Aragonite-Based Scaffold Versus Microfractures and Debridement for the Treatment of Knee Chondral and Osteochondral Lesions

Results of a Multicenter Randomized Controlled Trial

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Background: Lesions of the articular cartilage, with or without involvement of the subchondral bone, are a common cause of pain and dysfunction in the knee. Although several treatment options have been developed, the majority of previous clinical trials examined patients with isolated or focal midsized defects, which rarely represent the condition found in the general population. Rather, cartilage lesions are often associated with the presence of mild to moderate osteoarthritic changes.

Purpose: The present multicenter randomized controlled trial compared the clinical and radiographic outcomes of an aragonite-based osteochondral implant with a control group (arthroscopic debridement/microfractures) in patients affected by joint surface lesions of the knee, including those with concurrent mild to moderate osteoarthritis.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: A total of 251 patients were enrolled in 26 medical centers according to the following criteria: age 21 to 75 years, up to 3 cartilage defects of International Cartilage Regeneration & Joint Preservation Society grade 3a or above located on the femoral condyles and/or trochlea, total treatable area from 1 to 7 cm^2, bony defect depth $\leq$8 mm, and knee osteoarthritis grade 0 to 3 according to Kellgren-Lawrence score. Patients were randomized to the aragonite-based implant or debridement/microfracture control arm in a 2:1 ratio. Evaluation was performed at 6, 12, 18, and 24 months based on overall Knee injury and Osteoarthritis Outcome Score (KOOS) as the primary endpoint, and the KOOS subscales (Pain, Quality of Life, Activities of Daily Living), percentage of responders, and International Knee Documentation Committee (IKDC) subjective score as the secondary endpoints. Patients also underwent magnetic resonance imaging evaluation at 12 and 24 months to assess defect fill grade. Failures (ie, need for any secondary treatment) and adverse events were also recorded.

Results: The implant group showed a statistically superior outcome in the primary endpoint and all secondary endpoints at each follow-up. The magnitude of improvement in the implant group was twice as large as that in the control group in terms of mean KOOS improvement at 2 years. Responder rate (defined as at least a 30-point improvement in overall KOOS) was 77.8% in the implant group as opposed to 33.6% in the control ($P < .0001$). Statistically superior results were seen in the IKDC score as well. At 24 months, 88.5% of the implanted group had at least 75% defect fill on magnetic resonance imaging as compared with 30.9% of controls ($P < .0001$). The failure rate was 7.2% for the implant group versus 21.4% for control.

Conclusion: This aragonite-based scaffold was safe and effective in the treatment of chondral and osteochondral lesions in the knee, including patients with mild to moderate osteoarthritis, and provided superior outcomes as compared with the control group.

Registration: NCT03299959 (ClinicalTrials.gov identifier).

Keywords: osteoarthritis; aragonite; scaffold; cartilage regeneration; osteochondral; microfracture

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Knee articular cartilage lesions are common and often associated with a severe effect on patients' quality of life and working ability.[14,16,34] If left untreated, these lesions