

THE INFLUENCE OF CEMENTED FEMORAL STEM CHOICE ON THE INCIDENCE OF REVISIONS FOR PERIPROSTHETIC FRACTURE AFTER PRIMARY TOTAL HIP REPLACEMENT: AN ANALYSIS OF NATIONAL JOINT REGISTRY DATA

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Abstract

Periprosthetic fracture (PF) after primary total hip replacement (THR) is an uncommon but potentially devastating complication. We analysed data on 257,202 primary THRs with cemented stems and 390 linked first revisions for PF recorded in the National Joint Registry (NJR) of England and Wales to determine if cemented femoral stem brand was associated with the risk of having revision for a PF after primary THR. All cemented femoral stem brands with more than 10,000 primary operations recorded in the NJR were identified. The four most commonly used cemented femoral stems were: Exeter V40 (n=146,409), CPT (n=24,300), C-Stem (n=15,113) and Charnley (n=20,182).

We compared the revision risk ratios due to PF amongst the stems using a Poisson regression model adjusting for patient factors. Compared to the Exeter V40, the age, gender and ASA grade adjusted revision rate ratio for the cemented CPT stem was 3.89 (95%CI 3.07,4.93), for the C-Stem 0.89 (95%CI 0.57,1.41) and for the Charnley stem 0.41 (95%CI 0.24,0.70). Limitations of the study include incomplete data capture, analysis of only PF requiring revision and that observation does not imply causality. Nevertheless, this study demonstrates that the choice of a cemented stem is associated with the risk of revision for PF.

Introduction

A periprosthetic fracture (PF) following a total hip replacement (THR) is an uncommon, but potentially devastating complication. It typically requires further surgical intervention and is associated with increased morbidity and mortality¹. A periprosthetic fracture can either occur intra-operatively or post-operatively. The incidence of post-operative periprosthetic fracture is between 0.6% and 1.2%²⁻⁵. The Swedish Hip Arthroplasty Register has shown that the annual incidence of a PF was between 0.045% and 0.13% and that the incidence was rising³. It accounts for 8% of the reasons for undertaking a revision hip operation in the National Joint Registry (NJR) 10th annual report⁶ after aseptic loosening (40%), pain (23%), dislocation (13%), lysis (13%), adverse soft tissue reaction (13%), infection (12%) and acetabular wear (12%).

Using large registry datasets to analyse relatively rare conditions such as periprosthetic fractures allows researchers to identify patterns or trends in outcomes, which might otherwise be missed in smaller scale prospective studies. Registry data does have limitations and the interpretation of the results has to be tempered appropriately. The data has to be complete and accurate and whilst associations may be identified, causality cannot be determined solely from registry data.

The Vancouver classification is the most commonly used system for a PF around a THR⁷. Fractures around a well-fixed stem (Vancouver B1 type) do not often require revision whereas Vancouver B2 and B3 stems usually require revision⁸. The risk factors for sustaining a periprosthetic fracture post-operatively after primary THR are varied and include older age (over 70 years old), female gender⁹, osteoporosis and rheumatoid arthritis¹⁰. There have been very few studies that have specifically looked at the influence of cemented femoral stem design on the risk of PF¹¹. One study has suggested that certain cemented stems are associated with higher incidences of PF and that the shape, stem design and type of fixation might have a significant influence on the risk of needing a revision for PF after primary THR¹². The aim of our study was to identify if there are significant differences in the incidence of first revision for PF for the four most commonly implanted cemented stems, as registered in the NJR.

Methods

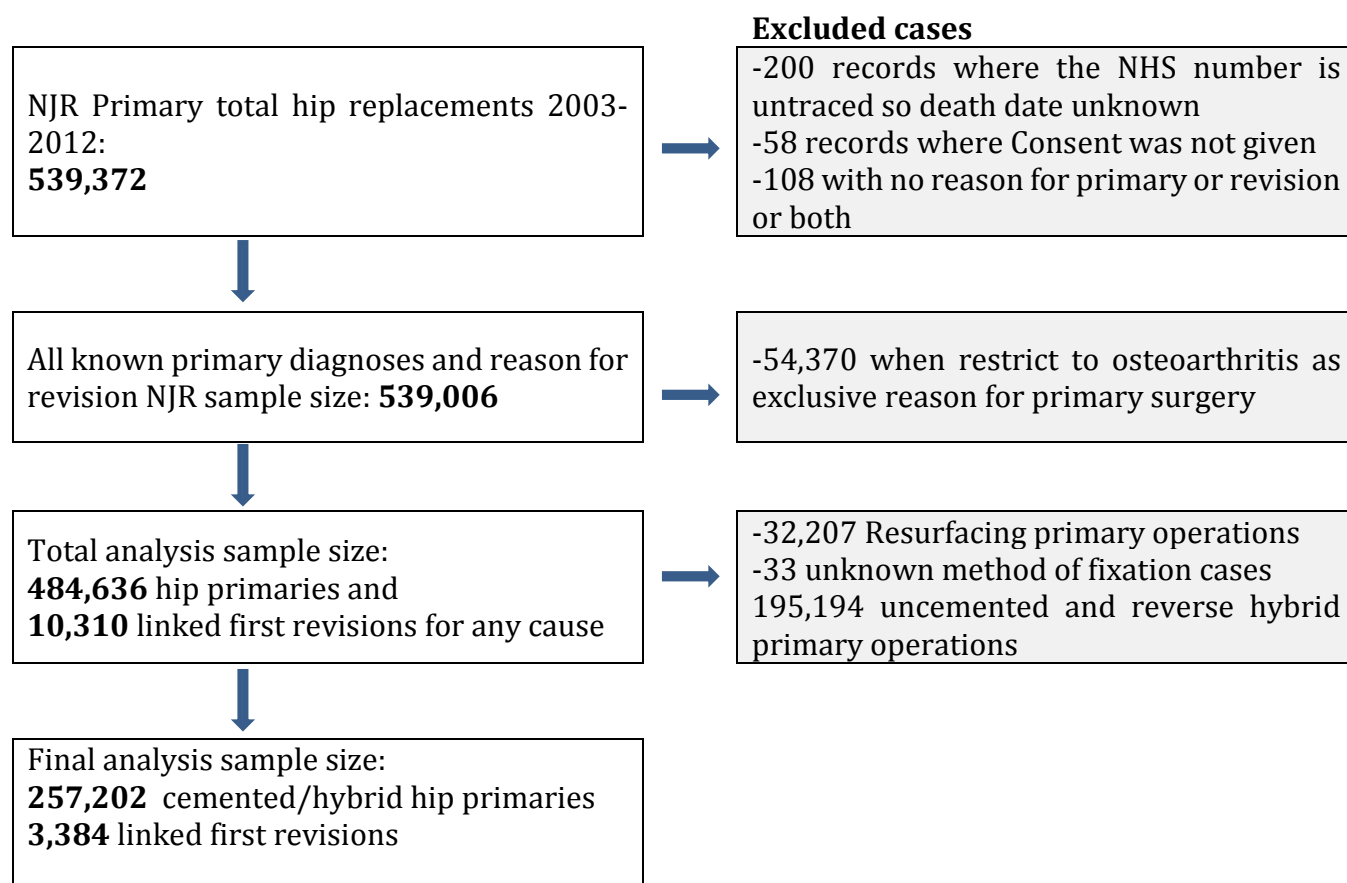
Data source and procedures

We undertook a prospective observational study of cemented primary THRs and the risk of first revision due to periprosthetic femoral fracture of a range of cemented stem brands using National Joint Registry (NJR) primary cemented hip records and first revision surgeries linked to these. The NJR was established in April 2003 and collects patient and surgical information about all hip replacement surgeries carried out in NHS hospital orthopaedic units, treatment centres and private hospitals in England and Wales. The NJR patient details, for those whose NHS number can be traced, are submitted to the Office for National Statistics (ONS) via the NHS Patient Demographic Service to obtain verified death dates for patients and these are then linked to the NJR data source.

Starting with all 539,372 NJR primary hip operations done between the 1st April 2003 and the 31st December 2012, we linked any subsequent first revision of the prosthesis occurring after the primary to the primary record (Figure 1). We excluded 200 cases without a traceable NHS number (by the Patient Demographic services), as we would not know whether the patient subsequently died in follow up, and a further 58 records where the patient had not given consent for their details to be used in research. Reasons given by the clinician for primary and revision operation were linked to the dataset. Clinicians are able to give more than one reason for performing primary or revision surgery. Reasons for primary surgery include osteoarthritis, rheumatoid arthritis, avascular necrosis and trauma. We restricted analysis to patients with a diagnosis solely of osteoarthritis. This left an analysis sample of 484,636 hip primaries and 10,310 linked first revisions of the primary joint where at least one reason for revision surgery had been given by the clinician.

We concentrated on THRs with known fixation method for the stem at surgery restricting to primaries with cemented femoral stems. This led to further exclusions; 32,207 resurfacing operations (as these do not involve the implantation of a stem), 195,194 uncemented and reverse hybrid THR and 33 primaries where the method of fixation was not known. Our final analysis sample consisted of 257,202 primary THRs using cemented stems and 3,384 linked first revisions for any reason. Of these first revisions, 390 were revisions for PF.

Figure 1: Consort¹³ flow diagram of cases included and excluded for analysis



Outcomes and predictors

Our primary outcome was first revision due to PF. As is the case for primary reasons for hip replacement, surgeons can indicate one or more reasons for revision surgery on the minimum data collection forms; these include aseptic loosening (of the stem or socket), implant fracture (of the stem/socket/head), incorrect sizing of head and socket, pain, malalignment, infection, lysis and wear of the acetabular or liner or polyethylene component in addition to periprosthetic fracture.

Three versions of the minimum data collection form have been issued over the analysis period and over time the reasons for revision options have also been modified. In the first version of the minimum data collection form, periprosthetic fracture was listed solely as *periprosthetic fracture* but in the latter two versions it was possible to opt for the site of the fracture-stem or socket. For the purposes of this analysis, we present an overall binary indicator of periprosthetic fracture requiring a revision of the femoral stem. Any indication of a PF was included (irrespective of whether other causes had been indicated for a particular case) and assumed to be the main reason for carrying out revision hip surgery.

The method of fixation used at primary surgery indicates how the implanted stem and cup/head combination are secured into place. This can either be *cemented* (both stem and cup are cemented), *uncemented* (stem/cup both not cemented), *hybrid* (cemented stem/uncemented head) or *reverse hybrid* (uncemented stem/cemented head). Here, the type of cemented stem component and the risk of revision for PF were of prime interest and so all cemented and hybrid cases were retained to create the total number of cemented femoral stems used in this study.

To assess the effect of different stem brands on the outcome of revision for PF, we identified all cemented femoral stem brands with more than 10,000 primary operations on record in the NJR to ensure reasonable numbers were at risk of revision for PF for the follow up period.

An ordered categorical variable of grouped age at primary was derived using the five age classes <65, 65-69, 70-74, 75-79, 80+ years. The NJR records the American Society of Anaesthesiologists' (ASA) grade of a patient at primary and revision surgery. It is a measure of surgical fitness and is defined on a six point scale describing the state of the patient's general health at time of surgery ranging from P1 (fit and healthy) to P6 (likely to die in next 24 hours)¹⁴. Categories P3 to P5 were combined due to small cell numbers and no patients were observed to be in the most severe category of health (P6) in the analysis samples.

The four cemented femoral stem brands analysed were: Exeter V40 (Stryker, Mahwah, New Jersey, USA), Charnley stem (DePuy International, Leeds, UK), CPT (Zimmer, Warsaw, Indiana, USA) and the C-Stem (DePuy International, Leeds, UK).

Statistical Analysis

We compared the overall revision rate for PF per 1,000 person-years across all cemented stems with those for each of the four femoral stem brands using person-time incidence rates (PTIR). PTIR¹⁵ is the result of dividing the total number of revisions for PF for the brand by the total time (in years) of all primary hip replacements using the brand that are at risk of revision and is a statistical term used in NJR annual reports.

We used a Poisson regression model to assess the effect of stem brand and patient and surgical factors on the rates of revision for PF. The Poisson model is able to take account of the variable follow-up times for implanted joints. A series of Poisson univariable and multivariable regression analyses were carried out. Univariable models examined in turn, the association between each of the factors - stem brand, age, gender, ASA grade - and the risk of revision for PF. Next, multivariable regression models were fitted to determine which combination of factors were associated with risk of PF. We compared multivariable models treating age and ASA grade as categorical with more parsimonious models where a linear increase in the ASA grade and age categories is assumed. Likelihood ratio tests were used to compare models treating age and ASA grade as categorical with more parsimonious models in which these were treated as linear.

We checked for signs of a lack of fit of the Poisson model to the data due to a breakdown of underlying modelling assumptions, such as from overdispersion (the case when the sample mean and variance are not equal), by calculating the ratio of the model deviance to the residual degrees of freedom. The Poisson is appropriate if this ratio is close to 1. We also recalculated the standard errors of the model parameters found in the final Poisson model described above using robust standard error estimation to verify that the standard errors found originally (using maximum likelihood estimation) were similar. The original standard errors will be much smaller than those found using robust standard errors if there is overdispersion.

All statistical analyses were carried out using Stata 13 (StataCorp. 2013. *Stata Statistical Software: Release 13*. College Station, TX: StataCorp LP).

Results

Restricting to brands used in 10,000 or more primary cemented stem THR resulted in the inclusion of four stem brands for comparative analysis; the Exeter V40, Charnley, CPT and C-Stem. These represented 80% of all cemented femoral stem operations. Periprosthetic fracture (PF) accounted for 390 (12%) of all revisions for any reason; restriction to the four cemented brands yielded 329 revisions for PF or 13% of all revisions.

All cemented primaries had a median follow-up time of 3.8 years, IQR (1.8,5.9) and a maximum follow up time of 9.8 years. The median time to revision amongst all cemented stems for any reason was 1.9 years with IQR (0.6,4.0) and for revision due to periprosthetic fracture was 2.1 years with 25% of revisions for PF occurring within 6 months of the primary surgery and 75% of all revisions for PF occurring up to 4.4 years after the primary THR. Time to failure for any reason and PF only and follow-up time distributions across the four stem brands overall were essentially the same as for all cemented stems.

However, time to revision distributions for PF varied by brand; the first 25% of PF revisions for each of the CPT, Exeter V40 and C-Stem implants occur up to about 6 months but for the Charnley the first quarter of revisions for PF occur up to 2.1 years after the primary surgery. Median time to revision for PF is 5 years for the Charnley compared to 3.9, 2.3 and 1.8 for the C-Stem, CPT and Exeter V40. Just over a quarter of all first revisions for any reason of CPT stems have PF as the reason for revision compared to circa 10% or below of all revisions for the other three brands having a revision for PF. Patient age distribution at primary and proportion of males having primary THR across the four brands are broadly similar (Table 2).

Patients having first revision surgery for PF tended to be slightly older and less fit for revision surgery than the general patient having first revision surgery for any cause; 57% have revision for PF aged 75+ years compared to 42% in general having first revision surgery for any reason, and 36% of PF revision surgeries were performed on patients with an ASA grade of P3 or worse compared to 27% for those revised for any reason. Following primary surgery, men were more likely than women to be revised for PF ($p<0.001$) even though only about a third of primaries are carried out on men (Table 1). Chi-squared tests of association between the binary outcome of revision for PF after primary or not and each of the categorical factors age group and ASA grade group found very weak evidence of a relationship between age category at primary surgery and the likelihood of revision for PF ($p=0.07$) and no evidence of an association between ASA grade and risk of revision for PF ($p=0.16$). The contingency tables used to test these associations are not shown but can be derived from Table 1.

Figure 2 shows that the revision rate for PF for the CPT stem is far higher at 1.3 revisions per 1,000 person-years (95%CI 1.1 to 1.6) compared to all cemented brands and the Exeter V40, C-Stem and Charnley brands (with PTIRs 0.38, 0.33, 0.29 and 0.13 revisions per 1,000 person-years respectively).

Table 3 shows the results of the univariable and multivariable analyses. Univariable models indicated that gender, age and brand were associated with risk of revision for PF and weak evidence was found of a non-linear association of ASA grade with risk of revision for PF ($p=0.062$ for addition of ASA grade as categorical after testing linear trend of ASA grade, $p=0.279$). Inclusion of brand, age and gender in multivariable Model 1 resulted in evidence of a linear trend across age categories (likelihood ratio test for linear adequacy of age group yielded $p=0.14$). Model 2 shows ASA grade was not significantly associated with the rate of revision for PF when added to Model 1 ($p>0.05$ for models with ASA grade treated as linear and categorical). The most parsimonious multivariable Poisson model, Model 1, indicated the revision rate for the CPT stem was 3.97 (95% CI 3.13,5.02) times higher than that of the Exeter V40, the C-Stem revision rate was comparable to that of the Exeter V40 and the Charnley revision rate was significantly lower than the Exeter V40 with a rate ratio of 0.41 and 95% CI [0.24,0.70]. Men were twice as likely to be revised for PF compared to women and compared to patients aged under 65 at primary, the revision rate for PF increased linearly by 1.14 per 5-year primary age category up to 80 years and above.

The appropriateness of the final Poisson multivariable model was checked using robust standard errors estimation of the model coefficient standard errors for the final model and by calculating the ratio of the deviance to the residual degrees of freedom for Model 1. In both cases there was no indication of overdispersion or other modelling assumption violations.

Discussion

This study represents one of the largest series of revisions for periprosthetic fracture following primary THR, with 390 cases analysed, as recorded in the NJR of England and Wales. Gender and age of the patient can influence the risk of revision for PF after primary THR. In addition, the choice of cemented stem brand has a significant influence on the risk of revision for a PF with the use of a CPT stem being associated with the highest risk of a revision for PF compared to any of the other cemented stem brands considered.

There are a number of different femoral stem designs available for use in cemented total hip replacements. The design of the femoral stem follows one of two biomechanical principles of achieving mechanical stability within the femoral canal whilst under continuous axial loading. The first design method follows the “force-closed” or “loaded-taper” principle whilst the second method follows the “shape-closed” or “composite-beam” principle¹⁶. The original Charnley (DePuy International Ltd, Leeds, UK) “flat-backed” cemented stem is an example of a composite beam design with a collar or flange. The commonest cemented femoral stem used in the UK is the Exeter V40 stem (Stryker, Mahwah, New Jersey, US), which is an example of the “force-closed” design. The stem is highly polished, and tapered in 2 planes (dual-tapered) and is designed to subside into the femoral canal and bone cement mantle as a wedge. The CPT stem (Zimmer, Warsaw, Indiana, US) is similar in design with a dual tapered, highly polished stem. On visual inspection the most obvious difference between the Exeter and CPT stems is the radius of the corner between the top and lateral edges of the stem – the part of the stem we term the stem “shoulder”. The Exeter’s shoulder has a bigger radius than the CPT. The C-Stem (DePuy International Ltd, Leeds, UK) is highly polished and triple tapered but it does not have a top edge that is perpendicular to the lateral edge. Its shoulder has a bigger radius than either the Exeter or the CPT. In our study, only the C-Stem was included in the analysis and the C-Stem AMT (also manufactured by DePuy International Ltd, Leeds, UK) was not included due to insufficient number of cases (less than 10,000). Figure 3 provides illustrations of the different stems described above.

There have been very few studies that have specifically examined the influence of different cemented stem brand on the risk of revision for PF. Data from the Swedish registry showed a higher incidence of PF for the Charnley and Exeter compared with the Lubinus cemented stem¹⁰ and that this was due to the difference in stem shape and design. The authors suggested that the Charnley and Exeter stems were shorter and straighter compared to the anatomically shaped Lubinus stem, and therefore more difficult to position and achieve an adequate cement mantle within the femoral canal. Furthermore another study of 21 PF around a well-fixed cemented polished tapered stem showed a unique fracture pattern thought to be as a result of the design of the hip replacement¹⁷. A study from the Nordic Arthroplasty Register database, analysed 152 cases of revision for PF using two cemented stem designs (Exeter and Lubinus)¹². There was an incidence of 0.07% for cemented stems at two years following primary THR. The Exeter stem had a five times higher hazard ratio compared to the Lubinus stem, with an incidence of 0.14%. This supports the results from our study in which the Exeter stem had an incidence of 0.12% revision for PF. However, we found that the collared Charnley cemented stem design (similar to the Lubinus) had the lowest incidence of revision for PF at 0.07%. The Swedish National Hip Arthroplasty Register study of 1049 periprosthetic fractures had 448 such fractures following a primary THR that were Vancouver B2 and B3 types from 1997 to 2000⁸. In the Vancouver B2 group, 91% were revised with or without internal fixation and 100% of cases were revised in the Vancouver B3 group. Interestingly, the Charnley stem had the highest incidence of PF compared to the Exeter and Lubinus stems but the study did not analyse the incidence of revision for a PF between the 3 different stem brands.

Furthermore, there was no significant difference between the stem brands when comparing Vancouver classification types. Our study has demonstrated that the Charnley stem had the lowest incidence of revision for a PF compared to the other cemented brands and that the CPT stem had a significantly higher incidence.

One theory as to why some cemented stems have a higher risk of needing to be revised for PF is that the design of “force-closed” polished cemented stems, which subside and “wedge” in the femoral canal, creates an axial loading effect within the cement-bone mantle, producing an increase in the hoop stresses in the adjacent bone, increasing the risk of sustaining a femoral PF¹⁸. It is possible that even a small difference in the shape of the stem may influence the hoop stresses through the proximal bone and increase the risk of sustaining a PF needing a revision. A study comparing the CPT and the C-stem cemented into synthetic femoral bones under an axial and torsional load, demonstrated different periprosthetic fracture patterns¹⁹. The Charnley stem is not designed to subside and instead has a collar and this may confer a protective effect in the risk of needing a revision for a PF. The study by Brodén (2014) showed a high incidence (3.3%) of early PF with the CPT stem and suggested that the polished taper design may act as a wedge splitting the femur following a fall²⁰.

There are several limitations with this study. The NJR does not record data on PF that were not revised. Other types of PF that require alternative management such as fixation will not be recorded in the NJR. This study does not classify the type of periprosthetic fractures sustained as a complication of a primary THR and so, it is assumed that the vast majority of revisions undertaken were for Vancouver B2 or B3 type periprosthetic fractures. This is likely to be true as one would not expect Vancouver A or C type fractures to usually require a revision and only a small proportion of B1 type fractures would necessitate a revision. However, the key outcome in this study is the need to revise a stem for a PF and therefore whether there is sufficient (B2) or insufficient bone stock (B3) does not alter the prevalence of revision for PF as the primary outcome. Classifying PF in cemented tapered stems can be difficult. The indications for revising a stem for a B2/B3 PF may vary depending on the surgeon’s analysis of the likelihood of the stem being loose. We accept that some PF cases may have been fixed rather than revised as a result and therefore would not be included in the NJR data. Although some risk factors for sustaining a periprosthetic fracture have been accounted for in the analysis, such as age and gender, specific risk factors such as osteoporosis and hypothyroid disease have not been included in the analysis as such data is not readily available in the NJR. Linking NJR data with other datasets such as Hospital Episode Statistics (HES) to identify other patient co-morbidities or health indicators (e.g osteoporosis) would allow for greater adjustments in the modelling approach for this study but at the time of this study, access to HES data was restricted. We have therefore used ASA grade as a surrogate marker for a patient’s health status but accept that this is a crude measure of health and does not take into account other potential risk factors for osteoporosis and therefore risk of PF. The age and gender of the patients across the 4 different femoral stem groups were similar and it is assumed that the prevalence of risk factors such as osteoporosis is therefore spread evenly across the different groups.

Data validation in registries remains a significant issue and for this reason, only linked data of primary THR to revision THR was used in this analysis. It is therefore possible that some revisions for PF for the stems analysed are missing from the dataset. Revision data may be incomplete and the relative frequency in which the different types of stems included in this analysis may vary over the time period for collection of NJR data. We have deliberately analysed the four commonest cemented stems as recorded in the NJR in order to ensure sufficient numbers of cemented stems available for analysis.

Unfortunately, at present, the NJR is unable to state the level of completeness and accuracy of revision THR data. Clearly, under-reporting of revisions could affect the final analysis of this data.

Finally, an assumption has been made that the revisions registered are for PFs occurring post-operatively and exclude intra-operative fractures as such a complication is recorded as a separate entry on the data form submitted. Such intra-operative periprosthetic fractures mostly occur with uncemented stems or resurfacing arthroplasty and do not usually require revision surgery.

As with most registry data, the results from this study do not suggest that one type of stem is necessarily superior to another. All of the cemented stems analysed in this study have ODEP (Orthopaedic Devices Evaluation Panel) 10A* ratings and have a good survivorship track record. The findings of our study, together with that from the Swedish¹⁰ and Nordic Arthroplasty Registers¹² lends weight to the observation that the stem design and type of fixation may have an influence on the risk of needing a revision for a PF. Having shown this observation, what is required are further studies, including biomechanical or finite element analysis, comparing the different stem designs and fixation methods, to examine if the shape of the stem and the use of cement influence the stresses through the proximal bone.

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Table 1: Hip primary and revision for PF cemented stem joint distributions broken down by patient characteristics; gender, age (grouped) and ASA grade

Patient factors at primary surgery	Number of primaries n=257,202 (% in brackets)	% revised due to PF ^{a,b}	Patient factors at revision surgery	Number of revisions for any reason ^c n=3,384 (% of all revisions)	Number of revisions due to PF ^c n=390 (% of all PF revisions)
Gender			Gender		
Female	166,779 (64.8)	0.12	Female	1,996 (59.0)	201 (51.5)
Male	90,423 (35.2)	0.21	Male	1,388 (41.0)	189 (48.5)
		p<0.001 ^b			
Age Group at primary			Age Group at revision		
<65	49,196 (19.1)	0.18	<65	682 (20.2)	57 (14.6)
65-69	43,228 (16.8)	0.12	65-69	557 (16.5)	53 (13.6)
70-74	57,446 (22.3)	0.13	70-74	715 (21.1)	60 (15.4)
75-79	54,340 (21.1)	0.17	75-79	743 (22.0)	95 (24.4)
80+	52,992 (20.6)	0.16	80+	687 (20.3)	125 (32.1)
		p=0.069 ^a			
ASA Grade			ASA Grade		
P1 (fit and healthy)	36,803 (14.3)	0.12	P1 (fit and healthy)	272 (8.0)	19 (4.9)
P2	178,727 (69.5)	0.16	P2	2,214 (65.4)	231 (59.2)
P3-P5 (incapacitating disease or worse)	41,672 (16.2)	0.13	P3-P5 (incapacitating disease or worse)	898 (26.5)	140 (35.9)
		p=0.164 ^a			

Notes:

^a Chi squared test of association between age group at primary or ASA grade at primary and the proportion revised. Full contingency table of each of age group and ASA grade versus revision for PF or not is not shown here.

^b P-value based on a test for gender differences in the proportion revised. Full contingency table of gender versus revision for PF or not is not shown here.

^c Age group and ASA grade for the revision columns are the age of patient and ASA grade at time of revision surgery.

Table 2: Brand breakdowns of number of primary THR by patient characteristics at primary (age distribution of patient, percentage of primaries performed on male joints), time to revision distribution and incidence of revision for PF.

Femoral Stem Brand	Number of primary THR	Median and IQR of age of patient at primary operation in years	Percentage Male (%)	Number of first revisions ¹	No. of first revisions due to PF (% of all first revisions ¹)	Incidence of PF (%)	Number revised for PF within a year (% of all brand revisions within a year)	Median and IQR of time to revision for PF (years)
<i>All cemented</i>	<i>257,202</i>	<i>73 IQR(67,78)</i>	<i>35</i>	<i>3,384</i>	<i>390 (12)</i>	<i>0.15</i>	<i>129 (11)</i>	<i>2.1 IQR(0.5,4.4)</i>
Exeter V40	146,409	72 IQR(66,78)	36	1,625	182 (11)	0.12	66 (11)	1.8 IQR(0.5,4.1)
CPT	24,300	73 IQR(67,79)	33	416	111 (26)	0.46	35 (22)	2.3 IQR(0.6,4.3)
Charnley Cemented	20,182	73 IQR(67,76)	36	346	15 (4)	0.07	1 (2)	5.0 IQR(2.1,5.6)
C-Stem Cemented	15,113	71 IQR(64,76)	38	205	21 (10)	0.14	6 (10)	3.9 IQR(0.4,5.6)

Notes:

¹For all reasons/causes for first revision as indicated on the minimum data set form.

Table 3: Univariable and multivariable Poisson regression models of the effect of stem brand and patient factors on revision rate for periprosthetic fracture for cemented femoral brands (based on the cemented sample of brands with n=206,004).

	Univariable model RR [95% CI], p-value for model ^a	Multivariable model 1 ^b RR [95% CI]	Multivariable model 2 RR [95% CI]
Brand			
Exeter V40	1.00	1.00	1.00
C Stem Cemented	0.88 [0.56,1.38]	0.87 [0.55,1.37]	0.88 [0.56,1.38]
CPT	3.91 [3.09,4.95]	3.97 [3.13,5.02]	3.93 [3.10,4.97]
Charnley	0.41 [0.24,0.69], p<0.001	0.41 [0.24,0.70]	0.42 [0.25,0.70]
Gender			
Female	1.00	1.00	1.00
Male	1.89 [1.52,2.34], p<0.001	1.95 [1.57,2.43]	1.97 [1.59,2.50]
Age			
<65	1.00		
65-69	1.02 [0.69,1.51]		
70-74	1.40 [0.96,2.03]		
75-79	1.81 [1.26,2.61]		
80+	1.51 [1.05,2.19]		
<i>p-value for non-linear association</i>	p=0.002	p=0.002	
<i>Linear Age (per category)</i>	1.14 [1.06,1.24]	1.14 [1.06,1.24]	1.15 [1.07,1.25]
<i>p-value for linear trend</i>	p=0.001	p<0.001	
<i>Likelihood ratio test for linear adequacy of age</i>	p=0.16	p=0.14	
ASA grade			
P1	1.00		1.00

P2	1.45 [1.04,2.01]		1.45 [1.04,2.01]
P3-P5	1.25 [0.82,1.90]		1.23 [0.80,1.87]
<i>p-value for non-linear association</i>	p=0.062		p=0.059 ^c
<i>Linear ASA grade</i>	1.11 [0.92,1.35]		
<i>p-value for linear trend</i>	p=0.279		p=0.332
<i>Likelihood ratio test for linear adequacy of ASA grade</i>	p=0.036		p=0.031

^a Based on the likelihood ratio test comparing a model with no covariates with the univariable model including the factor shown.

^b Final model parameters shown for the most parsimonious model with linear age.

^c As evidence is found against linearity of ASA grade, this is also the p-value for the likelihood ratio test comparing Models 1 and 2 with the null hypothesis that Model 1 is an adequate fit.

Figure 2: PTIR for the four cemented stem brands and associated 95% confidence interval. The overall PTIR for all cemented femoral stems is shown as a red horizontal line for comparison.

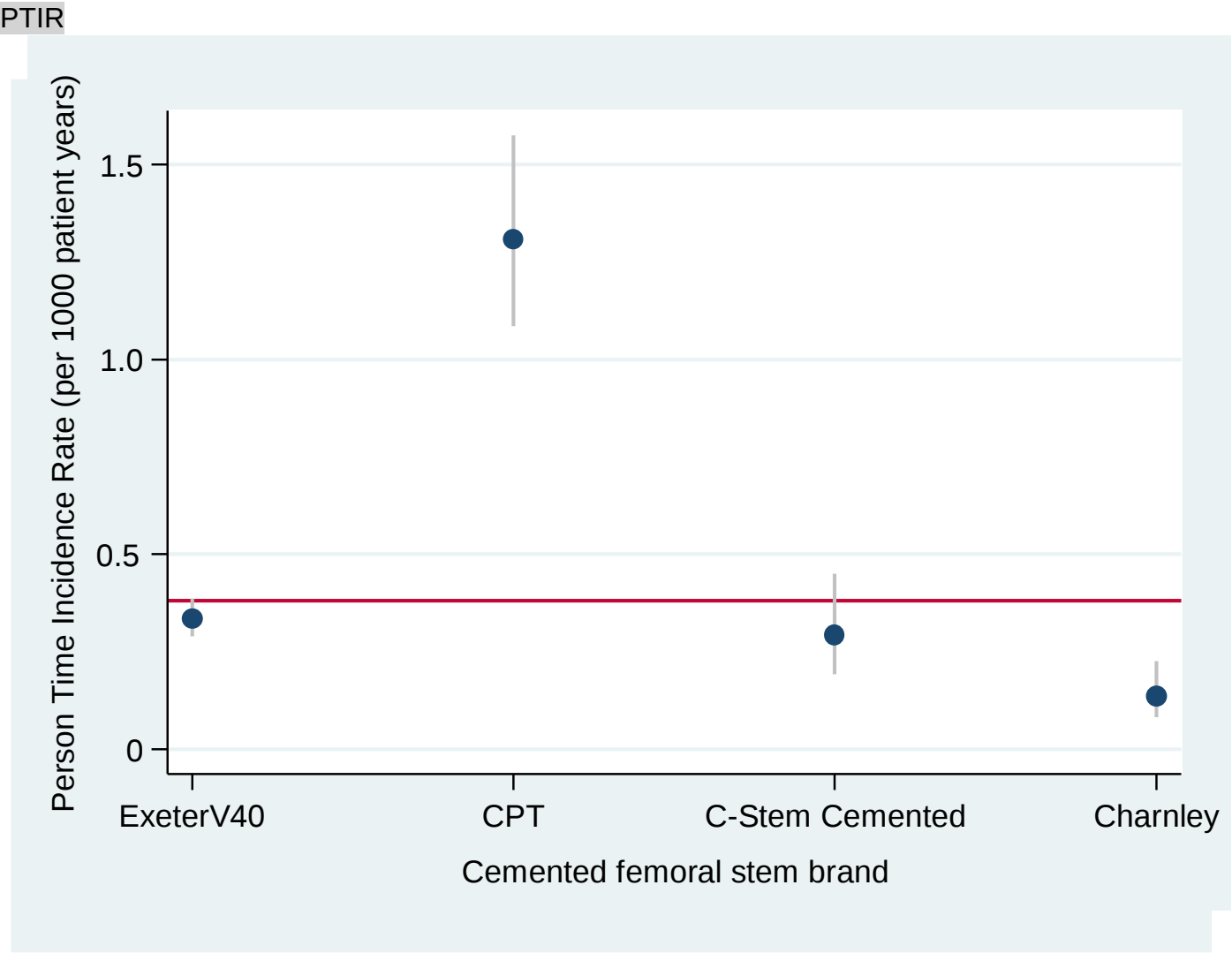


Figure 3: Images of the 4 different cemented femoral stems used in the analysis

	Exeter V40 (Stryker, Mahwah, New Jersey, USA)
	CPT (Zimmer, Warsaw, Indiana, USA)
	Charnley stem (DePuy International, Leeds, UK)
	C-Stem (DePuy International, Leeds, UK)