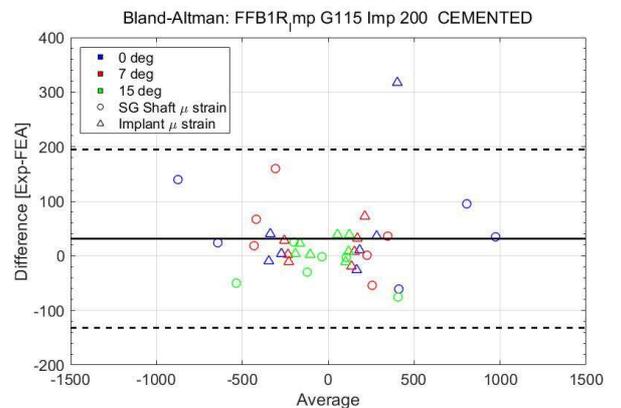
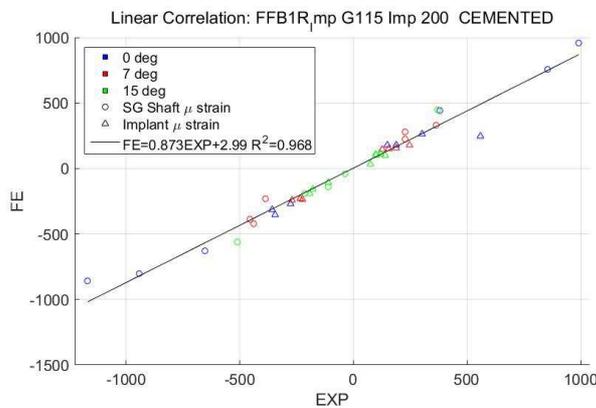
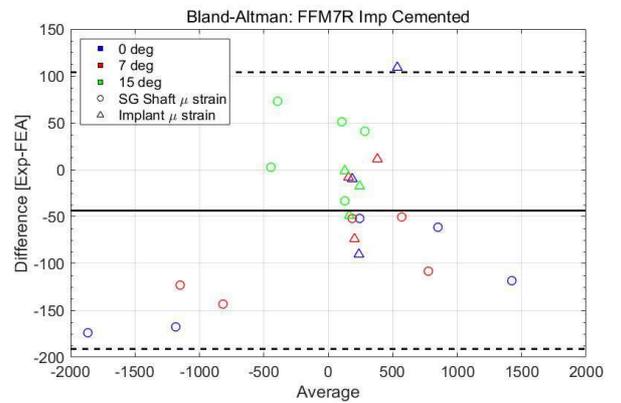
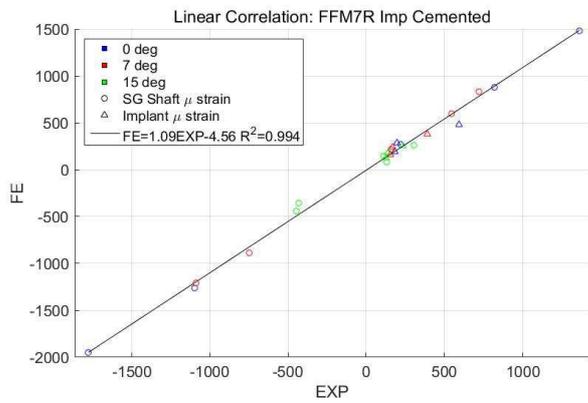


Figure B.10: LC and BA plots for all four implanted femurs

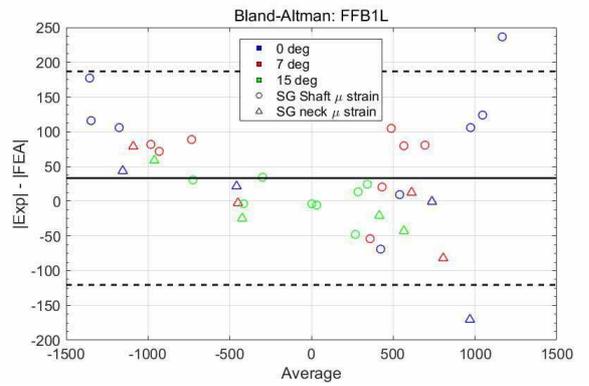
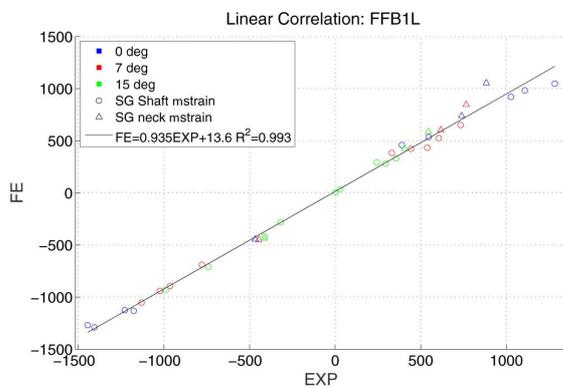
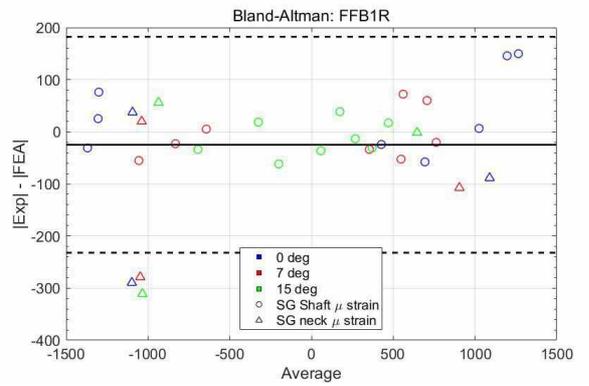
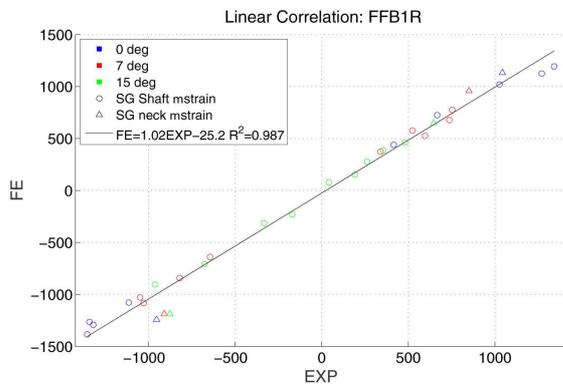


Figure B.11: LC and BA plots for FFB1 intact femurs