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# Stable Fixation of a Cementless, Proximally Coated, Double Wedged, Double Tapered Femoral Stem in Total Hip Arthroplasty: A 5-Year Radiostereometric Analysis

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ABSTRACT

*Background:* The objective of this 5-year prospective study of 51 hips was to assess migration of a cementless tapered femoral stem using radiostereometric analysis (RSA), plain radiographs (radiolucencies), and patient-reported outcome measures (PROMs).

*Methods:* Forty-seven patients (51 hips) agreed to participate in this prospective RSA study. All patients received a Taperloc stem. Tantalum beads were inserted into the femoral bone surrounding the stem to measure migration using RSA. RSA films, plain radiograph, and PROM follow-up were obtained immediately after surgery, 6 months, 1, 2, 3, and 5 years after surgery.

*Results:* The median (interquartile range) subsidence was 0.03 mm (−0.23 to 0.06) at 5 years, with no significant differences over time. Four outlier stems had >1.5 mm of subsidence by 1 year. No stem showed radiolucencies in more than 3 zones during the 5 years. All PROMs remained favorable at 5 years, suggesting an excellent outcome. There were no stems revised for mechanical loosening; 1 stem was revised for an infection.

*Conclusion:* After initial settling, the cementless tapered femoral stems in our series were stable. The 4 outlier stems with >1.5 mm of subsidence by 1 year remain stable at 5 years. RSA was the most sensitive method of detection for stems at greater risk for potential future failure. This report adds contributions to the positive results associated with this type of fixation. The results at 5 years showed excellent midterm survivorship in this cohort with a cementless tapered femoral component.



Fixation of the femoral stem using a cementless technique was introduced in the 1980s to reduce aseptic loosening of cemented stems, secondary to bone resorption and osteolysis from either wear particles or the cement [1-3]. However, early inferior results of the cementless fixation and improved second generation cementing techniques prompted the restored use of cemented stems [2]. Several reports show excellent results with no difference in outcome between cemented and cementless stems, despite some concerns of increased thigh pain and osteolysis with cementless stems [4-9]. Large registry studies show excellent results of cemented stems, and despite this, the preponderance of cementless fixation is increasing [10,11]. Because such varied reports of each fixation type exist, the demand is high for short-term and midterm follow-up studies which use the most accurate measurement methods that allow for the prediction of failure in the long term [12].

Radiostereometric analysis (RSA) is the most accurate and sensitive method of measuring stem migration [13-15]. Migration measured by RSA detects early loosening of stems that is otherwise imperceptible on plain films [16,17]. In addition, Karrholm et al [18] demonstrated the power of RSA as a predictive tool of late failure of cemented stems by showing an association between migration of 1-2

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mm within the first 2 years and later revision. Kobayashi et al also determined that migration of ≥2 mm and the presence of a radiolucency also of this size predicts a 50% risk for revision by 10 years [19].

Although subsidence and radiolucencies are essential measures to monitor implant performance, patient-reported outcome measures (PROMs) are increasingly important to provide valuable information on the patient's assessment of their intervention [20,21]. Many studies report on revisions or reoperations as the end point of interest; however, there is a need to assess performance in multiple dimensions including PROMs and the presence of radiolucencies, and accurate indicators of implant failure such as RSA migration. Revisions and reoperations are important metrics for measuring success at the population level; however, more sensitive measures such as RSA, combined with PROMs and radiolucency data allow for in-depth analysis on the patient level. To our knowledge, no report explores the association among stem subsidence measured by RSA, femoral bone remodeling assessed by measuring radiolucencies on plain films, and PROMs. The objective of this 5-year prospective study was to (1) monitor the migration of a cementless proximally porous-coated tapered femoral stem at the midterm (5 years) using RSA; (2) assess any bone remodeling around the femoral component on plain films; and (3) explore if there are associations among radiolucencies, subsidence measured by RSA, and PROMs.

## Methods

### *Patients*

This analysis is a midterm report on the stems of patients enrolled in a 10-year prospective, RSA, plain radiograph, and clinical outcome study whose broader focus is on the performance of vitamin-E–diffused highly cross-linked polyethylene (HXLPE). This study consisted of 47 patients (51 hips as 4 patients had both hips enrolled), all of whom gave informed consent to participate (Fig. 1). All patients (32 males and 15 females) had a primary diagnosis of osteoarthritis, and the median (range) age of the cohort at the time of surgery was 61 years (26-75 years). The median (range) body mass index was 27.8 (20-44). The surgeries were performed by 4 arthroplasty surgeons at 1 center. Any patient between the ages of 20-75, with a diagnosis of osteoarthritis who demonstrated ability to return for regular follow-up, was asked to participate. Patients requiring revision surgery, those with complex diseases or a compromised mental status, which would subsequently make surgery too risky, or patients with bony structures that substantially deviated from the general norm were excluded from consideration.

All patients received a cementless, modular lateralized, proximally coated, double-wedged, double-tapered femoral stem (Taperloc), a porous titanium acetabular shell (Regenerex), a vitamin-E–diffused, irradiated highly cross-linked ultra high molecular weight polyethylene liner (E1), and a 32-mm cobalt-chromium femoral head (all components were from Biomet, Warsaw, IN). Results from the acetabular side (E1 wear and Regenerex cup stability) were reported separately. Tantalum beads (1.0-mm diameter) were inserted into the greater trochanter, the lesser trochanter, and at the distal end of the femoral stem using a specialized bead gun inserter (Fig. 2). The beads were inserted in a dispersed arrangement for the purpose of monitoring stem migration using RSA (median of 7 beads were inserted). All patients were allowed to weight bear as tolerated after surgery.

Surgeries were performed with either the anterolateral (32 hips) or posterolateral (19 hips) approach. In the posterolateral cases, the capsule and rotators were repaired. After dislocation and resection of the femoral neck at the desired level, the femoral canal was opened and broached in a stepwise fashion using increasing sizes. When the correct size was obtained, judged by the fill of the calcar area, rotational stability and proper seating of the broach were evaluated at the level of resection in which the stem was inserted.

### *RSA and Plain Radiograph Follow-Up*

Twenty-four hips received postoperative RSA films immediately after surgery and before hospital discharge that served as the baseline for all subsequent image comparisons. Twenty-seven hips could not have films taken before discharge and those patients returned up to 6 weeks after surgery for postoperative radiographic assessment. The median (range) of immediate postoperative follow-up was 14 days (0-43). Additionally, RSA films were taken at 6 months, 1, 2, 3, and 5 years after surgery. The films were taken in the supine position with the uniplanar calibration cage (cage 43; RSA Biomedical, Umeå, Sweden) beneath the patient. The UmRSA 6.0 software (RSA Biomedical) was used to measure femoral stem migration in 3 orthogonal planes over time. Motion of the center of the femoral head, (determined by automated edge detection) which served as a surrogate for the entire stem, compared to the fixed femoral segment, formed by at least 4 femoral beads, defined stem migration [18]. Double examinations were collected at least twice over the 5-year period and were used to calculate the

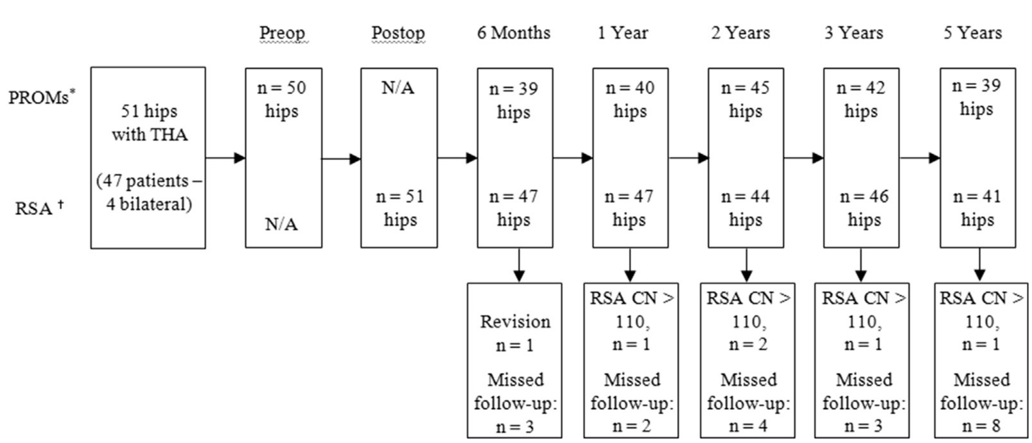


**Fig. 1.** Total number of hips with PROMs and RSA films at each time interval. Any necessary RSA exclusions, from the number of hips with films, are listed as branches. Preoperative RSA films and postoperative PROMs are N/A. *The number of PROMs in each time exludes patients who missed their appointment and/or did not return for follow-up, refused the survey, the research coordinator was unavailable, or had technical difficulties with survey administration tool. †The number of RSA analyses in each time period excludes patients who missed their appointment and/or did not return for follow-up or any RSA-related exclusions, such as a CN that was too high. PROM, patient-reported outcome measure; RSA, radiostereometric analysis; N/A, not applicable; Preop, preoperative; Postop, postoperative; CN, condition number; THA, total hip arthroplasty.