A New Solution For Cementless Femoral Fixation In Total Hip Replacement: A Radiostereometric Analysis

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Introduction: Cementless prostheses have replaced cemented prostheses in many practices. Previous studies have shown that fatigue of the cement mantle around the femoral stem can be a common precursor of aseptic loosening of the component, which can cause stem failure. Cement techniques can result in more intense stress-shielding and higher shear loads, which may lead to increased micromotion of the prostheses. Other studies have shown that canal-filling metal stems may not be uniformly stable at all contact areas with the femur under physiological loading. If micromotion occurs before the bone-prosthesis interface is established through bone ingrowth, a fibrous layer develops, preventing solid anchorage of the prosthesis. Failure to preserve a stable bone-prosthesis interface leads to aseptic loosening of the stem resulting in pain and revision. A new mode of cementless fixation of the femoral component was developed for use in total hip replacement (THR) where 5 monocortical locking stem screws are implanted following insertion of the stem (Figure 1). This new technique provides immediate anchorage by solving two problems: load-induced micromotion at the bone-implant interfaces; and stress-shielding of the proximal femur. We aimed to evaluate the stability of the THR stem in-vivo using radiostereometric analysis (RSA) at 6 months, 1, 2 and 5 years postoperatively.

Methods: Fifteen patients, all with a primary diagnosis of osteoarthritis, gave informed consent to participate in this RSA and clinical outcomes study. The patients, six males and nine females, with an average age of 50 years (range: 35 to 62 years) had surgery between 2008 and 2011. Each patient received a press-fit acetabular cup, a 28 mm cobalt-chromium femoral head, and the new stem with the 5 monocortical locking screws tapped through the medial cortex and locked in the stem. In order to monitor stability using RSA, 3 tantalum markers, 0.8mm in diameter, were attached to the stem at the time of manufacturing. Markers were also implanted into the pelvis, femoral bone and polyethylene at the time of surgery. All patients completed preoperative and postoperative questionnaires, Harris Hip Score (HHS) and UCLA Activity Score, at each follow-up visit for evaluation of functional outcomes. RSA follow-up was obtained 4 to 6 weeks, 6 months, 1 year, 2, and 5 years postoperatively. Double exams were used to calculate the precision of the technique defined by the 95% confidence interval. The Wilcoxon signed rank test was used to determine if migration and rotation were significant over time at p≤0.05.

Results: All 15 patients had 6 month, 1 and 2 year follow-up, and 8 patients have reached the 5 year follow-up. The postoperative film pair was established as the baseline for all RSA assessment of translation and rotation. The median± standard error (SE) stem subsidence (y-axis distal translation) was -0.03±0.04 mm at 6 months, 0.07 ±0.06 mm at 1 year, 0.06 ±0.05 mm at 2 years, and 0.04±0.33mm at 5 years (Figure 2). The median± SE stem rotation (y-axis rotation) was 0.17±0.17 degrees at 6 months, -0.08±0.24 degrees at 1 year, 0.52±0.35 degrees at 2 years and 0.60±0.46 degrees at 5 years. The Wilcoxon signed-rank test showed that there were no statistically significant differences in migrations and rotations over time. The median±SE HHS improved from 55±0.90 preoperatively to 93±0.59 at 2 years. The median± SE UCLA Activity Score improved from 4±0.19 preoperatively to 6±0.33 at 2 years. Both the HHS and UCLA scores had statistically significant improvements (both p=0.001) at 6 months, 1 and 2 years postoperatively compared to the preoperative scores.

Discussion: RSA results indicate that the stem, employing this new fixation technique with its five monocortical locking screws, is stable at 5 years. Previous reports have indicated that subsidence greater than 1 to 1.15mm at 2 years have a significantly greater likelihood of failure, and we do not see this level of subsidence in our cohort (1). Immediate surgical fixation of the stem via these screws appears to inhibit early micromotion and thus may prevent the formation of a fibrous layer between the bone and the component. Stress-shielding is an ongoing concern in cementless stem fixation due to clinically relevant issues such as periprosthetic fractures and the difficulty of some surgical techniques, such as the complicated removal of the stem with strong distal anchorage at revision surgery. In the absence of a fibrous layer, the likely boney ingrowth into the femoral component may ultimately decrease the rate of aseptic stem loosening in these THR patients. A similar canine THR stem has been successful in veterinary surgery for over 15 years (3). Long-term follow-up from these studies showed stable fixation and strong bony ingrowth which decreased the risk of aseptic loosening compared to standard canine THR stems; these long-term results are encouraging(2,3). Longer-term follow-up of our cohort is necessary to definitively determine if this stem will remain stable and eliminate the problems associated with stress-shielding.
Significance: The RSA results indicate that the new uncemented stem is stable at 5 years and may decrease the incidence of stress-shielding that is typically associated with uncemented stems.

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References: