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

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Abstract

Background Highly crosslinked polyethylene (HXLPE) in THA was developed to reduce particle-induced peri-prosthetic 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 peri-prosthetic osteolysis.

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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.

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 post-operatively 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

Centerpulse Inc (currently Zimmer Inc, Warsaw, IN, USA) (Inter-opTM) or Zimmer Inc (TrilogyTM).

Study 1 was a single-center study on patients receiving primary THA from 1999 to 2002. The inclusion criteria for this study required that each patient had at least one followup radiograph at 7-year followup or greater. One hundred fifty-nine patients met these criteria. The number of hips contributed compared with the total number of cases performed at our center during the appropriate time period is shown (Table 1). This prospective registry study was designed to assess the impact of clinical and radiographic factors on the wear performance of electron beam-irradiated and melted HXLPE. Our arthroplasty service collects Level IV clinical data on patients undergoing THA in an institutional review board-approved joint registry. The registry was queried for patients fitting the inclusion criteria. There were 174 hips (159 patients) with minimum 7-year radiographic followup. A 28-mm femoral head was used in 100 hips and a 32-mm head was used in 74 hips. Eighty-eight were men and the age at surgery ranged from 31 to 85 years (average, 60 years). Time from surgery ranged from 7 to 13 years. A subset of 45 hips (42 patients) had a minimum 10-year followup. Of these hips, 29 had a 28-mm femoral head and 16 had a 32-mm femoral head. Twenty-four were men and the average age at surgery was 56 years (range, 33–79 years). Time from surgery averaged 12 years (range, 10–13 years). The clinical measures used to evaluate patients were the Harris hip score, EQ-5D, and the UCLA activity scores.

A set of patients with primary THA performed by a single surgeon (WHH) from 1984 to 1996 using conventional gamma sterilized in air polyethylene served as a historical control. This group consisted of 162 hips (145 patients) coupled with 26-mm or 28-mm femoral heads. These patients were matched by primary diagnosis and time from surgery. We recorded age at surgery, acetabular cup inclination angle, and acetabular cup version angle on all patients. Preoperatively and at each followup visit, we recorded an EQ-5D score [17], Harris hip score [26], and UCLA activity score [46]. The standard of care followup schedule at our institution is 1, 3, 5, 7, 10, and 13 years after surgery.

Study 2 was a retrospective multicenter followup study with standard femoral head sizes (26–32 mm). This study was designed to assemble a large patient cohort having specific followup criteria to determine if femoral head penetration rates increase after the first 5 years of in vivo use. Six academic centers agreed to contribute radiographic data to this study: Massachusetts General Hospital, Boston, MA, USA; Presbyterian Hospital, Albuquerque, NM, USA; Rush Medical Center, Chicago, IL, USA; Washington University, St Louis, WA, USA; Mayo Clinic, Rochester, MN, USA; and Sahlgrenska University Hospital, Goteborg, Sweden. Strict radiographic inclusion criteria were established that required a minimum of four radiographs per patient: one at 1 year; at least one from 2 to 4.5 years; one from 4.5 to 5.5 years; and at least one from 5.5 to 9 years followup. Four hundred fifty-one THAs (420 patients) performed between 1998 and 2003 were included in this

Table 1. Contributions of patient data by center

Centers	Hips contributed	Patients contributed	Recruitment range	Total primary THAs performed*
Study 1				
MGH	174	159	January 8, 1999, to December 16, 2002	1124
Study 2				
Albuquerque	39	39	July 3, 2000, to April 29, 2002	189
Goteborg	19	19	May 30, 2000, to December 8, 2003	71
Mayo	92	86	February 10, 1999, to July 11, 2003	907
MGH	215	197	August 2, 1999, to December 16, 2002	957
Rush	58	51	January 11, 2000, to July 5, 2002	727
Wash University	28	28	November 1, 1999, to January 31, 2003	140
Total	451	420		2991
Study 3				
Chapel Hill	83	74	December 2, 1999, to March 24, 2003	117
MGH	215	197	January 13, 1999, to September 27, 2004	1765
Utah	234	206	January 4, 2002, to July 25, 2006	280
Total	532	477		2162

* Totals represent the number of primary THA performed with this type of HXLPE with appropriate head sizes; some patients from MGH are common to all studies; the total number of patients represented in the three studies is 768; MGH = Massachusetts General Hospital; HXLPE = highly crosslinked polyethylene.

study. The number of hips contributed compared with the total number of cases performed at each center during the appropriate time period are listed (Table 1). The diameter of the femoral heads used was: 26 mm in eight hips; 28 mm in 225 hips; and 32 mm in 45 hips. In addition to the standard method of calculating wear rates described subsequently, wear rates were computed for two time periods, an early period and late period. The early period was from 1 year to 5.5 years and the late period was from 5.5 years to 9 years followup using all data points available for each patient. The 4.5- to 5.5-year film needed for inclusion acted as the end point for the early period and the starting point for the late period.

Study 3 was a multicenter followup study with large-diameter femoral heads. This study was designed to determine if the use of femoral heads greater than 32 mm in diameter resulted in an increase in volumetric wear. Three centers contributed patients to this study: Massachusetts General Hospital, Boston, MA, USA; Utah Bone & Joint Center, Salt Lake City, UT, USA; and Chapel Hill Orthopedic Surgery & Sports Medicine, Chapel Hill, NC, USA. The inclusion criteria required patients with primary THA using cobalt-chrome femoral heads (28, 32, or 36 mm), electron beam-irradiated and melted HXLPE as a bearing couple, a minimum 5-year followup, and at least a 1-year and 5-year radiograph. Five hundred thirty-two hips (477 patients) were included in this radiographic followup study having had their THAs performed from 1999 to 2006. The number of hips contributed compared with the total number of cases performed at each center during the appropriate time period is listed (Table 1). The diameter of the femoral heads used were: 28 mm in 130 hips; 32 mm in 105 hips; and 36 mm in 297 hips.

All plain radiographs of all the patients in the three studies were analyzed by a single external nontreating orthopaedic surgeon (HP) and graded for the presence of periprosthetic osteolysis at the bone/implant interface. The findings were approved by two attending orthopaedic surgeons (HM, YMK). Hip Analysis Suite software (University of Chicago, Chicago, IL, USA) was used to measure femoral head penetration into the polyethylene using all available AP radiographs obtained between the early postoperative to latest followup event [8, 41].

Linear and volumetric wear rates were calculated by three different techniques: (1) by calculating the change between the 1-year film and the longest followup film and dividing by time; (2) by creating a scatterplot of the penetration and volumetric change between the 1-year film and each subsequent followup film; and (3) by creating a scatterplot of penetration for each patient individually. Each technique used the 1-year film as the baseline so that the effect of polyethylene creep was minimized. In addition to reporting the wear data based on individual head sizes,

the wear data were also combined into groups of standard head sizes, which included 28-mm and 32-mm heads versus the 36-mm head size.

In the single-center study, Study 1, we compared age at surgery, acetabular cup inclination angle, acetabular cup version angle, EQ-5D score, Harris hip score, UCLA activity score, and linear wear rates between the current and historical control groups. The linear wear rates from the longest followup analysis method were used. Univariate Pearson correlations with respect to the variables and a multivariate analysis were performed. In all studies, linear and volumetric wear rates for the standard head sizes and large head sizes were compared using a Mann-Whitney test. The slopes of the population regression best fit lines were tested for differences at the 95% confidence level using a Zar test. Kruskal-Wallis analysis of variance was used to analyze the effect of femoral head size on wear.

Results

Wear rates from the single-center study (Study 1) were lower ($p < 0.002$ in all cases) in all groups having HXLPE at both minimum 7- and minimum 10-year followup when compared with the conventional polyethylene historical control group using all three analysis methods. In contrast to the control group, the femoral head penetration in the HXLPE did not increase over time after the first year nor did the scatter of the data increase with time (Fig. 1). There was no difference ($p = 0.23$ – 0.90) in the femoral head penetration rates of the patients with 28- mm or 32-mm femoral heads articulating against HXLPE at either the minimum 7-year or minimum 10-year followup interval (Table 2). There was no correlation between cup inclination/version and wear.

The latest clinical patient-reported outcome of patients with HXLPE (Table 3) did not vary between the minimum 7- and minimum 10-year followup groups. The average weighted Health Index, EQ-5D, of 0.7 and 0.8 are within the range of reported values of a normal population [31] as is 85 and 87 of the Harris hip score [9]. Although there are no norms in the literature for the UCLA activity score, the values reported here are consistent with generally acceptable values of patients undergoing primary THA. Therefore, we could find no differences in the patient-reported outcomes, which would indicate that the patients with HXLPE fared differently than the general population of patients undergoing primary THA.

There was no difference ($p = 0.45$) in the femoral head penetration rates among the three head size groups in the larger multicenter analysis (Study 2). The femoral head penetration data as derived from the three analytical methods (Table 4), were similar to that reported for the single-center series. The strict inclusion criteria of this study also allowed

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 at 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 ($\mu\text{m}/\text{year}$)*	Group regression ($\mu\text{m}/\text{year}$)	Individual regression ($\mu\text{m}/\text{year}$)*
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 $\pm$ 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 noncross-linked 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

Table 6. Summary of wear rates: Study 3, multicenter large head

Type of polyethylene	Linear wear		
	First to last ($\mu\text{m}/\text{year}$)*	Group regression ($\mu\text{m}/\text{year}$)	Individual regression ($\mu\text{m}/\text{year}$)*
28-mm HXLPE	19.0 ± 80.6	2.0	-3.4 ± 57.7
32-mm HXLPE	10.5 ± 102.5	1.0	-0.7 ± 121.3
36-mm HXLPE	76 ± 167.1	27.0	15.3 ± 199.2
Kruskal-Wallis	$p < 0.0001$	N/A	$p = 0.214$

Type of polyethylene	Volumetric wear		
	First to last (mm^3/year)*	Group regression (mm^3/year)	Individual regression (mm^3/year)*
28-mm HXLPE	7.3 ± 24.7	2.0	2.3 ± 23.5
32-mm HXLPE	9.3 ± 29.2	3.0	-0.6 ± 64.4
36-mm HXLPE	75.5 ± 81.9	15.2	4.3 ± 81.2
Kruskal-Wallis	$p < 0.0001$	N/A	$p = 0.721$

* Values are mean $\pm$ SD; HXLPE = highly cross-linked polyethylene; N/A = not available.

Fig. 3 The group regression graph of the multicenter large head series, Study 3. Although one analytical method indicated a difference in femoral head penetration rate for 36-mm femoral heads, there was no difference in the slope of the linear regression lines.

(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?

The primary limitation of this study, like with any long-term observational study, is in getting an increasingly aging group of patients to return for routine office visits. This raises concerns of study bias and calls into question whether

the results are generalizable and indicative of what can be expected in the larger population of patients undergoing THA. These concerns are especially relevant in single-surgeon or single-center studies such as Study 1 of this article. We have attempted to minimize such concerns by collecting data from a large number of medical centers across the United States and Europe with a large number of surgeons contributing patient radiographs for analysis. Another limitation of this study relates to the difficulty in accurately measuring small displacements of the femoral head into the acetabular component from plain radiographs

taken over a number of years. There is an inherent uncertainty in such measurements, which is compounded by variability in image quality. This limitation was addressed by assembling a large number of patient radiographs having multiple observations over time. It was further minimized by having a control cohort with polyethylene known to have a well-established average wear rate for comparison. Another limitation of this study is the lack of contemporary controls or randomization between conventional and HXLPE. However, Weinstein et al. [51], in a Spine Patient Outcomes Research Trial (SPORT) study, showed no result difference in cohorts randomized to different treatment modalities compared with the observational cohort exposed to the same treatment panorama.

The single-center prospective registry series (Study 1) address the issues of long-term wear performance and the possible effect of using a new technology on the long-term outcome of patients undergoing THA as judged by patient-reported outcome measures. We could not demonstrate an increase in the femoral head penetration over time in patients having conventional sized femoral heads (28–32 mm) in either the minimum 7-year followup group or the smaller minimum 10-year group. This is the largest and longest term single-center report on the clinical performance of this form of HXLPE. The patient-reported outcomes are in line with what one would expect of patients undergoing contemporary primary THA and may indicate that this patient group is representative of the current state of the art.

The multicenter study of patients undergoing primary THA, Study 2, of patients with conventional femoral head sizes of 28 and 32 mm, was stimulated by a preliminary report from a radiostereometric analysis center in Sweden, which indicated that there may be an increase in the rate of femoral head penetration after 5 years of *in vivo* use [30]. If true, this could suggest some type of change had occurred in the polyethylene. The study design of this multicenter study allowed for the assessment of wear rates at an early time period, up to 5 years from surgery, and a late time period after 5 years from surgery. This detailed evaluation of polyethylene performance is the first of its kind. This study provides the strongest data available indicating that the extremely low *in vivo* wear rates observed with this type of HXLPE remains unchanged over time.

The second multicenter study, Study 3, focused on the radiographic outcome and wear analysis of primary THA using femoral head diameters greater than 32 mm to determine if the wear of the HXLPE was affected with the use of larger diameter femoral heads. Unlike in the first two studies, the results from the three statistical methods used were not in agreement (Tables 5, 6). Although no differences could be demonstrated relating to femoral head diameter in Studies 1 and 2, which compared 28- and

32-mm heads, in Study 3, which combined 28- and 32-mm heads against 36-mm heads, one technique of data analysis, namely the first to last method, indicated an increase in both linear and volumetric wear among the 36-mm head size group. However, the other two data analysis techniques did not demonstrate a difference in either linear or volumetric wear based on femoral head diameter. This points out the strengths and weaknesses of each method. The strength of the first to last method is that it uses the maximum number of patients in the statistical analysis, whereas its weakness is that it does not use any radiographic measurement between the first year and latest followup. The strength of the group regressions method is that it uses all of the radiographic measurements available and its weakness is that the data cannot be used in multivariate analysis and it violates the rule that each wear observation should be treated independently. The strength of the individual regression method is that it treats each patient as an independent variable and the data can be used in a multivariate analysis, whereas its weakness is that many patients are excluded from the analysis as a result of the fact that each patient needs at least three radiographic measurements to create a slope of the linear regression line. Although the individual regression method is the most valid statistical approach, its use is best suited for very large populations with multiple intermediate observations. Therefore, in assessing radiographic wear data, because of these differing strengths and weaknesses, we continue to advocate the use of all three analytical methods. This approach allows other researchers to compare their data with this report in various ways depending on the nature of their followup. Although this study cannot conclusively determine if the wear rate of this material is affected by the use of large-diameter head sizes, the differences reported here are small and the wear is below the generally accepted threshold for producing periprosthetic osteolysis [22, 24].

The studies presented here indicate that the use of the formulation of HXLPE analyzed in these studies has resulted in a dramatic decrease in the rate of polyethylene wear in patients followed as long as 13 years after primary THA. In comparison with historical controls using conventional UHMWPE, the incidence of periprosthetic osteolysis resulting from polyethylene wear has been eliminated. Furthermore, although there are a few reports of using CT scans to identify extremely small lytic areas adjacent to the implants that cannot be seen on a plain radiographs [37], there have been no reports of clinical importance of periprosthetic osteolysis with the use of any form of HXLPE worldwide. Although other innovations that have been introduced to address periprosthetic osteolysis resulting from wear debris such as metal-on-metal and ceramic-on-ceramic bearings have resulted in the appearance of new complications such as pseudotumors

and squeaking [12, 34, 48–50], the modification to the existing polyethylene bearing material by adding crosslinks has not resulted in any unforeseen deleterious effects.

The stepwise approach to introducing new medical technology outlined by Malchau [35] was modified for the introduction of HXLPE and has been discussed by Malchau et al. [36]. Several additional outcome studies including randomized radiostereometric analysis evaluation were also started when electron beam and melted HXLPE was first made available for clinical use. These studies were conducted in coordination with our laboratory and others to provide early clinical performance data on this new bearing material [4, 7, 19, 20]. The data from these early studies indicated no adverse effects with the use of this new material and confirmed the preclinical in vitro wear data. These early reports were presented in major national and international orthopaedic scientific venues before their publication. As these early positive scientific findings were made public, larger diameter femoral heads greater than 32 mm were introduced for clinical use, which triggered other early clinical studies of patients receiving these larger diameter femoral heads [23]. This modified stepwise approach balanced the caution of using new technology with the desire to use a material that had the potential of drastically reducing the incidence of the major cause of late-term failure of THA, particle-induced periprosthetic osteolysis.

This series of clinical and radiographic studies of 768 patients is the largest study of patients undergoing primary THA having one formulation of HXLPE. We found an increase in linear and volumetric wear with femoral head diameters of 36 mm by using one statistical method; however, the magnitude of this increase in wear was small and to date not clinically important because no osteolysis was found in this cohort. This finding was not confirmed using the other two statistical methods. Although continued longer-term studies are warranted, the successful application of crosslinking technology has all but eliminated the incidence of polyethylene particle-induced periprosthetic osteolysis in THA.

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