Introduction: The treatment of osteochondral lesions continues to be a challenge, given the limited capacity of articular tissues for self-healing. In many cases, the repair tissue generated by current treatment methods is biomechanically inferior, and can degrade when placed under the rigorous mechanical demands of the joint. This study reports the results of ex vivo biomechanical testing of repair tissue generated by a novel, bi-phasic scaffold used to treat an osteochondral defect in a load-bearing area of the caprine stifle joint.

Materials & Methods: Animal Model: A 6 x 6 mm cylindrical osteochondral defect was created in the medial femoral condyle of the caprine stifle joint. A bi-phasic scaffold, consisting of type I collagen with a composite of β-tricalcium phosphate and poly lactic acid (Kensey Nash Corporation, “KNC”, Exton, PA), was press-fit into the defect. The contralateral limb was used as control. Animals were sacrificed at 6 months (n = 5), 12 months (n = 5), and 18 months (n = 4). The knees were wrapped with soft tissue; the site of implantation was inspected for evidence of tissue ingrowth and cartilage damage.

Biomechanical Test Sites: Four test sites were identified on each knee: 3 on the femur and 1 on the tibia, as follows: distal from the defect (D), adjacent to the defect edge (A), at the middle of the scaffold implantation site (KNC) or the corresponding position on the control limb (C). One area on the tibial plateau corresponding to the contact point with the femoral condyle at full extension was also tested (Fig 1).

Method of Testing: Each femur was oriented so that the cartilage area of interest was perpendicular to a porous indenter (diameter 1.25 mm) attached to the upper actuator of an Enduratec testing machine (ELF 3200, BOSE). A compressive load of 20 g was applied at a rate of 5 g/s; and held for 1 hr. At the completion of testing the indentation fixture was replaced with a needle fixture to measure cartilage thickness.

Data Extraction and Analysis: Displacement-time data were numerically fit to the biphasic indentation creep solution to determine three intrinsic material coefficients at each test site: aggregate modulus (Ha), Poisson’s ratio (ν) and hydraulic permeability (k).

Values for the shear modulus (μ) were calculated from the parameters, Ha and ν. Statistical analysis to detect site specific difference in properties as a function of time was conducted using Kruskal-Wallis One Way Analysis of Variance on Ranks followed by Tukey’s test or Dunn’s test.

Results: Gross inspection of the femoral condyles revealed that percent fill of the scaffold site increased with time: from 50-60% at 6 months to 70-95% at 18 months. At all timepoints, the edges of the site of implantation were filled with tissue and integrated with the surrounding host tissue. Little damage was seen across the femoral condyles. The tibial plateaus manifested wear patterns that was similar to the contralateral knees.

There was no evidence of synovitis. There were no significant differences between the Aggregate Modulus (Fig 3), Permeability (Fig 4), or Dynamic Modulus (Fig 5) at the site of scaffold implantation and the corresponding site on the control (unoperated) limbs at 6, 12, and 18 month timepoints. The site adjacent to the implant (site A) had a statistically significantly lower permeability as compared to the corresponding 6 month implanted site (p = 0.04); but no further statistical decrease in permeability at 18 months was noted. The control group exhibited a statistically significant decrease in the shear modulus at site D (test site removed from the location of the defect) at 12 months when compared to the 6 month timepoint (p = 0.02) but there was no statistically significant difference between the 12 and 18 month modulus at this site.

Discussion: We have demonstrated that a resorbable bi-phasic scaffold implanted into an osteochondral defect produces a repair that exhibits biomechanical properties similar to un-operated articular cartilage. The similarity was evident as early as 6 months post-operatively and was maintained through to 18 months. While previous studies have shown integration of scaffolds with articular cartilage to be especially challenging, our study demonstrates that the repair tissue at the site of this integration has biomechanical properties similar to that of normal articular cartilage. On the basis of these results, the bi-phasic scaffold will be further investigated as a treatment option for focal osteochondral defects.

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