PLLA Fiber-Reinforced Scaffold for Total Meniscus Replacement in an Ovine Model

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**Introduction:** Meniscal injuries are the most common intra-articular knee injury in the United States. The menisci play an integral role in load bearing, shock absorption, stability, and lubrication the knee; any injury can lead to degeneration of the joint, causing patients pain and discomfort. The most common procedure is meniscectomy, or removal of the damaged areas; however, long-term results have shown a direct correlation between the amount of tissue removed and cartilage deterioration. Therefore, there exists a need for a meniscal replacement. Previously, our group developed a polyarylate fiber-reinforced collagen-hyaluronan sponge for total meniscal replacement. The goal of this study was to evaluate a poly (L-lactic) acid (PLLA) reinforced sponge in an ovine model.

**Methods:** PLLA was melt-spun, extruded, and drawn into 100 micron fibers (NJCBM, Piscataway NJ). Fibers were woven in a semi-lunar wedge shape with elongated tails for fixation. A collagen-hyaluronan dispersion (type I bovine Achilles collagen: 20 g/L, sodium hyaluronate 0.25 g/L) was injected and spread over the scaffold, frozen, lyophilized, and EDC-cross-linked. Scaffolds were game irradiated at 25kGy. Total medial meniscectomies were performed in the right hind leg of nine sheep. Two bone tunnels were drilled at the anterior and posterior meniscal horns, the and the tails were guided through the tunnels and fixed via interference screws (Smith and Nephew, Andover MA). The implant was secured to the peripheral tissue using sutures. Three sheep were sacrificed at each of three time points (16w, 24w, 32w), and the right medial meniscus implants and articular surfaces were recovered. Three 4mm diameter x 4mm height cylindrical plugs (one from anterior, body, and posterior sections) were taken from each explant and tested using Mow’s biphasic confined compression creep test in order to obtain aggregate modulus and permeability. Five micron cross-sectional slices were taken from each of the three sections of each explants and stained with H&E and Masson’s trichrome. Five micron slices from the right femoral condyles were stained with Safranin-O and graded with the Mankin Score.

**Results:** All sheep returned to normal gait and load bearing after surgery and showed no pain or discomfort after the initial recovery period. One sheep (16w time point) was removed from the study due to pregnancy. At sacrifice, scaffold remained firmly anchored to the bone tunnels. Though most had degraded, fibers were present in all implants at the tunnel sites. However, significant thinning and extrusion was noted in the body of all implants, and ruptures were noted at 32w in the body of the meniscus. Tissue in-growth appeared significantly greater in the anterior section than body and posterior sections. Aggregate modulus and permeability yielded no statistically significant results based on time or section (Figure 1). The average Mankin scores were 2.75, 4.17, and 4.00 for 16w, 24w, and 32w, respectively. The articular surfaces contained areas of osteophytic growth as well as bone erosion (Figure 2), with increasing severity with time.

**Discussion:** While Mankin scores suggest an improvement over meniscectomy controls (unpublished results), the abnormal reactions observed on the articular surfaces were not present in the previous poly
arylase study, suggesting that the reactions were due to the presence of PLLA fiber. After two months, PLLA has been shown to degrade into lactic acid and if the acid is not cleared, it can cause autocatalytic degradation. This local build-up of acid in direct contact with the articular surfaces is a potential reason for the osteophytes and bone erosion. The sudden loss in mechanics may have also contributed to this; implant failure in the body of the meniscus (experiencing the greatest stress) could have shifted the load in the joint, causing these abnormal reactions. While low group sizes prevented statistically significant results, there is a decreasing trend in aggregate modulus, most likely due to the lack of ECM deposition. This can be attributed to cells that are not experiencing a functional load due to an extruded, thin implant. This lack of ECM deposition was seen in the implant histology.

**Significance:** The use of PLLA fibers in a reinforced collagen sponge in an ovine model caused implant failure, decreasing compressive mechanics, and abnormal joint reactions, and future work should aim to use an alternative fiber type.
Fig 1. (Top) Aggregate modulus and (Bottom) permeability of anterior, body, and posterior sections of explants at 16w, 24w, 32w.
Fig 2. Gross observation on osteophyte development and bone erosion on the (Top) femoral condyle and (Bottom) tibial plateau