Five-year prospective clinical and radiological results of a new cannulated cemented polished Tri-Taper femoral stem

We describe the results at five years of a prospective study of a new tri-tapered polished, cannulated, cemented femoral stem implanted in 51 patients (54 hips) with osteoarthritis. The mean age and body mass index of the patients was 74 years and 27.9, respectively.

Using the anterolateral approach, half of the stems were implanted by a consultant orthopaedic surgeon and half by six different registrars. There were three withdrawals from the study because of psychiatric illness, a deep infection and a recurrent dislocation. Five deaths occurred prior to five-year follow-up and one patient withdrew from clinical review.

In the remaining 51 hips the mean pre-operative Oxford hip score was 47 points which decreased to 19 points at five years (45 hips). Of the stems 49 (98%) were implanted within 1° of neutral in the femoral canal. The mean migration of the stem at five years was 1.9 mm and the survivorship for aseptic loosening was 100%. There was no significant difference in outcome between the consultant and registrar groups. At five years, the results were comparable with those of other polished, tapered, cemented stems. Long-term surveillance continues.

Patients and Methods

The Tri-Taper stems were produced from wrought, high-nitrogen stainless steel in four sizes ranging in length from 130 mm to 140 mm with the offset increasing incrementally from 37.2 mm to 47.3 mm. Pre-clinical fatigue testing was performed in accordance with the ISO7206-412 and ISO7206-8 standards. All the components had a neck-shaft angle of 135° and a polished finish with a surface roughness of 0.2 μmRa. The trunnion was a 12/14 Eurocone Morse taper suitable for attachment of cobalt chrome, stainless steel or ceramic modular heads. The proximal end of the stem cannulation was recessed and threaded for attachment.
ment of instruments to implant or remove the components and for insertion of a threaded screw to seal the channel.

The protocol for the clinical investigation was submitted to the Medical Devices Agency and approved before implementation. The approval of the local ethics committee was also granted.

The study group was confined to patients with osteoarthritis who were suitable for primary total hip replacement. All the patients were aged between 65 and 85 years at the time of surgery and provided informed consent, understood the aims of the study and were willing to comply with the post-operative review programme. Individuals were excluded from the study if the prospect of recovery to independent mobility was compromised by co-morbidity or if death was anticipated within five years.

Between September 1997 and November 1999, 51 patients (54 hips) received the Tri-Taper stem (Cremascoli-Ortho, Milan, Italy) at St Helier Hospital, Carshalton, UK. There were ten men (ten hips) and 41 women (44 hips) with a mean age at the time of surgery of 73.8 years (65.6 to 84.8). The mean weight at surgery was 71.3 kg (49 to 117) with a mean body mass index of 27.9 (19.6 to 42.93).

The patients were placed in the lateral decubitus position for an anterolateral approach to the hip. Those aged from 65 to 75 years received an uncemented AnCA Fit acetabular component with a polyethylene insert of internal diameter 28 mm (Cremascoli-Ortho). Patients aged from 75 to 85 years received a standard cemented ultra-high-molecular-weight polyethylene component with an internal diameter of 28 mm (Cremascoli-Ortho). Cobalt-chrome heads (28 mm) (Cremascoli-Ortho) were applied to 53 of the Tri-Taper stems. In error the remaining hip received a 28 mm ceramic head (Cremascoli-Ortho).

The femoral cement was vacuum mixed and inserted at four minutes by a gun in a retrograde manner. The femoral component was then inserted slowly over the guide wire, six minutes after mixing the cement until its reference line corresponded to the level of transection of the femoral neck.

Three marker beads (Orthodesign Ltd, Dorset, UK) were inserted into the cancellous bone of the greater trochanter before the introduction of cement as reference points for migration studies.

Half of the implants were inserted by one consultant (REF) and the remainder by six registrars at different stages in their training. The allocation of surgeon for each patient was random. Post-operatively, low-molecular-weight heparin (Tinzaparin, 3500 IU) was injected subcutaneously once daily and a total of three doses of intravenous cefuroxime (750 mg) was administered. Analgesia was given as required. Rehabilitation followed a standardised hospital protocol with early mobilisation bearing full weight.

Clinical data were collected pre-operatively, at six months and at one, two, three and five years after surgery. The pre-operative and post-operative Oxford hip score was determined and radiographs obtained. Radiological analysis was performed using the standardised system of terminology for reporting results according to Johnston et al. The proximal femur was divided into 14 zones as described by Gruen, McNiece and Amstutz. Each radiograph was examined under direct vision for the presence of radiolucent lines about the cement-bone and the cement-stem interface, fracture of the cement, resorption of the calcar and cortical hypertrophy.

All radiographs were digitised and stored in ‘tiff’ format for analysis using Scion Image software (Beta 4.01;
Frederick, Maryland) for Windows, developed by the National Institutes of Health (Bethesda, Maryland). This allowed measurement of the position and alignment of the stem from the anteroposterior (AP) and lateral radiographs. The alignment was recorded in degrees of valgus or varus with respect to the axis of the femoral canal. The distance measured from the mid-point of the femoral canal to the mid-point of the tip of the stem defined the position of the tip which was recorded in millimetres.\textsuperscript{20}

Vertical migration of the femoral stem was measured on AP standing radiographs\textsuperscript{21,22} taken post-operatively, at six months and at one, two, three and five years after surgery using Scion Image software. The accuracy of this method has been shown to be 0.61 mm with an inter-observer error of 0.12 mm\textsuperscript{21} (Fig. 1).

All data were recorded on case-report forms and entered into our hip registry database by a clinical research assistant (MK, JR, GF). An independent auditor validated the whole data set (AC). All adverse events, whether directly or indirectly attributable to the Tri-Taper stem, were recorded and notified to the Local Research and Ethics Committee, the Medical Devices Agency and reported according to the Sponsor’s Investigators Site Procedure for Adverse Event Reporting in Clinical Trials.

Statistical analysis. This was performed using GraphPad Prism (v4.03) (San Diego, California) for comparison of results between different groups. A two-paired Student $t$-test was used to study the mean differences between groups. The statistical significance was set at $p \leq 0.05$.

Results
Over the five-year period, one patient was withdrawn within the first year because of a psychiatric illness and two revisions were undertaken, one for wound infection and the other for recurrent dislocation when both the acetabular component and femoral stem were revised. Five deaths occurred, all secondary to co-morbidity, and one patient elected to withdraw from the clinical review. Because of insufficient data acquired from the two patients who withdrew within the first year, they were excluded from the clinical and radiological analysis. Therefore, of 52 hips available for analysis, 45 were reviewed at five years (Fig. 2).

**Oxford hip score.** The mean Oxford score was compared according to age and the operating surgeon (Fig. 3). There was no significant difference between those aged 65 to 75 years and 75 to 85 years five years after operation. The pre-operative Oxford score in the registrar group (mean 49, SD 19.82) was significantly higher than that for the consultant (mean 44.4, SD 21.23; $p = 0.0229$). However, there was no significant difference between the registrar and consultant groups at any stage post-operatively.

**Radiological findings.** An independent observer (PS) carried out analysis of the AP and lateral radiographs. No femoral stem had fractured and there were no cases of aseptic loosening during the study. A total of 45 femoral stems subsided at the prosthesis-cement interface. All radiolucent lines were at the cement-bone interface and there were no cement mantles broken. No radiolucent lines were seen at the prosthesis-cement interface. The radiolucent lines
recorded were non-progressive and did not exceed 2 mm in thickness. Resorption of the calcar was not greater than 2 mm in height or width in any case. At five years, formation of heterotopic bone graded according to the classification of Brooker et al.\textsuperscript{23} was grade 0 in 19 (43.2\%) of hips, grade I in 15 (34.1\%), grade II in 7 (15.9\%) and grade III in 3 (6.8\%). One patient required excision of heterotopic bone at three years. No radiographs showed any evidence of resorption, hypertrophy or endosteal cavitation of the femur.

**Tri-Taper stem migration.** The tip of the Tri-Taper stem migrated distally during the first six months by a mean of 1.37 mm (n = 50; SD 1.31). After the first year the mean distal migration was 1.69 mm (n = 50; SD 1.21) and at five years 1.89 mm (n = 41, SD 1.24). Migration of the stem by age group and operating surgeon is shown in Figure 4. Neither analysis revealed a significant difference in the pattern of migration between the two groups at any time point.

**Position and alignment of the femoral stem.** The measurement of alignment of the femoral stem on the AP radiograph showed that 15 (30\%) stems were in the precisely neutral position. The mean valgus angle was 0.27° (SD 0.16°) in 14 (28\%) stems and the mean varus angle was 0.40° (SD 0.26°) in 21 (42\%) stems.

Alignment data for the femoral stem were grouped into 1° increments from the neutral axis of the femoral canal. We found that 49 stems (98\%) were aligned within 1° and all were aligned within 2° with respect to the central axis of the canal.

The position of the tip of the femoral stem within the femoral canal on the AP radiograph was central in 15 (30\%) stems, lateral (valgus) to the centre with a mean distance of 0.91 mm (SD 0.37 mm) in 14 (28\%) and medial (varus) to the centre with a mean distance of 1.28 mm (SD 0.65 mm) in 21. A total of 47 (94\%) stems were within 2 mm from the centre point of the femoral canal.

Measurement of the position of the femoral stem on the lateral radiograph showed that nine (18\%) were in neutral, 17 (34\%) were anterior with a mean anterior distance of 1.1 mm (SD 0.59) and 24 (48\%) were posterior with a mean...
posterior distance of 1.18 mm (SD 0.46 mm) to the centre point of the canal. All the stems were aligned within 2 mm from the centre of the femoral canal on the lateral radiograph. There was no significant difference between the two groups of surgeons (p > 0.722).

**Serious adverse events.** No device-related adverse events occurred within the five-year period. A total of 20 non-device-related serious adverse events were reported; 11 were due to co-morbidity, two (3.7%) to trochanteric bursitis, two (3.7%) to superficial wound infection, one (1.85%) to deep wound infection requiring revision, one (1.85%) to significant heterotopic ossification requiring excision, one (1.85%) to deep-vein thrombosis, and one (1.85%) to peri-operative foot drop which recovered. One patient (1.85%) required exchange of the femoral head for adjustment of leg-length. Five deaths were reported which were all due to co-morbidity.

**Discussion**

In our study the mean pre-operative Oxford hip score was 46.79 (SD 7.37), which decreased to 19.0 points at four years and was maintained at five years. At five years, the improvement in the hip score was independent of the operating surgeon or the age of the patient at the time of surgery. This is consistent with the expected improvement after total hip replacement and is comparable with that reported by Dawson et al. and Fitzpatrick et al. 

Radiological analysis showed survival of 100% for aseptic loosening at five years and no adverse events for the device were identified.

The distance and pattern of migration measured for the Tri-Taper stem were typical for polished, tapered, cemented stems. As anticipated, migration was most rapid during the first six months with progressive stabilisation thereafter. It is now generally accepted that this pattern is desirable for polished, tapered, cemented stems and does not adversely affect the long-term performance. The pattern of migration in our study was unaffected by the grade of the operating surgeon and the age of the patient at the time of surgery. Whether this should be attributed to a reproducible surgical technique or an inherently tolerant device is not known.

Malposition of the implant can lead to sub-optimal long-term results in cemented total hip replacement. It has been identified that there is an increased incidence of premature loosening and radiolucent lines at the cement-stem and cement-bone interfaces in stems which are orientated in more than 5° of varus. Varus orientation of the stem has been associated with poor results in a number of studies and has been attributed to the resultant thin cement mantle in the calcar or poor cement support at the tip of the stem.

The cannulated stem technique for obtaining centralisation and alignment of the stem was first devised by Koster et al. Their collarless, straight, tapered, stem with a rectangular cross-section was designed with a central longitudinal channel (CF30 stem, Allopro; Sulzer Medica, Baar, Switzerland). At follow-up at six years, they found that 94% of the stems were in neutral alignment and 98% were centred in the cement distally. Our results with the cannulated Tri-Taper stem showed comparable reproducibility of the position of the tip of the stem with 49 (98%) within 1˚ and all within 2˚ of neutral alignment. The clinical benefit of cannulation of the stem is debatable. Although the study of Koster et al. and our study have shown better control of the position of the tip of the stem than has been reported with conventional stem centralisers, there is no evidence to suggest that this relatively minor improvement would result in an improved clinical outcome.

We have no roentgen stereophotogrammetric data for the Tri-Taper stem to evaluate the torsional stability of the component. However, our results at five years have not identified any radiological evidence to indicate that the proximal flutes were compromising the cement mantle. In both revision cases, the cement mantles were undamaged.

Cannulation of the stem only controls longitudinal alignment. It does not help the surgeon to control rotation of the stem or the level of implantation. These variables are vital to optimise joint stability, to maximise the range of movement and to ensure equality of leg length.

We identified a shortcoming of the Tri-Taper design. The stem was designed with a stem-head offset which increased incrementally with size. This was not ideal since in large men, with large head-shaft offsets, the femoral cortices may be very thick, producing narrow ‘champagne-glass’ femoral canals. By contrast, small osteoporotic women, generally have smaller head-shaft offsets and capacious ‘stove-pipe’ medullary canals.

The head-shaft angle of the Tri-Taper stem may be sub-optimal. The neck-shaft angle of the human femur varies with age. At birth it is about 150°, decreasing to 140° at 18 months and averaging 126° in the adult. In old age the angle may decrease further to around 120°. A femoral stem with a greater than normal neck-shaft angle and a physiological offset will need to be seated more deeply than normal to avoid increasing the length of the leg. Whether this is beneficial is unclear. We found that it was necessary to ensure that the lateral shoulder of the Tri-Taper stem was seated more distally than with other stems. We autographed the resultant cavity in the medial aspect of the greater trochanter with bone harvested from the femoral head. However, at the calcar, the cement mantle was thinned since the stem was positioned more distally. This may be detrimental.

We have studied the early and intermediate clinical and radiological results for a new cannulated Tri-tapered femoral component. At five years the new device has behaved as predicted in the hands of seven surgeons with different levels of experience. The results are comparable with those of other polished tapered stems reported in the literature. This is in accord with the Medical Device Directive (93/42/
ECC). An option of a reduced neck-shaft angle and a provision of variable femoral offsets independent of stem size will allow better matching to the normal geometry. Long-term surveillance of the device is ongoing.

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