• A Novel Fiber-Reinforced Scaffold for Reconstruction of the Meniscus

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INTRODUCTION:

The meniscus is a C-shaped disc of fibrocartilage which plays a critical role in the protection of the articular cartilage of the knee by transmitting loads through the joint, distributing high stresses evenly on the underlying surfaces, providing shock absorption, and aiding in joint lubrication. Despite the recognized importance of the tissue, arthroscopic removal of a torn meniscus is one of the most commonly performed orthopaedic operations in the United States. Long-term follow-up of total and subtotal meniscectomies has consistently shown the positive correlation between degenerative changes in the knee and the amount of meniscal tissue removed. Unfortunately, due to the limited vascularity of the meniscus, and consequently, its limited healing potential, few viable alternatives exist for significant meniscal deficiency. Current scaffolding and allograft technologies have not demonstrated the long-term clinical success necessary to be considered the ‘gold standard’ for meniscal replacement. We are currently developing a fiber reinforced meniscus analog whose design is based on the geometry and microstructure of the normal meniscus. The objective of this study was to explore the potential utility of the scaffold as a replacement for deficient meniscal tissue. This was accomplished by evaluating the response to a functional implantation in the ovine knee joint.

METHODS:

Scaffolds were fabricated by weaving a resorbable polymer fiber into an organized pattern, mimicking the geometry of the meniscus and forming two strong anchor points for attachment to the tibial plateau. A mold was formed around the weave and then a collagen dispersion was injected into the mold. This was frozen and then lyophilized, resulting in a collagen sponge embedded with fibers arranged to provide circumferential and radial strength to the construct.

The biological incorporation of the fiber-reinforced scaffold was evaluated in a functional in vivo ovine model. The medial menisci of 12 sheep were removed and replaced with 1000 fiber meniscus scaffolds. Scaffolds were attached to the synovial wall with suture. Six animals were sacrificed at 8 weeks and six at 16 weeks. As a control, four other sheep underwent a meniscectomy. The scaffold sections and medial femoral condyles were excised, fixed in formalin and then processed for standard histological analysis. Slides were analyzed and graded in a random, blinded fashion by a pathologist for inflammation, vascularization, neo-tissue formation, and scaffold degradation. All surgeries were performed using an IACUC approved protocol.

A ‘second generation’ meniscus scaffold with an improved collagen matrix and superior fixation method has been developed and preliminary evaluations have been completed. The collagen dispersion now contains chondroitin sulfate, hyaluronic acid, and a higher concentration of type I collagen. Confined compression testing has been performed to determine the creep response of the second generation scaffold as compared to the first generation and native ovine meniscus. Samples (n=5/type) were compressed at 0.1 MPa until the deformational response approached equilibrium. The aggregate modulus and permeability constant was then calculated for each sample.

All results were statistically analyzed using a two-way ANOVA with pairwise comparisons by the Student-Newman-Keuls method.

RESULTS:

Scaffolds were implanted with minimal complication. Animals regained full function of the surgical leg by 2 weeks post-operatively. At sacrifice, no gross degenerative changes in the articular cartilage surfaces were observed. Scaffolds were fully intact and firmly adhered to the surrounding tissue. Scaffold anchor attachments to the tibial plateau were structurally sound. Even at a gross level, the tissue integration and ingrowth into the scaffolds were obvious (Figure 1).

DISCUSSION:

The ‘second generation’ scaffold had improved mechanical properties in compression compared to its predecessor. The aggregate modulus was much higher and approached that of the native meniscus. The permeability was also improved allowing a more closely matched deformational response curve to the native meniscus.

The tissue ingrowth observed grossly was confirmed by histological analysis. At 8 weeks post-op, there was a combination of blood vessels, inflammatory cells, and fibroblasts surrounding individual fibers of the scaffold, and deposition of new collagen (Figure 2). Ingrowth of tissue was found throughout the cross section of the scaffold. At 16 weeks post-op, inflammation had largely subsided, and there were increased amounts of new collagen.

Analysis of the femoral condyle cartilage at 16 weeks post-op (Figure 3) suggested no significant damage occurred in knees with the total meniscus replacement compared to unoperated controls.

The second generation replacement scaffold has been designed and fabricated, with improved mechanical properties in tension and compression, and an optimized surgical fixation method. Long-term meniscus replacement studies using second-generation scaffolds are underway.