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The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Alarming High Rate of Implant Fractures in One Modular Femoral Stem Design: A Comparison of Two Implants

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ARTICLE INFO

Article history:

Received 11 January 2017

Received in revised form

20 April 2017

Accepted 6 May 2017

Available online xxx

Keywords:

total hip arthroplasty
modular femoral stem
fatigue fracture
catastrophic failure
fretting

ABSTRACT

Background: Reports of implant fracture at the modular junction have been seen in modular neck designs, stem-sleeve modular femoral stems, and diaphyseal engaging bi-body modular stems. To date, however, there has never been a direct comparison between 2 different implant designs from the same modular family. The purpose of this study is to compare the rate of implant failure of 2 such stem-sleeve modular femoral stem designs, the S-ROM and Emperion, to further identify factors which increase the risk of this mode of failure.

Methods: A retrospective, single surgeon, review of our institutional database was performed to compare the 2 groups of patients.

Results: A total of 1168 total hip arthroplasty procedures were included in our analysis, 547 (47%) with Emperion and 621 (53%) with S-ROM. Eight (1.5%) fractures in 7 patients occurred in the Emperion group compared to 1 (0.2%) fracture in the S-ROM group ($P = .015$).

Conclusion: The precise cause of the stem fractures in our study remains unknown and is likely multifactorial. Given the unexpectedly high rate of catastrophic implant failures in the form of stem fracture at the stem-sleeve junction, we recommend more judicious use of modularity in primary total hip arthroplasty.

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Modularity in total hip arthroplasty (THA) increases options to address leg length, offset, version, and proximal femoral deformity. Implant designs featuring modularity gained in popularity in the past 2 decades due to their utility in a wide spectrum of THA cases. Concerns over modularity failure in the form of taper tribocorrosion and catastrophic implant failure have tempered enthusiasm for use of such implants. Reports of implant fracture at the modular junction have been seen in modular neck designs, stem-sleeve

modular femoral stems, and diaphyseal engaging bi-body modular stems [1–7]. To date, however, there has never been a direct comparison between 2 different implant designs from the same modular family.

Multiple implant companies manufacture stem-sleeve modular femoral stems for utilization in both the primary and revision setting. Two such implants include the S-ROM design (DePuy Orthopaedics, Warsaw, IN) and the Emperion femoral stems (Smith and Nephew, Memphis, TN) (Fig. 1). Both these stem designs allow for proximal and distal fixation with independent femoral preparation to accommodate proximal and distal size mismatch. Once the sleeve is impacted proximally, the stem allows for adjustment of version as it is cylindrical in shape and is ultimately impacted and fixed in both the distal bone as well as the Morse Taper at the stem-sleeve junction. Both stem designs allow for multiple offset options.

By convention, the S-ROM and Emperion stems have different ways of designating their offset options. In the S-ROM group, for each stem size, there are different neck length options. Then there

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to <http://dx.doi.org/10.1016/j.arth.2017.05.031>.

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<http://dx.doi.org/10.1016/j.arth.2017.05.031>

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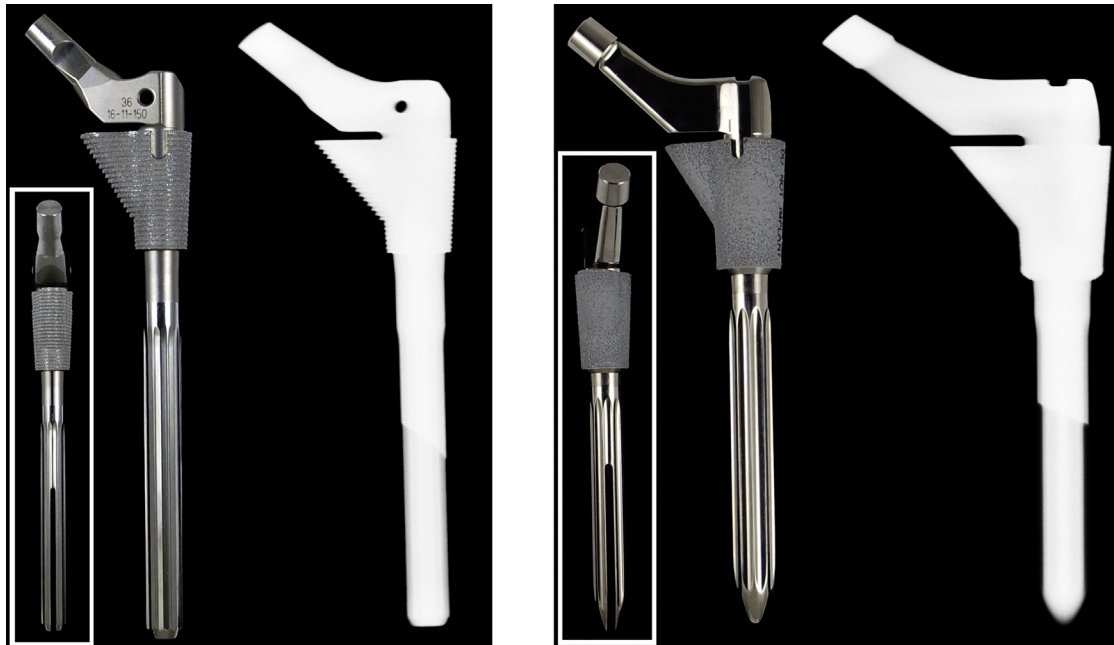


Fig. 1. S-ROM (left) (DePuy Orthopaedics) and Emperion (right) (Smith and Nephew) femoral stems. Images obtained with permission from George Branovacki MD, Author, Ortho Atlas, Hip Arthroplasty U.S. Femoral Implants 1938–2008.

are often different offset options for each neck length. Emperion, in contrast, offers a standard and high offset option for each stem size and they differ based on stem size. Each company provides their true offset for each option available.

Advances in biomaterials have led to a reduction in implant breakage. Modular femoral neck designs attempted to address the instances of modular fracture by changing from a titanium junction to a cobalt chromium (CoCr) junction. However, beyond material composition itself, modular femoral neck fractures have been demonstrated to occur in patients with high offset, increased varus neck-shaft angles, and a large body mass index (BMI)

[1–4,8,9]. Fatigue fracture of the stem generally occurs as a result of cyclic cantilever loading in the regions of stress concentration [10]. This is especially true in the clinical setting of rigid distal stem fixation (both cemented and cementless fixation), inferior biomaterial, or defects within the biomaterial and suboptimal design geometry. Stem body breakage in some monoblock designs occurs primarily because of rigid distal fixation combined with cyclic cantilever loading and stress concentration leading to eventual fatigue failure. Similar biomechanical principles can be applied to breakage at the taper junction in 2-piece modular femoral stems [11].

Table 1
Clinical Results (N = 1168).

	Emperion (n = 547)	S-ROM (n = 621)	P Value	Fractures (n = 9)
Stem fractures	8 (1.5) ^a	1 (0.2)	.015	—
Age at surgery (y)	66.9 ± 11.4 ^b	60.4 ± 12.3	<.001	62.2 ± 10.8
Sex			.199	
Male	221 (40)	274 (44)		7 (78)
Female	326 (60)	347 (56)		2 (22)
Body mass index	29.3 ± 6.6	28.8 ± 5.6	.150	38.3 ± 7.6 ^c
Side			.887	
Right	300 (55)	338 (54)		6 (67)
Left	247 (45)	283 (46)		3 (33)
Principal diagnosis			<.001	
Osteoarthritis	535 (98)	542 (87)		9 (100)
Hip dysplasia	4 (1)	59 (10)		
Other	6 (1)	20 (3)		
HH pain score	15.9 ± 8.6	15.8 ± 8.9	.914	13.3 ± 5.1
HH functional score	19.4 ± 7.3	20.5 ± 7.2	.025	11.2 ± 8.3
HH total score	54.0 ± 14.4	55.0 ± 14.1	.332	43.2 ± 13.8
Femoral offset (mm)	40.2 ± 4.1	38.5 ± 5.2	<.001	41.1 ± 4.0
Femoral stem size (mm)	13 (9-19) ^d	13 (9-15)	.003	13 (9-15)
Femoral head size (mm)	36 (22-52)	36 (30-36)	.009	36 (32-52)

HH, Harris Hip (HH scores are ≤6 mo prior to surgery); ANOVA, analysis of variance.

^a Data are expressed as number (%).

^b Data are expressed as mean ± standard deviation.

^c Significantly higher body mass index vs the other 2 cohorts (P < .001; one-way ANOVA, Tukey's honest significant difference post hoc test).

^d Data are expressed as median (range).

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