A Polycarbonate-Urethane Meniscal Implant: Size Increments and Population Coverage

INTRODUCTION:
The medial meniscus plays an important role in the distribution of loads in the knee joint, by distributing joint contact forces over a larger area and limiting the contact pressure developed in the articular cartilage. Geometrical similarity dictates the degree of conformity between the menisci and the condyles, and it has been shown that even very small changes in allograft meniscal implant sizes demonstrate a dramatic change in stress levels [1]. Specifically, we recognize that an accurate match between the implant size and candidate knee is critical for the success of an artificial meniscal implant, as a means for restoring the contact pressure distribution to normal and thus delaying joint degeneration. We hypothesized that an artificial hyper-elastic polycarbonate-urethane (PCU) meniscal implant reinforced with polyethylene (Dyneema™, DSM corp.) fibers could provide improved joint congruency and cartilage protection through size availability and material pliability. Therefore, our aims in this study were (i) to determine the necessary increments of implant size that provide optimal pressure distribution on the articular cartilage surfaces, and (ii) to predict the number of required implant sizes that will cover the candidate population, based on experimental and computational studies.

METHODS:
A set of 12 geometrical parameters, representing typical lengths and widths of the meniscus and joint bone contours were measured in 130 MRI scans of a mixed population of males and females (62±10 yrs., “The Osteoarthritis Initiative” (OAI) database). Mean values of this data were calculated in order to define the most prevalent (‘reference’) implant size in the general population. A meniscal implant was then created (The NUsurface™) by means of an MRI-based reconstruction of femur and tibia geometrical surfaces of a cadaver knee, which corresponded to the reference size definitions (Fig. 1).

The next step was to test experimentally and computationally the effect of larger/smaller implant sizes on the biomechanical functionality of the implant. Thus, an array of various PCU implant sizes was created by increasing/decreasing the reference implant size by 1-2% increments to cover the range of ±10%. These sizes were evaluated in the joint setting in terms of implant location, pressure distributions and resistance to static loading as follows:

Experimental evaluation of size increments
An experimental evaluation of the implants’ performances was conducted; first by indicating whether the implant is located properly within the joint space (no PCL impingement, no extrusion of the implant), and second, by measuring pressure distributions on the tibial plateau surface in a 5% range around the ‘true’ joint space. The meaning of this being that a relatively lenient safety-range exists for the choice of implant by the surgeon. This finding, together with our statistical analysis of the natural distribution of sizes of the knee in the general population imply that an array of 9 implant sizes would adequately accommodate the needs of 95% of the population, both female and male (Fig. 3). Furthermore, biomechanical analyses of internal loads within the various implant components remained within the safety limits reported by the manufacturers, not exceeding 15MPa and 50% strain for the PCU matrix, and 310MPa and 3.4% for the Dyneema™ reinforcement fibers.

RESULTS:
The experimental evaluation of the implant sizes narrowed our focus to the range of ±10% due to adverse PCL interference at larger sizes and implant extrusion out of the joint at smaller sizes. A qualitative visual examination of the pressure maps followed also by a quantitative evaluation (pressure score, [2]), showed that a ±2.5% deviation in the implant size still yielded an optimal pressure distribution similar to that of the patient specific reference implant. Similar results were attained for the computed (FE) analyses of the compressive contact stresses. In addition, internal stresses within the implant components remained within the safety limits reported by the manufacturers, not exceeding 15MPa and 50% strain for the PCU matrix, and 310MPa and 3.4% for the Dyneema™ reinforcement fibers.

DISCUSSION:
Experimental and computational methods have been employed to assess the effect of correct matching between a meniscal implant size and a candidate knee. Both methods confirmed that our PCU meniscus implant performs equally well in distributing joint compressive loads on the tibial plateau surface in a 5% range around the ‘true’ joint space. The meaning of this being that a relatively lenient safety-range exists for the choice of implant by the surgeon. This finding, together with our statistical analysis of the natural distribution of sizes of the knee in the general population imply that an array of 9 implant sizes would adequately accommodate the needs of 95% of the population, both female and male (Fig. 3). Furthermore, biomechanical analyses of internal loads within the various implant sizes under joint compression assured that these remain well below safety limits in all cases, although fatigue tests are underway to strengthen this claim.

REFERENCES: