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Rim Cracking of the Cross-Linked Longevity Polyethylene Acetabular Liner After Total Hip Arthroplasty

By Stephen S. Tower, MD, John H. Currier, MS, Barbara H. Currier, MChE, Kimberly A. Lyford, AB, Douglas W. Van Citters, PhD, and Michael B. Mayor, MD

Investigation performed at the Thayer School of Engineering, Dartmouth College, Hanover, New Hampshire

Background: Studies have suggested that cross-linked polyethylene bearings reduce wear rates from 40% to 100% compared with conventional polyethylene. However, the reduced mechanical properties of highly cross-linked polyethylene have the potential to be a limiting factor in device performance. We reviewed a series of retrieved acetabular liners with a fracture of the superior rim to assess the factors that played a role in their failure.

Methods: Four Longevity acetabular bearings, which had been retrieved from two patients after seven to twenty-seven months in vivo, were visually examined for clinical damage, were assessed with use of Fourier transform infrared spectroscopy to determine the level of oxidation, and were analyzed for mechanical properties and fracture surface characterization. Control data were obtained from never-implanted devices and from global reference ultra-high molecular weight polyethylene bar stock as an industry calibration material.

Results: All four retrieved liners demonstrated articular surface wear modes, which in most cases were rated as moderate, and none were rated as severe. All showed cracking or rim failure of the liner at the superior aspect along the groove in the polyethylene that engages the locking ring of the shell. The retrieved liners had no measurable oxidation, and the mechanical properties were comparable with those of never-implanted material.

Conclusions: There was no notable in vivo degradation of the retrieved liners. Important factors related to failure appear to be thin polyethylene at the cup rim, relatively vertical cup alignment, and the material properties of the highly cross-linked polyethylene that are decreased relative to conventional polyethylene. The critical dimension with respect to rim failure in modular liners appears to be the minimum thickness at the equatorial region.

Clinical Relevance: For a given implant design and loading, highly cross-linked polyethylene may be more susceptible to fatigue damage, such as rim cracking, than is conventional polyethylene. The potential for excess rim loading on thin polyethylene should be assessed carefully when the use of a cross-linked liner and a large femoral head is being considered, particularly in a cup with a more vertical abduction angle.

Cross-linked polyethylene for application in orthopaedic bearings was developed to reduce wear and to address the problem of particulate-induced osteolysis. Many studies have demonstrated reduced debris generation of cross-linked polyethylene in hip simulator models¹⁻⁵. Various manufacturers of orthopaedic devices have advertised wear rate reductions of 40% to 100% for their respective brands of cross-linked polyethylene⁶.

Investigations have indicated that there is a trade-off between wear resistance and other important mechanical properties⁶⁻⁸. It has been suggested that these reduced mechanical properties could become a limiting factor under some circumstances of component design and loading. Reduced strength and toughness may play an important role in the fracture of liner rims and locking mechanisms that result in a failed arthroplasty component regardless of improved abra-

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sive wear on the articular surface. Crowninshield et al.⁹ noted that the additional resistance to dislocation afforded by larger femoral heads diminishes to near zero at acetabular component abduction angles of $>67^\circ$. However, their analysis showed that for a 40-mm head size, the maximum tensile stress in the polyethylene liner is more than five times greater in a vertical cup under a subluxation scenario compared with a stable cup with an abduction angle of 45° .

In this study, we looked at four retrieved acetabular liners with cracking of the superior rim, all of which were the same device design and were made from the same brand of highly cross-linked polyethylene. Our purpose was to determine the factors that played a role in these failures.

Materials and Methods

Four Longevity acetabular bearings (Zimmer, Warsaw, Indiana) that had been retrieved from two patients were analyzed in this study. Both patients underwent primary total hip arthroplasty, and both required revision and subsequent rerevision. The in vivo duration of the bearings ranged from seven to twenty-seven months. The Longevity bearing material is manufactured with use of electron-beam irradiation cross-linking at a nominal dose of 10 Mrad with subsequent above-melt temperature annealing. Three Longevity acetabular bearings that had never been implanted were analyzed for baseline properties of the cross-linked polyethylene. The control material for oxidation tests was global reference ultra-high molecular weight polyethylene bar stock from a single lot of 4150HP resin, which was nonirradiated and non-cross-linked, provided by the Hospital for Special Surgery as a calibration material for orthopaedic industry comparative tests¹⁰.

Each acetabular bearing was examined visually with use of a binocular dissecting microscope (Nikon, Tokyo, Japan) with a magnification factor of ten. One bearing was examined with a scanning electron microscope (model JSM-5310LV; JEOL, Peabody, Massachusetts) to characterize its fracture surfaces. The bearings were rated for clinical damage on a scale from 0 (none) to 3 (severe)¹¹. The clinical damage ratings for cracking and delamination were used to assess fatigue damage of the polyethylene in these cross-linked retrievals. A cracking or delamination rating of 3 indicates fatigue failure of the material.

The bearings were bisected through the apex with use of a band saw. Cross sections (approximately 200 μm thick) were cut from the bearing with use of a microtome (Jung, Heidelberg, Germany). Thin sections for mechanical test specimens were taken from one retrieved bearing that was of sufficient size for mechanical testing.

Fourier transform infrared spectroscopy was used to determine the level of oxidation in each bearing. Fourier transform infrared absorbance spectra were obtained with use of either an AutoIMAGE FTIR (Fourier transform infrared) microscope (Perkin Elmer, Norwalk, Connecticut) or a Spectrum BX11 microscope (Perkin Elmer). Oxidation measurements with use of the infrared microscope were made and as a function of depth on a vertical cross section of each bear-

ing. Parameters for the measurements were thirty-two scans per 100- μm depth interval, with use of a wave-number interval of 2 cm^{-1} and an aperture of $100\text{ }\mu\text{m}^2$. Oxidation measurements with use of the Spectrum BX11 were made on a series of cross sections.

We evaluated the incorporation of oxygen into the polyethylene by examining the carbonyl region of the Fourier transform infrared spectra wave numbers between 1800 and 1660 cm^{-1} . The carbonyl region, measuring carbon-oxygen double bonds, indicates the presence of ester, ketone, aldehyde, and carboxylic acid. The reported oxidation level of the thin section of the bearing was defined as the measured ketone (1718 cm^{-1}) peak height normalized to the 1368 cm^{-1} peak height⁶. This method allows separate evaluation of the absorbed species (ester, 1738 cm^{-1}) as well as the oxidation products (ketone in the present study) in the assessment of bearing oxidation.

To measure mechanical properties, uniaxial tensile tests were performed on thin sections taken from each bearing that had sufficient size and thickness for sampling (one retrieved liner and three never-implanted controls). The tests were carried out on ASTM International Type-V samples¹² according to a protocol described in detail elsewhere¹³.

Results

The retrieved liners demonstrated burnishing, scratching, abrasion, and creep that were in most cases rated as moderate (2 on the scale of 0 to 3)¹¹, implying that there were easily detected levels of change in the material surface. None were rated as severe in these wear modes. There was no instance of pitting or delamination. All of the liners showed severe cracking or failure at the rim with damage evident at the superior aspect at the groove in the polyethylene that engages the locking ring of the Trilogy shell (Zimmer) (Fig. 1).

The three never-implanted controls had oxidation that was at or below the oxidation measured in the reference ultra-high molecular weight polyethylene material¹⁰. None of the retrieved Longevity liners (which had been in vivo from seven to twenty-seven months) had measurable oxidation.

The mechanical properties of the retrieved bearings were comparable with the properties measured in the never-implanted Longevity bearings. The ultimate tensile strength of the retrieved bearing was an average of 42.7 MPa, and that of the never-implanted control material was an average of 43.0 MPa. The elongation at break (average, 220%) was slightly below that of the never-implanted control (250%). The ASTM minimum standard for ultimate tensile strength is 27 MPa, and the standard for elongation is 250%¹⁴.

Clinical Case Details

The first patient (Case 1), a woman who weighed 98 kg and had a body mass index of 34, underwent a right total hip arthroplasty when she was fifty-two years old for progressive arthrosis following open reduction and internal fixation of an acetabular fracture. A Trilogy shell (Zimmer) with a 48-mm outer diameter and a Longevity liner with a 28-mm internal

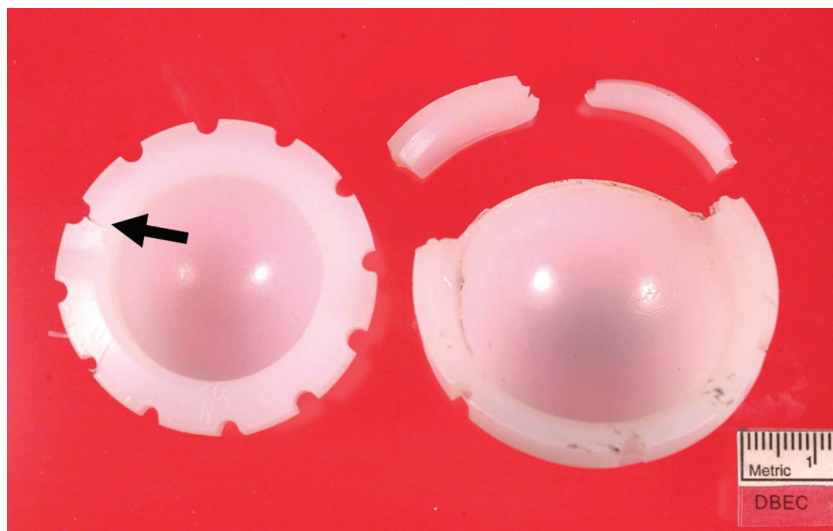


Fig. 1

Components retrieved from the first patient (Case 1). *Left*: The acetabular liner implanted during the primary arthroplasty and retrieved after eleven months in vivo. The arrow indicates the location of a crack in the rim of the liner. *Right*: The revision acetabular liner retrieved after twenty-three months in vivo. Two segments of the rim were found dissociated from the liner at retrieval.

diameter and a 10° lip oriented in the posterosuperior direction were implanted during the primary arthroplasty. Radiographs showed a cup abduction angle of 69° and anatomic anteversion. The primary replacement was complicated by several posterior hip dislocations, but it functioned well until ten months after surgery when the patient complained of sub-

luxation and clicking with weight-bearing. Eleven months after the primary procedure, revision to a Trilogy shell with a 54-mm outer diameter, inserted with multiple screw fixation in the superior quadrant, and a Longevity liner with a 36-mm internal diameter was performed. Initial fixation seemed secure, and the cup abduction angle was 51°. Anteversion of the

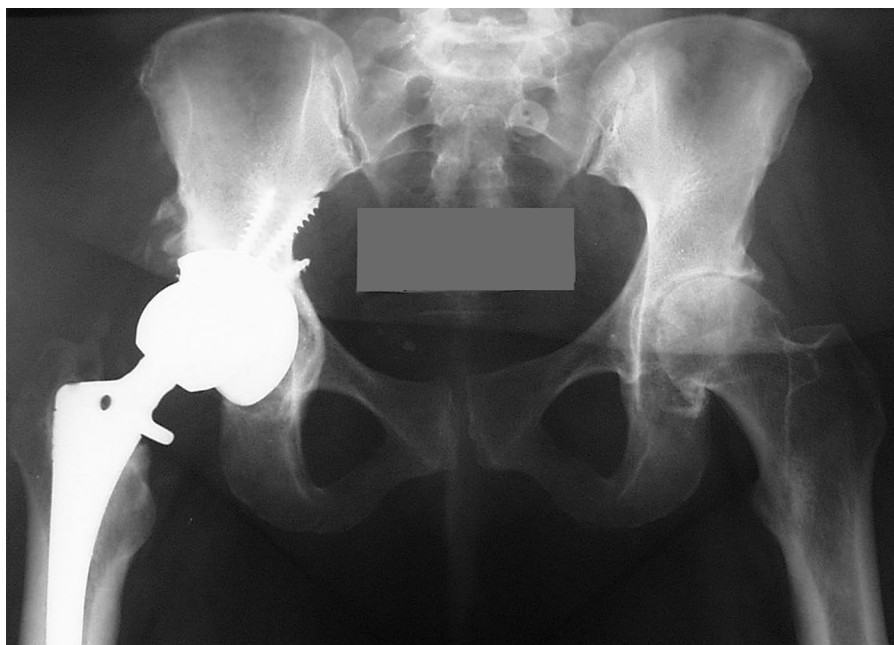


Fig. 2

Anteroposterior radiograph of first patient (Case 1) made fourteen months following revision surgery. The cup abduction angle was 62° at that time.

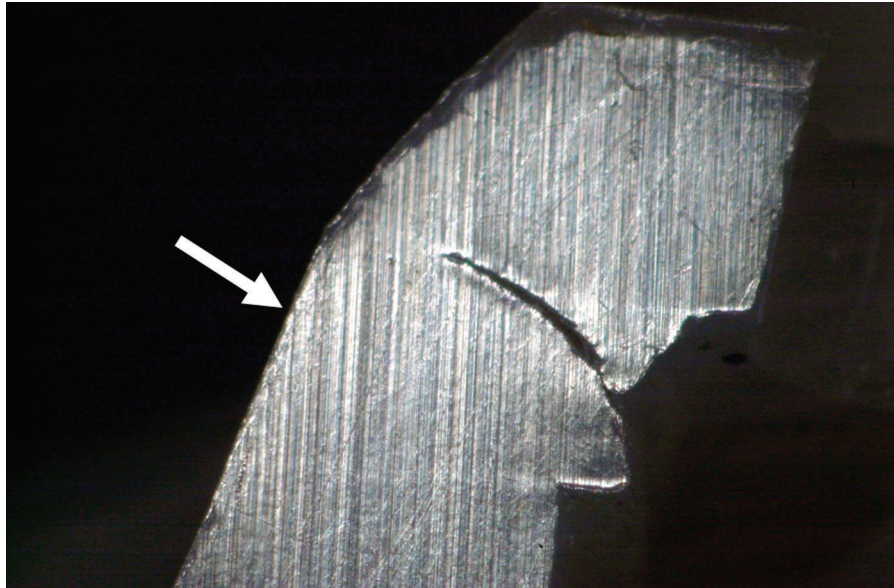


Fig. 3

Cross section of the primary liner from the second patient (Case 2), taken near one end of the fractured segment, confirming that the fracture initiated at the outer edge of the liner and propagated inward toward the articular surface (indicated by arrow).

revision shell appeared normal. The primary liner appeared intact at the time of removal, but on later inspection it was noted to be cracked at the junction of the lip and the shell.

At fourteen months after the revision, radiographs showed that cup abduction had increased to 62° and a gap estimated at 3 mm in zone 3¹⁵ was noted as the shell had pivoted to a more vertical position (Fig. 2). By eighteen months after the revision, the cup abduction angle had increased to 68°. The patient was again having symptomatic subluxations. A second revision was performed twenty-three months after the first revision. The retrieved Longevity liner was found to be fragmented at the superior quadrant.

The second patient (Case 2), a woman who weighed 91 kg and had a body mass index of 32, with a valgus arthritic dysplastic right hip underwent primary arthroplasty with a 52-mm-diameter Trilogy shell and a 32-mm Longevity liner with a neutral lip. The abduction angle of the acetabular shell was 69° with minimal anteversion. Seven months after the primary arthroplasty, the patient noted clicking of the hip with weight-bearing, which was confirmed on radiographs that demonstrated superior subluxation. The acetabular component was revised to a 56-mm-diameter Trilogy shell with a 32-mm Longevity liner with a neutral lip. Twenty-two months after revision, the patient again noted subluxation with weight-bearing and underwent a second revision. At that revision, fragmentation of the Longevity liner was noted at the superior quadrant.

Fracture Surface Analysis

The character of the fracture surface of the primary liner from the second patient (Case 2) showed evidence of the mode and sequence of these rim failures. The cracking in the liner rims

appeared to have been initiated at the outer edge, near the 90° intersection of the flange and the cylindrical section of the cup. This is consistent with a corner stress concentration and the loading that would result from the rim contact seen in the prerevision radiograph. The crack propagated inward toward the articular surface of the liner and extended laterally around the cup perimeter for the length of one rim segment between the peripheral machined notches. In the instance of the primary liner from this patient, the crack propagated inward only partially through the thickness of the rim, helping to establish the failure sequence (Fig. 3). The fracture surfaces on the primary liner from this patient were the only fracture surfaces among the retrieved devices that had remained undisturbed and were therefore appropriate for fracture surface analysis.

Discussion

We noted early failure of four Longevity cross-linked polyethylene acetabular liners in two patients. Analysis of the bearings from these patients indicates that the Longevity polyethylene was not oxidized, and it is likely that the mechanical properties at the time of retrieval were similar to what they had been at the time of manufacture since we noted no substantial *in vivo* degradation⁶⁻⁸. The important factors related to failure appear to be the relatively thin polyethylene at the cup rim, the relatively vertical cup alignment, and the material properties of 10-Mrad remelted cross-linked polyethylene that are somewhat decreased relative to those of conventional polyethylene.

The importance of the moderate wear seen on the articular surface of the liners is not clear. In our experience, a moderate wear rating is not uncommon even in devices implanted for less than twenty-four months. This may be a manifestation

of the so-called bedding-in (plastic deformation) following implantation. Furthermore, rim fracture and dislodgment of the liners as well as the vertical orientation of the cups in these hips may have increased the degree of wear.

In these surgeries, the decision to use relatively large femoral heads (36 mm and 32 mm in diameter) was made because of concerns about recurrent dislocation. This resulted in polyethylene liners that were very thin in the area of major joint reaction loading. In all four cracked liners, the minimum thickness at the rim-locking mechanism was <4 mm. We believe that while the anticipated wear rate of the cross-linked polyethylene liners made this strategy appear reasonable, the resultant stresses acting at the lip of the cups, which were implanted at a relatively vertical angle, played a major role in the failure of these cups.

A similar case of liner failure has been reported in a device made from a different brand of highly cross-linked polyethylene (Crossfire; Stryker, Mahwah, New Jersey), which is gamma-irradiation cross-linked as opposed to electron beam-irradiation cross-linked. In a series of twenty-four retrieved Crossfire cross-linked polyethylene liners, Kurtz et al.¹⁶ reported the failure of one liner (with an internal diameter of 28 mm in a 48-mm shell implanted at 59° of abduction). Severe equatorial damage to the liner and failure of the locking mechanism were noted in a liner retrieved from an obese female patient who had undergone total hip arthroplasty 3.9 years previously. However, the authors of that study attributed these changes to wear that was due to a phase-transformed zirconia femoral head rather than to material failure of the cross-linked polyethylene.

Other studies have pointed to the importance of thin polyethylene at the rim as a factor in liner failure. Berry et al.¹⁷ reported thirteen catastrophic liner failures in a series of 4220 modular acetabular components at two large institutions. The ten retrieved devices studied in detail were non-cross-linked polyethylene liners representing three different designs. The one feature common to all of those liner failures was a polyethylene thickness at the rim of <5 mm.

It is important to note that modular liner thickness is often specified on the basis of the nominal material thickness at the apex of the liner. The dimension that is critical in the potential for rim failure is the minimum thickness at the

equatorial region, including indentations that are part of the locking mechanism. In offset liners, the minimum rim dimension can be substantially less than the specified nominal thickness.

The reduced toughness of the highly cross-linked polyethylene compared with non-cross-linked polyethylene⁶ likely contributed to fatigue failure of the liners in the current study. The calculated toughness of Longevity (10 Mrad melt-annealed cross-linked polyethylene) is decreased by half compared with non-cross-linked reference polyethylene made of the same resin type (62 MPa compared with 129 MPa)⁶. Thus, for any given implant geometry and loading, highly cross-linked polyethylene is more susceptible to fatigue damage, such as rim cracking, than is non-cross-linked material.

The long-term benefit of the low wear rate afforded by cross-linked polyethylene can be realized only if near-term mechanical failures are avoided. The potential for rim loading on thin polyethylene, particularly in patients with a relatively vertical cup orientation, should be assessed carefully when considering the use of a cross-linked liner and a large-size femoral head.

This study is limited by the small number of failed cups analyzed. While one notable common factor is that all of the liners were made from one brand of highly cross-linked ultra-high molecular weight polyethylene, a number of other common factors likely played an important role in the failure of the devices. The prevalence of this type of rim failure is not known and will require a much broader investigation of device failures. ■

Stephen S. Tower, MD
Anchorage Fracture and Orthopedic Clinic, 3260 Providence Drive, Suite 200, Anchorage, AK 99508

John H. Currier, MS
Barbara H. Currier, MChE
Kimberly A. Lyford, AB
Douglas W. Van Citters, PhD
Michael B. Mayor, MD
Thayer School of Engineering, Dartmouth College, 8000 Cummings Hall, Hanover, NH 03755. E-mail address for J.H. Currier: john.currier@dartmouth.edu

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