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Title

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

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Declaration of interest statement

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

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Abstract

Background

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

Methods

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

Findings

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

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

Interpretation

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

Introduction

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

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

Methods

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

Specimen preparation

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

Experimental setup

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

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

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

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

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

Results

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

Table 1. The measured distance between under surface of the calcar collar and cut calcar surface 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.

Effect of calcar collar contact

Where CCC occurred versus where no CCC occurred, median (interquartile range [IQR]) fracture 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), median (interquartile range [IQR]) rotational displacement was less (16.6 [15.5 to 22.3] degrees versus 21.2 [18.9 to 28.1] degrees, p= 0.07, Fig 4), median torsional stiffness (IQR) was greater (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 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).

Effect of initial separation

CCC was achieved prior to fracture in all cases in group one, 50% in group two and 0% in group three. For all trials where CCC was achieved, the median (range) ACC was 0.40 (0.00, 3.37) mm versus 6.15 (3.06 to 6.88) mm, where CCC was not achieved (p <0.01). The median (range) PCC for those trials where CCC was achieved was 0.85 (0.00 to 3.71) mm versus 5.97 (2.23 to 7.46) mm, where CCC was not achieved (p <0.01). Binomial logistic regression estimated OR of failure to obtain CCC increased 3.8 fold (95% CI 1.6 to 30.2, p <0.05) for each millimetre of PCC in the model. When the odds of CCC were modelled with ACC, the ACC was not a significant predictor of CCC (OR 45.2, [95% CI 2.1 to 1 x10^{6}, p =0.2). The model predicted that 95% chance of CCC prior to fracture was associated with a PCC of 1 mm or less.

Discussion

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

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

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

Uniformity in composite femur specimens is a distinct advantage in terms of anatomical consistency and absence of regulatory burden. Whilst the use of composite femur analogues are broadly comparable to human femurs (Gardner et al., 2010), they may not exhibit comparable rate dependent change in stiffness (Zdero et al., 2010), which occurs in human femurs (Courtney et al., 1994). Composite femurs are an advantage in scenarios where variations in methods and materials between laboratories may prevent reproduction of experimental results, however it prevents direct immediate comparison between results using composite femurs and clinical practice. In addition, the testing of intramedullary implants also brings into question the validity of homogenous foam in composite femurs as a substitute for human cancellous bone. It is likely that the behaviour of the stem inside a homogenous foam is different to the behaviour in a human femur, which varies in mechanical properties in both length along the femur and also across the axial cross-section (Oftadeh et al., 2015; Yang et al., 2012). In addition the coefficient of friction between a stem and artificial bone is dissimilar to human trabecular bone (Grant et al., 2007). The homogenous foam inside a composite femur represents the average for non-cortical femoral component such that the overall mechanical properties of the femur are similar to a human femur. In human femora the trabecular bone strength is likely to be less in the femoral neck and subtrochanteric region than in the femoral head (Oftadeh et al., 2015), but in the composite femur they are the same, which may make the implant unnaturally stable during simulated PFF. Whilst these discrepancies may prevent unfettered translation of these findings into clinical practice with absolute confidence, we feel that given the underlying mechanism has been previously demonstrated in cadaveric samples (Johnson et al., 2020; Lamb et al., 2019), our results represent mechanism which is likely to be replicated with human femurs. Given these constraints, we expect that in human femurs the relative movement between stem and femur would be greater and that the real PCC which might be associated with a 95% chance of successful CCC is slightly larger.

The main limitation of this study is the use of composite bones to model implant behaviour during PFF. Despite this being a previously adopted approach (Fottner et al., 2017; Ginsel et al., 2015; Klasan et al., 2019; Morishima et al., 2014; Pepke et al., 2014; Schmidutz et al., 2017), further studies using fresh frozen cadaveric specimens are required for clinical validation of these results. This study did not quantify relative motion between the femur and stem. Future studies should seek to quantify the relative displacement between the stem and femur, which is likely to be an important factor when estimating the effect of the calcar collar on stability and resistance to fracture. We estimated torsional stiffness without precise measurements of size and length of femur and compared directly between specimens despite the small differences in specimen length due to small differences in neck cuts. We estimate that the effect on stiffness estimates is negligible and should not affect the overall conclusions. This study did not simulate PFF occurring around an osseointegrated stem because a validated model of simulated in vitro osseointegration does not exist. Since a large proportion of PFF occur within the first 90 after implantation, when osseointegration is unlikely to be complete, our experiments still represent a clinically relevant model. Although the benefit of CCC as visualised on high speed video is demonstrated in this study, the load from the calcar to the collar has not been directly measured and thus future recommendations may be improved with direct measurement of calcar collar mechanics in future trials. Despite rigorous methodology the variability in measurements in this study was larger than expected and further studies to investigate sources of variability and refinement of methods would be useful to reduce variability and the requirement for large sample sizes.

Conclusions

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

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Figures:

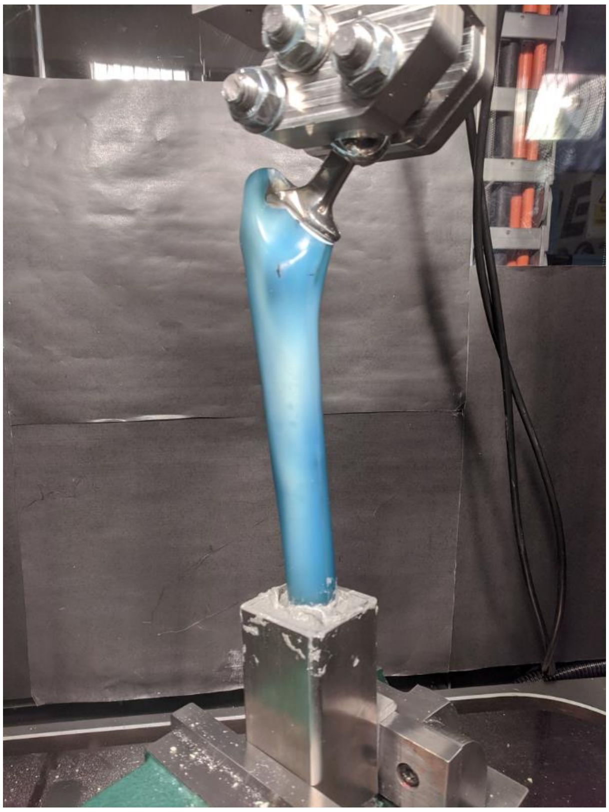

Fig 1: Example of experimental set up in group 1 (no calcar collar gap).

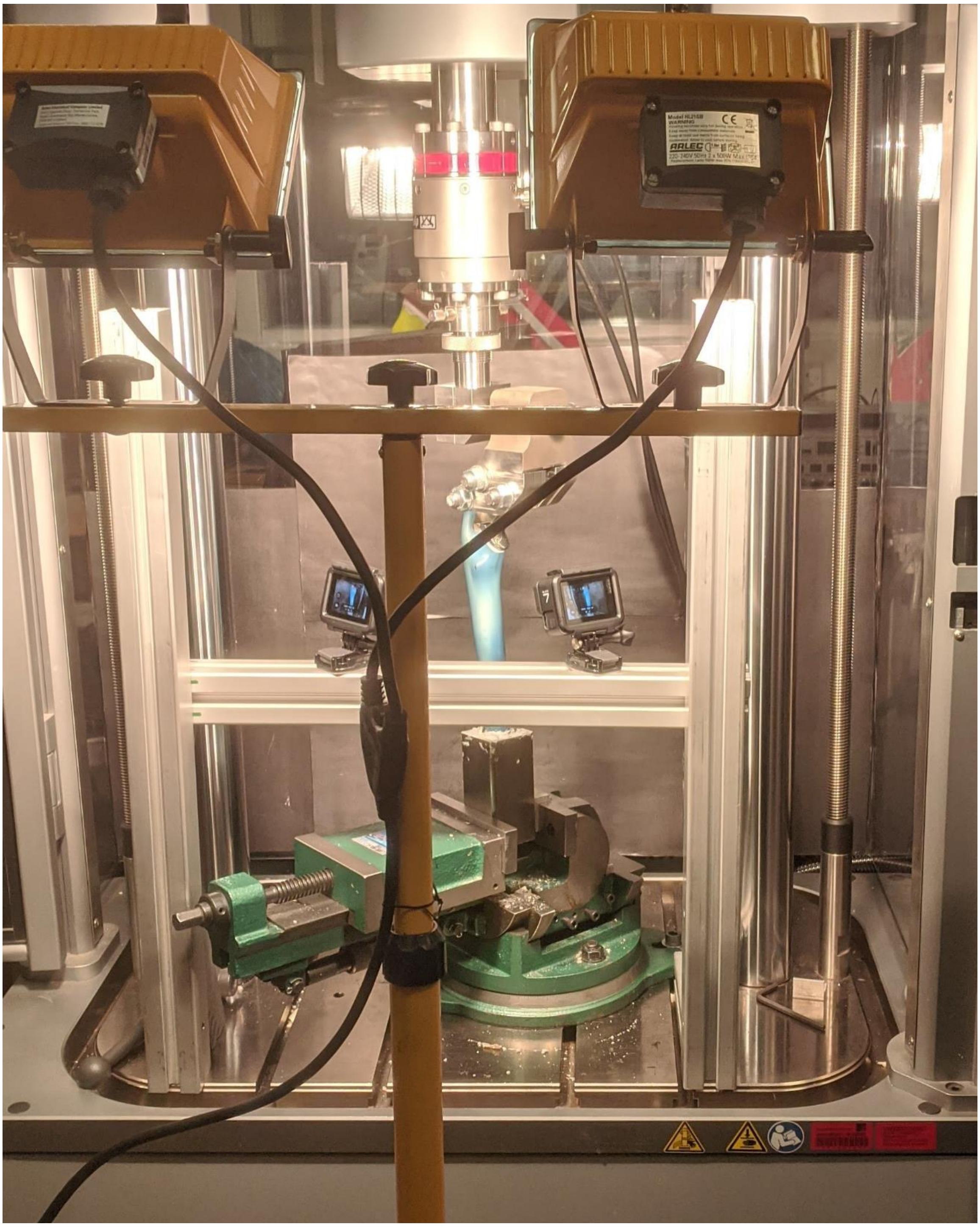

Fig 2: Example of experimental set up with camera position and lighting.

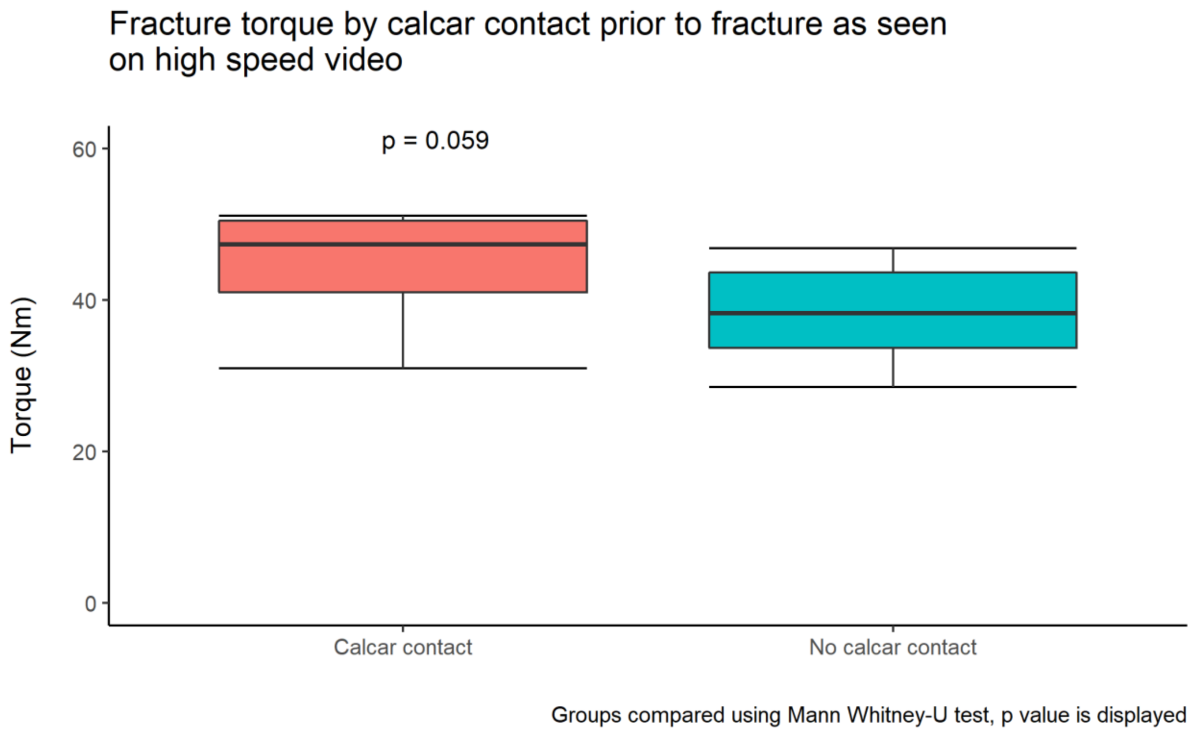

Fig 3: Boxplot comparing maximum fracture torque prior to fracture stratified by calcar collar contact

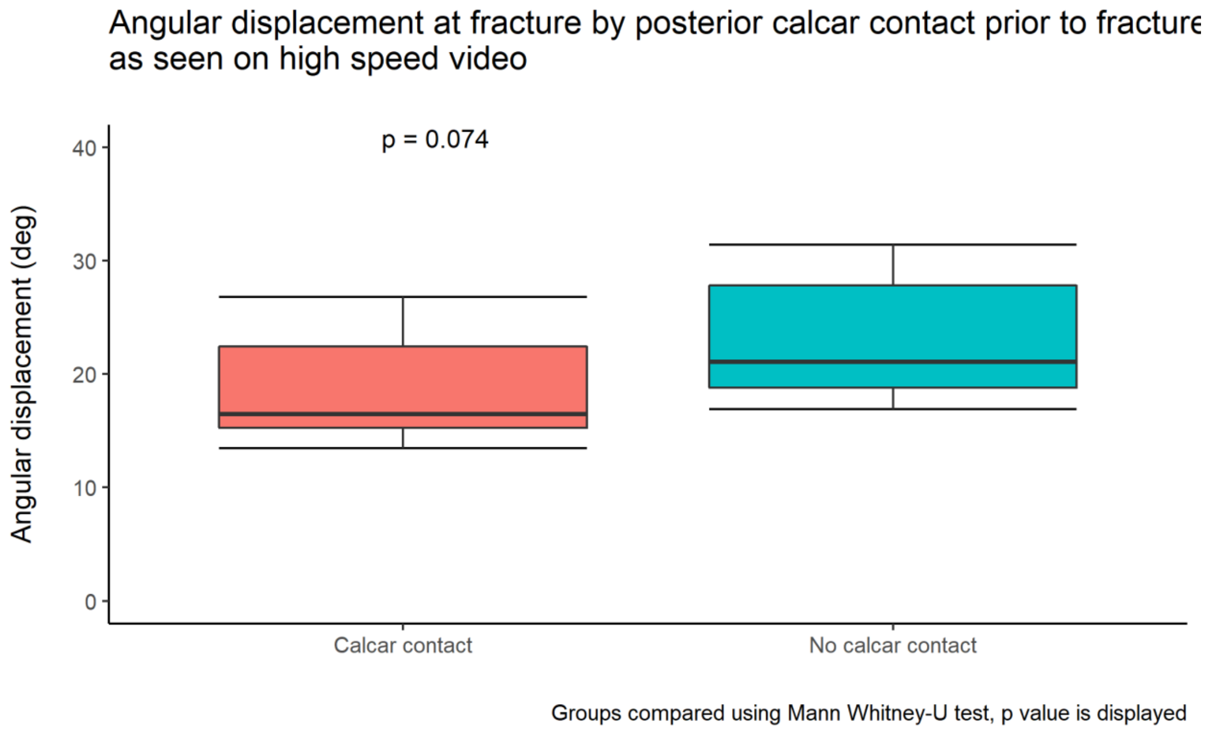

Fig 4: Boxplot comparing angular displacement prior to fracture stratified by calcar collar contact

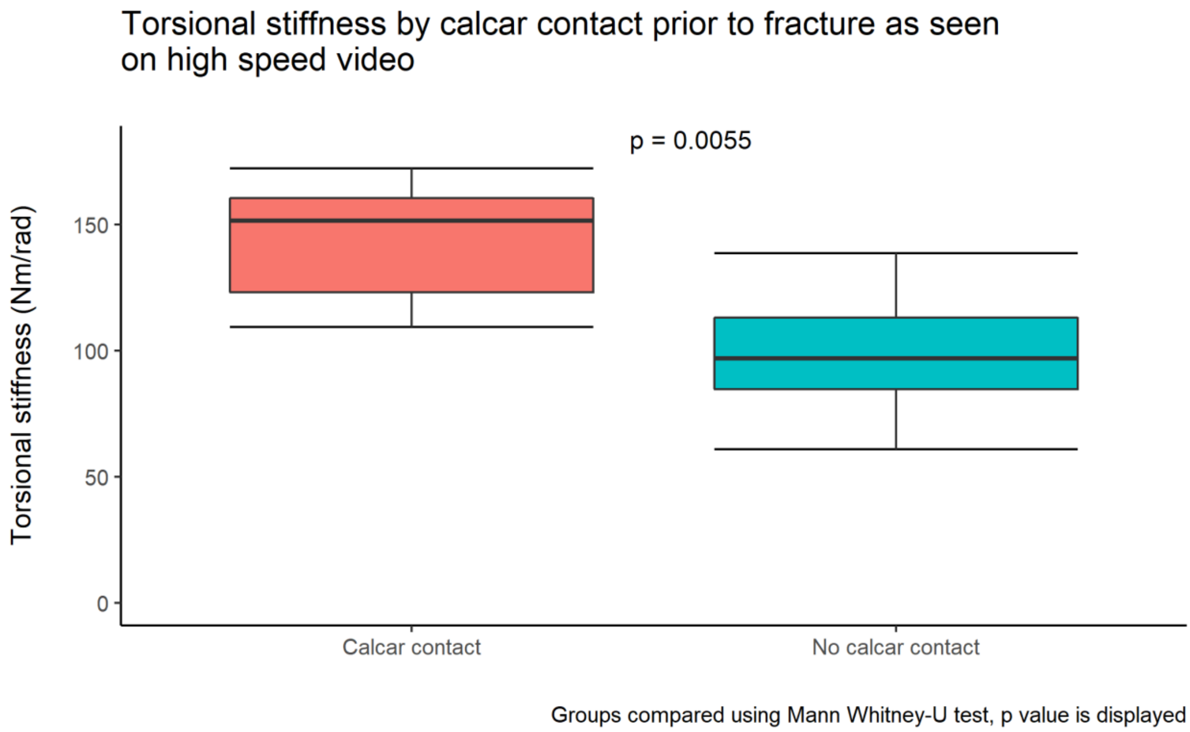

Fig 5: Boxplot comparing torsional stiffness from initiation of angular displacement to fracture stratified by calcar collar contact

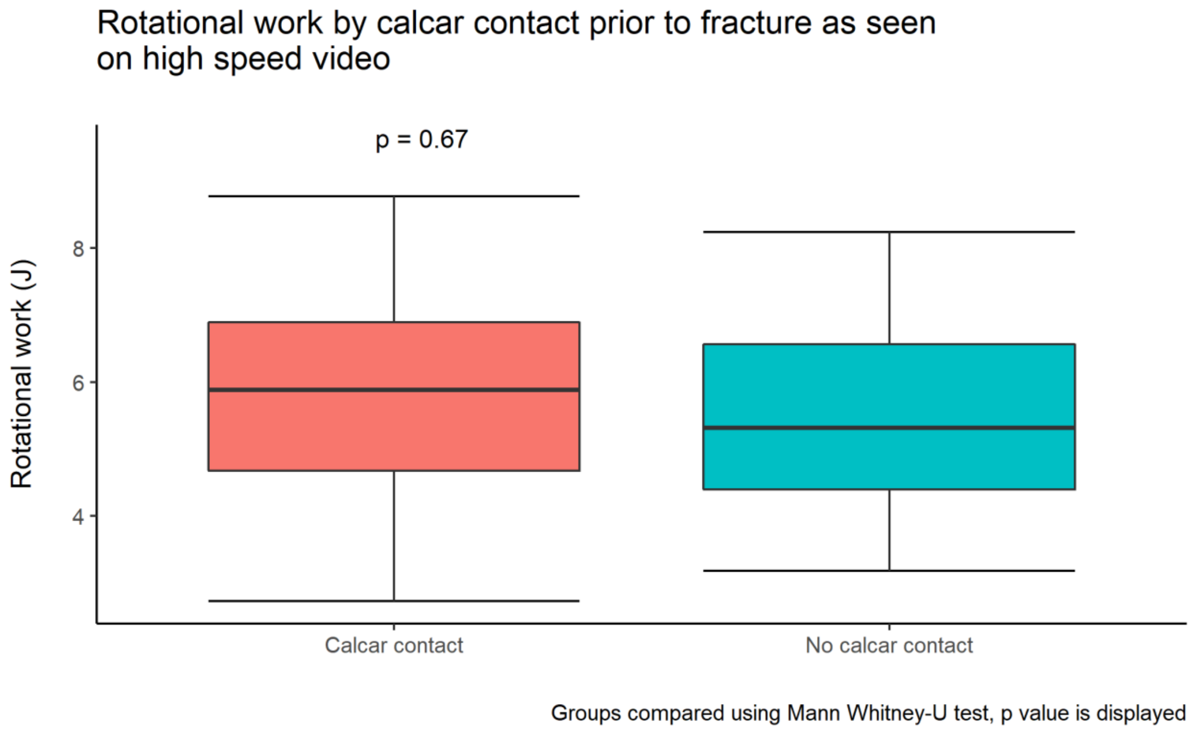

Fig 6: Boxplot comparing rotary work from initiation of angular displacement to fracture stratified by calcar collar contact