

Micro-wear features on unique 100-Mrad cups

Two retrieved cups compared to hip simulator wear study

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ABSTRACT We studied the micro-wear phenomena of unique, extensively cross-linked polyethylene cups (cross-linked with 1,000 kGy-irradiation) that had been used briefly in Japan. Two retrievals (at 15 years) came from the Japanese “SOM” hip system (implanted 1971–78). These were compared to a set of 0kGy and 500–1,500 kGy cups run in our hip simulator. The polyethylene cups that had not been cross-linked had the greatest wear. The worn areas had a burnished appearance and were clearly separated from the unworn region by a distinct ridge-line. The worn areas had lost all machine tracks, showed a large amount of UHMWPE ‘flow’, and long PE fibrils. The associated surface rippling was degraded. These features were considered synonymous with severe polyethylene wear. In contrast, the worn areas in the very cross-linked cups had a visibly matte surface and no ridge-line. Micro-examination showed that the machine tracks were still present. Ripple formations were less obvious than in the cups that were not cross-linked, polyethylene surface fibrils were scarcer and all the fibrils were much smaller than in the cups that were not crosslinked. Our two retrieved cups and the simulator cups confirmed the greater wear-resistance of very cross-linked polyethylene. It should also be noted that the SOM cup design and processing were unique and differed greatly from that of modern polyethylene cups.

ene oxide gas (EtO: not cross-linked UHMWPE) or by a 25–35 kGy gamma-radiation dose in air (surface-oxidized: moderately cross-linked) (Schmalzried et al. 1992). The new polyethylene cups utilize new UHMWPE resins and higher irradiation doses, very different from those used in the past 30 years. The modern cups (500–100 kGy dose) have been studied in various laboratories and there is general agreement that less wear occurs with more cross-linking (Wang et al. 1996a, Bragdon et al. 1997, Clarke et al. 1997, McKellop et al. 1997, Chiesa et al. 1999, Gillis et al. 1999, Muratoglu et al. 1999a, b, Spiegelberg et al. 1999).

Three groups have reported clinical results with very cross-linked cups and each group used distinctive processing (Oonishi et al. 1995, 1999a, Wroblewski et al. 1996, Grobbelaar et al. 1999) The clinical data have been limited. The South African study used a chemically-treated, cross-linked cup surface. A brief update has reported little in the way of concerns about wear or osteolytic problems in two series (Grobbelaar et al. 1999). The study from England used zirconia ceramic heads and chemically, cross-linked cups. Despite some concerns raised by other groups using zirconia (Clarke et al. 2003), this study continues with excellent results and no reoperations to date (Wroblewski et al. 2000).

The Japanese cups in our study came from the series of 71 cases (1971–78) using 1 000 kGy cups. These were frequently referred to as “HDP” (Oonishi et al. 1995 1988) in the manner of Charnley

Current knowledge of UHMWPE wear concerns 30 years of experience with cups sterilized by ethyl-

and Wroblewski, but were, in fact, UHMWPE (RCH-1000, Hoechst, Germany). The polyethylene bars were irradiated with a 1,000-kGy dose from a cobalt source in triple-sealed plastic bags in air. The cups were implanted as the “SOM” THR system (Mizuho Medical Instruments Inc., Japan). The radiographic study followed 28 SOM cases over a 20-year period and found wear of 0.072–0.076 mm/year, which was 3.3-fold lower than in the T-28 controls (Oonishi et al. 1995). This was a smaller reduction than would have been predicted by the laboratory wear studies.

We were fortunate to obtain the only two SOM retrievals (15-year follow-up) reported in this 30-years’ experience. We also did a wear study with 1,000 kGy-irradiated cups (Oonishi et al. 1999b). As noted in other simulator studies, our wear-rates for cross-linked cups were so low as to be immeasurable. Our simulator cups were not intended to be duplicates of the SOM cups from the 1970s, but were to be investigated concerning the value of 500–1 500 kGy irradiation for contemporary cups. After sterilization in air with 1 000 kGy, our UHMWPE rods had been machined to remove the surface layer of oxidized material. Then a heat treatment was given to remove any free radicals. Finally, the cups were machine shaped. If these cups had been meant for clinical use, the next step would have been sterilization using gas plasma techniques.

Our study objective was to compare the micro-wear phenomena of the two retrieved cups to that of the simulator cups. Our hypothesis was that the micro-examination of the 1 000 kGy retrieved and simulator cups would show very few signs of wear-debris formation.

Methods

We had access to 5 cups retrieved from the 1970s in Japan. Two of these were the unique, very cross-linked SOM cups with a radiation dose of 100 Mrad (1 000 kGy) (Table 1). For comparison, we

Table 1. Data concerning retrieved UHMWPE cups

Parameter	SOM cup 0 Mrad	SOM cup 100 Mrad)	T-28 cup 2.5 Mad)
Manufacturer	MMI ^a	MMI ^a	Zimmer
Retrieved cups	1	2	2
Duration of implantation, year	8	15	13, 18
Femoral head size, mm	28	28	28
alloy	COP	COP	stainless steel
Off-shelf cups	2	2	none
Resin	RCH-1000	RCH-1000	Himont 1900
Molecular weight	1×10 ⁶	1×10 ⁶	2–4×10 ⁶

^a Mizuho Medical Instrument

also had 1 SOM cup with no cross-linking at all. As our control cup, we had two T-28 cups with conventional cross-linking and a radiation dose of 2–3 Mrad from the same period (Zimmer, Warsaw, IN). The retrieved cups that had not been cross-linked (sterilized by ethylene oxide gas) are called retrieved-PE and the 100 Mrad cups retrieved-XL. The retrieved-PE and retrieved-XL cups (all cemented) came from operations performed in the early 1970s (Table 1).

In the past, UHMWPE cups had many deep circumferential machine tracks which, depending on the manufacturer and period, could be seen as ‘furrows’ of varying depth, pitch and frequently irregular. During wear, as the UHMWPE surface flows, these furrows can become smeared or abraded and mistaken for cracks or other types of wear (Walker and Bullough 1973, Dowling et al. 1978, McKellop 1995, Oonishi et al. 1995). Therefore, we studied ‘off-the-shelf’ cups from the same manufacturers and the same period to visualize the condition of the cup bearings ‘before’. The “off-the-shelf” cups (virgin-PE; virgin-XL) were used to map the original as machined surfaces. The cup surfaces were examined first by stereomicroscopy (× 10–20 magnification) and then by LV-SEM (Philip XL30 FEG). Sections were cut from each cup using Atkinson et al.’s method (1985) for SEM analysis of the bearing surfaces. Image-analysis techniques were used on SEM micrographs to quantify the size and shape of the wear features.

The inferior portion of the cup is generally viewed as a habitually non-weight bearing region

Table 2. Manufacturer and PE cups treatments studied in stimulator

Parameter	0 Mrad	50–150 Mrad	2.5 Mrad
Experiment #	HE061	HE061	HE072
Manufacturer	Kyocera	Kyocera	Sulzer
Resin	GUR4150	GUR4150	GUR1020
Sterilization	none	in air	in nitrogen
Treatment	machined	annealed under vacuum, machined	packaged in nitrogen
Serum	30%	30%	90%
Additive	EDTA, sodium azide	EDTA, sodium azide	EDTA, sodium azide
Duration	6.2 Mc	6.2 Mc	10 Mc
Femoral head	alumina 26 mm	alumina 26 mm	CoCr 28 mm

and has a matte appearance (Dowling; McKellop/Modes). The superior region of UHMWPE cups generally has a smooth surface, due to the micro-polishing wear processes (Dowling et al. 1978) A border region usually called the ridge-line (Dowling et al. 1978), separates these two regions of wear. In the main wear region, there are various micro-wear phenomena to be observed (Dowling et al. 1978, Atkinson et al. 1985, McKellop 1995, Oonishi et al. 1995 Yamamoto et al. 1999). Specific details of wear considered in our study included the presence of the original machined tracks (evidence of minimal wear), the occurrence of ripples, indicative of a strain-hardening mechanism in the PE surface layer, and PE fibrils, suggesting incipient wear debris (Bragdon et al. 1996, Wang et al. 1996b).

The experimental simulator cups had a range of radiation (500, 1000, 1 500 kGy; N = 3 each) to include that used clinically in Japan (Bioceram Division of Kyocera Inc., Kyoto, Japan). The control simulator cups were of standard polyethylene and had not been subject to radiation. The non-irradiated simulator cups that had not been irradiated are called simulator-PE and the extensively cross-linked cups are called simulator-XL. The 3 cups that had not been irradiated and the 9 gamma-irradiated UHMWPE cups were mounted in UHMWPE adaptors facing upwards in a multi-channel hip simulator (Shore Western Manufacturing Inc., Monrovia, CA) (Paul 1966, Oonishi et al. 1999b). The UHMWPE, which had about the same stiffness as bone cement, simulated the cement backing used with these cups. A commercial bovine serum (Hyclone Laboratories, Logan,

UT) was diluted to a 30% solution to give a protein concentration of 20 mg/mL, with the addition of EDTA and sodium azide (Clarke et al. 1997, McKellop et al. 1997). The hip-loads were run with a physiological Paul load-profile (min 0.2 kN; max 2 kN at 1 Hz) (Oonishi et al. 1999b). The serum was changed every 250,000 cycles and its temperature monitored, but not controlled (Table 2).

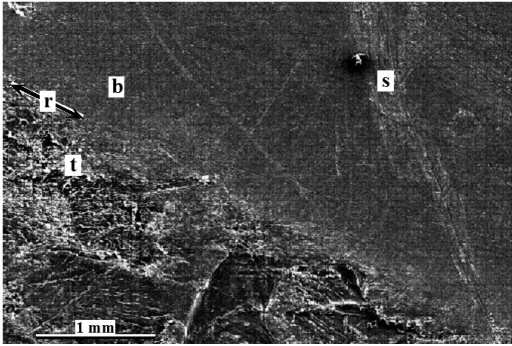
Results

On the retrieved-PE cup after 8 years of follow-up, the ridge-line was distinct and SEM analysis showed that the original machine marks had been worn off from the main region of wear (Figure 1a). The smoothly worn surface had many criss-cross scratches 1–20 μm wide from 3-body abrasive wear. At higher magnifications, we found much evidence of surface flow and realignment. Numerous fibrils from 0.1 to 0.5 μm diameter and 10–20 μm long were seen lying semi-detached on the surface (Figure 1b). Below these, there were many fibrils still attached to the surface, which looked like folds and fronds mainly facing the area of sliding. Some folds or fronds also resembled clusters of surface nodules (< 1 μm diameter).

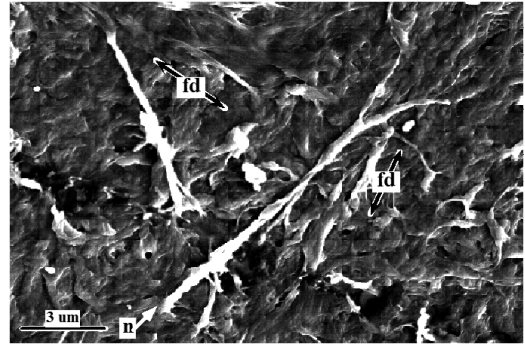
On the two XL cups (1 000 kGy irradiation) retrieved after 15 years, we found no ridge-lines, no smoothly worn surface typical of the other retrieved cups and no fissures or surface delaminations. With the exception of the exact center of the wear zone, the original machine tracks (20–50 μm periodicity) were visible throughout (Figure 2a). The central dome area had many very fine scratches and a few white spots (Figure 2b). We found considerable evidence of UHMWPE flow and realignment around nodule-like structures. As a result, 0.1–0.2 μm wide clefts formed in the surface matrix (Figure 2c). The fold and frond formations were somewhat uncommon in these XL cups and they were becoming semi-detached fibrils about 2–3 μm long.

The simulator-PE cups had wear rates exceeding 50 mm^3 per million cycles. These had the typical,

Figure 1. Worn surface of retrieved 0-Mrad SOM cup after 8 years of use in a patient.

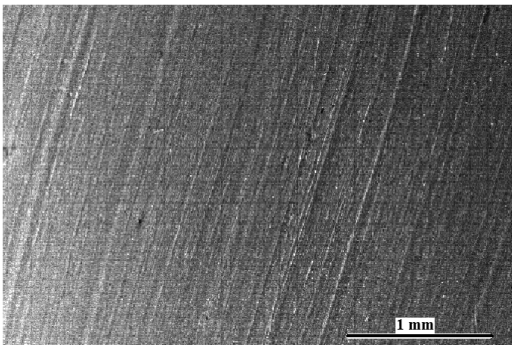


Area of transition (t) and burnished load-bearing surface (b) separated by ridge-line (r). Very scratched areas (s) are also seen (x27).

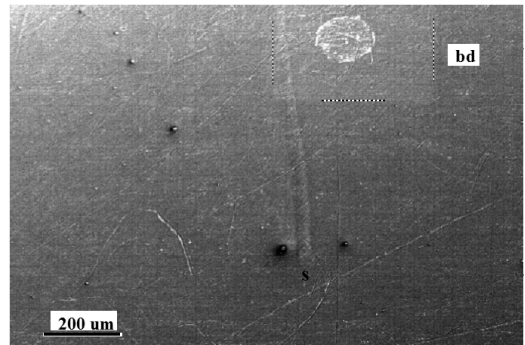


Signs of the mechanics of PE surface flow (fd) resulting in surface nodules (n), which have decomposed to form small flakes or fibrils and even large partly-detached fibrils (x10,000). 2 axes of PE flow were seen in this area (fd).

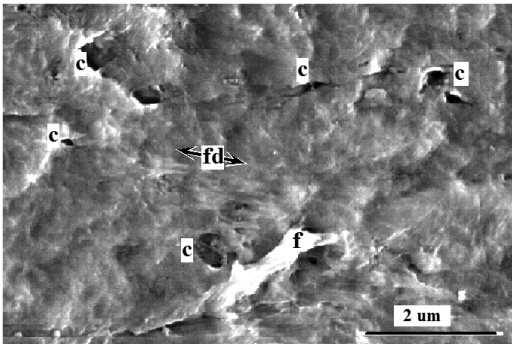
Figure 2. Worn surface of retrieved 100-Mrad SOM cup after 15 years of use in a patient (ID# SOM83-2).



Machine tracks in rim area (unworn) of cup (x30).



Low-power view of weight-bearing area showing a few scratches (s) enclosed by a square that indicates SEM beam-damage (bd; x50).

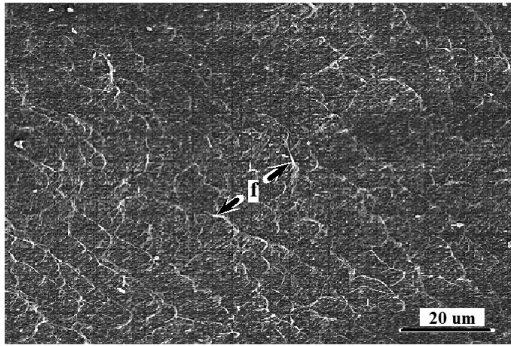


c. High-power view of worn surface showing direction of PE (fd), which also created clefts (c) as the surface moves in response to shear stresses. One 2- μm long frond (f) is visible since it developed into a partly detached fibril (x12,800).

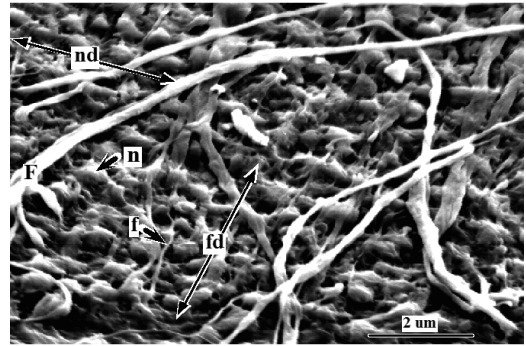
smoothly-worn surface with a distinct ridge-line separating the worn area from the matte appear-

ance of the unworn surface. On the micro-scale, the simulator-PE worn regions had lost their original machine tracks. These burnished surfaces had a few large scratches from 3-body abrasive wear and occasional white spots 50–200 μm in diameter. The machine tracks were seen only at the cup rim. At higher magnification, the worn surfaces showed numerous fibrillar structures aligned mainly in the direction of sliding (Figure 3a). These formed regular rows with a periodicity of 1–2 μm . The fibrillar structures were seen as large, elongated PE fibrils that averaged 0.2 μm in diameter; many were over 10 μm long and usually attached at one end to the cup surface. They were found at a frequency of about 10 000 per square millimeter. Below these surface fibrils were located arrays of PE nodules

Figure 3. Appearance of 0-Mrad PE cups (not cross-linked) after 6.2 million cycles in simulator.

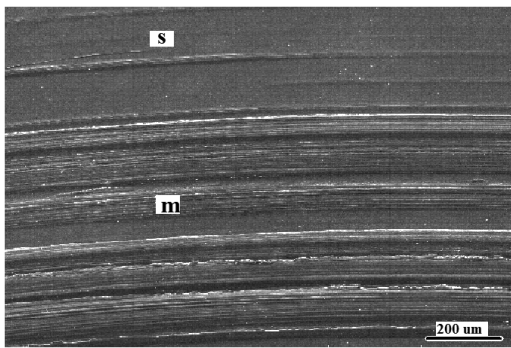


Numerous elongated filaments (f) of PE partly detached from surface of cup ($\times 1,500$).

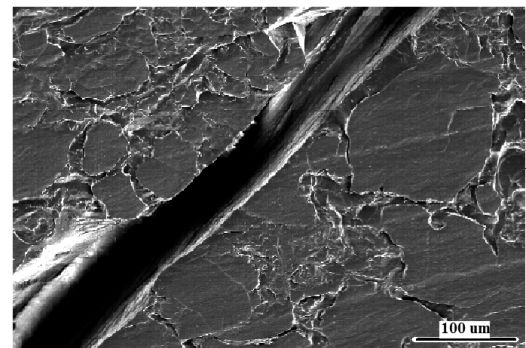


Abundant number of nodules (n) with their main direction indicated by arrow (nd). Many fine fibrils (f), semidetached from the surface, extending from the nodules. Their chief direction indicated by an arrow (fd) showing the main direction of shearing. Many large fibrils (F) can also be seen for long distances on this surface ($\times 10,000$).

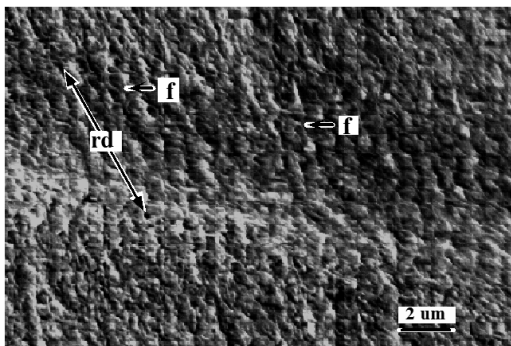
Figure 4. Appearance of extremely cross-linked PE cups after 6.2 million cycles in simulator (to 6.2 Mc).



Alternate areas of burnished, smooth appearance (s) with machine tracks (50 Mrad; $\times 178$).



Delaminating surface plates, ranging from 50 to 200 μm , adjacent to surface fissure (150 Mrad; $\times 200$).



Surface scratch traversing numerous ripples at right angles to main ripple direction (arrow = rd). The nodules have short fibrils (f) attached to their peaks (100 Mrad; $\times 8,000$).

that varied from 0.2 to 0.5 μm in diameter (Figure 3b). Many PE fibrils less than 0.1 μm in diameter had also formed on top of these nodules. No surface features, such as “ripples”, were seen on these worn simulator-PE cups. Both retrieved-PE and simulator-PE surfaces had the same range of fibril frequency (about 30 000–50 000 per mm^2).

None of the simulator-XL cups had the typical smooth appearance of the worn simulator-PE cups. The original machine marks could still be seen in the cup rim and in some parts of the central weight-bearing areas (Figure 4a). The machine-track periodicity averaged 50 μm . A few surface cracks, about 3–5 mm long, were seen, oriented in

Table 3. Summary of frequency of PE micro-wear phenomena in SEM, showing a good correlation between in-vitro (simulator) and retrieved (patient) cups

Cross-linking	M-tracks	Ripples	Nodules	Fibrils	Wear
0 Mrad					
in vitro	0	(+)	++	+++	+++
retrieved	0	0	++	+++	+++
2.5 Mrad					
in vitro	0	++	+	++	++
retrieved	0	+	+	++	++
100 Mrad					
in vitro	+++	++	(+)	(+)	(+)
retrieved	++	+	(+)	(-)	+
50–150 Mrad					
in vitro	+++	++	(+)	(+)	(+)
retrieved	NA	NA	NA	NA	NA

M-track = machined tracks (in weight-bearing region).
 +++ = many, ++ = very frequent, + = moderate numbers,
 (+) = uncommon, 0 = not seen, NA = not applicable.

a slightly circumferential and oblique direction to the machine tracks (Figure 4b). Bordering these macro-fissures were surface areas 1–2 mm wide with many delaminating flakes 50–200 μm in diameter. Occasional “white” spots, also 50–200 μm in diameter, were seen in these delaminated areas, and some had numerous fibrils. These were more common in the simulator-XL cups than in the simulator-PE cups. At higher magnifications, small focal areas in the regions of wear had regular ripples on all simulator-XL cups with 0.6–1.0 μm periodicity (Figure 4c). The ripples were aligned perpendicularly to the main motion, as also shown by the 3-body wear scratches. Occasional fibrils, less than 1 μm in length, were seen on top of the ripples.

Discussion

Numerous authors have discussed the mechanisms involved in abrasive, adhesive and fatigue wear (Walker et al. 1973, Cooper et al. 1993, McKellop et al. 1995, Oonishi et al. 1995). However, the emphasis provided by Wang et al. on the strain-hardening phenomenon of the surface polyethylene layer was extremely helpful in explaining the micro-wear phenomena seen on our retrieved and simulator cups. The key feature of hip cup motion was that it produced the formation of fine surface

Table 4. SEM observations of PE micro-wear phenomena in simulator and retrieved cups

Cross-linking	Fibrils width (μm)	Fibrils length (μm)	Nodule diameter (μm)	Frequency of fibrils (No/mm) ²
0 Mrad				
in vitro	0.2–0.5	>10	0.2–0.5	>10,000
retrieved	0.1–0.5	>15	0.6–1.0	6,000–8,000
2.5 Mrad				
in vitro	0.2–0.5	1–8	0.3–0.5	5,000–6,000
retrieved	0.2–0.3	1–8	0.1–0.5	5,000–6,000
50–150 Mrad				
in vitro	0.2–0.3	>1	–	500–1,000
retrieved	0.2–0.3	2–3	–	50–100

ripples perpendicular to the sliding direction” (Wang et al. 1996b). In this wear model, alternating traction (friction) forces produced by the CoCr ball induced the accumulation of ripple formations with 1–2 μm periodicity on the polyethylene surface. The PE wear fibrils could then be teased out of the top of each ripple and then torn off completely. Our other hypothesis is that on high-wear polyethylene surfaces, the loss of many UHMWPE fibrils from adhesive wear caused the ripples to decompose into the nodules seen on our high-wearing simulator-PE cups. In low-wear cups, this process either did not occur or else the ripples had time to reform.

The partly detached PE fibrils in our study were probably incipient wear particles. Therefore we can evaluate the validity of our estimates for incipient wear debris as regards other estimates of particulate wear volumes. From our SEM studies, the frequency of the fibrils on unirradiated and 25 kGy cups could be about 50 000/mm² (Tables 3 and 4). If we assume that these were distributed evenly over a worn area of 100 mm² then there would be 5 million particles available for release in any one cycle. Estimates of the debris released from conventional polyethylene cups have varied from 50 to 100 billion per year of activity. This corresponds to 50 000–100 000 polyethylene particles being liberated every time the patient takes a step. Comparison of these two estimates suggested that probably 1 of 100 fibrils would be released as a particle during each wear cycle. Therefore while it was possible that such polyethylene fibrils were formed and released simultaneously in every wear

cycle, the above ratio suggested that it was a continuous fatigue process.

We can also assess how much wear occurs by the numbers and lengths of the polyethylene wear fibrils produced. The great mobility of the polyethylene surface that was not cross-linked was shown by the extensive patterns of surface flow. Therefore, the high-wear cups produced the greatest amount of surface 'flow', the largest number of long PE fibrils, some $> 20 \mu\text{m}$ long, and the associated ripples had usually broken down into nodules. Such worn surfaces had a visibly smooth appearance and a distinct ridge-line separated worn and unworn regions. The appearance of our retrieved-PE and simulator-PE cups was synonymous with high wearing polyethylene, and both types had the highest wear, as in previous studies

In the low-wear cups, the ripples were uniformly intact, showed a few very small fibrils. Such worn cups had a visibly matte surface and no ridge-line. In cups with very high-wear resistance, even the formation of ripples was less obvious and the creation of surface fibrils was much less common. This was the consistent appearance on the retrieved-XL and simulator-XL cups, which confirmed our initial hypothesis.

One somewhat disquieting finding was the presence of large fissures in our simulator-XL cups. McKellop also reported a similar fissure in their cross-linked cups (McKellop et al. 1997), and suggested that it had been caused by malfunction of their simulator machine. In our opinion, the development of such fissures in two different studies of simulator-XL cups was more than a coincidence. It seems more likely that these defects reflected a loss of strength or fatigue resistance of very cross-linked cups. However, this also illustrates an important feature which should be borne in mind when seeking a better polyethylene. We should not ignore loss of mechanical strength and fatigue resistance since the requirements in-vivo patient are far more complex than in the simulator study.

It was clear from our simulator studies that the 1 000 kGy cups had much better wear-resistance than the cups that were not cross-linked. We found marked traces of the original machine tracks everywhere, except in a small central dome area of the cups. It was also encouraging that our two 1 000

kGy retrieved-XL cups had similar low-wear characteristics—i.e., less extensive polyethylene flow, fewer surface ripples and hardly any polyethylene fibrils. The limitations of our study were that we had access to only two retrieved 1 000 kGy cups from an initial group of 71 patients and we had no detailed information about these two cases. It must also be emphasized that the processing of the SOM cups from the 1970s era was very distinct and differed greatly from that of current cross-linked cups. Therefore, our observations are not generally applicable to the new UHMWPE inserts used in today's metal-backed cup designs.

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