Calcar collar is protective against early periprosthetic femoral fractures around cementless primary total hip arthroplasty: A registry study with biomechanical validation.

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Abstract

Aims

To estimate the 90-day risk of revision for periprosthetic femoral fracture (PFF) associated with design features of cementless femoral stems and to investigate the effect of a collar on early PFF risk using a biomechanical in-vitro model.

Patients, materials and methods

337 647 primary THAs from the National Joint Registry (UK) were included in a multivariable survival and regression analysis to identify the adjusted hazard of PFF revision following primary THA using cementless stems. The effect of a collar in cementless THA on early PFF was evaluated in an in-vitro model using paired fresh frozen cadaveric femora.

Results

Prevalence of PFF revision was 0.34% (1180/337647) and 44.0% occurred (520/1180) within 90 days of surgery. Implant risk factors included: collarless stem, non grit-blasted finish and triple tapered design. In the in-vitro PFF model a medial calcar collar consistently improved construct stability and fracture resistance.

Conclusion

Analysis of stem design features in registry data is a useful method to identify implant characteristics which affect the risk of early PFF around cementless femoral stems. Calcar collar reduced early PFF risk and this was confirmed by biomechanical testing. This approach may be useful in the analysis of other uncommon arthroplasty failure modes.

Introduction

Periprosthetic femoral fracture (PFF) occur in up to 5% of primary total hip arthroplasty (THA)[1, 2] . Management of these cases is complex and costly with reported one-year mortality between 11 and 13%[3, 4]. A significant proportion require revision surgery which is expensive and has unpredictable outcomes[5]. The incidence of PFF is predicted to increase by 4.6% per decade, over the next 30 years[6]. Modifiable risk factors for PFF need to be explored to minimise the incidence of this significant complication.

Implant choice remains one of the few surgically modifiable risk factors and the risk is highest around cementless stems[1, 7-11]. The risk of PFF is greatest in the early post-operative period and is four-fold around cementless versus cemented stems in the first 90 days[11]. Risk of PFF differs between implant brands[7, 10]. Cementless stems are a heterogeneous group, with many variations in surface treatments, body shapes, lengths and various combinations of collars and wings, even within a single stem model. Comparison using stem models categorised by design groups

has previously been performed[12] but the contribution of a specific design feature to the risk of PFF is difficult to ascertain. Analysis of PFF revision rates attributable to specific design features may better inform future implant design. The overall incidence of PFF is relatively low and large sample sizes available in arthroplasty registries are needed to establish association between design features and risk of PFF.

Early PFF around cementless stems most commonly cause a Vancouver A_{1-2} fracture type or “new B_2” (fracture of calcar with lesser trochanter) [13-17]. These fracture patterns suggest a torsional mechanism[16] which can be simulated using a combination of rotational and axial forces[18-20], thus design features which prevent early PFF can be tested in a simulated setting. Current evidence relies on methods which are difficult to interpret due to non-standardised methods and the use of quasi-static loading which do not accurately replicate fracture mechanics[21]. Fracture loads between patients are not comparable due to differences in age and bone mineral density[22], within patient (paired) comparison may provide more robust results[21, 23]. It is important that design features are robustly tested to ensure that there are plausible mechanisms by which clinical data can be explained.

Implant design features which potentially alter the risk of early PFF include medial calcar collar, which reduces subsidence, increases rotational stability and the force to fracture in a quasi-static loading model[24, 25]. Increasing sagittal taper has been associated with increased PFF risk [10, 26]. Anatomical stem designs have been associated with lower risk of PFF versus tapered designs in cementless stems[10]. Additionally, modern surface finishes are reported to have greater primary stability, which may reduce the risk of early PFF[27].

The first aim is to establish design features which are associated with increased risk of early PFF revision surgery from the UK national joint registry (NJR). The second aim is to experimentally investigate the underlying mechanism by which a collar alters early PFF risk.

Materials and Methods

Registry analysis

The NJR records patient and surgical data for all THAs performed at hospitals in England and Wales since 2003[28]. This study used all primary THAs with a stemmed cementless femoral implant in the NJR from 2003 to 2016. Femoral implant catalogue codes were used to gather manufacturer provided implant design data.

Participants

Registry data

349 161 THAs were eligible for analysis. Exclusions were: implantation prior to formal reporting of Intraoperative periprosthetic femoral fracture (IOPFF) in 01/04/2004 (n = 3270), missing follow up data (n = 4), missing design data (n= 590), non-standard length stems (tip finished before the diaphysis or at the mid-diaphysis, n= 7038) and 612 cases were excluded from regression due to insufficient numbers for meaningful analysis (indications: previous arthrodesis, previous infection, malignancy [n = 247] , fully porous coated stems [n = 143], and approach: trochanteric osteotomy [n = 222]). 337 647 cases were included in subsequent analyses. Institutional ethical approval was granted for this study.

Patient and surgical variables

Variables included were patient age (years), gender, American Society of Anaesthesiologists group (1-2 vs 3-5), side of operation, surgical approach (anterolateral [Hardinge, anterolateral and lateral], posterior, other), computer guided surgery, minimally invasive surgery, surgeon grade (consultant/non-consultant), hospital type (National Health Service [NHS], Independent hospital, Independent treatment centre), indication for surgery (osteoarthritis, trauma including hip fracture, avascular necrosis, inflammatory arthritis, previous trauma, paediatric hip disease and other) and IOPFF (yes/no).

Implant variables

All registry variables relating to stem design: calcar collar (yes/no), surface finish, surface features and stem shape were included in subsequent analysis. Surface finishes were coded (MIN = mineralised with hydroxyapatite or calcium phosphate, POR = non-mineralised porous finish, GRIT = grit blasted or roughened, NONE = no surface finish). Stems were then coded according to surface finishes in proximal and distal regions (proximal:distal, e.g. MIN:NONE stands for a stem coated proximally with hydroxyapatite and no distal surface finish). Surface shape (Flat, Horizontal ridges, Vertical ridges), Stem shape in cross section (rectangular, oval or round), body taper in the coronal, sagittal or axial plane (Single, double or triple taper respectively) and sagittal stem shape (curved vs straight) were included.

Outcomes

The primary outcome of registry analysis was implant survival until PFF revision within 90 days.

Statistical analysis

Non-normally distributed continuous variables were expressed as median values with interquartile range (IQR). Since the dataset was large and multiple comparisons were made, a significance level of $p < 0.01$ was chosen. Survival was estimated using a Cox multivariable model. PFF revision at 90 days only counted if not preceded by IOPFF to reduce confounding. Implants in patients who died or were not revised for PFF at 90 days were censored. HR estimates were adjusted for all other patient, surgical and design variables (Table 2 and 3). Multivariable regression estimated the adjusted hazard ratio of revision with 95% confidence intervals (HR [CI 95%]) for each implant design factor. All analyses were performed using R (v3.5.1, R, Vienna, Austria). Regression models were stratified by gender to satisfy the assumptions of proportionality and then assessed using the concordance statistic. For biomechanical testing the maximum torsional moment prior to failure of the specimen was compared between samples. Due to the small number of specimens, no test for significance was computed.

Biomechanical testing

Specimens and preparation

This study was performed in accordance with local ethical guidelines and regulations of Hamburg University School of Medicine. Biomechanical assessment of the effect of calcar collar on pre-osseointegration PFF was performed by comparing maximum moment to fracture between collared and collarless Corail (DePuy, Leeds, UK) implants which are identical in every way apart from the presence of a calcar collar. To minimise cost of precious donated fresh frozen femora a small sample size was used. 5 pairs of fresh frozen human female femora were dissected within 48-hours post-mortem, frozen at -20℃ (2 freeze-thaw cycles per specimen), and defrosted overnight before biomechanical testing and kept moist using saline solution and plastic wrapping (Table 1). One pair of femora was excluded due to IOPFF and one pair due to adhesive failure between implant head and load applicator during mechanical testing.

Preparation and fixation was performed by a single experienced surgeon (JL) to minimize variability. Femora were stripped of soft tissue and scanned using a 16-row Computer tomography scanner (CT, Brilliance 16 CT; Philips Healthcare, Hamburg, Germany) with a solid calibration phantom (Bone Density Calibration Phantom; QRM, Möhrendorf, Germany) to assess bone mineral density[29] and screen for pre-existing fractures and/or bony disease. Femora were prepared using standard equipment as per manufacturer's guidelines. Calcar reaming was performed on each femur and primary stability was assessed manually for each stem. Prior to stem implantation a plastic replica implant identical to the final implant was inserted into the cavity to reduce CT artefact and CT scanning was repeated to look for IOPFF. In each pair, one femur was implanted with a Corail collarless stem and the other with a Corail collared stem (both stems DePuy [standard offset, 135 degrees], Leeds, UK) of equal size and offset (Figure 1). Stem stability was assessed manually and collar contact was confirmed when the implant was fully seated. CT scanning was repeated to ensure correct implant placement and exclude IOPFF. CT images were analysed using FIJI (ImageJ v1.52, NIH, USA).

Experimental setup

The test set up was adapted from previous methods[19]. A rotational method was chosen because this has previously been shown to reproduce PFF at the level of the stem[19-21] and is likely to be a common mechanism of injury in early PFF around cementless stems[16]. Specimens were embedded distally in polymethylmethacrylate inside steel pots and stabilised with reinforcing screws to prevent axial rotation of the femur. Specimens were aligned in 6 degrees of varus in the coronal plane and vertical in the sagittal plane. Depth was adjusted so 40mm of diaphysis remained between the stem tip and the fixative. A 32mm CoCr head (DePuy, Leeds, UK) was fitted to the stem and fixed to the load applicator with adhesive (Figure 2). A vertical load was applied to the specimen to simulate single leg stance (1500N) for ten seconds to allow bedding in and stabilisation of stem press-fit[30]. The head was rotated internally through 45^0 in one second to simulate a traumatic event and obtain more realistic mechanical properties of the proximal femur [31] (MTS 858.2; Eden Prairie, MN, USA). Video recording at 5000hz (CamRecord 5000, Optronis, Kehl, Germany) and 60Hz during trials (GoPro 4, GoPro, California, USA) and CT-scanning after fracture were performed to identify fracture patterns.

Results

Registry analysis

The two year prevalence of PFF revision was 0.21% (707/337647) and the overall prevalence of PFF revision was 0.34% (1180/337647), 44.0% occurred (520/1180) within 90 days and 48.9% (578/1180) occurred within 6 months of surgery (Figure 3). Median (IQR) follow-up time was 5.5 years (3.13 – 8.10). Baseline demographics are displayed in Table 2. Most cementless stems were collarless double tapered with a fully mineralised coating (Table 3).

Influence of design factors on 90 day PFF revision risk

The regression model correctly predicted early PFF in 72% of the cases (concordance statistic 0.72). After adjustment for all patient, surgeon and surgical variables, design variables which significantly increased the risk of PFF revision within 90 days, were collarless design (HR 4.7 [CI 3.5 – 6.3], p<0.001), surface finish (reference GRIT:GRIT coating: MIN:MIN coating, HR 4.6 [CI 2.3-9.3], p<0.001; MIN:NONE coating, HR 4.8 [2.3 – 9.95], p<0.001; POR:GRIT coating, HR 7.9 [CI 2.8 – 21.7], p <0.001; and POR:NONE coating, HR 4.8 [CI 2.8 – 21.7], p<0.001). Triple taper design also increased early PFF revision risk (HR 1.8 [CI 1.4 – 4.1], p<0.01, Figure 4).

Calcar collar was selected as the design feature and subjected to biomechanical testing because of large estimated effect with narrow confidence intervals, which suited testing on smaller samples and the availability of a cementless stem design with and without a collar which is otherwise identical.

Biomechanical testing of risk factors for early PFF revision

Maximum torsional moment prior to fracture in all femur pairs was greater for the collared implant versus a collarless implant (Figure 5).

Collarless stems deformed the trabecular bone adjacent to the stem body during rotational moment application until the implant engages with the cortex and produced smaller fractures of the posterior calcar. The collared implants rotated less within the femur, until the posterior collar engaged with the cut edge of the cortex and then moved in this position with the femur until a fracture occurred. Collared stems produced larger fractures compared to collarless stems (Figures 6 and 7).

Discussion

Almost half of all PFF revisions around cementless stems occurred within six months of implantation. Collarless implants were associated with a nearly five-fold relative risk of early PFF versus collared implants. Early PFF revision risk is significantly increased in all mineralised and non-mineralised porous coated cementless stems and in stems which are tapered from lateral to medial in the axial plane. The biomechanical testing reproduced early in-vivo periprosthetic fracture patterns[13, 14] and confirmed that PFF with a collarless stem occurs with less force than an otherwise identical collared stems.

Calcar collars may improve implant stability through imparting compressive loads on the calcar and were commonly used on cementless implants to reduce stem subsidence[25]. Problems with imperfect calcar collar contact after insertion and a randomized controlled trials (RCT) showing no benefit have discouraged its use[32]. Revision due to PFF within 90 days is uncommon (0.3%) and an appropriately powered RCT to show the benefit of a collar with the end-point of PFF would require unrealistically large patient numbers. This study shows that a collar is associated with an almost five-fold reduction in early PFF revision risk, probably due to earlier cortical load transfer during rotational traumas. Cortical bone is anisotropic and strongest when loaded in compression[33, 34]. During rotational injury the collar can load the calcar in compression increasing the force required for a fracture. We propose that this mechanism increases the force required to cause a PFF around a collared implant versus collarless implants. The calcar possibly acts as a check-rein which prevents excessive peri-prosthetic trabecular deformation in rotational injuries and may improve the resistance to trabecular deformation after high energy injuries which do not cause cortical fracture.

Proximal porous coating has been shown to increase load transfer to the proximal femur[27, 35] and increase force required to fracture using an axial loading PFF model[27]. We have demonstrated an increased risk of early PFF with mineralised and non-mineralised porous coated stems. Where there is no direct calcar loading, it may be preferable to load the femoral shaft during rotational insult, which is innately more flexible than the stiffer proximal metaphyseal bone[36]. We have shown an almost doubled risk of early PFF associated with cementless stems which are tapered medial to lateral in the axial plane versus conventional double tapered stems. Medial to lateral taper is thought to increase proximal loading of the femur[37] and has been successfully incorporated into cementless designs[38]. When compared to double tapered stems, a triple taper (medial to lateral) may increase the loading of trabeculae adjacent to the narrower medial implant surface during an injury, leading to greater trabecular deformation and greater risk of eventual cortical fracture.

This registry analysis estimated the risk of PFF revision, whilst this includes most cases of PFF in UK practice[39] it was likely to be an underestimate of real PFF incidence, which also includes cases where PFF undergo internal fixation or conservative management[2]. The 2 year prevalence of PFF revision was lower than the 0.47% prevalence of PFF revision reported by Thien et al.[7], which may partly be due to different surgical practices and implant usage. We excluded patients with IOPFF from the analysis of early PFF to reduce confounding, it may be that a proportion of early PFF are due to unrecognised or unreported IOPFF which propagate during the early post-operative stage. We assumed the likely fracture pattern around cementless femoral stems based on the best available evidence but we were unable to verify the mechanism and pattern of injury in our registry data because the patient notes and radiographs were not available. Our choice of implant characteristics investigated was based on review of the literature but this may change as we gain a deeper understanding of how design influences early PFF risk. The implant design itself or the combination of certain implant features might have biased our findings. This should be investigated in more detail in the future. Given that this is a new approach to the analysis of registry data, we hope that the influence of further variables on early PFF risk or other research questions will be investigated in a similar way.

We made use of paired femora to match biomechanical trials on likely confounders. Simulation of the soft tissues or other possible fracture mechanisms should also be investigated to allow comparison to in vivo joint forces. The findings of the biomechanical study are limited by the small numbers and that only one implant design investigated. It still needs to be shown that the results can be generalized to other stem designs, even so this seems reasonable, since the observed effect can be explained biomechanically. Given our efforts to eliminate IOPFF prior to testing, replication of in-vivo fracture patterns and the additional information gained by video footage, we are confident that the trends observed would be confirmed statistically with larger sample sizes.

The combination of registry analysis and biomechanical testing allows appraisal of existing design features and has the potential to influence future implant design. Other infrequent modes of failure could also be addressed by this approach. This might help to make total hip arthroplasty even more successful than it already is. These results demonstrate a significant increased risk of early PFF revision associated with collarless implants, mineralised and porous non-mineralised coated implants and triple tapered cementless stem designs. We also have suggested a plausible biomechanical mechanism via which a calcar collar reduces the risk of early PFF. Given the predicted rise in PFF rates, the use of a medial calcar collar may help to improve future cementless stem survival by reducing the risk of early PFF.

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Table 1. Donor demographics for female femora used in biomechanical testing

Trial	Collar	Age (years)	Height (cm)	Side	BMD [gHA/cm^3]
1	Yes	67	154	Right	1.35
1	No	67	154	Left	1.31
2	No	85	157	Right	1.08
2	Yes	85	157	Left	1.08
3	No	76	158	Right	1.33
3	Yes	76	158	Left	1.42

BMD indicates bone mineral density measured in grams of hydroxyapatite per cubic centimetre

Variable		Total n = 337647
Gender (%)	Male	148093 (43.9)
	Female	189554 (56.1)
Side (%)	Left	153432 (45.4)
	Right	184215 (54.6)
Age group (%)	11 to 49	25787 (7.6)
	50 to 59	62063 (18.4)
	60 to 69	121046 (35.8)
	70 to 79	97603 (28.9)
	80 to 117	31148 (9.2)
ASA grade (%)	1	62846 (18.6)
	2	233422 (69.1)
	3	40091 (11.9)
	4	1248 (0.4)
	5	40 (0.0)
Organisation type (%)	NHS	216733 (64.2)
	Independent Hospital	104548 (31.0)
	Treatment centre	16366 (4.8)
Indication (%)	Osteoarthritis	317054 (93.9)
	Acute trauma including hip fracture	5467 (1.6)
	Avascular necrosis of the hip	4960 (1.5)
	Previous trauma	1982 (0.6)
	Inflammatory arthritis	3239 (1.0)
	Other	2074 (0.6)
	Paediatric disease	2871 (0.9)
Approach (%)	Posterior	203688 (60.3)
	Anterolateral	117953 (34.9)
	Other	16006 (4.7)
Surgeon grade (%)	Consultant	293799 (87.0)
	Non consultant	43848 (13.0)
Computer guided surgery (%)	FALSE	328547 (97.3)
	TRUE	9100 (2.7)
Minimally invasive surgery (%)	FALSE	303936 (90.0)
	TRUE	33711 (10.0)

Table 2. Baseline characteristics of cases included in survival and regression analysis. ASA indicated American Society of Anaesthesiologists

Variable		Total n = 337647
Collar (%)	Collared	117222 (34.7)
	Collarless	220425 (65.3)
Surface finish location (%)	GRIT:GRIT	13056 (3.9)
	MIN:GRIT	9804 (2.9)
	MIN:MIN	223229 (66.1)
	MIN:NONE	73576 (21.8)
	POR:GRIT	1595 (0.5)
	POR:NONE	16387 (4.9)
Taper (%)	Double taper	275481 (81.6)
	Single taper	54203 (16.1)
	Triple taper	7963 (2.4)
Metaphyseal surface shape (%)	Flat	140459 (41.6)
	Horizontal ridges	184872 (54.8)
	Vertical ridges	12316 (3.6)
Diaphyseal surface shape (%)	Flat	73024 (21.6)
	Vertical ridges	264623 (78.4)
Metaphyseal cross section (%)	Rectangular	303364 (89.8)
	Oval	34173 (10.1)
	Round	110 (0.0)
Sagittal body shape (%)	Straight	331201 (98.1)
	Curved	6446 (1.9)

Table 3. Baseline stem design characteristics of cases included in survival and regression analysis. Surface finish location indicated the surface finish of proximal:distal surface areas. GRIT Grist blasted or roughened surface, MIN mineralised surface, POR non mineralised porous surface, NONE no surface finish.

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