



FRACTURE OF HIGHLY CROSSLINKED UHMWPE ACETABULAR LINERS



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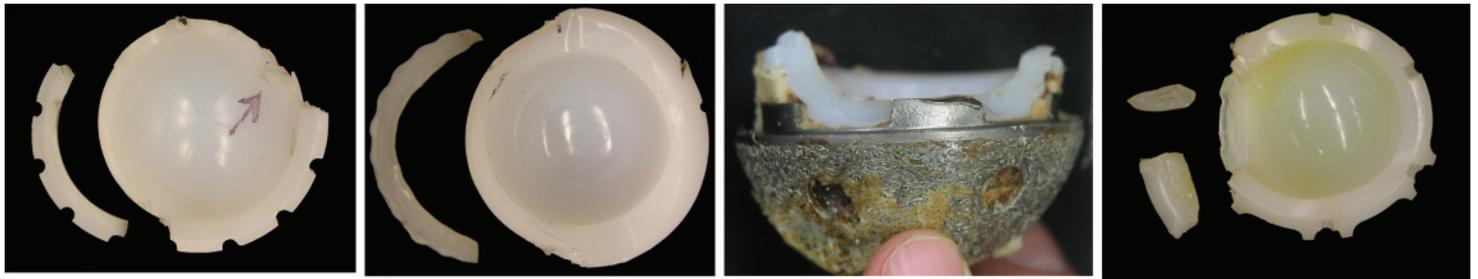


Figure 1. Cases 1-4, respectively. The liner in all four cases experienced a catastrophic fracture of the rim, originating at a stress concentration. Case statistics are listed in Tables 1-5.

INTRODUCTION

Four well-placed crosslinked UHMWPE acetabular liners of distinct design were retrieved subsequent to fracture failure of the rim (Fig. 1). In each case, electron microscopy of the fracture surface (fractography) revealed fatigue initiation markings associated with a stress concentrating feature in the rim (see below). Fracture surface investigation demonstrated that crack propagation in all cases followed contours of tensile stresses (as shown on facing page in Figure 11). FEA simulations were performed to examine whether direct rim loading, e.g., femoral neck impingement, could be the cause of the observed failures.

METHODS

The retrieved liners were modeled and meshed in detail using ABAQUS v6.7 (Simulia, Providence RI). Material properties were piecewise fit to those in Kurtz et al. [1]. Femoral neck impingement was simulated by a 500 N distributed force over a 5 mm wide sector of the rim. Crack initiation and propagation was inferred from the magnitude and orientation of the maximum principal stress, which is the extreme value of the local tensile stress and thus the driving force for crack growth phenomena. Oxidation index and crystallinity were obtained as in [2-3].

RESULTS

The simulations of each case show a crescent-shaped region of tensile stress surrounding the region of contact. In all cases, the magnitude of the maximum principal stress reaches its peak on the outer surface of the rim, at the root of a notch. Figure 2 schematically shows the orientation of the tensile stress for Case 1, which is in agreement with the crack opening direction in the retrieved liners. See below for more case details. All implants were free of significant oxidation.

All four simulations predicted a tensile stress in excess of 11 MPa at the point of observed crack initiation, implying that crack propagation was enabled by rim loading in all four cases. The tensile stress, S , required to propagate a crack is given by $S=K/Y(\pi a)^{-1/2}$, for a stress intensity factor K , a geometric factor $Y \sim 1$, and crack length a . Given a stress intensity for crack inception, K_{incept} , of 0.7 MPa \sqrt{m} [4], the approximate tensile stress required to grow an initiated crack from a 2 mm notch ($Y=1$) is 8.8 MPa.

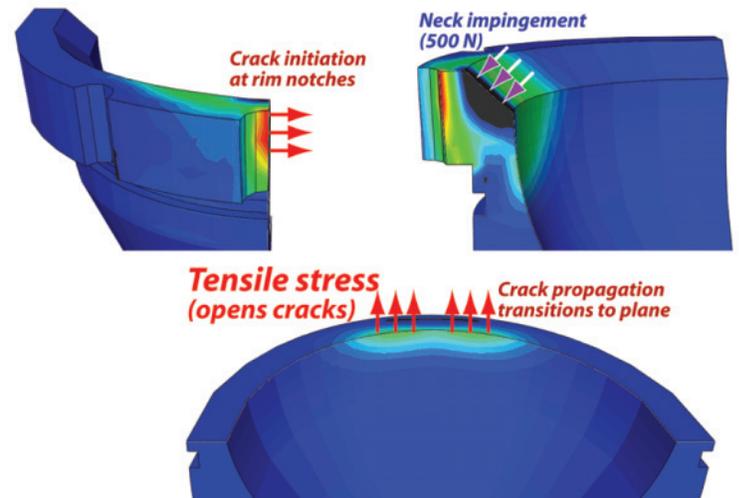


Figure 2. Max. tensile stress due to impingement. Red arrows show orientation of stress and thus predicted crack opening direction. These predictions match the observed crack paths and orientations.

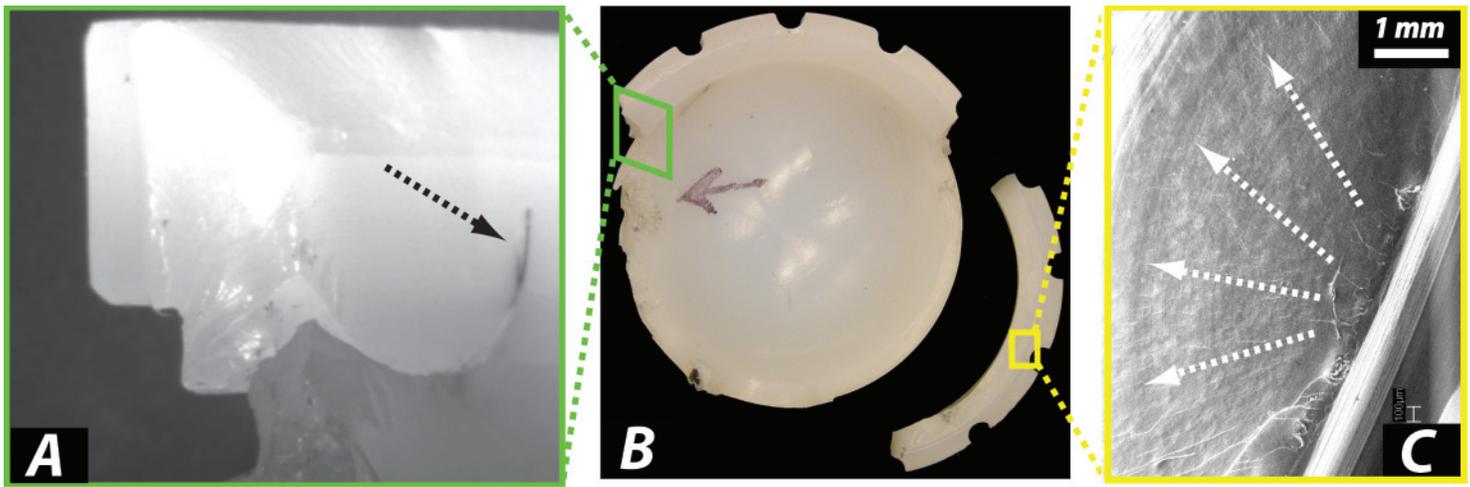


Figure 3. Fracture initiated on the underside of the rim, as shown by the procession of clamshell markings (3C). Cracks propagated in a crescent path (3A) and likely also initiated at the root of the rim notch. Multiple fractures initiated in this case, and a large arrested crack is indicated by the arrow in 3A. The crack also joins with the locking ring groove under the rim.

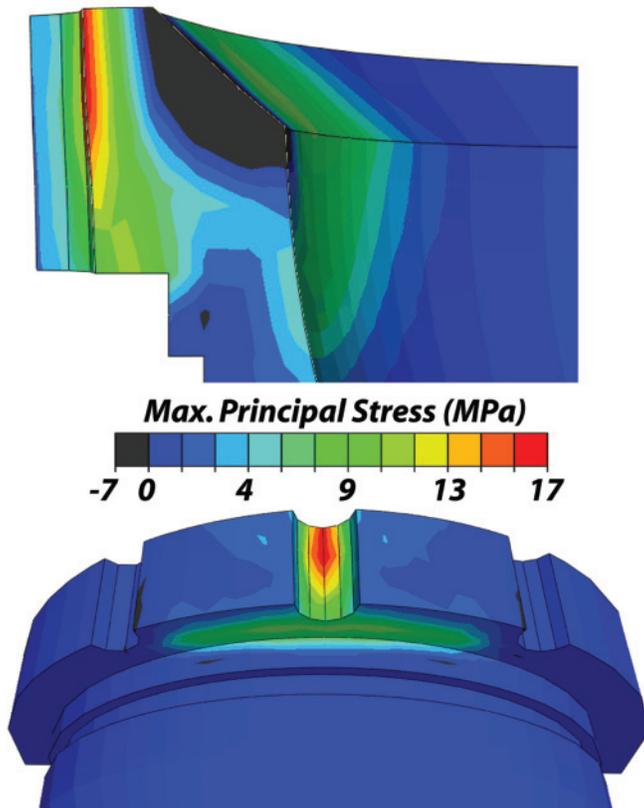


Figure 4. Tensile stress is maximum at the root of the notch and is substantial through a large portion of the thickness of the rim (Figure 4A). Note that 4A is the same cross-section and orientation as the fracture surface shown above in Figure 3A. Tensile stress under the rim is also severe enough to propagate cracks, and Figure 3C shows initiation markings at this location.

ZIMMER - TRILOGY/LONGEVITY

Case history A 62-year-old female with a BMI of 30 underwent uncomplicated primary total hip arthroplasty for osteoarthritis with a 52 mm Trilogy acetabular component and 36 mm Longevity acetabular liner (Zimmer, Warsaw, IN). Vertical inclination of the cup was 40 degrees and anteversion, measured by the method of Ackland et al. [5] was 45 degrees. She returned for routine follow-up one year after surgery and reported pain and “noises” in her hip. Radiographs demonstrated eccentric position of the femoral head in the acetabulum consistent with liner dissociation. Revision of the acetabular component was performed. Both the femoral component and acetabular shell were well fixed. The liner was found to be fractured along the rim and dissociated from the metal shell (Figure 3).

Findings The predicted maximum value of the principal stress in this case was 17 MPa, occurring at the root of the rim notch. The rim was modeled in contact with the metal backing, thus developing substantial tensile stresses (10 MPa) on the underside of the rim. Cracks likely initiated at both locations, while clamshell markings (initiation artifacts) are seen in the latter in Figure 3C. Cracks propagated between the rim notches following the tensile stress contours, which are crescent shaped. The cracks also linked with the circumferential groove in the implant, as seen in Figure 3A. Figure 3A also shows a large arrested crack in the rim. Intact components may harbor large arrested cracks, such as seen here, recommending the routine inspection of intact explanted liners. Such cracked implants may be on the verge of fracture and more data is needed on how pervasive arrested or nascent cracks are.

Table 1. Case 1 data and material analysis results

Implant Characteristics		Retrieval Analysis	
Manufacturer	Zimmer	Length of overhanging PE	8.56 mm
Design	Trilogy	PE thickness at rim	2.2 mm
Polyethylene	Longevity	Peak tensile stress	17 MPa
Radiation dose	10 Mrad	Notch radius at initiation	0.28 mm
Patient Characteristics		Oxidation index	0.07
Anteversion angle	45°	Crystallinity	50.8
Vertical inclination	40°		
Duration in-vivo	1 year		

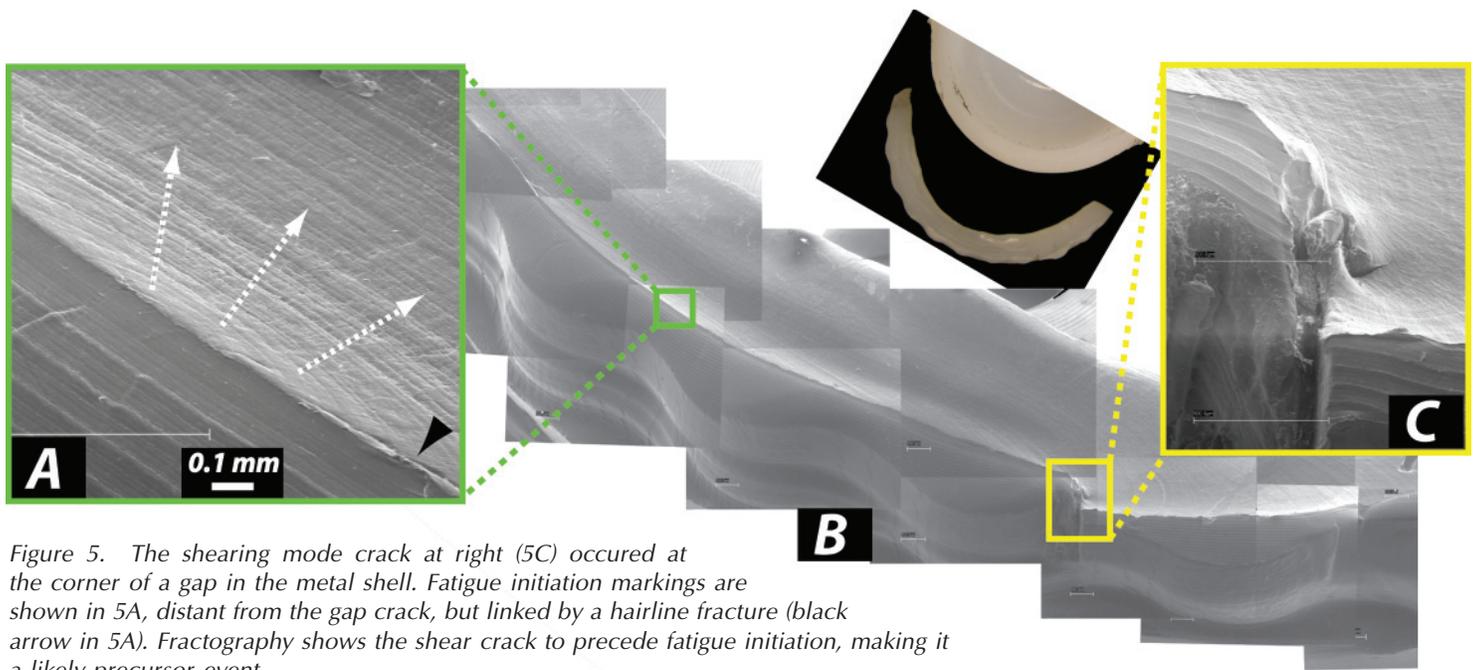


Figure 5. The shearing mode crack at right (5C) occurred at the corner of a gap in the metal shell. Fatigue initiation markings are shown in 5A, distant from the gap crack, but linked by a hairline fracture (black arrow in 5A). Fractography shows the shear crack to precede fatigue initiation, making it a likely precursor event.

SMITH AND NEPHEW - REFLECTION/XLPE

Case history A 25-year-old female with a BMI of 35 had been treated previously for Perthes disease with proximal femoral osteotomy and later hardware removal. She developed degenerative arthritis of the hip and underwent primary total hip arthroplasty with a 48 mm Reflection cup and 28 mm XLPE acetabular liner (Smith and Nephew, Inc., Memphis, TN). Vertical inclination of the cup was 44 degrees and anteversion was 25 degrees. Three months after surgery she suffered a fall to her knees and developed pain and squeaking in her hip. She presented 10 days after the fall. X-rays demonstrated eccentric position of the femoral head in the acetabular liner consistent with dissociation.

Findings This design appears to have largely mitigated stress concentrations. However, there is a gap in the metal counterpart to the spline below the rim leaving it unsupported in that segment, resulting in a stress concentration at the two corners of the gap. The simulation shows tensile stresses exceeding 23 MPa at these locations, matching observed cracks in the spline (Figure 5C). The fractography shows fatigue initiation occurring remote from and subsequent to the spline gap fracture (Figure 5A). These two fracture features are linked by a hairline fracture, and thus the gap fracture is likely a precursor to the observed fatigue initiation. Recall that the results of Case 1 (Figure 4) demonstrated how tensile stress can develop on the underside of the rim, leading to crack propagation there. This simulation case also applies a 0.5 mm radial inward displacement to the spline to simulate an assembly press-fit. This develops the tensile stress seen on the inner surface of the liner and appears necessary to predict the failure, unlike in the other three cases.

Table 2. Case 2 data and material analysis results

Implant Characteristics		Retrieval Analysis	
Manufacturer	Smith and Nephew	Length of overhanging PE	3.25 mm
Design	Reflection	PE thickness at rim	4.6 mm
Polyethylene	XLPE	Peak tensile stress	26 MPa
Radiation dose	10 Mrad	Notch radius at initiation	0.26 mm
		Oxidation index	0.09
		% Crystallinity	52.3
Patient Characteristics			
Anteversion angle	25°		
Vertical inclination	44°		
Duration in-vivo	5 months		

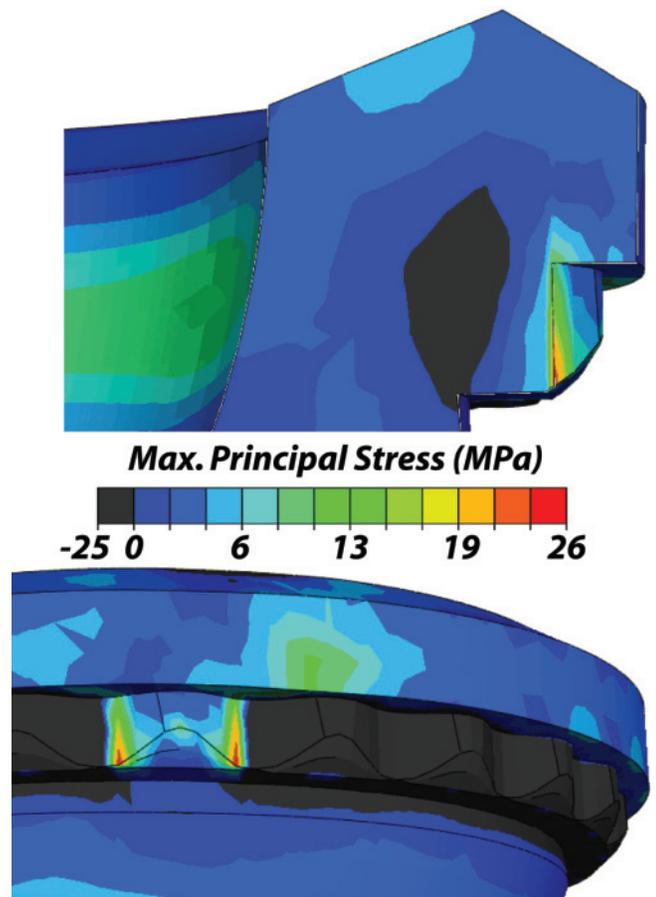


Figure 6. The stress during impingement is concentrated in exactly the same region seen in the observations (Figure 5). The stress in the cross-section is shallow, possibly explaining why failure was not catastrophic at this location.

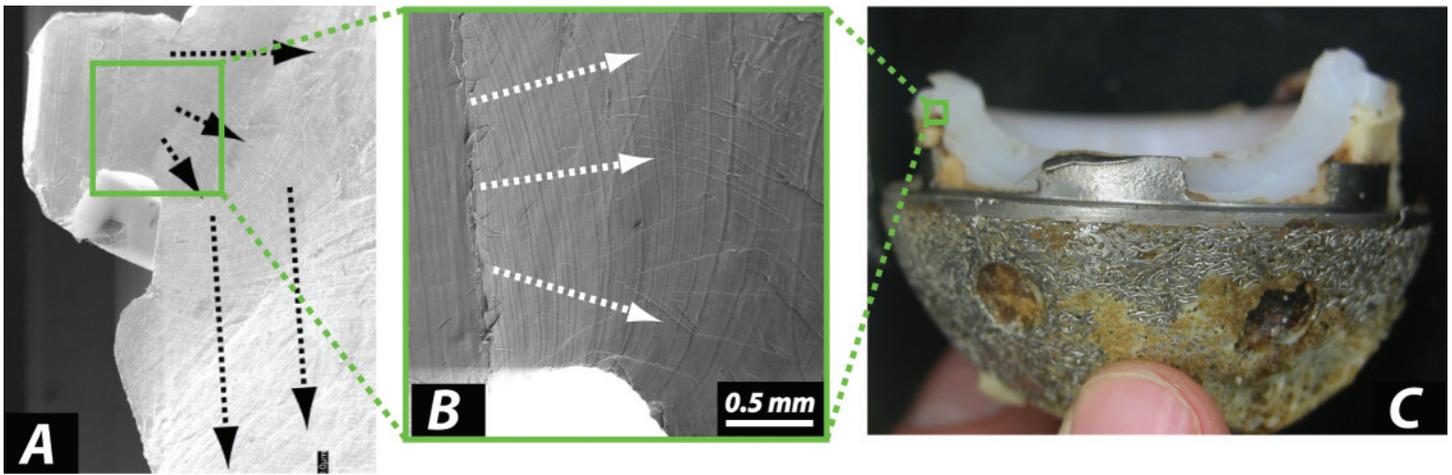


Figure 7. Fracture initiated at the corner of a slot cut into the rim (7A and B) and propagated in the characteristic crescent path. Note that this case used a crosslinked liner in a revision that did not match the metal shell height, resulting in a larger than normal amount of overhanging rim.

SULZER/ZIMMER - HARRIS-GALANTE II/DURASUL

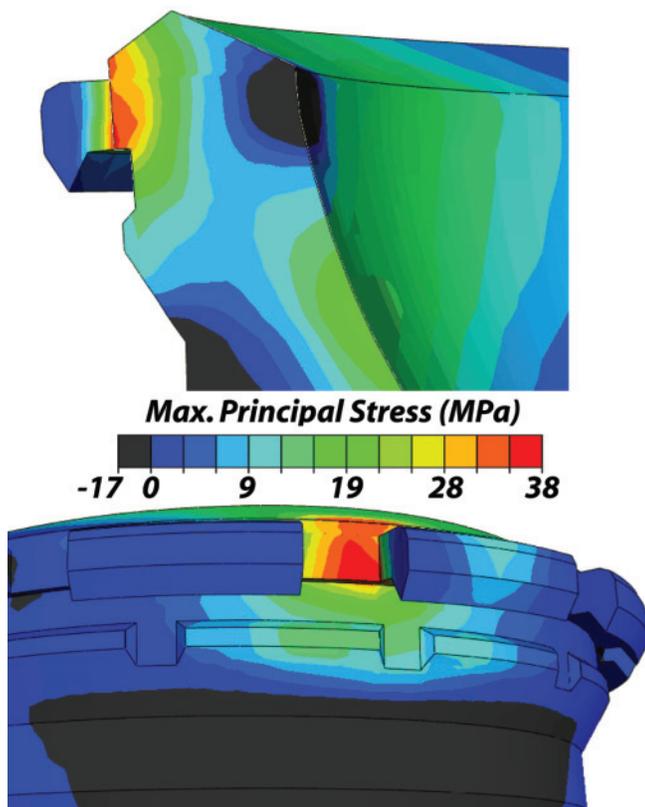


Figure 8. Predicted tensile stresses in this case are the greatest of the series, which is expected given the extent of exposed rim above the metal backing. Stress through the thickness is also high enough to readily drive fracture.

Case history A 74-year-old female with BMI of 21 had been treated previously for osteoarthritis of the hip with total hip arthroplasty when she was 60 years of age. A 54 mm Harris-Galante II acetabular component, 26 mm elevated rim acetabular liner, and cemented CPT stem (Sulzer, Austin, TX) were used. Vertical inclination of the cup was 51 degrees and anteversion was 8 degrees. Twelve years after primary THA she developed pain associated with subsidence of the femoral component and osteolysis. One year later, she fell and sustained a periprosthetic femur fracture. This was treated with revision to a 250 mm cemented Versys stem (Zimmer) and circlage fixation of the femur. The acetabular liner was worn, but the metal shell was well fixed and retained. A 32 mm Converge acetabular liner (Zimmer) was cemented into the metal shell. Two years after revision the patient experienced a posterior dislocation of the hip requiring closed reduction. Five months later while sitting in a chair she experienced another dislocation and revision THA was then performed. The rim of the acetabular liner was found to be fractured and the entire acetabular component was removed (Figure 7).

Findings This liner had the greatest amount of unsupported UHMWPE above the metal backing, nearly 10 mm in some locations, and thus experienced the greatest stress in this case series (36 MPa) during simulated impingement. It is important to note that the liner was fixed into a metal backing from a previous surgery that did not interface with the designed locking mechanism and necessitated bone cement for bonding during revision. This case shows that the height of the unsupported rim affects the stress during impingement, and that the interfacing of components may be more critical when employing crosslinked UHMWPE.

Table 3. Case 3 data and material analysis results

Implant Characteristics		Retrieval Analysis	
Manufacturer	Sulzer/Zimmer	Length of overhanging PE	9.24 mm
Design (Shell/Liner)	Harris-Galante II/ Converge	PE thickness at rim	4.3 mm
Polyethylene	Durasul	Peak tensile stress	38 MPa
Radiation dose	9.5 Mrad	Notch radius at initiation	<0.1 mm
		Oxidation index	0.03
		% Crystallinity	44.6
Patient Characteristics			
Anteversion angle	8°		
Vertical inclination	51°		
Duration in-vivo	2 years 5 months		

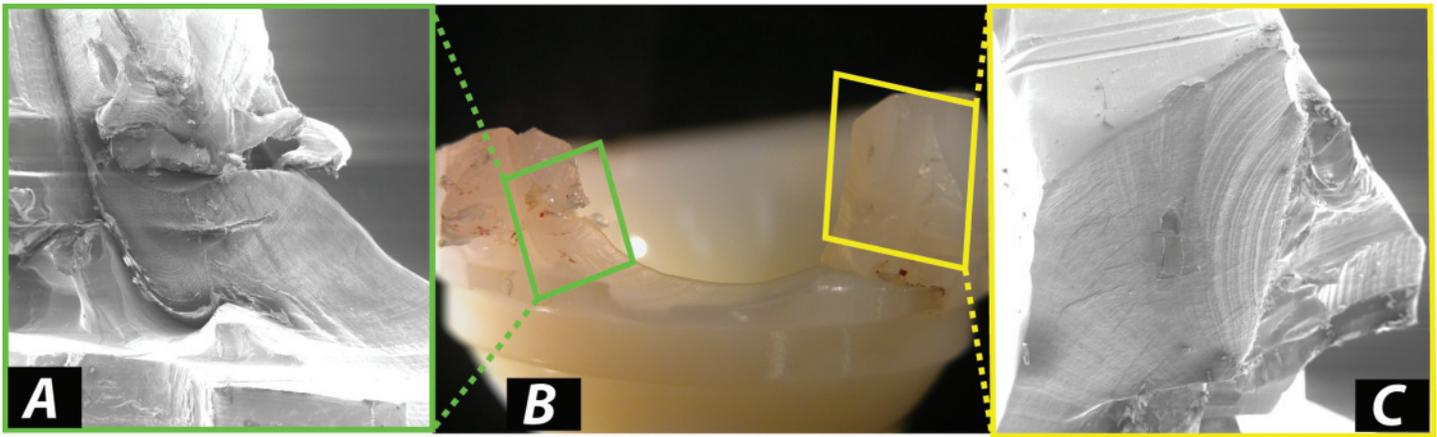


Figure 9. The sharp corners of milled slots in the rim initiate fractures, clearly shown in C. Multiple such fractures initiated independently. This case took the longest to fail, implying that while crack initiation was widespread, crack propagation was somehow limited.

DEPUY - S-ROM/MARATHON

Case history A 23-year-old female with a history of systemic lupus erythematosus and renal failure underwent primary THA for avascular necrosis with a 45 mm S-ROM acetabular component (DePuy, Warsaw, IN). The vertical inclination of the cup was 48 degrees and anteversion was 10 degrees. Eight years later the patient underwent revision of both the femoral component and acetabular liner. The acetabular shell was well fixed, and a Marathon acetabular liner (DePuy) was inserted. Five years later the patient reported a popping sensation in her hip. Revision THA was performed and the liner was found to be fractured.

Findings The predicted magnitude of stress is relatively low at 12 MPa, and agrees with the initiation location observed from fractography. The locking mechanism of this design has acute slots milled vertically in the rim, from which cracks can propagate. The corner of the slot appeared very acute upon microscopic inspection. Such a sharp corner may readily allow fatigue initiation, while the low stress experienced inside the liner would inhibit propagation. This liner employs a lower radiation dose (5 Mrad), which is known to yield improved fatigue performance [4]. This liner was in-vivo for the longest in the series, 5.4 years, which may have been enabled by the comparatively elevated fatigue properties of the moderately crosslinked UHMWPE and the relatively low stress during impingement.

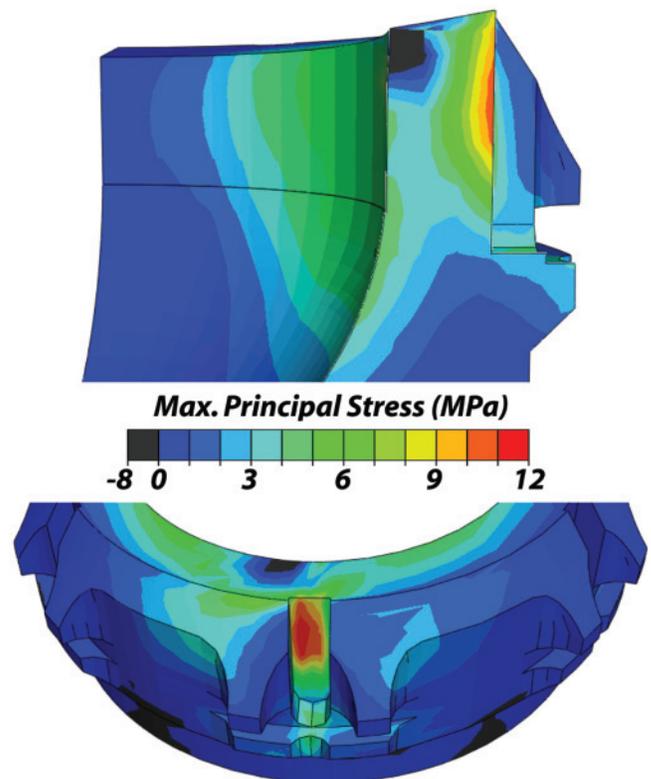


Figure 10. Tensile stress peaks at the observed initiation location, though it is the least severe of all implants in the series. The corner of the slot is the sharpest of the stress concentrations in the series, possibly explaining the ease of initiation that contrasts with inhibited propagation due to the overall low magnitude of tensile stress in the liner. The UHMWPE employed in this case is only moderately crosslinked, which may further frustrate crack propagation.

Table 4. Case 4 data and material analysis results

Implant Characteristics		Retrieval Analysis	
Manufacturer	DePuy	Length of overhanging PE	7.87 mm
Design	S-ROM	PE thickness at rim	5.7 mm
Polyethylene	Marathon	Peak tensile stress	12 MPa
Radiation dose	5 Mrad	Notch radius at initiation	0.18 mm
Patient Characteristics		Oxidation index	0.10
Anteversion angle	10°	% Crystallinity	51.7
Vertical inclination	48°		
Duration in-vivo	5 years 5 months		

DISCUSSION

Case reports of fractures along the rim of highly crosslinked UHMWPE modular components have been attributed to implant malposition and thin polyethylene along the rim of the components [6-7]. Although surgical technique clearly influences the risk of impingement, impingement is a very common observation in retrieved acetabular components, even if malposition has not occurred [8].

It is a common misconception that crosslinked UHMWPE is intrinsically resistant to fatigue initiation and therefore will not be susceptible to fatigue fractures - the results of this work demonstrate otherwise. Crosslinking comes at the expense of ultimate strength and strain, and resistance to fracture, rendering this material more susceptible to brittle behavior in the presence of stress concentrations, discontinuities, or flaws. It is well known that fatigue can either proceed in a characteristically brittle or ductile manner [9], and recent work has demonstrated that UHMWPE fatigues in a brittle manner despite its extensive conventional ductility [10]. This behavior becomes more detrimental as the material becomes less tough due to crosslinking.

It is instructive to note that fractures in ceramic orthopaedic bearings are infrequent but catastrophic, and have led to the near total elimination of stress concentrations or elaborate locking mechanisms in those systems. Ceramic bearings also have little or no overhanging material in the form of a liner rim to mitigate impingement related damage. All of these practices can be prudently extended to UHMWPE without undue complexity as a result.

Crosslinked UHMWPE is a safe and effective bearing material, but it must be employed in a way that mitigates the ability for cracks to initiate or propagate. Conventional designs that employ crosslinked UHMWPE may not be robust enough to prevent fracture failure, as seen in these cases, and must be rigorously reevaluated prior to adaptation of new bearing materials. New designs employing highly crosslinked UHMWPE should reduce the effect of stress concentrations, the amount of overhanging material that extends beyond the metal backing, and the likelihood of impingement in-vivo.

CONCLUSIONS

- Crosslinked UHMWPE is mechanically inferior (reduced toughness and ultimate strength and strain) to conventional UHMWPE, and behaves like a ceramic in fracture and fatigue with fracture mechanics similar to a ceramic material.
- Fractures originate at stress concentrations in unsupported rims during impingement. We recommend the elimination of these features.
- Fractures can arrest after initiation because of low tensile stresses inside the liner. Clinically functioning highly crosslinked UHMWPE liners may harbor nascent or arrested cracks and therefore be on the verge of catastrophic failure. More study is needed on this issue. Such cracks may be clearly visible upon removal of intact liners.
- Legacy designs employing new materials must be reevaluated for safety and efficacy.

REFERENCES

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Table 5. Case data and material analysis results

Case	1	2	3	4
Implant Characteristics				
Manufacturer	Zimmer	Smith and Nephew	Sulzer/Zimmer	DePuy
Design (Shell/Liner)	Trilogy	Reflection	Harris-Galante II/Converge	S-ROM
Polyethylene	Longevity	XLPE	Durasul	Marathon
Radiation dose (Mrad)	10	10	9.5	5
Heat Treatment	Remelted	Remelted	Remelted	Remelted
Liner Size	36mm	28mm	32mm	28mm
Patient Characteristics				
Age	62	25	74	37
Sex	Female	Female	Female	Female
BMI	30	35	21	—
Anteversion Angle	45°	25°	8°	10°
Vertical Inclination	40°	44°	51°	48°
Duration in-vivo	1 year	3 months	2 years 5 months	5 years 5 months
Retrieval Analysis				
Length of overhanging PE	8.56 mm	3.25 mm	9.24 mm	7.87 mm
Oxidation Index	0.07	0.09	0.03	0.10
% Crystallinity	50.8	52.3	44.4	51.7

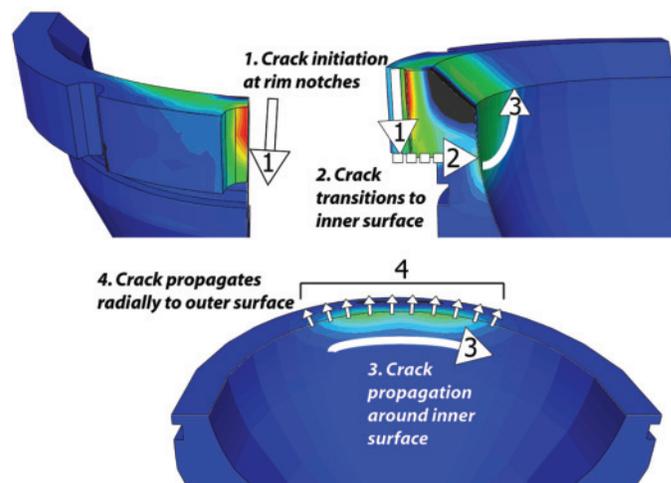


Figure 11. Schematic of crack advance, as inferred from the contours and orientation of tensile stress due to impingement. Note that Steps 2 and 4 are frustrated, as the tensile stress is low in the middle of the cross section and on the outside of the liner. Thus, arrested cracks may exist in intact implants outside of weight bearing region.