Aragonite-Based Scaffold for the Treatment of Joint Surface Lesions in Mild to Moderate Osteoarthritic Knees

Results of a 2-Year Multicenter Prospective Study

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Background: Osteoarthritis (OA) is considered a contraindication to most cartilage repair techniques. Several regenerative approaches have been attempted with the aim of delaying or preventing joint replacement, with controversial results. Currently, there is a paucity of data on the use of single-step techniques, such as cell-free biomimetic scaffolds, for the treatment of joint surface lesions (JSLs) in OA knees.

Purpose: To present the 2-year follow-up clinical and radiological outcomes after implantation of a novel, cell-free aragonite-based scaffold for the treatment of JSLs in patients with mild to moderate knee OA in a multicenter prospective study.

Study Design: Case series; Level of evidence, 4.

Methods: A total of 86 patients, 60 male and 26 female, with a mean age of 37.4 ± 10.0 years, mild to moderate knee OA, and a mean defect size of 3.0 ± 1.7 cm^2, were recruited at 8 medical centers according to the following criteria: radiographic mild to moderate knee OA (Kellgren-Lawrence grade 2 or 3); up to 3 treatable chondral/osteochondral defects (International Cartilage Repair Society grades 3 and 4) on the femoral condyles or trochlea; a total defect size $\leq$7 cm^2; and no concurrent knee instability, severe axial malalignment, or systemic arthropathy. All patients were evaluated at baseline and at 6, 12, 18, and 24 months after implantation using the Knee injury and Osteoarthritis Outcome Score (KOOS) and International Knee Documentation Committee (IKDC) subjective score. Additionally, magnetic resonance imaging (MRI) was performed to assess the amount of cartilage defect filling at the repaired site.

Results: Significant improvement on all KOOS subscales was recorded from baseline (Pain: 49.6 ± 13.1; Activities of Daily Living [ADL]: 56.1 ± 18.4; Sport: 22.8 ± 18.8; Quality of Life [QoL]: 23.5 ± 16.5; Symptoms: 55.4 ± 19.9) to the 24 months' follow-up (Pain: 79.5 ± 21.1 [$P < .001$]; ADL: 84.1 ± 21.4 [$P < .001$]; Sport: 60.8 ± 31.9 [$P < .001$]; QoL: 54.9 ± 30.4 [$P < .001$]; Symptoms: 77.7 ± 21.2 [$P < .001$]). The IKDC subjective score showed a similar trend and improved from 37.8 ± 14.7 at baseline to 65.8 ± 23.5 at 24 months ($P < .001$). MRI showed a significant increase in defect filling over time: up to 78.7% ± 25.3% of surface coverage after 24 months. Treatment failure requiring revision surgery occurred in 8 patients (9.3%).

Conclusion: The use of an aragonite-based osteochondral scaffold in patients with JSLs and mild to moderate knee OA provided significant clinical improvement at the 24-month follow-up, as reported by the patients. These findings were associated with good cartilage defect filling, as observed on MRI.

Keywords: osteoarthritis; aragonite; scaffold; cartilage regeneration; cartilage repair; osteochondral; Agili-C; joint preservation; cartiheal

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Knee joint surface lesions (JSLs), that is, chondral and osteochondral defects, have always been a treatment challenge for surgeons,[11] especially in the presence of joint degeneration. Osteoarthritis (OA) has been considered