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ORIGINAL RESEARCH ARTICLE

Excellent mid-term results of a new polished tapered modular cemented stem: a study of 113 hip replacements with minimum 5-year follow-up

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ABSTRACT

Background: This prospective cohort study reports the medium-term clinical and radiographic results of 113 hips treated with a hybrid total hip replacement (THR) with a new cemented tapered cobalt-chrome (Co-Cr) stem with a titanium (Ti) modular neck (ProfemurXm®).

Method: Between October 2008 and December 2010 we performed 115 consecutive hybrid THR with the ProfemurXm® in 105 patients.

Results: Survivorship of the implant (stem and modular neck) at a mean of 6.5 years (min 5-max 8) was 100% with the endpoint revision for any reason. No implant was at risk for revision or showed signs of loosening. The mean Harris Hip Score was 89/100, mean Oxford Hip Score was 43/48, mean WOMAC was 91/100. No patient had thigh pain, no patient reported squeaking. There were no dislocations in this cohort. No implant showed development of radiolucent lines (RLL), either at the stem-cement or cement-bone interface. No hip showed osteolysis or calcar resorption. The mean femoral subsidence of the stem within the cement mantel was 0.31 mm (range 0-0.6 mm) after 6.5 years. With the use of this modular stem, 93% of hips showed no measurable leg length difference after THR, and leg length could be restored within a 5-mm limit in 99% of hips.

Conclusions: The mid-term results of this new polished stem were excellent, without adverse effects from the use of modularity.

Keywords: Leg length restoration, Modular neck, Polished tapered stem, Total hip

Introduction

Total hip replacement (THR) is a very successful procedure with an almost absent femoral failure rate due to aseptic loosening, if a polished cemented taper is being used (1). Long-term data from the original Exeter hip showed excellent results (2). Concerns in THR remain instability and leg length discrepancy (LLD) (3). In order to address these concerns, modular necks were introduced. The ProfemurXm® was developed to incorporate the perceived advantages of the taper-slip design and modularity. A finite element study by Simpson et al (4), showed that this modular device had similar stress distributions to the surrounding bone and cement compared to the Exeter stem. They anticipated that this modular device would have similar short-term clinical performance to that of the original Exeter stem, with the additional advantages of increased modularity. We performed a prospective study to analyse the clinical and radiographic results in a consecutive series of patients operated with this stem design, and we report on the medium-term results. To the best of our knowledge, this study is the first to report on this particular stem design. Special attention was given to analysis of the radiological behaviour of this stem with a modular neck.

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Material and methods

After approval from the Ethical Committee of the hospital, a prospective study was set up. Between October 2008 and December 2010 we performed 115 consecutive hybrid THR with the ProfemurXm® in 105 patients. Formal approval for publication of data was obtained from all patients.

The stem that was studied is a new highly polished taper, made of cobalt-chrome-molybdenum (CoCrMo) alloy, and with a female taper in the metaphysis for use with a modular neck (MicroPort Orthopedics Inc.; formerly Wright Medical). The stems are designed to act as a taper slip, following the Exeter philosophy. The modular necks are made of titanium-aluminium-vanadium (TiAlV) alloy (Ti6Al4V-ASTM F136) and have a 12/14-mm cylindrical taper at 1 end to seat the femoral head and a 9 × 18 mm conical elliptical taper at the other end (MicroPort Orthopedics Inc.; formerly Cremascoli). Since 2012 a CoCr taper is available for use, but in the study population only Ti necks were used.

2 patients had an acetabular revision within 1 year (stem remained in situ, but modular neck was exchanged for access) and were therefore excluded from the study, leaving a cohort of 113 hips in 103 patients in the study. 12 patients had died with their THR in situ at the time of final review. There were no deaths related to the surgery and all occurred between 1 and 5 years after surgery. Of the remaining 101 hips, 3 patients with 4 hips refused a follow-up visit but were known to have their implant in situ, and 2 moved abroad and were completely lost to follow-up. This left 95 hips in 86 patients for review (Tab. I). All had clinical and radiographic evaluation. There were 61 female and 34 male patients. Mean age at surgery was 67.6 years (range 44-89 years). 31 were graded as Charnley category A, 19 category B and 45 category C patients. The indications for THR were: osteoarthritis (n = 90), avascular necrosis (n = 4) and chondrolysis (n = 1). 3 patients had simultaneous bilateral THR performed. All patients had a hybrid THR with a press fit uncemented Ti acetabular component. A ceramic liner was used in 57 hips and a polyethylene liner in 38. Table II lists the used stem sizes. A variety of modular necks was used (Tab. III) and coupled with a ceramic head (Biolox Delta, CeramTec). Head size was 28 mm in 6 hips, 32 mm in 55 hips, and 36 mm in 34 hips.

All surgeries were performed by the senior author (J.F.A.S.), in a standard operating room, wearing SteriShield protection (Stryker). Simplex + tobramycin bone cement (Stryker Orthopaedics) was used for all femoral components. A double incision minimal invasive surgery (MIS) posterolateral approach was used for all patients and patients received IV cefazolin during 24 hours (3 × 1 g). Preoperative planning was performed using a software planning system (Impax, Agfa Health Care). Exact femoral offset and leg length were recreated on the template and distance in mm was calculated from neck of the stem to the most proximal point of the greater trochanter. This distance was recreated and checked intraoperatively. Clinically, leg length was checked before incision and after insertion of trial modular necks, including the use of quadriceps tension in full hip extension and 90° knee flexion. Combined anteversion was aimed at 30°-40°. Cup anteversion was guided by the transverse ligament and aimed at 15°-20°. Version in the frontal plain and varus in coronal plane was adapted/changed by the modular neck at final trial reduction according to clinical stability testing, aiming to adhere to the calculated offset and minimising the risk of lengthening. Postoperatively a multimodal venous thromboembolism (VTE) prophylaxis protocol was used with mechanical compression devices at night (AV-Impulse™ foot pumps) and aspirin or low-molecular-weight heparins (enoxaparine 40 mg) daily for 4 weeks. Patients received indomethacin during 5 days, starting the night before surgery, with omeprazole 20 mg orally as a protective measure.

Clinical scores used were: University of California Los Angeles (UCLA) Activity Score (min 0-max 10), Oxford Score (min 12-max 48), Harris Hip Score (HHS) (%), and Western Ontario and McMaster Universities Arthritis Index (WOMAC) (%). Patients were specifically asked for any presence of squeaking or clicking. X-ray evaluation consisted of digital anteroposterior (AP) pelvis and lateral hip. X-rays were evaluated for component positioning and possible migration, evaluation of implant-cement and cement-bone interface, the presence of heterotopic bone according to Brookers classification (5), cement grading according to the classification of Barrack (6) and the presence of radiolucent lines (RLL) and osteolysis. Femoral subsidence of the stem within the cement mantel was measured on the digital AP hip x-ray, with maximum magnification, and calculated to an accuracy of 0.1 mm from the shoulder of the stem to the cement mantel proximally in zone 1. Leg length was measured radiographically on a standing AP pelvis by referencing to the teardrop line and calculating the difference from the pelvic transverse axis to the lesser trochanters to an accuracy of 1 mm.

Statistical analysis was conducted with SPSS v21.0 (IBM-SPSS) using a Wilcoxon signed-rank test to determine significance in clinical improvement. A p value <0.05 was considered statistically significant.

TABLE I - Study layout (n = hips)

Entered in prospective study	115
Excluded (acetabular revision – stem remained in situ) in 1st year: -2	113
Died during study period (with implant in situ): -12	101
Lost to follow-up: -2	99
Refused final review but had implant in situ (were contacted by phone and functioning well): -4	95

TABLE II - Stem sizes used

Size 0	30
Size 1	24
Size 2	30
Size 3	10
Size 4	1
Total	95

TABLE III - Titanium modular necks used

Short straight	10	Long straight	3
Short varus 8°	4	Long varus 8°	5
Short varus + anteverted 6°	12	Long varus + anteverted 6°	19
Short anteverted 8°	10	Long anteverted 8°	9
Short anteverted 15°	5	Long anteverted 15°	15
Short varus 15°	1	Long varus 15°	2
Total short necks	42	Total long necks	53

Results

The mean follow-up was 78 months (min 50-max 93, median 77 months) with a standard deviation of 8 months.

There were no revision surgeries in the study population. There were no major perioperative complications, and there were no clinical VTE events. There were no infections. There was 1 patient with a temporary femoral nerve palsy on the contralateral side, due to pressure of a malpositioned pubic support.

Clinical evaluation

Clinical results were excellent showing significant improvement in all clinical scores.

The mean HHS improved from 31 (range 2-68) to 90 (range 44-100) ($p<0.0001$).

The mean WOMAC score improved from 30 (range 3-58) to 91 (range 46-100) ($p<0,0001$). The mean UCLA Activity Score improved from 3 (range 1-6) to 6 (range 3-8) ($p<0.0001$). The mean Oxford score was 44 (range 21-48) at follow-up.

No patient reported clicking or squeaking. No patient reported thigh pain.

Radiographic evaluation

There were 88 hips graded as Dorr type A and 7 type B. Cement grading of the femur was: grade A 92, grade B 3 and grade C 0. There were no signs of radiographic loosening or osteolysis. No stem had RLL in more than 1 zone, and no stem showed progression of RLL. No RLL at all were found in 87 hips. No femur showed new RLL at final follow-up. 8 stems had 1 RLL (4 hips in zone 4, 3 hips in zone 6 and 1 hip in zone 3) on the immediate postoperative x-ray. These RLLs remained unchanged over time. The stem was in neutral alignment in 91 hips, in varus in 3 (all 2°) and in valgus in 1 (2°). The rate of heterotopic ossification was very low: 95% of hips showed no sign at all (Brooker grade 0). Heterotopic ossification was found in 5 patients: Brooker grade 1 in 5 hips (4%), grade 2 in 0 (0%), grade 3 in 1 (1%). No hip showed signs of calcar resorption. Mean subsidence of the stem within the cement mantel was 0.31 mm (range 0-0.6 mm, median 0.3 mm). No measurable LLD was found in 88 hips (93 %) and 99% of hips were within 5 mm limit of difference (range -5 to +10 mm, median 0 mm).

Discussion

The taper slip principle with the use of a polished stem, as described by the Exeter group, has been shown to produce excellent results in THR in the long term (1, 2). It has become the golden standard in cemented THR, and produces remarkably good long-term results. The stem is able to subside within the cement mantel, hereby compressing the cement and cement-bone interface. This allows for a continuous physiologic loading of the proximal femur and contributes to secure fixation in the long term. This design principle has been called the Taper Slip (7), and was initially described by Ling (8). The ProfemurXm® has design features similar to the Exeter stem, but its metaphysis has been widened to accommodate for a modular neck. The stem is slightly shorter than the Exeter stem, and is made of a different alloy (CoCrMo vs. stainless steel for the Exeter). Both have a highly polished surface finish. Before clinical introduction of this modular stem, a finite element model study was performed by Simpson et al (4). The changes in bone and cement mantle stress/strain were assessed for varying amounts of neck offset and version angle for the modular-neck device for 2 simulated physiologic load cases: walking and stair climbing. This was compared with finite element results for the Exeter stem. For the 2 load cases, stresses and strains in the bone and cement mantle were similar for all modular-neck geometries, and comparable to the bone and cement mechanics surrounding the Exeter. The findings suggested that the Exeter and the ProfemurXm® distribute stress to the surrounding bone and cement in a similar manner. The average cement stresses at the calcar and implant tip showed minimal variation between the modular-neck models and the Exeter, and were well below the fatigue strength of the cement mantle.

The present study is the first to show clinical results with the ProfemurXm®, a CoCr stem with a modular neck. Significant clinical improvement was confirmed. We showed excellent results at a mean of 6.5 years follow-up. Stem and modular neck survival was 100%, and no implant was at risk. No patient was reported to have mid thigh pain. No patient with a ceramic-on-ceramic bearing couple showed signs of squeaking.

The behaviour of the stem is similar to the Exeter stem, with slow subsidence of the stem within the cement mantle. We showed a mean subsidence of 0.31 mm (0-0.6 mm) at 6.5 years follow-up. RSA-data from Murray et al (9) showed a mean of 0.7 mm (0.5-0.9 mm) at 2 years and 1.3 mm (1.0-1.6) at 10 years for the Exeter stem. Our results show that the ProfemurXm® shows a smaller amount of stem subsidence. We showed no patient with calcar resorption, further adding to the proof of normal physiologic loading of the proximal femur.

We showed a high degree of excellent cementing with 92% of hips having grade A cementing according to the classification of Barrack. No "horse collar" is needed to keep the pressure onto the cement mantel when the stem is in situ during curing of the cement. This might be beneficial for less well-trained surgeons to achieve good cementing results when performing cemented femoral THR. It should be mentioned however, that due to the different design proximally, the stem should be introduced - after pressurising the cement in the femoral canal - on average 2 minutes earlier with Simplex bone cement compared to the Exeter stem to seat the stem fully.

No hip showed a sign of development or progression of radiolucencies, either at the stem-cement or at the cement-bone interface. Minor radiolucencies at the cement-bone interface seen at the postoperative x-ray and limited to 1 zone, are of no clinical importance if they are nonevolutive. They represent minor imperfections of the cementing. No hip showed any sign of osteolysis. The 0% rate of osteolysis and new radiolucencies is excellent, and favours the hypothesis that this stem design might mirror the excellent results of the original Exeter stem in the long term.

At the time of the study set-up, modular necks were becoming popular and many companies introduced a modular neck stem. Modularity in THR theoretically allows for a better reconstruction of normal anatomy and biomechanics of the hip joint (10, 11). The disadvantages of additional modular junctions include an increased risk of mechanical failure and the production of metal debris that may cause advanced local tissue reaction (ALTR), including the formation of so called pseudotumours (12).

In a modular neck-stem there is a double taper as the trunnion of the distal part of the neck engages with a bore created within the stem, as well as the proximal engagement of the neck with the head. This junction is subject to both axial and bending stresses. Fretting corrosion is strongly influenced by the distribution of pressure at the interfaces, and also by the surface finish and roughness. In a systematic review, Esposito et al (13) found that THR component features associated with tribocorrosion included trunnion geometry and large-diameter femoral heads.

Assembly of different alloys can cause galvanic corrosion. Retrieval analysis and in vitro studies on coupling Ti6Al4V and CoCrMo alloys have shown that this combination is not leading to increased corrosion (14). Toni et al (15) and Traina et al (16) were the first to report on the use of the present modular neck, and showed good clinical results without apparent adverse effects, including ALTR, to the modularity. Omlor et al (17) measured the Ti levels in serum in patients with a modular THR with this Ti modular neck coupled with a cementless Ti stem. They found low Ti serum levels, and no statistically different levels compared to stems with fixed necks. Also, clinical results at long-term were good. We have shown that the systemic levels of Co and Cr in patients, treated with this cemented CoCr stem and a Ti modular neck, is low when used with conventional head diameters (18). In this study of asymptomatic high activity patients no patient was shown to have elevated Co ion levels and all patients had Cr ion levels below the detection limit.

Modular neck fractures have been a cause of concern. Its incidence with the Ti modular necks used in this series has been reported to be 0.13% worldwide over a period of 20 years, with a higher incidence for varus long modular necks (source MicroPort Orthopaedics). In 2012 Microport introduced a CoCr modular neck since in vitro data showed a 2-fold increase in load to failure of this alloy compared to Ti alloy modular necks. Therefore, it was argued that CoCr alloy would be better for the long necks (since long necks have a higher fracture risk). In 2014 the long Ti necks were withdrawn from the market. The change in alloy might however increase the risk of ALTR. In the study population only Ti necks were used (CoCr necks were introduced later). The excellent clinical data of this study may not be applicable for the CoCr modular necks of this design. In fact it might be more safe to use a Ti modular neck whenever possible. The incremental risk of neck fracture has to be weighed against the lower risk for ALTR due to tribocorrosion. Therefore, we continue to use the Ti alloy version for the short modular necks, and limit the CoCr alloy version to the long modular necks.

The clean assembly of the modular neck onto the stem is critical. In an in vitro study, Grupp et al showed a more than twofold increase in micromotion at the taper junction when necks were assembled in a contaminated environment compared to so called clean assembly (19). It has been shown in an arthroplasty register that the incidence of neck fractures in modular versus nonmodular necks of this particular design is not different (20). We believe that attention should be paid to clean assembly. Furthermore, impingement of the neck onto the rim of the acetabular component might be an extrinsic factor leading to damage of the neck, secondary corrosion and fracture. Attention should be given intraoperatively to address this issue. Obviously, the small incremental risk of modularity has to be balanced against the possible advantages of modularity.

The excellent results on achieving near correct leg length while obtaining a 0% dislocation rate in this series can be attributed in at least a part to the use of modular necks. The reported incidence of LLD varies from 1% to 27% with conventional stems, while some authors even take a 10-mm limit for symptomatic LLD (21). LDD from 3 mm to 70 mm have been described, with more patients having LLD for cementless stems compared to cemented stems. Our data favour well in comparison, with only 1% of patients having a LLD of >5 mm, and 93% of patients having no measurable LLD. Since the introduction of the present modular neck more than 20 years ago, several authors have described the advantages of modular necks to restore correct offset and leg length in THR (15, 16), without clear disadvantages. Registry data have shown a higher rate of revision for modular necks (relative risk of 10.6 vs. 6.3 for fixed necks at 10 years) (22), but data are skewed by various designs on the market, of which some have been withdrawn due to a very high failure rate (23).

The strengths of the present study are the prospective collection of data in a consecutive series of patients, the completeness of data and the fact that this is the first study to report on this particular modular stem type. Also we present medium-term data, with minimum 5-year follow-up. Weaknesses are the relative small numbers, the single centre and surgeon design, and absence of a control group with fixed neck design.

In conclusion, the ProfemurXm® polished modular tapered stem produced excellent clinical results with 100% implant survival at a mean of 6.5-year follow-up and with a radiographic behaviour similar to the Exeter stem. No adverse effects to the use of the used Ti modular neck have been observed. Although femoral stems with modular necks have fallen out of grace due to problems with certain designs, this report confirms the excellent results that can be achieved with a cemented polished CoCr stem and titanium modular neck with ceramic heads up to 36-mm diameter without any signs of adverse reactions at medium-term follow-up.

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Disclosures

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