

Total Articular Knee Replacement Using Polyurethane

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Abstract

This study reviewed the early use of polyurethane for total knee resurfacing, the long-term results of polycarbonate urethane (PCU) for total knee replacement and conducted wear simulator testing of PCU. In 1959 and 1960, 10 patients underwent total articular polyurethane knee replacement (polyethylene was not available). The polyurethane was placed on the articular surface of the femur with metal surfaces on the tibia and patella. In 1996 and 1997, four patients received a newer PCU tibial insert in revision procedures; all had well-fixed prostheses, but no revision polyethylene implants were available. In addition, this study evaluated six new PCU tibial inserts in a 10-million cycle (Mc) wear simulator. All 10 of the early knees performed well clinically and 2 knees were functional for more than 30 years. Of the four more recent patients, all knees remain functional at more than 20 years' follow-up with no signs of wear or osteolysis. Wear simulator testing found mean material loss of 14.2 mg/Mc which equates to a volumetric wear of 11.9 mg/Mc, similar to the wear of conventional polyethylene. Polyurethane performs well as conventional polyethylene but not better than current cross-linked polyethylene tibial inserts. Its large wear particles (mean, 11 μm) and biocompatibility are less likely to cause an inflammatory response leading to pain and bone loss. Newer, superior polyurethanes can again be considered a candidate material for the tibial insert of a total knee replacement. A larger study may be able to validate polyurethane as an alternative material for joint replacement.

Keywords

- ▶ polyurethane
- ▶ knee resurfacing
- ▶ knee replacement
- ▶ arthroplasty
- ▶ polyurethane wear

Before polyethylene, interpositional, metal-on-metal, acrylic, or one- or two-piece hemiarthroplasty procedures were used for knee joint arthroplasty. Many of the early designs were hinge prostheses or independent compartmental designs that did not function like a normal knee. When polyethylene became available, total condylar prostheses such as those designed by Insall and several others came into common use. These implants were functional rather than anatomic in design.¹⁻⁵ Starting in 1952, Townley used an anatomically shaped tibial articular plate that preserved both cruciate ligaments.⁶ He also resurfaced the patella with a metal prosthesis. This ensemble was a hemi- rather than total arthroplasty procedure.^{6,7} During 1959 and 1960, he

combined a polyurethane resurfacing of the femur with his tibial and patellar hemiarthroplasty implants to provide a total knee replacement. The polyurethane ground away, though, within a few years (▶ **Fig. 1**). Subsequently, the knee functioned as a hemiarthroplasty for the tibial-femoral and patellofemoral joints. Townley published this method for total hip resurfacing but not for the knee.^{8,9} At that time, polyurethane was used primarily as a bone glue.¹⁰⁻¹² However, its use led to nonunion and infection in some cases¹³ and the manufacturer (Merrill) stopped producing the polyurethane material after 6 years of use.¹⁴

Recently, improved polyurethane preparations have been reintroduced and several clinical and experimental trials

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Fig. 1 These anteroposterior and lateral radiographs of the right knee were taken 33 years following total knee resurfacing implant arthroplasty. The femur was resurfaced with polyurethane foam, the tibia was resurfaced with a Townley articular replacement, and the patella was resurfaced with a McKeever Vitallium prosthesis. The polyurethane has worn away, but the knee functions well clinically.

have been performed using polyurethane as an articular surface. Polyurethane can be considered a candidate material for the tibial insert of a total knee replacement. The reasons to consider polyurethane over polyethylene are (1) it is more heat stable, (2) it is hydrophilic rather than hydrophobic, (3) the wear debris produces less cytokine response and osteolysis, and (4) the wear particles are of a larger size.¹⁵⁻¹⁸

The author asked: (1) What are the past results using polyurethane foam for anatomic total knee resurfacing arthroplasty? (2) What are the wear simulator results of testing polycarbonate urethane (PCU)? and (3) What are the long-term clinical results of using PCU for total knee replacement?

Materials and Methods

Early Knee Resurfacing

The author searched the patient and research records of Dr. Charles O. Townley with his request to study his use of polyurethane foam as a bearing surface in resurfacing knee implant surgery. Townley implanted a tibial articular plate implant of his design in 170 patients between 1952 and 1972. Ten of these patients received polyurethane foam to resurface their femur, with stainless steel surfaces used as the counter face on their patella and tibia. The polyurethane replaced the articular surface of the femur, and thus, the first anatomic total resurfacing of the knee was performed.

The polyurethane was formed by mixing a prepolymer with a catalyst at the time of operation in a manner similar to the preparation of polymethylmethacrylate.¹⁹ The eburnated femoral bone was prepared with anchor holes. The polyurethane was bonded to the femur including both condyles and trochlea. The polyurethane foam hardened to a firm consistency in 20 minutes.¹² The prepared femur was then brought into contact with the tibial and patellar prostheses, which were protected with a plastic sheet, thereby



Fig. 2 This is a photograph of a polyurethane tibial insert designed for a bicruciate total knee application.

allowing the polyurethane to conform to the articulating tibial and patellar prostheses.

Wear Simulator Testing

In 1996, polyurethane-polycarbonate was reformulated for use in joint implant surgery, and it was subjected to extensive testing.^{15,16} The present study tested six polyurethane tibial inserts in a specially designed wear simulator (►Fig. 2). This wear simulator was a predicate of and functioned the same as the AMTI KS-2-6-1000 simulator used in recent years. The wear simulator testing was performed according to ISO 14243-1:200. One insert served as a soak control and received a vertical load only and five received a full compressive load. Lubrication was with diluted calf serum and the wear test was performed at $37 \pm 1^\circ\text{C}$. The tested implants were removed from their original sterile packing and were treated with accelerated oxidative aging according to ASTM F2003. Their initial dry weight was recorded. Prior to the wear simulation testing, the tibial inserts were soaked in serum and measured weekly until there was less than a 10% weight change. Next, the implants were presoaked for 7 days in the lubricant, cleaned, and weighed again. Samples were assigned randomly to undergo full wear testing. The test parameters were a maximum load of 2,600 N, a flexion angle of 0 to 60 degrees, an anterior-posterior force of -265 to 110 N, and an internal and external rotational torque of -1 to 6 Nm.

The simulation was continued for a total of 10×10^6 cycles at a frequency of 1 Hz. All five tested inserts were for a bicruciate knee. Three were tested as separate medial and lateral inserts and two inserts were joined anteriorly by a narrow bridge to make a one-piece insert. One insert combination was 2 mm thicker laterally than medially and all the inserts were 8 mm medially. Every 0.5×10^6 of the components was measured gravimetrically according to ISO 14243-1:200 and ASTM F2025. Two methods were used. In Method 1, the average wear rate was determined by linear regression of the implants' weight over time. In Method 2, the total weight was calculated by subtracting the final weight after complete drying from its initial weight and dividing by 10 million cycle (Mc). The volumetric wear can be determined using the density of PCU (1.19 g/mL).

Total Knee Replacement Using PCU

In 1996 to 1997, the Western Institutional Review Board approved the use of polyurethane tibial inserts in four patients based on their compelling and unique clinical situations. Also, the lack of toxicity of PCU, its history of many other uses in the body, and compelling test data were considered. Three patients had a bicruciate total knee replacement and one had a posterior cruciate-retaining prosthesis. The bicruciate polyurethane inserts had a slight concavity for the medial insert and a slight convexity with a posterior slope for the lateral insert. The original diagnosis was rheumatoid arthritis in one patient and osteoarthritis in three patients. The patients' ages were 35, 46, 48, and 53 years at the time of surgery. All were active and all provided their specific written consent. All patients had a prior total knee arthroplasty that failed due to polyethylene wear. Since no compatible polyethylene replacement prostheses were available, they opted for polyurethane rather than a much more complex revision that would have involved removing well-fixed, well-oriented, and clinically proven femoral and tibial components. Postoperatively, the patients were evaluated biennially with clinical examinations, radiographs, and Knee Society scores.²⁰ The knees were examined for signs of warmth or effusion. Radiographs were evaluated for radiolucent lines around the implant, osteolysis, polymer wear, or other signs of implant failure.

Results

Early Knee Resurfacing

Review of the patient records found that none of the 10 polyurethane knee resurfacing arthroplasty procedures from 1959 and 1960 failed. None was revised and all 10 patients achieved a stable knee with 95 degrees of flexion and substantial pain reduction. The polyurethane wore away completely over 3 to 7 years in each patient. Two patients were available for follow-up at more than 30 years after surgery and both remained independent and functional. Their Knee Society scores were 84 and 82. No significant bone loss or effusion was present. The other eight patients died from 3 to 14 years following surgery of unrelated causes.

Wear Simulator Testing

All five loaded inserts maintained their fixed positions between the tibial trays and femoral component throughout the testing. None of the implants demonstrated significant visual damage (► **Table 1**). The total wear after 10 Mc was 132.4 ± 20.6 mg when measured by Method 1 and 151.3 ± 15.0 mg when measured by Method 2. The average wear was 13.2 mg/Mc by Method 1 and 15.1/Mc by Method 2. The mean volumetric wear was $11.1 \text{ mm}^3/\text{Mc}$ by Method 1 and $12.7 \text{ mm}^3/\text{Mc}$ by Method 2. There were 232 particles isolated from the lubricant by filtration and were imaged by scanning electron microscopy. The mean diameter of the particles was 11 μm (range, 0.49–103.9 μm).

Total Knee Replacement Using PCU

All four patients achieved excellent or good clinical results. The Knee Society scores were 91, 93, 87, and 84, improved

Table 1 Ten-million cycle polyurethane wear (mg)

Inserts tested	Method 1	Method 2
Insert 1	-111.7	-127.3
Insert 2	-109.6	-149.9
Insert 3	-157.8	-169.2
Insert 4	-135.4	-151.8
Insert 5	-147.3	-158.2
Average \pm standard deviation	-132.4	-151.3

from preoperative scores of 57, 60, 61, and 58, respectively. There were no clinical or radiographic signs of wear of the polymer and no revisions were performed (► **Figs. 3** and **4**). The follow-up periods for these four patients are 20, 21, 21, and 22 years, respectively.

Discussion

Polyurethane was clinically successful when it was first used in 1959 and 1960 in knee resurfacing procedures. Polyurethane as a bearing surface for revision total knee articular replacement was also completely successful in the four patients treated in 1996 and 1997. In both situations, this was the least intrusive option available for the patients. Polyurethane showed limited wear in the simulator studies.^{16,18,21} The durability, however, was very similar to the conventional polyethylene used in several other current systems.^{22–24} The PCU wear with the bicruciate knee was very similar to polyethylene wear with the same bicruciate knee design.²⁴ Therefore, there is no definite advantage of the polyurethane from a wear standpoint for total knee replacement. This has also been confirmed by several other studies. Similarly, polyurethane has provided no definite advantage for total hip replacement or resurfacing in terms



Fig. 3 This is the anteroposterior knee radiograph of a 36-year-old woman with juvenile rheumatoid arthritis. She underwent bilateral total knee replacement at the age of 21 years. After 15 years, there is complete wear through of the polyethylene. The right knee has well-fixed components. The right tibia is not a modular implant, and there are no replacement polyethylene components available for it.



Fig. 4 This anteroposterior radiograph of the same patient was taken 20 years following revision (patient age 56 years) using a polyurethane tibial insert on the right. The left was revised with an available replacement polyethylene tibial insert. Tibial and femoral components were not otherwise revised. The knees were performing well at last follow-up 21 years following surgery.

of wear when compared with highly cross-linked polyethylene.^{16,17}

Although this study found successful clinical outcomes with the knees revised and wear testing results comparable to conventional polyethylene, there are limitations. The present study is limited by the very small numbers of patients treated. The follow-up, however, is long and much longer than most other reports on total knee replacement. Also, only one type of PCU polymer was tested and used of the several potentially available.

Polyurethane wear debris invokes less tissue reaction and osteolysis than polyethylene, but this was not established in the present work. Wear debris can still be a consideration when choosing an implant material. Delrin and other polymers have been used in the past as alternatives to polyethylene.²⁵

There have been previous studies of PCU as a compliant bearing acetabular material.^{16,17} The 14.2 mg/Mc wear in the present study falls within the range of 9.2 to 19.1 mg/Mc that was found for an acetabular insert. A hip prosthesis, however, is engineered to promote optimal lubrication via elastohydrodynamic lubrication.¹⁶ The tribology of a tibial insert and the interperson variability in knee anatomy, shape of the femur, or femoral prosthesis results in a mixed lubrication pattern that increases wear.²¹ Wear rates of total knee replacement prostheses have been from 7.25 to 15; 16 mg/Mc for conventional polyethylene. Wear rates of 0.56 to 2.07 mg/Mc for certain highly cross-linked polyethylenes with or without vitamin E have been reported.²⁰⁻²²

There are several other testing reports of polyurethane use for unicompartmental and total knee replacement. Polyurethane has been termed a compliant layer or cushion bearing. Under moderate loads, the polyurethane layer had a reduced and favorable coefficient of friction compared with polyethylene. Under more severe conditions, the values increased with polyurethane, and there were small scratches and tears in the polyurethane. In simulator tests, dimples due

to creep sometimes occurred. Both flat and contoured surfaces have been tested. A combination of polyurethane and polyethylene has also been suggested.^{15,18}

Three of the four patients treated in 1996 and 1997 received bicruciate knee prostheses. The bicruciate implant has been very successful in the few long-term studies available.^{7,26} There may be some functional advantages, and this knee implant may provide more stability and have less wear over extended periods. With a bicruciate prosthesis, it is possible to balance the medial and lateral compartments separately. Tibial inserts of different thicknesses can be used. The wear testing in this report suggests there is no increase in wear with a 2-mm thicker lateral insert compared with the medial. Differential thickness of inserts was also used successfully with the MacIntosh hemiarthroplasty and Townley anatomic total knee prostheses.^{3,7}

There are several advantages to polyurethane compared with polyethylene. Polyurethane has greater wettability, heat stability, and compliance (cushion bearing). It wears well, and polyurethane wear debris particles are larger, producing less cytokine reaction and less osteolysis. The chemical structure of polyurethane closely resembles an amino acid and is a well-tolerated foreign body.^{12,16}

The original polyurethane was intended to allow fibrocartilage and bone to grow through the porous polyurethane. The chemical reaction between the prepolymer and catalyst liberated carbon dioxide and heat, expanding the mass as a foam and forcing it to adhere to the bone.^{10,12,16} It was intended to serve as an articular barrier that would resorb eventually.²³ Later work found that the polyurethane foam did not always resorb and various reactions and an increase in infection occurred with its use.¹³ Polyurethane fell from favor and interest did not return for another 25 years.

There may be a wear advantage for PCU compared with predicate conventional polyethylenes but not to the current highly cross-linked polyethylenes. Highly cross-linked polyethylene in knees with limited constraint has very little wear. There has been very little clinical use of polyurethane. The polyurethane performed well for the four patients treated in 1996 and 1997, and each patient continues to enjoy excellent function and revision-free survivorship of their prosthesis. The original experience from 1959 and 1960 was also favorable, with the two surviving patients ambulating with useful prostheses more than 30 years after surgery. These clinical and wear testing results provide support for the use of polyurethane, and it may merit renewed investigation.

Conflict of Interest

None.

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