

Aging Performance of a Compliant Layer Bearing Acetabular Prosthesis in an Ovine Hip Arthroplasty Model

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Abstract: The wear performance of a polyurethane compliant layer (CL) material formed into an acetabular component and implanted into a sheep model of cemented total hip arthroplasty was assessed at 6, 12, 24, and 48 months. Four (11%) of 36 acetabular components debonded from the cement and one component was slightly loose at the cement-bone interface. There was no macroscopic evidence of fracture, wear, or deformation of the CL material on the articular surface of the acetabular components. Small numbers of polymeric wear particles was found in the hip synovial tissues of 10 sheep, most commonly in the early time groups, and were likely associated with initial wear of surface asperities. The wear performance of the CL was unchanged during a 48-month implantation period. **Key words:** hip, arthroplasty, polyurethane, wear, in vivo.

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Natural joints have much lower coefficients of friction than artificial joints, and it has been shown that natural joints have a component of fluid film lubrication. Under this lubrication regimen, some of the load is carried by a thin film of synovial fluid [1]. If the surfaces do not come into direct contact,

then the likelihood of wear of these surfaces is markedly reduced. Hip joint prosthesis bearings have been shown to operate with mixed lubrication regimens in which the surfaces come into direct contact and wear can be expected [2]. There is strong evidence that aseptic loosening of joint arthroplasty prostheses in the medium to long term is associated with an adverse tissue response to wear particles liberated from the bearing surfaces of prostheses [3-5]. Consequently, attempts to limit the production of wear particles have generally looked at increasing the wear resistance of the bearing surfaces. Another approach to improving wear performance is to modify the articulating surface mechanics to increase fluid film lubrication.

Laboratory studies have shown that compliant materials such as polyurethane can perform in a similar way to that of cartilage and function with a continuous fluid film separating the articulating surfaces [1]. However, data are lacking to demonstrate the durability of these compliant materials applied as a layer to the articulations of joint

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arthroplasty prostheses when subjected to in vivo conditions. This study was part of a program of research to investigate the application of a biomedical polyurethane compliant layer (CL) system for application as a bearing for joint arthroplasty. The aim of this in vivo study, using a sheep total hip arthroplasty (THA) model, was to investigate the aging wear performance of the polyurethane CL material formed into a THA acetabular component design. In particular, fracture or wear of the CL material was examined during a 48-month period. The histological appearance of local and systemic tissues and the clinical and radiographic performance of the THA implant system were also assessed.

Materials and Methods

Left unilateral THA was performed on 36 skeletally mature Merino wether sheep (Fig. 1). Sheep were from one flock to minimize variation. Implant performance was assessed at 6, 12, 24, and 48 months. The first 8 arthroplasties performed were assigned to the 6-month group so that wear data were available early in the study to justify the longer term implantation of the CL system. The remaining sheep were randomized, using a random



Fig. 1. Anteroposterior in vivo radiograph of a sheep hip implanted with the THA prosthesis that includes the Corethane CL acetabular component.



Fig. 2. Sheep THA prosthesis comprising a Corethane CL acetabular component, a stainless steel double-taper femoral component, and a plastic centralizer.

number schedule, to the 12-month group ($n = 9$), the 24-month group ($n = 10$), and the 48-month group ($n = 8$). Two sheep died of unrelated causes after 30 months from implantation raising concerns about attrition caused by aging. Four sheep, randomized to the longer term groups, were therefore reassigned to the 24-month group to give 14 sheep in the 24-month group and 5 sheep in the 48-month group.

The CL acetabular components were formed by injection molding a 1.6-mm Corethane 80A polyurethane resin, forming the CL bearing surface, onto a Corethane 75D hard polyurethane backing (Howmedica Inc, Limerick, Ireland; Fig. 2). The CL acetabular component had a 15° hood. The nonarticulating component backing incorporated 4 radial grooves, 12 mm in length and 1.5 mm in depth, as well as 2 circumferential grooves extending for two thirds of the circumference at that level. The grooves were included to aid cement fixation. The outside and inside diameters of the CL acetabular component were 32 and 22.6 mm, respectively. The femoral stem was a scaled-down version of the modular polished double-taper Exeter stainless steel femoral stem (Howmedica Inc, Rutherford, NJ). The femoral component had a stem length of 71 mm and a modular 22.2-mm

Table 1. Loosening Grades of Acetabular and Femoral Components at Retrieval and Histological Features of Hip Synovial Tissues

Study group	Early sacrifice or full term	Reason for early sacrifice	Sheep ID (time to early sacrifice)	Acetabular loosening		Femoral loosening		Histological features (+, present; -, absent)					
				p-c	c-b	p-c	c-b	Polymeric particulate	Lymphocytes	Granulation tissue	Calcium pyrophosphate/chondroid metaplasia		
6 mo	Early sacrifice	Femoral fracture Obturator nerve damage	GW46 (5 d)	0	0	0	0		No histology—killed less than 1 mo postoperatively				
			GW52 (3 wk)	0	0	0	0		No histology—killed less than 1 mo postoperatively				
	Full term			GW45	0	0	2	2	-	+		+	-/-
				W63	0	0	0	1	+	+		+	-/-
				GW47	1	1	1	1	+	+		+	-/-
				GW48	0	0	0	0	+	-		+	-/-
				GW49	0	0	0	1	-	+		+	-/-
GW50	0	0	0	0	+	-		-	-/-				
12 mo	Early sacrifice	Femoral fracture	W21 (19 d)	0	0	0	0		No histology—killed less than 1 mo postoperatively				
			Full term	Severe limp	W4 (2 mo)	3	0	0	0	-	+		+
	GW54	3			0	0	0	+	-		+	-/+	
	GW60	1			2	3	3	+	+		+	-/+	
	W5	0			0	0	0	+	-		+	+/+	
	W6	0			0	0	0	-	+		+	-/+	
	W7	0			0	0	0	+	-		+	-/-	
	W19	0	0	0	0	-	+		-	+/+			
W20	1	0	0	0	-	-		+	+/+				
24 mo	Early sacrifice	Femoral fracture Femoral fracture Severe limp	W8 (5 d)	0	0	0	0		No histology—killed less than 1 mo postoperatively				
			W10 (8 d)	0	0	0	0		No histology—killed less than 1 mo postoperatively				
			W13 (3 mo)	3	0	0	0	-	+		+	-/-	
	Full term	Unknown cause Reticulopericarditis Severe limp	W23 (8 mo)	0	0	0	0	-	+		+	-/+	
			W12 (20 mo)	0	0	0	0	-	+		+	+/+	
			GW53 (21 mo)	3	0	0	0	+	-		+	+/-	
			W9	1	0	0	0	-	-		+	+/+	
			W11	0	0	0	0	-	+		+	+/+	
			W15	0	0	0	0	-	-		+	+/+	
			W16	0	0	0	0	+	-		-	+/+	
			W17	0	0	0	0	-	-		-	+/+	
			W18	0	0	0	0	-	-		+	+/+	
			W24	0	0	0	0	-	+		-	+/+	
W26	0	0	0	0	-	-		+	-/+				
CL 48 mo	Early sacrifice	Femoral fracture Renal dysfunction	GW58 (13 d)	0	0	0	0		No histology—killed less than 1 mo postoperatively				
			GW59(36 mo)	1	0	0	0	-	-		+	+/+	
	Full term			W14	0	0	0	0	-	-		-	+/+
				GW56	0	0	0	0	-	-		+	+/+
				GW55	0	0	0	0	-	-		-	+/-

p-c Indicates prosthesis-cement interface; c-b, cement-bone interface.

Loosening grades (7): 0, solid; 1, fluid movement only at interface; 2, slight movement, requires hammering/leverage; 3, loose, removable by hand. Grades 0 and 1, fixed prosthesis, grades 2 and 3, loose prosthesis.

femoral head with a 16-mm head offset (Fig. 2). This provided a radial bearing clearance of 0.2 mm between the head and the acetabular component.

The surgical and perioperative management protocols for hip arthroplasty in this sheep model have been described in detail previously [6]. A lateral approach was used. The femoral component was implanted using second-generation cementing techniques (Surgical Simplex, Howmedica Inc, Rutherford, NJ). The acetabulum was prepared with successively increasing size reamers up to 30 mm, using a tissue protector. Four 4.5-mm-wide cement key holes were drilled. After preparing the bone bed with saline and 1.5% hydrogen peroxide, cement (Surgical Simplex, Howmedica Inc, Rutherford, NJ), mixed manually until of "doughy" consistency (approximately 5 minutes), was packed into the acetabulum. Thumb pressure was applied to evenly distribute the cement, particularly into the drill holes. Using a positioning rod and a trial head attached, the acetabular component was introduced with the component hood positioned at 45° to the sagittal plane. Excess cement was removed, and after curing of the cement, the strength of the bond to the acetabular component was confirmed by digital palpation. Sheep were transferred to a sling postoperatively to allow hoof-touching weight bearing only for 24 hours. Thereafter, the sheep were at pasture continuously and free to move. The gait of the sheep was assessed weekly.

At the time of euthanasia, passive range of movement in the operated and the contralateral hip joint was determined by physical examination. The degree of femoral and acetabular component loosening was determined at retrieval using an intraoperative grading system [7] (Table 1). For this, thumb pressure was applied across the femoral head noting any fluid movement at the cement-bone or prosthesis-cement interface. For the acetabular component, thumb pressure was applied to the articulating surface and any exposed rim of the component. Any fluid or gross movement between the prosthesis and the cement, observed through the transparent material of the component, was documented. Acetabular component loosening was assessed again at the time of removing the component from the bone.

Tissue samples were taken from 4 sites of the synovium of both hips for histological assessment using light microscopy. The sections were examined to exclude infection, to assess the local tissue response to the implant, and to detect the presence and relative concentration of polymeric wear particles. Lymph node and visceral organ

tissues that included the lung, myocardium, kidney, liver, and spleen were examined for the presence of wear particles or abnormal tissue development. Histopathologic investigations were not performed on tissues from sheep killed at less than 1 month postoperatively.

The acetabular components were visually inspected using a magnifying lamp for macroscopic evidence of significant damage or wear of the articulating surfaces, defined as fracturing, pitting, grooves, or delamination, resulting in loss of the original surface finish. Any deformation of the CL material, without loss of the original surface finish, was recorded as such, but cold flow deformation could not be distinguished from smooth wear at this magnification. Impingement damage was defined as deformation of the edge of the acetabular component through mechanical impingement.

Anteroposterior (AP) contact radiographs were taken of the explanted femurs and acetabula using a Faxitron cabinet (Hewlett Packard, McMinnville, Ore). Osteolysis [8], cement fracture, and radiolucencies at the acetabular and femoral prosthesis to cement (prosthesis-cement) and cement to bone (cement-bone) interfaces were reported by zone [9,10] on the AP radiographs. An acetabular component with a continuous radiolucent line of greater than 1 mm in thickness at the cement-bone interface in all 3 zones was classified as radiographically loose [11]. A femoral component was classified as possibly loose if there was a cement-bone radiolucency occupying between 50% and 99% of the stem interface or probably loose if there was a cement-bone radiolucency at 100% of the interface [12].

Results

Twelve sheep (33%) had unmanageable complications and were killed earlier than scheduled, 6 at less than 1 month postoperatively. Ten complications were unrelated to the acetabular component and included 5 postoperative femoral fractures (14%), obturator nerve damage, one renal failure, one reticulopericarditis, and one unknown cause of death. There were no overt signs of joint infection. Three sheep (8%) were killed early for severe limp that was caused by a loose acetabular component that had debonded from the cement. Twenty-four sheep (61%) were killed at full term and had no discernable abnormalities in gait.

There was no macroscopic evidence of damage to the CL material of the articulating surface with no fractures, pitting, grooves, or delamination evident for any of the acetabular prostheses (Figs. 3

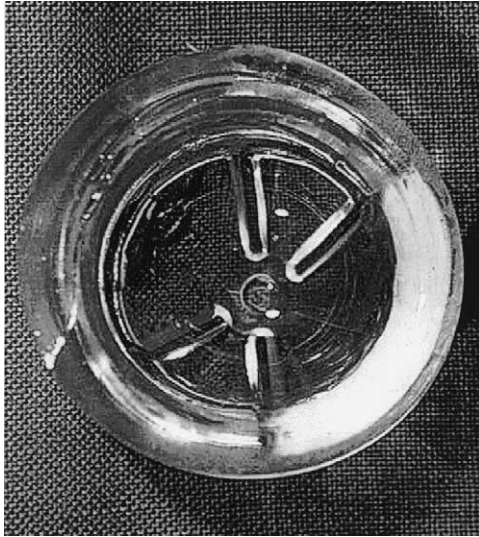


Fig. 3. Explanted Corethane CL acetabular component. The articulating surface of the component is unremarkable after 36 months in vivo (gradation scale, 5 mm).

and 4). There was also no macroscopic evidence of deformation of the CL material without loss of the original surface. Impingement damage was noted on the hood of 34 of the 36 acetabular components. Macroscopically, the smooth appearance of the CL material was disrupted at the site of impingement (Fig. 4). The severity of impingement damage varied from mild to severe, and for cases of severe impingement, separation of the soft CL from the harder CL material on the back of the component was evident. There was no wear damage of the articulating surface of the femoral heads, with the polished surface of the heads being preserved.

The loosening grades recorded for the acetabular and femoral components at retrieval are presented in Table 1. The acetabular component was loose at the prosthesis-cement interface in 4 sheep (11%). Three of these sheep were killed early, as described above, and a sheep was in the 12-month group and killed at full term. No further debonding of the component was observed after 12 months. One acetabular component (3%) had slight movement at the cement-bone interface requiring some levering to remove and had fluid movement at the prosthesis-cement interface. This was in a sheep in the 12-month group. The femoral stem in this sheep was, however, grossly loose. One additional femoral stem from a sheep in the 6-month group was graded as loose at both interfaces ($n = 2$, 6%). The acetabular component in this sheep was well fixed. All acetabular and femoral components in

sheep in the 24- and 48-month groups killed at full term were well fixed.

Varying amounts of hypertrophic connective tissue had formed at an overlying part of one or all of the ventral, dorsal, cranial, and caudal aspects of the acetabular rim of all retrieved acetabular components. The presence of this hypertrophic tissue did not impair the animal's gait, as all sheep had normal gait and had, at most, only 10° reduction in passive range of motion in adduction and flexion/extension of the operated limb compared with the nonoperated side.

Radiolucencies at the acetabular cement-bone interface were observed on the contact radiographs of sheep in each time group. Radiolucencies occupied, on average, 70% (range, 25%-100%) of the interface. Most commonly, radiolucencies extended between the lateral zone I [9] and mid-zone II, with incomplete radiolucencies in the medial zone III. Consistent with this, a thin incomplete fibrous membrane was frequently noted at the cement-bone interface and particularly at the periphery of the cement mantle. One acetabular component in a sheep in the 12-month group was radiographically defined as loose, but at the time of retrieval, the component was solidly fixed at both interfaces.

No femoral components were graded radiographically as possibly loose. One stem in a sheep in the 6-month group was graded as probably loose. This stem had a loosening grade of 2 at both the cement-bone and prosthesis-cement interfaces at

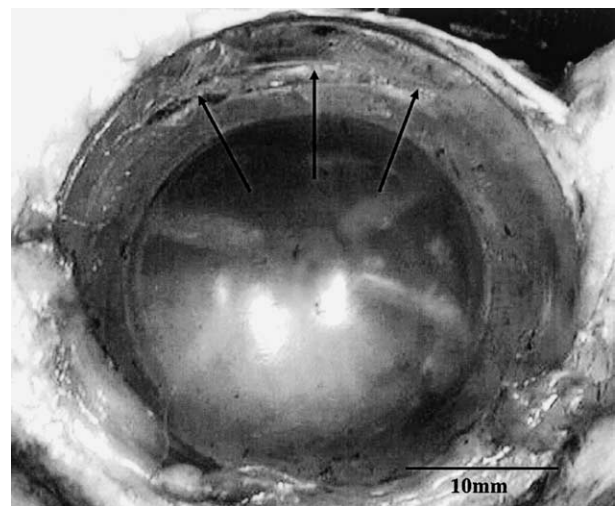


Fig. 4. Corethane CL acetabular component in situ before explantation at 24 months. The arrows highlight the area of impingement damage on the hood of the component, which was a common finding.

the time of retrieval (Table 1). There was no radiographic evidence of cement fracture or osteolysis around either the acetabular or femoral components. Medial femoral calcar resorption was a common finding.

Hyperplasia of the synovial lining cells of the hip capsule tissue was a common feature, as was fibrin or fibrinlike material deposited on the synovial surface. Necrosis, particularly near the synovial surface, was observed only in the synovial tissue from the sheep in the 6-month group. Polymorphonuclear cells were observed in the synovial tissues from 3 sheep in the 6-month group, from 2 sheep killed early for severe limp and subsequently found to have a debonded CL component and from a sheep in the 24-month group. In all but one case, the concentration of these cells was low and not suggestive of an acute inflammatory response. A generally mild infiltrate of other inflammatory cells, including plasma cells and lymphocytes, was also commonly present in the synovial tissues. Lymphocytes were more common in the synovial tissues from sheep in the 6-month ($n = 4$, 75%) and 12-month ($n = 3$, 43%) groups compared with those from sheep in the 24-month ($n = 2$, 25%) and 48-month-time groups ($n = 0$, 0%).

The hip synovial tissue was characteristic fibro-connective tissue. Small localized infiltrates of active subsynovial granulation tissue, comprised most often of macrophages and multinucleated giant cells, were commonly present in the hip synovium. In 10 (47%) of the 30 synovial tissues analyzed, a low concentration of polymeric particles, birefringent under polarized light and

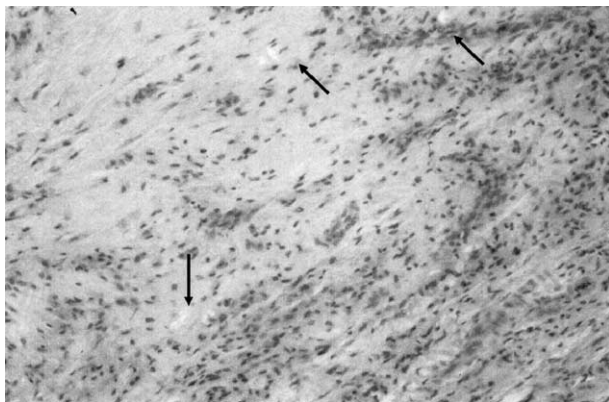


Fig. 5. Photomicrograph of hip synovial tissue from a sheep in the 12-month group, showing mild infiltrate of macrophages and a low concentration of birefringent particles (arrows) (polarized light; hematoxylin-eosin stain, original magnification $\times 200$).

assumed to be polyurethane material, was identified (Fig. 5). Macrophages and giant cells were found in association with these particles or cement debris. In no cases were particulates found in the synovial tissues from the contralateral hip. The wear particle length ranged from 5 to 50 μm . Larger wear particles were occasionally identified. There was an occasional macrophage aggregation found in the absence of detectable polymeric material, although submicron particulate, not visible under light microscopy, may have been present. Excluding cases killed early, the incidence of polymeric wear in the synovial tissues was 67% in the 6-month group, 57% in the 12-month group, 13% in the 24-month group, and 0% in the 48-month group. The highest concentration of polymeric wear debris was found in the hip synovium of a sheep in the 24-month group killed at 21 months and found to have a debonded acetabular component. The histology of the acetabular membrane in this one case of loosening showed fibrovascular connective tissue with some localized areas of chronic inflammation and only one site where a low concentration of polymeric debris was identified. Some extracellular large polymeric particles were noted.

Deposits of calcium pyrophosphate (pseudogout) were seen in the synovial tissue of 3 of the sheep in the 12-month group and in all but one of the sheep killed at full term in the 24- and 48-month groups. Energy-dispersive x-ray analysis of the tissues containing the pseudogout did not find any elements derived from the polyurethane in the region of the deposits. Chondroid metaplasia was not seen in the tissues from the 6-month sheep but was observed in the tissues in all but one sheep in the 12-month group, in all of the sheep in the 24-month group, and in all but one sheep in the 48-month group killed at full term (Table 1). There were no significant or relevant histopathologic changes in the visceral organs.

Discussion

This is the first CL component study using this sheep THA model, and the primary aim was to examine the aging performance of the CL material, which was found to be excellent after implantation periods of up to 48 months.

Notably, there was no macroscopic evidence of wear or fracture of the polyurethane CL material at the articular surface of the acetabular component after 6, 12, 24, or 48 months of implantation. This macroscopic finding was confirmed by the results of tribological analyses, which have been reported in

detail previously [13,14]. The tribological analyses showed that surface finish, as a function of time, improved as the asperities, present at the time of manufacture, were abraded in only high load-bearing regions. After an initial period of hydration, the chemical and mechanical stability of the polyurethane CL system was relatively unchanged over the 48-month implantation period. This lack of wear supports the hypothesis that these surfaces function in vivo with fluid film lubrication [13,14].

It has been shown that many materials, often particulate in form and including implant biomaterials, of which macrophages have difficulty in disposing, can promote macrophage survival and even proliferation [15]. Thus, the fine polymeric debris observed in the hip capsule in the long-term sheep may in fact be the wear particles generated in the early postoperative period by smoothing off of the surface asperities, with minimal wear following this. Electron microscopy studies would be necessary, however, to determine whether submicron wear particles are present in the tissues. The noninflammatory appearance of the synovial tissue suggests that this would not be the case. Importantly, these results suggest that wear of the CL material did not increase over the period of the study.

It is unlikely that the prosthesis-cement loosening of the acetabular component, or debonding, in this study was related to the material properties of the component, but rather was related to the model itself, as impingement wear has been a feature of non-CL acetabular components in this model (unpublished results). Debonding did not increase with time in situ, as would be expected if this was a material issue. The impingement occurring to the acetabular hood most likely predisposed the component to debonding. The canine model of cemented THA has also been shown to be an aggressive model for examining acetabular fixation and wear caused by mechanical mechanisms, including impingement damage and cement breakdown [16]. In long-term canine cemented acetabular component retrievals, these mechanical conditions resulted in marked third-body wear of the ultrahigh molecular weight polyethylene-articulating surface and implant-on-implant wear [16]. Similar conditions were most likely present in this sheep model; however, despite this, the CL material withstood wear.

Good radiographic results of the cemented tapered femoral stem were obtained which is consistent with the clinical results for this prosthesis design [17,18]. Acetabular radiolucencies at the cement-bone interface were common early, but

there was no deterioration in radiographic appearance over time. Despite the radiographic appearance, the sheep functioned well clinically for the duration of the study, and the components were well fixed at the time of retrieval. Similarly, in a study of cemented THA in dogs [19], thick connective tissue was found at the acetabular bone-cement interface even at early postoperative periods in clinically successful THA. The presence of radiolucent margins around asymptomatic cemented acetabular components in human THA is also a common clinical finding [9,20,21].

Lymphoplasmacytic infiltrates, suggestive of an immune response, were regularly observed in the synovial tissues, particularly from sheep killed early and those in the earlier time groups. There were no lymphoplasmacytic infiltrates observed in synovial tissues from sheep killed at 48 months, suggesting a cellular response that subsides over time. The presence of calcium pyrophosphate and chondroid metaplasia in the synovial tissue also appeared to be related to the period of implantation, with these features being more commonly observed in the 24- and 48-month-time groups. Calcium pyrophosphate is known to induce chronic inflammatory reactions [22], although there was minimal evidence of this response in the tissues examined in this study. The deposition of calcium pyrophosphate in tissues at revision THA in humans is rare [22] and is often observed together with chondroid metaplasia. Associations between these tissue deposits and implant materials, wear, and patient-related factors have not been investigated because of the low incidence in humans; however, metal ions, either from metal wear particles or due to corrosion of the metal stem, may predispose to the formation of calcium pyrophosphate [22]. Long-term data from sheep THA using other materials are not available to determine if a direct association exists between the long-term implantation of the CL material and these tissue changes.

Summary

In conclusion, the major finding of the study was that there was no deterioration in the wear performance of the CL material of the sheep THA acetabular component with time in situ. No surface damage of the CL articulating surfaces was evident macroscopically. Furthermore, all data indicated that the clinical and radiographic performance of the CL acetabular component were not compromised by the in situ age of the CL material. Within the limits of light microscopy,

there was a low concentration of polymeric wear particles in the synovial tissues of sheep, mainly in the early time groups. The polyurethane CL material for THA prosthesis articulations remains an intriguing prospect.

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