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Bone&JointScience
Our Innovation in Focus

Vol 01 – No 02 – January 2011

RSA analysis of early migration of the uncemented SMF◊ vs SYNERGY◊ stem: A prospective randomized controlled trial

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Abstract

Quantification of early stem migration can be utilized to predict loosening risk and long-term clinical success in uncemented THA. The purpose of the current study was to compare early clinical outcomes and migration patterns of the newly developed SMF stem to that of the clinically successful uncemented SYNERGY stem. To date, thirty-seven (37) patients were consented and enrolled in this prospective randomized controlled trial (RCT). Patients were evaluated clinically before and after surgery utilizing Harris Hip Score and WOMAC score. Radiostereometric analysis (RSA) was performed for all stems. At an average follow-up of 0.61 years, distal translation, anteversion and 3D translation were comparable between stems. In addition, there was no difference in clinical scores between groups. While additional follow-up is required to further assess subsidence through two years, the initial hypothesis of equivalent early stem performance appears to be confirmed.

Introduction

Contemporary advances in surgical technique and implant design have led to significant improvements in total hip arthroplasty (THA) outcomes.[1] Postoperative function continues to improve, while revision risk has decreased considerably over the last 10-20 years.[1,2] However, despite these advances, the long-term success of THA continues to be limited by the relatively high incidence of aseptic loosening. [1-3] Approximately 30% of all THA revisions can be attributed to loosening and periprosthetic lysis.[3] While initial attempts to improve stem fixation utilizing bone cement were clinically successful, the majority of contemporary THA procedures are uncemented.[3-5] This approach is thought to ensure optimal bony ingrowth, thereby limiting loosening risk.[5, 6] However, available cumulative revision rates for 151,063 cemented and uncemented THA procedures appear to be equivalent at upwards of nine years follow-up.[3]

Regardless of fixation, aseptic loosening is associated with increased relative motion between the stem and femoral bone.[1,2] In uncemented THA, initial migration occurs as the stem continues to embed itself into the periprosthetic bone following surgery.[1] Excessive stem migration can inhibit bony ingrowth, leading to increased relative micro-motion.[1,7,8] Moreover, this increased micromotion is positively correlated with increased loosening and revision risk.[1,9-12] For existing THA technologies, stem migration must be carefully monitored to limit patient risk.[5,13] Furthermore, as new implant designs are introduced, quantifying early migration may allow researchers to estimate implant survival.[5] While long-term, longitudinal safety studies remain essential, commonly used plain radiographs lack the ability to detect implant movement during early clinical follow-up.[5,10] Therefore, short-term imaging studies capable of precisely identifying micromotion appear most suitable.[5]

Two imaging technologies are commonly reported in the literature. Einzel-Bild-Roentgen-Analyse- femoral component analysis (EBRA-FCA) is a technology that has been successfully utilized to detect stem migration and micromotion in THA.[10,11,14,15] EBRA-FCA is accurate to within ± 1.5mm, has a specificity of 100%, and has a sensitivity of 78% for detecting motion in excess of 1.0mm.[14,15] In addition, this technology is relatively cost effective, requiring only comparable postoperative radiographs.[14] However, radiostereometric analysis (RSA) remains the standard for detecting postoperative stem motion.[15] While RSA requires the insertion of specialized markers into the implant and periprosthetic bone, and is relatively resource intensive, this technology offers superior accuracy to within 0.2mm.[16-18]

Short, modular uncemented stems represent a relatively new THA design. They are comparatively easy to insert, are bone conserving and eliminate the need for distal fixation. However, the long-term performance of these stems is yet to be established. In addition, migration and micromotion patterns are largely unknown. The purpose of the current study was to compare the short-term clinical outcomes and migration patterns of a newly developed short, modular stem (SMF◊) to that of a standard clinically successful uncemented stem (SYNERGY◊). We hypothesized that clinical outcomes would not differ between stems, and that migration patterns assessed by RSA would be similar.

Methods

After approval was obtained from the Hospital Ethics Board, to date, 37 patients requiring THA have been enrolled in this prospective RCT. To date, there are 19 men and 18 women, with an average age of 61.47 years (Table 1).

Patients were randomized to receive one of the two stems. Seventeen (17) patients were implanted with a short, modular uncemented stem (SMF stem; Smith & Nephew, Inc., Memphis, TN, USA; Figure 1). This titanium alloy (Ti-6Al-4V) stem is straight, tapered, and proximally loading. Each stem is proximally coated with STIKTITE◊ (Smith & Nephew, Inc., Memphis, TN, USA), a proprietary porous surface comprised of asymmetric titanium grains. The SMF stem mates with a cobalt chrome 12/14 taper modular neck with multiple offset and version offerings. In contrast, 20 patients were implanted with a standard uncemented stem (SYNERGY; Smith & Nephew, Inc., Memphis, TN, USA). This device has an established record of clinical success, with reported survival of 95.1%-99.5% at 6.3-9 years.[3,19] A radiographic view of the SYNERGY and SMF stems in vivo can be found in Figure 2. All patients received a cementless R3◊ (Smith & Nephew, Inc., Memphis, TN, USA) acetabular component with a 32mm inner diameter polyethylene liner.

A standard RSA technique[20] was used, in which 0.8mm tantalum beads were implanted into the proximal femoral bone and were fixed to each study stem by the manufacturer to allow the determination of relative movement of these two segments. Standard dual-plane RSA radiographs were performed immediately postoperative (within the three to four

Table 1: Summary of Study Demographics

Number of Cases	37
Female	18
Male	19
SMF stem	17
SYNERGY stem	20
Average age	61.47 yrs
Average BMI	31.22
Average follow-up	0.61 yrs
Number of revisions	0
Number of deaths	0

Figure 1: SMF stem (Smith & Nephew, Inc., Memphis, TN, USA).

days following surgery), at six weeks, three and six months, and at one and two years postoperatively. The UmRSAT (RSA Biomedical Innovations AB, UMEA, Sweden) was used to assess stem movement. All the analysis was performed by skilled operators who had extensive experience with this RSA system. A total of three stems were excluded from the current analysis. One (1) stem from each group was identified with no shoulder bead. One (1) additional SYNERGY◊ patient was identified with inadequate tantalum beads in the bone.

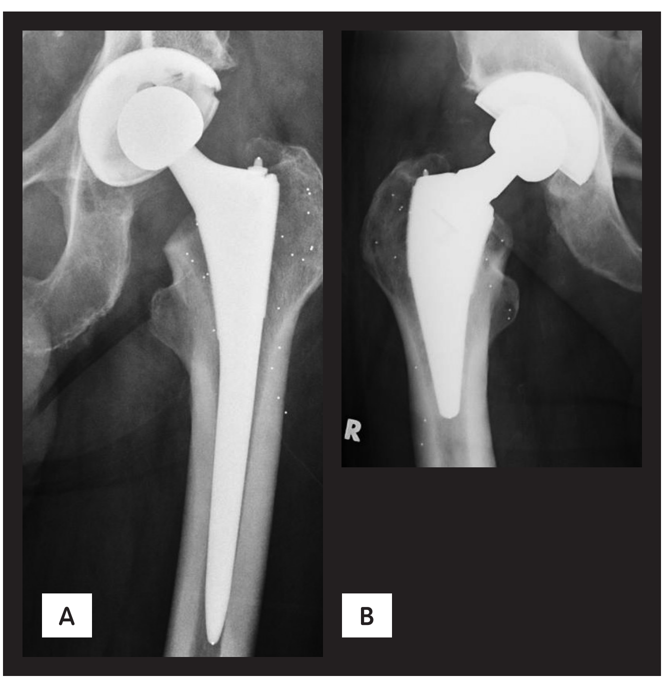
All patients were prospectively evaluated clinically before and after surgery using the Harris Hip Score (HSS) and WOMAC score. There was no significant difference between groups preoperatively. The average preoperative HHS and WOMAC scores for the SMF◊ group were 20 ± 5.77 and 37.13 ±18.4, respectively. For the SYNERGY group, preoperative HHS and WOMAC scores were 15.83 ± 6.69 and 36.32 ± 16.91, respectively.

Results

The average follow-up at this time is 0.61 years. Distal translation of the SMF stem was -0.42mm ± 0.54, -0.76mm ± 1.03, and -0.78mm ± 1.05 at six weeks, three months, six months, and one year, respectively (Figure 3). In comparison, distal translation of the SYNERGY stem at the six weeks, three and six month intervals was -0.44mm ± 0.63, -0.40mm ± 0.46, and -0.67mm ± 0.6, respectively. Internal rotation is reported in Figure 4. Anteversion of the SMF stem was 0.36° ± 0.7, 0.48° ± 0.64, 0.8° ± 1.0 and 0.64 ± 1.18 at each interval; anteversion for SYNERGY was 1.58° ± 3.1, 1.83° ± 3.8 and 3.89° ± 5.11 upwards of 6 months, postoperatively. Finally, 3D translation for SMF was 0.57mm ± 0.55, 0.95mm ± 0.99, 0.92 ± 1.1, and 1.13mm ± 1.62 at each respective interval (Figure 5); 3D translation for SYNERGY was 0.76mm ± 0.9, 0.77 ± 0.98, and 1.36mm ± 1.34 at six weeks, three and six months. Across all RSA variables, subsidence and rotation of the SMF stem appears to stabilize by the six month interval. Overall, RSA results for SMF and SYNERGY stems were equivalent.

Postoperative clinical scores for each group are reported in Table 2. At latest follow-up, the total HHS score was 93 ± 6.65 and 88.75 ± 6.57 for SMF and SYNERGY, respectively. SMF HHS pain and function scores were 43.33 ± 1.56 and 40.67 ± 5.73, as compared to 41.83 ± 4.13 and 38 ± 3.46 for SYNERGY. The total WOMAC score was 84.88 ± 9.80 and 80.30 ± 16.04 for SMF and SYNERGY, respectively. SMF WOMAC pain, stiffness, and function scores were 88.01 ± 9.9, 75.96 ± 17.28, and 86.31 ± 10.09, compared to 84.58 ± 14.84, 73.96 ± 26.36, and 79.04 ± 14.48 for SYNERGY.

Figure 2: Radiographic comparison of the SYNERGY (A) and SMF (B) stems in vivo.



Discussion

This prospective RCT reports early outcomes for the newly developed SMF stem. When compared to the clinically successful SYNERGY control, SMF demonstrated similar migration subsidence and rotation patterns, with stabilization achieved by the six month interval. Moreover, HHS and WOMAC scores support excellent relative clinical outcomes for the SMF group. The initial hypothesis of equivalent early stem performance is confirmed.

Krismer et al.[11] previously reported several potential stem migration patterns in THA, including early onset migration followed by continued subsidence, early stability followed by late onset subsidence, and continual stability throughout observation. Early results from the current study are consistent with a fourth migration pattern, where early migration is followed by stem stabilization.[11] This pattern has also been reported elsewhere in the literature. Campbell et al.[5] observed a mean subsidence of 0.73mm at six months, 0.62mm at one year, and 0.58mm at two years. The authors concluded that confinement of migration to the first six months was indicative of good clinical outcomes, and may be a predictor of long-term stability in new uncemented stems. A similar migration pattern was reported by Strom et al.[21], who noted significant migration of an uncemented stem from one week to three months, followed by stem stabilization. The available data suggest that initial subsidence followed by stabilization is indicative of long-term clinical success.[5,11] The definitive cause of early onset subsidence remains unclear.[5,11,21,22] However, periprosthetic bone quality, stem design, and operative impaction variability can all contribute to stem migration.[5,11,21,22] Moreover, postoperative unrestricted weight bearing can significantly increase stem subsidence, but does not appear to compromise stem stabilization.[22]

While the pattern of stem migration is indicative of long-term stability, the degree of subsidence is still of concern. As noted previously, increased migration is positively correlated with increased revision risk.[1,9-12] Karrholm et al.[9] have suggested that subsidence of cemented stems should not exceed 1.5mm during the first two years. Moreover, migration of 0.5-1.0mm may represent an increased risk of failure.[9] By that standard, mean migration of the uncemented SMF stem can be considered acceptable. It must be noted that some individual stems in the current study have exceeded this reported threshold. However, following the stabilization observed with this specific migration pattern, there is no evidence of increased failure risk. Additional follow-up is required to further assess subsidence through the two-year interval.

Table 2: Clinical Scores (Mean ± SD)

Outcome variable	SMF	SYNERGY
Harris Hip Pain Score		
Pre-operative	**20** ± 5.77	**15.83** ± 6.69
Latest	**43.33** ± 1.56	**41.83** ± 4.13
Harris Hip Function Score		
Preoperative	**26.31** ± 6.28	**23.58** ± 5.93
Latest	**40.67** ± 5.73	**38** ± 3.46
Harris Hip Total Score		
Pre-operative	**54.75** ± 5.44	**45.14** ± 10.49
Latest	**93** ± 6.65	**88.75** ± 6.57
WOMAC Pain		
Pre-operative	**38.33** ± 23.89	**37.5** ± 19.75
Latest	**88.01** ± 9.9	**84.58** ± 14.84
WOMAC Stiffness		
Pre-operative	**35** ± 23.24	**36.72** ± 15.46
Latest	**75.96** ± 17.28	**73.96** ± 26.36
WOMAC Function		
Pre-operative	**36.96** ± 20.82	**34.74** ± 17.98
Latest	**86.31** ± 10.09	**79.04** ± 14.48
WOMAC Total		
Pre-operative	**37.13** ±18.4	**36.32** ± 16.91
Latest	**84.88** ± 9.80	**80.30** ± 16.04

Figure 3: Proximal and distal translation of the SYNERGY° and SMF° stems.

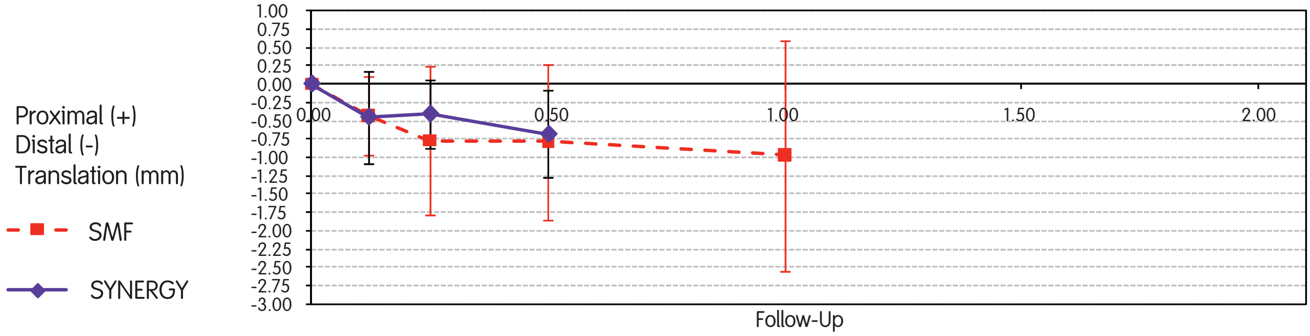


Figure 4: Anteversion and retroversion IE rotation of the SYNERGY and SMF stems.

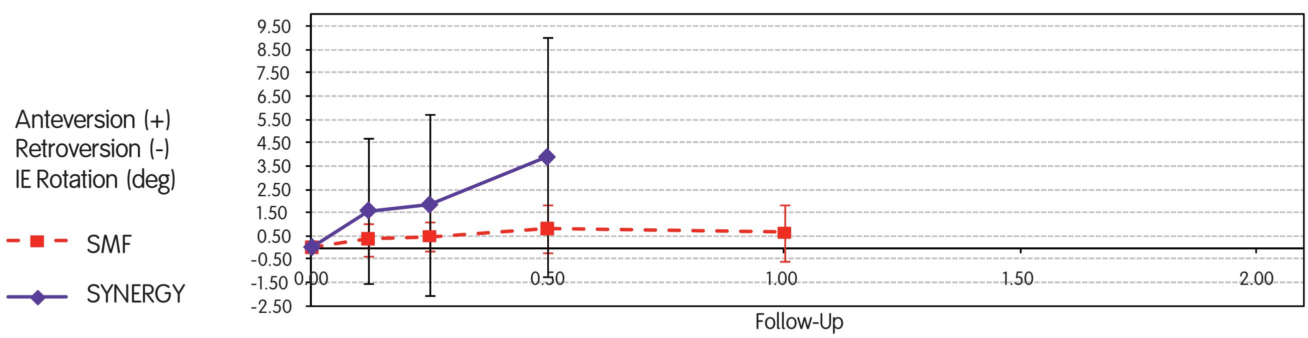
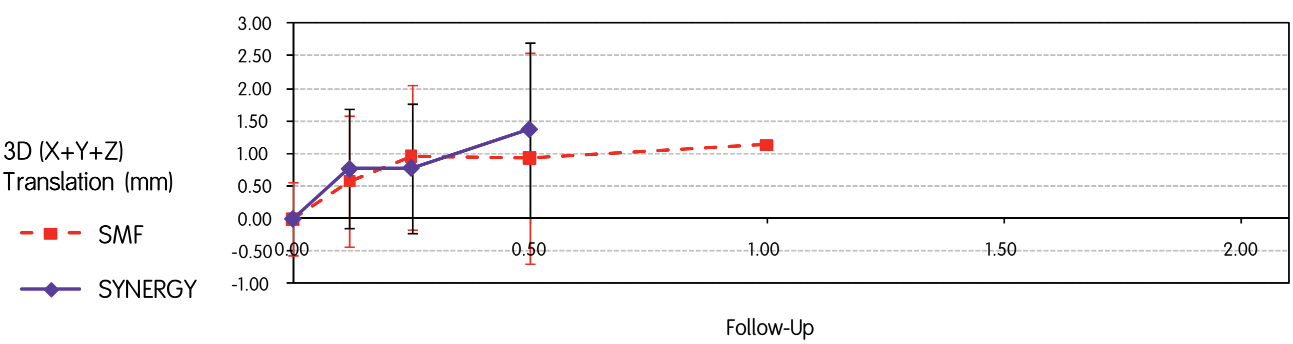


Figure 5: 3D translation of the SYNERGY and SMF stems.



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US: Lit. No: 7138-1571 REV0

Produced by the Research and Clinical Departments,
Smith & Nephew, Inc.
Published by KLEOS, the medical education service
from Smith & Nephew

Published January 2011

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