Short-Term in Vivo Wear of Cross-Linked Polyethylene

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Background: Cross-linked polyethylene was developed to reduce volumetric wear in prosthetic joints. Hip simulator studies have shown promising results with regard to wear reduction. This study evaluated the short-term in vivo wear of a moderately cross-linked polyethylene.

Methods: Linear head penetration, as an assessment of in vivo polyethylene wear, was measured in two groups of patients after total hip replacement. Twenty-four hips received a conventional polyethylene insert and thirty-four, a cross-linked polyethylene liner; both inserts were manufactured by the same company. Linear and volumetric wear rates were measured on radiographs with use of a validated computer-assisted technique and were adjusted for patient-related factors. Patient activity was assessed by a computerized two-dimensional accelerometer worn on the ankle.

Results: Patients with a conventional polyethylene insert showed a mean linear wear rate of 0.13 mm per year and a mean volumetric wear rate of 87.6 mm^3 per year. The group with a cross-linked polyethylene liner showed a mean linear wear rate of 0.02 mm per year and a mean volumetric wear rate of 17.0 mm^3 per year. Wear in the group with cross-linked polyethylene was 81% lower than that in the group with conventional polyethylene ($p < 0.00001$). Accounting for differences in patient activity, the adjusted wear rates per million cycles for a patient weight of 70 kg were 53 mm^3 per million cycles for conventional polyethylene and 15 mm^3 per million cycles for cross-linked polyethylene, a 72% reduction ($p = 0.0002$). No factor, other than the type of polyethylene, was found to influence the difference in wear rates between the two groups.

Conclusions: The results of this study are promising. The in vivo wear reduction with this cross-linked polyethylene is consistent with the predictions of hip simulator studies.

Level of Evidence: Therapeutic study, Level II-1 (prospective cohort study). See Instructions to Authors for a complete description of levels of evidence.

Ultra-high molecular weight polyethylene has been the preferred acetabular bearing material in total hip replacements for more than thirty years[1]. The aggregate clinical experience has indicated a low probability for gross material failure in this application[2]. The fundamental limitation is wear resistance[3]. High volumetric wear has been associated with component loosening and osteolysis[4-7].

Cross-linking has been used to improve the wear resistance of polyethylene[8,9]. Wear simulator studies have indicated that cross-linking can reduce the type of wear that occurs in acetabular components by more than 95%[8,10,11]. However, laboratory wear simulations may not be predictive of in vivo performance. For example, hip simulator tests have indicated a 9% reduction in the wear of Hylamer polyethylene (DePuy DuPont Orthopaedics, Wilmington, Delaware)[12], but clinical experience has demonstrated higher in vivo wear rates[3,13,14]. Clinical studies of cross-linked polyethylene are, therefore, critical to confirm the results obtained from in vitro studies.

The manufacturing processes of the currently available acetabular bearing components differ with respect to the type of irradiation (gamma radiation or electron beam), the radiation dose, the method of thermal stabilization (remelting or annealing), machining, and final sterilization[15]. For this reason, each product should be considered separately, and the specific wear characteristics should be established through clinical studies.

This study compared the in vivo wear characteristics of Marathon cross-linked polyethylene (DePuy, Warsaw, Indiana) with a conventional polyethylene (Enduron; DePuy).

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Materials and Methods

The study protocol was approved by our institutional review board. In vivo wear rates, measured as linear head penetration, were measured in two groups of patients with well-functioning total hip replacements who received either cross-linked polyethylene or conventional polyethylene liners as the acetabular bearing and had a minimum of two years of radiographic follow-up. Patients were included on the basis of their willingness to participate in the activity-assessment protocol.

TABLE I Volumetric Wear Rates for the Conventional and Cross-Linked Polyethylene Liners

	Volumetric Wear* *(mm³ per yr)*			
		Size of Femoral Head		
	Total	28 mm	32 mm	P Value
Conventional polyethylene liners	87.6 ± 79.2 (24)	69.6 ± 64.4 (2)	89.23 ± 81.5 (22)	0.83
Cross-linked polyethylene liners	17.0 ± 19.2 (34)	15.8 ± 17.6 (27)	21.7 ± 25.3 (7)	0.53
P value	<0.00001	0.08	0.008	

*The values are given as the mean and the standard deviation, with the number of hips in parentheses.

The first group consisted of twenty-four patients who received a primary total hip replacement with use of a conventional polyethylene liner (Enduron; DePuy) as the acetabular bearing. The mean duration of follow-up was twenty-six months (range, twenty-four to twenty-seven months). There were eleven men and thirteen women, with a mean age (and standard deviation) of 74 ± 9.9 years (range, forty-six to eighty-five years) at the time of the index operation and a mean body-mass index of 27.3 ± 4.1 (range, 18.6 to 35.2).

The polyethylene liners used in this group were machined from non-cross-linked ram-extruded bars of GUR 1150 resin (Ticona, Summit, New Jersey) and were sterilized with use of gamma irradiation in air. All patients received the same cementless acetabular components (Duraloc; DePuy) with a mean outer shell diameter (and standard deviation) of 60 ± 4.3 mm (range, 52 to 66 mm). The mean thickness of the polyethylene insert was 14.3 ± 2.4 mm (range, 10 to 19 mm). The mean shelf life of these components was 14.5 ± 13.4 months (range, 0.8 to 59.5 months). The femoral heads were 28 mm in two hips and 32 mm in twenty-two hips. Nineteen heads were made of cobalt-chromium, and five were ceramic.

The second patient group consisted of thirty-four hips in thirty-four patients who received a primary or revision total hip replacement with use of Marathon cross-linked polyethylene (DePuy) as the acetabular bearing. The mean duration of follow-up was thirty-three months (range, twenty-four to fifty-three months). Twenty-six primary total hip replacements and eight revisions were performed in eleven men and twenty-three women. They had a mean age (and standard deviation) of 60 ± 14 years (range, twenty-six to eighty-three years) at the time of the index operation and a mean body-mass index of 30.9 ± 5.2 (range, 21.3 to 41.4).

The polyethylene liner used in this group was made of calcium-stearate-free GUR 1050 resin (Ticona). The cups were machined from the center of a ram-extruded bar that had been cross-linked by gamma irradiation to 5 Mrad and remelted at 155°C for twenty-four hours. The finished cups were sterilized with gas plasma. All patients received cementless modular acetabular components (Duraloc or Pinnacle; DePuy). The mean outer diameter of the acetabular components was 56 ± 3.8 mm (range, 50 to 66 mm). The mean thickness of the polyethylene insert was 13.6 ± 2.0 mm (range, 11 to 19 mm). The femoral heads were 28 mm in twenty-seven hips and 32 mm in seven hips. Thirty-one heads were made of cobalt-chromium, and three were made of ceramic.

Patient activity was assessed postoperatively with use of a computerized two-dimensional accelerometer (StepWatch Activity Monitor; Cyma, Seattle, Washington) by previously described methods[3,16-19]. Additionally, the activity was graded with use of the University of California at Los Angeles (UCLA) activity score[20].

Linear head penetration, as an assessment of in vivo polyethylene wear, was measured on anteroposterior radiographs of the pelvis, made with the x-ray beam centered on the symphysis pubis. Radiographs were made postoperatively and at the latest follow-up with use of the same x-ray machine and a standardized protocol for all patients with a total hip replacement. The radiographs were digitized with a UMAX Mirage IISE scanner (UMAX Data Systems, Hsinchu, Taiwan) with a backlight attachment and with use of a pixel density of 200 dots per inch. The linear vector of liner penetration evident on the radiographs was measured with use of the Martell Hip Analysis Suite (version 4.0). This validated two-dimensional, edge detection-based computer algorithm[21,22] allows calculation of volumetric wear as described by Martell and Berdia[22]. Values of anteversion and lateral inclination of the acetabular shells were calculated with use of the Hip Analysis Suite. All radiographic analyses were performed by the same observer (C.H.).

The relative effect of numerous patient-related factors, including activity, age, gender, body-mass index, and previous surgery, on polyethylene wear was assessed. The relationship between wear and activity was assessed with use of previously described methods[3]. In order to compare wear rates with the results from hip simulator tests, the results were adjusted for wear per million cycles and a 70-kg patient weight. The relation between wear and use was evaluated, with use defined as the total sliding distance multiplied by patient weight and divided by 70 kg[3].

The effect of implant and surgical technique variables was also assessed. These factors included head size, head material, liner thickness, femoral offset, femoral offset change, horizontal center of rotation, vertical center of rotation, center of rotation change, limb length, acetabular inclination, and acetabular anteversion. These measurements were made directly from the radiographs and were adjusted for magnification.

Statistical analysis was performed with use of the Stata software (version 5.0; Stata, College Station, Texas). The differences between the two groups were evaluated with use of the

Student t test or a two-sample Wilcoxon rank-sum test, as appropriate. A univariate regression analysis was used to identify the influence of numerous variables on volumetric wear rates. A stepwise multivariate analysis was performed to adjust the differences in volumetric wear rates by the differences between the two groups. A p value of ≤0.05 was considered significant.

Results

Patients in the cross-linked liner group were younger (p = 0.0001), had a higher body-mass index (p = 0.006), a lower UCLA score (p = 0.04), a smaller acetabular size (p = 0.0001), and a smaller femoral head size (p < 0.00001) than did the patients in the conventional liner group. Conventional components were 0.7 mm thicker than the cross-linked components (p = 0.2). With regard to patient activity, both groups were similar: the evaluation with the accelerometer showed an average activity (and standard deviation) of 1.96 ± 0.84 million cycles per year (range, 0.63 to 4.31 million cycles per year) in the conventional group and 1.97 ± 1.2 million cycles per year (range, 0.1 to 5.0 million cycles per year) in the cross-linked group.

The mean lateral opening of the acetabular components was 44° ± 8.0° (range, 25° to 61°) for the conventional liners and 49° ± 5.0° (range, 38° to 56°) for the cross-linked liners (p = 0.007). The mean anteversion of the acetabular components was 18° ± 8.0° (range, 1° to 31°) for the conventional liners and 13° ± 7.0° (range, 4° to 31°) for the cross-linked liners (p = 0.01).

Wear Rates

Hips with conventional polyethylene showed a mean linear wear rate of 0.13 ± 0.1 mm per year (range, –0.1 to 0.4 mm per year) and a mean volumetric wear rate of 87.6 ± 79.2 mm^3 per year (range, 4.6 to 283.6 mm^3 per year), whereas hips with cross-linked polyethylene showed a mean linear wear rate of 0.02 ± 0.1 mm per year (range, –0.1 to 0.2 mm per year) and a mean volumetric wear rate of 17.0 ± 19.2 mm^3 per year (range, 0.1 to 70.1 mm^3 per year). The volumetric wear in the cross-linked group was 81% lower than that in the conventional group (p < 0.00001) (Table I).

After adjustment for wear per million cycles and 70-kg patient weight, conventional liners demonstrated a mean volumetric wear rate of 53 ± 46.3 mm^3 per million cycles (range, 2.3 to 191.4 mm^3 per million cycles), whereas cross-linked liners showed a mean volumetric wear rate of 15 ± 16.3 mm^3 per million cycles (range, 0.1 to 52.3 mm^3 per million cycles), a 72% reduction with the cross-linked polyethylene (p = 0.0002).

None of the variables analyzed with univariate regression analysis demonstrated strong correlations with yearly volumetric wear rates for either group. In order to account for the differences between the groups, a multivariate stepwise regression analysis was performed. The type of polyethylene was the only factor influencing the values of yearly volumetric wear rates (p < 0.0001).

In the hips with conventional polyethylene, no significant relation was found between wear and time (r = 0.3, p = 0.157). A correlation was found between the short-term wear of conventional polyethylene liners and joint use (r = 0.46, p = 0.025). In the hips with the cross-linked polyethylene liners, total volumetric wear was not related to time (r = 0.05, p = 0.76) or to use (r = 0.14, p = 0.51).

Discussion

The results of this in vivo study demonstrated that the volumetric wear rate for cross-linked polyethylene was 81% lower than that for conventional polyethylene. The total penetration of the femoral head into the acetabular polyethylene is due to a combination of creep and wear. The contribution of creep to linear penetration is highest immediately following implantation, but it decreases exponentially with time over about two years[23,24]. Recent laboratory tests have demonstrated that the creep characteristics of conventional and cross-linked polyethylene are similar[25-27]. In a short-term study of modular components, Young et al. noted that, in addition to the penetration of the head into the liner, conformational change (backside wear) between the modular acetabular liner and the metal shell may also contribute to linear penetration[28]. Therefore, the difference between the rates of linear penetration for the two materials in the present study as a result of wear reduction may increase with a longer duration of follow-up absent creep and conformational changes.

Previous hip simulator studies with similar cross-linked and conventional polyethylene components showed wear rates per million cycles of 5 mm^3 and 37 mm^3, respectively[29,30]. As wear in hip simulator studies is measured by the weight loss of the polyethylene liner, creep does not influence the wear rate in such laboratory tests. Adjusted for the measured activity and the weight of a 70-kg patient, the volumetric wear rates per million cycles in the present study were 53 mm^3 in the conventional group and 15 mm^3 in the cross-linked group. Considering the effects of creep and conformational change discussed above, the degree of wear reduction per million cycles with cross-linked polyethylene observed in vivo (72%) and in vitro (86%) was similar.

A potential limitation of this study was that the patients were not randomized. However, the detailed multivariate stepwise regression analysis indicated that differences in patient and surgical technique variables did not appreciably influence the wear rates. For clinical studies of wear, a salient variable is patient activity as it relates to the use of the prosthesis[3,31]. For this study, we used the most accurate reported methodology available to assess the use of the prosthesis[18,19]. We found no difference in the average number of cycles per year between the two groups. Not only does this methodology allow us to include the actual activity level as a factor when comparing the wear rates of the two groups, but it also facilitates direct comparison with wear simulator studies. As has been previously reported[3], a significant association was found between activity and wear of conventional polyethylene (p = 0.025). The lack of a stronger correlation between activity and the wear of the cross-linked polyethylene was simply due to the uniformly low wear rate seen in this short-term study. We will continue to follow this cohort.

In summary, compared with conventional polyethylene, cross-linked polyethylene showed an 81% reduction in the clinical wear rate and a 72% reduction in wear per million cycles. Considering some contribution of creep to the total head penetration, the degree of clinical wear reduction was comparable with that demonstrated in laboratory wear simulations. Longer follow-up is needed to determine whether there will be a corresponding reduction in the occurrence of osteolysis. ■

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