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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.

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

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

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