**Implantable “Sensate” Medial Condyle Surface Replacement Allows Shear and Axial Load Sensing**

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**Introduction:** Cartilage damage caused by trauma, leads to osteoarthritis and afflicts millions annually. Current treatments such as autologous chondrocyte implantation, microfracture, and mosaicplasty all have had mixed success, which has led to additional research into cartilage regeneration strategies. The long-term goal of this work is to develop an approach that can be used in patients with large focal chondral defects and early stage arthritis. The aim of this study was to design and construct a medial condyle surface replacement scaffold to anchor autologous adipose derived stem cells at the lesion site in order to regenerate articular cartilage on the medial condyle. An additional aim was to monitor *in vivo* joint loading utilizing strain gauges and an implantable transmitter. Criteria for success of the surface replacement were that it needed to be easily implanted, durable enough to remain intact under physiological loads, and designed to facilitate load monitoring and cell attachment.

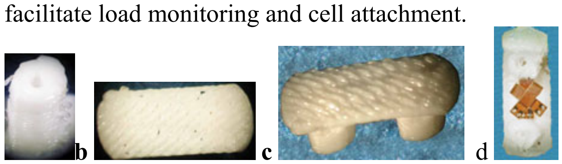

**Figure 1**: Medial condyle constructed with PBT. Peg construction (a), top surface (b), complete scaffold, (c) and strain gauge orientation (d) pictured.

**Methods:** A cadaveric canine stifle was used to collect bone structure measurements from the medial femoral condyle using a SCANCO microCT scanner at a 9 micrometer resolution. These measurements were utilized to create a model in Solidworks and Quickslice software, which was ported to a rapid prototyping machine. The model surface consisted of an elipse-shaped construct formed from two concentric 9 mm circles (Figure 1). The scaffold had two 4 mm diameter pegs in the center of the circles, 5 mm apart, and 5 mm in height. The pegs were cylinders with 2 mm inner diameter channels to encourage bone ingrowth once placed into the stifle joint. The scaffold was built out of polybutylene terephthalate (PBT) using a Stratasys 1650 Fused Deposition Modeler. The dimensions and strength characteristics were established on the benchtop utilizing a cadaveric canine stifle joint. In addition, finite element (FEA) analysis was run on the design using ABAQUS software. Adjustments were made to the dimensions based on this testing to optimize the design. Strain gauges were attached in a rosette pattern (Figure 1d) and the scaffold was placed in a Darofoam block to simulate *in vivo* support. The setup was tested using a materials testing system (MTS) to document the structural properties of surfaces and pegs in shear and axial loading while simulating physiological loading. Following MTS testing, a second cadaveric canine stifle was prepared to insert a scaffold, which was press fit into the medial condyle to determine the difficulties expected during placement. Once it was in place, the stifle was placed through a range of flexion, extension, and axial loading to ensure proper function of the scaffold in the condyle.

**Results:** Benchtop testing demonstrated that optimal peg height was 5 mm to secure the scaffold and prevent the peg from breaking off. The ideal distance between the pegs was 4 mm, which provided sufficient support and allowed adequate space for gauge attachment. Three to four layers were adequate in the construction of the joint interfacing surface. This provided optimal flexibility with sufficient strength so that the implant would conform to the radius of curvature at the implantation site. MTS testing demonstrated that this design withstands 5 kg of shear force and over 40 kg of axial loading (Figure 2a). Stress and strain calculations were conducted from strain gauge measurements. The measurements and our calculations were similar to accepted tabulated values. Finite element modeling performed with a load of 40kg, indicated highest stress values were at the base of the scaffold pegs (Figure 2b). Surgical grade Masterbond EP42HT epoxy was utilized to reinforce this region without compromising scaffold flexibility.

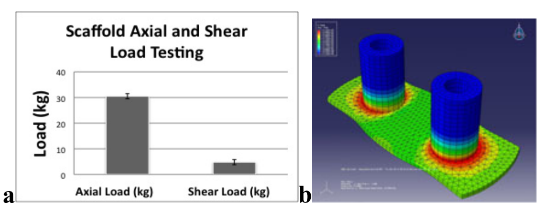


**Figure 2(a)**: Scaffold axial and shear load testing. Deviations (error bars) were small for both tests (N=21, shear; N=16, axial). **2(b)** FEA image of scaffold.

**Discussion and Conclusion:** The results of this study show that a condyle surface replacement made of PBT is durable enough to withstand physiological forces and can be utilized to measure joint forces. Current *in vivo* testing in a canine model is underway with a medial surface replacement in four test animals. Ongoing studies will include additional *in vivo* implantation and load measurements. The results of this benchtop study demonstrate that a condyle replacement can be effectively implanted into the canine stifle to facilitate measurement of joint loads and principal load directions. The surface design facilitates adipose derived stem cell attachment to serve as an alternative treatment for the resurfacing of large chondral defects present within the knee joint.

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