

Strain Shielding for Cemented Hip Implants

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Abstract

Background: Long-term survival of hip implants is of increasing relevance due to the rising life expectancy. The biomechanical effect of strain shielding as a result of the implant insertion may lead to bone resorption, thus increase risk for implant loosening and periprosthetic fractures. Patient-specific quantification of strain shielding could assist orthopedic surgeons in choosing the biomechanically most appropriate prosthesis.

Methods: Validated quantitative CT-based finite element models of five femurs in intact and implanted states were considered to propose a systematic algorithm for strain shielding quantification. Three different strain measures were investigated and the most appropriate measure for strain shielding quantification is recommended. It is used to demonstrate a practical femur-specific implant selection among three common designs.

Findings: Strain shielding measures demonstrated similar trends in all Gruen zones except zone 1, where the volumetric strain measure differed from von-Mises and maximum principal strains. The volumetric strain measure is in better agreement with clinical bone resorption records. It is also consistent with the biological mechanism of bone remodeling so it is recommended for strain shielding quantification. Applying the strain shielding algorithm with three different implants for a specific femur suggests that the collar design implant is preferable. Such quantitative biomechanical input is valuable for practical patient specific implant selection.

Interpretation: Volumetric strain should be considered for strain shielding examination. The presented methodology may potentially enable patient-specific pre-operative strain shielding evaluation so to minimize strain shielding. It should be further used in a longitu-

dinal study so to correlate between strain shielding predictions and clinical bone resorption.

26 *Keywords:*

27 Hip prosthesis, strain shielding, finite element analysis

28 **1. Introduction**

29 Total hip replacements (THRs) are a common procedure (Pabinger and Geissler, 2014;
30 Kurtz et al., 2007) with a revision rate of 6.45% after five years and 12.9% after ten years
31 (Labek et al., 2011). Almost half of patients are expected to undergo a revision surgery
32 within 25 years (Evans et al., 2019). Long-term THR survivorship is of increasing relevance
33 due to the rising life expectancy, thus, investigation of the biomechanical prosthesis-femur
34 response is of interest.

35 Cemented femoral prostheses are implanted in the majority of THRs in several coun-
36 tries (Swedish Hip Arthroplasty Register, 2018; National Joint Registry for England, Wales,
37 Northern Ireland and the Isle of Man, 2018; The New Zeland Joint Rregistry, 2019). The
38 cemented stems are frequently reported to have a better clinical outcome compared to ce-
39 mentless stems (Yang et al., 2019; Lin et al., 2019; Mäkelä et al., 2014; Veldman et al., 2017;
40 Barenius et al., 2018; Abdulkarim et al., 2013). The uniformly distributed cement mantle
41 forms a mechanical interlock between the bone and the stem enabling an even and gradual
42 load transfer (Kuehn et al., 2005).

43 Inserting a metallic prosthesis into a femur changes the state of stress and strains in
44 bone's tissue, leading to a decrease in bone mineral density (BMD) due to "stress shielding"
45 or better termed "strain shielding". BMD changes reduce implants' mechanical stability,
46 thus increasing the risk for aseptic loosening (Sundfeldt et al., 2006). Bone strength is also
47 decreased, thus increasing the risk for periprosthetic fracture. The combined factors are the
48 cause for 60% of THR revisions (Sadoghi et al., 2013; Ulrich et al., 2008).

49 Bone remodeling is governed by mechanical stimuli (Klein-Nulend et al., 2013), thus it
50 is conceivable that post-operative strain shielding affects implant's long term biomechanical
51 performance. Quantification of the strain shielding may assist surgeons in choosing the most
52 appropriate patient specific implant, especially in view of the new 3D printing technologies.

53 Strain shielding can be quantified using finite element analyses (FEA), that allow to
54 determine strains within intact and implanted femurs under physiological loading conditions
55 (Trabelsi et al., 2011; Bessho et al., 2007; Schileo et al., 2014; Rohlmann et al., 1983; Pettersen
56 et al., 2009; Yosibash et al., 2012; Katz et al., 2018). In the current study, quantitative-CT
57 (QCT) based finite element (FE) models of five femurs, both males and females, at different
58 ages and in intact and implanted states (different prostheses) were considered. These models
59 were experimentally validated in previous studies (Katz et al., 2018; Katz and Yosibash,
60 2020) and in Appendix A (accounting both for femoral and implant strains) and are used
61 here to determine strain shielding.

62 A quantitative assessment of strain shielding depends on: (a) the loading conditions,
63 (b) the regions in the femur which the strain shielding is computed, (c) the type of strains
64 considered (strain measures, i.e. equivalent von-Mises strain, principal max strain, etc).

65 A variety of "physiologic-like" loading conditions are documented in past literature. Some
66 are simple, considering hip contact force alone (Goshulak et al., 2016), some include the
67 abductor muscles (Pettersen et al., 2009; Hirata et al., 2013) and some consider multiple
68 muscles (Abdullah et al., 2010; Yamako et al., 2014; Moussa et al., 2017; Szwedowski et al.,
69 2012; Cilla et al., 2017). Since the femoral head is replaced by a prosthesis, it is conceivable
70 that the hip contact force is the load that has the largest influence on strain variations in the
71 bone tissue. Thus, the hip contact force is the loading considered for quantifying the strain
72 shielding in the different regions in the femur.

73 In many previous studies only bone's surfaces (Pettersen et al., 2009; Abdullah et al., 2010)
74 or prosthesis surfaces (Yamako et al., 2014; Moussa et al., 2017) were examined rather than
75 the bone tissue inside the femur. Drawing quantitative conclusions based only on the bone-
76 prosthesis interface is problematic because of bone-implant contact assumptions. Relying
77 on the femur's outer surface alone is also limited since bone remodeling is manifested in
78 the inner bone tissue. Thus, considering femur's inner tissue for strain shielding assessment
79 should be the proper choice.

80 Change in strain distribution in the bone tissue, i.e. the difference between the strain
81 field before and after the prosthesis is inserted, was rarely quantified and mostly qualitatively

82 discussed in past studies. In the few studies where this difference was quantified, a relative
83 difference was commonly used (Pettersen et al., 2009; Goshulak et al., 2016). Such an ap-
84 proach may be misleading because in areas where strains are small, a small change will cause
85 a large relative difference, predicting high bone resorption. We adopt here the procedure
86 in (Cilla et al., 2017), and consider an absolute value of strain change for quantification of
87 strain shielding.

88 The appropriate strain measure to evaluate strain shielding remains an open question.
89 A variety of strain and stress measures were considered, based on: von Mises stress (Hirata
90 et al., 2013; Yamako et al., 2014; Matsuyama et al., 2016; Moussa et al., 2017), von Mises
91 strain (Pettersen et al., 2009; Szwedowski et al., 2012), Tresca stress (Abdullah et al., 2010),
92 strain energy density (Yamako et al., 2014; Szwedowski et al., 2012), principal strains (Cilla
93 et al., 2017) and principal stresses (Abdullah et al., 2010). Because the biological mechano-
94 sensation mechanism is strain-driven (Klein-Nulend et al., 2013; Liu et al., 2010; Weinbaum
95 et al., 1994) we concentrate on strain related measures.

96 The aim of the current work is to: (a) Propose an algorithm for strain shielding quan-
97 tification following the insertion of cemented hip implants. (b) Examine if strain shielding
98 depends on the selected strain measure. (c) Examine if the adopted strain shielding may
99 explain clinical data available in past publications (BMD changes following THR).

100 By using the recommended strain shielding measure the surgeon may quantify, among
101 available prostheses, which one minimizes the shielding. Such an analysis is demonstrated
102 by investigating the strain shielding among three common designs: regular, high offset and
103 collar .

104 The presented methodology has the potential to be incorporated in clinical practice and
105 in longitudinal studies to correlate predicted strain shielding with clinical outcome.

106 **2. Methods**

107 *2.1. Femurs and Prostheses*

108 Five fresh frozen femurs from four donors (male and female at various ages) and five
109 different cemented hip prostheses were considered. A summary of donors and prostheses is

110 provided in Table 1 and shown in Figure 1. All femurs were QCT-scanned in their intact
 111 condition and after prosthesis insertion.

112 Patient specific QCT-based FE models were constructed for each of the femurs in intact
 113 and implanted states. These models were validated by experiments under stance loading
 114 conditions in Katz et al. (2018); Katz and Yosibash (2020) and in Appendix A (that details
 115 the experiments performed on FFI1R).

116 Briefly, the intact femurs were loaded in stance position by applying a hip contact force to
 117 their head at various angles. The femurs were thereafter implanted with different cemented
 118 prostheses by an orthopedic surgeon and re-tested. On all femurs and prostheses strain gauges
 119 were bonded to monitor the strains during loading (FFI1R was monitored using digital image
 120 correlation). The measurements were used to validate the FE models which are used herein.

Table 1: Donors and prostheses details.

		Donor					Prosthesis		
		Gender	Age (y)	Height (cm)	Weight (kg)	Side	Death cause	Manufacturer	Model
(a)	FFM7R	Female	75	162	41	R	cervical cancer	Protec	LOT 2018 7.5 mm
(b)	FFB1R	Male	67	178	84	R	heart failure	Protec	LOT 2132 10 mm
(c)	FFB1L					L		Groupe Lepine	PAV [®] H015 0214
(d)	FFY	Male	20	185	68	L	drug overdose	Aesculap	ISONIC NK 082 s8
(e)	FFI1R	Female	80	168	97	R	heart disease	DePuy Synthes	CORAIL [®] polished 11

121 2.2. Finite element analyses (FEAs)

122 Strains in the bone are investigated by using high-order linear FE analyses (Szabo and
 123 Babuska, 1991) of the intact and implanted femurs. FE models of all bones were generated
 124 based on QCT scans, and were shown to well predict the strains on femurs' and prostheses'
 125 surfaces (Katz and Yosibash, 2020; Katz et al., 2018; Yosibash et al., 2012).

126 FE models of implanted femurs were generated by virtually inserting the prosthesis into
 127 the intact femur while mimicking it's actual position, determined by CT scans and X-rays of
 128 the implanted femurs. The prostheses models were constructed from 3D scans of the actual
 129 implants.

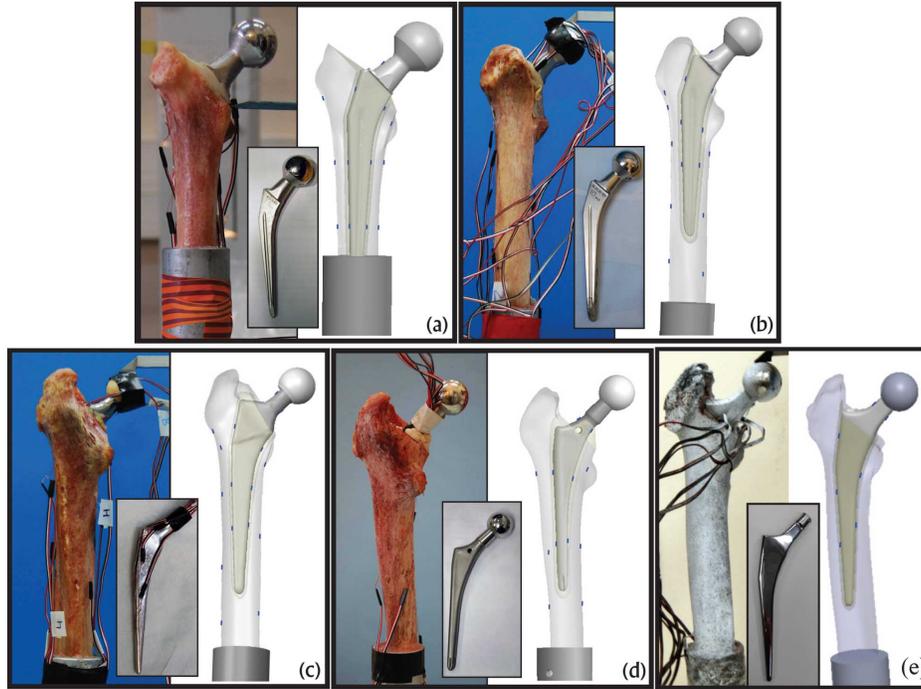


Figure 1: The five femurs and prostheses (blue points denote location of strain gauges). (a) FFM7R (b) FFB1R (c) FFB1L (d) FFY (e) FFI1R. Images (a)-(d) are from Katz et al. (2018).

130 The contact conditions between bone and implant as well as the cement thickness and
 131 distribution cannot be defined accurately from QCT scans or X-ray radiographs. A perfect
 132 bonding condition was applied on bone implant interface (cement thickness was shown to
 133 have minor influence on cortical bone strains in Katz et al. (2018), thus it was set to zero).

134 Because only the femoral head is replaced, we choose to apply only the hip contact force
 135 in our experimentants and FEA to assess the difference between the intact and implanted states.
 136 Loading directions of 0° and 7° were considered, as also used in the FE validation studies
 137 (Katz et al., 2018). In the FEAs the location and direction of the simulated force was kept
 138 identical in both intact and implanted models so that the moment acting on the intact and
 139 implanted femurs is the same. FE calculated femoral strains were extracted at the plane
 140 of prosthesis symmetry (midplane). Three different strain measures on the midplane were
 141 considered for strain shielding quantification:

- 142 • von-Mises strain (equivalent strain) - commonly used for bones in the literature (Pet-

143 tersen et al., 2009).

$$\varepsilon_{vM} = \sqrt{\frac{(\varepsilon_1 - \varepsilon_2)^2 + (\varepsilon_2 - \varepsilon_3)^2 + (\varepsilon_3 - \varepsilon_1)^2}{2}} \quad (1)$$

144 • Volumetric strain ($\text{trace}(\varepsilon)$). This measure is considered because bone remodelling is
145 pressure related. Biological load sensing mechanism is attributed to volumetric strain
146 (Henstock et al., 2013):

$$\varepsilon_t = \varepsilon_1 + \varepsilon_2 + \varepsilon_3 \quad (2)$$

147 • Maximum principal strain - commonly used in bones as a failure criterion (Schileo et al.,
148 2008a; Yosibash et al., 2010).

$$\varepsilon_{mp} = \max(\varepsilon_1, |\varepsilon_3|) \quad (3)$$

149 where $\varepsilon_1, \varepsilon_2, \varepsilon_3$ are the principal strains.

150 To allow a comparison between the different femurs, belonging to donors of different body
151 weights, we normalize the strains in the FEA by considering a hip contact force equal to
152 donor's weight.

153 *2.3. Quantification of strain shielding*

154 The intersection of the prosthesis midplane and the femur is divided into seven zones
155 similar to the clinical Gruen zones (Gruen et al., 1979) as illustrated in Figure 2(c). The
156 zones are defined as follows: zones 1 and 7 are above lesser trochanter, zone 1 being the greater
157 trochanter and zone 7 being the calcar region. Zones 2,3 (laterally) and 5,6 (medially) are
158 of equal length and are separated at the middle between the lesser trochanter and tip of
159 the prosthesis. Zone 4 starts at the tip of the prosthesis and ends distally at a distance of
160 15mm. Most zones are in the femoral shaft, where the cortical bone dominates the mechanical
161 response. The trabecular bone is removed during the implantation procedure (by broaching
162 or reaming) and the gap between the prosthesis and the cortex is filled with cement. Thus,
163 in zones 2-7 only the cortical cross-section area is considered (defined as the area in which
164 $\rho_{ash} > 0.7$ [gr/cc] (Schileo et al., 2008b)). In zone 1 (greater trochanter) where very little

165 cortex is found, a small offset of $\sim 3\text{mm}$ from the prosthesis is dismissed, this gap represents
 166 the cement (Isaac et al., 2000) and is thus irrelevant for strain shielding evaluation. In each
 167 zone i the average strain difference ϵ_j^i is computed, defined by:

$$\epsilon_j^i = \frac{\iint_{\Omega_i} \epsilon_j^{implanted} - \epsilon_j^{intact} d\Omega_i}{\Omega_i} \quad (4)$$

168 where j is either vM , t or mp and Ω_i ($i=1$ to 7) are the various Gruen zones i.e. ϵ_j^i is the
 169 strain shielding measure i in Gruen zone j . Negative ϵ indicates reduced strains predicting
 170 bone resorption, while positive ϵ is an indication of increased strains. The methodology for
 171 the computation of the different ϵ_j^i s is illustrated in Figure 2.

172 Strains computed in intact and implanted models (at the implant's midplane) were con-
 173 sidered in the same location if the distance between the corresponding points was below
 174 0.5mm . The resulting pointwise difference of each of the strain measures is illustrated in Fig-
 175 ure 2(c). These were computed for the five femurs, each implanted by a different prosthesis.
 176 The average difference over each Gruen zone was considered.

177 To allow comparison between the three examined measures so to determine which is
 178 the most indicative for clinical use. The strain shielding obtained in each Gruen zone was
 179 presented as percentage of the strain shielding in Gruen zone 7 (where strain shielding is
 180 mostly pronounced).

181 *2.4. Selection of an "optimal" implant*

182 To demonstrate the use of the quantitative strain shielding for a specific patient we chose
 183 FFI1R as an example. FFI1R was implanted with the CORAIL[®] prosthesis (DePuy Synthes,
 184 Raynham, MA, USA) which has several design variations. To investigate the induced strain
 185 shielding, three different designs of the CORAIL[®] prosthesis were examined: polished 'stan-
 186 dard', polished 'high offset' and a polished 'collared' design that was virtually constructed
 187 based on the cementless design. These were virtually implanted in the FE model of FFI1R.
 188 Strain shielding was computed and compared between the three prostheses.

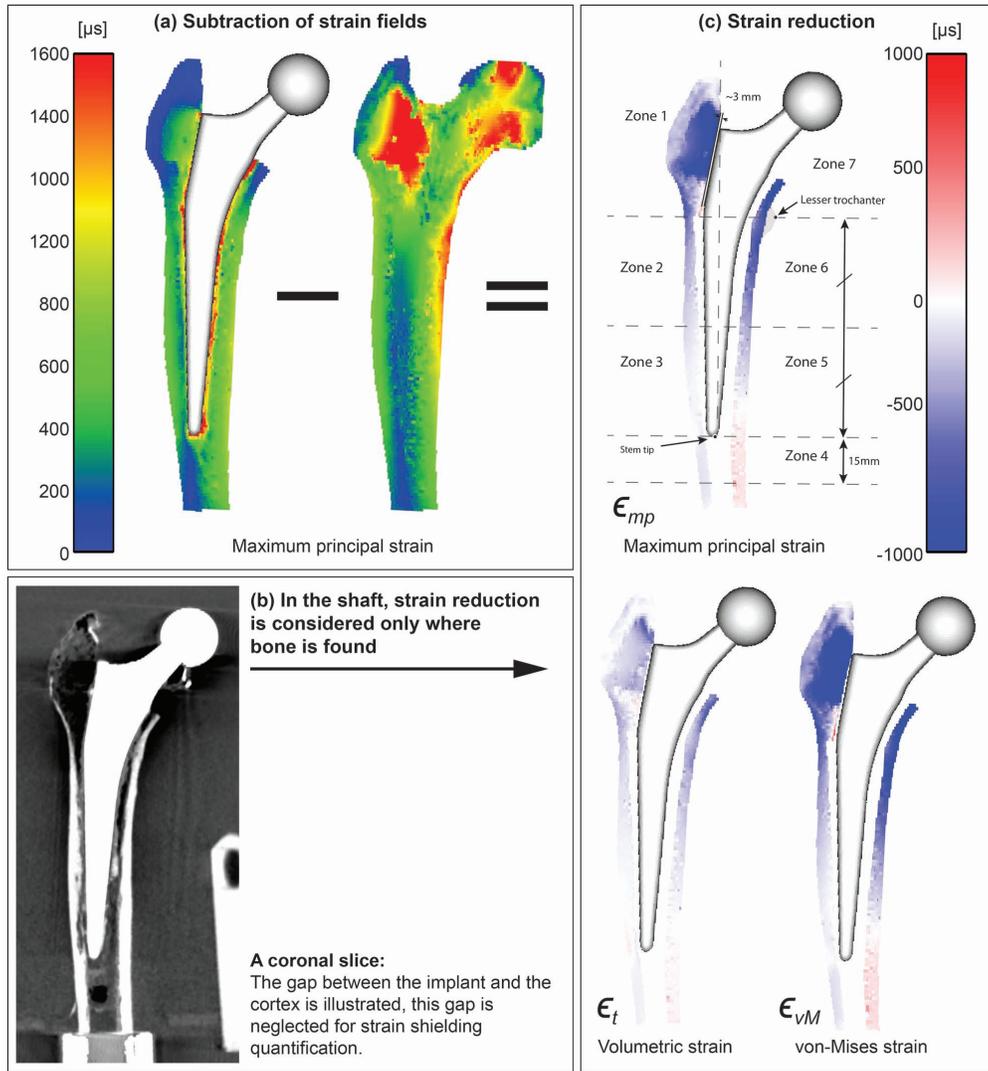


Figure 2: Strain shielding quantification algorithm. (a) Subtraction of the strain field obtained at prosthesis midplane. (b) Illustration of the gap found between bone and prosthesis at the shaft. At the shaft, only areas containing cortical bone are considered. (c) The obtained strain reduction fields, three measures are examined. These fields may be further divided and averaged over the illustrated Gruen zones.

189 3. Results

190 3.1. Strain shielding measures

191 The three strain shielding measures (ϵ_{VM} , ϵ_{mp} and ϵ_t), in the seven Gruen zones under two
 192 hip contact force directions were computed for all femurs. For example, Figure 3 illustrates
 193 the change in the volumetric strain. One may observe that different femurs have different

194 cortical areas for strain shielding assessment: for example, zones 7,6 and 5 in FFM7R are
 195 much smaller compared to the other femurs.

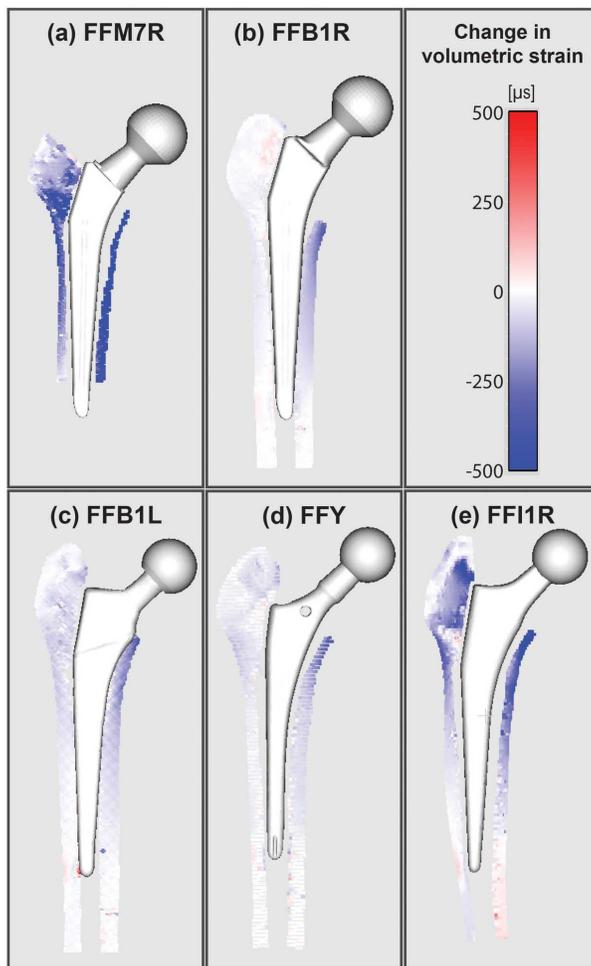


Figure 3: Volumetric strain reduction for the five examined femurs (7° angle considered).

196 Histograms presenting strain shielding percentage relative to zone 7 are shown in Figure
 197 4. In Gruen zones 2-6, all strain shielding measures show similar reduction in all femurs
 198 under both loading conditions. Zone 1 (greater trochanter) is exceptional in which the strain
 199 shielding measures disagree. The general trend suggests that von-Mises and principal strain
 200 measures similarly predict a rise in strain shielding compared to zone 2. The volumetric
 201 strain however, predicts lower values which are similar or below the values in zone 2. A
 202 slightly more pronounced strain shielding was found at 0° loading than at 7° in all zones.
 203 Zone 7 (calcar region) experienced the most pronounced strain shielding in all cases.

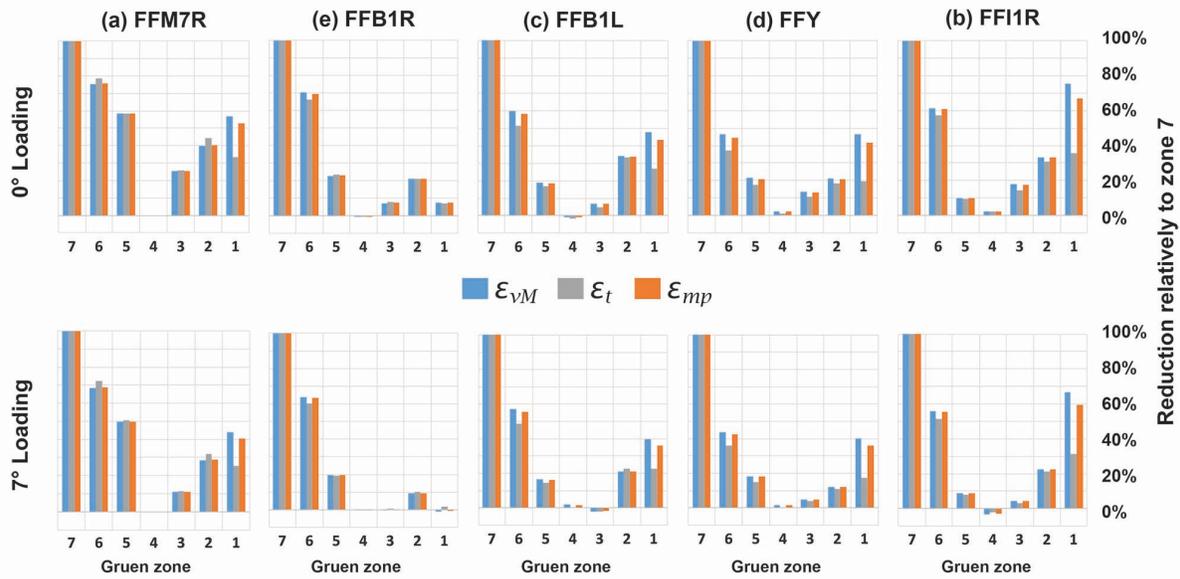


Figure 4: Strain shielding in Gruen zones (absolute difference) relatively to zone 7. Different strain shielding measures examined.

204 A general pattern in strain shielding relative to zone 7 can be observed regardless of the
 205 examined strain measure and considering both loading angles in zones 2-6: zone 2: <35%
 206 ($22\pm 8\%$); zone 3: <18% ($6\pm 6\%$); zone 4: <2% ($0\pm 2\%$); zone 5: <23% ($16\pm 5\%$); zone 6:
 207 <70% ($55\pm 9\%$). In zone 1 the strain measures disagree, ϵ_{vM} and ϵ_{mp} predicted values of
 208 <75% ($38\pm 23\%$) while ϵ_t resulted in lower predictions of <48% ($20\pm 11\%$).

209 We exclude FFM7R where the prosthesis penetrated the imbedding cylinder (see Figure 1)
 210 causing additional constraint on the prosthesis by covering its distal end. FFM7R is provided
 211 only to examine the difference between the different strain shielding measures. However, it
 212 cannot be used to derive the typical strain shielding pattern relatively to zone 7. It does not
 213 represent strain shielding in a typical femur.

214 3.2. Examination of different prostheses for a specific femur

215 FE simulations of the intact FFI1R and after different prosthesis insertion are illustrated
 216 in Figure 5. Strains reduction relatively to the intact state is evident. The collared prosthesis
 217 induces high strains at the calcar region compared to other prostheses. The high offset design
 218 increases strains distally.

219 Choosing the strain shielding measure as the volumetric strain, we computed the strain
220 shielding for the three prostheses implanted virtually in FFI1R (Figure 6). The hip contact
221 force is applied to the femur and prosthesis at 7° .

222 Comparing to the "regular prosthesis", the collared prosthesis affects only Gruen zone 7
223 reducing strain shielding by 20%. The high offset prosthesis affects all zones by reducing
224 strain shielding. In zones 3,4,5 strains are increased rather than shielded. In zones 2 and 6
225 strain shielding was reduced by 37% and 21% respectively. Zone 7 however, is least affected
226 (3%).

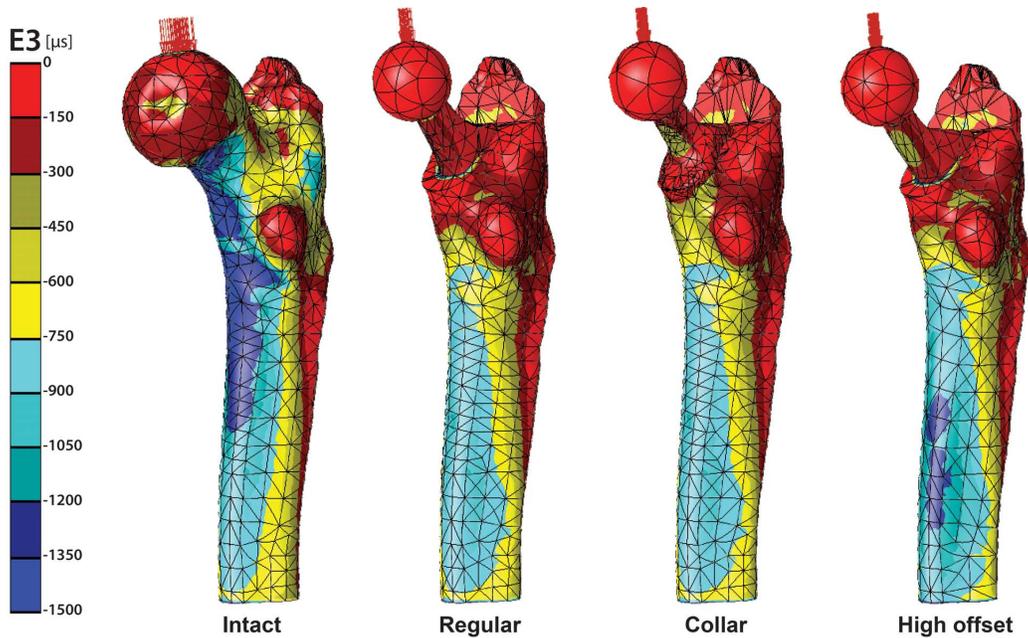


Figure 5: FFI1R simulated in an intact state and with the three examined prostheses.

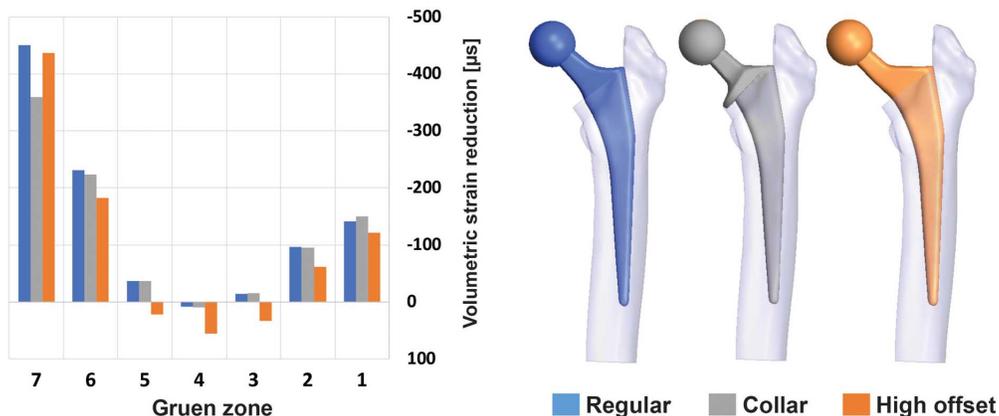


Figure 6: Strain shielding based on volumetric strain (ϵ_t) for the three CORAIL prostheses implanted in FFI1R FE model and loaded at 7° .

227 4. Discussion

228 A systematic algorithm for strain shielding quantification has been presented. It aims to
 229 enable pre-operative evaluation of strain shielding so to match the most appropriate implant
 230 for a specific patient. Such a methodology may assist in improving implant designs as well
 231 as in designing patient specific implants by additive manufacturing.

232 First, we demonstrated that FEA of five femurs with five different implants represents
 233 well the experimental observations (in Katz et al. (2018), Katz and Yosibash (2020) and
 234 Appendix A), and may be reliably used to quantify strain shielding. This is essential since
 235 strains within the bone tissue cannot be measured but only computed. Strain shielding was
 236 quantified using different strain measures, resulting in similar strain reduction patterns in all
 237 Gruen zones with the exception of zone 1 where the volumetric measure differed from the
 238 von-Mises and the max-principal strain measures.

239 4.1. Comparison of different strain measures

240 Principal maximum (ϵ_{mp}) and von-Mises strain (ϵ_{vM}) measures predicted similar strain
 241 shielding patterns. The volumetric strain measure ϵ_t was different, mostly in Gruen zone
 242 1. According to the results presented in Figure 4, in all examined femurs (with the single
 243 exception of FFB1R where no difference was found between the strain measures), ϵ_{mp} and

244 ϵ_{vM} measures imply that strain shielding is more pronounced proximally i.e. Gruen zone 1
245 experiences high strain shielding, particularly higher than zone 2. The volumetric strain ϵ_t
246 however, suggests that zone 1 experiences strain shielding rates lower than or similar to zone
247 2.

248 The strain shielding pattern based on ϵ_t is in a better agreement with clinical bone re-
249 sorption records. Several studies documented BMD changes in patients following a cemented
250 hip replacement (Jayasuriya et al. (2013); Li et al. (2007); Venesmaa et al. (2003); Digas
251 and Karrholm (2008); Buckland et al. (2010); Bieger et al. (2011); Knutsen et al. (2017)
252). These are based on dual-energy X-ray absorptiometry (DEXA) and also refer to Gruen
253 zones which are common and familiar to the clinical community. All studies report a similar
254 trend - the least bone resorption usually occurs around the tip of the prosthesis at zones
255 3,4,5 followed by zones 2,6. Largest reduction in BMD is found in zone 7. This trend is well
256 captured by the methodology suggested herein regardless of the strain measure considered.
257 In zone 1, the clinical studies report strain shielding rates below or similar to zone 2 (with the
258 single exception of (Buckland et al., 2010) who examined a similar implant as (Jayasuriya
259 et al., 2013) resulted in contradicting findings in zone 1). Based on clinical observations
260 of BMD reduction we propose the volumetric strain as the appropriate strain measure for
261 strain shielding quantification. Additionally, the use of volumetric strain for strain shielding
262 evaluation is consistent with the biological mechanism attributed to bone remodeling, shown
263 to be regulated by hydrostatic pressure (Klein-Nulend et al., 2013; Liu et al., 2010; Henstock
264 et al., 2013; Scheiner et al., 2016; Pastrama et al., 2018). To the best of our knowledge, no
265 previous study considered volumetric strain measure for strain shielding assessment.

266 Comparing the strain shielding patterns obtained at 0° and 7° loading, no significant
267 difference is observed. The relative strain shielding is slightly more pronounced at 0° loading
268 than at 7° . At 0° the moment acting on the femur is larger, leading to larger strains. This
269 effect is more pronounced in the intact femur leading to larger strain reduction in comparison
270 to the implanted configuration, i.e. causing a more pronounced strain shielding. The overall
271 trend, however, does not change. Thus among the examined stance position loadings, a single
272 direction at 7° may be sufficient for strain shielding assessment.

273 4.2. Choosing an "optimal" implant

274 To demonstrate a potential preoperative use of the presented algorithm, we examined the
275 strain shielding based on volumetric strain (ϵ_t) induced by three common prostheses on the
276 same femur. All prostheses were of the same size, referred to as "regular", "high-offset" and
277 "collar". The "collar" polished design was virtually constructed since in reality it is cementless
278 and nonpolished.

279 The "collar" affects only Gruen zone 7 (reducing strain shielding by 20%) while other
280 zones are unaffected. The high offset prosthesis increases the moment acting on the femur
281 thus increasing the strains. Consequently, strain shielding is reduced in all zones. Zone 7
282 however, where strain shielding is mostly pronounced, is least affected, experiencing the least
283 reduction in strain shielding (3%). Additionally, an increase in strain is obtained distally in
284 the zones around the prosthesis tip (zones 3-5) which may increase the risk of periprosthetic
285 fractures (type B2 and C periprosthetic fractures defined in Schwarzkopf et al. (2013)).
286 Despite the positive influence on zones 2 and 6 (strain shielding reduced by 37% and 21%
287 respectively), the overall effect of the high offset implant is mostly negative. Thus, the collar
288 design may be preferable for the examined femur when considering biomechanical effects.

289 4.3. Correlating strain shielding with clinically observed BMD reduction

290 It is conceivable that post operative strain shielding assessment is correlated with long
291 term BMD changes however, it has yet to be proven. Only limited evidence is found in
292 the literature on the correlation between FE based BMD reduction predictions and clinical
293 observations. A study performed by (Hirata et al., 2013) found a correlation between the
294 simulated postoperative 'equivalent stress' to bone mineral density (BMD) change in zone 7
295 (20 patients). A low coefficient of determination was reported ($r^2=0.27$). A stress measure
296 was computed and only FE models of implanted femurs were considered. No comparison
297 to the intact state of the bone was performed. These modifications may improve the corre-
298 lation and reveal additional correlations examining other Gruen zones. Another study by
299 (Szwedowski et al., 2012) considered different algorithms for remodeling using FE methods
300 compared to clinical observations of BMD change (3 patients). Bone remodelling algorithms

301 aim at predicting long term outcome based on the post-operative conditions. A long term
302 outcome involves time-dependent modeling assumptions as well as bone prosthesis contact
303 conditions that make these predictions questionable. To the best of our judgement only
304 postoperative mechanical conditions (relatively to the intact state) may be used to correlate
305 with patient specific long term outcome. The aforementioned studies (Hirata et al., 2013;
306 Szwedowski et al., 2012) are among the few that addressed clinical observations to validate
307 their BMD predictions (both considered cementless prostheses).

308 *4.4. Limitations and future work*

309 The strain shielding algorithm may be used in a longitudinal study to correlate between
310 predictions and bone resorption. A pre-operative CT scan must be available to allow the
311 creation of a patient specific FE model of the intact and implanted femur. Such a patient
312 must then be monitored for BMD changes at the Gruen zones. The BMD changes are to
313 be compared to the pre-operatively predicted strain shielding to examine correlation in each
314 Gruen zone separately. Such a study is a prospective long term one that must be performed
315 in the future.

316 Additionally, more loading configurations simulating activities such as for example stair
317 climbing, should also be examined.

318 It is also important to study whether different prostheses are more appropriate for different
319 patients, or does there exist a unique design that is optimal for majority of patients. Using
320 the suggested methodology, a comparison of different prostheses for same patient, or different
321 patients with same prosthesis may be of financial significance for clinical centers.

322 In our study we assumed that the surgeon does not deviate from the planned position of
323 the prosthesis. The robustness of prosthesis' performance to small deviations in orientation
324 will be studied in the future.

325 **Conflict of Interest**

326 YK, NS, MS have no conflicts of interest to declare. ZY has a financial interest in
327 PerSimiO.

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480 **Appendix A. FFI1R validation**

481 The FE model of FFI1R was validated by experimental observations. Strains in the
 482 experiments on bone's surface were measured by digital image correlation (DIC). Validation
 483 was performed for both intact and implanted configurations. Comparison between the FE
 484 results and the experimental observations for the intact femur are detailed in Katz and
 485 Yosibash (2020) and are presented in Figure A.7. The implanted femur was loaded in two
 486 loading configurations (7° and 0°), strain gauges (SG) were applied to the prosthesis prior
 487 to implantation (experimental protocol is similar to the one presented in Katz et al. (2018)).
 488 The agreement between the experimental results and the FE simulations for the implanted
 489 femur are shown in Figures A.8 and A.9.

490 A good agreement was obtained for both implanted and intact femur states including
 491 measurements on the prosthesis inside the femur.

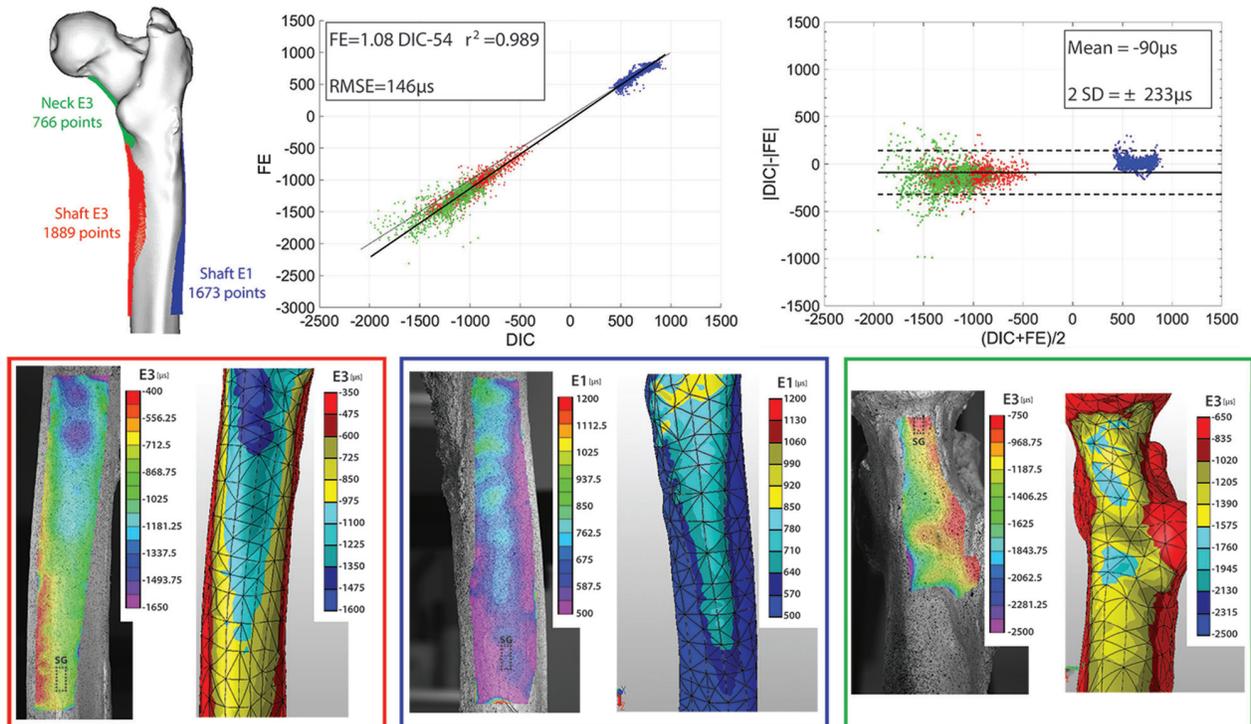


Figure A.7: Comparison of the strain fields obtained from DIC measurements to FE predictions at 7° under 1000N loading for the intact FFI1R. Linear correlations and Bland Altman plots are presented. All units are micro-strains. **The results are taken from Katz and Yosibash (2020)**

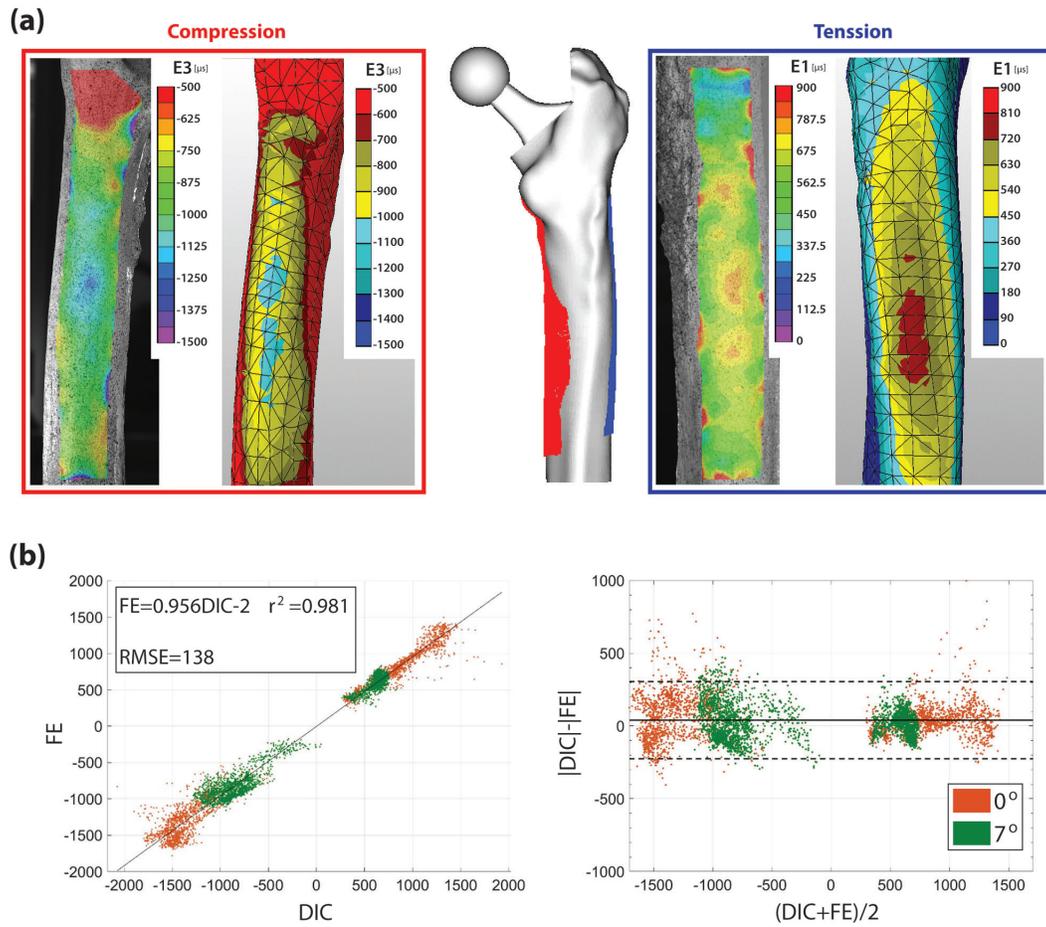


Figure A.8: Validation of the predicted surface strains for the implanted FFIIR. (a) Comparison of the strain fields obtained from DIC measurements to FE predictions at 7° under 1000N loading. (b) Bland Altman and linear correlation plots comparing FE predictions to DIC measurements. Both 7° and 0° loading angles were considered under 1000N loading. All units are micro-strains.

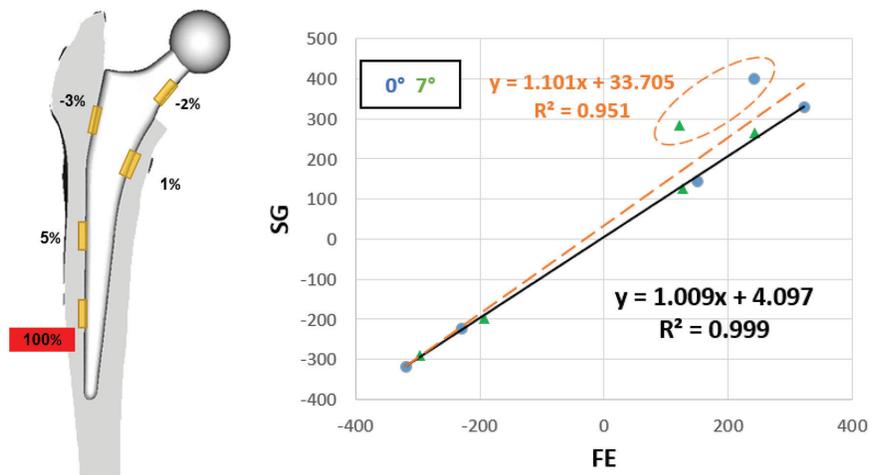


Figure A.9: Comparison of the SG measurements to FE predictions on the implants surface. Left: The SG locations on the implant surface with the average **relative** difference between experimental and predicted strains. Right: A linear correlation plot. Four out of the five examined SGs showed a very good agreement.