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ARTHROSCOPIC EVIDENCE OF CARTILAGE REGENERATION IN SEVERE KNEE CARTILAGE DEFECTS AND OSTEOARTHRITIS FOLLOWING TREATMENT WITH ALLOGENEIC UMBILICAL CORD-DERIVED MESENCHYMAL STROMAL CELLS (CHONDROCELL-EX)

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Background: Background: Knee cartilage defect is a difficult condition to treat. Currently, there are no satisfactory treatments for grade 3 International Cartilage Repair Society (ICRS) defect. Allogeneic umbilical cord-derived mesenchymal stromal cells (UC-MSCs) offers a safe and convenient potential therapeutic option for ICRS grade 3 knee articular cartilage defect because of their immunomodulatory functions and ability to promote cartilage differentiation. Despite subjective functional improvements reported by patients in many studies, objective arthroscopic images of gross cartilage regeneration are rarely obtained and it is not known if the improvement is merely due to reduction of joint inflammation or associated with cartilage regeneration.

Objective: The aim of this study was to assess the efficacy of allogeneic umbilical cord-derived mesenchymal stromal cells in patient with knee articular cartilage defects and to demonstrate cartilage regeneration using follow-up arthroscopy.

Methodology: This is a single-arm, open-label, compassionate study at the Universiti Kebangsaan Malaysia Medical Centre (UKKMC) with 12 months follow-up period. Subjects with knee articular cartilage defect ICRS 3 diagnosed via diagnostic arthroscopy were treated with allogeneic UC-MSCs (Chondrocell-Ex, Cytopeutics, Malaysia) and assessed in five subsequent visits. During the visits, assessment was done following Visual Analog Score (VAS), International Knee Documentation Committee (IKDC), Tegner Activity Score (TAS), and Knee injury and Osteoarthritis Outcome Score (KOOS) scoring. At the end of the study, subjects underwent another arthroscopy and gross morphology of the knee articular cartilage was directly visually reassessed.

Results: Six female subjects (mean age of 46.8±5.4 years) with single knee injury received the treatment. All patients had knee cartilage defect of 2.5cm or larger. We observe no procedure or stromal cell related adverse events during the 1 year follow up. VAS, IKDC, TAS and KOOS significantly improved in these subjects with VAS/KOOS, and TAS/IKDC score at 3 months and 6 months post therapy onwards until 12 months. Direct visualization during follow-up arthroscopy confirmed total coverage of previously defected articular cartilage in all patients.

Conclusion: Allogeneic UC-MSCs (Chondrocell-Ex) is well tolerated and feasible as a treatment in patients with moderately-severe knee articular cartilage defect, with arthroscopic evidence of total cartilage regeneration.