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Clinical Multicenter Studies of the Wear Performance of Highly Crosslinked Remelted Polyethylene in THA

Charles R. Bragdon PhD, Michael Doerner BS, John Martell MD, Bryan Jarrett BS, Henrik Palm MD, Multicenter Study Group, Henrik Malchau MD, PhD

Abstract

Background Highly crosslinked polyethylene (HXLPE) in THA was developed to reduce particle-induced periprosthetic osteolysis. A series of clinical studies were initiated to determine the clinical efficacy as judged by patient-reported scores, radiographic osteolysis, and wear analysis of one form of HXLPE.

Questions/purposes The purposes of this series of studies were to (1) determine the wear rates of one form of HXLPE; (2) report long-term (7–10 years) patient-reported outcome measures; (3) assess the effect of femoral head size on wear; and (4) determine the incidence of periprosthetic osteolysis.

Methods A single-center and two multicenter studies were conducted on 768 primary patients (head size 26–36 mm) undergoing THA at eight medical centers. Patient-reported outcome scores, radiographic grading for osteolysis, and radiographic wear evaluation were performed.

Results Serial plain radiographs showed no periprosthetic osteolysis in the three studies. The average femoral head penetration rates did not correlate with time in vivo for patients with standard femoral head sizes. Although there was an indication of higher wear in patients with 36-mm diameter femoral heads, it was below the threshold for producing osteolysis.

Conclusions The introduction of this HXLPE substantially improved the prognosis of patients after THA up to 13 years as judged by clinical scores, incidence of osteolysis, and polyethylene wear measurements.

Level of Evidence Level III, therapeutic study. See the Guideline for Authors for a complete description of levels of evidence.

Multicenter Study Group: Harry E. Rubash MD, Young-Min Kwon MD, PhD, John Clohisy MD, Richard White MD, Craig Della Valle MD, Daniel Berry MD, Paul F. Lachiewicz MD, Kim Bertin MD, Per-Erik Johanson MD, William H. Harris MD

H. E. Rubash, Y.-M. Kim, W. H. Harris
Massachusetts General Hospital, Boston, MA, USA

J. Clohisy
Washington University in St Louis, St Louis, MO, USA

R. White
Presbyterian Hospital, Albuquerque, NM, USA

C. Della Valle
Rush University Medical Center, Chicago, IL, USA

D. Berry
Mayo Medical School, Rochester, MN, USA

P. F. Lachiewicz
Chapel Hill Orthopedic Surgery and Sports Medicine, Chapel Hill, NC, USA

K. Bertin
Utah Bone & Joint Center, Salt Lake City, UT, USA

P.-E. Johanson
Sahlgrenska University Hospital, Gothenburg, Sweden

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This work was performed at The Harris Orthopaedic Laboratory, Massachusetts General Hospital, Boston, MA USA.

C. R. Bragdon (✉), M. Doerner, B. Jarrett, H. Malchau
The Harris Orthopaedic Laboratory, Massachusetts General Hospital, 55 Fruit Street, GRJ 1126, Boston, MA 02114, USA
e-mail: cbragdon@partners.org

J. Martell
University of Chicago Medical Center, Chicago, IL, USA

H. Palm
Hvidovre University Hospital, Copenhagen, Denmark

Introduction

Osteolysis secondary to polyethylene wear debris generation has been identified as the leading cause of late-term failure of total joint arthroplasties [25, 27–29, 38–40, 52, 53]. The incidence of periprosthetic osteolysis around primary THA with conventional polyethylene has been reported as high as 37% at 8 to 10 years [55]. Highly crosslinked polyethylene (HXLPE) was introduced to decrease wear and periprosthetic osteolysis to increase the long-term survivorship of THA. Several methods have been developed to produce HXLPE [2, 22, 32, 42, 45]. One form of HXLPE, the electron-beam irradiated crosslinked and melted polyethylene, has been extensively evaluated in vitro with long-term wear simulation up to 20 million cycles as well as aggressive third-body wear testing using the Boston hip simulator (AMTI, Watertown, MA, USA) [3, 6, 44]. This series of preclinical studies documented both the reduction of secondary oxidation and improved wear of HXLPE by gravimetric analysis compared with conventional polyethylene. Electron beam-irradiated and melted HXLPE was cleared for clinical use by the FDA in 1998 and has now been used clinically for more than 10 years.

The early experience of Charnley using femoral head sizes as large as 41.5 mm in diameter revealed high wear of the plastic bearing surface used in THA, first with Teflon and then with high-molecular-weight polyethylene [15, 16, 54]. This led to the restriction of the diameter of the artificial femoral head to 32 mm or less [14, 15]. Preclinical studies of electron beam-irradiated and melted HXLPE indicated no measureable wear of the polyethylene using femoral diameters as large as 46 mm [43], allowing the return to Charnley's original concept of using femoral head diameters greater than 32 mm. The use of larger diameter femoral heads in THA affords greater ROM, decreased implant impingement, and protection against dislocation [10, 11, 13].

Early reports in the clinical performance of electron beam-irradiated and melted HXLPE at 2 to 5 years postoperatively indicated extremely low average in vivo annual wear rates ranging from negative values to 0.06 mm/year, high patient-reported outcome scores, and no signs of periprosthetic osteolysis [1, 5, 7, 18, 20, 21, 23, 47]. However, a recent clinical study suggested an association between larger diameter femoral head sizes (36 mm and 46 mm in diameter) and volumetric wear rates at 5 to 8 years followup [33]. In light of these early reports, continued long-term followup and performance evaluation were needed.

Therefore, the two clinical studies initiated by our laboratory at the time that this new formulation of HXLPE was made clinically available (1998 for standard head sizes and 2002 for larger head sizes) were continued. In addition, to increase the number of patients undergoing primary THA followed and to minimize the possible bias associated with single-center designer series, we have also partnered with several other centers to establish multicenter studies. The purpose of this article is to summarize the clinical, radiographic, and in vivo wear results generated by a single-center and two multicenter studies conducted by our laboratory of patients undergoing primary THA having electron beam-irradiated and melted HXLPE: (1) the single-center clinical study documented the longest term followup available; (2) one multicenter study assembled the largest number of patients with standard-sized femoral heads; and (3) the second multicenter study assembled the largest series of patients having THAs with femoral head diameters greater than 32 mm.

These clinical studies were designed to address the following research questions: Does the early reported decrease in wear with the use of HXLPE continue to midterm (7–10 years) followup? Are patient-reported outcome scores affected by the use of HXLPE? Can this decrease in wear be confirmed in a larger multicenter study? Does the wear rate increase with the use of femoral head sizes greater than 32 mm? Does the incidence of particle-induced periprosthetic osteolysis decrease with the use of HXLPE?

Materials and Methods

All patients received primary THA using cobalt-chrome femoral heads and electron beam-irradiated and melted HXLPE as a bearing couple. All components used are cleared by the FDA. All acetabular components were metal-backed concentric designs manufactured either by

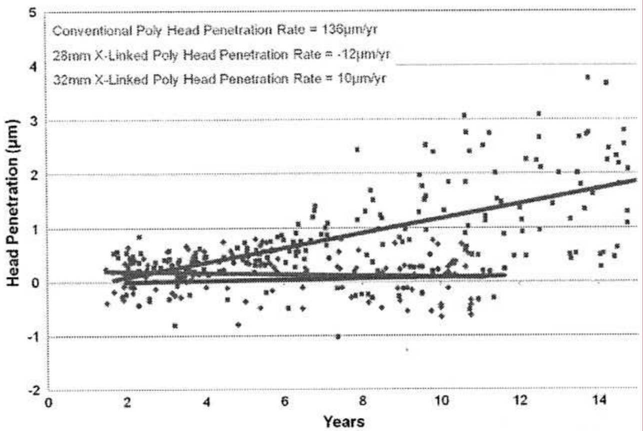

Fig. 1 Comparison of the femoral head penetration over time in patients receiving conventional or HXLPE with conventional head sizes using the group regression method. Although the femoral head penetrated is a constant rate of 0.1 mm/year with conventional polyethylene, there was no correlation between femoral head penetration and time in the HXLPE group regardless of femoral head size.

Table 2. Summary of wear rates: Study 1

Type of polyethylene and followup	First to last (μm/year)*	Group regression (μm/year)	Individual regression (μm/year)*
Conventional polyethylene	101 ± 140.8	139.6	99.2 ± 131.8
28-mm HXLPE minimum 7 years	19 ± 75	4.6	3.1 ± 109.4
32-mm HXLPE minimum 7 years	8.5 ± 86.2	0.8	10.0 ± 83.3
28/32-mm HXLPE minimum 7 years	18.0 ± 79.2	4.1	10 ± 105
28-mm HXLPE minimum 10 years	12.5 ± 43.7	−10.2	6.4 ± 73.4
32-mm HXLPE minimum 10 years	6.5 ± 73.8	11	8.1 ± 36
28/32-mm HXLPE minimum 10 years	10 ± 56.2	−4.9	12.7 ± 104.0

Mann-Whitney: $p < 0.002$ for all comparisons of HXLPE against conventional polyethylene; * values are mean ± SD; HXLPE = highly crosslinked polyethylene.

Table 3. Summary of clinical scores: Study 1 single-center study

Followup	Harris hip score	EQ-5D	UCLA
Minimum 7-year	87 ± 15	0.8 ± 0.2	6 ± 2
Minimum 10-year	85 ± 16	0.7 ± 0.3	6 ± 2

Values are mean ± SD.

Table 4. Summary of wear rates: Study 2, multicenter standard head

Time period	First to last (μm/year)*	Group regression (μm/year)	Individual regression (μm/year)*
Early period	8.6 ± 910	−0.03	−20.7 ± 229
Late period	9.8 ± 209	−40	1.0 ± 290
	p = 0.46	p = 0.12	p = 0.45

* Values are mean ± SD.

femoral head penetration rates to be analyzed in an early, 1- to 5-year, and a late period, greater than 5 years. There was no difference in the femoral head penetration rate between the early and late time periods ($p > 0.12$) (Table 5; Fig. 2).

The femoral head penetration data from the multicenter followup study with large-diameter femoral heads, Study 3, indicates an increase in penetration and volumetric wear with the use of large heads in one of the statistical methods used. In contrast, there was no difference in penetration or volumetric wear between standard head sizes (combined 28 and 32 mm) versus the 36-mm head size (Table 6). Using the longest followup method, we found a difference ($p = 0.0001$) in the linear and volumetric wear rates based on head size. This difference could not be demonstrated with either of the other two analysis methods, the individual regression method or the group regression method (Fig. 3).

Table 5. Summary of wear rates: Study 3, multicenter large head

Type of polyethylene	Linear wear		
	First to last (μm/year)*	Group regression (μm/year)	Individual regression (μm/year)*
28/32-mm HXLPE	17 ± 92.4	4.0	−5.2 ± 102.2
36-mm HXLPE	76 ± 167.1	27.0	15.3 ± 199.2
Mann-Whitney test	p = 0.0001	p = 0.185	p = 0.11
Type of polyethylene	Volumetric wear		
	First to last (mm^3/year)*	Group regression (mm^3/year)	Individual regression (mm^3/year)*
28/32-mm HXLPE	19.6 ± 27.2	2.0	1.9 ± 42.8
36-mm HXLPE	75.5 ± 81.9	15.2	4.3 ± 81.2
Mann-Whitney test	p = 0.0001	p = 0.43	p = 0.55

* Values are mean ± SD; HXLPE = highly crosslinked polyethylene.

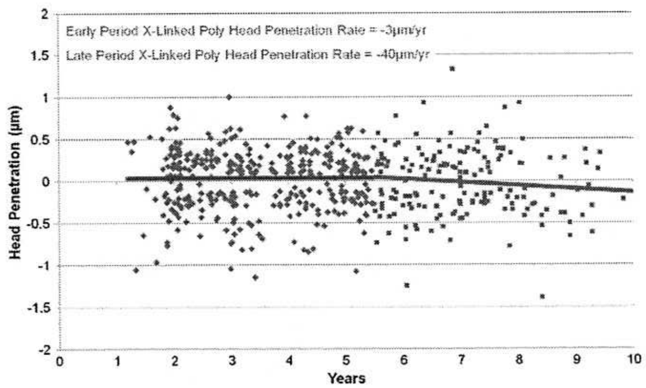

Fig. 2 Steady-state wear plotted against time with regression lines for the early and late periods. There was no difference in the rate of femoral head penetration between the early and late time periods.

The results of the radiographic analysis of all patients in the three studies revealed no indication of periprosthetic osteolysis around the acetabular or femoral components of any patient. None of the HXLPE components showed radiographic loosening, failure, or fracture. In addition, there are no reports from any of the centers of cases in which revisions were performed as a result of polyethylene wear in this study population. In contrast, in radiographic analysis of the 10-year followup films of the noncrosslinked polyethylene control group, the overall incidence of periprosthetic osteolysis was 13.5%, acetabular osteolysis was 3.75%, femoral osteolysis 11.90%, and osteolysis on both sides 2.50%. Furthermore, 22 of these patients (13.75%) have had revision surgery for reasons related to polyethylene wear and osteolysis after this 10-year radiographic evaluation.

Discussion

The high incidence of particle-induced periprosthetic osteolysis in THA [25, 27–29, 38–40, 52, 53] led to the development of HXLPE as a bearing surface. The formulation used in this study, irradiated and subsequently melted, has now been in clinical use for over 10 years. This series of clinical studies was designed to answer the following clinical questions: Does the early reported decrease in wear with the use of HXLPE continue to midterm