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Paper #186

A Multicenter Randomized Controlled Trial Comparing Collagen-Augmented Chondrogenesis Technique with Microfracture in the Knee

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Summary:
In this multicenter, randomized trial, clinical and imaging results indicate that the C-ACT is effective and safe to treat cartilage defect compared with simple microfracture.

Abstract:

Background

To remedy the imperfection of the microfrature, needs for some augmentation techniques have been expressed. However, the efficacies of the proposed methods are unclear. Collagen-augmented chondrogenesis technique (C-ACT using CartiFill™) is intended to repair cartilage defect and considered to be safe and efficacious compared with microfracture. (Study design: A multicenter, randomized, parallel-group trial)

Method

One hundred patients with knee cartilage defect were randomly assigned into the control group (treated with microfracture alone, 48 patients) or investigational group (treated with modified microfracture using C-ACT, 52 patients). At 12 and 24 months after the surgery, clinical and MRI outcomes were assessed for the efficacy and adverse events. Clinical outcomes were obtained by the analysis of the visual analog scale (VAS) for pain score, VAS 20% improvement rate based on minimal clinically important improvement (MCII), Knee injury and Osteoarthritis Outcome Score (KOOS), and International Knee Documentation Committee (IKDC) score. The MRI outcomes in terms of 50 % defect filling and the ratio of Repair Tissue to Reference Cartilage (RT / RC) were quantified by T2 mapping. The modified magnetic resonance observation of cartilage repair tissue (mMOCART) assessment was also performed to analyze the cartilage tissue repair.

Result: The groups had similar characteristics at baseline. At 24 months postoperatively, the odds of the VAS 20% improvement rate based on MCII was 2.808 times higher in the investigational group than in the control group (P = 0.0471). Compared with the baseline, the KOOS and IKDC score showed significant improvement in both groups at 12 and 24 months after the treatment without between groups difference. MRI outcome demonstrated that the odds of 50 % or more defect filling at 12 month was 3.984 times higher in the investigational group than in the control group (P = 0.0377). Also, the odds of RT / RC in the investigational group becoming '1 or more' was 11.37 times higher than in the control group (P = 0.0153). Compared with the control group, the mMOCART score in the investigational group showed improvement in Degree of defect repair and filling of the defect (P = 0.0201), Integration to border zone (P = 0.0062), and Effusion (P = 0.0079) with statistical significance. There were no adverse events in both groups.

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Conclusion

In this multicenter, randomized trial, clinical and imaging results indicate that the C-ACT is effective and safe to treat cartilage defect compared with simple microfracture.