INTRODUCTION: Few options exist to repair damaged knee menisci, oftentimes leading to a partial or full meniscectomy. However, removal of meniscal tissue can result in joint degeneration, therefore scaffolds designed to elicit rapid infiltration of cells and tissue growth in the defect site are under development.

The objective of this study was to assess the long-term in vivo performance of a biodegradable porous polyurethane scaffold in a partial meniscectomy ovine model. Our hypothesis was that scaffold implantation would promote tissue ingrowth without detrimentally affecting adjacent articular cartilage compared to non-scaffold implanted control knees.

METHODS: 50 skeletally mature Columbia X Rambouillet ewes were subjected to unilateral partial surgical excision of the lateral meniscus. An arthrotomy was performed to expose the lateral meniscus. A longitudinal cut connecting two radial cuts in the mid posterior and anterior horns were made to allow a wedge of meniscus to within 1mm of the capsule to be removed. In 20 animals, the defect was left unfilled. The scaffold used to fill the defect site in the remaining 30 animals was an 80% porous biodegradable aliphatic polyurethane with pore sizes of less than 400 microns (Actifit™, Orteq Ltd., Cambridge, UK). The Three 3-0 Ethibond sutures were placed in the cranial, lateral and caudal aspect of the implant in a horizontal mattress fashion. The animals were not immobilized after surgery. 10 scaffold-implanted animals were euthanized at 3, 6 and 12 months; n=10, 5 and 5 partly-meniscectomized animals were euthanized at 3, 6 and 12 months, respectively.

Outcome measures included: (i) gross appearance of the knee at the time of dissection (ii) histological appearance and grading of the tibial plateau, and (iii) histological assessment of the meniscus. Accordingly, after sacrifice, the knees were opened and visually inspected for synovitis or cartilage damage, and the percent of the defect that was filled with new tissue was estimated. After gross examination, the meniscus and the tibia were fixed in formalin, embedded in paraffin, sectioned, and stained with haematoxylin and eosin and alcian blue. The latter three items were graded as 1=no changes, 2=changes at the synovium or cartilage damage, and 3=tissue. This result may be influenced by the early time-point at which damage was assessed.

RESULTS: All animals resumed normal gait within one week of surgery and none were euthanized as a result of continued pain or limb disuse. Four animals (3 partly-meniscectomized & 1 scaffold-implanted) died from causes unrelated to the surgery. The scaffold-implanted animal died at 2 weeks post-surgery and was included in the analysis. Gross inspection: All knees demonstrated some evidence of synovitis at 3 months, consistent with a normal reaction to surgery; by 12 months synovitis was absent in all but 5 knees, and was not associated with presence of the implant. For scaffold-implanted knees, %fill was variable: 74 ± 16%; 54 ± 21% and 48 ± 24% at 3, 6 and 12 months, respectively. For the non-scaffold implanted groups, percent fill was 52 ± 22%; 60 ± 18% and 28 ± 10% at the same time-points. There was no statistically significant difference between groups at any time-point (Mann Whitney; p>0.09). The tissue that filled the meniscectomy site was generally translucent in appearance; while that which filled the scaffold tended to be dense and fibrous (Fig 1). Integration between the scaffold and surrounding tissue was variable, with some knees demonstrating full and complete integration (Fig 1A) and others demonstrating some evidence of separation predominantly posteriorly.

DISCUSSION: We have described the gross and histological appearance of a porous urethane scaffold and its surrounding tissue after 12 months of implantation into a partial meniscal defect ovine model. Cells had infiltrated the scaffold as early as 2 weeks-post-implantation and by 3 months the scaffold was populated with cells surrounded by extracellular matrix. Matrix generation persisted within the scaffold for the remainder of the study and local integration with the native meniscus was observed grossly and histologically. Tissue ingrowth also occurred into the empty defects, indicating that the ovine model has some capacity to heal partial meniscal defects. There was no difference between the damage seen on the tibial plateau with or without scaffold placement, suggesting that the scaffold does not abrade against adjacent tissue. This result may be influenced by the early time-point at which cell infiltration occurred.

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