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Basic Science

Thirteen-Year Evaluation of Highly Cross-Linked Polyethylene Articulating With Either 28-mm or 36-mm Femoral Heads Using Radiostereometric Analysis and Computerized Tomography

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ABSTRACT

Background: The objective of this 13-year prospective evaluation of highly cross-linked ultra high molecular weight polyethylene (HXLPE) was to (1) assess the long-term wear of HXLPE articulating with 2 femoral head sizes using radiostereometric analysis (RSA) and to (2) determine if osteolysis is a concern with this material through the use of plain radiographs and computerized tomography (CT).
Methods: All patients received a Longevity HXLPE liner with tantalum beads and either a 28-mm or 36-mm femoral head. Twelve patients (6 in each head size group) agreed to return for 13-year RSA, plain radiograph, and CT follow-up. The 1-year and 13-year plain radiographs as well as the CT scans were analyzed for the presence of osteolysis.
Results: The 13-year mean ± standard error steady-state wear was 0.05 ± 0.02 mm with no significant increase over time or between the 2 head size groups. Two patients' CT scans showed radiolucent regions in the acetabulum of 4.51 cm^3 and 11.25 cm^3, respectively. In one patient, this area corresponded to a partially healed degenerative cyst treated with autograft during surgery. The second patient had an acetabular protrusio treated with autograft, and the CT scan revealed areas of remodeling of this graft. One patient's 13-year plain radiographs showed evidence of cup loosening and linear radiolucencies in zones 2 and 3.
Conclusion: There was no evidence of significant wear over time using RSA. The CT scans did not show evidence of osteolysis due to wear particles. These results suggest that this material has reduced wear compared to conventional polyethylene, irrespective of head size.

Aseptic component loosening, a consequence of progressive osteolysis caused by wear of the ultra high molecular weight polyethylene (UHMWPE), is the leading cause of failure in total hip arthroplasty (THA) [1-5]. The accumulation of polyethylene wear debris in the joint space induces a macrophage-charged response that results in accelerated bone resorption contiguous to the prosthesis, eventually leading to loosening of the component [3,6-10]. Because this phenomenon was identified 20 years ago as the sole cause of high THA failure rates, researchers and clinicians alike have focused intently on improving the surface against which the femoral head articulates to significantly reduce wear [2,11].

When UHMWPE is irradiated with an electron beam, highly reactive free radicals are produced, which combine with each other resulting in the formation of cross links [2,12]. Because some free radicals do not form cross links, the irradiated UHMWPE is subjected to a melting process to eliminate oxidation-prone free radicals by allowing additional cross links to form [2,12]. This highly cross-linked UHMWPE (HXLPE) was introduced in 1998 to decrease osteolysis secondary to the accumulation of polyethylene

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wear debris and increase the long-term survivorship of THA [2,11,13,14]. Thorough in vitro and in vivo evaluation of this polyethylene revealed that cross linking the material and diminishing the presence of free radicals reduced oxidation and significantly improved wear properties compared to conventional UHMWPE [2,4,5,9,15-19]. A lower prevalence of osteolysis among patients with HXLPE has also been reported, which is due to the smaller number and less frequent irregular morphology of wear particles compared to conventional UHMWPE [2,9]. Although HXLPE particle size is smaller, which may induce a greater inflammatory response than larger particles, HXLPE has a significantly lower volumetric wear rate than conventional UHMWPE, so the particulate load is substantially reduced [2].

Another challenge to the survivorship of THA is recurrent dislocation, which is often ameliorated through the use of larger head sizes. Greater stability in larger heads arises from an increase in the head-to-neck ratio and a larger jump distance, which therefore offers a broader angle of motion before impingement with the acetabular cup [20-22]. In the 1950s, Charnley pioneered the use of large diameter femoral heads but soon promoted significantly smaller head sizes after discovering that large heads induce an unfavorable amount of torque on the articulating surface, leading to loosening [23-25]. More recently, because bearing surfaces have advanced, the prevalence of larger head sizes rose again [26,27]. However, the success of larger heads was once again compromised by the increased wear of UHMWPE that they caused compared to the wear with their smaller diameter counterparts [28,29]. The preponderance of larger head sizes seen in the most recent years results from in vitro studies using hip simulators and clinical studies that have indicated that HXLPE has the ability to maintain its dramatically reduced wear rates compared to conventional UHMWPE, irrespective of head size [15,30-32].

Significantly improved wear properties and, therefore, a reduction in the once pervasive osteolysis, coupled with HXLPE's superior performance when articulating with larger head sizes, make this an attractive material for modern THA. Because osteolysis had devastating consequences to patients with UHMWPE, there was a need for close monitoring of patients with HXLPE into the long term to ensure that HXLPE did not produce the same outcome. Computerized tomography (CT) scans allow for a thorough examination for the presence of osteolysis that may not be detectable on plain radiographs. The objective of this study was (1) to assess the long-term in vivo penetration of the femoral head into the HXLPE and the long-term true wear of the HXLPE material articulating with either 28-mm or 36-mm femoral heads, using radiostereometric analysis (RSA) and (2) to assess plain radiographs and CT scans for the presence of any bone remodeling and/or osteolysis.

Methods

Patients and Surgery

Twenty-nine patients (18 males and 11 females) gave consent to participate in this prospective RSA study approved by the institutional review board at 1 center. Any patient who had a diagnosis of osteoarthritis, required primary THA, was between the ages of 20-75 years and had the ability to return for regular follow-up, was asked to participate. Patients who had difficulty understanding the protocol, inflammatory disease, bony structures that would have required nonstandard surgical techniques and/or nonstandard implants, or required revision surgery, were excluded.

The surgeries took place at 1 center by 4 arthroplasty surgeons from November 2001 to December 2003. Each patient received an HXLPE liner (Longevity, Zimmer, Warsaw, IN), a cementless acetabular cup (Triology, Zimmer), a tapered cementless press-fit femoral stem (either VerSys, Zimmer, or Natural Hip System, Sulzer Orthopaedics), and either a 28-mm or 36-mm cobalt-chromium femoral head. Sixteen patients received a 28-mm femoral head and 13 patients received a 36-mm head. Two surgeons implanted only 28-mm heads, and the other 2 surgeons implanted 36-mm heads except for in instances when a shell smaller than 50 mm was required. Either 12-14 (depending on acetabular cup size) tantalum beads of 1.0-mm diameter were placed into the HXLPE liner intraoperatively using a custom device, which allowed for RSA measurement of femoral head penetration into the HXLPE over time.

The formulation of the polyethylene used in these patients was made from stock UHMWPE which was subsequently irradiated to 100 kGy by an electron beam to form cross links. The irradiated UHMWPE was then melted above its melting point to allow residual free radicals to recombine and therefore reduce oxidation. The liners were then machined from this material and sterilized using gas plasma.

Thirteen-Year Follow-Up

This study was originally intended to follow these patients and obtain RSA and plain radiographs at 6 weeks, 6 months, 1, 2, 3, 4, 5, and 10 years after surgery. The study was extended to 13 years to allow for long-term assessment of the patients, and a CT scan was added to the protocol for this 13-year visit. All patients were asked to sign a new consent form for study participation for this visit due to the addition of the CT scans. Of the 29 patients originally enrolled in the study, 24 were eligible for participation at the 13-year interval because 2 patients were deceased, 1 had withdrawn consent to participate before the 10-year interval, 1 patient was revised for recurrent dislocation (28-mm head), and 1 patient was revised for a femoral fracture during the immediate postoperative period.

Twelve patients (8 males and 4 females; 6 patients in both the 28-mm and 36-mm head size groups) of the 24 eligible patients agreed to return for RSA films, plain radiographs, and a CT scan at the 13-year interval, and only these patients are included in this report (Fig. 1). Twelve patients were thus not included in the analysis: phone interviews were held with 9 patients who were unwilling to return for 13-year follow-up to ensure that their hips had not been revised, and 3 patients' phone numbers on record were out of service and, thus, unreachable.

Radiostereometric Analysis

From the immediate postoperative visit through the 5-year visit, all RSA images were taken in the standing position with one fixed and one portable x-ray source. In this orientation, the uniplanar calibration cage (cage 43, RSA Biomedical, Umeå, Sweden) with 2 digital cassettes was placed behind the standing patient and 2 radiographs were taken simultaneously. From 10 years through the most recent follow-up, all RSA films were taken in the supine position with the calibration cage beneath the patient. Two digital cassettes were placed within the cage and the film pair was taken with 2 fixed, ceiling mounted x-ray sources. It has been shown that standing films are comparable to supine films when measuring wear using RSA [33].

The UmRSA 6.0 software (RSA Biomedical) was used to measure femoral head penetration and the steady-state wear in the 3 orthogonal planes. Motion of the center of the femoral head with respect to the segment of the cup unit defined wear. The center of the femoral head was calculated by the program after manually marking the edge of the head. The cup unit segment was defined by at least 6 beads labeled in the polyethylene which were combined