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1 Title

2 Calcar-Collar Contact during Simulated Periprosthetic Femoral Fractures Increases Resistance to
3 Fracture and Depends on the Initial Separation on Implantation: A Composite Femur in vitro study

4

5 Authors

6 Jonathan N Lamb ^a, BSc, MBBS, MRCS,

7 Oliver Coltart ^b,

8 Isaiah Adekanmbi ^c,

9 Hemant G Pandit ^a,

10 Todd Stewart ^b.

11

12 ^a Leeds Institute of **Rheumatic and Musculoskeletal** Medicine (LIRMM), School of
13 medicine, University of Leeds, Chapel Allerton Hospital, Leeds LS7 4SA, UK; ^b School of
14 Mechanical Engineering, University of Leeds, Leeds LS2 9DX, UK; ^c DePuy International,
15 Johnson and Johnson, Leeds, St Anthony's Rd, Leeds LS11 8DT, UK;

16

17 Corresponding author: J N Lamb j.n.lamb@leeds.ac.uk

18

19 **Declaration of interest statement**

20 The authors declare limited conflicts of interest which are detailed in the accompanying declaration
21 form.

22

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25 Abstract

26

27 *Background*

28 A calcar collar may reduce risk of periprosthetic fracture of the femur, through collar contact. We
29 estimated the effect of collar contact on periprosthetic fracture mechanics using a collared fully
30 coated cementless femoral stem and then estimated the effect of initial calcar-collar separation on
31 the likelihood of collar contact.

32 *Methods*

33 Three groups of six composite left femurs with increasing calcar-collar separation in each group,
34 underwent periprosthetic fracture simulation in a materials testing machine. Fracture torque and
35 rotational displacement were measured and torsional stiffness and rotational work prior to fracture
36 were estimated. Calcar collar contact prior to fracture was identified using high speed camera
37 footage.

38 *Findings*

39 Where calcar-collar contact occurred fracture torque was greater (47.33 [41.03 to 50.45] Nm versus
40 38.26 [33.70 to 43.60] Nm, $p=0.05$), Rotational displacement was less (16.6 [15.5 to 22.3] degrees
41 versus 21.2 [18.9 to 28.1] degrees, $p=0.07$), torsional stiffness was greater (151.38 [123.04 to
42 160.42] rad.Nm^{-1} versus 96.86 [84.65 to 112.98] rad.Nm^{-1} , $p<0.01$) and rotational work was similar
43 (5.88 [4.67, 6.90] J versus 5.31 [4.40, 6.56] J, $p=0.6$).

44 Odds ratio (OR) of not achieving collar contact (95% confidence interval) increased 3.8 fold (95% CI
45 1.6 to 30.2, $p<0.05$) for each millimetre of separation in the regression model. 95% chance of collar
46 contact was associated with a separation of 1 mm or less.

47 *Interpretation*

48 Surgeons should reduce calcar-collar separation at stem implantation to a maximum of 1mm to
49 increase the chance of calcar-collar contact during injury and reduce the risk of early post-operative
50 PFF.

51 Introduction

52 A calcar collar on a cementless stem has been shown to improve immediate vertical and rotational
53 stem stability (Demey et al., 2011; Keaveny and Bartel, 1993; Vidalain et al., 2011) and is
54 recommended for patients with poor bone quality or history of fracture (Vidalain et al., 2011).
55 Recent observational studies have identified a strong association between the presence of a medial
56 calcar collar and a reduced risk of revision surgery for periprosthetic fracture of the femur within 90
57 days of implantation (PFF)(Lamb et al., 2019). This observation has been validated with
58 biomechanical studies (Johnson et al., 2020; Lamb et al., 2019). A suggested hypothesis is that a
59 medial calcar collar may act to reduce relative movement between the implant and the proximal
60 femur during rotational injuries, through calcar collar contact (CCC) (Johnson et al., 2020; Lamb et
61 al., 2019). This was observed when comparing collared to collarless stems, but it is possible that such
62 an observation may be due to unknown differences in stem mechanical properties because of the
63 presence of a medial calcar collar. To validate this hypothesis, one needs to assess the impact of
64 removal of CCC on the resistance to PFF. In addition, a medial calcar collar may not be well seated on
65 the cut surface of the calcar in clinical practice (Markolf et al., 1980) or a small gap may be the
66 intention of the stem designers to improve press-fit in some collared stem designs (Smith &
67 Nephew, 2020). The effect of increasing initial separation on the resistance to PFF is not defined. It is
68 important for surgeons to understand what difference this may make to the proposed benefits of a
69 medial calcar collar during an injury which may lead to periprosthetic fracture of the femur. The aims
70 of this study are to:

- 71 1- Estimate the effect of calcar collar contact on periprosthetic fracture mechanics using a
72 collared fully coated cementless femoral stem.
- 73 2- Estimate the effect of initial calcar collar separation on the likelihood of calcar collar contact
74 during in vitro periprosthetic fracture.

75

76 Methods

77 To assess the effect of CCC on pre-osseointegration PFF, three groups of six composite femurs
78 (Osteoporotic femur, SawBones, WA) with increasing calcar-collar gap in each group, were subjected
79 to a previously published PFF simulation technique (Ginsel et al., 2015) and the maximum moment
80 prior to fracture was compared.

81 *Specimen preparation*

82 Pre-operative implant size selection and neck cut to recreate preoperative offset and leg length was
83 planned using proprietary software (IMPAX Orthopaedic Tools, Agfa Healthcare) following plain
84 anteroposterior radiographs with a 25mm diameter scaling ball. Preparation and fixation was
85 performed according to manufacturer's guidance by a single experienced surgeon (JL) to minimize
86 variability. Given that the effect of calcar-collar separation on chance on CCC was not known, an
87 approach to produce trials in which fractures would occur both with and without CCC was adopted.
88 A distribution of calcar-collar separation was generated using a range of planned neck resection
89 based on best to worst case clinical scenario. Neck resection was standardised in all cases and then
90 subsequently increased between groups using the manufacturer supplied calcar mill to a line marked
91 on the femoral neck (group 1 = no additional resection, group 2 = 3mm additional resection, group 3
92 = 6mm additional resection). Additional resection was performed using the calcar reamer on a
93 smaller sized rasp down to a mark on the outer cortex indicating the additional required neck
94 resection. After preparation, distal femoral resection was performed so that 120mm of specimen
95 remained distal to the stem tip (40mm from stem tip to fixation and 80mm was available for
96 fixation). Specimens were fixed into square profile steel pots using a rapid setting resin fixative
97 (G&B Epoxy Acrylate Resin, G&B Fissaggi, UK) at six degrees from vertical in the coronal plane and
98 vertical in the sagittal plane (Fig 1). Femurs were implanted with a fully coated collared cementless
99 femoral stem (Corail KA size 12, DePuy Synthes, Leeds UK) in accordance with manufacturer
100 guidelines and inspected visually for intraoperative fractures. To measure the initial separation
101 between the collar and the cut surface of the calcar, the distance between the under surface of the
102 collar and the calcar at the mid-point on the anterior and posterior surfaces were measured using
103 feeler gauges for gaps below 1mm or a micrometre for gaps above 1mm. These measures were
104 named anterior collar calcar distance (ACC) and posterior calcar collar distance (PCC).

105 *Experimental setup*

106 The potted specimen was secured into a clamp which was secured to the base of the materials
107 testing machine and the specimen position was adjusted in two planes to ensure precise positioning.
108 High resolution, high speed video recording (120 frames per second at 1080p resolution using GoPro

109 Hero 7, GoPro, California, USA) was set up at calcar height at 45 degrees to the frontal plane and 90
110 degrees from each other (Fig 2).

111 Periprosthetic fractures of the femur were simulated in a materials testing machine (ElectroPuls
112 E10000, Instron, USA) using a previously published methodology. This involved initial load of 1500 N
113 followed by the application of a rotation (45 degrees) until fracture. Rotation was applied directly to
114 the femoral head using a custom clamp that additionally ensured that the rotation axes was aligned
115 to the anatomical axes

116 Fracture torque and rotational displacement of the stem-femur specimen were measured and
117 torsional stiffness (rotary displacement divided by torque) and rotational work prior to fracture were
118 estimated (area under rotatory displacement torque curve). CCC prior to fracture was identified
119 visually on reviewing frame stills from camera footage for each trial.

120 Results between trials where calcar contact did and did not occur were compared using Mann-
121 Whitney U tests. The ACC and PCC were compared between trials where the CCC was and was not
122 achieved. Logistic regression estimated the odds ratio (OR) with 95% confidence interval (CI) of
123 failing to achieve CCC for a given ACC or PCC. Statistical significance was set to $p < 0.05$.

124 **Results**

125 The calcar-collar separation immediately after stem implantation is given in table 1.

126

127 **Table 1.** The measured distance between under surface of the calcar collar and cut calcar surface
128 immediately after stem implantation and prior to loading during each trial.

Planned CC separation (mm)	ACC median (mm)	ACC range (mm)	PCC median (mm)	PCC range (mm)
0	0.15	(0.00 to 0.75)	0.375	(0.00 to 0.90)
3	3.30	(2.81 to 4.07)	3.48	(0.94 to 4.63)
6	6.63	(5.80 to 6.88)	7.19	(5.74 to 7.46)

Note: All measurements are given in millimetres as measured immediately after stem implantation. CC indicates calcar-collar, ACC indicates the calcar-collar distance measured on the anterior surface of the specimen and PCC indicates the calcar-collar distance measured on the posterior surface of the specimen.

129

130 *Effect of calcar collar contact*

131 Where CCC occurred versus where no CCC occurred, median (interquartile range [IQR]) fracture
132 torque was greater (47.33 [41.03 to 50.45] Nm versus 38.26 [33.70 to 43.60] Nm , p= 0.05, Fig 3),
133 median (interquartile range [IQR]) rotational displacement was less (16.6 [15.5 to 22.3] degrees
134 versus 21.2 [18.9 to 28.1] degrees, p= 0.07, Fig 4), median torsional stiffness (IQR) was greater
135 (151.38 [123.04 to 160.42] rad.Nm⁻¹ versus 96.86 [84.65 to 112.98] rad.Nm⁻¹, p <0.01, Fig 4) and
136 median (IQR) rotational work was similar (5.88 [4.67, 6.90] J versus 5.31 [4.40, 6.56] J, p= 0.6, Fig 5).

137 *Effect of initial separation*

138 CCC was achieved prior to fracture in all cases in group one, 50% in group two and 0% in group
139 three. For all trials where CCC was achieved, the median (range) ACC was 0.40 (0.00, 3.37) mm
140 versus 6.15 (3.06 to 6.88) mm, where CCC was not achieved (p <0.01). The median (range) PCC for
141 those trials where CCC was achieved was 0.85 (0.00 to 3.71) mm versus 5.97 (2.23 to 7.46) mm,
142 where CCC was not achieved (p <0.01). Binomial logistic regression estimated OR of failure to obtain
143 CCC increased 3.8 fold (95% CI 1.6 to 30.2, p <0.05) for each millimetre of PCC in the model. When
144 the odds of CCC were modelled with ACC, the ACC was not a significant predictor of CCC (OR 45.2,
145 [95% CI 2.1 to 1 x10⁶, p =0.2). The model predicted that 95% chance of CCC prior to fracture was
146 associated with a PCC of 1 mm or less.

147 Discussion

148 Fracture torque and construct stiffness increased when a collared cementless stem made contact
149 with the femoral calcar prior to fracture versus a collared stem with no CCC. The odds of CCC
150 decreased with increasing initial calcar collar separation at the time of implantation.

151 Increased fracture torques for collared versus collarless stems have been demonstrated in two
152 independent biomechanical studies using different methodology (Johnson et al., 2020; Lamb et al.,
153 2019). This is the first experimental evidence demonstrating that CCC prior to fracture is crucial to
154 significantly increased fracture torque and construct stiffness. As previously demonstrated, the stem
155 tips posteriorly in our trials and the posterior edge of the calcar collar could be seen to contact the
156 calcar surface. It is likely that CCC leads to load transfer from the stem to the relatively stiff cortex
157 polymer, which deforms rather less than the medullary foam, whereas when there is no CCC, the
158 stem loads adjacent foam which deforms more easily under load and reduces the overall stem-
159 femur construct stiffness. This work confirms that CCC rather than the presence of a calcar collar per
160 se, is a key mechanism which acts to increase resistance to rotational PFF mechanisms.

161 The odds of achieving CCC prior to fracture decreased with increasing initial calcar-collar separation.
162 In this study the PCC and not the ACC was a significant predictor of the CCC. This is likely to be
163 because the trial used internal rotation (stem head moves posterior relative to anatomical axis),
164 which lead to engagement of the posterior collar and calcar. If the rotary displacement was reversed
165 that ACC distance is likely to make contact with the calcar and in this situation the ACC will become a
166 significant predictor of CCC. Although external rotation of the femur during a fall is a common
167 mechanism, not all PFF with rotational mechanism are caused by internal rotation of the stem
168 relative to the femur and surgeons should ensure that the ACC and PCC are both minimised to
169 increase likelihood of CCC during all rotational injuries. Given that following insertion cementless
170 femoral stems may subside 1mm along the anatomical axis of the femur during normal function in
171 the first three months following implantation (Van Der Voort et al., 2021), we recommend that
172 surgeons should aim to reduce any gap between calcar and under surface of the stem collar to a
173 maximum of 1mm to increase the likelihood of protection against early post-operative PFF.

174 Uniformity in composite femur specimens is a distinct advantage in terms of anatomical consistency
175 and absence of regulatory burden. Whilst the use of composite femur analogues are broadly
176 comparable to human femurs (Gardner et al., 2010), they may not exhibit comparable rate
177 dependent change in stiffness (Zdero et al., 2010), which occurs in human femurs (Courtney et al.,
178 1994). Composite femurs are an advantage in scenarios where variations in methods and materials
179 between laboratories may prevent reproduction of experimental results, however it prevents direct

180 immediate comparison between results using composite femurs and clinical practice. In addition, the
181 testing of intramedullary implants also brings into question the validity of homogenous foam in
182 composite femurs as a substitute for human cancellous bone. It is likely that the behaviour of the
183 stem inside a homogenous foam is different to the behaviour in a human femur, which varies in
184 mechanical properties in both length along the femur and also across the axial cross-section
185 (Oftadeh et al., 2015; Yang et al., 2012). In addition the coefficient of friction between a stem and
186 artificial bone is dissimilar to human trabecular bone (Grant et al., 2007). The homogenous foam
187 inside a composite femur represents the average for non-cortical femoral component such that the
188 overall mechanical properties of the femur are similar to a human femur. In human femora the
189 trabecular bone strength is likely to be less in the femoral neck and subtrochanteric region than in
190 the femoral head (Oftadeh et al., 2015), but in the composite femur they are the same, which may
191 make the implant unnaturally stable during simulated PFF. Whilst these discrepancies may prevent
192 unfettered translation of these findings into clinical practice with absolute confidence, we feel that
193 given the underlying mechanism has been previously demonstrated in cadaveric samples (Johnson
194 et al., 2020; Lamb et al., 2019), our results represent mechanism which is likely to be replicated with
195 human femurs. Given these constraints, we expect that in human femurs the relative movement
196 between stem and femur would be greater and that the real PCC which might be associated with a
197 95% chance of successful CCC is slightly larger.

198 The main limitation of this study is the use of composite bones to model implant behaviour during
199 PFF. Despite this being a previously adopted approach (Fottner et al., 2017; Ginsel et al., 2015;
200 Klasan et al., 2019; Morishima et al., 2014; Pepke et al., 2014; Schmidutz et al., 2017), further studies
201 using fresh frozen cadaveric specimens are required for clinical validation of these results. This
202 study did not quantify relative motion between the femur and stem. Future studies should seek to
203 quantify the relative displacement between the stem and femur, which is likely to be an important
204 factor when estimating the effect of the calcar collar on stability and resistance to fracture. We
205 estimated torsional stiffness without precise measurements of size and length of femur and
206 compared directly between specimens despite the small differences in specimen length due to small
207 differences in neck cuts. We estimate that the effect on stiffness estimates is negligible and should
208 not affect the overall conclusions. This study did not simulate PFF occurring around an
209 osseointegrated stem because a validated model of simulated in vitro osseointegration does not
210 exist. Since a large proportion of PFF occur within the first 90 after implantation, when
211 osseointegration is unlikely to be complete, our experiments still represent a clinically relevant
212 model. Although the benefit of CCC as visualised on high speed video is demonstrated in this study,
213 the load from the calcar to the collar has not been directly measured and thus future

214 recommendations may be improved with direct measurement of calcaneal collar mechanics in future
215 trials. Despite rigorous methodology the variability in measurements in this study was larger than
216 expected and further studies to investigate sources of variability and refinement of methods would
217 be useful to reduce variability and the requirement for large sample sizes.

218 Conclusions

219 These results demonstrate that calcar-collar contact and not a calcar collar per se, is crucial to
220 maximising the protective effect of a stem with a collar on the risk of post-operative periprosthetic
221 fractures of the femur. Increased post-operative gap between collar and calcar reduced the
222 likelihood of calcar collar contact during a simulated periprosthetic fracture of the femur. Surgeons
223 should aim to reduce calcar-collar distance to a maximum of 1mm following implantation to increase
224 the chance of calcar collar contact during injury and reduce the risk of fracture.

225

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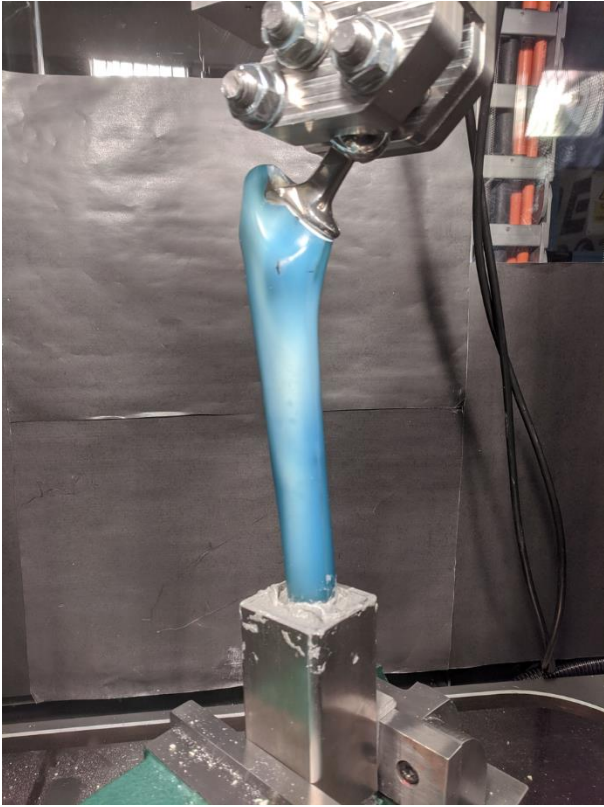
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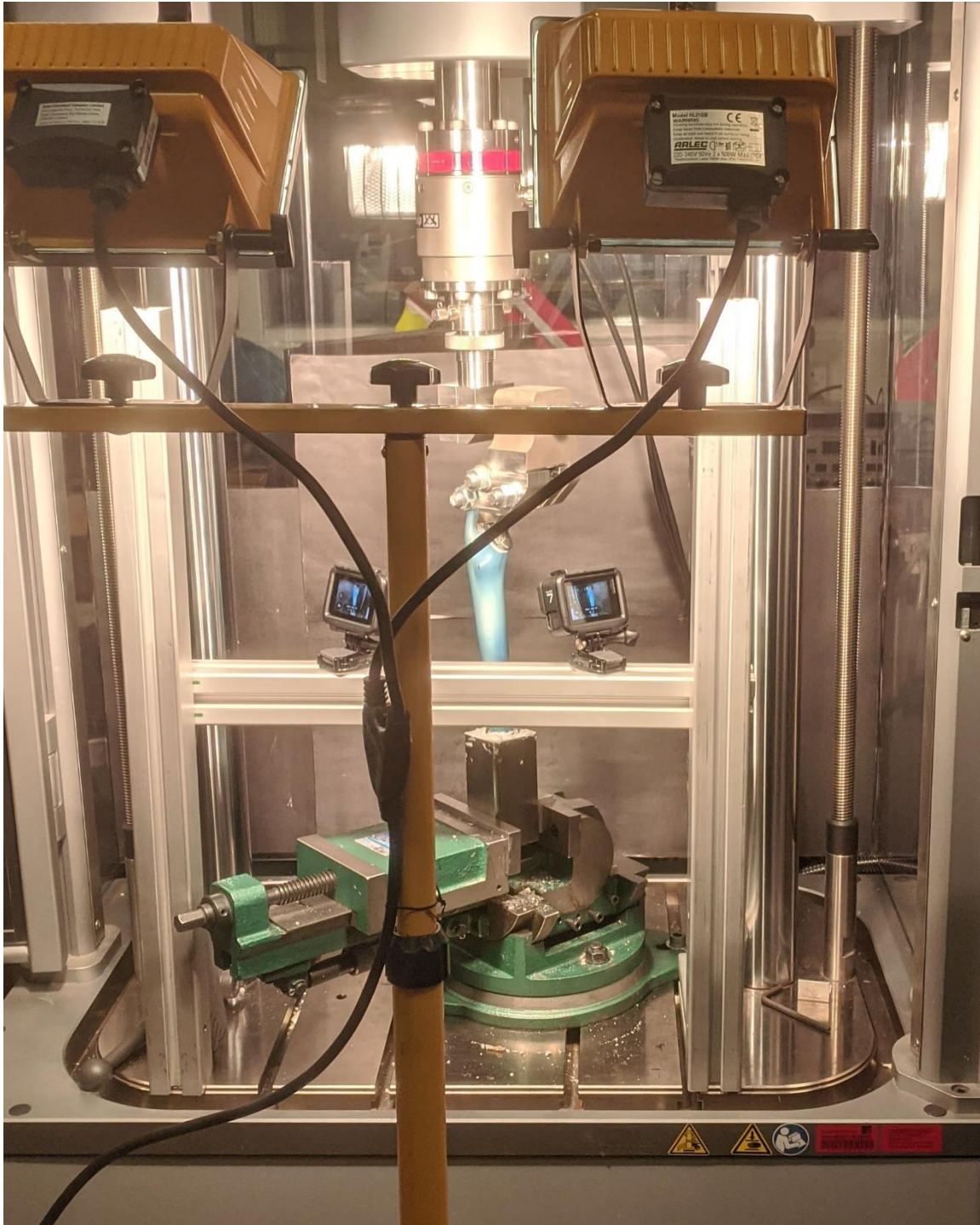
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290 Figures:



291

292 Fig 1: Example of experimental set up in group 1 (no calcar collar gap).

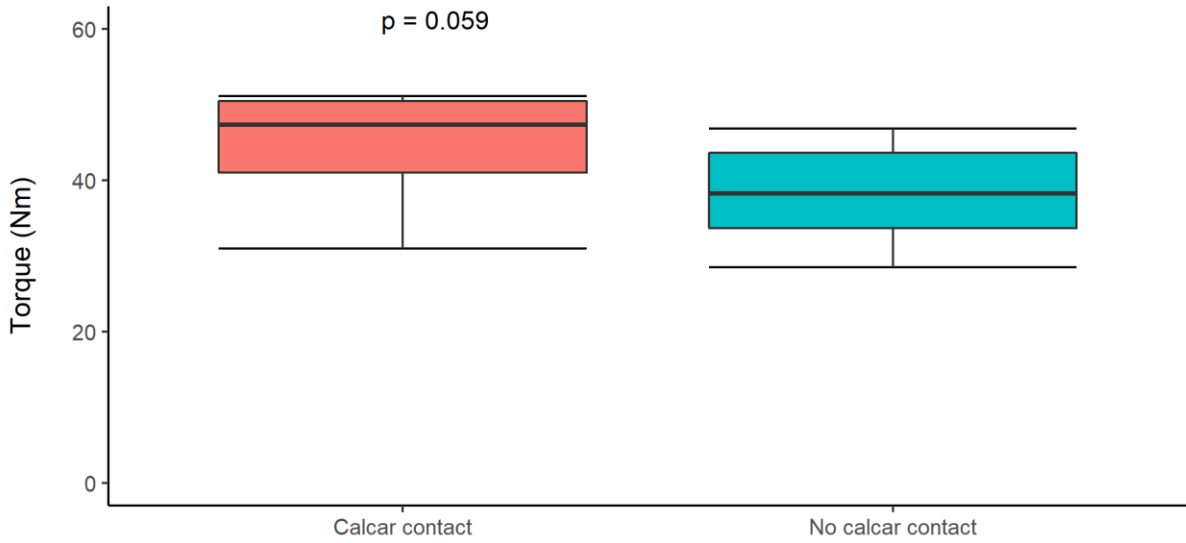


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294 Fig 2: Example of experimental set up with camera position and lighting.

295

Fracture torque by calcar contact prior to fracture as seen on high speed video



Groups compared using Mann Whitney-U test, p value is displayed

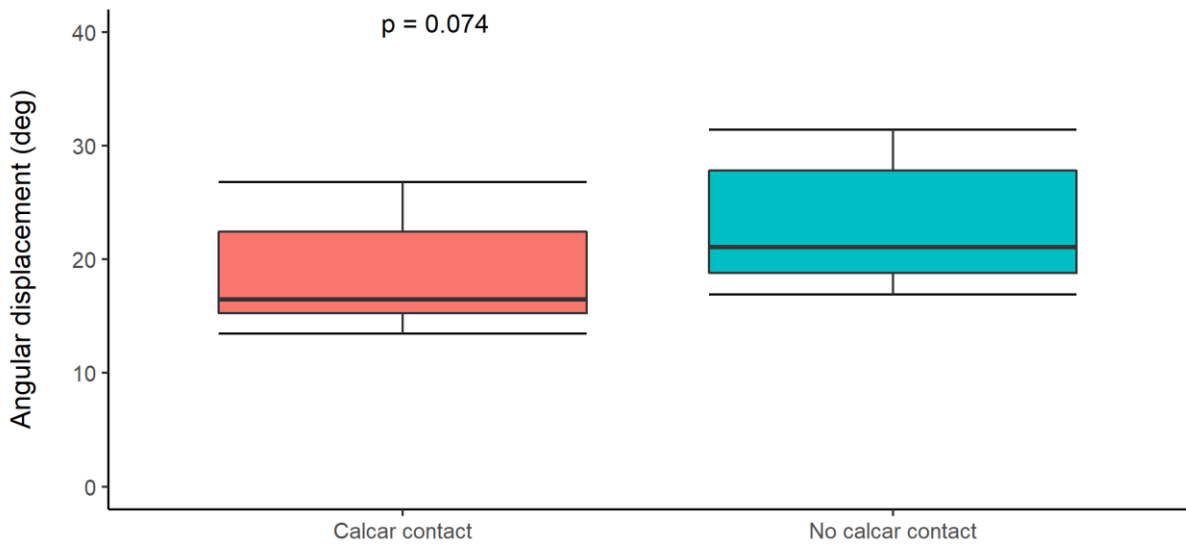
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297 Fig 3: Boxplot comparing maximum fracture torque prior to fracture stratified by calcar collar

298 contact

299

Angular displacement at fracture by posterior calcar contact prior to fracture as seen on high speed video

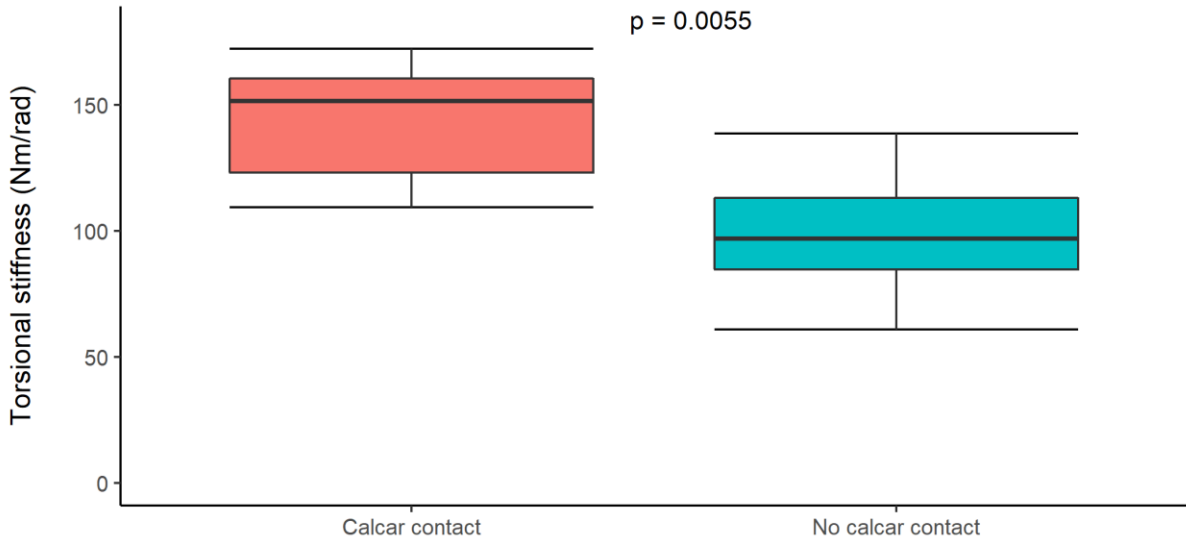


Groups compared using Mann Whitney-U test, p value is displayed

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301 Fig 4: Boxplot comparing angular displacement prior to fracture stratified by calcar collar contact

Torsional stiffness by calcar contact prior to fracture as seen on high speed video



Groups compared using Mann Whitney-U test, p value is displayed

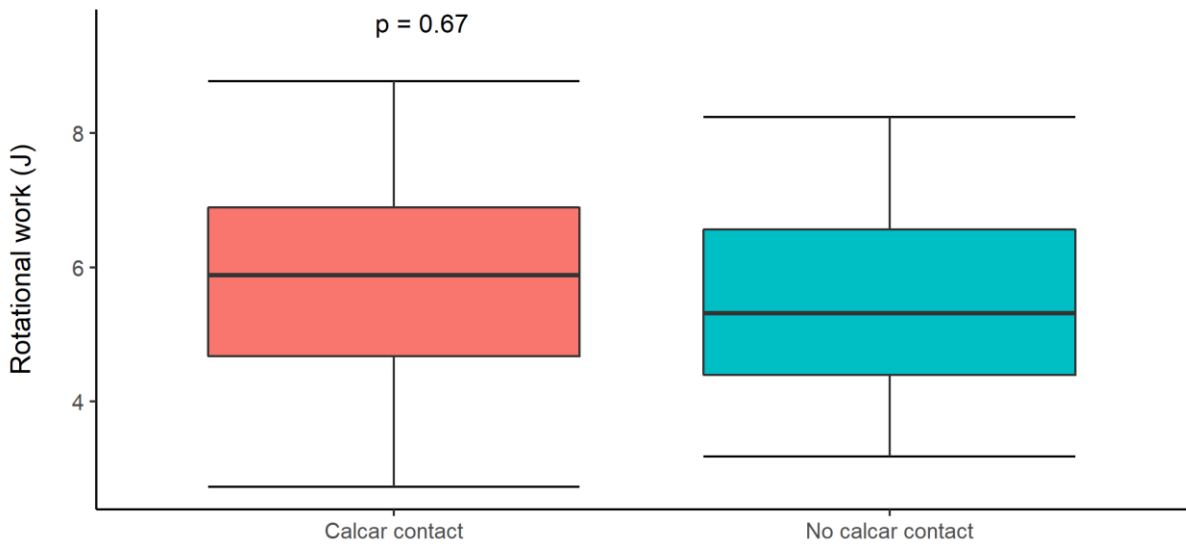
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303 Fig 5: Boxplot comparing torsional stiffness from initiation of angular displacement to fracture

304 stratified by calcar collar contact

305

Rotational work by calcar contact prior to fracture as seen on high speed video



Groups compared using Mann Whitney-U test, p value is displayed

306

307 Fig 6: Boxplot comparing rotary work from initiation of angular displacement to fracture stratified by

308 calcar collar contact