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Explantation and Analysis of the First Retrieved Human Acetabular Cup Made of Polycarbonate Urethane: A Case Report

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ABSTRACT: This report describes the first human retrieval of a polycarbonate-urethane (PCU) acetabular cup implanted for 10.5 months that was revised for pain of unknown origin. By using a micro-CT analysis, the articulating surface was determined to have a wear rate of less than 1.4 mm^3 per year. An analysis of the synovial fluid retrieved at the time of revision found an average particle size of 1 μm diameter. Overall, the surgical findings and analysis were consistent with the results observed in laboratory and animal studies. The histology and synovial fluid analysis found sparse evidence of particulate debris and no synovitis, indicating the potential of this articulating material for use as a bearing surface.

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

I. INTRODUCTION

Polyurethane material was first used in humans as an acetabular cup in 1960 by Charles Townley.[1] Use of this material to make acetabular cups actually predates by two years John Charnley's first use of ultrahigh molecular weight polyethylene (UHMWPE) for the same indication.[2] Despite positive early results, the use of polyurethane as a bearing material was not pursued further because of the commercial availability and popularity of polyethylene,[1] and serious efforts to further research polyurethane's possible use as a weight-bearing material did not resume until 1974.[3] Since then, several other preclinical studies and reports have shown that using a soft, compliant material such as polyurethane may be an alternative low-friction elastomeric bearing surface that embodies material advantages to UHMWPE, such as retention of a tribologically important fluid film between the implant and the articulating surfaces.[4–12]

Because of the development of a new generation of polyurethane materials, specifically engineered for their stability and lubricity properties, studies of the wear behavior[10–12] and in vivo performance have been performed. In particular, after analyzing samples from a comprehensive four-year sheep hip study[4,6,7] using a soft polycarbonate-urethane (PCU) material (80A shore hardness and a modulus of elasticity similar to articular cartilage) for an articulating material, these researchers[7] concluded in 2005, "…there are no contra-indications against human clinical trials." In 2006, a human clinical study was begun in Europe to evaluate this identical class of polyurethane, polycarbonate urethane, as a weight-bearing material in total hip arthroplasty. This case report describes the background and results from the analysis of a retrieved cup from that clinical study.

II. PATIENT INFORMATION

In February 2006, a 68-year-old female (identified in the study and in this paper as patient AI #051) had a femoral neck fracture of her left hip. The patient was 168 cm tall and weighed 68 kg. Four to five days after fracturing her hip and after signing an informed consent document, the patient was entered into a femoral neck fracture study approved by the local Ethics Committee and German Competent Authority. The patient was implanted with a 52 mm (outer diameter) acetabular cup made entirely out of shore hardness 80A polycarbonate urethane (TriboFit Acetabular Buffer Cat. No.1001 0052, Active Implants Corp, Memphis, Tennesee). The articular cartilage in the acetabulum was removed by reaming to expose bone. A 2 mm deep circumferential groove was created in the acetabulum using a special instrument. Because this was the first case implanted by this technique, some difficulty was encountered in creating the groove and a modification was needed after one of the groove-cutting blades broke. Because of the shape of the groove was intended to match the outer surface of the cup, the compliant polycarbonate-urethane cup could be slightly compressed and flexed into the groove for secure fixation.

Once the acetabular cup was in position, a modular Mueller straight stem (Zimmer, Inc.) was cemented into the femur and a 46 mm Biomet cobalt-chrome modular head with a –2 neck adaptor was attached to the 12/14 mm taper. The degree of motion of the operated hip for each time point measured is shown in Table 1.

Approximately eight months after the surgery, the patient fell and fractured her shoulder. Some time after the shoulder injury, the patient complained of hip pain and the first CT scan of the hip was performed. In the CT scan, the location of the polycarbonate-urethane cup could not be determined (see Fig. 1) Although no postoperative CT scan was taken, since the imaging made it appear as though the metal head was adjacent to the bone, the integrity of the cup was questioned. Consequently, a revision of the left hip was scheduled and performed 10.5 months after the initial implantation. Infection was ruled out by appropriate laboratory studies.

At the time of revision, 10 cc of clear liquid was in the hip joint and was removed for further analysis. It was determined that the cup had not "disappeared," but was undamaged, intact, and well fixed to the acetabular bone. Histological samples were also taken at this time. Because the cartilage and bone removed during the original surgery was minimal and no cement or porous coating was used, the patient was readily revised to a primary press-

TABLE 1. Motion Measurements over Time

	Range of motion (deg)	Abduction (deg)	Adduction (deg)	Internal rotation (deg)	External rotation (deg)
1.5 months	105	15	15	20	25
3 months	110	25	20	25	30
6 months	120	25	20	20	30
9 months	115	25	20	30	20

All of these measurements were essentially the same for each time point and the un-operated, normal right hip. Although it had no effect on the clinical performance, the patient occasionally noticed a brief and transient squeaking noise early in the morning.

fit 54 mm (outer diameter) metal shell containing an UHMWPE insert. Thus, the patient was able to be revised with an acetabular component that was 2 mm greater in diameter than the original PCU prosthesis, which was of a primary not a revision design, and was press fit into position. After revision, the patient's hip pain went away.

III. RESULTS

III.A. Weight Measurement Report of Retrieved Cup

Since a preoperative weight measurement of the implanted cup was not practically feasible, the weight of the retrieved cup was measured and compared to an average of three identically sized, dry, unused cups from the same production batch. The average weight of an unused cup was 14.090 grams (± 0.037 standard deviation). The retrieved cup was cleaned and dried and found to weigh 13.545 grams. Therefore, by assuming the average dry weight of the unimplanted samples was indicative of the cup implanted in body fluids for 10.5 months (neglecting the weight loss due to surgical removal), the weight loss of the retrieved cup was conservatively calculated to be as much as 0.545 grams

III.B. Independent Radiological Review

As seen in the immediate postoperative and pre-revision X-rays in Figure 2, an increase in the size and conspicuity of supra-acetabular radiolucencies occurred, with a greater degree of surrounding supra-acetabular sclerotic bone changes (cysts). These subcortical cystic changes matched the findings on postoperative hip CT (Fig. 1). An independent reviewer agreed that the cup could not be seen on either the CT or the X-ray and believed that some evidence of the cysts can be seen in the preoperative X-rays.

III.C. Histological Analysis

Two independent pathologists analyzed the histological samples from this case report (Fig. 3). One reported, "Overall, the reaction is much less exuberant than that seen in the usual par-

FIGURE 1. Ten month postop CT scan.

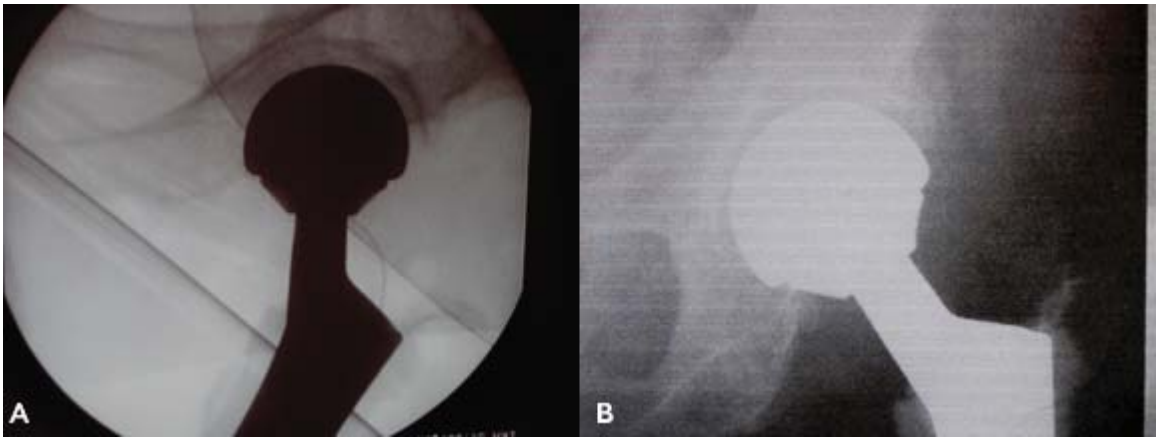

FIGURE 2. Figures showing patient AI #051 immediately postop **(A)** and seven months post op **(B).**

ticle disease associated with joint replacement. In fact, without polarized light (microscopy to identify birefringent PCU particles), the reaction is fairly easy to overlook and underestimate." The second pathologist reported, "The presence of macrophages indicates low grade inflammation. There is no evidence of severe inflammation or malignancy."

III.D. Synovial Fluid Analysis

Approximately half the aspirated fluid from the hip was sent to the hospital pathology lab for routine checks. The other half was sent to an independent laboratory for particle analysis using two different methods. The first method used a laser diffraction analysis and determined that the average particle size in the synovial fluid was 0.9 μm in diameter (equivalent spherical diameter). With the use of a scanning electron microscope (SEM), a second method determined that the average size of the particles was 2.9 μm diameter (range: 0.5–90 μm, plus one at 200 μm). The calculated total particle mass in the fluid was 14.7 mg as determined by a counting method and 5.0 mg as determined by a filtering method. By using the higher value, by assuming a density of the PCU of 1.19 g/cc, and by taking a ratio, the maximum volume of particles in the synovial fluid was calculated to be 13.4 mm^3 over a year's time. Further energy dispersion spectroscopy analysis determined that these particles were primarily composed of C and O in proportions consistent with the chemical makeup of polycarbonate urethane.

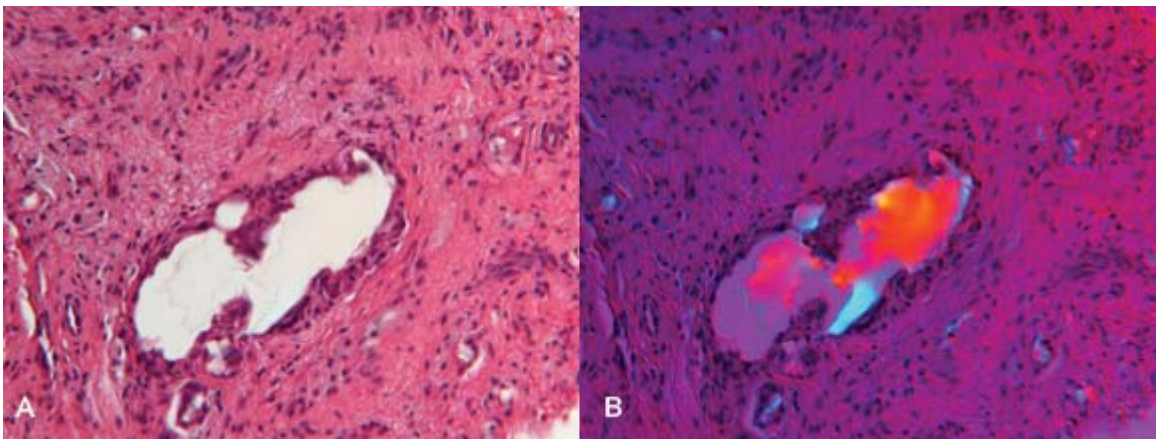

FIGURE 3. Histology slides from patient AI #051 showing little adverse reaction.

III.E. Wear Mechanisms of Human Retrieved Polycarbonate-Urethane Acetabular Components

The articulating surface of the polycarbonate-urethane cup retrieval appeared smooth and glossy, and exhibited minimal macroscopic wear, similar to components evaluated in hip simulations and animal studies. Overall, the articulating surface of the human retrieval showed that the wear mechanism was similar to and consistent with the microelastohydrodynamic lubrication and minimal wear observed in theoretical analyses,[3,5] in wear studies,[10–12] and in animal studies.[4] Evidence of macroscopic back-side abrasive wear on the retrieved cup was also present. An elemental analysis confirmed that the white coloration on the back side of the cup was calcium carbonate deposited onto the implant surface. This material is not the same as the calcium pyrophosphanate and chondroid metaplasia seen in a sheep study.[4] By comparing to the articulating surfaces of the three nonimplanted control cups, a micro-CT analysis of the retrieved cup was able to differentiate the front-side from the back-side wear. This analysis determined that the wear rate at the bearing surface for the retrieved cup was less than 1.4 mm^3 per year, annualized, which is equal to or less than that predicted in laboratory wear simulation studies[10–12] that used serum instead of synovial fluid for lubrication.

III.F. Analysis of Retrieved Cup

With the use of optical microscopy, the retrieved cup was examined for wear. The cup was divided into four sections and the thickness measured in triplicate for each zone. (Table 2).

III.G. Surface Assessment

The retrieved component was visually examined under a stereomicroscope for evidence of wear and/or macro- or microfatigue damage (Fig. 4). An abbreviated variant of the Hood[13] method was used to evaluate each face of the components for the presence and/or absence of six different modes of damage, namely, plastic deformation, scratching, burnishing, pitting, delamination, and abrasion that are typically observed in UHMWPE orthopedic implants.[6] Each damage mode was graded on a 0–3 scale as shown in Table 3.

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 an 18. With the use of the four zones mention above, Table 4 summarizes the values for the retrieved liner. The values obtained indicate that the articulating surface of the PCU cup had very mild abrasive, burnishing, and scratching.

III.H. White-Light Interferometry

The surface topography of the articulating surface of the retrieved cup and a nonimplanted control were measured using white-light interferometry (WLI). Nine measurements were taken of the retrieved component and six measurements were taken on the control component. Table 5 shows the average values for roughness (R_a) and waviness (W_a).

Figure 5 shows a scanning electron micrograph of the parting seam of the retrieved cup. Prior to surgery, the parting line, created during the injection-molding process, was a semicircular straight line on the back side of the cup going from one edge over the dome to the other side. Since the

TABLE 2. Average Dimension of Retrieved Cup Compared to Nonimplanted Control

Liner ID No.	Zone 1 thickness (mm)	Zone 2 thickness (mm)	Zone 3 thickness (mm)	Zone 4 thickness mm)
AI #051	2.5 ± 0.05	2.7 ± 0.01	2.7 ± 0.04	2.6 ± 0.10
Control 1		2.8 ± 0.06		

± values are standard deviations

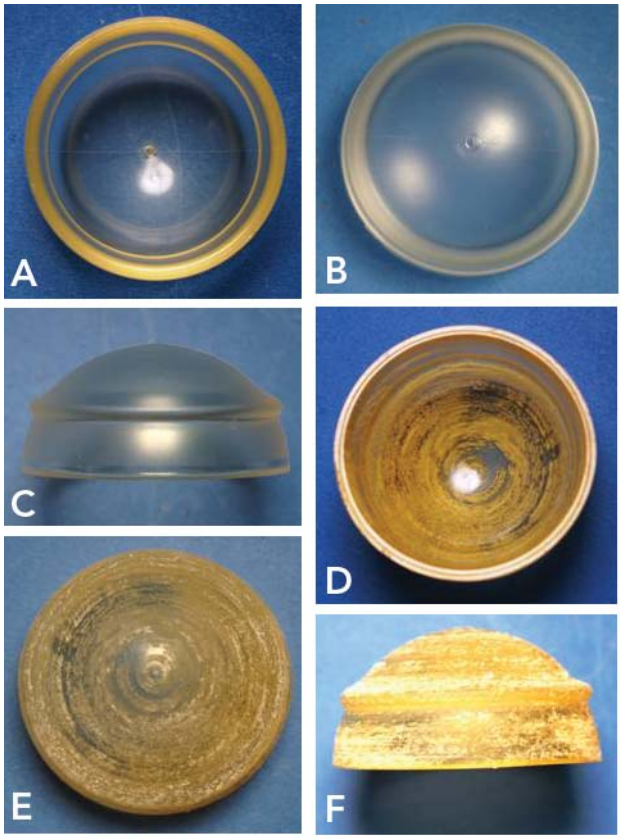

FIGURE 4. Photodocumentation of control **(A–C)** and patient AI #051 retrieval **(D–F).**

parting line on the retrieved cup is wavy, this finding indicates that a maximum back-and-forth oscillating rotary action of approximately 60 μm (peak to peak) was occurring in vivo on the back side of the cup between the bone and the cup.

IV. DISCUSSION

Although this paper is only one case, it is similar to another paper at press in this same journal of a similar case report. The overall surgical findings, data, and images collected from this case report and the other give credence to the use of this snap-fit design. The findings from both explants corroborate the wear data found in laboratory studies, the findings in sheep hip studies,[4,6,7,11] and the results predicted by theory.[3,5] It is presumed that the large head size (46 mm) assisted in achieving the observed large postoperative range of motion where initial results were considered clinically excellent. The articulating surface had a measurable reduction in the surface waviness over the 10.5 months

TABLE 3. Damage Score Definitions

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 that this damage scoring technique is limited to assessment of the extent, but not the severity, of damage modes.

TABLE 4. Total Wear Scores by Quadrant

Zone 1	Zone 2	Zone 3	Zone 4	Average
3	2	3	2	3

of implantation and minimal wear (less than 1.4-14 mm^3 per year). The primary wear mechanism of the articulating bearing surface was microabrasion and microadhesion. The particles of PCU found in the synovial fluid were larger and fewer than would have been expected with an UHMWPE acetabular cup implanted for the same time period. The histology and synovial fluid at the time of the PCU cup explantation showed minimal reactivity and no signs of synovitis, further indicating that the articulating material wear was below that required to induce inflammation.

Furthermore, to interpret the 10.5 month retrieved PCU cup wear results properly, it is necessary to review two studies of wear on retrieved human UHMWPE cups implanted for about the same time. Schmalzried et al.[14] calculated in a series of 12 autopsy cases that the wear was 36 mm^3 per

TABLE 5. White-Light Interferometry Measurements (Average ± Standard Deviation)

	AI #051	Control
R_a (μm)	0.104 ± 0.064	0.104 ± 0.016
Wa (μm)	0.078 ± 0.065	0.145 ± 0.047

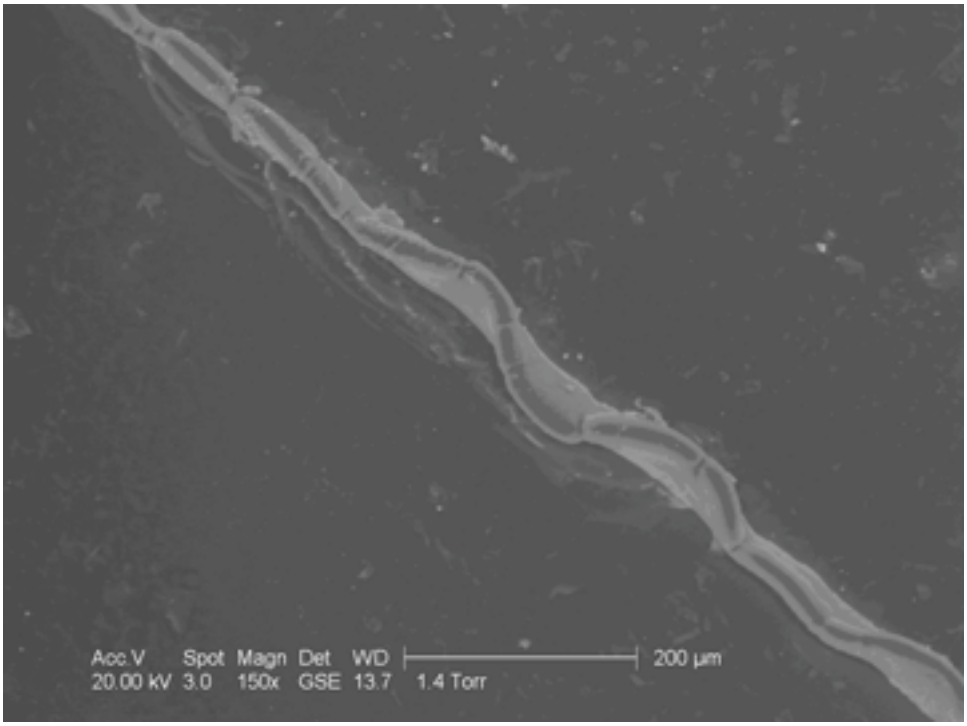

FIGURE 5. Figure showing the back-side seams for patient AI #051 (150×).

year on average. Jasty et al.[15] calculated 35 mm^3 in an autopsy study of 22 cases. Using the larger number on the PCU retrieval wear (14mm^3 per year) demonstrates that the UHMWPE wore 2.5 times more that PCU, almost identical to what was predicted in the wear simulator.

On the back side was evidence of some abrasive macroscopic wear of the implanted component. Evidence indicates that the bone and the back side of the cup were occasionally moving back and forth against each other with a peak-to-peak amplitude of at least approximately 60 μm. It can be speculated that this oscillating motion was probably caused by walking activity. The calculated amount of particle debris in the analysis of the synovial fluid and the peri-implant tissues was less than that calculated using comparative analysis of controls (unused implants), which highlights the limitations of using nonpaired preoperative implants for comparison. Whether the difficulty of creating the groove intraoperatively or the 4–5 day delay in femoral neck fracture repair surgery had any influence on the results cannot be speculated. Further study of back-side wear of these types of all elastic, direct-to-bone contact plastic cups is warranted. For high-risk patients, such as those with preoperative acetabular cysts or highly osteoporotic bone, fixing the cup inside a metal shell prior to implantation may be advantageous.

An important finding from this case report is that CT scans alone should not be used to evaluate the positioning of a PCU cup. CT artifact from the cobalt-chrome head makes the head appear larger than it really is and "shadows" the imaging of the cup. Another important finding of this case was the ability of this type of this snap-fit PCU acetabular cup to be revised to a primary press-fit acetabular cup.

At the time of the revision surgery, a thin layer (less than 1 mm) of fibrous tissue was present between the cup and the host bone. Whether this fibrous tissue would have thickened and/or prevented further abrasion of the back side of the cup is speculative. To remove the chance of this possibility, some type of barrier, metallic or otherwise, on the back side may be indicated, especially in cases where the acetabular bony bed may be compromised.

V. CONCLUSIONS

We have presented a case report of a 10.5 month retrieved polycarbonate-urethane (PCU) acetabular cup from a human. The analysis of the retrieved snap-fit PCU cup demonstrated both a mechanical preservation of structural integrity under in vivo loading and a biocompatibility of PCU debris in the peri-implant tissues. An analysis of the wear surface of the retrieved human cup corroborates previous in vitro laboratory wear and in vivo animal studies. The finding of back-side wear on this retrieved cup indicates that further study and/or design is needed. Can the observed wear in this case be mitigated through changes in surgical implantation or the use of a metal shell? If back-side wear does occur, will it stabilize with time through the formation of a fibrous layer? Only further clinical results will be able to answer these questions.

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