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Biological and Clinical Evaluation Of Intraoperative Retention Of Autologous Chondrocytes On Type I/III Collagen Scaffold (Ortho-ACI™) For Cartilage Repair

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Summary:
This study has shown that retention of chondrocytes on type I/III collagen scaffold following intraoperative seeding enables the repair of articular cartilage with low graft-related complications.

Abstract:
INTRODUCTION
Matrix induced Autologous Chondrocyte Implantation (MACI), characterised by its utilisation of type I/III collagen scaffold seeded with autologous chondrocytes, is considered as a second generation of the ACI technique. Although substantial clinical evidence exists on the repair of articular cartilage by MACI, the high cost on manufacture has prevented its market development. To optimise the cost effectiveness of MACI, we have developed a new intraoperative procedure (Ortho-ACI™) of seeding chondrocytes onto the type I/III collagen scaffold. Herein we report on validation of the procedure and clinical outcomes of Ortho-ACI™.

METHODS
We tested the capability of cell retention on type I/III collagen scaffold in the theatre setting by PKH26 staining and confocal microscopy at various time points after seeding (7, 15, 20, 40, 60, 90 and 120 minutes) . We also compared the molecular profile (markers: collagen II, aggrecan, Sox9, HAPLN1) of chondrocytes seeded onto the scaffold at 20 minutes and 4 days (former preoperative seeding method). Upon validation of chondrocyte retention and molecular profile on the scaffold, fifteen patients with 25 cartilage defects (mean size 3.9cm2) received the procedure and were assessed by arthroscopic or magnetic resonance imaging (MRI) follow-up. Arthroscopic and MRI outcome gradings of excellent, good, poor or no infill were assigned by individual assessment of graft repair reporting. Associations between repair outcome and variables such as operative age, graft size and location, surgery history were also investigated.

RESULTS
Intraoperative chondrocyte-seeded scaffolds evidenced 79% cell retention at 7 minutes, increasing to 97% cell retention after 20 minutes and 99% by 90 minutes. Molecular profiling of scaffold-seeded chondrocyte expression at 20 minutes was more consistent with primary chondrocytes than 4 day profiles. The majority of patients had multiple defects, with a mean of 1.7 grafts per case. Most grafts were to patella defects (36%), then medial femoral condyle and trochlea (total 80%). Good or excellent MRI outcomes were noted in 100% of grafts at a mean 25 months follow-up (n=5). Good or excellent second look arthroscopy outcomes were noted in 83% of cases at a mean 17 months follow-up (n=24). Complications directly related to the graft were noted in only 29% (7/24) of cases, with all presenting as graft edge tissue overgrowth. No associations were found between repair outcome and surgical variables, although interestingly, 6 of the 7 graft overgrowth cases were graded as excellent arthroscopic repair.

CONCLUSION

The Ortho-ACI™ procedure, utilizing chondrocytes seeding onto collagen scaffold in the theatre, retains viable cells with suitable molecular profile for implantation. With a limited number of cases, Ortho-ACI™ demonstrated good to excellent MRI and arthroscopic repair outcomes. Although more long-term data is needed, the findings of this study suggest that the Ortho-ACI™ procedure is safe, clinically effective and represents an innovative and cost-effective ACI procedure.