Examination of Porous-Coated Patellar Components and Analysis of the Reasons for Their Retrieval

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One-hundred-fifteen retrieved, porous-coated, uncemented patellar knee components of a wide variety of designs were examined for type and amount of tissue ingrowth and for wear and creep of the polyethylene-articulating surface. Examples of well-fixed patellar components of all designs presented regions of bone ingrowth independent of pore size, number of fixation pegs, and the presence or absence of coating on the pegs. Polyethylene breakdown, including delamination, pitting, subsurface cracking, and separation from the metal backing, was common. Comparative analysis indicates that solutions exist and include increasing congruency and polyethylene thickness and eliminating metal fixation buttons.

INTRODUCTION

Porous coating of femoral hip prostheses began its clinical evaluation in the United States in 1977 as an alternative to fixation by bone cement. The success of fixation by tissue ingrowth of the porous coating of the femoral component as evidenced by histological analysis[1] lead to its application to the acetabulum and to the components of the total knee. Acetabular, patellar, and tibial prostheses that had previously been composed entirely of polyethylene required the application of a metal backing to which the porous coating could be applied. By necessity, this metal backing took the place of some of the previous polyethylene thickness.

The problems of patellar resurfacing are more severe than tibial or acetabular replacement, as there is insufficient room for both a metal backing and a thick polyethylene insert without either removing sufficient bone stock that fracture of the patella becomes a very real possibility, or over-stuffing of the joint resulting in pain and limited flexion. Therefore, many of the current designs provide a very thin polyethylene bearing that is at risk for failure as described in 1988 by Lombardi[2] and Bayley.[3] Examination of components retrieved for polyethylene failure or separation as well as those components retrieved for other reasons often reveal the presence of particulate polyethylene wear debris at the margins of the bone ingrowth surface, leading to concerns for long-term breakdown of this interface as described by Willert,[4] Mirra,[5] and Howie.[6] In this study we have examined 115 porous-coated patellar knee prostheses provided to us for analysis of tissue ingrowth and polyethylene wear in an effort to assess the reasons for failure.

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MATERIALS AND METHODS

All retrieved specimens were sent in formalin and an effort was made to obtain patient information (Table I) and reason for retrieval (Table II). These prostheses were provided to us by surgeons throughout the world, hence the difficulty in obtaining complete clinical histories. The porous coating of each prosthesis was first visually examined for the presence of bone adherence and, if present, the prosthesis was dried, emedded, sectioned, ground, polished, stained (with hematoxylin and eosin), and each 20 μm-thick section was examined using a Zeiss Photomicroscope III. In all cases the polyethylene articulating surface was examined using a modification of the techniques described by Hood and Wright in their 1983 paper.[7] Their categories of abrasion, pitting, burnishing, delamination, and surface deformation (creep) were used, as was surface cracking (cracking) described in their 1982 paper. The categories of embedded PMMA debris and scratching were eliminated; these components were uncemented and the differentiation between abrasion and scratching was not found to be useful. Unfortunately, with the majority of prostheses sent to us there was no indication of the orientation of the component in the patient. Therefore, because we were unable to determine anterior, posterior, medial, and lateral quadrants a single assessment for degree of wear was made using a scale of 0 to 3. The scores are explained as follows: 0 = no wear; 1 = less than 10%; 2 = 10–50%; and 3 = greater than 50% of the surface is involved or severe

TABLE I. Patient Information

Type	N	Duration (mos)	Age (yrs)	Weight (lbs)
AMK	3	7.7 (3.3)	67.5 (4.9)	*
(DePuy)		$n = 2$	$n = 2$	$n = 1$
LCS	27	15.0 (13.7)	61.2 (16.2)	201.6 (43.2)
(DePuy)		$n = 24$	$n = 22$	$n = 16$
Miller-Galanté	7	12.6 (18.7)	69.6 (12.3)	178.3 (81.6)
(Zimmer)		$n = 6$	$n = 5$	$n = 3$
Ortholoc	10	20.2 (15.5)	64.4 (11.6)	*
(DCW)		$n = 9$	$n = 9$	$n = 1$
PCA	30	31.4 (19.1)	61.6 (9.7)	199.7 (44.3)
(Howmedica)		$n = 22$	$n = 27$	$n = 19$
Synatomic	36	31.6 (23.6)	63.4 (12.7)	184.4 (23.2)
(DePuy)		$n = 21$	$n = 25$	$n = 15$
Tricon	2	28.1 (10.9)	56.5 (9.2)	215 (7.1)
(Richards)		$n = 2$	$n = 2$	$n = 2$

N = Total number of this type of component received.
n = Number of received components with polyethylene bearing available for analysis.
( ) = Standard deviations.
* = No data.
The numbers and types of components sent to our laboratory for analysis do not in any way relate to the numbers of devices in use nor their rates of failure.

localized wear is present (Table III). Some prostheses were retrieved due to separation of the polyethylene bearing from the metal backing. In these cases, separation was stated as the reason for retrieval in Table II, and a 3 for severe was listed for cracking of the component in Table III.

RESULTS

Of the 30 retrieved PCA prostheses, 21 demonstrated evidence of significant wear (≥2) of the articulating surface. In two cases the components had been retrieved due to fracture and separation of the polyethylene from the metal backing resulting in metal-on-metal articulation. Both anatomic and domed PCA patellar components were examined. Twelve of 16 dome prostheses showed significant wear (≥2), 9 of 14 anatomic components presented significant (≥2) polyethylene wear (Fig. 1).

Twenty-seven LCS movable bearing patellar components were examined. None were retrieved for separation of the polyethylene from the metal backing, while 10 of the prostheses demonstrated wear resulting in an assessment of greater than 1. Two components demonstrated creep of the polyethylene at the margin of the prosthesis which caused it to overlap the metal backing prohibiting the 45° range of motion typically provided by these devices.

TABLE II. Reason for Retrieval of Patellar Components

Type	n	Infection	Malposition	Loose	Pain	Patella Fracture	Dislocation	Poly Separation	Other	No Info
AMK (DePuy)	2	0	0	0	2	0	0	0	0	1
LCS (DePuy)	26	1	2	3	15	1	0	1	3	1
Miller-Galanté (Zimmer)	4	1	0	0	2	0	0	0	1	3
Ortholoc (DCW)	9	0	0	0	4	0	1	0	4	1
PCA (Howmedica)	23	0	0	4	12	0	1	0	6	7
Synatomic (DePuy)	26	3	0	1	8	1	1	6	6	10
Tricon (Richards)	1	0	0	0	1	0	0	0	0	1
Sum	91	5	2	8	44	2	3	7	20	24
% Total		5.5	2.2	8.8	48.4	2.2	3.3	7.7	22	

n = Number with patient data available.
The numbers and types of components sent to our laboratory for analysis do not in any way relate to the numbers of devices in use nor their rates of failure.

TABLE III. Wear Ratings by Patella Type

Type	Overall Wear	*N*	Abrasion	Burnishing	Pitting	Cracking	Delamination	Creep
AMK (DePuy)	1.3 (0.6)	2	1.3 (1.2)	2.0 (1.0)	0.7 (0.6)	0	0	1.0 (1.0)
LCS (DePuy)	1.4 (0.7)	27	1.1 (0.8)	1.4 (0.5)	1.0 (0.8)	0.3 (0.6)	0.5 (0.9)	0.5 (0.6)
Miller-Galanté (Zimmer)	2.3 (0.5)	7	1.3 (1.4)	2.0 (0.6)	1.1 (1.3)	0.7 (1.1)	1.1 (1.3)	2.1 (0.4)
Ortholoc (DCW)	2.0 (1.2)	10	1.0 (0.9)	1.3 (0.8)	0.9 (1.3)	1.2 (1.5)	1.3 (1.4)	1.4 (1.3)
Synatomic (DePuy)	2.2 (0.9)	30	1.7 (0.8)	1.9 (0.8)	1.8 (1.0)	1.1 (1.2)	1.4 (1.4)	1.2 (1.0)
Tricon (Richards)	2.3 (0.7)	36	1.1 (0.9)	1.9 (0.7)	1.9 (0.8)	1.2 (1.4)	1.3 (1.3)	1.6 (1.2)
	3.0 (0.0)	2	1.5 (2.1)	2.0 (0.0)	1.5 (2.1)	1.5 (2.1)	1.5 (2.1)	2.0 (1.4)

N = Number of polyethylene bearings examined.
( ) = Standard deviations.
The numbers and types of components sent to our laboratory for analysis do not in any way relate to the numbers of devices in use nor their rates of failure.

Six of 10 Ortholoc patellar prostheses demonstrated significant (≥2) wear. Additionally, 6 of the 10 prostheses were retrieved for separation of the polyethylene from the metal backing resulting in metal-on-metal contact. In 60% of the cases with relatively short (less than two years) postoperative durations, wear assessments of greater than 1 were demonstrated.

Thirty-one of 36 Synatomic prostheses demonstrated evidence of polyethylene wear (>1). Of these, 19 were retrieved for separation of the polyethylene from the metal backing; the remaining 5 had ratings equal to one.

Of the 7 Miller-Galanté prostheses retrieved, 3 had articulating surfaces of Poly II (carbon-fiber-reinforced polyethylene); the remaining 4 were standard polyethylene. All showed significant (≥2) polyethylene wear. One was retrieved for separation of the polyethylene from the metal backing.

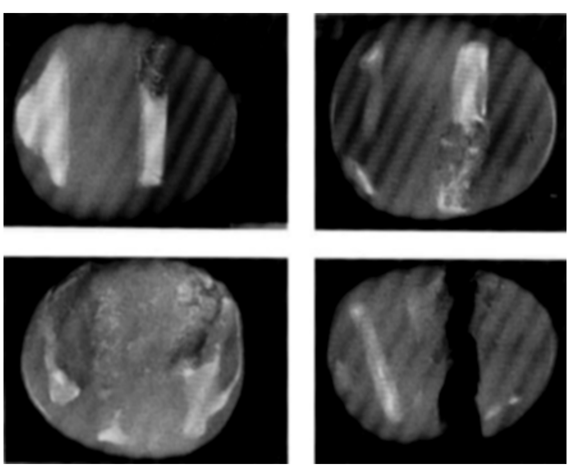

Figure 1. Anatomic, metal-backed patellar components, from top to bottom, left to right: (a) initiation of pitting damage; (b) pitting and initiation of delamination; (c) severe pitting and delamination; (d) severe cracking leading to separation of polyethylene from metal backing.

HISTOLOGICAL RESULTS

Bony ingrowth of at least some regions of the porous coating of specimens of each type (though not all devices of any type) of porous-coated, uncemented patellar prostheses were seen indicating that pore size, composition, and fixation mechanisms are all sufficient, under ideal conditions, to permit bony ingrowth. Prostheses with porous-coated locating pegs frequently demonstrated bone ingrowth at the base of the pegs. Polyethylene wear debris was generally found at the margins of both severely worn and separated components. The debris was often associated with an aggressive fibrous tissue layer and associated osteoclastic activity in adjacent bone. Therefore, all of the mechanisms appear to be present to permit long-term loosening of even well bone-ingrown prostheses.

DISCUSSION

Patellar components are limited in overall thickness by the bone stock available in the patella and the concern for over stuffing of the joint, thereby limiting flexion. Therefore, the metal backing reduces the space available for polyethylene by its thickness (typically 3–4 mm). The resulting polyethylene thickness is always less than the 6 mm cited as necessary for nonconforming surfaces by Wright and Bartel.[8] At locations of the fixating lugs and margins of the component, the polyethylene thickness may be less than 3 mm (range found in our retrievals is 1.8 to 3.8 mm; Fig. 2). This thin layer of polyethylene must transmit high loads which results in very high contact stresses causing creep, which can then loosen the polyethylene on the metal backing leading to the potential for separation. Additionally creep reduces the polyethylene thickness thereby further increasing the stresses causing early fatigue failure.

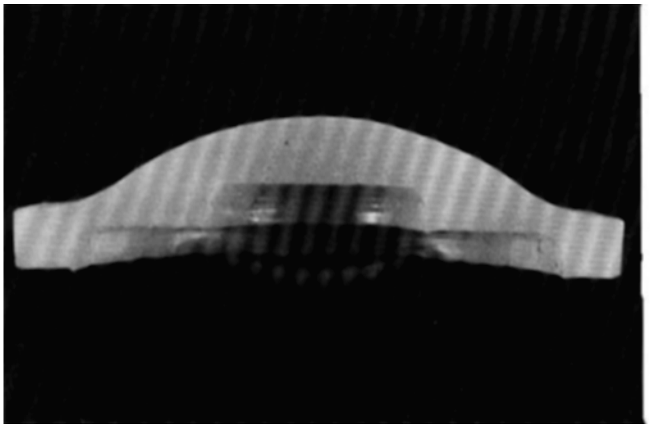

Figure 2. Dome type, metal-backed patellar component sectioned to demonstrate limited polyethylene thickness.

Examination of patellar articulation reveals that in many designs the areas in contact are very small and that the region of contact moves from the dome of the component at full extension to the periphery during flexion. This oscillating loading between the dome and the edge of the component mimics the technique that an individual might use in an effort to pop the polyethylene off the metal backing; a clinical result in approximately 7.7% of the components we examined.

The LCS patellar component, whose geometry permits a continuous, congruent articulation between the femoral component and the polyethylene patellar surface, showed less evidence of wear. For all patellar components, the degree of polyethylene wear was positively correlated with duration of implantation ($p < 0.01$). No other direct correlation was seen.

One interesting phenomenon was noted which provides insight into the complex forces present at the polyethylene/metal articulation. The polyethylene dome of the Synatomic patellar prosthesis is fixed to the metal backing by a round locating lug. Thirteen of 36 of these prostheses demonstrated, by the concentric scratching of both the metal and undersurface of the polyethylene, the ability of the bearing surface to spin around the lug at the time of retrieval (Fig. 3). It appears that creep of the polyethylene component eliminates the locking to the metal backing and provides a new surface for articulation.

Separation of the polyethylene from the metal backing of the Ortholoc patellas generally occurs in two stages. The first is circumferential cracking along the metal fixation lug perimeter resulting in a freeing of the center of the dome, leaving an annular ring. This results in metal-on-metal contact (femoral and patellar components) and is followed by separation of the remaining annular ring of polyethylene from the metal backing (Fig. 4).

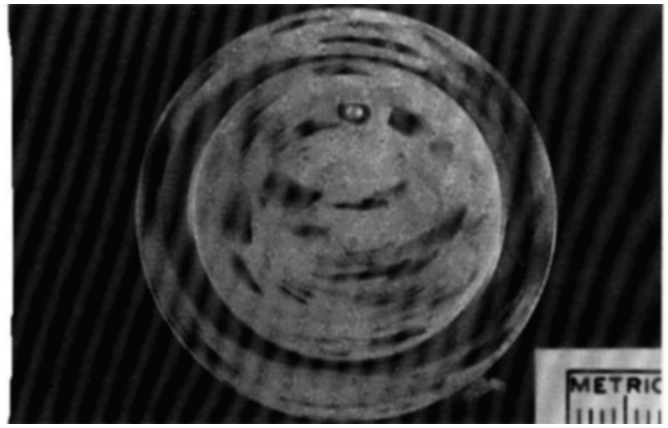

Figure 3. Pattern of burnishing of metal backing of a well-fixed patellar component indicates that the polyethylene articular surface was rotating relative to backing.

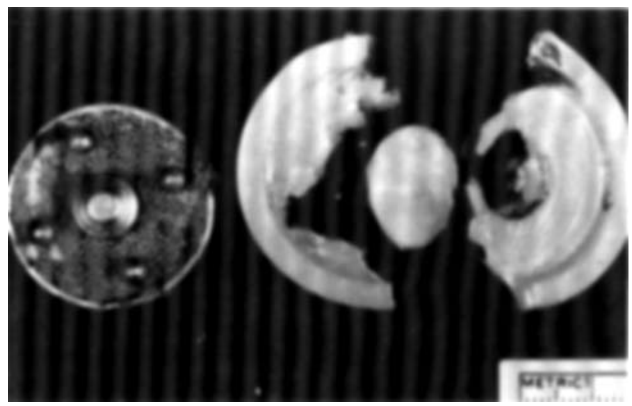

Figure 4. Thin polyethylene surrounding metal locating leg has deformed and cracked, central dome has popped free leaving annular ring of polyethylene which subsequently broke in half.

CONCLUSIONS

The majority (67.2%) of porous-coated, uncemented, metal-backed patellar prostheses which we examined demonstrated significant (≥2 on a scale of 0 to 3) wear. Examination of the contact areas between the femoral component and the articulating surfaces of these devices reveals that these areas are generally small, are often not continuous over the range of motion of the knee, and occur at regions of limited polyethylene thickness. The stresses in the polyethylene as a result of these small contact areas are high, as revealed by the presence of delamination and pitting which are a result of the subsurface cracking which occurs. Fully congruent geometries demonstrate little evidence of wear at all time periods and deserve consideration as an alternative to the dome and anatomic type designs prevalent today.

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REFERENCES

1. Collier, J. P.; Mayor, M. B.; Bobyn, D.; Engh, C.; Orr, T. The Histology of Tissue Ingrowth into Porous Metal-Coated Hip Prostheses in Five Humans. 9th Annual Meeting of the Society for Biomaterials, Birmingham, Alabama, April 27–May 1, 1983.

2. Lombardi, A.V. Jr.; Engh, G. A.; Volz, R. G.; Albrigo, J. L.; Brainard, B. J. Fracture/dissociation of the polyethylene in metal-backed patellar components in total knee arthroplasty. J. Bone Jt. Surg. 70-A:675–679; 1988.
3. Bayley, J. C.; Scott, R. D.; Ewald, F. C.; Holmes, G. B. Failure of the metal-backed patellar component after total knee replacement. J. Bone Jt. Surg. 70-A:668–674; 1988.
4. Willert, H. G.; Semlitsch, M. Reactions of the articular capsule to wear products of artificial joint prostheses. J. Biomed. Mater. Res. 11:157–164; 1977.
5. Mirra, J. M.; Marder, R. A.; Amstutz, H. C. The pathology of failed total joint arthroplasty. Clin. Orthop. 170:175–183; 1982.
6. Howie, D.W.; Vernon-Roberts, B.; Oakeshott, R.; Manthey, B. A rat model of resorption of bone at the cement–bone interface in the presence of polyethylene wear particles. J. Bone Jt. Surg. 70(2):257–263; 1988.
7. Hood, R.W.; Wright, T. M.; Burstein, A. H. Retrieval analysis of total knee prostheses: a method and its application to 48 total condylar prostheses. J. Biomed. Mater. Res. 17:829–842; 1983.
8. Wright, T. M.; Bartel, D. L. The problem of surface damage in polyethylene total knee components. Clin. Orthop. 205:67–74; 1985.
9. Wright, T. M.; Hood, R.W.; Burstein, A. H. Analysis of material failures. Orthop. Clin. North America. 13(1):33–43; 1982.

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