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# PROSPECTIVE CLINICAL TRIAL ASSESSING A SHORT FEMORAL STEM PROSTHESIS IN TOTAL HIP ARTHROPLASTY

**Orthopaedics**

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## ABSTRACT

**BACKGROUND AND PURPOSE:** We undertook a prospective clinical trial assessing the Nanos® short stem cementless femoral prosthesis. The primary objective was to assess the implant for subsidence and rotational stability via Radiostereometric Analysis (RSA). The secondary objective was to assess functional outcome.

**PATIENTS AND METHODS:** 28 patients undergoing unilateral Total Hip Arthroplasty (THA) using a short stem prosthesis were compared to a control group using a standard Corail® stem. Both stems were uncemented and the procedures performed by the same surgeons. Data collection points were preoperative, 3 months and 2 years post operatively. RSA radiographs were performed to assess subsidence and rotational stability. Functional analysis was undertaken using the Oxford Hip Score (OHS).

**RESULTS:** The short stem showed a median subsidence of 0.12mm at 3 months with a further 0.09mm in the 3-24 month interval. Median posterior translation of prosthesis head (retroversion) was 0.21mm at 3 months, with a further 0.07mm in the 3-24 month interval. Varus/valgus displacements measured were minimal. The mean OHS improved from 23 preoperatively to 44 at 3 months and 43 at 24 months review. There were 2 early revisions: one for leg length discrepancy and one for early loosening secondary to under-sizing of the implant. There were no significant differences to the control group.

**INTERPRETATION:** THA patients with this stem demonstrated good stability and excellent short-term functional results, however the high revision rate in our series remains a concern.

## KEYWORDS

hip arthroplasty; short stem; Radiostereometric Analysis

**Introduction:**

Total Hip Arthroplasty (THA) is one of the most successful and cost-effective orthopaedic procedures and remains the treatment of choice for long-term pain relief in patients with diseased and damaged hips.

In recent years, there has been an increase in uncemented THA in young and more active patients [1]. Uncemented femoral stems of many designs now provide dependable long-term fixation and excellent, near normal function in patients of all ages, sex and level of activity. Nevertheless, a number of issues related to conventional diaphyseal or meta-diaphyseal anchorage of uncemented stem fixation could be further improved, such as, optimization of load transfer to the proximal femur to minimise fracture risk and maximise proximal bone preservation; elimination of proximal-distal anatomical mismatch concerns, including bowed femurs (variations in proximal femoral diaphyseal anatomy) and facilitation and reproducibility of femoral stem insertion, especially with minimally invasive approaches. Concern about potential metaphyseal bone loss during future revision, especially in younger patients, has led to the quest for a more bone-preserving implant.

The uncemented short stem has been suggested to be the answer to these issues [2]. By following the anatomic curvature of the femoral neck and more proximal loading of the femur, short stems may restore biomechanical proportions better than conventional stems. Other reported advantages include less thigh pain [3,4] and ease of use in minimally invasive surgery because of the more medial entry point of the stem in the femoral neck [5]. The curved broaches and stem can be inserted along a curved track to avoid the abductor attachments. Furthermore, femoral neck preservation in THA has been shown to improve rotational stability, and allows for easier revision surgery should this be required [6].

There is a paucity of studies on this prosthesis due to its relatively new design. International joint registries do not contain data for this stem leaving long-term survivorship and failure rates relatively unknown.

The aim of our study was to perform a prospective clinical trial to determine if this short stem femoral prosthesis demonstrated adequate stability and rate of subsidence using Radiostereometric Analysis (RSA) and functional outcomes in patients undergoing THA.

**Patients and Methods:**

Following ethical approval for the study, 28 patients awaiting THA were recruited between February 2012 and December 2012 at a single institution. Patients with osteoporotic bone, Dorr type C femora, pronounced coxa valga or varus, inflammatory or infective arthropathy, previous ipsilateral hip surgery, neuromuscular or cognitive co-morbidity were excluded.Patient flow is detailed in Figure 1 (short stem) & Figure 1a (control).

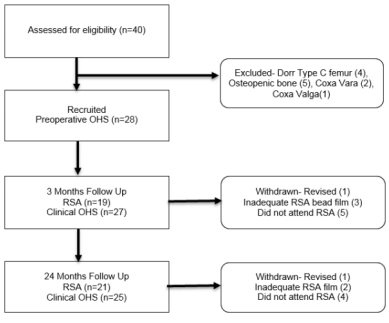


**Figure 1:** Schematic representation of Patient Flow for short stem

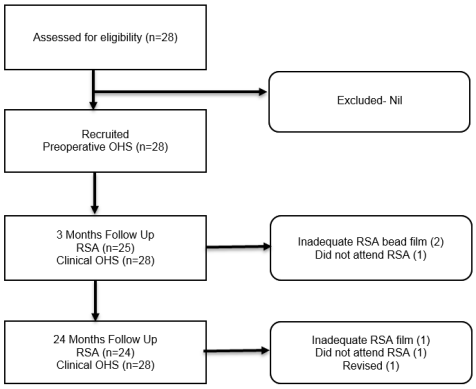


**Figure 1a:** Schematic representation of Patient Flow for control

The mean age of the 20 female and 8 male patients receiving a short stem was 63 years (range 40-78). There was no significance in demographics between the groups (Table 1). Indications for total hip arthroplasty were primary osteoarthritist in 23 patients (82 %), secondary osteoarthritis from hip dysplasia in 4 patients (14 %) and osteonecrosis of the femoral head in 1 patient (4 %).

**Table 1: Cohort Demographics.**

| | Corail® (n=28) | Nanos® (n=28) | T-Test |
|---|---|---|---|
| Mean age (and S.D.) | 64(+/- 6) | 61(+/-11) | 0.18 |
| Age range | 51-71 | 40-78 | |
| M:F | 9:19 | 8:20 | |

All hips were accessed using a standard posterior approach. Procedures were performed or directly supervised by one of three experienced surgeons. A standard rehabilitation and nursing care pathway was used routinely. All patients in the study received the uncemented metaphyseal anchored short stem, a press-fit porous coated acetabular cup with highly cross-linked polyethylene (REFLECTION®, Smith & Nephew, Memphis, TN, USA), and a ceramic head (Figure 2 & 3).

**Fig. 2 The NANOS® femoral short stem in anterior–posterior and lateral view**

**Fig. 3 The REFLECTION® Acetabular shell**

The control group of 28 age and gender matched patients (Table 1) were identified from our prospective database. These patients received a standard uncemented Corail® stem. Their operations were performed by the same surgeons.

Primary outcomes included prosthesis migration patterns (subsidence and antero-posterior and medio-lateral movement) and complications, while the secondary outcomes included functional scores. Hip function was assessed using the 12 item Oxford Hip Score (OHS) self-reported questionnaire scoring 0 (worst score) to 48 (best score). Data was collected preoperatively, and 3 months and 24 months postoperatively.

RSA was carried out by implanting 1mm Tantalum beads in the proximal femur intra-operatively and using cross-exposed plain film X-rays to measure micro-motion by comparing serial images as per standard RSA protocol [7]. RSA examinations were carried out postoperatively during the first week, at 3 months and 24 months to analyse stem migration in X/Y/Z planes. The femoral component's prosthetic head is compared relative to marker groups implanted in the femur. The prosthetic head was shape-matched with ellipse reconstruction techniques and represents the only point on the stem measured, as no tantalum markers were attached to it. The X-axis therefore shows medio-lateral head migration, which infers stem rotation in varus/valgus, the Y-axis shows cranio-caudal migration (subsidence of head representing stem as whole) and the Z-axis shows antero-posterior head migration (inferring stem rotation in ante/retroversion). Hence stem rotation is not shown directly in degrees but is inferred by the translations of the head relative to femur. All examinations were performed using the RSA uniplanar cage 43 and measurements were done with UmRSA 6.0 software (RSA Biomedical, Umeå, Sweden). In accordance with published guidelines for RSA analysis [8] mean error of rigid body fitting < 0.3 mm was used as a cut-off limit and condition numbers were monitored with all but two cases < 150.

Intraoperative and postoperative complications were identified during the first two postoperative years at scheduled patient follow up, from patient's survey responses and correspondence from the general practitioners.

**Results:**

**Primary Outcomes:**

**1. Implant Migration:**

Migration patterns of the short stem implant with 21 valid RSA analyses are provided in Table 2. At 3 months postoperatively, median head subsidence was 0.12mm, with a further 0.09mm mean subsidence occurring by 24 months (Figure 4). Neither the 3 nor 24 month subsidence demonstrated significant difference with respect to the control group (p=0.71 and p=0.32 respectively, Table 2). Three patients subsided more than 1mm by 3 months, out of which two had stabilised by 24 months and one was lost to follow-up. Individual patient stem subsidence is also shown collectively (Figure 5) clearly displaying stabilisation patterns.

| Migration Pattern Median (Range) | 0 to 3 months (n=19) | 3 to 24 months (n=20) |
|---|---|---|
| Subsidence (mm): Y-axis | -0.12 (-3.32 to 0.09) (p=0.71) | -0.09 (-0.52 to 0.16) (p=0.31) |
| A-P translation (mm): Z-axis | -0.21 (-3.01 to 0.44) | -0.07 (-0.87 to 0.48) |
| M-L translation (mm): X-axis | 0.09 (1.90 to -1.42) | 0.06 (0.57 to -0.12) |

**Table 2: Migration of the Femoral Stem.**

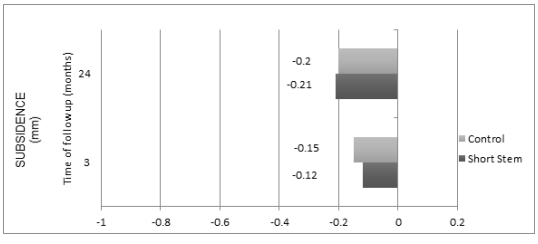


**Figure 4: Median Subsidence (mm) to 2 years postoperatively. (Distal - / Proximal +).**

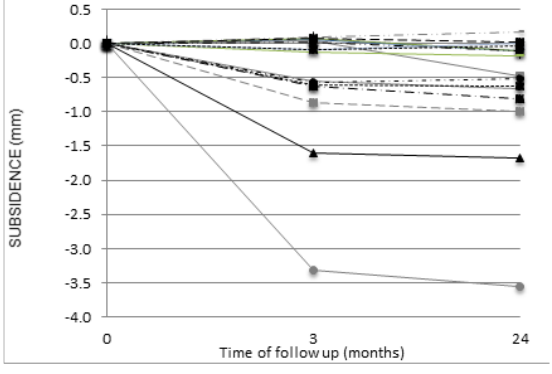


**Figure 5: Stem subsidence (mm) of individual cases (Distal - / Proximal +).**

Median head posterior translation (consistent with retroversion) was 0.21mm at 3 months, with a further 0.07mm posterior translation by 24 months (Figure 6). Four patients displayed posterior head translations >1mm at 3 months, out of which the three with 24-month follow-up later stabilised. There was no significant difference between the groups.(p=0.21 and 0.71 respectively).

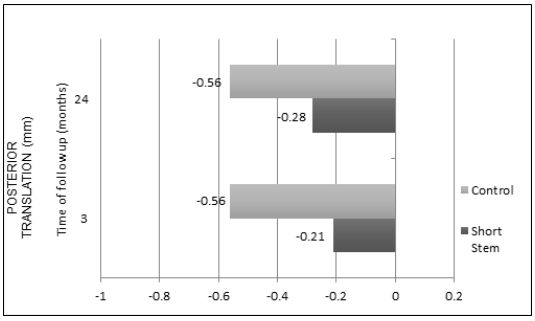


**Figure 6: Median Antero-posterior translation (mm) at 3 and 24 months follow-ups. (Anterior + / Posterior -).**

At 3 months postoperatively, median head medial translation (consistent with rotation into varus) was 0.09mm, with a further 0.06mm occurring by 24 months (Figure 7). Two patients had medial translation >1mm at 3 months and both had stabilised by 24 months. In general, individual implant migration was minor and very little change occurred between the 3 and 24-month analyses. Once again, results were not significantly different with respect to the control group (p=0.23 and 0.27 respectively).

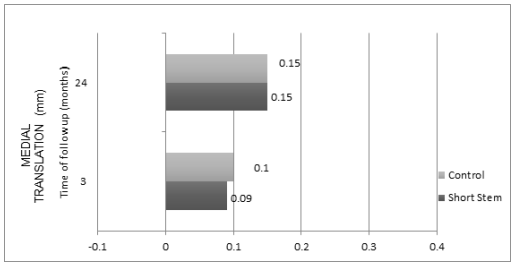


**Figure 7: Median Medio-lateral translation (mm) to 2 years postoperatively (Medial + / Lateral -)**

**2. Complications:**

There were two revisions in both the control group and the short stem group. Of the short stem cohort, the first was in a 43 year old female who felt her operated leg was shorter after surgery. RSA migration was 0.36mm migration in the Y-axis (below the average of the cohort); therefore subsidence was discounted from contributing to her problem. The patient opted to undergo a revision procedure at 5 months from index operation, with the change of head from 28mm+0 to 28mm+12. Post revision surgery, RSA revealed a 9.24mm Y-axis increase, in keeping with the intended limb lengthening. The procedure was uncomplicated and the patient was happy with her resultant leg lengths.

The second revision was in a 52-year-old male complaining of ongoing groin pain and limping with significant subsidence on plain radiographs at 6 weeks follow up. Of note, he was templated for a size 3 stem, however was implanted with a size 2. The procedure was performed by a senior trainee supervised by an experienced consultant. No RSA data was produced as the revision procedure was carried out before the 3-month mark. Intraoperative findings revealed a loose stem. The stem was revised to a conventional uncemented collared stem and the patient reported high satisfaction at subsequent consultations.

**Secondary outcome:**

**Oxford Hip Score:**

The mean OHS improved from 23 preoperatively to 43 at 24 months , which is categorised as an excellent clinical result [9]. One patient scored 19 at 3 months follow-up, which improved to the maximum of 48 in the next 3 months. The control group demonstrated similar results, with the mean OHS increasing from 26 preoperatively to 44 at 24 months. Table 3 shows that the OHS difference in the 3 and 24 month follow up between the cohorts was not statistically significant.

| Mean OHS and S.D. (months) | Corail® (n=28) | Nanos® | T-Test |
|---|---|---|---|
| 0 | 26+/-8.0 | 23+/-6.6 (n=28) | 0.11 |
| 3 | 41+/-6.0 | 44+/-4.6 (n=27) | 0.07 |
| 24 | 44+/-5.0 | 43+/-5.6 (n=26) | 0.39 |

**Table 3:** Hip Function to 2 years postoperatively.

**Discussion:**

The accuracy of RSA for the detection of movement has been described as between 0.1 and 0.8 mm [7] and is widely accepted as the gold standard in radiological migration analysis [10,11].The use of RSA allows for smaller sample sizes with reliable results after a relatively short follow up. Results of RSA at 2 years have been demonstrated to be predictive of early failure, and can obviate the need for long-term follow-up studies. Our results demonstrated excellent early clinical outcomes with adequate stability in the 24 months post-operative period with the exception of one implant that was undersized and subsided early. A number of other studies have assessed clinical and radiological outcome of this prosthesis [12,13,14,15,16].

Götze et al [12] compared 36 patients with this implant with 36 patients with a long stemmed, conventional femoral prosthesis. Patients underwent Dual Emission X-Ray Absorptiometry (DEXA) which revealed bone ingrowth lateral/distally. Similar to our finding, hip scores were excellent and comparable to conventional femoral stem results. No revisions were reported and there were no signs of loosening or migration at one year on plain radiographs.

Zeh et al [13] assessed Bone Mineral Density (BMD) following implantation of this stem. DEXA scan showed a significant increase in BMD in Gruen Zone 6 (12%) and a decrease in Zone 1 (15%), 2 (5%) and 7 (12%), which was interpreted as reflecting a distal load transfer in the metaphysis of the femur. Logroscino [14] compared two uncemented short stems for their osseointegration using DEXA and BMD scans at one year follow up, showing both the implants preserve metaphyseal bone stock and increase peri-prosthetic BMD.

Kaipel et al [15] published data on migration characteristics of a short stem on a prospective analysis of 49 patients at 2 years follow up. The Harris Hip Score increased from 47.9 to 98.1. Migration analysis (computer-assisted Einzel-Bild-Roentgen-Analyse system) revealed 10% had increased vertical stem migration of 1.5 mm (average subsidence) that might predict late aseptic loosening. 90% showed stable migration patterns indicating a good long-term outcome. Similar to our cohort, they had one case of an undersized stem, which was revised early.

Ettinger [16] evaluated 72 short stems for 5 years, using functional scores and plain radiographs. Harris Hip Score increased from 47 pre-operatively to 98 at the final follow-up and overall survival rate was 100% with no revisions. At 2 years follow up, our findings have shown significant improvement in hip scores as well, but with two early revisions.

Banerjee [2], in a review of short stem femoral components, stated overall mean stem survivorship for all stems was 99.6% at 5 years. Unfortunately, this review included 9 different short stems. However, a review article by Castelli and Rizzi [17] mention technical issues and complications relating to the insertion of uncemented short stem implants. Similar to our cohort, they reported a higher incidence of complications, such as mal-positioning of the stem, and noted the lack of long-term results.

Buddle [18] observed 18 short stems which showed good primary stability and secondary stabilisation over a period of 24 months. At 2 years, our findings have demonstrated similar results with good primary stability and minimal migration to 24 months.

The Nanos stem is not for all patients. There are manufacturer's recommended contra-indications including radiologically detected osteopaenia, coxa valga (>145°), coxa vara (<125°) and body mass index of >30 [16]. Our results demonstrate the need for meticulous templating and implant sizing, and the authors feel experienced hip surgeons should perform the implantation. Our main indications for the prosthesis now include patients with type A femora (thick cortices and narrow canal) to avoid excessive reaming and those with proximal

femoral deformities or hardware in situ precluding the use of a standard stem (Figure 8).

**Figure 8: Preoperative and postoperative radiographs of a patient with hardware precluding the use of a standard stem.**

Our study has some limitations. Whilst our control group was of similar average age and gender, it was not randomised. Although we have complete functional scores, there were some gaps in RSA data collection. Firstly, we were unable to achieve full RSA analysis on all our patients due to technical difficulties in visualisation of RSA beads. As there were no tantalum markers in the stem, the head was shape-matched with ellipse reconstruction techniques and represented the only point on the stem measured. Hence stem rotation (Z-axis) is not shown directly in degrees but is inferred by the translations of the head relative to femur in millimetres. Secondly, 2 patients dropped out of the study due to early revision surgery, and 4 failed to attend for RSA follow up.

**Conclusion:**

Tha patients with this stem demonstrated good stability and excellent short-term functional results both individually and when compared to a standard stem, however the high revision rate in our series remains a concern.

**Ethics, registration, funding and potential conflicts of interest:**

This study was approved by the local ethics committee (2010-090) on 30/9/2010. A research grant of AU$10,000 was received from Smith and Nephew. Smith and Nephew were not involved in study design, the collection, analysis or interpretation of data, nor the writing of the report. There are no conflicts of interest to declare.

**Author Contributions:**

William Mee: Data collection and manuscript
Jami Ilyas: Manuscript
Riaz Khan: Surgeon, manuscript and chief editor
Daniel Fick: Surgeon
Nils Nivbrant: RSA Analysis
Samantha Haebich: Manuscript and statistical analysis

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