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Clinical and Radiologic Outcomes of a Fully Hydroxyapatite-Coated Femoral Revision Stem: Excessive Stress Shielding Incidence and its Consequences

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ABSTRACT

Stress shielding remains a concern in total hip arthroplasty. The consequences of stress shielding in hydroxyapatite-coated femoral component revisions were evaluated in a prospective cohort study. A total of 106 patients operated on by revision total hip arthroplasty were identified. Sixty-three patients were eligible for clinical and radiologic assessment of osseointegration, bone remodeling, and stress shielding. Five patients showed evidence of excessive stress shielding. One patient experienced a periprosthetic fracture. No adverse events occurred in the remaining patients with a low rate of thigh pain and reliable osseointegration. This is the only available study concerning mid- to long-term consequences of excessive stress shielding in hydroxyapatite-coated revision stems. We advocate surgeons using these stems to remain vigilant and be aware of possible stress shielding side effects.

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Failure of total hip arthroplasty (THA) continues to present a significant clinical challenge. The number of revision hip arthroplasties performed each year has increased exponentially over the last half century, and these increases have been sustained over the first 5 years of the new millennium: numbers are between 4% and 26% worldwide for revision hip surgery [1]. Kurtz et al [2] constructed a model to predict the future rate of revision THA in the United States from 2005 to 2030. They projected a 137% increase in 2030. As the revision burden increases, achieving reliable and durable fixation between the implant and host bone presents a challenge.

Femoral component loosening is a common mechanical failure and is of great concern in the orthopedic literature. Stress shielding is a mechanical cause of bone loss [3]. This phenomenon is caused because the natural stress distribution through the femur is altered. The implant will carry a portion of the load and distribute some of the load to the midshaft region of the femur. This causes a reduction of stress in some areas of the remaining bone, primarily in the proximal metaphyseal region. If bone experiences little or no stress, there will be a loss of bone mass in that region. This is known as bone resorption and can cause the prosthesis to loosen from the bone. Potential adverse effects of stress shielding may be stem, bone, or interface failure or deficient bone stock when a (re)-revision is required. Clinical and animal experimental studies have revealed factors influencing stress shielding, which include stem stiffness, stem shape, stem coating extent, fit between stem and bone, bone quality, and patient weight [3,4]. Cemented and proximally porous-coated femoral revision stems have demonstrated disappointing clinical results to date [5-11]. An alternative in femoral revisions to bypass the problem of stress shielding is the use of fully hydroxyapatite (HA)–coated femoral stems. Such stems show favorable results with mechanical failure rates of 1% to 6.9% as compared to higher failure rates using cement revision arthroplasty with similar length of clinical follow-up (FU) [12-17].

Hydroxyapatite coating has been shown to promote osteoconduction in both primary and revision cases [18,19]. As a result of these biologic properties, it is feasible that the requirement for augmentary bone could be reduced or eliminated in many if not most cases. Studies using radiostereometric analysis showed reduced migration of HA-coated prosthetic components and better radiographic results and survival rates with HA-coated stems when compared with identical press-fit components [20]. Although the preliminary results of fully HA-coated femoral stems show promising clinical results, concerns over stress shielding still exist. There is paucity of evidence for the mid- to long-term clinical performance of fully HA-coated femoral revision implants. We present our institutional results for the mid- to long-term outcome of the Restoration HA femoral revision stem (Stryker, Mahwah,

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NJ), in which we discuss the clinical performance, radiologic outcome, and clinical consequences of stress shielding.

Methods

Patient Selection

A cohort analysis was performed in a prospective study design of all patients who underwent revision THA at our institution using a fully HA-coated revision hip stem between January 1998 and January 2007. In the study period, 106 patients received a fully HA-coated Restoration stem. All patients were included with a minimum FU of 60 months. There were no exclusion criteria. A total of 63 patients were eligible for final assessment.

Primary study outcome was the clinical performance and radiologic outcome of the aforementioned revision stem with specific focus on stress shielding occurrence.

The surface of this femoral implant is acid-etched titanium alloy with a circumferentially applied 50-μm HA surface coating. The distal portion of the stem is 0.5 mm tapered, and the shaft-neck angle is anatomical 127°. The stem comes in multiple diameters up to 22 mm and lengths of 155, 205, and 265 mm (Fig. 1).

All procedures were performed by or under the supervision of 2 specialist hip surgeons. In all patients, a posterior approach to the hip was used, with an extended trochanteric osteotomy if required to facilitate cement removal. In most of the patients, a 1-stage revision was achieved. In the postoperative treatment protocol, 3 patients were treated with non–weight bearing; 51 patients, with partial weight bearing; 6 patients had full weight bearing; and in 3 patients, the postoperative weight-bearing protocol was not specified.

This study was approved by the medical ethical committee of our institution (no. 08-4-048) and conducted according to current Good Clinical Practice and ISO 14155 guidelines. All patients signed informed consent before participation in this study.

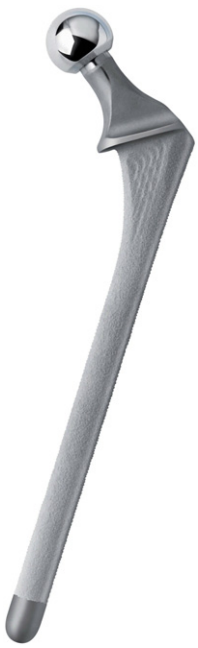

Fig. 1. Restoration HA stem. Stem fabricated of titanium alloy roughened by a chemical etching process. Hydroxyapatite is plasma sprayed over the entire length of the stem. Designed with a large proximal cross-section to provide for improved load distribution over a broad area. Distally, the design incorporates a cylindrical section to more effectively use the available bone of the diaphysis. The stem design incorporates a physiologic 127° neck-stem angle, neck length ranges, and a C-taper head to provide the surgeon with the ability to restore near-anatomical head position for proper leg length and biomechanical function.

Clinical Assessment

A clinical examination was performed postoperatively at 6 weeks, 6 months, 12 months, and after minimum 60 months clinical FU, and the following were recorded: range of motion, incidence of thigh pain, and the level of physical activity. Furthermore, the Oxford Hip Score (OHS), Harris Hip Score (HHS), and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores were assessed. Radiologic assessment of osseointegration, bone remodeling, and assessment of stress shielding in all Gruen zones were matched to clinical assessment time points. Radiologic outcome was assessed postoperatively at 6 weeks; at 6, 12, and 60 months; and at the last FU visit. A zonal analysis of the radiolucent lines, as outlined by Engh et al [13], was used to catalog the relevant changes in bone morphology and the bone implant interface characteristics in all Gruen zones. Radiologic outcome was assessed by 2 reviewers.

Results

Patients

Forty-three patients were lost to FU: 3 patients moved abroad, 1 patient died, 1 patient had significant Parkinson, and 38 patients withdrew consent because of refusal to participate in the study or incomplete adherence to FU schedules. A total of 63 patients were eligible for final assessment. The patients (38 females and 25 males) had an average age at the time of surgery of 58 years (range, 27-76 years), body mass index of 27 kg/m^2 (range, 17-41 kg/m^2), and mean American Society of Anesthesiologists classification of 2 (range, 1-3). The hip pathologies that necessitated primary arthroplasty procedures were arthritic conditions, avascular necrosis, trauma, and congenital dysplasia. In 4 patients, the revision stem was used in a primary arthroplasty procedure. The reasons for the revision arthroplasty procedures were aseptic loosening of 1 or more components (22 patients), recurrent dislocations (8 patients), pain (6 patients), polyethylene wear (5 patients), malposition (4 patients), fracture (6 patients), girdlestone situation (2), and infection (1 patient). The mean revision rate was 3 revisions in the whole study population (Table).

Table
Baseline Demographic Data of Patient Cohort.

Baseline Characteristics	n = 63
Age (y), mean (SD)	58 (27-76)
Male	25 (40)
Female	38 (60)
BMI, n (%)	
<30	44 (70)
>30	14 (22)
N/A	5 (8)
ASA classification n (%)	
I	12 (19)
II	35 (56)
III	5 (8)
IV	–
N/A	11 (17)
Reason revision n (%)	
Pain	6 (10)
Septic loosening	1 (2)
Aseptic loosening	22 (35)
Recurrent dislocations	8 (13)
Polyethylene wear	5 (8)
Fracture	6 (10)
Girdlestone situation	2 (3)
Malposition	4 (6)
N/A	9 (14)

Abbreviations: BMI, body mass index; N/A, not available; ASA, American Society of Anesthesiologists.

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