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Very Large Diameter Polymer Acetabular Liners Show Promising Wear Simulator Results

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ABSTRACT: Thinner and larger acetabular components are more stable and are useful for resurfacing. This study performed wear simulator tests of the largest polyurethane (PUR) and highly cross-linked polyethylene (XLPE) liners available. The results were compared with conventional polyethylene (ConvPE) to determine wear, survivorship, wear debris particles generated, and oxidative degradation.

Two-piece acetabular components with a 4-mm poly liner, a 2-mm metal backing, and 1 mm of porous coating with an inner diameter of 51 mm were tested. Cobalt chromium (CoCr) and titanium nitride (TiN)-coated titanium-resurfacing femoral components were counter-face surfaces. Acetabular components were tested at 45° and 65° inclinations, with both 300 μm and an increase of 1 mm in radial clearance.

After 30 million cycles, PUR had 56% ($p < 0.001$) less wear and cross-linked had 93% ($p < 0.001$) less wear than ConvPE. TiN-coated femoral implants had 23% less wear than CoCr when used with cross-linked polyethylene. Wear increased by 16% at 65° and by 19% when radial clearance increased with cross-linked polyethylene. Polymethylmethacrylate debris ultimately failed ConvPE, but not the cross-linked polyethylene or PUR.

XLPE acetabular liners are compatible with >20 years of expected use in active patients.

KEY WORDS: total hip replacement, hip resurfacing, highly cross-linked polyethylene, polyurethane, conventional polyethylene

I. INTRODUCTION

The natural femoral head size of most patients presenting for total hip replacement (THR) or resurfacing is between 40 and 52 mm.[1–4] Prior experience with conventional polyethylene (ConvPE) has suggested that the minimum thickness should be 6–8 mm and, with a suitable metal backing, the acetabular component composite thickness becomes 14–16 mm; therefore, the resulting femoral head size usually has been limited to 32–36 mm.[5–9] Natural-size femoral heads are more resistant to dislocation and may have biomechanical advantages.[2,3,10] To better achieve the function of a natural hip, a thin-polymer, large-capacity acetabular component is needed for both resurfacing and replacement procedures.

Previous attempts to use polyethylene for hip resurfacing were unsuccessful due to the poor performance of ConvPE.[2,11,12] Thicker components were not bone conserving. Polyurethane (PUR) and highly cross-linked polyethylene (XLPE) prepared to 3 or 4 mm are candidate materials to meet the need for a thinner bearing surface. To date, the largest capacity acetabular components used clinically have been 44–48 mm.[12,13] The 51-mm implants tested in this study are the largest that are available with XLPE or PUR and are used for resurfacing.[2–4,6,12–14]

Two piece rather than one-piece acetabular components are desirable because they allow for a secure and simple impactor for the metal backing and for supplemental screw fixation. In addition, exchanging the acetabular bearing is possible and desirable with a two-piece construct in case of infection and/or wear. Thin shells are desirable for bone conservation, but there is a limit due to deformation and breakage. It is important, however, to fully support the polymer.

In any hip arthroplasty, the wear rate is influenced by the smoothness and hardness of the metal counter face. Titanium nitride (TiN) coatings have many applications in tools and are applied increasingly to orthopedic implants. TiN-coated ($TiAl_6V_4$)

implants have favorable biocompatibility and have been used for many years for THR, knee replacement, and hip resurfacing, in particular to avoid an adverse reaction to wear debris.[6,10,15,16] This is the first test of TiN-coated femoral resurfacing implants used with XLPE and PUR.

In wear simulator and clinical studies, XLPE has demonstrated significantly lower wear rates compared with ConvPE.[3,8,11,13,17–20] However, there are still some concerns over the biologic activity of the wear debris from XLPE, so some interest remains in alternative polymers such as PUR.[21–24] The purpose of this study was to evaluate both PUR and XLPE as candidate materials for large-diameter THR and resurfacing. The hypothesis was that PUR and XLPE would have the benefits of low wear and large head size. This would support and expand the current clinical use of very thin and very large polymer acetabular components for resurfacing and possibly for stable large-diameter THR. This study addressed the following questions: (1) what is the wear, associated wear debris, and oxidation of each material?; (2) is there a difference in performance based on inclination angle, presence of third-body debris, or increased radial clearance?; and (3) is there a difference in wear between a cobalt chromium (CoCr) and TiN femoral prosthesis?

II. MATERIALS AND METHODS

The study tested 4-mm-thick, 51-mm-capacity acetabular implants made from XLPE, PUR, and ConvPE. The PUR was developed along with several others in previous studies[25] and was selected based on considerations about load-bearing capacity and resistance to oxidative wear.

The XLPE, PUR, and ConvPE cylindrical specimens were machined into acetabular liners (Bridgeport CNC Mills, Hardinge, Inc., Elmira, NY). Their inner/outer dimensions were 51 mm/64 mm, respectively. The acetabular bearings were machined to a uniform 4-mm thickness and all implants were sterilized using ethylene oxide. The ConvPE (MediTech-Quadrant, Fort Wayne, IN) used GUR 1050 resin (Ticona, Kieselbach, Germany). The XLPE used components that were prepared by the same vendor from GUR 1020 resin cross-linked with 7.5 mRad of gamma irradiation and remelted at 155°. The properties of XLPE, PUR, and ConvPE are shown in Table 1. The tensile strength of the PUR was comparable to XLPE and ConvPE. The ConvPE had an elongation break of 384%, slightly higher than either PUR or XLPE.

There was one 49-mm CoCr femoral component tested against a 51-mm XLPE acetabular component to determine the effect of increasing the radial clearance by 1 mm. Knowledge of the wear performance of XLPE in circumstances of increased radial clearance can be helpful if there is an imperfect match during acetabular revision surgery with a retained, well-fixed femoral replacement or resurfacing prosthesis.[14] All other femoral components were 51-mm CoCr- or TiN-coated $TiAl_6V_4$ femoral heads. The TiN ceramic surface layer coating was 8 μm that was deposited using a physical vapor deposition process (Ionbond, Rockaway, NJ). The surface roughness of the femoral components was <3 μm. The radial clearance was 300 μm.

Each acetabular bearing was seated into a $TiAl_6V_4$ shell. The shells were hemispherical with inferior extensions and an anatomic inferior cut out. This shell geometry was first described in 1973 to reduce

TABLE 1: Properties of polymers

Properties	ConvPE	XLPE	PUR
Hardness, shore D	65	61	70
Density (mg/mm^3)	0.936	0.936	1.19
Yield strength (mpa)	21 ± 3	22.6 ± 4	21 ± 3
Ultimate tensile strength (mpa)	55 ± 5	57.5 ± 6	66 ± 6
Elongation at break (%)	466 ± 37	288 ± 12	292 ± 17

impingement and psoas tendon irritation.[2,6,10,15] The shells had five fixation holes and were porous coated with sintered commercial pure titanium beads on the outer surface to give an average pore size of 350 µm and a volume porosity of 30%. They were 2-mm thick and the porous coating was 1 mm. The shells provided a locking mechanism for the polymer bearings that consisted of recessed grooves with flexible locking tabs and three anti-rotational key ways. The bearings are placed into the locking mechanism on a snap-fit basis (Fig. 1).[6,10,15] The locking mechanism was disabled to facilitate testing.

Testing was performed using a 12-station (nine dynamic and three soak controls) biaxial hip simulator (MTS, Inc., Eden Prairie, MN) with a computer controller for duration of 30 million cycles. The acetabular components were positioned with an acetabular abduction angle of 45° or 65°. Test protocols followed guidelines established by the American Society for Testing and Materials (ASTM), the International Organization for Standardization (ISO), and the Food and Drug Administration (FDA). Thirty-six specimens were presoaked for 48 hours in lubricant and nine other specimens (three each of XLPE, PUR, and ConvPE) were maintained as dry controls. All specimens were supplied in their original sterile packaging as intended for use in patients. The simulator was run three times. Specimens were subjected to accelerated aging according to ASTM F2003-00.

Specimens were selected randomly to serve as controls or test. Both unloaded and vertical only loaded controls were tested. Twenty-seven specimens underwent full gait testing per ISO 14242 at three independently controlled motions (abduction–adduction, flexion–extension, internal rotational, and vertical loading; Table 2). Individual closed stations were used to avoid cross-contamination. The Bergmann curve was programmed for a peak load of 2.1 kN and a rotational frequency of 1.0 Hz.[26] All testing was conducted in 30% diluted bovine calf serum with the addition of 0.2% sodium azide to retard bacterial degradation and EDTA to limit the formation of calcium deposits on test components. Polymethylmethacrylate (PMMA) particles were added to eight stations at a concentration of 0.15 mg particles/mL as a third-body challenge.[7,27,28]

Testing was interrupted every 250,000 cycles to clean the polymer liners and to measure mass loss per ASTM 1714-96 and FDA guidelines. Bovine

FIG. 1: Photograph of the two-piece TiN-coated acetabular component and femoral resurfacing that was tested to 30 million cycles.

TABLE 2: Twenty-seven specimens selected randomly for full gait testing

Specimen Type	ConvPE	XLPE	PUR
	n		
CoCr/45°	1	2	2
CoCr/65°		2	2
CoCr/PMMA/65°	1	2	2
CoCr/1 mm ↑1 mm clearance		1	
TiN/45°		2	2
TiN/65°		2	2
TiN/PMMA/65°		2	2

serum was refreshed at every measurement interval. Used serum was labeled per station and measurement interval and then frozen for subsequent particle analysis per ISO 17853 and ASTM F1877.

Gravimetric measurements were taken using a scale with a precision of ±0.01 mg (A-200DS, Fisher Scientific, Waltham, MA). To ensure correct measurements, four repeated measurements of each polymer were taken and the average of the measurements was calculated (Table 3). One or two specimens of each test condition were used, with several measurements of each specimen (Table 2). The specimens were dried at room temperature under vacuum and weight changes were determined via calibrated analytical scale accurate to 0.0001 g.

TABLE 3: Wear of polyurethane and polyethylene

Materials	Wear Rate (mg/mc)	Volumetric (mm^3/mc)	Linear (mm/y)
XLPE			
TiN	8.8	9.4	0.005
CoCr	11.5	12.3	0.0006
TiN @ 65°	12.6	13.4	0.0066
CoCr @ 65°	13.7	14.6	0.0071
TiN/PMMA @ 65°	14.6	15.7	0.008
CoCr/PMMA @ 65°	16.9	17.8	0.010
CoCr/↑1 mm clearance	14.2	15.1	0.0075
ConvPE			
TiN	128.3	137.0	0.067
CoCr	149.6	159.6	0.091
CoCr/PMMA @ 65°	387.6	414.1	0.203
PUR			
TiN	72.3	60.7	0.029
CoCr	78.4	65.9	0.032
TiN @ 65°	98.7	82.9	0.040
CoCr @ 65°	116.7	98.0	0.048
TiN/PMMA @ 65°	129.4	108.8	0.053
CoCr/PMMA @ 65°	156.6	131.6	0.064

Wear particle filtration and imaging were performed via scanning electron microscope at a working distance of 8 mm and with accelerated voltage of 20 kV; 10 images with a magnification of 10,000× were captured digitally (4Pi Revolution, 4Pi Analysis, Inc., Durham, NC). Samples were taken at 1, 5, 10, 20, and 30 million cycles; 10 mL of serum combined with 10 mL of 5 N NaOH was collected from each station. The specimens were filtered and dried for 24 hours. Particle length was measured manually using ImageJ software. Length was determined using maximum Feret's diameter method. Wear particle analysis was performed to determine the relative size of the particles and an estimate of their number.

The polymer and femoral specimens were inspected visually and with optical microscopy to look for damage. The worn polymers were inspected for white banding, machine marks, delamination, scratches, or cracking.[8,19] A microtome was used to determine the oxidation index after the wear testing.

A two-tailed equal variance *t*-test was utilized to analyze the difference in wear rates between test groups.

III. RESULTS

Hip wear simulation, wear debris, and oxidation analyses were performed on 4-mm-thick XLPE, PUR, and ConvPE acetabular liners used for resurfacing. All test samples survived the 30 million cycles. Visual inspection did not reveal any change in their appearance except for ConvPE challenged with PMMA at 65° (Fig. 2). A low level of damage was identified at high magnification on the PUR and ConvPE implants' articulating surfaces, but not on the XLPE surface. Some wear grooves were noted along the articulating path and there were also some scattered pits. The machining marks were still identifiable on the XLPE implants (Fig. 3).

Gravimetric measurements showed a constant wear rate after 2 million cycles that was maintained for the duration of the testing. During the initial run-in, there was mass gain even compared with the soak controls, making the run-in wear rate calculation unreliable. Linear regression was used for the cumulative weight loss and demonstrated excellent fit at $R^2 \geq 0.99$. The wear rate for all three bearing surfaces is shown in Table 3. The volumetric wear was calculated using the known density of the polyethylene of 0.936. The density of the PUR was 1.19. The linear wear was also calculated using available equations, which allowed comparison with other studies, including measurements from radiography and computed tomography.

The average wear of PUR was 2.3 times lower than ConvPE over 30 million cycles in the simulator ($p < .001$). The average wear rate of XLPE was 14.6

FIG. 2: Photograph showing XLPE (left) and ConvPE (right) inserts after 30 million cycles with PMMA challenge. Severe wear of the ConvPE can be seen.

FIG. 3: Photograph of a tested acetabular component showing scratches on the XLPE after 30 million cycles. The original machine markings remain visible.

times lower than ConvPE and one-third of PUR ($P \leq .001$). There was a 16% increase in wear between components placed at 45° versus 65° for XLPE and a 19% increase when the radial clearance was increased by 1 mm using XLPE.

Challenge with PMMA particles increased wear by a factor of 2.6 for ConvPE against CoCr and 3.1 against a TiN femoral component (Fig. 4). There was limited increase in wear with PMMA challenge with XLPE against either counter-face (Fig. 3). At 65° and with PMMA challenge, the wear was easily visible on the ConvPE with the naked eye (Fig. 2) and the wear was increased by 70% over 45°.

FIG. 4: Photograph showing burnishing of the TiN-coated femoral component after 30 million cycles when exposed to PMMA challenge.

Wear particles were analyzed after 1, 5, 10, 20, and 30 million cycles. For ConvPE and XLPE, there was an increase in the number of submicron particles between 1, 5, and 30 million cycles ($p = 0.72$). PUR generated 3.4% submicron particles compared with 30% with ConvPE and 41% with XLPE ($p \leq 0.03$ and $p \leq 0.02$).

The concentration of particles on the back side was one to two orders of magnitude lower than those from the articulating surface. The particles were collected separately by back side washing (rather than from the lubricant) when the implants were removed, weighed, dried, measured, and inspected. The mean particle size was 12 μm for PUR (range, 0.5–73 μm), 1.2 μm for ConvPE (range, 0.3–48 μm), and 0.52 μm for XLPE (range, 2–26 μm). The volume particles generated were estimated at $2–6 \times 10^6$ for PUR, $6–12 \times 10^6$ for XLPE, and $30–50 \times 10^6$ for ConvPE challenged with PMMA.

The oxidation index of wear simulator specimens was 0.03–0.05 for all three materials. Surface images of all samples by optical microscopy and visual analysis were similar except for the ConvPE challenged with PMMA debris at 65°, which showed advanced wear (Fig. 2).

IV. DISCUSSION

There is a need for thin, durable, large-capacity polymer acetabular components for hip resurfacing and highly stable hip replacements. XLPE and PUR are candidate materials. XLPE is known to perform well and the 51-mm components tested are several millimeters larger than any previously tested implants. A specific PUR was also tested because of its limited osteolytic potential. PUR was compared with Conv PE and XLPE articulating against both a TiN-coated titanium and a CoCr-coated femoral component. This study found that PUR showed 56% lower wear than ConvPE ($p < 0.001$). The XLPE had a 93% reduction in wear compared with ConvPE. The wear of the 4-mm-thick, 51-mm-capacity PUR and XLPE components tested was not increased over the 8- to 10-mm-thick, 32- to 36-mm XLPE components used for THR.[8,13,17–19] The XLPE material tested is already in common use at smaller capacity and 2- to 4-mm thicker sizes.

PUR generated fewer submicron particles than ConvPE and XLPE.[27,29,30] The XLPE had 10% more submicron particles compared with ConvPE, but the amount was still very low and the overall wear was below the expected osteolytic threshold.[29–31]

The type of particles generated by wear may be just as important as the wear volume. Particles generated by metal-on-metal prostheses are predominantly in the nanometer size range[22,32] and polyethylene particles are in the micrometer size.[33] Nanometer-size particles are disseminated through the tissues in the body and are measurable in blood. The high activity of metallic nano-debris enhances their corrosive properties.[31,34,35] Particles produced by polyethylene are larger, in the 0.2–10 μm size range. This particle size is not disseminated systemically, but is most active in the tissues surrounding the hip by stimulating cytokines and producing osteolysis.[29,31,33] PUR particles are typically >1 μm, they do not disseminate, and are less inflammatory to the tissues.[21,30,36] PURs have comparable resistance to oxidative degradation compared with polyethylene.[21,30,36] The particle and wear analyses show that PUR is a suitable and superior material compared with ConvPE. However, XLPE performed better than PUR.

There are limitations to this study. Only one of the several possible PUR choices was tested. Other PURs have performed well in simulator and clinical testing.[21,23,24,30,36–38] The PUR specimens were compared withonly one type of ConvPE and one type of XLPE rather than to several types. Only two femoral head sizes (49 and 51 mm), one acetabular diameter (51 mm), and one acetabular thickness (4 mm) were used. There are both clinical and wear simulator data showing that XLPE of 3.8 mm and a diameter of 44 mm has excellent survivorship[3,13] Prior wear simulator studies of 3-mm XLPE of 46 mm showed very little wear.[27,28] It has been shown that opposite ConvPE, larger-diameter PUR implants have less wear compared with smaller implants.[23]

Large-capacity XLPE may have other differences compared with ConvPE. The wear characteristics of XLPE are not affected as significantly by moving from a 45° to a 65° inclination angle. In addition, there was a limited increase in wear when the radial clearance was increased by 1 mm. Prior clinical studies have noted severe wear with component failure when the radial clearance between the femoral head and acetabular bearing diameters were increased to >1.5 mm with ConvPE.[34] Radial clearances up to 0.75 mm have been used successfully in prior polyethylene hip designs.[39,40] The present study tested to 1.3 mm of radial clearance.

PURs have a very similar chemical structure to amino acids and are biologically more compatible than polyethylene. PURs are hydrophilic compared with polyethylene and benefit more easily from fluid film lubrication. They also perform well under the elevated heat conditions known to exist clinically after THR and resurfacing procedures.[14] PUR wear debris is well tolerated compared with polyethylene debris.[21,24,33,36,40]

PUR was first used for hip resurfacing in 1960. All PUR hip-resurfacing procedures failed due to wear, but the function was quite good and there was no osteolysis.[40] The PUR formulation (Ostamer, William S. Merrell Co., Cincinnati, OH) was made by mixing a prepolymer with a catalyst at the time of operation that hardened into a firm plastic mass. Ostamer was intended primarily as a bone glue, but it could be formed into any desired surface.[41,42] The same innovator who performed the hip-resurfacing procedures with Ostamer designed the PUR for this study.[25] The PURs currently available are more pliable, they lubricate better, and they have better wear characteristics than the predicates.

The first bearing surface life endurance test for a resurfacing implant was in 1953.[43] There is one prior wear simulator study using a 47-mm TiN-coated resurfacing femoral component with polyethylene. The wear conditions were different, with a 5 Hz speed and water as the lubricant. This prior study also found minimal wear at 48 million cycles, which would be consistent with more than 30 years of clinical use.[16,44] The present study is the first test of TiN used against XLPE and PUR.

In conclusion, this study found that PUR has lower wear and less particle generation compared with ConvPE and that XLPE is more wear resistant than both PUR and ConvPE. The satisfactory performance of XLPE of 4-mm thickness tested against a 51-mm femoral component is consistent with its favorable clinical results and supports its continued use for hip resurfacing and large-diameter THR. Both low wear and increased femoral head size are possible with XLPE. By extending the 4-mm acetabular component offering to 51 mm, nearly all patients presenting for a polyethylene hip resurfacing can be accommodated.

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