Journal of Long-Term Effects of Medical Implants, 18(1): 69–74 (2008)

Retrieval Analysis of a Polycarbonate-Urethane Acetabular Cup: A Case Report

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ABSTRACT: An acetabular cup made of a compliant polycarbonate-urethane material has been introduced as an alternative bearing solution. This case study examines the use of this acetabular cup in a single patient at 12 months. The cup had minimal loss of thickness with the most being in the superior area (approximately 10%) and minimal loss of weight (2.4%). On the back side was evidence of abrasive macroscopic wear on one side of the implanted component in the area of directional loading from the head to the acetabulum. On the front side, the wear rate was determined to be minimal (less than 15 mm^3 per year), meaning that most of the change in thickness and weight was caused on the back side. The retrieved synovial fluid appeared normal in color and volume at the time of revision. The histology of the tissue taken showed minimal wear particles and minimal reactivity, confirming that the patient did not have any signs of synovitis. The analysis of the cup confirms the preclinically determined low wear articulation and biocompatibility of polycarbonate-urethane as a weight-bearing material. In summary, the surgical findings, data reviewed, and images taken from this case report warrant further study.

KEY WORDS: PCU, total hip arthroplasty, alternative bearing, tribology, hip replacement, active implants, polycarbonate urethane

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I. INTRODUCTION

Hip arthroplasty is currently the standard care for the treatment of arthritic degenerative disease and fracture of the hip. Today three types of bearing surfaces are prevalent in the hip arthroplasty field: ceramics, metals, and polymers. Each of these bearing surfaces is associated with particular strengths and controversies. Ultrahigh molecular weight polyethylene (UHMWPE) has historically been known to produce elevated wear rates, associated with inflammatory bone loss in certain patients. Hard-on-hard bearings, including ceramic and metal bearings, were introduced with the goal to reduce clinical wear rates to below the osteolysis threshold observed with historical polyethylene. However, ceramic bearings have been known, in rare cases, to squeak and to potentially fracture, and metal-on-metal systems release metallic ions into the body, for which the long-term human health risks remain unknown. Many attempts to improve current hip bearing systems, particularly UHMWPE, have been investigated, ranging from carbon-fiber reinforcement, high-pressure crystallization, and elevated doses of cross-linking, as well as, most recently, the addition of vitamin E. While each of these changes has been performed to reduce wear and improve oxidation resistance, each has introduced new controversies into the material and performance characteristics for novel orthopedic bearing materials. Currently, the scientific community has not yet reached consensus as to which of the currently available bearing surface options are optimal for total hip replacement.

Polycarbonate urethane (PCU) has been evaluated extensively over the past decade as a new weight-bearing joint system.[1–7] In 2006, a human clinical study was begun in Europe to evaluate the use of polycarbonate urethane as a new weight-bearing material for total hip arthroplasty in patients with femoral neck fractures. This report describes the case and retrieval analysis of a polycarbonate-urethane cup from that study.

II. PATIENT INFORMATION

In February, 2006, a 70-year-old female (165 cm tall, weighing 58 kg) patient with Parkinson's disease experienced a femoral neck fracture of her left hip. This patient, referred to hereafter and in the study as patient AI #001, had multiple comorbidities, including osteoporosis, and a history of L4-S1 fusion for symptomatic spondylolisthesis. After obtaining informed consent to participate in an Ethics Committee approved study, the patient was implanted with a 52 mm diameter cup made of a soft (80A hardness), compliant polycarbonate-urethane material. (TriboFit Acetabular Buffer Catalog No. 1001 0052, Active Implants Corp, Memphis, Tennessee). The surgical procedure consisted of removing the acetabular articular cartilage and exposing the bone. An approximately 2 mm groove was cut into the bony bed around the circumference of the acetabulum. It should be noted that during implantation, a blade broke in the grooving instrument and the patient had to be rereamed and regrooved for an implant that was one size larger. The polycarbonate-urethane cup was inserted by elastically snapping the cup into position using finger pressure. After positioning the acetabular component, a 46 mm Smith & Nephew cobalt-chrome modular head and stem were implanted. At six months postoperatively, she had a 120 deg range of motion in flexion, 30 deg abduction, 10 deg adduction, and 10 deg of internal and 40 deg of external rotation. At nine months postoperatively, she had a 105 deg range of motion in flexion, 35 deg abduction, 20 deg adduction, and 35 deg of internal and 30 deg of external rotation, all essentially equal to the unoperated right hip.

Immediately after surgery, the patient developed a urinary tract infection, followed by a case of gastroenteritis, and was readmitted for a case of toxic hepatopathia. At the three-month follow-up visit, the patient complained of gastrointestinal pain. Nine months after surgery, the patient continued to experience pain and, among other considerations, was evaluated for possible hip infection symptoms, although the blood work was negative. An aspirate of the hip was taken, and little synovial fluid could be obtained. Because the blood work was negative, and it took three weeks for anything to grow out of the tissue aspirate, it was believed at the time that the positive culture was caused by sample contamination. Since the patient continued to complain of hip pain, a revision of the left hip

was scheduled and performed 12 months after the initial implantation.

At the time of revision, a normal amount of minimal synovial fluid was present (~1 mL) and its color appeared typical. A sample of the fluid was checked for infection and none was present. Histological analysis of tissue taken at the time of surgery confirmed that the patient's hip was not infected.

During revision, the acetabular cup was found to be intact and well fixed to the acetabular bone. After removal of the cup, histological samples were taken adjacent to the back side of the cup. Because the cartilage and bone removed during the original surgery was minimal, the patient was revised to an identically sized 52 mm (outer diameter) metal shell with a UHMWPE component. After the revision surgery, the patient's hip pain persisted, and was attributed to her spine pathology.

III. WEIGHT MEASUREMENT REPORT OF RETRIEVED CUP

Weight measurements were taken of the retrieved cup and were compared to a reference weight determined by the average of three unused cups from the same production batch. The reference weight average was 14.090 grams. The retrieved buffer was cleaned and found to weigh 13.7864 grams. Therefore, by assuming that the average weight on a dry unimplanted cup was representative of the starting weight of the implanted cup, the weight loss of the retrieved buffer cup can be calculated to be approximately 0.303 grams or 2.1%.

IV. HISTOLOGICAL ANALYSIS

An independent pathologist analyzed the histological samples from this case report (Fig. 1). With the use of an H&E stain, 120 histological slides from eight locations of the acetabulum were created with only one location having any polycarbonate-urethane particles found.

V. WEAR ANALYSIS

The articulating surface of the polycarbonate-urethane cup retrieval appeared smooth and glossy, with minimal macroscopic wear. Evidence of macroscopic back-side abrasion was present on the back side of the retrieved cup—the superior medial side in the area of loading (Fig. 2). ATR-FTIR confirmed that the white discoloration on the back side of the buffer was not a deposit of any heavy element, but was instead a protein deposit. A micro-CT analysis revealed that the bearing surface wear rate for the retrieval was less than 15 mm^3 per year.

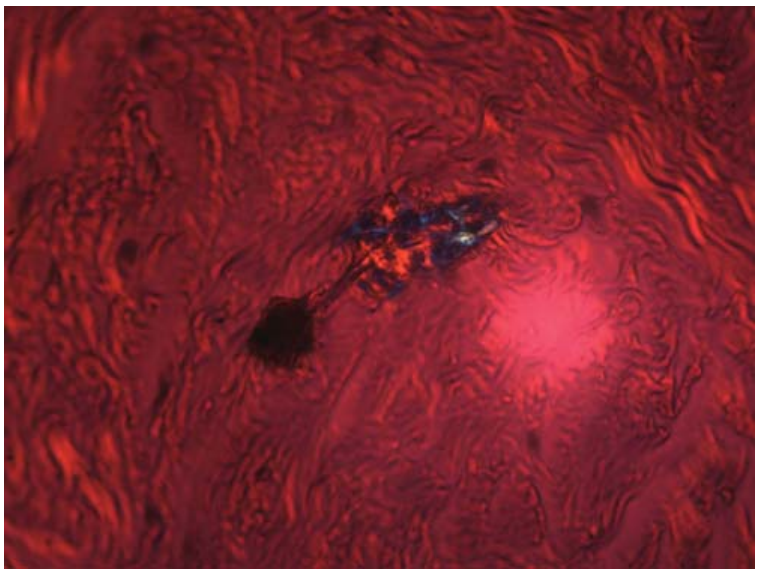

FIGURE 1. Histology slides from patient AI #001 showing little adverse reaction to particulate debris.

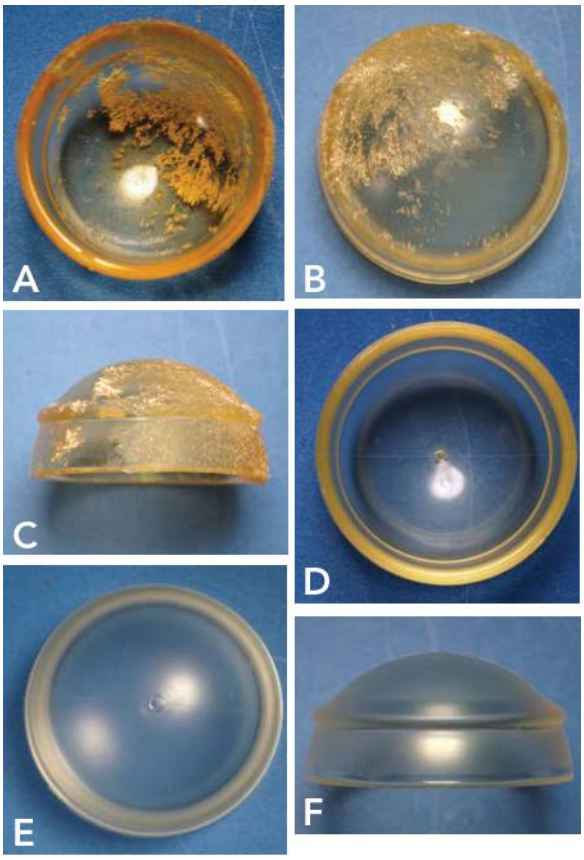

FIGURE 2. Photographic documentation of patient AI #001 retrieval (left) and unimplanted control (right).

VI. ANALYSIS OF RETRIEVED CUP

The implants were examined using optical microscopy to determine the regions of minimal and maximal adhesive abrasive wear, which could be used to establish the anterior-posterior orientation of the components. By knowing the side on which the implant was located in vivo, the medial-lateral orientation could also be established. With the use of a quadrant system, thickness and mass were measured in triplicate for each zone (Table 1).

VII. SURFACE ASSESSMENT

The components were visually examined under a stereomicroscope for evidence of wear and or macro- or microfatigue damage (Fig. 2). An abbreviated variant of the Hood method[8] was used to evaluate each face of the components for the presence and/or absence of damage modes (e.g., plastic deformation, scratching, burnishing, pitting, delamination, abrasion) typically observed in retrieved UHM-

TABLE 1. Average Dimensions and Mass Compared to Unimplanted Control

Liner ID#	Superior thickness (mm)	Inferior thickness (mm)	Medial thickness (mm)	Lateral thickness (mm)	Mass (g)
AI #001	2.5 ± 0.12	2.7 ± 0.02	2.8 ± 0.02	2.7 ± 0.03	13.7616 ± 0.0002
Control #1		2.8 ± 0.06			14.1064 ± 0.0002

TABLE 2. Damage Mode Scale

Damage score	Extent of damage
0	Absence of damage mode
1	10% coverage of wear surface
2	10–50% coverage of wear surface
3	50% coverage of wear surface

Note: This damage scoring method is an assessment of the extent but not the severity of the damage that occurred in vivo.

WPE orthopedic implants.[8] Each damage mode was graded on a 0–3 scale (Table 2).

Based on this scoring method and the six modes of damage described above, the maximum damage score that an implant could possible receive would be 18. With the use of the nomenclature established above to identify each quadrant of the components, a wear score was assigned. Table 3 summarizes the values for retrieval for patient AI #001. These values indicate that relative to UHMWPE retrievals, this cup had very mild abrasive, burnishing, and scratching scores.

TABLE 3. Totaled Wear Scores by Quadrant

Liner ID	Superior	Medial	Lateral	Inferior	Average
AI #001	4	4	3	3	4

VIII. WHITE-LIGHT INTERFEROMETRY

The surface topography of the articulating surface of one retrieved and one control acetabular liner were measured using white-light interferometry (WLI) using a NewView 5000 Model 5032 equipped with advanced texture analysis software, MetroPro 8.1.3 (Zygo, Middlefield, Connecticut). Nine measurements were taken on each retrieved component and six measurements were taken on the control component. Table 4 shows the average values for roughness (Ra) and waviness (Wa). The waviness represents the low-frequency features, and the roughness represents the high-frequency features.

IX. DISCUSSION AND CONCLUSIONS

We have presented a case report of a retrieved polycarbonate-urethane (PCU) acetabular cup that had been implanted for 12 months in a human. Overall, the surgical findings, data, and images collected from this case report were encouraging and similar to what was found in sheep[1] and predicted in laboratory studies.[2,5–7] The cup had minimal loss of thickness with the most being in the superior area (approximately 10%) and minimal loss of weight (2.4%). On the back side was evidence of abrasive macroscopic wear on one side of the implanted component in the area of directional loading from the head to the acetabulum. On the front side, the wear rate was determined to be minimal (less than 15 mm^3 per year), meaning that most of the change in thickness and weight was caused on the back side. This volumetric wear rate compares favorably

TABLE 4. White-Light Interferometry Measurements (Average ± Standard Deviation)

	AI #001	Control #1
R_a (μm)	0.056 ± 0.066	0.104 ± 0.016
Wa (μm)	0.073 ± 0.061	0.145 ± 0.047

with that of standard UHMWPE retrievals found in the literature. Schmalzried et al.[9] and Jasty et al.[10] reported in vivo volumetric wear rates of 36 and 35 mm^3 per year, respectively. The articulating surface had a marked reduction in the surface roughness by a factor of about 2; the same reduction as was found with the identical articulating material after implanted for three years in hip of sheep.[4]

The synovial fluid appeared normal in color and volume at the time of revision. The histology of the tissue taken showed minimal wear particles and minimal reactivity, confirming that the patient did not have any signs of synovitis. All of these findings indicate that the material was well tolerated by the body. The fact that the acetabular component could be easily revised with an identically sized component was viewed as a positive feature of this new type of hip replacement system.

Although this retrieval is only from one patient, the analysis of the cup confirms the preclinically determined low wear articulation and biocompatibility of polycarbonate urethane as a weight-bearing material.[1,3,4] Also, it is unknown whether the rereaming and regrooving had any significant effect on the outcome. Continued evaluation of this new material for use in hip replacement surgery in humans is warranted.

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