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Periprosthetic femoral fractures around the original cemented polished triple-tapered C-stem
 femoral implant: A consecutive series of 500 primary total hip arthroplasties with an average
 follow-up of 15 years.

4

5 Abstract

6

7 Introduction: The true incidence of periprosthetic femoral fracture (PFF) around cemented polished 8 taper-slip implants remains largely unknown. Registries usually only capture PFFs that result in 9 revision, missing those managed non-operatively or treated by open reduction and internal fixation 10 (ORIF). This study reports the long-term rate of PFF with the original triple-tapered C-stem femoral 11 implant.

12

Materials and Methods: A prospective review of a consecutive series of 500 primary total hip arthroplasties (THAs) performed at a single centre between March 2000 and December 2005, with average follow-up of 15 years (12-19 years).

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17 Results: There were 500 consecutive THAs in 455 patients. Seven PFFs (1.4%) occurred in seven 18 patients at an average of 7.9 years (range 2-11.5) from the primary arthroplasty. Five PFFs were 19 managed by ORIF, one Vancouver B3 fracture was revised for a loose implant and one patient was 20 treated non-operatively. Average age at primary operation was 74 years (67 - 87) and BMI averaged 21 27.3 (22 - 31). There was no typical fracture pattern and no statistically significant associations with 22 patient demographics (age, gender, BMI, diagnosis) or prosthetic details (size, offset, alignment, cement 23 mantle, subsidence). Survivorship to the occurrence of PFF was 99% (97.3 - 99.6%) at 10 years and 24 97.8% (95.5 – 99.0%) at 15.

25

Conclusion: A PFF rate of 1.4% at an average follow-up of 15 years represents the true incidence of
PFF with the use of the original triple-tapered C-Stem femoral implant, similar to that of published
Exeter series (1.85%) but lower than the CPT (3.3%).

29

30 Keywords:

31 Periprosthetic femoral fracture, cemented, polished, taper-slip, hip arthroplasty.

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- 34

35 Introduction

Periprosthetic femoral fracture (PFF) is an infrequent, yet potentially devastating complication of total hip arthroplasty (THA), which is associated with poorer functional outcomes, significant morbidity and an increased overall 12-month mortality of 11% [1]. In 2020 it was reported that patients admitted to hospital with PFF were at increased risk of developing post-operative COVID-19 infection [2].

Increased life expectancy and the longevity of physically active adults into older age [3] has
led to a projected increased demand for primary THA in the UK of 134% by 2030 [4]. Coinciding with
this, an estimated increased incidence of PFF of 4.6% every decade until 2045 has also been predicted
[5].

The management of PFF is complex and can result in further costly re-operations, prolonged rehabilitation and persisting dysfunction [6,7]. The true incidence of PFF remains unknown, but a prevalence of 0.1% to 4% has previously been estimated [3,7–9]. National joint registries, except the Swedish Hip Arthroplasty Registry, record only those PFFs which necessitate revision, failing to capture those managed non-operatively or by ORIF [10,11].

50 Uncemented implants are associated with an increased rate of PFF [12,13] but it is less clear 51 what impact the design specifics of cemented stems have on the incidence. The two categories of 52 cemented stems are the taper-slip (force-closed) and the composite beam (shape-closed). Taper-slip 53 stems provide excellent long-term results [14–16] and their use dominates the hip arthroplasty market 54 in the United Kingdom [17].

A statistically significant increased risk of PFF for taper-slip stems compared to composite beams has been reported [18,19] despite which, there remain few published series addressing the issue and reporting the long-term results of taper-slip stems [14,15,20,21] with only one previous publication on the long-term results of the original C-stem [16]. The aim of this study was to determine the true long-term incidence of PFF in a prospective cohort of 500 consecutive cemented polished triple-tapered original C-stem femoral implants.

61

62 Methods and Materials

63 Data was collected prospectively on 500 consecutive primary THAs in 455 patients performed
 64 between March 2000 and December 2005. Ethical approval for this study was not required.

The original cemented polished triple-tapered C-stem featured a 9/10 rather than the later 12/14 trunnion and was used in all cases, having the same dimensions as the later C-stem AMT, other than the extended shoulder (both DePuy International, Leeds, UK). All operations were performed at a single centre under the care of four Orthopaedic Consultants, in laminar flow operating theatres.

A posterior surgical approach was used with a stay suture in the short external rotators to protect
 the sciatic nerve. A box chisel was used to access the piriform fossa, then a blunt-ended tapered reamer
 before sequential broaching of the canal to obtain a cement mantle of at least 2mm. Trial reduction was

performed to assess leg length and stability, before a cement restrictor of appropriate size was inserted,and the canal prepared with pulse lavage.

A third generation cementing technique was used, with vacuum-mixed Palacos-R Bone Cement (Heraeus GmbH, Hanau, Germany) containing Gentamicin inserted in retrograde fashion with a cement gun. The cement was constantly pressurised prior to the insertion of the femoral prosthesis with a hollow polymethyl-methacrylate (PMMA) tip centraliser, which was then held until the cement had set. The prosthesis was then reduced and stability, leg-length and offset re-assessed before closure of the short external rotators and capsule as a single layer with loop PDS, but without trans-osseous sutures.

80 Outpatient review began at six weeks, then continued annually for five years and every second 81 year thereafter. Plain radiographs were performed prior to discharge, then at twelve months and each 82 clinical review thereafter.

Antero-Posterior radiographs of the pelvis were taken using a standardised technique, with the X-ray centred over the symphysis pubis and the patellae pointing upwards. Femoral component alignment was measured with respect to the long axis of the femur (neutral being within five degrees) and the cement mantle was graded using the Barrack system [22]. Subsidence was measured using the Fowler technique [23] and PFF was categorised using the Vancouver Classification [24,25].

88

89 Statistical analysis

90 Descriptive statistics were presented for relevant variables at THA level by fracture outcome 91 (PFF or not). For continuous variables statistics such as mean, median, standard deviation (SD), first 92 and third quantiles (Q1, Q3), and number of observations were calculated. For categorical variables, 93 count and percentage of each category were presented. To test the difference in the variables between 94 the fracture and non-fracture groups, t-tests were performed for continuous variables and Fisher's exact 95 test for categorical variables. Survival analysis was performed with the end point as time to PFF or to 96 the latest follow-up (if no PFF), and Kaplan-Meier survival estimates were plotted for the entire cohort. 97 In addition, a series of Cox regression model was used to explore variables associated with PFF. All 98 statistical analyses were conducted using Stata (StataCorp LLC, Texas, USA).

99

100 **Results**

101There were 500 consecutive primary THAs in 455 patients, with 282 females (62%) and 173102males (38%). Average age at surgery was 68.8 years (range 23 – 92) and average BMI was 29 (range10318-42). The most common indication for surgery was primary osteoarthritis (80.6%, Table 1).

104During follow-up 244 (54%) patients died (265 THA, 53%), 23 patients (5%) with 25 THA105(5%) declined further follow-up [8 moved out of region (10 THA), 15 due to poor health (15 THA)],106with only 3 further patients (0.7%) with 3 THA (0.6%) being lost to follow-up. Fourteen femoral107implants (2.8%) in thirteen patients (2.9%) were revised [1 late sepsis, 3 aseptic loosening (one with a108PFF), 10 during revision of a loose acetabular component]. Of the remaining 172 patients (37.8%) with

109 193 THA (38.6%), 13 (2.9%; 13 THA, 2.6%) residing in care homes declined radiological follow-up.

- 110 These patients underwent a telephone consultation to confirm that they remained satisfied, had not
- 111 suffered any complications and consented to a review of their medical records and radiological images,
- none of which subsequently demonstrated any PFF. This left a total of 180 THA (36%) in 159 patients
- 113 (34.9%) with complete clinical and radiological follow-up (Figure 1).
- High offset femoral stems were used in 288 cases (58%), with the average combined femoral
 offset (stem plus head) for the entire series being 44.1mm (range 35-54mm, Table 2).
- Seven PFFs occurred in seven patients (1.4%, Table 3), with a mean time from operation of 7.9
 years (2-11.5). There was one Vancouver Type A fracture, three Type B1, two Type B2 and one Type
 B3 fracture. None were distal to the tip of the implant (Vancouver C).
- The mean age at time of surgery was 74 years (67 87) in the PFF group compared to 68.6 years (23 - 92) in the non-fracture group, which was not statistically significant (p = 0.187). There were four fractures in female patients and three in males, with four being right sided and three left. The average BMI was 27.3 (22 - 31) in the PFF group compared to 28.6 (18 - 42) and the pre-operative diagnosis in all PFF cases was osteoarthritis (Table 3).
- 124 Femoral prosthesis alignment was neutral in five cases, varus in one and valgus in one, with 125 cement mantle quality being Barrack Grade A in three cases and Grade B in four. Prosthetic offset (stem 126 plus head) averaged 45.1 (41 – 52) in the fracture group compared to 44.1 (35 - 54), with subsidence 127 of the femoral component at 12 months averaging 0.9mm in both groups. Distal femoral cortical 128 hypertrophy (DFCH) occurred in 6 cases (0.12%), none of whom suffered a PFF.
- Five PFFs were managed by ORIF, one B2 fracture was treated non-operatively as the patient was unfit for surgery and the B3 fracture underwent revision for aseptic loosening of the stem (Table 3). There were no subsequent re-operations in any of these patients, four of whom died at an average of 16.5 months (range 3 to 36) from the date of fracture.
- 133 Statistical analysis of age, gender, pre-operative diagnosis, operated side, BMI, implant size, 134 prosthetic offset (stem plus head), Barrack classification and femoral alignment demonstrated no 135 statistical significance between the fracture and non-fracture groups (Table 4). A series of Cox 136 regression models was performed with variables in Table 4 as covariates. Because the sample size was 137 small (only seven PFF), the model was restricted to include a single continuous or dummy variable. It 138 was found that none of the variables had a statistically significant association with PFF.
- Kaplan-Meier survivorship, with PFF as the end-point, was 99.0% (292 THA at risk, 97.3 –
 99.6%) at 10 years and 97.8% (114 THA at risk, 95.5 99.0%) at 15 years (Figure 2).
- 141

142 **Discussion**

143The PFF rate was 1.4% in a consecutive cohort of 500 cemented polished triple-tapered C-stem144femoral implants, using third generation cementing and Palacos R+G bone cement, with long-term

145 follow-up averaging 15 years. There was no typical fracture pattern or statistically significant 146 associations with patient demographic or prosthetic details.

147 The Exeter (Stryker, New Jersey, USA) and CPT stems (Zimmer, Warsaw, Indiana, USA) are 148 double-tapered femoral implants and comprise in excess of 75% of the UK market share [17]. The C-149 stem has a third taper, running from lateral to medial, for proximal loading of the calcar to reduce 150 negative bone remodelling in the long-term [16] and only six cases (0.12%) in the current series 151 developed DFCH confirming that this was being achieved.

152 Force-closed femoral implants achieve stability by means of controlled subsidence within the 153 cement mantle, acting as a wedge and generating hoop stresses in the cement-bone construct [10]. The 154 polished implant surface allows micromotion at the implant-cement interface without abrasion, 155 facilitating controlled subsidence due to the visco-elastic property of bone cement called creep, which 156 is non-recoverable deformation under load. PFF in taper-slip implants is typically caused by a low-157 velocity rotational injury with forced axial loading [10] and it has been postulated that the wedge shape 158 of the prosthesis, which is not fixed within the cement mantle, will transmit momentarily increased 159 hoop stresses at the cement-bone interface leading to an increased risk of PFF compared to composite 160 beam stems, which are fixed within the cement mantle [19].

- 161 The Vancouver classification system guides optimum management of PFF for both cemented 162 and uncemented prostheses [24,25] and has been integrated into the Unified Classification System, to 163 characterise periprosthetic fractures around any joint [26]. Due to the complexity relating specifically 164 to polished taper-slip implants, Maggs et al recently advocated a sub-classification of B2 fractures 165 distinguishing between those in which the cement-bone interface is well fixed and those in which it is 166 loose, as this determines the definitive management [10].
- National joint registries now provide the majority of arthroplasty outcome data, but with the
 exception of the Swedish Hip Arthroplasty Registry, capture only those patients in whom a
 complication has necessitated revision surgery [10,11]. In the case of PFF, this will not include fractures
 treated by ORIF or non-operatively due to patient frailty and in a recent study of 539 PFFs, 23% (122
 PFFs) were managed non-operatively, 31% (169 PFFs) by ORIF alone and 46% (246 PFFs) by 'revision
 and/or fixation' [27].
- 173 Registries therefore underestimate the incidence of PFF [1,8,10] but inconsistencies can also
 174 occur with the revision data itself [28]. A recent study assessing risk factors for PFF compared the
 175 German Arthroplasty Registry data to insurance record ICD codes, discovering a 13.7% discrepancy
 176 with regards to PFF being the actual cause of revision [29].
- 177 In the current study only the single patient with the Vancouver B3 PFF, which underwent 178 revision would have been captured by the National Joint Registry (NJR). An inaccurate PFF incidence 179 of 0.2% would therefore have been estimated, as opposed to the actual rate of 1.4%, with an average 180 follow-up of 15 years.

Where registry data is lacking, well conducted single, or multi-centre, case series can give insight into the true rates and management of PFF. Due to their proportion of market share, the Exeter and CPT stems constitute the majority of the reported series assessing the risk and rates of PFF with taper-slip designs.

Mahon et al reviewed 829 Exeter V40 stems reporting a PFF rate resulting in revision of 0.36%, with a mean follow-up of 12.4 years [21] and Petheram et al reported a PFF rate resulting in revision of 0.78% in a series of 382 Exeter Universal stems with an average follow-up of 22.4 years [14]. Westerman et al reviewed the first 540 Exeter V40 stems performed at their centre in the two years following its introduction, reporting a PFF rate of 1.85% at a mean follow-up of 12.4 years [20].

190 The CPT stem is similar in design to the Exeter, but has a wider shoulder. One study of 191 191 CPT stems with a mean follow-up of 15.9 years reported only one PFF (0.52%) leading to revision, 192 which occurred at five years [15,30], however, another reported a PFF rate of 3.34% in a series of 1403 193 hips, with a mean follow-up of only 4 years [7]. In an observational cohort study, Mohammed et al 194 compared PFF rates at a single centre during the transition from the standard use of a CPT stem to the 195 Lubinus SP2 composite beam. At two years the CPT group had sustained 18 PFFs (3.31%) and the 196 Lubinus group only two (0.37%) [6]. The latter two studies had a limited duration of follow-up, and in 197 the current series the fractures occurred at an average of 7.9 years, with only one during the first four 198 years, consistent with the 7.6 years reported in a large study in 2022 [31].

In a Registry based study, Palan et al reported incidences of PFF, based only on revision, of 0.12% for the Exeter V40 stem, 0.14% for the C-stem and 0.46% for the CPT, which, as expected, were markedly lower than in the cohort studies [19]. This study also postulated that the CPT's higher PFF rate may be down to having a larger, broader shoulder than both the Exeter and the C-Stem [19].

In a biomechanical study, Erdhart et al compared the periprosthetic fracture patterns around the CPT and the C-Stem. Ten double-tapered CPT stems and 10 triple-tapered C-stems were cemented into synthetic femurs and subjected to axial compression. There were seven Vancouver B fractures in the CPT constructs and three Vancouver C. In all ten C-stem constructs the fractures occurred at the tip of the implant with the cement mantle remaining intact, suggesting there is less harmful strain produced to the cement mantle in torsion than in other designs [32]. There was, however, no typical fracture pattern in the PFF cohort in the current study (Table 3).

- The only previously published long-term series with the original C-stem included 621 arthroplasties performed using trochanteric osteotomy. At a mean follow-up of 13 years there were no instances of PFF, but fractures of the femoral prosthesis occurred in two cases [16]. There were no cases of femoral prosthesis fracture in the current study.
- The strength of the current study is that data was collected prospectively, with only three patients (0.66%) being lost to follow-up, two of them after 10 years, allowing an accurate determination of the outcome of almost every THA. One limitation germane to all longitudinal studies is the number

of patients who will inevitably die during the follow-up period, which, in the current study, was 244
patients (54%) with 265 THA (53%) at an average follow-up of 15 years.

219

220 Conclusion

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The incidence of PFF in this prospective cohort of 500 THAs using the original cemented polished triple-tapered C-stem femoral implant was 1.4% after 15 years of follow-up. This is similar to the PFF rates reported for the polished double-tapered Exeter V40 but lower than for the CPT.

225 With an increased incidence of PFF predicted over the next three decades, a more detailed 226 knowledge of the risk profile for specific implant designs is required. This could be achieved either by 227 expanding the minimum data set for National Joint Registries to include all PFFs managed by any 228 means or alternatively, by widening the scope of National Hip Fracture Databases to include PFFs in a 229 similar way that femoral shaft and distal femoral fractures have recently been included in the Best 230 Practice Tariff in the United Kingdom. Large long-term single, or multi-centre, studies of individual 231 prostheses would remain of great value, as they include more detailed demographic and radiological 232 analysis, in order to augment the currently limited body of knowledge on this subject.

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235 Declaration of conflicting interests

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238

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349 Figures



- 352 Figure 2 Kaplan-Meier Survival Curve for Entire Cohort



357 <u>Tables</u>

Table 1: Pre-operative diagnosis

Pre-operative diagnosis	Number	%
Osteoarthritis	403	80.60%
AVN	51	10.20%
Rheumatoid Arthritis	19	3.80%
NOF	7	1.40%
Paget's Disease	4	0.80%
DDH	3	0.60%
Other	13	2.60%

358

359

Table 2. Femoral Stem Sizes

Femoral Stem Size		Number	%		
	1	26	5.20%		
	2	67	13.40%		
HO2		80	16.00%		
	3	65	13.00%		
HO3		102	20.40%		
	4	39	7.80%		
HO4		80	16.00%		
	5	4	0.80%		
HO5		26	5.20%		
	6	7	1.40%		
	7	4	0.80%		

Abbreviations – HO = High Offset stem

360

362 Table 3: Fracture Type and Management, Patient, Prosthesis and Radiological findings.

363

364	Patient V	ancouve	r Mx	Time	Age	Gender	BMI	Side	Dx	Stem	Offset	Align	Barrack	Subs-12
365	1	A	ORIF	133	68	М	25	R	OA	HO3	47	VAR	В	0.5
366	2	B1	CON	24	79	Μ	31	L	OA	2	41	Ν	А	0.5
367	3	B1	ORIF	84	78	F	29	R	OA	4	42	Ν	А	1
368	4	B1	ORIF	64	87	F	23	R	OA	HO2	45	Ν	А	1
369	5	B2	ORIF	138	67	М	30	R	OA	HO4	52	Ν	В	0.5
370	6	B2	ORIF	88	71	F	31	L	OA	HO2	42	Ν	В	2
371	7	В3	REV	137	68	F	22	L	OA	4	45	VAL	А	1

372

373 Abbreviations:

- 374 Mx: how the fracture was managed
- 375 ORIF: is Open Reduction and Internal Fixation.
- 376 Con: is Conservative management
- 377 Rev: is Revision
- 378 Dx: pre-operative diagnosis
- OA: is Osteoarthritis
- 380 Time: number of months until fracture
- 381 Align: is alignment of the stem
- 382 Var: is Varus
- 383 N: is Neutral
- 384 Val: is Valgus
- 385 Barrack: is the grading of the cement mantle
- 386 Offset: is the combined offset of the stem plus the head
- 387 Subs-12: is subsidence at 12 months
- 388

389 Table 4. Summary of Statistical Analysis

Variables	Non-fracture (N = 493)	Fracture (N = 7)	p-value
Age			0.187
Mean (SD)	68.61 (10.73)	74.00 (7.53)	
Median (Q1, Q3)	70.0 (64.0, 75.0)	71.0 (68.0, 79.0)	
N (% Non-missing)	493 (100.0%)	7 (100.0%)	
BMI			0.468
Mean (SD)	28.61 (4.78)	27.29 (3.86)	
Median (Q1, Q3)	29.0 (25.0, 32.0)	29.0 (23.0, 31.0)	
N (% Non-missing)	380 (77.1%)	7 (100.0%)	
Offset			0.537
Mean (SD)	44.13 (4.31)	45.14 (3.89)	
Median (Q1, Q3)	44.0 (41.0, 48.0)	45.0 (42.0, 47.0)	
N (% Non-missing)	493 (100.0%)	7 (100.0%)	
Side			1.000
Right	273 (55.4%)	4 (57.1%)	
Left	220 (44.6%)	3 (42.9%)	
Gender			0.704
Female	318 (64.5%)	4 (57.1%)	
Male	175 (35.5%)	3 (42.9%)	
Femoral Stem Size			0.685
1	26 (5.3%)	0 (0.0%)	
2	66 (13.4%)	1 (14.3%)	
HO2	78 (15.8%)	2 (28.6%)	
3	65 (13.2%)	0 (0.0%)	
HO3	101 (20.5%)	1 (14.3%)	
4	37 (7.5%)	2 (28.6%)	
HO4	79 (16.0%)	1 (14.3%)	
5	4 (0.8%)	0 (0.0%)	
HO5	26 (5.3%)	0 (0.0%)	
6	7 (1.4%)	0 (0.0%)	
7	4 (0.8%)	0 (0.0%)	
Barack Classification			0.340
A	326 (66.1%)	3 (42.9%)	
В	149 (30.2%)	4 (57.1%)	
D	12 (2.4%)	0 (0.0%)	
Unknown*	6 (1.2%)	0 (0.0%)	
Alignment			0.686
Neutral	335 (68.0%)	5 (71.4%)	
Right	106 (21.5%)	1 (14.3%)	
Left	46 (9.3%)	1 (14.3%)	
Unknown*	6 (1.2%)	0 (0.0%)	
- T-tests used for continu	ous variables and Fisher's Exact t	est used for categorical	variables
 Abbreviations: HO = Hi 	gh Offset stem		
- * Unknown: 6 patients	died before 12-month follow-up i	radiographs were obtair	ned

Table 5. Summary of

Studies

			Average Follow-up	PFFs, Hips		Time to PFF	Average age		
Author	Implant Name	Manufacturer	(yrs)	(n)	PFF %	(yrs)	(yrs)	Comments	
Westerman et al [20]	Exeter V40	Stryker	12.4	10 of 540	*1.85%	10.9	67.7	6 PPFs were cause for stem revision (1.11%)	
Mahon et [21]	Exeter V40 Exeter	Stryker	12.3	3 of 829	0.36%	6.9	67.8	Only details PFF as cause of revision	
Petheram et al [14]	Universal	Stryker	22.4	3 of 382	0.78%	-	66.3	Only details PFF as cause of revision	
Yates et al [30], Burston et al [15]	СРТ	Zimmer	10 then 15	1 of 191 182 of	*0.52%	5	64.9	Both papers report on same cohort at 10 & 15 years respectively	
Palan et al [19]	Exeter V40	Stryker	3.8	146,409 111 of	0.12%	-	72	Registry Data - Only details PFF as caused of revision	
Registry data based on revision.	СРТ	Zimmer	п	24,300	0.46%	-	73	н	
	Charnley	DePuy	п	15 of 20,182	0.07%	-	73	н	
	C-Stem	DePuy	"	21 of 15,113	0.14%	-	71	н	
Broden et al [7]	СРТ	Zimmer	4.0	47 of 1403	3.35%	7 months	82	Elderly cohort - mean age 82 years	
Mohammed et al [6]	СРТ	Zimmer Waldermar	2.0	18 of 543	3.31%	2 months	82	Follow-up only to two years	
	Lubinus SP2	Link	2.0	2 of 534	0.37%	п	п	п	