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Periprosthetic Stress Fractures at the Sleeve/Stem Junction of the Sivash-Range of Motion Modular Femoral Stem

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Abstract: We report on 13 cases of periprosthetic stress fracture at the sleeve/stem junction using the Sivash-Range of Motion femoral prosthesis. Radioisotope bone scans confirmed the incidence of fracture, and review of the lateral radiographs revealed anteromedial notching of the distal sleeve on the metaphyseal throat of the femur. Treatment in all cases was expectant with full resolution of symptoms. However, there were 3 cases of recurrence, 1 of which needed revision to a more distally loading stem. This is a rare complication when using this prosthesis, but we recommend a slight alteration of the entry point for the femoral reamer when using this stem and advise nonsurgical management if it occurs, as the natural history is for the condition to settle.
Keywords: femur, notching, S-ROM, stress fracture.

The Sivash-Range of Motion (S-ROM; DePuy Orthopaedics Inc., Warsaw, Ind) prosthesis is a proximally modular cementless femoral prosthesis with an excellent track record in both primary and revision hip replacement surgery. In our institution, the senior author has personally implanted 1237 S-ROMs at the time of writing. During this period of time, a distinct phenomenon of periprosthetic fracture of the femur corresponding at the level of the sleeve/stem interface of the S-ROM component has been noted. There have been no reports to date of this phenomenon elsewhere in the literature.

The purposes of this report were to describe a previously unreported clinical condition, describe the patient and implant characteristics of those with fractures, assess for any correlation that might indicate those at risk, hypothesize as to the possible cause, and describe the natural history and recommend a treatment protocol.

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Materials and Methods

Implant Design

The S-ROM consists of a distally polished titanium stem with distal splines 1.25 mm high. There are a variety of stems available, both straight and curved. Between the proximal body and the distal splines is a tapered portion that is surrounded by a sleeve that comes in various sizes per stem diameter. The sleeve consists of a conical and a spout portion, which are either fully porous coated or hydroxyapatite coated. The sleeve is designed with ZTT steps that convert hoop stresses to compressive forces at the bone-implant interface. A milling process is used to prepare the bone at the calcar. The sleeve is implanted first, and the stem is then implanted through the sleeve and engages the taper proximally via a cold weld.

Patient Characteristics

Patients were retrieved off the practice database, which records all complications related to surgery. The period covered by the database was from February 1993 to June 2009. There were 1237 primary total hip arthroplasties using the S-ROM prosthesis on the database. There were 13 patients in total, 8 men and 5 women. Surgery was carried out on 8 right hips and 5 left hips. The average age at surgery was 55.3 years (range, 39-66 years). Factors recorded included body mass index (BMI), primary diagnosis, whether the patient had any previous surgery on the hip, morphologic type of femur, whether the primary surgery was associated with any complication, time from index procedure to onset of symptoms, nature

Table 1. Table Showing Patient Characteristics, Primary Diagnoses, and Time Frames Involved

	Age (y)	BMI (kg/m^2)	Primary Diagnosis	Previous Operation	Time to Fracture (mo)	Time to Resolution (mo)
Patient 1	49	27.2	OA	No	34	6
Patient 2	52	25.3	SUFE	THR—TARA	89	5
Patient 3	53	25.5	DDH	No	24	6
Patient 4	64	29.4	OA	No	19	5
Patient 5	66	26.2	SUFE	Yes	16	10
Patient 6	48	27.2	SUFE	No	7	5
Patient 7	55	28.1	OA	No	28	6
Patient 8	50	28	DDH	No	24	4
Patient 9	53	24.9	AVN	No	35	3
Patient 10	61	20.6	DDH	Yes—DVO	26	13
Patient 11	62	29.1	DDH	Yes—Scope	19	6
Patient 12	39	25.2	Inflammatory	No	45	5
Patient 13	67	32.3	OA	No	23	5

OA indicates osteoarthritis; SUFE, slipped upper femoral epiphysis; THR, total hip replacement; TARA, total articular resurfacing arthroplasty; DDH, developmental dysplasia of the hip; AVN, avascular necrosis; DVO, derotation varus osteotomy.

of the presentation and onset of pain, investigations, time to recovery, recurrence, treatment, various sizes of the modular components of implants used, whether further surgery was subsequently performed, and whether surgery was performed on the contralateral hip.

All radiographs from prearthroplasty through the latest follow-up were available for scrutiny. All patients were investigated with routine radiographs, radioisotope bone scan, and routine blood tests to overrule infection. All radiographs and bone scans were reviewed by the senior author and a senior radiologist as part of the prospective data collection. As part of this study review, all radiographs were retrospectively reviewed by 4 senior members of staff.

Statistical analysis was performed using SPSS for Windows (version 16.0) statistical package (SPSS Inc., Chicago, Ill). The Pearson coefficient was used to determine any correlation between BMI, primary diagnosis, and implant sizes and fracture.

Results

The mean BMI of the 13 patients was 26.85 kg/m^2 (range, 20.6-32.3 kg/m^2). Four patients had a primary diagnosis of dysplasia of the hip, 5 had a diagnosis of primary osteoarthritis, 3 had epiphyseal dysplasia, 1 had a history of inflammatory arthropathy in childhood, and the remaining patients had osteonecrosis, as shown in Table 1. Three patients had a history of previous surgery on the hip. Of the 13 patients, all except 1 had their surgery performed by the senior author. Morphologically, 8 patients had a Charnley type A proximal femur, and 5 had a Charnley type B.

Table 2 shows the sleeve, stem, body, neck, and head sizes. There was no correlation between BMI and sizes used (P > .05), or femoral morphology (P > .05). In addition, there was no correlation between the sleeve sizes and fracture (P > .1). Five patients had subsequent surgery for the contralateral side.

The mean time from index procedure to onset of symptoms was 28.3 months (range, 7-89 months). Of note, 1 patient who sustained an intraoperative calcar fracture was asymptomatic for 89 months. Eleven patients reported that the onset of their symptoms was sudden, in all cases corresponding with a stumble or some other form of minor physical activity. The remaining 2 patients could not identify a specific event

Table 2. Information Relating to Prosthetic Data

	Size Stem (mm)	Size Sleeve (mm)	Size Neck (mm)	Size Head (mm)	Size Cup (mm)
Patient 1	18 × 13 × 160	18FXXL	36 + 8	32/6	54
Patient 2	18 × 13 × 160	18DL	36 + 8	28/0	58
Patient 3	16 × 11 × 150	16FL	30 + 4	32/0	54
Patient 4	18 × 13 × 160	18DS	36 + 8	32/0	52
Patient 5	16 × 11 × 150	16DL	36 + 6	36/3	54
Patient 6	20 × 15 × 165	20FXXL	36 + 6	36/0	56
Patient 7	18 × 13 × 160	18BS	36 + 12	32/0	56
Patient 8	18 × 13 × 160	18DL	36 + 8	32/0	52
Patient 9	18 × 13 × 160	18DL	36 + 8	32/0	54
Patient 10	16 × 11 × 150	16BS	36 + 6	28/0	50
Patient 11	20 × 15 × 165	20FL	36 + 0	28/0	56
Patient 12	18 × 13 × 160	18DL	36 + 8	48	54
Patient 13	20 × 15 × 165	20FS	36 + 8	36/0	56

XXL indicates extra extra large; DL, size D large; FL, size F large; DS, size D small; BS, size B small; FS, size F small.

associated with onset, so were classified as having a "gradual" onset of symptoms. All presented to our service with new onset of pain in the thigh. The pain was typically localized anteromedially in the thigh, made worse on weight bearing.

All radioisotope bone scans were shown to demonstrate increased uptake in the region of the sleeve/stem interface (Fig. 1), indicative of a periprosthetic fracture. Of the 13 radiographs, reviewed by both the senior author and a senior radiologist at the time of presentation, none showed obvious signs of fracture on the initial radiograph. However, on the lateral view, all of the radiographs showed evidence of endosteal impingement from the sleeve anteromedially (Fig. 2), corresponding with the level at which bone scan changes were noted. This was not noted at the time of initial presentation but was evident upon retrospective review of the radiographs. In addition, with healing, periosteal callus formation could be seen on radiographs at the same level (Fig. 3). At the time of presentation, stress shielding was noted to be present in 2 cases, and spot welding was seen in 10 of the 13 cases.

Treatment, in all cases, was expectant. Patients were prescribed anti-inflammatory medication and analgesics and referred to physiotherapy for instruction regarding partial weight bearing for a period of 6 weeks. In all cases, there was complete resolution of symptoms, with a mean time from initial presentation to complete resolution of 6.07 months (range, 3-13 months).

The mean follow-up period from resolution of symptoms to the time of study review was 36 months (range, 10-61 months).

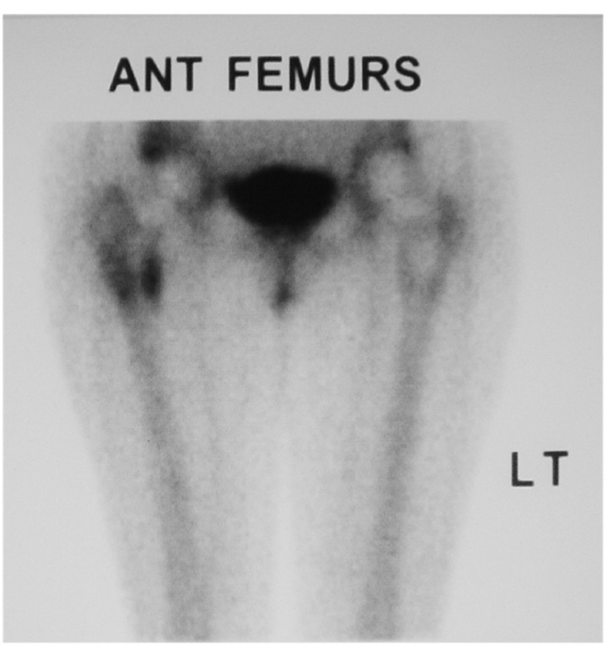

Fig. 1. Radioisotope bone scan showing increased uptake in the right femur at the level of the sleeve/stem interface. Note that this is particularly evident at the medial border.

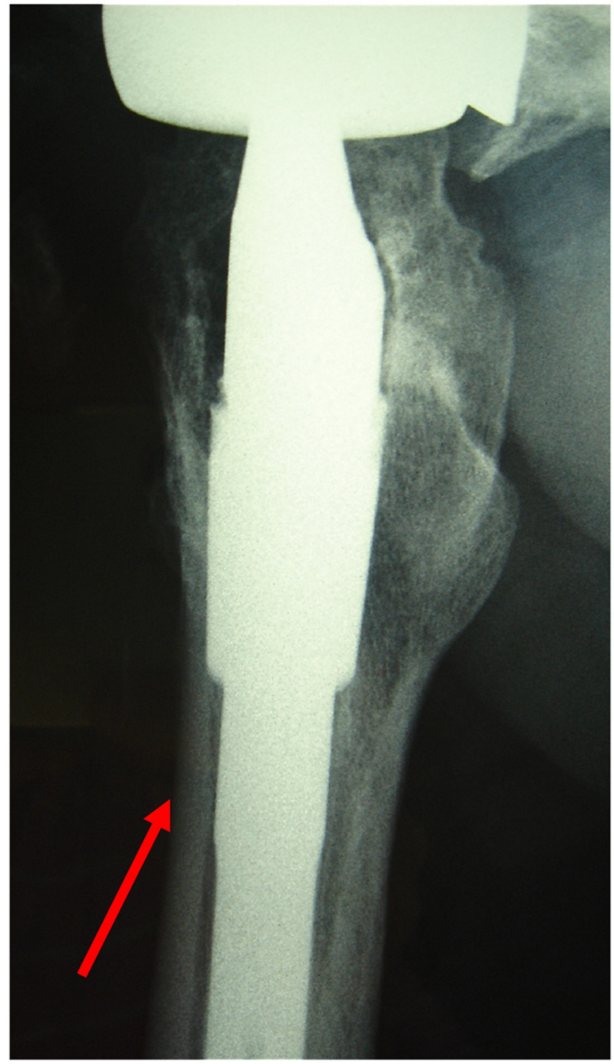

Fig. 2. Lateral radiograph showing notching of the distal sleeve anteromedially on the femoral metaphysis (arrow).

There were 3 cases of recurrence of symptoms. The average time to recurrence was 26 months (range, 12-36 months). One patient presented initially 3 years after his primary procedure having sustained a minor trauma. After confirmation of stress fracture on bone scan, the symptoms settled during a period of 5 months with noninvasive management. He re-presented 4 months later having injured himself while gardening. A repeat radioisotope bone scan confirmed recurrence of the stress fracture, which settled with a further course of anti-inflammatories and analgesics during a period of 5 months. He was discharged. However, he presented again with pain in the thigh 1 year later after a minor incident while playing golf. Scans confirmed a further occurrence of stress fracture. It was decided at this time to revise the femoral stem to a distally loading prosthesis. The S-ROM stem was explanted and a Solution stem (DePuy Orthopaedics Inc.) was implanted. He sustained no further episodes of pain and, at latest follow-up

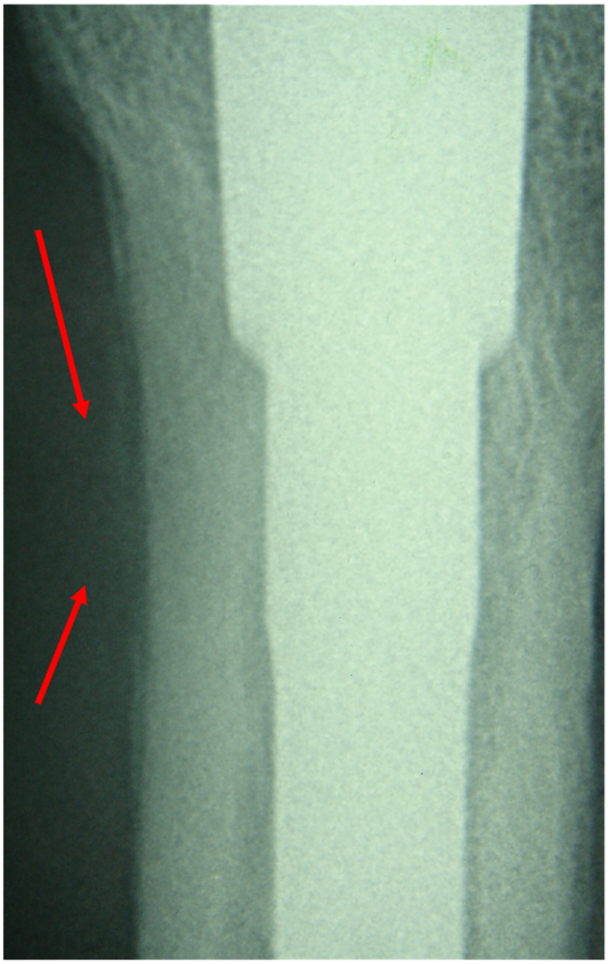

Fig. 3. Lateral radiograph showing periosteal neocorticalization following stress fracture (arrows).

(13 months postrevision), was doing well and mobilizing freely. The remaining 2 patients had recurrence at 12 and 30 months, respectively, after initial resolution of symptoms. In both instances, patients reported a minor trauma to the leg. After further periods of nonsurgical management, symptoms of both patients resolved completely, and they remain pain-free at latest follow-up, 18 and 23 months, respectively, after resolution of the recurrence of pain.

Discussion

Despite early skepticism, the S-ROM stem is now considered a mainstream implant for both primary and revision hip surgery. Its design and modularity are particularly suited to the treatment of complex anatomy, such as in dysplastic hips in the primary setting, and where there is osteolysis in the revision setting.

The results published in the literature to date have been outstanding [1-6]. The reported complication rate using the S-ROM is low. There has been one report on significant osteolysis [7], recorded at 42%, but in 80% of these cases, eccentric polyethylene wear was associated. In addition, osteolysis occurred distal to the sleeve/stem junction in only 1 of 59 hips, indicating that the modular junction succeeds in sealing the effective joint space. Corrosion at the modular junction has not been a problem, and there have been no reports of failure or fracture of the implant to date. Thigh pain has been a problem with cementless prostheses with large diameter stems. One of the innovations of the S-ROM stem was the coronal split. Cameron et al [8] demonstrated that this design feature reduced thigh pain from as high as 60% at 6 months for some prostheses to only 2.3% of patients experiencing pain at 1 year using the S-ROM and only 0.4% at 2 years. Of course, one possible explanation for thigh pain in these patients is that they had sustained unrecognized periprosthetic stress fractures, which resolved with expectant treatment, much like what we experienced with the patients in our series. Although hypothetical, it may be that had these patients had radioisotope bone scans performed, a number may have shown changes consistent with fracture. The senior author in this study has implanted 1237 S-ROM prostheses at the time of writing. Interestingly, the 13 cases in this study represent 1.05% of all cases, a figure remarkably similar to Cameron's rate of 0.4% of patients with thigh pain at 2-year follow-up.

In terms of onset, most patients reported a sudden onset of pain as opposed to gradual, with most reporting a specific traumatic event. All patients were x-rayed within 4 weeks of the onset of symptoms, with no obvious fracture noted in any of the radiographic films, as reviewed by both the senior author and a senior radiologist. However, a feature consistent with all lateral radiographs was notching of the sleeve on the anteromedial endosteal cortex of the femur. This was not noted at the time of initial presentation, but only upon retrospective review of the radiographs as part of the review for this study. Features consistent with healing stress fractures were noted on serial radiographs prospectively. Radioisotope bone scans were also performed at the time of the initial radiograph, and all scans showed increased uptake in the bone consistent with a periprosthetic stress fracture at the sleeve/stem interface.

What the pathophysiology of these fractures is not certain. The ZTT steps on the sleeve convert hoop stresses to compressive axial stresses, theoretically eliminating the chance of fracture. The stem is inserted into the sleeve via a Morse taper. In vivo, the taper is loaded in compression, which minimizes micromotion and provides rotational stability [9]. However, there are some theoretical concerns regarding the sleeve/stem junction. "Fretting" with the generation of metallic particles takes place, and as Bobyn et al [10] noted, fretting is "inevitable given sufficient load and loading cycles, and this must be accepted if we wish to gain the advantages offered by modularity." As mentioned, however, the incidence of osteolysis is low, so whether the generation of metallic particles is of sufficient magnitude to cause subtle osteolysis that can lead to fracture is speculative. As noted, all of the lateral radiographs showed consistent notching of the sleeve on the anteromedial cortex of the femoral metaphysis. This is due in part to the fact that the sleeve/stem junction is not a smooth taper on the outer surface, with a 2-mm circumferential "step" between the sleeve and the stem, and due in part to incorrect surgical technique in obtaining the correct entry point for the initial femoral reamer. We can confidently conclude that the fractures were caused by weakening of the metaphyseal throat of the femur anteromedially by surgical coring and impingement of the distal sleeve at that site, resulting in a stress riser at that point. Further biomechanical studies will be needed to fully verify this theory.

The rate of periprosthetic stress fracture in our practice is extremely low, at just more than 1%. It is therefore difficult to identify potential risk factors with respect to age, BMI, or implant sizes. We could not identify and predisposing factors for fracture, in that there was a variety of sleeve and stem sized noted, as well as a range of BMI from 20.6 to 32.3 kg/m^2. Furthermore, there was no correlation between BMI and sleeve or stem size, or with femoral morphologic type.

Treatment in all cases was expectant, with a combination of weight bearing as tolerated, simple analgesia, and nonsteroidal anti-inflammatories. Patients were encouraged to return to activities of daily living on a gradual basis, and the average time to resolution of symptoms was just more than 6 months. No patient required surgery at the initial stage for treatment of the stress fracture. There is a risk of recurrence, however, as shown by the 3 cases in this series. These were all treated expectantly, with good results in 2 of the patients. However, 1 patient had a further recurrence, and the decision was made to revise his prosthesis to a distally loading stem, bypassing the area of stress fracture. He settled fully.

This is, to our knowledge, the first report in the literature of this phenomenon. Many studies concerning the S-ROM do report a small incidence of thigh pain, and authors have hypothesized that this is due to the use of large stem sizes, especially those greater than 16 mm [11], which, theoretically, should not settle with time. More recently, Pierannunzii [12] has classified thigh pain postarthroplasty as being either "dynamic" or "static." In terms of the etiopathogenesis, dynamic is due to micromotion of the implant, whereas static is due to overload-related pain. Dynamic is seen in the setting of loose implants or those with fibrous ingrowth, and static is seen in the setting of a stable but painful femoral component. In both scenarios, one would not necessarily expect the pain to subside over time. However, as in our series, some authors who report thigh pain report on the resolution of symptoms over time [13]. We conclude that at least a proportion of these patients have sustained periprosthetic fractures, which would have been confirmed had radioisotope bone scans been performed and correlated with the lateral radiographs.

We believe that these fractures are due, in part, to surgical technique and, in part, due to implant design. In our practice, we now routinely use an entry point for the initial femoral reaming 4 to 5 mm posterolateral to the piriform fossa. This should help in preventing notching anteromedially. In addition, it may be that the sleeve/stem junction needs to be modified to create a smoother taper, thereby reducing any potential stress riser. This could be achieved with modification of the proximal reamer.

For those surgeons who do use the S-ROM, it is important to at least be aware of this potential complication. We advise modification of the entry point for femoral reaming as described. Where patients present with thigh pain postsurgery, we believe that careful scrutiny of the lateral radiograph and radioisotope bone scanning will reveal periprosthetic stress fracture where present. It is important to recognize that the initial treatment should be expectant and that the condition does resolve with fracture healing during a relatively short period of time. In cases of recurrence, we recommend that nonsurgical methods should again be employed, although it may be necessary to revise the stem in cases where there are repeated episodes of fracture. We continue to use the S-ROM in our practice, both for primary and revision surgery, acknowledging that the small risk of periprosthetic fracture is a small price to pay for the excellent long-term clinical results that we see and are reported elsewhere [1-6,11,14].

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