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An International Randomized Clinical Trial Evaluating Bst-Cargel®, A Novel Scaffold For Cartilage Repair, Demonstrates Superiority of Repair When Compared with Microfracture Alone Treatment

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Summary:
An international RCT with 80 patients evaluating BST-CarGel®, a novel chitosan-based scaffold applied to a cartilage lesion, showed superiority to microfracture alone for both the degree of lesion filling and the quality of cartilage repair tissue at 12 months by quantitative MRI and microscopic analyses of biopsies. Equivalent safety and clinical improvement at 12 months was also demonstrated.

Abstract:
Introduction:
An international, multicenter randomized clinical trial was conducted to evaluate the efficacy and safety of BST-CarGel® (Piramal Healthcare, Laval, Canada), for the repair of articular cartilage lesions, compared to microfracture alone. BST-CarGel® is a device composed of the biomaterial chitosan (polyglucosamine) which is applied over a microfractured lesion.

Materials and Methods:
80 patients at international sites (Canada, Spain, South Korea) were randomized (1:1) to either BST-CarGel® +microfracture or microfracture alone. Enrolled patients were aged 18 to 55, with BMIs=30 and had a single, symptomatic, grade III or IV lesion on their femoral condyles. They followed standardized 12 week post-operative rehabilitation. Quantity and quality of cartilage repair tissue was assessed at 12 months using quantitative MRI techniques. Supplemental structural data (ICRS I and II Histology Scoring and Polarized Light Microscopy (PLM) scoring) was also obtained from elective osteochondral biopsies taken at an average of 13 months from 38 consenting patients. Clinical improvement was measured at 12 months using WOMAC and SF-36 questionnaires, and safety was evaluated by monitoring adverse events.

Results:
Blinded MRI analysis demonstrated that BST-CarGel® met both primary endpoints by achieving statistical superiority for BST-CarGel® in greater % Lesion Fill (p=0.0105) and more cartilage-like repair tissue T2 values (p=0.0330) when compared with microfracture alone. WOMAC assessments for pain, stiffness and function yielded equivalent improvement for both groups at 12 months, which were statistically significant (p<0.0001) from baseline. Safety was comparable for both groups. When compared to microfracture, BST-CarGel® repair tissue showed improved ICRS macroscopic grading (p=0.0002) at second-look arthroscopy, superior collagen organization by PLM (p=0.0003), and improvements in most histological parameters (4/6 ICRS-I and 10/14 ICRS-II, with 8 at (p<0.05) or near significance

(p<0.11)).

Conclusions:
When compared to microfracture alone, the treatment of focal cartilage lesions with BST-CarGel® resulted in greater quantity and superior quality of cartilage repair tissue at 12 months as demonstrated by multiple, independent indicators.
Such notable improvement in hyaline structural characteristics should be predictive of longer term durability of repair and sustained clinical benefit compared to microfracture