

***Message intended for Healthcare Professionals Only

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OSTEOCHONDRAL REGENERATION WITH A TRI-LAYERED BIOMIMETIC RESORBABLE SCAFFOLD: IN VIVO STUDY IN A SHEEP MODEL UP TO 12 MONTHS OF FOLLOW-UP

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The treatment of osteochondral joint lesions requires the regeneration of both articular cartilage and subchondral bone tissue. Scaffold-based strategies aimed at mimicking the native osteochondral structure have been explored with mixed results. The aim of this study was to evaluate the regenerative potential of a tri-layered osteochondral cell-free scaffold in a large animal model at both 6 and 12 months of follow-up. Bilateral critical-sized osteochondral defects were created in 22 sheep. One defect was filled with the scaffold, whereas the contralateral was left empty. The repair tissue quality was evaluated at 6 and 12 months of follow-up in terms of macroscopic appearance, histology, trabecular bone formation, and inflammation grade. The mean global ICRS II score in the scaffold and control groups was 41 ± 11 vs 30 ± 6 at 6 months ($p = 0.004$) and 54 ± 13 vs 37 ± 11 at 12 months ($p = 0.002$), respectively. A higher percentage of bone was found in the treatment group compared to controls both at 6 (BV/TV $48.8 \pm 8.6\%$ vs $37.4 \pm 9.5\%$, respectively; $p < 0.001$) and 12 months (BV/TV $51.8 \pm 8.8\%$ vs $42.1 \pm 12.6\%$, respectively; $p = 0.023$). No significant levels of inflammation were seen. These results demonstrated the scaffold safety and potential to regenerate both cartilage and subchondral tissues in a large animal model of knee osteochondral lesions.

Intended Use IFU: Chondral lesions (ICRS Grade 3) and osteochondral lesions (ICRS Grade 4)

Keywords paper: Biomimetic scaffold; Knee; Large animal model; Osteochondral defect; Tissue regeneration.

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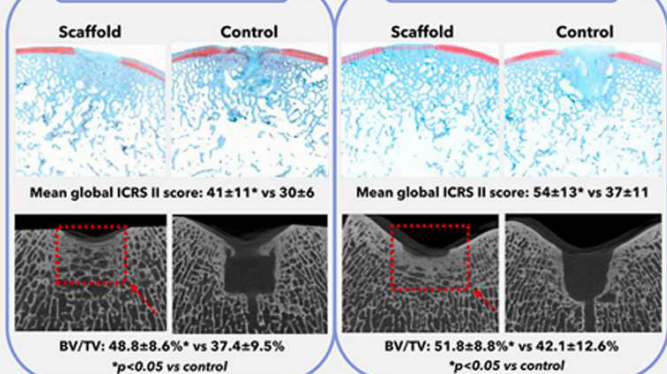
AIM

To evaluate the osteochondral regenerative potential of a cell-free tri-layered osteochondral scaffold in a sheep model

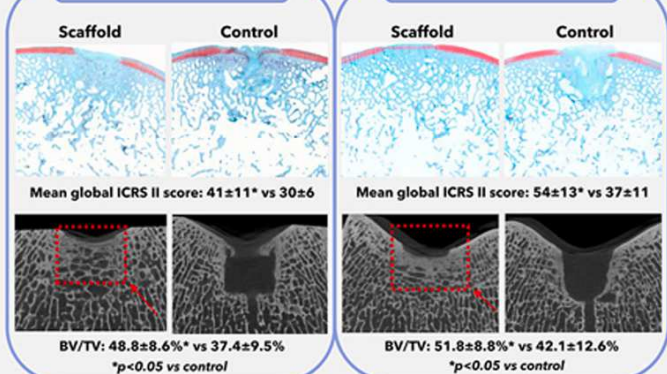
STUDY DESIGN



6-MONTH RESULTS



12-MONTH RESULTS



CONCLUSIONS

The scaffold is safe and showed potential to regenerate both cartilage and subchondral tissues in a large animal model of knee osteochondral lesions