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Paper #65

# BST-CarGel Treatment Results in Sustained Cartilage Repair Superiority Compared to Microfracture at 5 Years

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**Summary**:
An international cartilage repair RCT demonstrated sustained structural superiority of the repair tissue by quantitative 3D MRI for BST-CarGel treatment over microfracture alone at 5 years post-treatment. Both treatment groups showed significant and equivalent improvement over baseline at 5 years for all 3 WOMAC subscales ($p < 0.0001$). Equivalent safety for both treatments was demonstrated.

**Abstract**:
INTRODUCTION
BST-CarGel (Piramal Life Sciences, Bio-Orthopaedics Division, Laval, Canada) is a chitosan-based device which is applied over a microfractured cartilage lesion where it enhances early marrow-derived repair processes. A multicenter RCT was conducted to evaluate the efficacy and safety of BST-CarGel for cartilage repair in the knee compared to microfracture alone at 1 year and was continued under an extension protocol to evaluate 5 year post-treatment outcomes.

MATERIALS & METHODS
The international (Canada, Spain, South Korea) RCT enrolled 80 patients, aged 18 to 55, with BMIs<30 and symptomatic grade III or IV focal lesions on the femoral condyles. Patients were randomized (1:1) at the time of surgery to BST-CarGel or microfracture alone, and followed standardized 12 week rehabilitation. Repair tissue quantity and quality was evaluated as the primary endpoint up to 5 years by standardized MRI and three-dimensional quantification of lesion %Fill and T2 relaxation times. Secondary endpoints were clinical benefit determined using WOMAC questionnaires and safety at 1 and 5 years. General estimating equations were used for longitudinal statistical analysis of repeated measures.

RESULTS
Blinded MRI analysis demonstrated that BST-CarGel-treated patients showed a significantly greater treatment effect for lesion filling over the 5 year follow-up ($p=0.017$) compared to microfracture. A significantly greater treatment effect for BST-CarGel was also observed for repair tissue T2 relaxation times ($p=0.026$), indicating a more ordered and cartilage-like collagen structure compared to the microfracture group. The BST-CarGel and microfracture treatment groups both showed significant improvement from pre-treatment baseline at 5 years for all 3 WOMAC subscales of pain, stiffness and function ($p < 0.0001$). There was no difference between the treatment groups over the 1 to 5 year period for the WOMAC subscales. Safety by recording of adverse events was comparable for both groups over the 5 year study.

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CONCLUSION

At 5 years post-treatment, patients treated with BST-CarGel demonstrated sustained and significantly superior durability of repair over microfracture for repair tissue quantity and quantity. Additionally, the clinical benefit at 5 years for BST-CarGel was highly significant over the baseline levels of pain, stiffness and function, illustrating that BST-CarGel is a safe and effective treatment for symptomatic full-thickness cartilage lesions.