

## Original Research

# An Analysis of Hylamer and Polyethylene Bearings From Retrieved Acetabular Components

John P. Collier, DE\*

Lauren S. Bargmann, MS\*

Barbara H. Currier, ME\*

Michael B. Mayor, MD†

John H. Currier, MS\*

Brian C. Bargmann, MS\*

### A B S T R A C T

Hylamer and conventional polyethylene acetabular liners of the same design, revised for a variety of reasons, were examined and compared to assess the performance of Hylamer as a bearing material. Clinical damage modes, linear wear rates, oxidation levels, and mechanical properties were measured. In both series, many liners were retrieved for dislocation. Wear/osteolysis was the most common reason for retrieval in the Hylamer series, while none of the conventional polyethylene liners were retrieved for this reason. Nearly all liners exhibited abrasion, burnishing, scratching, and creep. The Hylamer liners had more cracking, delamination, and pitting. The Hylamer liners had an average linear wear rate of 0.32 mm/year, while the conventional polyethylene liners had an average wear rate of 0.20 mm/year. Due to sample size, no statistical difference in wear rate was noted between the two groups.

In general, both the Hylamer and conventional polyethylene showed oxidation peaks subsurface, resulting

from their exposure to gamma radiation in air. Liners with elevated oxidation had decreased ultimate tensile strength, elongation, and toughness. For given oxidation levels, the corresponding mechanical properties of Hylamer appeared lower than those of conventional polyethylene. The ultimate tensile strength values ranged from 14 to 33 MPa for Hylamer and 19 to 32 MPa for conventional polyethylene. Elongation ranges were 19% to 350% (Hylamer) and 80% to 375% (conventional).

The Hylamer retrievals in this study gave initial indications of performance; Hylamer appeared to behave similarly, but not superiorly, to conventional polyethylene, in the early functional period with respect to clinical wear and clinical performance. Both Hylamer and conventional polyethylene liners were degraded by gamma sterilization in air, with Hylamer liners demonstrating greater property changes.

The wear rate of acetabular bearings has been of interest to engineers and clinicians since the introduction of the

*From the \*Dartmouth Biomedical Engineering Center, Thayer School of Engineering, Dartmouth College, Hanover, and the †Dartmouth Hitchcock Medical Center, Lebanon, NH.*

*This research was funded by DePuy/DuPont Orthopaedics and the Veterans Administration service through grant A-473-3DA.*

*The authors thank Dana Lund for sample preparation, Dr Kenneth Saum for the FTIR data, and the contributing surgeons for retrieval specimens.*

*Reprint requests: John P. Collier, DE, Thayer School of Engineering, Dartmouth College, Cummings 8000, Hanover, NH 03755.*

total hip by Charnley in the 1960s. Charnley found that his selection of polytetrafluoroethylene (PTFE) for articulation against polished stainless steel led to high wear rates, osteolysis, and granulomatous reactions, resulting in the necessary revision of the bearings.<sup>1</sup>

In response to this unfavorable reaction, a more wear resistant polymer was sought. Ultra-high molecular weight polyethylene (hereafter called polyethylene) is among the most wear resistant of all polymers. Its selection by Charnley and its continued use and success have attested to its suitability for orthopedic applications. Nevertheless,

clinical results with polyethylene have demonstrated considerable variability in wear rates, with some liners demonstrating high wear rates. These high wear retrievals have been associated with the generation of large amounts of debris, osteolysis, and bone resorption, a leading cause of prosthesis failure in the hip.<sup>2</sup>

With adhesive and abrasive wear making polyethylene the weak link in hip arthroplasty, a variety of materials have been investigated as potential alternatives to polyethylene. In the 1980s, carbon-reinforced polyethylene (Poly II) was marketed and used in both hip and knee applications, but the

incidence of high wear led to its demise.<sup>3,4</sup> More recently, DuPont developed an "enhanced" polyethylene, Hylamer, which, according to specifications, has improved mechanical properties, oxidation resistance, and slightly improved wear characteristics as measured by both pin-on-disk testing and hip simulation.

Hylamer is a crystalline form of polyethylene on the order of 70% crystalline compared with the 50% crystallinity of conventional polyethylene. Increased temperature and extremely high pressure are used to increase crystallinity without sacrificing the molecular weight of the polyethylene. This occurs through a change in crystalline morphology to an extended chain. Such processing is thought to result in a material with enhanced physical properties that are expected to improve clinical longevity of the polyethylene.

Documented property changes in Hylamer include increased density, melting point, yield strength, tensile strength, modulus, creep resistance, impact resistance, and fatigue resistance. These characteristics can increase resistance to wear and oxidation.<sup>5,6</sup>

The wear of conventional polyethylene in acetabular liners has been well-documented. John Charnley wrote of wear and wear rates in the 1970s, claiming that the average wear rate in polyethylene was on the order of 0.18 mm/year for the first 5 years in vivo (22-mm head). However, 15% of the hips in the Charnley study had wear rates of 0.3 mm/year on average.<sup>7</sup>

The factors influencing the rate of wear are a source of continuing investigation: age, weight, sex, diagnosis, activity, femoral head size, component orientation, etc. Many are significant in some studies, but not in others.

Two recent reports have focused on the relative wear rate of Hylamer versus conventional polyethylene in the hip. Both studies were comprised of data from radiographic measurements and a limited number of retrievals.

In a retrospective cohort study by Livingston et al,<sup>8</sup> 233 total hip arthro-

plasties (implanted between January 1991 and December 1993) using Hylamer liners were evaluated. They found a statistically significant difference ( $P=.0000$ ) between the mean wear rate of Hylamer liners (0.27 mm/year) and 50 conventional polyethylene liners of a different design from a different manufacturer (0.12 mm/year). Interestingly, Hylamer was found to perform better when mated against DePuy femoral heads than when mated against other manufacturers' heads. Average patient ages between comparison groups were different, with patients being nearly 10 years younger in the Hylamer series. The average in vivo durations of the liners were not reported.

In a second study of 114 hips, 79 of which were Hylamer, Smith and Chandler<sup>9</sup> reported a higher wear rate for Hylamer as measured by radiographic techniques. Smith and Chandler provided wear data that indicate the wear rate for Hylamer was greater at 2 years than the wear rate for conventional polyethylene at 4 years. The average wear rate for the Hylamer liners was 0.27 mm/year while the conventional polyethylene had an average wear rate of 0.11 mm/year.

The present study assessed the clinical performance of Hylamer as a bearing material through the analysis of retrieved acetabular liners and compared this new bearing material to conventional polyethylene used in liners of the same design from the same manufacturer. Linear wear and wear rates were measured in retrieved liners, which were thoroughly examined to document their condition at the time of retrieval. In addition, oxidation assessment and uniaxial tensile testing of both Hylamer and conventional polyethylene provided insight into the changes in the material properties over time after gamma sterilization in air.

## MATERIALS AND METHODS

Thirty-four retrieved Hylamer and 8 retrieved conventional polyethylene acetabular liners of the same design were examined. The liners were selected

based on their in vivo duration ( $>1$  year) from a larger series of 63 Hylamer and 24 conventional polyethylene liners. The in vivo durations of those in the study ranged from 1 year to 6 years (Hylamer average=3.3 years [range=1-6.3 years] and conventional polyethylene average=1.6 years [range=1.1-2.2 years]). The average pre-implantation shelf life was 9 months for the Hylamer liners and 15 months for the conventional polyethylene liners. The average patient age was 58 years for both the Hylamer and conventional polyethylene liners. All liners had been gamma sterilized in an air environment.

Retrievals were rated macroscopically on a 0 (none) to 3 (severe) scale for the clinical damage modes of: abrasion, burnishing, cracking, creep, delamination, pitting, scratching, and overall wear. The ratings offered a basis for comparing clinical wear damage with material characteristics.

Wear of liners was measured using a dial micrometer with sensitivity of 0.0245 mm. The region of highest wear (thinnest region of the liner) was measured and compared with the thickest region (least wear) of the liner. The difference between the two was recorded as linear wear and included both wear and creep or head penetration. Retrieval artifact regions and those with noticeable creep were avoided to the extent possible when taking the wear measurements.

The wear rate was determined by dividing the total wear by the in vivo duration of the component, noting that the potential for error was exacerbated through extrapolation of wear measurements in liners with short implantation durations. Comparisons were made between the wear of Hylamer acetabular liners and the wear of conventional polyethylene acetabular liners of the same design.

To assess the oxidation levels and mechanical properties in the bearings, thin sections of polyethylene were required. Each acetabular component was cut in half with a band saw and embedded in an acrylic resin, leaving

the cross section exposed. Thin cross sections of polyethylene (200  $\mu\text{m}$ ) were obtained using a Jung microtome (Jung, Heidelberg, Germany).

To determine the extent of oxidation of the liners, Fourier Transform Infrared (FTIR) absorbance spectra were measured on the thin sections from 18 of the liners (10 retrieved HyLamer liners and 8 retrieved conventional polyethylene liners of the same design) with a Digilab Model 60A double-beam spectrometer with a UMA 300 IR microscope (Biorad Instruments, Cambridge, Mass). The infrared spectroscopy technique of Nagy and Li<sup>10</sup> was used to measure oxidation profiles of acetabular thin sections (200 to 250  $\mu\text{m}$  thick) as a function of depth into the component (maximum depth=4 mm).

Spectra obtained using thin sections provided oxidation measurements at the center of the liner beginning on the articular surface and progressing in 50- $\mu\text{m}$  increments toward the nonarticular surface. This study focused on the carbonyl region of the spectra (specifically wave numbers between 1750 and 1690  $\text{cm}^{-1}$ ), which measures the concentration of the carbon-oxygen double bonds found in esters, ketones, aldehydes, and carboxylic acids. The area of the entire carbonyl band from 1800  $\text{cm}^{-1}$  to 1660  $\text{cm}^{-1}$  was determined and normalized for sample thickness. This normalized area was used to evaluate extent of polyethylene oxidation.

Mechanical tensile tests of thin sections of the liners were used to compare the properties of the materials and the changes observed over time. The apparatus used for the tensile testing consisted of an Instron 8501 load frame (Instron Corp, Canton, Mass) with a servohydraulic actuator (model 3398-341), a 200-lb load cell (model 2518-806), and pneumatic-action sample grips designed to eliminate stress concentrations and premature failure at the grips.

Sample elongation was measured using a video extensometer. The gage length used was nominally 10 mm, and the samples were loaded at a rate of 0.2

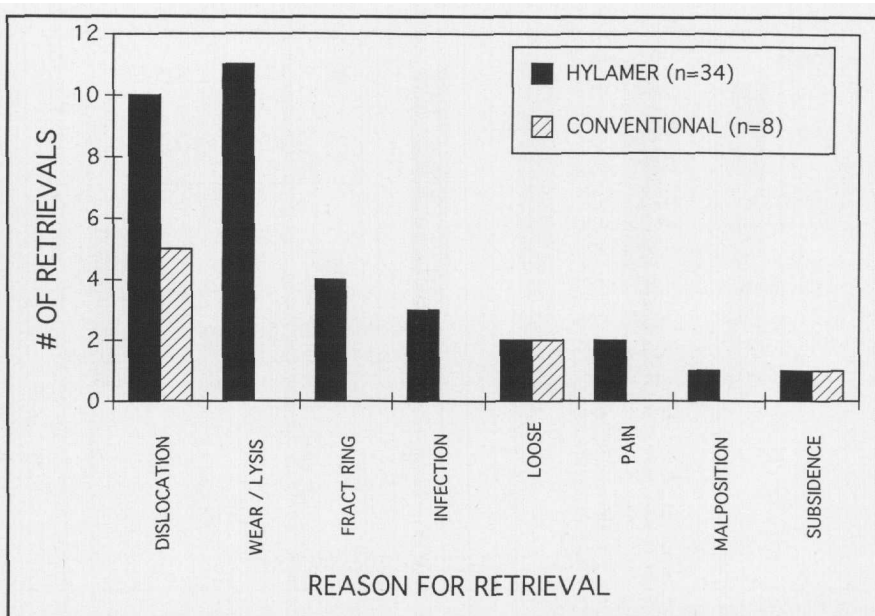


Fig 1: Reasons for retrieval of HyLamer and conventional polyethylene liners.

mm travel per second (nominal strain rate 100% per minute). An Instron Series IX data acquisition system recorded load and elongation throughout the tests, and the properties reported here are ultimate tensile strength, elongation at break, and toughness (a product of ultimate tensile strength and elongation).

## RESULTS

The first step in the study was to evaluate the reason for retrieval of the liners. Analysis of the two retrieval series showed that many liners in both series were removed for dislocation. Wear and osteolysis were the most common reasons for retrieval in the HyLamer series (Fig 1). Wear and osteolysis were not apparent in the conventional polyethylene liners, likely due to their shorter in vivo durations.

Examination of the retrieved HyLamer and conventional polyethylene liners showed little difference in abrasive wear damage modes. Nearly all liners exhibited abrasion, burnishing, scratching, and creep. The HyLamer liners had more cracking, delamination, and pitting. The difference in delamination was statistically significant ( $P=.03$ ) (Fig 2).

From linear wear measurements of the retrieval series, HyLamer liners showed an average linear wear rate of 0.32 mm/year (SD=0.21), while the conventional polyethylene liners had an average wear rate of 0.20 mm per year (SD=0.20) (Figs 3 and 4). Due to sample size, no statistical difference in wear rate was noted between the two groups.

In both series, duration of implantation ( $P=.00$ ), patient sex ( $P=.04$ ), and patient age ( $P=.04$ ) were significant predictors of linear wear. However, these factors coupled with polyethylene type (HyLamer or conventional) explained only 48% of the variation in wear.

FTIR measurements of oxidation (CO area/mil thickness) as a function of depth revealed increased levels of oxidation, with local maxima in the subsurface region in both HyLamer and conventional polyethylene retrieved liners, resulting from their exposure to gamma radiation in air. The difference in maximum subsurface oxidation levels between HyLamer and conventional polyethylene was not statistically significant. Oxidation levels of one HyLamer and one conventional polyethylene liner with similar histories are compared in Figure 5.

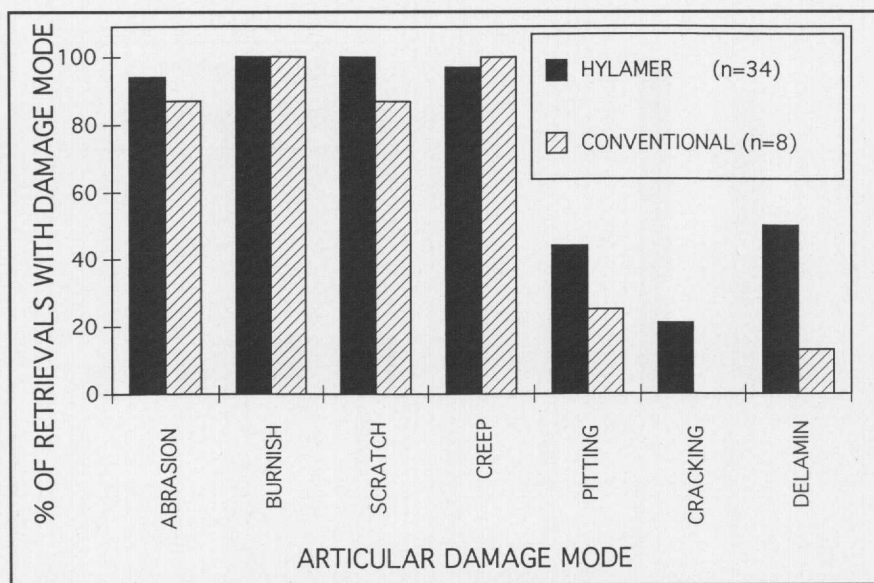


Fig 2: Clinical damage modes in liners.

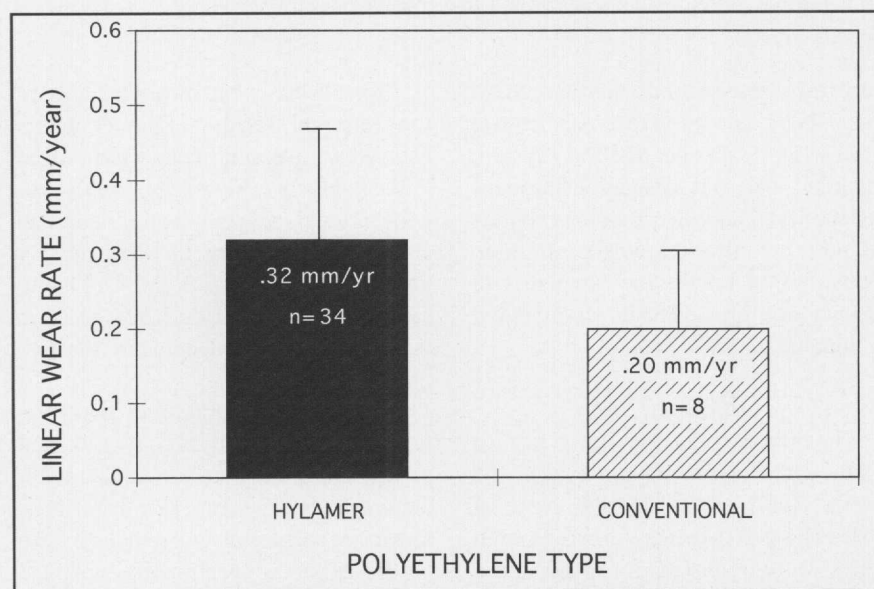


Fig 3: Average linear wear rates of Hylamer and conventional polyethylene.

Mechanical testing resulted in ultimate tensile strength values ranging from 14 to 33 MPa for Hylamer and 19 to 32 MPa for conventional polyethylene. Elongation ranges were 19% to 350% (Hylamer) and 80% to 375% (conventional). The difference between elongation in the Hylamer and conventional polyethylene liners was statistically significant ( $P=.02$ ).

Liners with elevated oxidation had decreased ultimate tensile strength, elongation, and toughness (Figs 6 and

7). The level of the maximum subsurface oxidation was a significant predictor of ultimate tensile strength ( $P=.00$ ) and elongation ( $P=.04$ ). For given oxidation levels, the corresponding mechanical properties of Hylamer appeared lower than those of conventional polyethylene.

## DISCUSSION

Concern over excessive wear of Hylamer liners (as determined by radiographic techniques) has been raised. To

evaluate the clinical performance of Hylamer, a series of liners chosen from a larger retrieval set were analyzed and compared with a set of same-design conventional polyethylene liners. These analyses demonstrated that clinical wear modes of retrieved Hylamer liners were comparable to conventional polyethylene liners. However, several Hylamer liners had wear rates that were measurably greater than the range observed in conventional polyethylene liners. Oxidation levels of both materials were found to increase with time post-gamma sterilization in air, and mechanical properties of both materials were found to be dependent on oxidation level, with strength and elongation decreasing with increasing oxidation levels.

Clinical wear modes seen in Hylamer retrievals were the same as seen in conventional polyethylene retrievals, indicating that Hylamer performs similarly to conventional polyethylene. However, the incidence of cracking, delamination, and pitting were higher in the Hylamer liners. The higher incidence of these fatigue damage modes likely can be attributed to the mechanical property deterioration found in some of the Hylamer liners as a result of having been gamma sterilized in air.

Sutula et al<sup>11</sup> showed that oxidation of polyethylene and subsequent reduction in mechanical properties are directly related to these fatigue damage modes in hips. Conventional polyethylene in this study did not suffer the same magnitude of mechanical property reduction and therefore suffered less fatigue. Additionally, the increased modulus of Hylamer, designed to provide better creep resistance, may negatively impact other failure modes involving fatigue. However, until retrieved liners that were not gamma sterilized in air are available, a direct material comparison without confounding variables will be difficult.

The oxidation levels of conventional polyethylene and Hylamer are similar and show similar trends. Although Hylamer has a different crystalline and

extended chain morphology, it is not immune to the damage induced by gamma sterilization in air and subsequent oxidation. Radiation is known to break polymer chains, creating available reaction sites that can result in oxidation of the polymer.

Subsurface oxidation was found in conventional polyethylene liners from 16 different manufacturers in previous studies, demonstrating the prevalence of damage caused by gamma sterilization in air.<sup>11</sup> Because of its higher crystallinity, Hylamer was thought to be more oxidation resistant, due to the assumption that oxygen can diffuse less rapidly into crystalline regions.<sup>6</sup> However, Hylamer may be more susceptible to oxidation than conventional polyethylene since it has less amorphous region. Oxidation occurs preferentially in amorphous regions and therefore may be more localized and concentrated in Hylamer.

The effect of oxidation is of great importance to the mechanical performance of both conventional polyethylene and Hylamer. The mechanical properties of both materials degrade with time after gamma sterilization in air, and this decline in strength and ductility is associated with the level of oxidation measured in the liner. Previous studies of conventional polyethylene report the presence of a highly oxidized subsurface white band region with poor mechanical properties.<sup>11</sup>

Interestingly, in this study, data suggest that for a given level of oxidation, the reduction in mechanical properties may be greater in Hylamer. Therefore, the impact of oxidation may be more detrimental in Hylamer. The mechanical properties measured in this study should be used only as a source of relative comparisons since the C-shaped geometry of liners precludes testing an American Society for Testing Materials (ASTM) specified geometry. The absolute value of the reported mechanical properties may be skewed; however, liner-to-liner comparison is possible.<sup>11</sup>

The reduced mechanical properties measured in these acetabular liners also

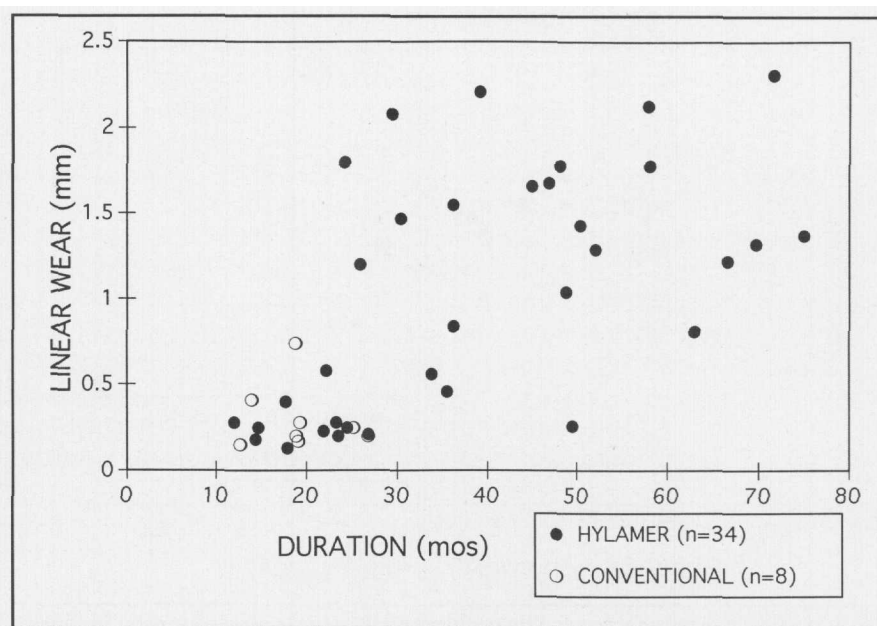


Fig 4: Linear wear versus duration of implantation.

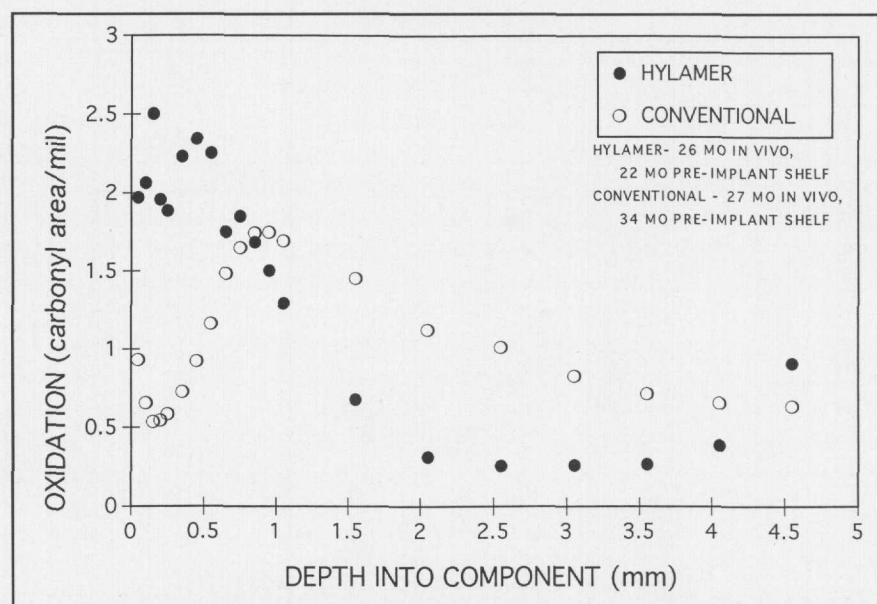


Fig 5: Oxidation levels of Hylamer and conventional polyethylene retrievals of the same design (levels measured at the articular surface).

might influence the wear rate. Fisher et al,<sup>12</sup> using pin-on-disk wear testing, reported nearly three times the wear rate in oxidized samples when compared with never-oxidized material, suggesting that embrittled polyethylene with poor mechanical properties may wear more rapidly. However, with the limited sample size in this study, no statistical correlation between oxidation and wear

rate was observed. The lack of statistical correlation may be impacted by the variety of reasons for retrieval. For example, chronic dislocation could cause inflated wear measurements even in liners that were not oxidized or embrittled. Another possibility is that oxidation and mechanical property decreases may not impact abrasive wear to the extent that they impact fatigue.

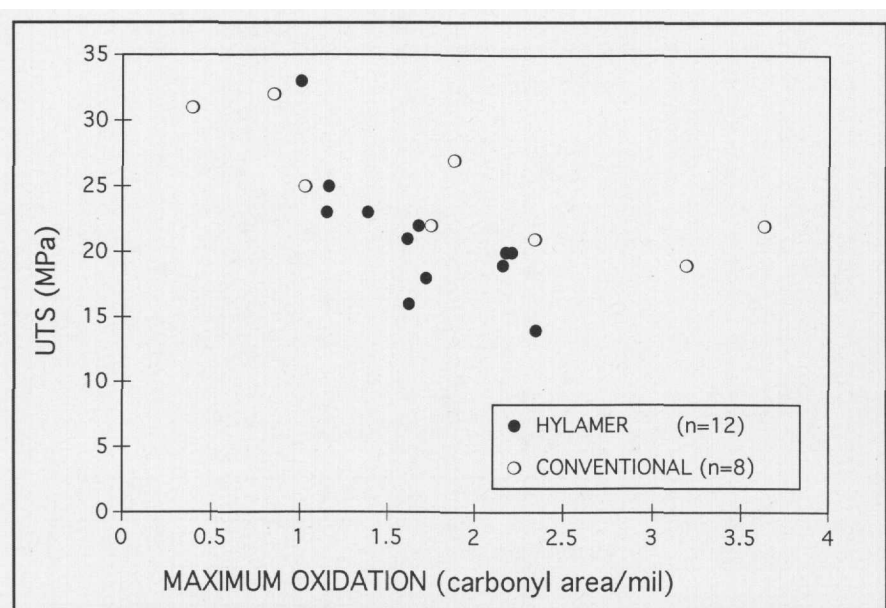


Fig 6: Ultimate tensile strength versus maximum oxidation level for Hylamer and conventional polyethylene retrievals of the same design.

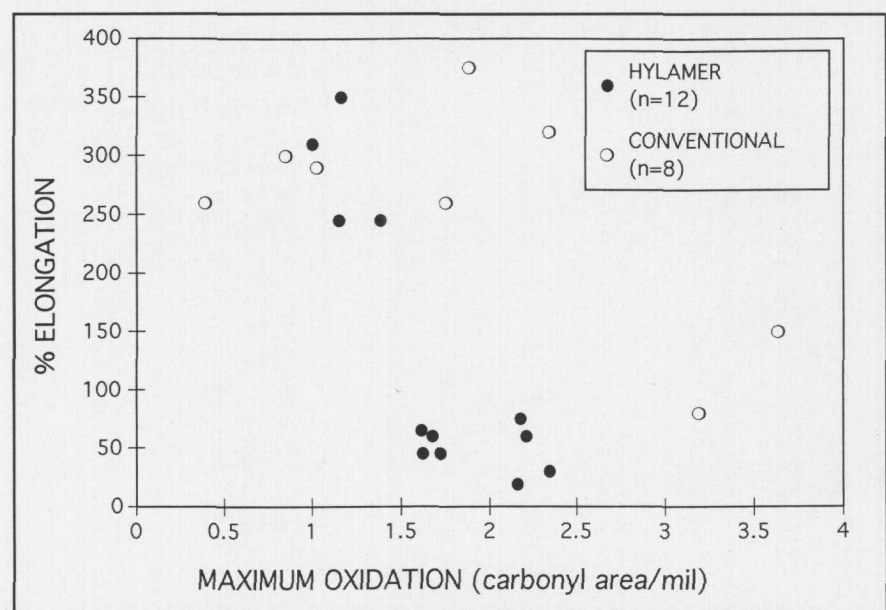


Fig 7: Elongation versus maximum oxidation level for Hylamer and conventional polyethylene retrievals of same design.

Early experimentation suggested that Hylamer wear rates would show slight improvement in wear resistance and that the improvements would become more dramatic with time.<sup>6</sup> However, previous clinical studies reported higher wear rates for Hylamer liners when compared with conventional polyethylene.<sup>8,9</sup> In this study, there was no statistical difference between

the wear rate of Hylamer (0.32 mm/year) and conventional polyethylene (0.2 mm/year). A sample size of 45 Hylamer and an equivalent number of conventional polyethylene liners would be required for a difference of that magnitude (0.12 mm/year) to be considered significant.

However, the fact that there was no statistical difference does not mean that

one should ignore the large differences in wear between Hylamer and conventional polyethylene. The measured values indicate that Hylamer liners in this series have more than a 50% increase in wear rate over conventional polyethylene. Unfortunately, information on head size, stem manufacturer, and fixation method of the devices is not consistently available for the liners in this study, and therefore, the effect of these variables on wear cannot be accounted for.

The findings here theoretically agree with those reported in literature. The measured wear rate for Hylamer in this study (0.32 mm/year) is slightly higher than the wear rate measured by Smith and Chandler<sup>9</sup> (0.27 mm/year), and Livingston et al<sup>8</sup> (0.27 mm/year) who used radiographic techniques in two independent studies. The average wear of conventional polyethylene in the study by Smith and Chandler<sup>9</sup> was 0.11 mm/year, while Livingston et al<sup>8</sup> found a rate of 0.12 mm/year.

Both Smith and Chandler,<sup>9</sup> and Livingston et al<sup>8</sup> reported the wear of conventional polyethylene for a different design, from a different manufacturer. In contrast, the wear rates of conventional polyethylene (0.20 mm/year) in this study were obtained from liners with the same design and manufacturer as the Hylamer liners. The difference in wear rates between Hylamer and conventional polyethylene in all of these studies hovers near a factor of two.

Overall, the wear rates for both Hylamer and conventional polyethylene in this study fell within the historic norms for polyethylene bearings. Charnley reported that 15% of hips in his study had average wear rates >0.3 mm/year during the first 5 years of implantation<sup>7</sup> (with a 22-mm head) compared with average Hylamer wear rates of 0.32 mm/year for liners (with 28- and 32-mm heads) with durations ranging from 1 to 6 years. The fact that the measured values were in the high end of the range can be partially attributed to the fact that these are retrievals that had failed for one reason or another and were not completely representa-



tive of the performance of the entire population.

Additionally, a concern associated with extrapolating wear rates from implants with short duration is the phenomenon of "wearing in." The wear rate may be highest during the wearing in period (the first years of implantation) in some liners. Charnley documented a 44% reduction in wear rates of liners when comparing the first 5 years of implantation to the last 4 years.<sup>7</sup> He also stated that the rate of wear in the first 2 years is nearly double the average wear rate for a longer period.<sup>13</sup> In addition, researchers warn that measurement of wear in the first couple of years is difficult as creep is being measured in addition to true wear.<sup>14-16</sup> The rates of wear of Hylamer liners found in this study are within the range found for conventional polyethylene and are far below the catastrophic wear rates seen in PTFE (2.26 mm/year).<sup>3,4,13</sup>

## CONCLUSION

The Hylamer retrievals in this study give initial indications of performance; Hylamer appeared to behave similarly but not superiorly to conventional polyethylene in the early functional period. Hylamer and conventional polyethylene retrieved liners demonstrated burrishing, scratching, and abrasion with comparable frequency. Fatigue damage and higher linear wear rates were more prevalent in the longer duration Hylamer series. Both the conventional polyethylene and Hylamer liners were degraded by gamma sterilization in air, with Hylamer liners demonstrating greater property changes.

## REFERENCES

1. Charnley J. Tissue reactions to polytetra-

fluoroethylene. *Lancet*. 1963; 2:1379.

2. Revell PA, Weightman B, Freeman MAR, Roberts BV. The production and biology of polyethylene wear debris. *Arch Orthop Trauma Surg*. 1978; 91:167-181.

3. Wright T, Fukubayashi T, Burstein A. The effect of carbon fiber reinforcement on contact area, contact pressure, and time-dependent deformation in polyethylene tibial components. *J Biomed Mater Res*. 1981; 15:719-730.

4. Li S, Burstein A. Current concepts review ultra-high molecular weight polyethylene. *J Bone Joint Surg Am*. 1994; 76:1080-1090.

5. Champion A, Li S, Saum K, Howard E, Simmons W. The effect of crystallinity on the physical properties of UHMPE. *Transactions from the 40th Annual Meeting of the Orthopaedic Research Society*. 1994; 2:585.

6. Champion A, Saum K, Simmons W, Howard E. Enhanced ultra-high molecular weight polyethylene for orthopedics applications. In: Wise DL, Trantolo DJ, Altobelli DE, Yaszemski MJ, Gresser JD, Schwartz ER, eds. *Encyclopedic Handbook of Biomaterials and Bioengineering*. New York, NY: Marcel Dekker; 1995:453-486.

7. Charnley J, Halley D. Rate of wear in total hip replacement. *Clin Orthop*. 1975; 112:170-179.

8. Livingston BJ, Chmell MJ, Spector M, Poss R. Complications of total hip arthroplasty associated with the use of an acetabular component with a Hylamer liner. *J Bone Joint Surg Am*. 1997; 79:1529-1538.

9. Smith S, Chandler H. In vivo wear rates of 'Hylamer' ultra-high molecular weight polyethylene and conventional ultra-high molecular weight polyethylene in a series of cases performed by one surgeon. *J Arthroplasty*. In press.

10. Nagy E, Li S. A Fourier transform infrared technique for the evaluation of polyethylene orthopaedic bearing materials. In: *Transactions, 16th Annual Meeting, the Society for Biomaterials*; 1990:3:109.

11. Sutula LC, Collier JP, Currier BH, et al. The impact of gamma sterilization on clinical performance of polyethylene in the hip. *Clin Orthop*. 1995; 319:28-40.

12. Fisher J, Chan KL, Hailey JL, Shaw D, Stone M. The effect of aging following irradiation on the wear of UHMWPE. *J Arthroplasty*. 1995; 10:689-692.

13. Charnley J. The wear of plastics materials in the hip joint. *Plastics and Rubber*. 1976; 1(2):59-63.

14. Weightman B, Swanson S, Isaac G, Wroblewski B. Polyethylene wear from retrieved acetabular cups. *J Bone Joint Surg Br*. 1991; 73:806-810.

15. Isaac G, Wroblewski B, Atkinson J, Dowson D. A tribological study of retrieved hip

prostheses. *Clin Orthop*. 1992; 276:115-125.

16. Rose RM, Crugnola A, Ries M, Cimino WR, Paul I, Radin EL. On the true wear rate of ultra high molecular weight polyethylene in the total hip prosthesis. *J Bone Joint Surg Am*. 1980; 62:537-549.

## EDITORIAL DISCUSSION

**ORTHOPEDICS:** Do you think your results would have been influenced by noting the following: whether or not the polyethylene cups were inside a metal shell; whether or not the cups were cemented; whether the thickness of the polyethylene in the component mattered; and whether there was a variation in the construct of the component and its shell?

**Collier et al:** The results comparing Hylamer and conventional polyethylene in this study would not likely have been impacted by the aforementioned variables, as this study compared only one acetabular component design from one manufacturer. Therefore, they were all metal backed, of the same constructs, etc. The results in this study focused on the variables unique to the polymers.

**ORTHOPEDICS:** You do not mention the size of the wear debris. Was there any variation in the size of the wear debris between Hylamer and polyethylene?

**Collier et al:** Wear debris was not collected nor examined in this study. However, some research has been done with respect to this specific question by other laboratories suggesting that there are differences in the wear particles from Hylamer and conventional polyethylene.