Radiostereometric Analysis Comparison of Wear of Highly Cross-Linked Polyethylene Against 36- vs 28-mm Femoral Heads

Charles R. Bragdon, PhD,*† Meridith E. Greene, BS,*† Andrew A. Freiberg, MD,*† William H. Harris, MD,‡ and Henrik Malchau, MD*†

Abstract: This study used radiostereometric analysis (RSA) to compare the femoral head penetration of 28- vs 36-mm-diameter femoral heads into highly cross-linked polyethylene in 2 groups of total hip arthroplasty patients. Thirty patients were enrolled in this RSA study using highly cross-linked polyethylene (Longevity, Zimmer Inc, Warsaw, Idaho) against either 28- or 36-mm-diameter cobalt chrome femoral heads. At 3-year follow-up, there was no significant difference in the total average femoral head penetration, including both creep and wear, using 3 methods of RSA measurement between the 2 groups. Importantly, after bedding-in, there was no further significant increase in the amount of femoral head penetration (ie, wear) with either head size between years 1 and 3. There were no radiographic signs of lysis or radiolucencies at a minimum 3-year follow-up. **Key words:** RSA, total hip arthroplasty, wear, hip, outcomes, polyethylene.
© 2007 Published by Elsevier Inc.

A new formulation of electron beam (e-beam)–irradiated and subsequently melted highly cross-linked polyethylene was first used clinically in total hip arthroplasty (THA) in December of 1998, and this material is now widely used in hip arthroplasty surgery. Extensive preclinical testing indicated that the cross-linked material had superior wear properties compared with the conventional polyethylene that was used in total hip arthroplasty at the time [1-3]. In addition, because of the melting step of the process, which reduces the free radicals created at the time of irradiation to undetectable levels, this cross-linked polyethylene does not undergo oxidation changes over time [1]. These oxidative changes have been shown to adversely affect the long-term mechanical properties of the material. Several early clinical reports using radiostereometric analysis (RSA) and other computer-assisted methods of measuring in vivo wear of THA indicate little to undetectable amounts of wear of the e-beam–irradiated polyethylene in vivo using standard-sized femoral heads [4,5].

The first THA implants introduced by Charnley et al [6] had an articulation consisting of a 42.8-mm femoral head. This concept of mimicking the size of the native femoral head was aimed at retaining hip stability and range of motion while avoiding component-on-component impingement. After early failures of the reconstruction due to the loosening of the components from the bone and wear of the Teflon bearing, the concept of the low-friction arthroplasty was introduced, which used polyethylene as the acetabular-bearing material and a femoral head diameter of 22.2 mm [7]. Over time, the diameter of the femoral head has been increased to include a selection of conventional head sizes ranging from 22 to 32 mm in

*From the *Orthopaedic Biomechanics and Biomaterials Laboratory, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts; †Department of Orthopaedic Surgery, Adult Reconstructive Unit, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts; and ‡Department of Orthopaedic Surgery, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts.*
Submitted January 16, 2007; accepted March 7, 2007.

Benefits or funds were received in partial or total support of the research material described in this article from Zimmer Inc (Warsaw, Ind).
Reprint requests: Charles R. Bragdon, PhD, Jackson 1126 Massachusetts General Hospital, Boston, MA 02114.
© 2007 Published by Elsevier Inc.
0883-5403/07/1906-0004$32.00/0
doi:10.1016/j.arth.2007.03.009

diameter. Several studies have now correlated increased polyethylene wear with increasing diameter of the femoral heads and increased impingement and dislocations with smaller diameter femoral heads [8-15]. In clinical practice using conventional polyethylene, the selection of head size has relied on a balance between minimizing wear and achieving joint stability while avoiding impingement. In vitro wear-testing results of e-beam–irradiated and subsequently melted, highly cross-linked polyethylene suggested that it is now possible to revisit the use of larger-diameter femoral heads in hip arthroplasty [16,17].

The most accurate method of measuring wear of polyethylene in THA patients is by using RSA, a 2-plane radiographic technique that reproduces 3-dimensional geometry [18-20]. This technique, developed by Goran Selvik [21], has been used in a number of orthopedic applications, where precise measurements of relative displacements are needed from radiographic images. However, this technique requires that a number of tantalum beads be placed into the acetabular implant. The need for these added markers limits the number of patients that can be enrolled in a clinical study. In addition, some implants, such as those made of cobalt chrome or tantalum metal, are too radiodense to allow visualization of the tantalum markers. Recently, a new technique has been developed that can locate the acetabular component by using image analysis of the implant projection to determine its 3-dimensional position [22].

The purpose of this study was twofold: the first is to use the standard RSA technique to assess the rate of penetration of the femoral head in 2 groups of THA patients who have received a form of highly cross-linked polyethylene that has markedly improved wear resistance; one group had a 28-mm-diameter femoral head and the other group had a larger, 36-mm-diameter femoral head. It is hypothesized that the penetration of the femoral head into the polyethylene will be significantly less using the cross-linked polyethylene compared with the conventional polyethylene and that there would be no increase in wear when a larger-diameter femoral head was used in conjunction with a highly cross-linked polyethylene. The second purpose was to perform a comparative study of the results of (*a*) the new marker-free RSA method and (*b*) a shell + marker method with that of (*c*) the standard RSA method which uses markers placed in the polyethylene acetabular component using the same set of radiographic films. It was hypothesized that the results would be similar using the 3 techniques.

Methods

Institutional review board approval was obtained for this nonconsecutive, nonrandomized clinical study. Thirty patients in need of primary THA were enrolled in this RSA hip study in which all patients received e-beam–irradiated and subsequently melted, highly cross-liked polyethylene. Sixteen patients received cementless Trilogy Acetabular components (Zimmer Inc, Warsaw, Ind) with 28-mm-diameter femoral heads, and 14 patients received the same type of components with a 36-mm femoral head diameter. Depending on the outer diameter of the polyethylene insert, up to 18 tantalum beads, 1.0 mm in diameter, were press fit into the peripheral flange of the polyethylene liner before insertion into the metal shell using a custom made alignment jig at the time of surgery (Fig. 1). Initial standing RSA radiographs were taken at the time of the first postoperative office visit within 6 weeks after surgery. Uniplanar standing radiographs of each patient were obtained in conjunction with the RSA calibration cage 43 (RSA Biomedical, Umea, Sweden). Subsequent radiographs were scheduled for 6 months postoperatively, at 1 year postoperatively, and yearly thereafter.

Femoral head penetration measurements were performed using the latest UmRSA software package version 6.0 (RSA Biomedical). This version can either use the 3-dimensional position of the tantalum markers to locate the acetabular component or use an edge-detection algorithm to determine the 3-dimensional center and alignment of the acetabular component based on the outside curvature of the shell and the rim of the component. Three different configurations of tantalum beads and the back shell were used to determine the penetration of the femoral head into the polyethylene liner. The standard method compared the position of the femoral head to the tantalum markers in the liner. In the markerless method, the penetration of the head was calculated with respect to the back shell without relying on any tantalum beads, and in the shell + marker method, the penetration of the head was calculated with respect to a combination of the beads in the liner and the back shell. Therefore, the shell + marker method used the most information in each radiograph. The 6-week films were used as reference films, and the total superior penetration values were calculated at each radiographic follow-up, and these values were normalized to time to

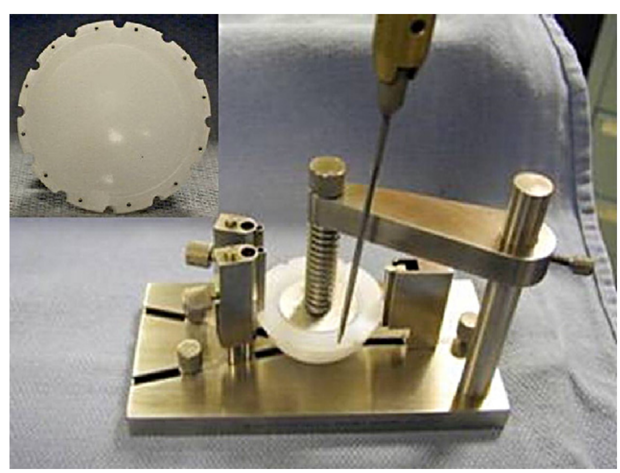

Fig. 1. Custom-made alignment jig used to press fit tantalum beads into the peripheral flange of the polyethylene liner before insertion into the metal shell with inlay image of completed polyethylene liner with tantalum beads.

give the total superior penetration rate. The steady-state wear rate was calculated in a similar fashion using the 1-year films as the reference for the subsequent annual radiographic follow-ups.

Statistical comparison of the results obtained by the 2 new methods was performed using a Mann-Whitney test. Results were judged to be significant at $P \leq .05$.

Results

The initial group of patients enrolled in the study consisted of 19 men and 11 women with an average of 56.1 (range, 36-77) years of age at surgery. The most common primary diagnosis was osteoarthritis (12 patients). Additional primary diagnoses were developmental abnormalities (7 patients), avascular necrosis (4 patients), slipped capital femoral epiphysis (2 patients), and other (5 patients). Since surgery, 4 patients refused follow-up for the study, and 1 hip was revised because of recurrent dislocation, leaving 25 patients for follow-up. Based on the most recent follow-up, the average self-administered outcome measures of this group were as follows: Harris hip score of 91.1, University of California at Los Angeles activity score of 4.6, total Western Ontario and McMaster Universities Osteoarthritis Index score of 11.3, Short Form-36 score of 73.1. No signs of osteolysis were present in any of the follow-up radiographs for any of the patients.

There was no significant change in femoral head penetration measured after the bedding-in period (ie, wear) from 1 to 3 years of follow-up for any analysis method or between the 2 head-size groups. There was no significant difference in the median rate of femoral head penetration for the 28-mm group or the 36-mm group among the 3 analysis methods used to determine the magnitude of femoral head penetration (Table 1), nor was there a significant difference in the median femoral head penetration rate between the 2 head sizes for any of the 3 analysis methods.

The shell + marker method uses the most information available in each radiograph. Using this method, the variance in the measurement of the 28-mm group was the lowest of the 3 methods. The variance in the measurement of the 36-mm group was also significantly lower with this method compared with the standard method ($P = .011$). Hereafter, the results of the shell + marker method are presented in detail.

At 1-year follow-up the median total femoral head penetration of the 28-mm femoral head group as measured by the shell + marker method was 0.055 ± 0.035 mm (Fig. 2). At 3-year follow-up, there was no significant change in the total femoral head penetration (0.062 ± 0.032 mm, $P = .93$). At 1-year follow-up, the median femoral head penetration of the 36-mm femoral head group was 0.070 ± 0.022 mm and not significantly different compared with that of the 28-mm group ($P = .88$). At 3-year follow-up, the penetration was 0.062 ± 0.063 mm/y, not significantly changed from that of year 1 ($P = .079$) and not significantly different compared with that of the 28-mm group ($P = .11$). The penetration measured at 3-year follow-up was similar for the 2 head sizes ($P = .37$).

In calculating the total femoral head penetration rates from the data of the shell + marker method, there was a significant decrease in the median rate of penetration for both the 28- and 36-mm femoral heads between 1-year and 3-year follow-up ($P = .035$ and $P = .037$, respectively) (Table 1), resulting from the fact that there was no significant change in the overall penetration of the 28- or 36-mm heads during this period (Fig. 2).

The median steady-state wear at 2 and 3 years for the 28- or 36-mm femoral head groups was below the detection limit of the RSA method. There was no significant difference in the median steady-state wear (Fig. 3) or the median steady-state wear rate (Table 2) at 2 and 3 years for either the 28- or 36-mm femoral head group.

Conclusion

Regardless of analysis method, no significant measurable wear of the highly cross-linked polyethylene was detected in either group. The 3 analysis methods were found to yield comparable femoral head penetration results. The results obtained using the marker-free version of the RSA software from the same set of radiographs show good agreement with the standard RSA method and shell + marker RSA method, which use tantalum beads attached to the implants. This method allows inclusion of images in which a sufficient number of markers are not visible for conventional RSA evaluation. Also, it would be of special utility when the radiodensity of the implant material interferes with the visualization of the implant markers. However, because the shell + marker method uses the most information available on the radiograph, it is

Table 1. Median Penetration Rate and SE at Each Follow-Up for Each of the 3 Methods and 2 Head Sizes

Method and Head Size (mm)	PO—1 Year (mm/y)	PO—2 Years (mm/y)	PO—3 Years (mm/y)
28 Standard RSA	0.057 ± 0.044	0.025 ± 0.019	0.035 ± 0.040
28 Shell + marker	0.054 ± 0.031	0.037 ± 0.010	0.021 ± 0.011
28 Markerless	0.068 ± 0.017	0.054 ± 0.010	0.019 ± 0.016
36 Standard RSA	0.111 ± 0.041	0.055 ± 0.016	0.046 ± 0.026
36 Shell + marker	0.077 ± 0.025	0.023 ± 0.023	0.021 ± 0.023
36 Markerless	0.037 ± 0.027	0.041 ± 0.014	0.015 ± 0.015

PO indicates postoperative.

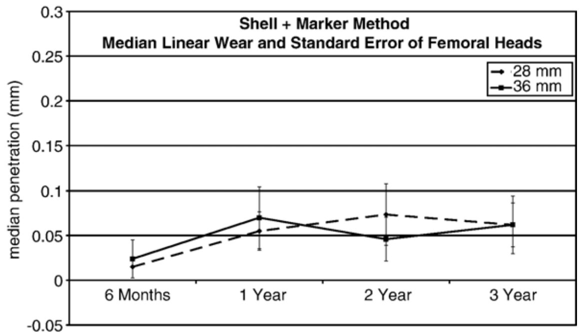

Fig. 2. Median superior penetration and SE of femoral heads within the 2 groups of patients using the shell + marker RSA method.

the most stable of the 3 methods. Therefore, when possible, femoral head penetration measurements are best performed using both the tantalum markers and the edge detection of the back shell.

In this study, using the most precise method of radiographic measurement to evaluate the use of a 36-mm-diameter femoral head against highly cross-linked polyethylene, we found no difference in the superior penetration of the femoral head at 3 years compared with the use of a 28-mm femoral head. The penetration measurements presented are based on the initial follow-up radiographs and therefore include the early bedding-in of the femoral head due to plastic deformation of the polyethylene insert as well as true wear. There was a significantly higher rate of penetration occurring between the postoperative film and the 1-year film than that of the 3-year film for both the 28- and 36-mm femoral heads, but this is accounted for in the bedding-in process of the polyethylene. Because there is no further change in the total penetration after the first year, the penetration rate decreases because of the same amount of penetration is being divided by greater and greater amounts of time. After 1 year, there is no significant change in the magnitude of femoral head penetration for either femoral head size.

The extremely low steady-state wear rates reflect that no significant measurable wear of the polyethylene liner after the bedding-in has occurred. The magnitude of bedding-in that occurs in the first year with this highly cross-linked material has been measured under in vitro loading conditions to be approximately 0.1 mm, indicating that very little actual wear has occurred in either head-size group in this clinical study [23].

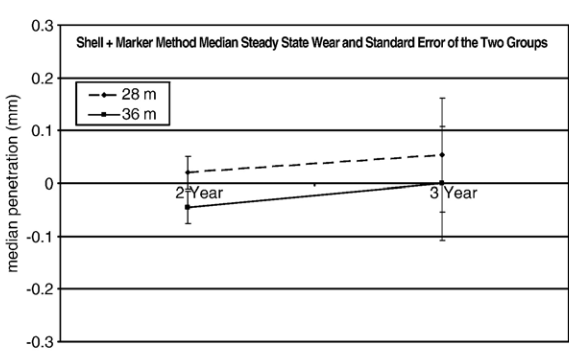

Fig. 3. Median steady state wear and SE within the 2 groups of patients using the shell + marker RSA method.

Table 2. Median Steady-State Wear Rate and SE at 2 and 3 Years' Follow-Up for Each of the 2 Head Sizes Using the Shell + Marker RSA Method

Head Size	2 Years	3 Years
28 mm	0.018 ± 0.018	0.026 ± 0.024
36 mm	−0.041 ± 0.030	0.000 ± 0.058

References

1. Muratoglu OK, Bragdon CR, O'Connor DO, et al. A novel method of cross-linking ultra-high-molecular-weight polyethylene to improve wear, reduce oxidation, and retain mechanical properties. Recipient of the 1999 HAP Paul Award. J Arthroplasty 2001;16:149.
2. Muratoglu OK, Merrill EW, Bragdon CR, et al. Effect of radiation, heat, and aging on in vitro wear resistance of polyethylene. Clin Orthop Relat Res 2003;253.
3. Bragdon C, Jasty M, Muratoglu O, et al. Third-body wear of highly cross-linked polyethylene in a hip simulator. J Arthroplasty 2003;18:553.
4. Digas G, Karrholm J, Thanner J, et al. Highly cross-linked polyethylene in total hip arthroplasty: randomized evaluation of penetration rate in cemented and uncemented sockets using radiostereometric analysis. Clin Orthop Relat Res 2004;6.
5. Bragdon CR, Barrett S, Martell JM, et al. Steady state penetration rates of electron beam–irradiated, highly cross-linked polyethylene at an average 45-month follow-up. J Arthroplasty 2006;21:935.
6. Charnley J. Arthroplasty of the hip: a new operation Lancet 1961;1:1129.
7. Charnley J. Total hip replacement by low-friction arthroplasty. Clin Orthop 1970;72:7.
8. Callaghan JJ, Brown TD, Pedersen DR, et al. Orthopaedic crossfire—larger femoral heads: a triumph of hope over reason! In the affirmative [see comment]. J Arthroplasty 2003;18(3 Suppl 1):82.
9. Callaghan JJ, Pedersen D, Johnston R, et al. Clinical biomechanics of wear in total hip arthroplasty. Iowa Orthop J 2003;23:1.
10. Jasty M, Goetz DD, Bragdon CR, et al. Wear of polyethylene acetabular components in total hip arthroplasty. An analysis of one hundred and twenty-eight components retrieved at autopsy or revision operations [see comments]. J Bone Joint Surg Am 1997;79:349.
11. Burroughs BR, Rubash HE, Harris WH. Femoral head sizes larger than 32 mm against highly cross-linked polyethylene Clin Orthop Relat Res 2002;150.

12. Burroughs BR, Hallstrom B, Golladay GJ, et al. Range of motion and stability in total hip arthroplasty with 28-, 32-, 38-, and 44-mm femoral head sizes. J Arthroplasty 2005;20:11.
13. Turner RS. Postoperative total hip prosthetic femoral head dislocations. Incidence, etiologic factors, and management. Clin Orthop Relat Res 1994;196.
14. Hedlundh U, Ahnfelt L, Hybbinette CH, et al. Dislocations and the femoral head size in primary total hip arthroplasty. Clin Orthop 1996;333:226.
15. Fackler CD, Poss R. Dislocation in total hip arthroplasties. Clin Orthop Relat Res 1980;169.
16. Bragdon CR, Jasty M, Muratoglu OK, et al. Third-body wear testing of a highly cross-linked acetabular liner: the effect of large femoral head size. J Arthroplasty 2005;20:379.
17. Muratoglu OK, Bragdon CR, O'Connor D, et al. Larger diameter femoral heads used in conjunction with a highly cross-linked ultra-high molecular weight polyethylene: a new concept. J Arthroplasty 2001;16(8 Suppl 1):24.
18. Bragdon CR. Evaluations of methods of measuring wear of polyethylene acetabular components in total hip arthroplasty. PhD Thesis, Department of Orthopaedics, Institute of Surgical Sciences, Göteborg, University, Sweden, 2004; [ISBN 91-628-6154-9].
19. Bragdon CR, Estok DM, Malchau H, et al. Comparison of two digital radiostereometric analysis (RSA) methods in the determination of femoral head penetration in a total hip replacement phantom. J Orthop Res 2004;22:659.
20. Bragdon CR, Malchau H, Yuan X, et al. Experimental assessment of precision and accuracy of radiostereometric analysis for the determination of polyethylene wear in a total hip replacement model. J Orthop Res 2002;20:688.
21. Selvik G. Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system. Acta Orthop Scand Suppl 1989;232:1.
22. Borlin N, Rohrl SM, Bragdon CR. RSA wear measurements with or without markers in total hip arthroplasty. J Biomech 2006;39:1641.
23. Estok DM, Bragdon CR, Plank GR, et al. The measurement of creep in ultrahigh molecular weight polyethylene: a comparison of conventional versus highly cross-linked polyethylene. J Arthroplasty 2005;20:239.