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A Cannulated Tri-Tapered Femoral Stem for Total Hip Arthroplasty: Clinical and Radiological Results at Ten Years

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ABSTRACT

We report the ten-year clinical and radiological outcomes of a novel cannulated, tri-tapered femoral stem, used in primary total hip arthroplasty (110 stems in 98 patients). At ten years, two Tri-taper stems had been revised for infection and dislocation. The mean Oxford Hip Score improved from 13.46 pre-operatively, to 37.04. Radiological analysis revealed radiolucent lines in 57 cases, but none exceeded 2 mm thickness. Stem subsidence was identified in 63 cases, with mean distal tip migration of 3.8 mm. Survivorship with revision for aseptic loosening as the end point was 100% at 10 years. Stem survival with revision for any cause was 98.2% (95% CI, 92.9% to 99.5%). The ten-year results of the Tri-taper stem are comparable to other polished, tapered femoral stems.

Design innovation and contemporary surgical techniques have sought to enhance the performance and longevity of total hip arthroplasty (THA). A new femoral stem for use in primary THA was developed, incorporating design features that had previously been reported in the literature as advantageous. The Tri-taper stem (Cremascoli-Ortho, Milan, Italy) was manufactured from wrought, high nitrogen stainless steel and had a polished finish, with surface roughness of 0.2 μmRa, for cemented fixation (Fig. 1). The stem was cannulated to facilitate accurate implant positioning over a guide wire that was attached to the centre of a cement restrictor. This ensured that the tip of the stem sat near the centre of the femoral canal. The proximal end of the longitudinal cannulation was recessed and threaded to allow the attachment of instruments to implant or remove the components.

The stem featured a Tri-taper design to improve proximal load transfer and reduce the risk of stress shielding. The wedge-shaped stem incorporated mediolateral and anteroposterior longitudinal tapers to transfer compressive load to the cement-bone interface and a lateral to medial taper to enhance load transfer to the medial cortex of the proximal femur. Rotational stability within the cement mantle was augmented by longitudinal recesses with smooth edges on the anterior, posterior and lateral aspects of the proximal segment. The Tri-taper stem was produced in four sizes, ranging from 130 mm to 140 mm in length, with a corresponding increase in the offset from 37.2 mm to 47.3 mm. All stems had a neck-shaft angle of 135°. The 12/14 Eurocone Morse taper trunnion accommodated a stainless steel, cobalt chrome or ceramic modular head.

The design rationale, operative technique and 5-year results from a pilot study of the Tri-Taper stem have been published [1]. We now present the ten-year outcome of a larger patient cohort.

Patients and Methods

A prospective clinical study of the Tri-taper femoral stem was commenced in 1997. Ethical committee and Medical Devices Agency approval was granted for the study. Patients with osteoarthritis of the hip, aged between 65 and 85 years and suitable for primary THA were eligible for participation. Patients with significant co-morbidities that could affect their recovery to independent mobility, or had a life expectancy of less than five years were excluded from the study. All patients provided written informed consent prior to enrolment.

Between September 1997 and October 2001, a consecutive series of 110 Tri-taper femoral stems were implanted in 98 patients undergoing primary THA. There were 71 women (81 hips) and 27 men (29 hips), with a mean age at surgery of 73.5 years (65.1 to 84.8). The mean body mass index was 28.6 (19.2 to 43.6). Sixty-six operations were undertaken by one consultant orthopaedic surgeon (REF) and 44 were performed by 11 training registrars.

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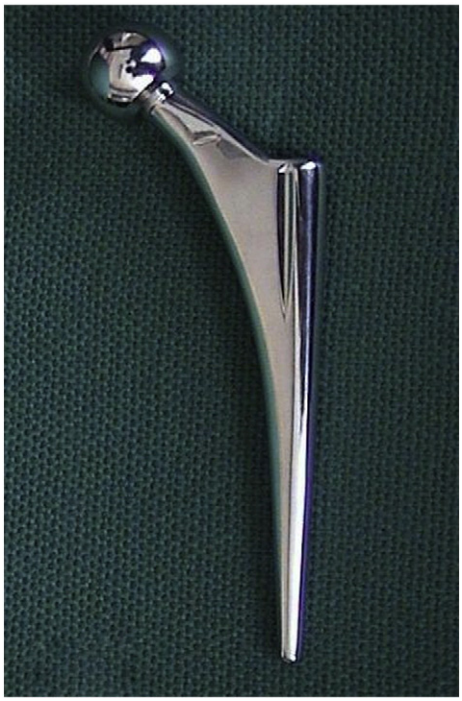

Fig. 1. Photograph of the Tri-taper femoral stem.

Surgery was performed in laminar air-flow theatres, with the patients placed in the lateral decubitus position. An anterolateral approach to the hip was used in 91 hips, a posterior approach in 19 hips. A Tri-taper femoral stem was implanted in all cases. The Tri-taper stem was cemented with two mixes of Palacos R cement (Schering-Plough Ltd, Welwyn Garden City, United Kingdom), using a third generation, retrograde cementing technique.

A 28 mm cobalt-chromium femoral head was implanted in 109 hips. The remaining one hip received a 28 mm ceramic head. The choice of acetabular component was age dependent. Patients under 75 years of age received an uncemented ANCA Fit acetabular component (Cremascoli-Ortho), with a polyethylene insert of internal diameter 28 mm (70 patients). Those over 75 years received a cemented Muller acetabular cup (Cremascoli-Ortho), which was fabricated from ultra-high molecular weight polyethylene and had an internal diameter of 28 mm (40 patients).

All patients received three peri-operative doses of intravenous antibiotic prophylaxis (cefuroxime 1.5 g at induction of anaesthesia and 750 mg eight and 16 hours later). Subcutaneous low molecular-weight heparin (Tinzaparin, 3500 IU, once daily) was administered until discharge. Post-operative rehabilitation followed the hospital's standard practise, with early mobilisation and full weight-bearing permitted.

Clinical and radiological data were collected pre-operatively; at six months; and at one, two, three, five and ten years after surgery. Annual Oxford Hip Scores [2] (OHS) were also obtained through postal questionnaires to assess functional outcome. Radiological evaluation was undertaken on standardised antero-posterior (AP) and lateral radiographs of the hip, using the assessment described by Johnston et al [3]. The radiographs were analysed by two independent examiners (FS, RR), who were not involved in the care of the patients, using the TraumaCad software (Voyant Health, Tel Aviv, Israel). Femoral radiolucent lines at the implant-cement and cement-bone interface were measured using the 14 zones described by Gruen et al [4]. Acetabular radiolucent lines were analysed according to the 3 zones described by DeLee and Charnely [5]. A radiolucent line was recorded only if it occupied at least 50% of the zone. The quality of the cement mantle was assessed using Barrack's classification [6]. Heterotopic ossification was documented using the criteria described by Brooker et al [7]. The alignment of the femoral stem was measured with respect to the axis of the femoral canal on AP radiographs. Stem migration was evaluated using three marker beads (Orthodesign Ltd, Dorset, UK) that had been implanted into the cancellous bone of the greater trochanter. The vertical distance from each marker bead to the tip of the stem was measured and a mean value obtained to calculate migration at each time point.

Statistical Analysis

Survivorship analysis was performed using Graph Pad Prism (v5.0) statistical software (Graph pad Software Inc, San Diego, California). Survival rate was calculated using Kaplan–Meier survivorship curves with 95% confidence intervals. End points were defined as revision of the Tri-taper stem for aseptic loosening and revision of the stem for any cause. An unpaired *t*-test was used to compare the mean difference in OHS between the consultant and registrar groups. The statistical significance was set at $P \leq 0.05$.

Results

At the ten-year time point, 22 patients (23 hips) had died, five patients (5 hips) had withdrawn from the study and two patients (2 hips) were lost to follow-up (at 5 and 9 years respectively). The average follow-up time was 8.9 years ± 2.2. All results from these patients, up to the point of loss from the study, were included in the final analysis. The reasons for patient withdrawal include: cancer (2 patients at 5.5 years and 9 years); psychiatric illness (2 patients at 1 year and 6 years) and after an above knee amputation following a road traffic collision at 8 years. These patients were contacted to ascertain the status of the THA at 10 years. Three patients had died with the original prosthesis in situ and two patients confirmed that the prostheses were still in place.

Adverse Events and Revisions

Two Tri-taper stems have been revised before ten years. The first patient developed a deep wound infection at one month and underwent open exploration, debridement and washout. *Staphylococcus aureus* was cultured and the patient started on appropriate long term antibiotics. The patient subsequently underwent revision of both components at 0.9 years. The second patient underwent revision of the stem and acetabular cup at 2.8 years for recurrent dislocation. A further two patients have undergone revision of the acetabular component only. These were for aseptic loosening at 7.4 years and dislocation with sub-optimal cup positioning (inclination angle 55°) at 8.1 years (Table 1).

Other adverse events include: excision of heterotopic ossification (three patients at 11, 12 and 13 months); open repair of abductor tendons (one year); and steroid injection of trochanteric bursitis (8 months). One patient developed a wound infection that required debridement and washout at two months. Three patients developed superficial wound infections within two weeks of surgery and were treated with oral antibiotics. One patient developed a transient sciatic nerve palsy. This had resolved by the six-month review. One patient developed lymphoedema in the ipsilateral limb. This resolved by eight months. There were two cases of hip dislocation. Both patients underwent revision surgery as previously described. Sixteen device-unrelated, adverse events were documented (nine cerebrovascular accidents and seven cardiac events).

Clinical Findings

The mean OHS improved from 13.46 (1 to 39) pre-operatively, to 37.04 (14 to 48) at ten years (Fig. 2). Comparison of the OHS by grade of operating surgeon showed no significant difference at ten years (Consultant group: mean OHS 37.81, SD 8.96; Registrar group: mean OHS 36.46, SD 8.46; $P = 0.4786$).