■ HIP

Clinical and radiological results of the collarless polished tapered stem at 15 years follow-up

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We prospectively followed 191 consecutive collarless polished tapered (CPT) femoral stems, implanted in 175 patients who had a mean age at operation of 64.5 years (21 to 85). At a mean follow-up of 15.9 years (14 to 17.5), 86 patients (95 hips) were still alive. The fate of all original stems is known. The 16-year survivorship with re-operation for any reason was 80.7% (95% confidence interval 72 to 89.4). There was no loss to follow-up, with clinical data available on all 95 hips and radiological assessment performed on 90 hips (95%). At latest follow-up, the mean Harris hip score was 78 (28 to 100) and the mean Oxford hip score was 36 (15 to 48). Stems subsided within the cement mantle, with a mean subsidence of 2.1 mm (0.4 to 19.2). Among the original cohort, only one stem (0.5%) has been revised due to aseptic loosening. In total seven stems were revised for any cause, of which four revisions were required for infection following revision of the acetabular component. A total of 21 patients (11%) required some sort of revision procedure; all except three of these resulted from failure of the acetabular component. Cemented acetabular components had a significantly lower revision burden (three hips, 2.7%) than Harris Galante uncemented components (17 hips, 21.8%) ($p < 0.001$).

The CPT stem continues to provide excellent radiological and clinical outcomes at 15 years following implantation. Its results are consistent with other polished tapered stem designs.

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The impressive survival of collarless polished double tapered femoral components has been demonstrated in originator series,[1-5] in non-originator series[6] and non-teaching centres[7] and in registry data.[8,9] There have been predictable patterns of subsidence at the stem-cement interface,[10] a factor that has been suggested to confer stability to the stem[11] and provide protection to the cement-bone interface.[4,12,13]

The collarless polished tapered (CPT) femoral component (Zimmer, Warsaw, Indiana) was originally developed as a collarless, highly polished, double-tapered prosthesis for distribution in the United States. Like the Exeter stem (Howmedica International Ltd, London, United Kingdom), from which the principles of its design have been taken, the CPT also employs the taper slip concept, allowing limited subsidence at the stem-cement interface and optimising the transfer of compressive load to surrounding bone.[13]

The CPT differs from the Exeter Universal stem in its broad lateral shoulder, more complete lateral taper and more rectangular proximal geometry. This shape was designed to maximise its rotational stability.[14-15]

This study reports the 15-year clinical and radiological results of the CPT femoral component implanted in a non-originator centre, and seeks to establish whether its results are equivalent to those reported for the Exeter stem.

Patients and Methods

A total of 191 total hip replacements (THRs) using cemented CPT stems were performed in 175 consecutive patients between November 1992 and November 1995. Of these, 68 (35.6%) were performed in men. The mean age at operation was 64.5 years (21 to 85) and 22 hips (11.5%) were implanted in patients < 50 years of age. At latest follow-up 88 patients (95 hips) had died (50%), which is comparable to other published data.[4,16] One further patient underwent a hindquarter amputation for occlusive vascular disease, leaving 95 hips in 86 patients available for review (Fig. 1).

Of the surviving patients 25 were men (29 hips) and 61 were women (66 hips). Their mean age at operation was 60 years (21 to 81), and the mean weight pre-operatively was 75 kg (44 to 111). The underlying diagnosis was atrophic osteoarthritis or rheumatoid

arthritis in 40 hips (42%), hypertrophic osteoarthritis in 37 hips (39%), developmental dysplasia in 11 (12%), and avascular necrosis in three (3%). The remainder comprised one patient with Perthes' disease, one with Paget's, and two with post-traumatic arthritis.

Two consultant teams carried out the THRs, with trainees operating under supervision accounting for approximately half of the cohort. Unless contraindicated, all patients received spinal anaesthesia. The posterolateral approach was used in all except three hips, when a transgluteal approach was used. Uncemented Harris Galante I acetabular components (Zimmer Ltd, Swindon, United Kingdom) were used in patients aged < 65 years, while cemented flanged polyethylene acetabular components (Charnley Elite (DePuy Ltd, Leeds, United Kingdom) or Zimmer flanged cup (Zimmer)) were used in those aged > 65 years.

Following rasping of the femoral canal, a Hardinge cement restrictor (Howmedica Ltd) was introduced, the canal washed with pressurised lavage, and cement (Palacos R with gentamicin (Kirby-Warrick Ltd, Bury St Edmunds, United Kingdom) inserted retrogradely using a cement gun with proximal pressurisation. Unless the size of the acetabular component was < 50 mm, all femoral heads were 28 mm in diameter. In smaller acetabular components 22mm heads was used. The posterior capsule and short external rotators were not repaired.

Patients were assessed clinically and radiologically at routine intervals by an author (BJB, AJB, PJY or GCB). Clinical outcome was determined by a combination of the Harris hip score (HHS)[17] and the Oxford hip score (OHS).[18] The OHS was recorded from 0 to 48, with 48 being the best score.[19]

Patients underwent anteroposterior (AP) radiography of both hips and a lateral radiograph of the affected hip pre-operatively, immediately following the procedure and then at three months post-operatively. Subsequent assessment periods varied but all patients underwent radiological assessment at five, ten and 15 years. This was undertaken by the lead author (BJB), with all revision cases undergoing a further review by the senior author (GCB).

Each radiograph was evaluated using described measurement techniques, in order to standardise comparison with other survival data.[20] All head sizes were known, therefore the magnification of each of the radiographs was determined from an initial measurement of the diameter of the femoral head.

The adequacy of the initial cementing was determined by the system reported by Barrack, Mulroy and Harris.[21] The minimum thickness of the cement mantle in the 14 zones of Gruen, McNeice and Amstutz[22] and Johnston et al[20] surrounding the stem and the three DeLee and Charnley[23] acetabular zones was measured. The degree of canal filling by the stem and the cement mantle was assessed at the mid-point of the lesser trochanter.

The presence of radiolucent lines (RLLs) (> 1 mm wide and > 5 mm long) at either the stem-cement or the cement-bone interfaces were noted. Osteolytic lesions (cystic lesion with endosteal scalloping and/or migration) were also recorded.

Heterotopic bone formation was recorded according to the criteria described by Brooker et al.[24] The degree of bone resorption from the proximal medial femur was measured according to the system of Engh, Bobyn and Glassman.[25]

The subsidence of the stem was determined on calibrated radiographs, using the greater trochanter, the shoulder of the prosthesis and the proximo-lateral cement mantle as radiological landmarks. A line of best fit was applied to the scatter plot to determine the subsidence curve.

The extent of linear wear of the acetabular component was measured according to the technique described by Latimer and Lachiewicz.[26]

Statistical analysis. Survivorship was plotted on Kaplan-Meier survival curves with 95% confidence intervals (CI), with the endpoints being revision of the femoral component due to aseptic loosening or osteolysis, and revision for any reason. Student's *t*-test, analysis of variance (ANOVA), Mann-Whitney, chi-squared, Fisher's exact, Spearman's rank correlation and Kruskal-Wallis tests were used where indicated. Statistical significance was set at p-value < 0.05.

Results

At a mean of 15.9 years (14 to 17.5), we obtained clinical follow-up in 100% and radiological follow-up in 95% of surviving hips. A total of five patients were too frail to undergo radiological assessment; thus, 90 hips in 81 patients were assessed radiologically. The fate of all stems, including those implanted into patients who have subsequently died, is known.

The mean HHS increased from 40 (20 to 61) pre-operatively to 78 (28 to 100) at final follow-up, when the mean OHS was 36 (15 to 48).

The relationship between acetabular wear and osteolysis with lower HHS just failed to reach statistical significance for the former evaluation (p = 0.06, Spearman rank correlation) and was not significant for the latter (p = 0.11, *t*-test), and was not significant for OHS values (p = 0.14, Spearman rank correlation; and p = 0.15, *t*-test, for wear and lysis, respectively). There was no association between either the HHS or OHS and heterotopic ossification (p = 0.92 and p = 0.90, respectively, both ANOVA). Similarly there was no difference in either latest HHS (p = 0.667, *t*-test) or OHS (p = 0.727, *t*-test) between those patients under and over 50 years at the time of implantation.

A total of 68 hips (72%) had complete cement mantles on the post-operative radiographs (Barrack grade A), while 22 (23%) had a full thickness defect in the mantle (Barrack grade C), which occurred most commonly in zone 1 and was always < 3 mm in length. A total of five hips (5%) had mantles that did not cover the tip of the stem (Barrack grade D).

Only one stem had a change in its alignment during the follow-up period. This patient had active Paget's disease, resulting in remodelling of the femur around the cement mantle, with the stem subsiding and collapsing into varus. Although

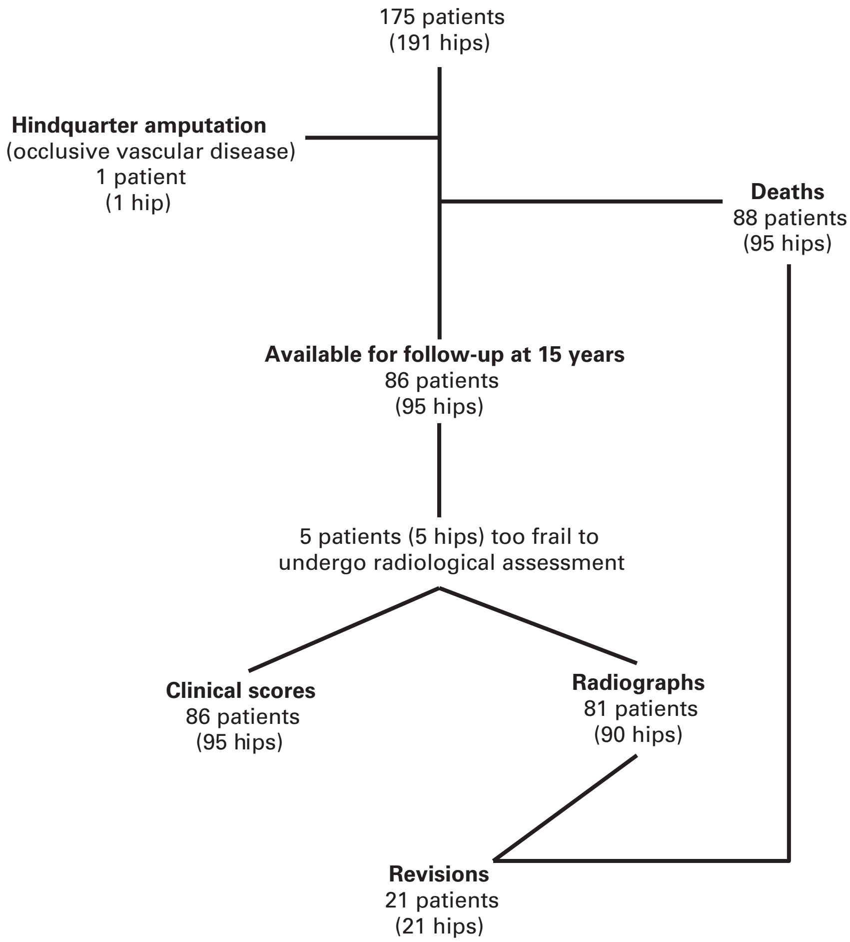

Fig. 1

Flow diagram illustrating outcome of original series of 175 patients (191 hips) at 15 years.

not revised to date (15.1 years), due to poor general health, the stem has been classed as a radiological failure.

All stems subsided within the cement mantle, to a mean subsidence of 2.1 mm (0.4 to 19.2; median 1.6 mm) at the final follow-up. Neither the HHS ($p = 0.175$, Spearman correlation), OHS ($p = 0.35$, Spearman correlation), post-operative Barrack grading ($p = 0.521$, Kruskal-Wallis), alignment of the stem ($p = 0.652$, Kruskal-Wallis), mean cement mantle thickness ($p = 0.289$, Spearman correlation), age ($p = 0.696$, Spearman correlation), gender ($p = 0.372$, Mann-Whitney) nor weight of the patient ($p = 0.893$, Spearman correlation) were associated with subsidence. There was a trend for thinner cement mantles in zone 7 to be associated with subsidence within the mantle ($p = 0.13$, Spearman correlation).

At final follow-up, 28 hips (31%) had either no or first degree resorption of the proximal medial femoral cortex[25] and 47 (52%) had second degree, 15 (17%) had third degree and no stems had fourth degree resorption. Loss of calcar bone was not related to the initial grade of cementing or calcar cementing but showed a trend to association with larger stems ($p = 0.09$, ANOVA).

There was no heterotopic ossification around 53 stems (59%), grade 1 in 12 (13%), grade 2 in ten (11%), grade 3 in nine (10%) and grade 4 in six (7%). There was no association between the more severe grades 3 and 4 and pain ($p = 0.387$, chi-squared). Heterotopic ossification was seen almost exclusively in males ($p < 0.001$, chi-squared) with hypertrophic osteoarthritis ($p < 0.001$, chi-squared).

Polyethylene wear rates were significantly greater in men ($p = 0.005$, Mann-Whitney) and associated with greater pre-operative patient weight ($p < 0.001$, Spearman correlation). There was a trend for wear to be greater in younger patients ($p = 0.087$, Spearman correlation). There was no association between rate of linear wear and restoration of offset ($p = 0.999$, Kruskal-Wallis), lateralisation of the centre of rotation of the hip ($p = 0.099$, Kruskal-Wallis), cemented or uncemented acetabular component fixation ($p = 0.279$, Mann-Whitney).

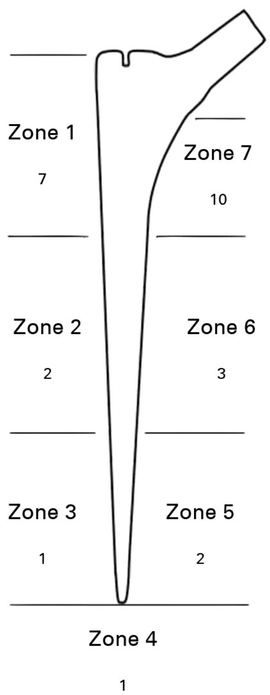

Fig. 2

Distribution of osteolysis according to the zones of Gruen[22] and Johnston.[20]

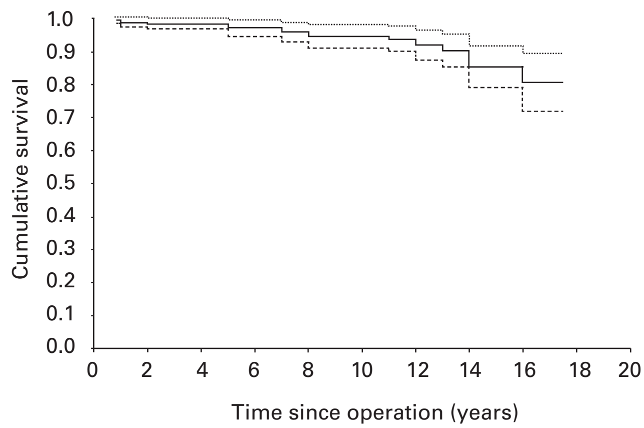

Fig. 3

Kaplan-Meier survival graph with 95% confidence intervals with the endpoint of re-operation for any reason.

Focal femoral osteolysis was present in 11 patients (12.9%) and was associated with greater polyethylene wear (p = 0.026, Mann-Whitney). Most defects were periarticular (Fig. 2). There was no relationship between osteolysis and the post-operative cementation in either zone 1 or zone 7 (p = 0.469 and p = 0.81, respectively, *t*-test). Osteolysis was no more common in those patients under 50 years of age at the time of the operation (p = 0.505, chi-squared).

A total of eight (4.2%) of the original 191 hips sustained at least one dislocation. In four hips this was a single episode in the early post-operative period, and four were recurrent. Two of these required revision to a captive acetabular component and a further two underwent revision of the acetabular liner. There was no association between head size (p = 0.571, Fisher's exact), degree of acetabular linear wear (p = 0.384, Mann-Whitney), restoration of offset (p = 0.476, chi-squared), gender (p = 0.476, Fisher's exact) or age of the patient (p = 0.081, Mann-Whitney) and dislocation.

Only one stem from the original cohort (0.5%) has to date been revised for aseptic loosening (revised at 13 years). This patient underwent a proximal femoral osteotomy as a child for dysplasia and subsequently required reaming of the intramedullary canal to gain enough access to permit insertion of the stem. A high rate of wear preceded the development of both acetabular and femoral osteolysis. The 16-year survivorship with endpoint being aseptic loosening of the stem was 98.9% (95% CI 97.6 to 100).

In total, seven stems (3.7%) have been revised. Other than the one described above, one was revised for infection, one for a peri-prosthetic fracture surrounding a well-fixed stem with no evidence of osteolysis, and four for secondary infection following revision of the acetabular component.

In total, 21 hips in 21 patients (11%) have undergone some form of revision surgery, mostly for failure of the acetabular component. Only three of 113 (2.7%) cemented acetabular components underwent revision, compared with 17 of 78 (21.8%) uncemented components (p < 0.001, Fisher's exact). The 16-year survivorship with endpoint being re-operation for any reason was 80.7% (95% CI 72.0 to 89.4) (Fig. 3).

Discussion

The CPT is currently the second most commonly used cemented femoral component in the National Joint Registry for England and Wales[27] and the third in the Australian register,[28] and it is being used with increasing frequency. Despite this, the literature on its survival is sparse.[14,29,30] This is in stark contrast to the Exeter design, from which the CPT was derived, which has excellent clinical and radiological follow-up in both its originating centre[1-5] and elsewhere.[6,7]

This study follows the same cohort of patients previously reported at a minimum of ten years post-operatively.[14] Our ten-year report showed that this femoral component was performing extremely well, with excellent clinical and radiological outcomes and a predictable pattern of subsidence; at this time no stem had been revised for aseptic loosening.

Our present data confirm the excellent performance stem at mean follow-up of 15.9 years. The 100% clinical follow-up and knowledge of the outcome of all hips (including those patients who have died) strengthens this review. The

mean HHS has dropped from 86 at ten years to 78 in this study, however these scores are equivalent to those reported for the Exeter Universal THR at 15 to 17 years from its originator centre.[4] The lack of any statistical association between wear or osteolysis and clinical scores may well result from the smaller size of the cohort, who are still alive at the final follow-up.

The forgiving nature of polished tapered stems to poor cementing is highlighted by the lack of association between adequacy of initial cementation with either stem subsidence or survival. Post-operative RLLs at the cement-bone interface have previously been observed to diminish following implantation with CPT stems, thought to result from the uniform taper compressing the creeping cement.[31]

With only one case with any measurable change in alignment, this stem seems resistant to such migration. Indeed, the CPT stem was initially designed as an impaction bone grafting revision stem, where central placement and rotational stability are paramount. For this purpose a broad lateral shoulder was added in order to increase the length of the taper laterally, ensure optimal valgus/varus positioning and improve rotational stability.

Change of alignment has been reported with the Exeter stem with as many as 18% migrating into valgus with subsidence.[2,6,32] We suspect that the broad lateral shoulder of the CPT protects against this. Many revised cemented stems have evidence of rotation within the cement mantle, indicating such failure is a three-dimensional process. Early internal rotation of Charnley-Elite stems (DePuy) has been shown to be predictive of failure.[32] We were unable to confirm the better rotational stability of the CPT as no radiostereometric analysis (RSA) was performed. However, it is known that any change in the geometry of the stem can have marked effects on rotational stability.[33] Stems with a wide, rectangular proximal geometry have been shown to be more stable in both uncemented[34] and in polished tapered designs.[35] The original C-stem femoral component (DePuy), with a very narrow shoulder was noted to have greater internal rotation than other polished tapered designs.[36] These findings add weight to previous finite element analyses, which showed that flat-sided implants provide more resistance to torsional forces than rounded implants.[15]

The mean subsidence increased slightly from 1.95 mm at ten years to 2.1 mm at 15.9 years, in line with predictions from the ten-year subsidence curve. This compares with 1.82 mm recorded for the Exeter Universal at its development centre.[4] All subsidence occurred at the stem-cement interface. This benign subsidence of the double taper permits the conversion of shear to radial compressive forces, which in turn are protective of the cement mantle and proximal calcar.[13]

Such good preservation of bone within the proximal femur was evidenced by the fact that more than 80% of stems had grade-2 bone loss or less.[25] The lack of cortical hypertrophy seen in any patient further highlighted the near normal loading patterns of the proximal femur. As the taper of the CPT narrows distally, the rigidity of the implant reduces, helping to distribute the load more evenly from proximal to distally and preventing stress concentration at the tip. As seen in the ten-year review larger, stiffer stems were negatively associated with the preservation of bone proximally, but the smaller numbers in this series, meant any association did not reach statistical significance ($p = 0.09$).

The benign subsidence of a polished tapered stem acts like a Morse taper, sealing off the endosteal cavity from wear debris. Our rate of osteolysis observed with the CPT was lower than that reported for other series of the Exeter Universal.[6] We suggest the broad lateral rectangular shoulder of the CPT stem might protect the proximal cement-bone interface more effectively than that of the rounded shoulder of the Exeter stem. Although such changes in proximal geometry are important, the polished surface finish is undoubtedly the most important variable in terms of survival of polished tapered stems. In the presence of a matte finish the same geometry consistently behaved as a composite beam with much higher rates of failure.[37]

We felt our high rate of dislocation in patients surviving to the latest follow-up (4.1%) is likely to be attributable to our failure to repair the posterior capsule and short external rotators at the time of surgery. Subsequently our practice has changed to include a repair.

Our revision rate for aseptic loosening of one stem (0.5%) is excellent and matches the results for the Exeter Universal stem.[4] We suspect that in this patient, a lack of cancellous bone, attributable to reaming of the canal prior to introducing the stem, prevented an adequate cement-bone interface from being formed. Combined with a high rate of wear and acetabular lysis, the polyethylene debris was able to penetrate into the femoral endosteum, resulting in osteolysis. Consequently we do not advocate use of a cemented polished tapered stem when reaming of the proximal femur is required prior to implantation. In all, four of our prostheses became infected secondarily following liner or acetabular revision, necessitating a two-stage revision. This highlights that any form of revision surgery is not a low risk procedure.

Failure of the acetabular component in younger patients has remained an issue. The weak link in our series has continued to be the Harris Galante 1 acetabular component, with 17 (21.8%) requiring revision, most being for aseptic loosening. Our concern regarding this particular design of component is shared by registry data.[8] In contrast we have highlighted the excellent results that can be achieved with cemented acetabular fixation in those patients aged > 65 years, achieving an all-cause revision rate of only 2.7% at latest follow-up. At a time when the use of all-cemented components is falling from in favour of uncemented components[27] it is important to draw attention to the fact that this series' advocacy for all-cemented fixation in the elderly is supported by the vast majority of registry data.[8,27-28,38,39] The relative success of cement-in-cement revision of such designs[40,41] also makes this an attractive option for the revision hip surgeon.

In summary the CPT stem continues to exhibit excellent long-term survivorship. Its results are in line with those reported for the Exeter Universal stem at 15 years.

Supplementary material

A table detailing the hips requiring revision is available with the electronic version of this article on our website www.bjj.boneandjoint.org.uk

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