A Novel Polycarbonate-Urethane Meniscal Implant: From Bench to First Clinical Experience

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Statement of Purpose: The menisci are semi-lunar wedge-shaped structures that play critical roles in load distribution, shock absorption, and joint congruity in the knee. Meniscal tears are common knee injuries that subsequently lead to degenerative arthritis, attributed primarily to the changes in stress distribution in the knee. In such cases there is need to protect the articular cartilage by either repairing or replacing the menisci. While traditionally, meniscal replacement involves implantation of allografts, problems related to availability, size matching, cost and risk of disease transmission limit their use. Another optional treatment is that of biodegradable scaffolds,s which are based principally on tissue engineering concepts. The variability in body response to biodegradable implants and the quality of the tissue formed still pose a problem in this respect, under intense knee loading conditions. Moreover, the aforementioned biological solutions are limited to younger patients <40 years old. Therefore, the goal of this study was, to develop a synthetic meniscal implant which can replace the injured meniscus, restore its function, and relieve pain.

Methods: A composite, non-fixed self-centering discoid-shaped meniscus implant (NUsurafce[®], AIC, Memphis, TN), composed of polycarbonate-urethane (PCU) and reinforced circumferentially with UHMWPE fibers is proposed (Fig. 1). The implants shape was based on an extensive MRI study of more than 100 knee scans [1]. The proposed structure aims to mimic the function of collagen fibers of the natural meniscus, which are arranged mainly circumferentially, within a hydrated matrix. Biomechanical evaluation of the implant was focused on in-vitro measurements of contact pressure under the implant in cadaver knees and computational finite element (FE) analyses [2,3]. Pressure distribution on the tibial plateau (under the meniscus implant) was measured by pressure sensitive films (Tekscan, MA) and quantified with respect to the natural meniscus. The effects of changes in geometrical and material properties of the composite structure were investigated as affecters of its pressure distribution ability. FE analyses were used to evaluate internal stress and strains, and to support the selection of optimal implant configuration. The last pre-clinical step was a large-animal (sheep) study in which the cartilage condition was evaluated microscopically over six months [4].

Results: Contact pressure distributions on the tibial plateau, were in good agreement with those measured under the intact natural meniscus prior to meniscectomy (Fig. 2). Specifically, peak and average pressures developed under the implant were found to similar to those of the natural meniscus. The contact area measured under the implant


Figure #1: the composite polycarbonate-urethane and UHMWPE meniscal implant developed in the study

(658 ± 135mm^2) was also restored when compared to the natural meniscus (642 ± 96mm^2). Outputs of the FE model confirmed that internal strains/stresses within the device components remained within the materials' allowed limits. The evaluation of an implant adapted to sheep showed no signs of wear or degradation of the materials. Histology showed relatively mild cartilage degeneration that was dominated by loss of proteoglycan content and cartilage structure. The total osteoarthritis score (Modified Mankin score) did not, however, differ significantly between the 3 and 6 month groups. First clinical results for the implant, with up to 2 years follow-up, demonstrate encouraging prospects for this concept in terms of pain relief.

Conclusions: In the current study, we presented the development of a novel PCU meniscal implant for the medial compartment of the knee, along with an overview of essential tests. It was found that (a) the implant is able to reduce the overall cartilage load associated with meniscectomy by effectively distributing joint loads, and (b) the implant completely prevents contact between opposing cartilage surfaces. The results of implantation in sheep can be considered exceptionally favourable in arresting joint degeneration, and first implantations have shown that arthroscopic implantation of the device is short and uncomplicated. Clinical follow-up of the device is underway.

Figure #2: Pressure maps obtained for the natural and optimal composite meniscal implant design
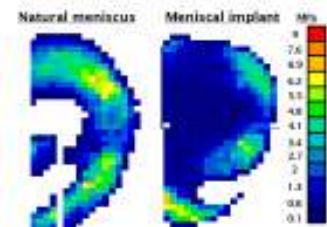
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