Modular Femoral Sleeve and Stem Implant Provides Long-term Total Hip Survivorship

David Le MD, Karen Smith CRA, Dylan Tanzer,
Michael Tanzer MD

Published online: 31 August 2010
© The Association of Bone and Joint Surgeons® 2010

Abstract

Background A femoral implant with a modular sleeve and stem has been designed to allow independent and complete metaphyseal-diaphyseal fit and fill as well as independent rotation to accommodate anteversion at the time of THA.

Questions/purposes In a prospective study we asked whether such a modular femoral sleeve and stem implant used during THA could provide (1) high long-term survivorship; (2) radiographically stable implants without radiolucencies, stress shielding, or osteolysis; and (3) high clinical scores in patients 15 to 20 years after a primary THA.

Patients and Methods We prospectively evaluated 31 hips that underwent a primary THA using a modular femoral component for clinical outcome (Harris hip score) and radiographic outcome (implant stability, femoral loosening, osteolysis and stress shielding) at a minimum followup of 15 years (mean, 17 years; range, 15–20.2 years).

Results There were no femoral revisions for aseptic loosening; all hips had radiographic evidence of bone ingrowth. Two well-ingrown components were revised for

late hematogenous infection. Some degree of proximal femoral disuse atrophy from stress shielding occurred in 23 hips (74%) but was nonprogressive and did not result in any failures or complications. Femoral osteolysis occurred in 18 hips (58%), but we cannot definitively determine whether or not the modular junction contributed to this.

Conclusions These data suggest this modular femoral stem can provide long-term survivorship with no cases of aseptic loosening at 15 to 20 years after primary THA. However, it may be prudent when using this femoral stem to consider an articulation with an alternative bearing or, if the modularity is not needed to address femoral anteversion and metaphyseal-diaphyseal mismatch, to consider a non-modular femoral stem.

Level of Evidence Level III, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Implant modularity can be an extremely beneficial feature for the surgeon at the time of cementless THA. It can permit complete metaphyseal fit and fill independent of diaphyseal fit and fill and facilitate the intraoperative correction of abnormal femoral anteversion by allowing rotation of the components.

One of the earliest designs of a modular femoral prosthesis is the S-ROM[®] femoral component (DePuy Orthopaedics, Inc, Warsaw, IN). It is a cementless, modular, cylindrical prosthesis composed of a hollow proximal sleeve and separate stem. The reason for modularity or multipiece stems is that there is no mathematical relationship between the diameter of the medullary cavity in

The institution of the authors has received funding from DePuy Orthopaedics, Inc, Warsaw, IN.

Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

D. Le, K. Smith, D. Tanzer, M. Tanzer (✉)
Division of Orthopaedic Surgery, McGill University, 1650 Cedar Avenue #B5159, Montreal, QC H3G 1A4, Canada
e-mail: michael.tanzer@mcgill.ca; tanzerm@gmail.com

the metaphysis and diaphysis [5]. The sleeve is oriented and placed in the best available metaphyseal bone first. The stem is then placed through the sleeve with the distal splines providing rotational stability. This feature of the S-ROM[®] provides intraoperative versatility, as the biomechanics of the hip reconstruction can be entirely separated from the fixation of the component. While the sleeve achieves fixation in the metaphysis and can be freely rotated to accommodate any deformity (such as in the case of developmental dysplasia of the hip) or asymmetry in the proximal femur, the type of stem and its version can then be adjusted independent of the placement of the metaphyseal sleeve.

Its present design has been used in North America since 1985 [17]. Although in use for 25 years, the longest-term studies of this implant report series over an 8- to 12-year time frame [1, 2, 5, 18]. Biant et al. [2] reported their prospective study of the 10-year (range, 5–16 years) clinical and radiographic results of 55 primary THAs using an S-ROM[®] femoral component. Half of these patients had severe hip dysplasia and 16% required a concomitant femoral osteotomy. None of the hips required revision for any cause. Cameron et al. [5] reported the results of a prospective analysis of 491 primary THAs using the S-ROM[®] femoral component at a mean followup of 11.5 years (range, 2–17 years). Overall, there were two revisions for aseptic loosening (0.4%), two for late sepsis, one for dislocation, and one for distal osteolysis. Adamany et al. [1] reported the results of a retrospective study of 34 S-ROM[®] femoral stems used for primary THA followed for an average of 12 years (range, 10–14 years) postoperatively. Survivorship analysis was based on the radiographic evaluation of 27 cases and telephone interviews with seven patients or their next of kin. Overall, there were no revisions for aseptic loosening and one hip underwent a revision for late sepsis from hematogenous spread. Our institution has used the S-ROM[®] stem for more than 21 years and we previously reported no cases of aseptic loosening in our patients at 6- to 12-year followup [18]. However, some degree of proximal femoral disuse atrophy from stress shielding occurred in 78% of the hips and some degree of femoral osteolysis occurred in 42%. Additional followup is needed to determine whether there is a consequence of both types of proximal femoral bone and to assess whether the implant's survivorship and clinical results are maintained in the long-term.

We therefore asked whether such a modular femoral sleeve and stem implant used during THA could provide (1) high long-term survivorship; (2) radiographically stable implants without radiolucencies, stress shielding, or osteolysis; and (3) high clinical scores in patients 15 to 20 years after a primary THA.

Patients and Methods

Of the previously reported and prospectively followed 50 patients with 59 primary cementless THAs using an S-ROM[®] femoral component implanted between July 1988 and January 1994 [18], 26 patients (31 hips) had complete clinical and radiographic data of at least 15 years and formed the basis of this study. Patients were selected based purely on the surgeon's discretion. Fifteen patients (19 hips) died of unrelated causes before their 15-year followup. None of these hips were revised or had radiographic signs of loosening at an average followup of 104 months. Another four patients (four hips) refused followup because they were being followed by another physician. Telephone interviews confirmed these four patients were functioning well at the time of the study and none had undergone a femoral revision. Five patients (five hips) could not be located and were lost to followup. Mean age of the patients at time of surgery was 52 years (range, 18–70 years). There were 17 women and nine men. The initial diagnosis was osteoarthritis in 17 hips (55%), developmental dysplasia in six hips (19%), avascular necrosis in five hips (16%), and rheumatoid arthritis in three hips (10%). The patient's joint involvement was classified as Charnley Group A in 17 patients, Group B in nine, and Group C in five [6]. The THA involved the right hip in 16 of the cases and the left hip in 15 cases. The minimum followup was 15 years (mean, 17 years; range, 15–20.2 years).

The S-ROM[®] modular femoral prosthesis was implanted using the standard posterolateral approach to the hip by a single surgeon (CEB). The femoral diaphysis was reamed progressively to the diameter of the stem, the metaphysis was reamed with conical reamers until both the anterior and posterior cortical bone was reached, and the calcar was milled with a side-cut drill to obtain cortical calcar contact. Metaphyseal preparation was performed anatomically and irrespective of its orientation to obtain maximum fill and cortical contact. After preparing the femur, the proximal modular sleeve was inserted anatomically. The stem, which was chosen based on the preoperative templating and intraoperative ability to restore leg lengths and offset, was introduced through the sleeve in the appropriate anteversion and impacted in place. In all cases, a cementless acetabular component with standard polyethylene was used. A Duraloc[®] 300 cup (DePuy) was used in 14 cases, an AML[®] cup with spikes (DePuy) was used in 12 cases, an Arthropor[®] III cup (Joint Medical Products/J&J/DePuy, Warsaw, IN) was used in four cases and a Harris-Galante[®] cup (Zimmer, Inc, Warsaw, IN) was used in one case. The femoral head size was 22 mm in one case, 28 mm in 22 cases, and 32 mm in eight cases.

Postoperatively, patients were kept nonweightbearing on crutches for 6 weeks after which they were allowed to

weightbear as tolerated without support. Patients were asked to increase their activities as tolerated and to include daily walking and side-lying abductions exercises. This was done independently and increased at the patient's own tolerance and motivation. There was no supervised physiotherapy.

All patients were followed prospectively with both a clinical and radiographic evaluation at 6 weeks, 3 months, 1 year, and yearly afterwards. The clinical evaluation consisted of a Harris hip score [12] at each visit. As part of the Harris hip score, patients were questioned specifically regarding thigh pain and, if present, to describe the intensity of it based on the pain scale portion of the Harris hip score. Pre- and postoperative radiographs included an AP hip and pelvis, as well as a frog leg and true lateral of the hip, at each visit.

All radiographs were evaluated according to the recommendations of Johnston et al. [13]. Implant stability was classified as bony ingrown, fibrous stable, or unstable according to the classification of Engh et al. [9]. Bone ingrowth was defined as an implant with no subsidence and minimal or no radiolucent lines around the porous portion of the stem. The presence of spot welds confirmed the stem was in bony ingrown. Stable fibrous ingrowth was defined as an implant with no progressive migration and extensive radiopaque line formation around the stem; these lines surrounded the stem in parallel fashion and were separated from the stem by a radiolucent space of up to 1 mm in width. An unstable implant was defined as one with definite evidence of either progressive subsidence or migration within the canal and was at least partially surrounded by divergent radiopaque lines more widely separated from the stem at its extremities. All radiographs were reviewed by two of the authors (DL, MT) at the same time so that a common agreement could be obtained.

Survivorship analysis was performed with the Kaplan-Meier estimator [8] with end points of revision for any reason and revision for aseptic loosening at 20 years after THA. Patients who died or were lost to followup were grouped together. They contributed to reducing the sample size or the number of patients contributing to the curve. They came into effect with each failure and contributed to a bigger proportion of decrease in survivorship.

Results

Overall, there were no femoral revisions for aseptic loosening. Two patients (two hips) had femoral revisions for late hematogenous infections. One patient was revised at 111 months and the second at 178 months. At surgery, both femoral implants had bony ingrowth and required an extended trochanteric osteotomy to remove. The 20-year

survival rate of the original cohort of 59 consecutive primary cementless THAs with an S-ROM® femoral component, with revision for any reason as the end point, was 84% (Fig. 1). This includes the two hips that underwent revision for late hematogenous infection in this study and one hip that was revised for dislocation in our earlier study [18]. The 20-year Kaplan-Meier survival rate, with revision for aseptic loosening as the end point, was 100%. Six acetabula (19%) were revised for severe polyethylene wear and osteolysis. In all cases, the acetabular revision involved a liner exchange, bone grafting, and retention of the acetabular shell.

At last followup, all 31 femoral components were classified as having bony ingrowth signifying radiographic stability. Trabecular streaming at the inferior border of the metaphyseal sleeve (so-called spot welds) were present in all cases (Fig. 2). There were no cases of implant migration, bead shedding, or implant fracture. Alignment of the stem was in neutral in 19 hips (61%), varus in nine hips (29%), and valgus in three hips (9%). The distal portion of the femoral stem completely filled the diaphysis in 15 cases, was undersized by 1 mm in seven cases, and undersized by 2 mm in nine cases. On the frog leg lateral radiograph, the metaphyseal sleeve had cortical contact in all cases. Radiolucencies were present in 26 hips (84%). No radiolucencies were noted along the porous-coated proximal sleeve (Fig. 2). All radiolucencies were along the polished distal portion of the stem and ran parallel to it. Adaptive bone remodeling or stress shielding was a prominent radiographic finding in Gruen Zone 7 (Fig. 3). Patchy or uniform cortical bone loss was present in 74% of

Fig. 1 A Kaplan-Meier survivorship curve demonstrates the probability of survival free of femoral revision for aseptic loosening or revision for any reason at 20 years postoperatively for the original cohort of 59 consecutive primary cementless THAs with an S-ROM® femoral component. The survival rate was 100% with revision for aseptic loosening as the end point and 84% with revision for any reason as the end point. The vertical bars represent the 95% confidence intervals.

Fig. 2 An AP hip radiograph taken 18 years postoperatively demonstrates the typical appearance of spot welds (arrows), trabecular streaming, and absence of radiolucencies adjacent to the porous-coated proximal sleeve of the S-ROM[®] stem.

Fig. 3 A 20-year postoperative AP hip radiograph demonstrates bony ingrowth with severe proximal femoral stress shielding with resultant cortical bone loss and loss of calcar thickness.

the hips, loss of calcar height occurred in 32%, and loss of calcar thickness occurred in 29% of the hips. There was no progression in the number of hips involved or the degree of stress shielding from our previous study. Cortical hypertrophy occurred in the distal diaphysis in two hips (6%), one in Gruen Zone 3 and one in Gruen Zone 5. Focal osteolytic lesions characteristic of an inflammatory response to wear debris were seen in 18 (58%) hips. The osteolysis was isolated to the greater trochanter in 14 cases. In four hips, an osteolytic lesion was present in the greater trochanter and in the region of the porous-coated proximal sleeve. In two hips, the osteolytic lesion was in Gruen Zone 1, and in the other two cases, it was in Gruen Zone 7. There were no cases of osteolysis distal to the porous-coated metaphyseal sleeve. Eccentric polyethylene wear of the acetabular liner was evident on the plain radiographs of 17 of the 18 hips with osteolysis. Only one case had femoral osteolysis without gross radiographic evidence of polyethylene wear (Fig. 4). There was no radiographic evidence of metallic debris in any of the cases.

The mean Harris hip score improved from 39 preoperatively to 83 at final followup. Pain was characterized

Fig. 4 A 19-year postoperative radiograph of an S-ROM[®] femoral component shows femoral osteolysis in Gruen Zones 1 and 7 (arrows). There is no apparent polyethylene wear of the acetabular liner.

as absent in 23 hips (74%), slight or occasional in three (10%), mild in two (7%), and moderate in three hips (9%). Thigh pain was reported in two cases and was only slight.

Discussion

Implant modularity in primary THA provides intraoperative versatility, as the biomechanics of the hip reconstruction can be entirely separated from the fixation of the component. Midterm results of the use of the S-ROM® prosthesis in primary THA have been encouraging [1, 2, 5, 18], but bone loss from stress shielding and osteolysis has been reported [18]. We therefore assessed whether the S-ROM® implant's survivorship and clinical results are maintained in the long-term and determined whether there is a consequence of the previously reported proximal femoral bone loss.

Our study, although prospective, is not without limitations. First, this is a nonconsecutive group of patients who received this implant at the surgeon's discretion. Second, although our followup did not include the entire original cohort, only four hips were truly lost to followup. The status of all the remaining hips was known and the implant had not failed. Finally, it is difficult to determine the exact relationship between the modular femoral stem and osteolysis since osteolysis is multifactorial.

Our data suggest high survival of the S-ROM® femoral component 15 to 20 years after primary THA. No femoral components required revision for aseptic loosening and none demonstrated evidence of radiographic loosening. Radiographic evidence of bone ingrowth into the proximal porous-coated sleeve was seen in all cases. The ability of this hip system to prepare and fill the proximal and distal portions of the femur independently of each other is likely a major contributing factor for the intimate proximal sleeve-cortical bone contact and the resultant bone ingrowth observed in all cases. Other studies report high survivorship of the S-ROM® stem at early followup [3, 4, 7, 18], but only three previous studies [1, 2, 5] have evaluated the outcome of this stem at a mean followup of at least 10 years. Biant et al. [2] reported a 0% aseptic loosening in 55 THA at 10 years, Cameron et al. [5] had a 0.4% aseptic loosening in 491 hips at 11 years, and Adamany et al. [1] reported no cases of aseptic loosening in 34 hips at 12 years. All of these authors concluded the low incidence of aseptic loosening justified the continued use of this stem in primary THA. Our study, with a mean followup of 17 years, represents the longest published report of the S-ROM® for primary THA. As in the previous reports, revision for implant loosening remains uncommon, even at 15- to 20-year followup. This report and the preceding

literature demonstrate the results of this stem do not deteriorate with time.

Proximal femoral bone atrophy from stress shielding was a common finding, occurring in 74% of the hips in this study. The stress shielding was prominent in the calcar region (Gruen Zone 7) but did not progress in frequency or severity from our previous report at 8.4-year followup [18]. Quantification of the bone loss in these patients using dual-energy xray absorptiometry has been previously reported by Rosenthal et al. [16] at 2 years postoperatively. Gruen Zone 7, the proximal medial cortex, was the site of greatest bone mineral loss, with a mean 11% loss in area and a mean 28% loss in bone mineral content. The effect of this bone loss raised concerns regarding its possible effect on implant fixation and femur integrity in the long term [18]. Although stress shielding of the calcar region remained common at 15- to 20-year followup, it did not adversely affect the outcome of the THA. No patients sustained a periprosthetic fracture, there were no cases of aseptic loosening, and the proximal femoral atrophy did not predispose or allow distal femoral osteolysis.

Our 58% incidence of femoral osteolysis draws attention to the concern of multiple modular junctions of a femoral stem like the S-ROM®. To date, five cases of catastrophic complications related to the S-ROM® modular stem-sleeve junction have been reported in the literature [10, 11, 14, 15]. Dissociation of the modular stem-sleeve junction has been reported in three hips and fracture of the proximal stem-sleeve junction has been reported in two hips. It has been hypothesized dissociation occurred because of undersizing of the femoral stem distally, thereby eliminating the mechanical interlock between stem and endosteal cortex and placing excessive demands on the modular interface [10, 14]. In our series, 52% of the stems were undersized distally and we did not have any catastrophic failures of the S-ROM® stem's modular junction at 15- to 20-year followup. We previously raised the concern that the stem modular junction could potentially cause femoral osteolysis by generating particulate metallic debris locally or by entering the joint space and causing third-body polyethylene wear [18]. We have no evidence of local metallic debris causing osteolysis in this study. Although focal regions of femoral osteolysis occurred in 18 (54%) cases, 17 of these hips demonstrated gross eccentric wear of the polyethylene liner on the radiographs. Furthermore, there were no cases of osteolysis isolated to or arising from the junction of the stem and the proximal porous-coated sleeve or radiographic evidence of metallosis at this site. Christie et al. [7] reported femoral osteolysis occurred in 5.7% of 175 S-ROM® femoral implants at a mean followup of 5 years, while Biant et al. [2] reported an osteolysis rate of 18% in 55 S-ROM® THAs at 10-year followup.

The higher rates of osteolysis in our study could possibly arise secondary to the longer followup period resulting in increased polyethylene wear. Whether or not this polyethylene wear could have been accelerated by particulate metal debris remains unknown. As a result, given the data gathered in this study were only clinical and radiographic in nature, it cannot be determined whether the femoral osteolysis was influenced by fretting debris from the S-ROM[®] stem-sleeve modular junction.

The consistent bone ingrowth observed with the S-ROM[®] modular proximal metaphyseal sleeve appears to serve as an effective barrier or seal from wear debris migrating distally and causing osteolysis. In this study, there were no cases of osteolysis occurring distal to the metaphyseal sleeve. Similar findings have been reported in the literature, with virtually all cases of osteolysis being proximal to the distal extent of the porous-coated sleeve [2, 7]. Only Cameron et al. [5] have reported the appearance of osteolysis distally in two of their 491 (0.4%) patients followed for a mean of 11.5 years.

Our data show the S-ROM[®] stem continues to provide reliable fixation at 15 to 20 years after primary THA. Bone ingrowth occurred in all cases and no hips demonstrated loosening or required revision for aseptic loosening. This may be attributed to the S-ROM[®] stem's instrumentation and design that allows close apposition of the porous-coated sleeve to cortical bone by permitting independent fit and fill of the implant within the proximal and distal regions of the femur. This study also provides some reassurance regarding the common occurrence and extent of proximal femoral stress shielding with this implant. Although 74% of the femora demonstrated proximal stress shielding, it did not progress from our previous study and did not result in any failures or complications at a mean followup of 17 years [18]. This study cannot definitively determine whether or not the modular junction contributes to the high rate of acetabular liner revision surgery and femoral osteolysis noted in this study. However, with this uncertainty, it may be prudent when using the S-ROM[®] femoral stem to consider an articulation with an alternative bearing or, if the modularity is not needed to address femoral anteversion and metaphyseal-diaphyseal mismatch, to consider a conventional femoral stem without a modular sleeve-stem junction.

Acknowledgments We thank Dr. C. Emerson Brooks for his continued support with this manuscript.

References

1. Adamany DC, Politi JR, Hauser WH. S-ROM hip prosthesis: 10- to 14-year results. *Orthopedics*. 2008;31:220.
2. Biant LC, Bruce WJ, Assini JB, Walker PM, Walsh WR. The anatomically difficult primary total hip replacement: medium- to long-term results using a cementless modular stem. *J Bone Joint Surg Br*. 2008;90:430–435.
3. Cameron HU. The 3–6-year results of a modular noncemented low-bending stiffness hip implant. *J Arthroplasty*. 1993;8:239–243.
4. Cameron HU. Modularity in primary total hip arthroplasty. *J Arthroplasty*. 1996;11:332–334; discussion 337–338.
5. Cameron HU, Keppeler L, McTighe T. The role of modularity in primary total hip arthroplasty. *J Arthroplasty*. 2006;21(Suppl 1):89–92.
6. Charnley J. Long-term radiological results. In: *Low Friction Arthroplasty of the Hip: Theory and Practice*. New York, NY: Springer; 1979:84.
7. Christie MJ, DeBoer DK, Trick LW, Brothers JC, Jones RE, Vise GT, Gruen TA. Primary total hip arthroplasty with use of the modular S-ROM prosthesis: four to seven-year clinical and radiographic results. *J Bone Joint Surg Am*. 1999;81:1707–1716.
8. Efron B. Logistic regression, survival analysis, and the Kaplan-Meier curve. *J Am Stat Assoc*. 1998;83:414–425.
9. Engh CA, Massin P, Suthers KE. Roentgenographic assessment of the biologic fixation of porous-surfaced femoral components. *Clin Orthop Relat Res*. 1990;257:107–128.
10. Fabi DW, Goldstein WM, Gordon AC. Dislocation of an S-ROM total hip arthroplasty secondary to traumatic femoral stem dissociation from the metaphyseal sleeve. *J Arthroplasty*. 2009;24:159–164.
11. Fanuele J, Bernini P. Dissociation of the modular femoral stem from the metaphyseal sleeve during reduction of a total hip arthroplasty dislocation. *J Arthroplasty*. 2007;22:140–142.
12. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty: an end-result study using a new method of result evaluation. *J Bone Joint Surg Am*. 1969;51:737–755.
13. Johnston RC, Fitzgerald RH Jr, Harris WH, Poss R, Muller ME, Sledge CB. Clinical and radiographic evaluation of total hip replacement: a standard system of terminology for reporting results. *J Bone Joint Surg Am*. 1990;72:161–168.
14. Kido K, Fujioka M, Takahashi K, Ueshima K, Goto T, Kubo T. Short-term results of the S-ROM: a femoral prosthesis operative strategies for Asian patients with osteoarthritis secondary to developmental hip dysplasia. *J Arthroplasty*. 2009;24:1193–1199.
15. Patel A, Bliss J, Calfee RP, Froehlich J, Limbird R. Modular femoral stem-sleeve junction failure after primary total hip arthroplasty. *J Arthroplasty*. 2009;24:1143–1147.
16. Rosenthal L, Bobyn JD, Tanzer M. Bone densitometry: influences of prosthetic design and hydroxyapatite coating on regional adaptive bone remodeling. *Int Orthop*. 1999;23:325–329.
17. Spitzer AI. The S-ROM cementless femoral stem: history and literature review. *Orthopedics*. 2005;28(9 Suppl):S1117–S1124.
18. Tanzer M, Chan S, Brooks CE, Bobyn JD. Primary cementless total hip arthroplasty using a modular femoral component: a minimum 6-year follow-up. *J Arthroplasty*. 2001;16(8 Suppl 1):64–70.