

# **Costal Chondrocyte-Derived Pellet-Type Autologous Chondrocyte Implantation for Treatment of Articular Cartilage Defect: a Randomized Phase 3 Clinical Trial Compared to Microfracture**

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## **INTRODUCTION:**

Costal chondrocyte-derived pellet-type autologous chondrocyte implantation (CCP-ACI) has been introduced as a new therapeutic option for treatment of articular cartilage defect. We had previously conducted phase 1 and phase 2 clinical trials and reported the efficacy and safety results for 5 years after treatment with CCP-ACI. We conducted phase 3 clinical trial to compare the efficacy and safety of CCP-ACI with microfracture (MFx) for repair of articular cartilage defects of the knee.

**METHODS:** A total of 104 subjects with an International Cartilage Repair Society (ICRS) grade 3 or 4 chondral defect (2 to 10 cm<sup>2</sup> in area; ≤ 4 cm<sup>3</sup> in volume) were recruited and were randomly assigned at a 1:1 ratio to the CCP-ACI group and the MFx group. CCP-ACI was performed by harvesting costal cartilage about 6 weeks before surgery. Implantation was performed without any marrow stimulation. Efficacy and safety were assessed at weeks 8, 24, and 48 after surgery according to the magnetic resonance observation of cartilage repair tissue (MOCART) score and clinical outcomes.

## **RESULTS:**

MOCART scores improved from baseline to 24 and 48 weeks postoperatively in both treatment groups. The MOCART scores in the CCP-ACI group was significantly greater than that in the MFx group at 24 and 48 weeks. The scores of complete defect repair, complete integration, and signal intensity of the repair tissue were significantly higher in the CCP-ACI group than the MFx group at 48 weeks. Clinical outcomes significantly improved at 24 and 48 weeks in both groups, but no statistical differences between the groups were observed.

**DISCUSSION AND CONCLUSION:** The treatment of CCP-ACI for cartilage defects has yielded promising results, demonstrating excellent structural regeneration and positive clinical outcomes.