# An UHMWPE-Hyaluronan Microcomposite Material for Partial Joint Resurfacing in a Goat Model

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## INTRODUCTION

Partial hemiarthroplasty is a procedure for early treatment of focal chondral or osteochondral lesions in which only the diseased portion of one joint surface is replaced. The purpose of this technique is to suspend progression to generalized osteoarthritis. During partial hemiarthroplasty, the lesion is reamed out and replaced with a permanent implant, which serves to fill the void left after tissue removal, provide an articulating surface for opposing cartilage, supply load transmission to subchondral bone, and furnish a biocompatible material for maintenance of adjacent healthy tissue. A microcomposite material consisting of ultra high molecular weight polyethylene (UHMWPE GUR 1020) and cross-linked hyaluronan was prepared with the aim of serving as the bearing component of a partial hemiarthroplasty device (1, 2). The feasibility of the material for partial resurfacing in the knee was tested using a large animal model. The aim of this *in vivo* study was to evaluate mid- and long-term (3, 6, 12 months) outcomes after implantation of the device in a 7 mm osteochondral defect in the goat stifle. One device was administered unilaterally in each goat and outcomes were assessed by visual inspection and histological evaluation.

## METHODS

Healthy, skeletally mature, male neutered goats (Boer-Cross) of approximately 4 years of age and 100-145 lb. weight were used as test subjects. All surgical procedures were conducted utilizing routine aseptic techniques and were approved by the IACUC. Under general anesthesia, the lateral facet of the trochlear groove was exposed via arthrotomy. A 7 mm diameter defect was surgically created using a drill bit, and further modified with a central hole to accept the stem of the partial resurfacing device. The device consisted of an articulating cap (7 mm diameter, 2 mm height) consisting of the UHMWPE-HA microcomposite material that was compression molded onto a titanium alloy (Ti-6Al-4V) fixation stem (Figure 1). The bone contacting portion of the stem was modified with a grit blasted finish. After implantation of the device, the arthrotomy was closed and the goats were fitted with a fiberglass cast reinforced Schroeder-Thomas splint. The splint was maintained for 2 weeks post-op followed by unrestricted range of motion for 3 months (n=5), 6 months (n=5), and 12 months (n=5). All animals were closely monitored during the post-op phase for general health, lameness, and pain. At necropsy, the joint capsule was opened for macroscopic assessment of the implant and joint structures, along with synovial fluid assessment. Tissue blocks consisting of the implant and peri-implant region, as well as the opposing tissue were procured for histological assessment of cartilage and subchondral bone.

**Figure 1. UHMWPE-HA Microcomposite on Titanium Stem.**

## RESULTS:

All animals recovered from surgery uneventfully with mild lameness (limp noticeable at trot) noted between 6 - 10 days after splint removal, after which time no lameness was observed. All animals survived until necropsy except one 12 month animal died of causes unrelated to the implant within 1 week of its scheduled necropsy.

Upon dissection of the stifle, all joints were found to be healthy and free of synovitis or other obvious arthropathy. Synovial fluid was normal in color, quantity, and viscosity, and cytologically within normal limits. At all timepoints, the partial resurfacing device was well-secured in the defect with no indication of loosening or dislocation (Figure 2). Similarly, no evidence of implant migration or subsidence was observed. Gross examination of the joint structures showed cartilage abutting the UHMWPE-hyaluronan microcomposite material and no implant-related kissing lesions or wear marks on the opposing cartilage.

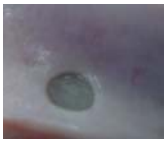

**Figure 2: Photo of UHMWPE-hyaluronan microcomposite and adjacent tissue at 6 months post-op.**

Histological evaluation of the device and surrounding tissue showed no overt inflammatory response, adjacent cartilage abutting the UHMWPE-hyaluronan microcomposite material, and areas of direct contact of adjacent trabecular bone with the Ti alloy fixation stem (data not shown). At 12 months post-op, the cartilage opposing the implant was normal or with some instances of mild surface fibrillation (Figure 3).

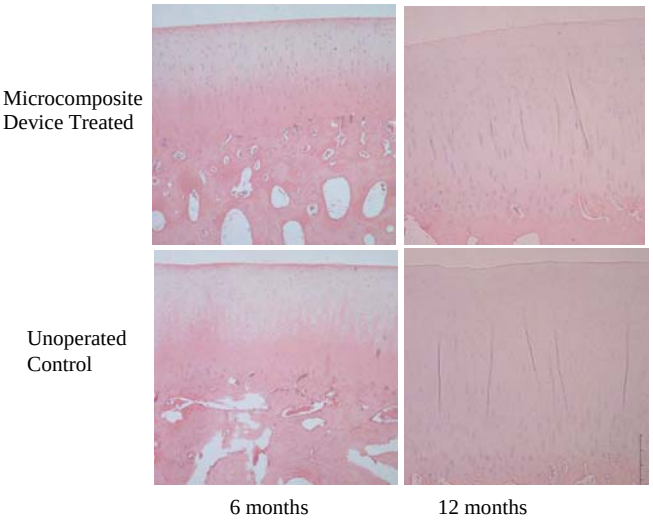


**Figure 3: Patella surfaces directly opposing the implant location.**

## DISCUSSION

This *in vivo* study indicates that the partial hemiarthroplasty device containing an UHMWPE-hyaluronan microcomposite bearing material is well tolerated in a large animal model through 12 months post-op. The cartilage opposing the device was absent of significant pathology, which is important for successful long-term hemiarthroplasty outcomes. In humans, total hemiarthroplasty of the hip with a metal bearing leads to symptomatic wear of cartilage around 5 years, while in dogs loss of cartilage with bone exposure is seen at 6 months (3, 4). With that in mind, the UHMWPE-hyaluronan microcomposite which showed no opposing articular wear at 1 year in the goat model may possess clinical promise as a partial hemiarthroplasty device.

**REFERENCES:** (1) Zhang M, King R, Hanes M, James SP. J Biomed Mater Res 78A:86-96, 2006. (2) Zhang M, Pare P, King R, James SP. J Biomed Mater Res 82A: 18-26, 2007. (3) Dalldorf PG, Banas MP, Hicks DG, Pellegrini VD. J. Bone Joint Surg. Am. 77: 877-882, 1995. (4) Cruess RL, Kwok DC, Duc PN, Lecavalier MA, Dang G-T. J. Bone Joint Surg. 66-B(4):592-597, 1984.

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