The Journal of Arthroplasty 31 (2016) 1251–1255

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Primary Arthroplasty

Five-Year Experience of Vitamin E–Diffused Highly Cross-Linked Polyethylene Wear in Total Hip Arthroplasty Assessed by Radiostereometric Analysis

Audrey K. Nebergall, BA [a, *], Anders Troelsen, MD, PhD [a, b], Harry E. Rubash, MD [a], Henrik Malchau, MD, PhD [a], Ola Rolfson, MD, PhD [a, c], Meridith E. Greene, PhD [a]

[a] Department of Orthopaedics, Harris Orthopaedic Laboratory, Massachusetts General Hospital, Boston, Massachusetts
[b] Department of Orthopaedics, Copenhagen University Hvidovre Hospital, Hvidovre, Denmark
[c] Department of Orthopaedics, Institute of Clinical Sciences at Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

ARTICLE INFO

Article history:
Received 15 September 2015
Received in revised form
17 November 2015
Accepted 1 December 2015
Available online 17 December 2015

Keywords:
total hip arthroplasty
radiostereometric analysis
polyethylene
vitamin E
patient-reported outcome measures

ABSTRACT

Background: Vitamin E–diffused highly cross-linked polyethylene (VEPE) was developed to reduce oxidation without compromising mechanical strength. The purpose of this study was to evaluate VEPE in vivo using radiostereometric analysis (RSA) and patient-reported outcome measures (PROMs).
Methods: Fifty-one hips were enrolled. Each patient received a VEPE liner, a porous titanium shell, and an uncemented stem with a 32-mm cobalt–chrome femoral head. Tantalum beads were inserted into the VEPE to measure femoral head penetration using RSA. RSA radiographs and PROMs were obtained preoperatively immediately after surgery, 6 months, 1, 2, 3, and 5 years after surgery.
Results: Forty-seven hips returned at 3 years, and 42 hip at 5 years. The mean ± standard error of the mean proximal head penetration into the polyethylene was 0.06 ± 0.01 at 5 years. The amount of head penetration did not change significantly with increasing time in vivo. The mean ± standard error of the mean Harris Hip Score was 58 ± 2 preoperatively, which improved significantly to 93 ± 2 at 5 years ($P < .001$).
Conclusion: The head penetration into VEPE liners was low compared with non-VEPE at 5 years. After settling of the liners in the early period, no significant head penetration occurred from 2- to 5-year follow-up. All PROMs improved significantly from preoperative to postoperative and remained very favorable at 5 years. This study documents the longest-term evaluation of in vivo wear performance of VEPE.

Long-term performance of total hip arthroplasty (THA) is often compromised by implant loosening secondary to osteolysis caused by wear of the ultrahigh molecular weight polyethylene (UHMWPE) lining the acetabular shell [1-4]. Cross-linking of UHMWPE through irradiation lowers wear compared with conventional nonirradiated polyethylene but also produces free radicals, which induces oxidation [5,6]. The highly cross-linked UHMWPE (HXLPE) may be subjected to a melting process, which allows further cross-linking of the material, thereby reducing the presence of free radicals [4,7]. However, melting after irradiation diminishes the strength of the material which may increase the risk for fracture in the future [8,9]. Alternatively, if HXLPE is annealed, fatigue strength is not as compromised as it is during melting, but free radicals remain, which may cause oxidation [4,8,10-14].

Vitamin E–diffused HXLPE (VEPE) was developed to address some of the shortcomings of HXLPE; namely to maintain low wear and eliminate free radicals while not compromising fatigue strength [8,10,12,15]. The added vitamin E stabilizes the residual free radicals by hindering the oxidative chain reactions of primary and secondary free radicals, thereby eliminating the need for

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.2015.12.023.

Clinical Trials Registration: NCT005519.

This study was funded by Biomet, Inc (Warsaw, IN) and the Harris Orthopaedic Laboratory (Boston, MA).

* Reprint requests: Audrey K. Nebergall, BA, Harris Orthopaedic Laboratory, Massachusetts General Hospital, 55 Fruit Street, Boston, MA, 02114.

http://dx.doi.org/10.1016/j.arth.2015.12.023
0883-5403/

melting [5]. Comprehensive in vitro evaluation has shown that the antioxidative properties of vitamin E improve performance by stabilizing free radicals while retaining the physical properties and strength of HXLPE [14,16,17].

Because the wear of HXLPE is very low compared with conventional polyethylene and wear of VEPE is expected to be comparable with that of HXLPE, it is necessary to use the most accurate and sensitive measurement method to detect penetration early. Radiostereometric analysis (RSA) was used in this study as it is the most accurate method of measuring femoral head penetration over time in THA [18,19]. Because of the accuracy of RSA, it is a valuable tool for early prediction of long-term implant prognosis in small cohorts [18-21]. This highly sensitive method allows for the use of smaller cohorts than other wear measurement techniques. Other techniques require much larger sample sizes to show the same effect as RSA. In addition, small cohort RSA studies are a critical step in evaluating new technologies according to Malchau's stepwise introduction [22]. The purpose of this prospective clinical study of 51 THAs was to evaluate femoral head penetration into the VEPE liners up to 5 years postoperatively. RSA was used to accurately measure relative displacement of the center of the femoral head compared with the polyethylene liner over time. Patient-reported outcome measures (PROMs) were evaluated at each follow-up interval to determine the patient's perception of their outcome at 5 years.

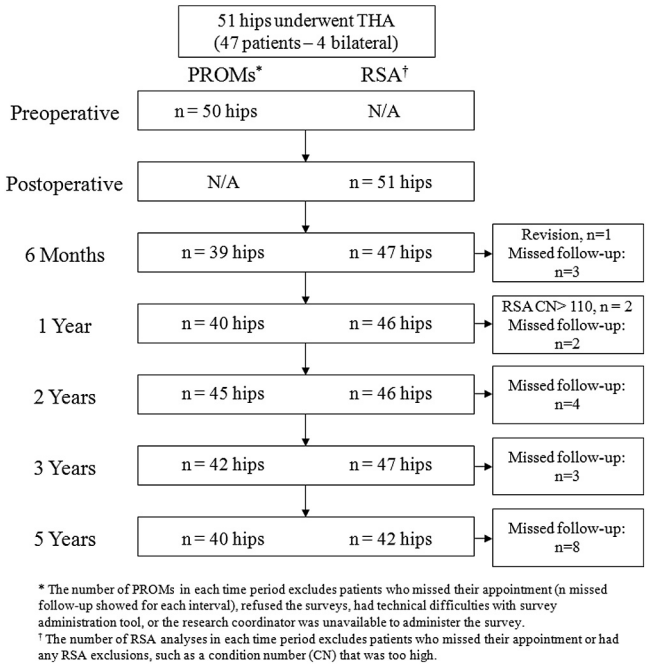

Fig. 1. Total number of hips included in the radiostereometric (RSA) and patient-reported outcome measure (PROM) analyses at each interval, with any necessary RSA exclusions and missed follow-up listed as branches. After taking the missed follow-up into account, all other patients missing PROMs either refused the surveys or the clinic had difficulty in administering the survey tool. Preoperative RSA films and postoperative PROMs are not applicable (N/A). THA, total hip arthroplasty.

Methods

Enrolled Patients

Forty-seven patients (32 males and 15 females), all of whom suffered from osteoarthritis, were recruited into a 5-year prospective, institutional review board–approved, RSA, and clinical outcome study. Inclusion criteria were patients with a diagnosis of osteoarthritis who required primary THA between the ages of 20-75 years. Any patient with a limited lifespan, difficulty in comprehending the study protocol, females who may become pregnant, or those who required a femoral head size other than 32 mm, were excluded from the study. Informed consent was obtained from all patients. Four patients had both hips enrolled in the study, for a total of 51 observed hips. All surgeries were performed at 1 center by 4 arthroplasty surgeons. The average age at the time of surgery was 59 years (range, 26-75 years).

Each patient received a VEPE liner (E1 antioxidant infused technology), a highly porous titanium acetabular shell (Regenerex), a lateralized, proximally porous-coated uncemented femoral stem (Taperloc), and a modular 32-mm cobalt–chromium femoral head (all components were from Zimmer Biomet Holdings, Inc, Warsaw, IN). Screws were inserted into the acetabular shell according to surgeon preference and either a posterolateral or anterolateral approach was used. A customized jig was used to press-fit 12 or 14 (depending on cup size) tantalum beads (1.0-mm diameter) into predrilled holes of each antirotational tab of the VEPE liner during surgery. Biplanar RSA radiographs were taken in the immediate postoperative period before discharge from the hospital, or if this was not possible, at the 2- to 6-week follow-up appointment. The average (range) of postoperative follow-up was 15 days (0-43 days). Additional RSA radiographs were obtained postoperatively at 6 months, 1, 2, 3, and 5 years. The total number of hips included in the RSA analysis at each interval was 47 hips at 6 months and 1 year, 46 at 2 years, 47 at 3 years, and 42 at 5 years (Fig. 1). As this was an efficacy study to establish early safety of VEPE, a control cohort was not recruited. At the time of study design, retrieval reports showed midterm oxidation of HXLPE; therefore, historical RSA wear measurements of HXLPE were used for comparison with this cohort [6,23].

Radiostereometric Analysis

Biplanar RSA views of the patient's operated hip were captured simultaneously using 2 fixed x-ray sources and a uniplanar calibration cage (cage 43; RSA Biomedical, Umeå, Sweden) with digital cassettes positioned beneath the examination table and the patient's operative hip. Each patient was oriented with their hip and the implant centered within calibration cage in both foci, which served as a frame of reference for the measurements over time. The UmRSA 6.0 software (RSA Biomedical) was used to analyze patient films. A three-dimensional reconstruction of the acetabular unit segment at each subsequent follow-up visit was derived from the calibration cage and the tantalum beads.

The backside of the shell was combined with the beads in the liner to make one segment that used a greater point count in the analysis than using the liner alone, thus allowing for more precise RSA measurements [24]. This acetabular unit (shell + liner) segment consisted of up to 6 matched beads (visible in both foci) in the liner and 3 points automatically assigned to the backshell by the software using edge detection. The center of the femoral head was defined as a single point, which was calculated from automated edge detection. Using the postoperative film as the baseline, the relative motion of the center of the femoral head to the acetabular unit was compared in all subsequent image pairs to determine femoral head penetration over time. The normal course for liner wear measurements involves an initial settling/bedding-in period (up to 1 year), followed by a more linear wear pattern (penetration after 1 year). To differentiate settling from true wear, penetration was defined by comparing all films back to the immediate postoperative film (as such, penetration included the settling period)