

## Novel Biomimetic Scaffold to Treat Osteochondral Defects: Pilot Clinical Study at 5 Year Follow-Up

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### Summary:

We report the clinical outcome at 5 years of follow-up of 25 patients treated with a novel biomimetic osteochondral scaffold.

### Abstract:

#### Introduction:

We performed a clinical pilot study using a newly developed nanostructured biomimetic scaffold to treat chondral and osteochondral lesions of the knee; its safety and manageability, as much as the surgical procedure reproducibility and the clinical outcome at medium term follow-up, were evaluated in order to test its intrinsic potential without any cells culture aid.

#### Materials and Methods:

The osteochondral scaffold used was obtained by enucleating equine collagen type 1 fibrils with hydroxyapatite nanoparticles in 3 different layers with different gradient ratios, at physiological conditions. 30 patients (9F, 21M, mean age 29.3 yy) affected by symptomatic grade III-IV chondral and osteochondral lesions of the knee (ICRS evaluation package) were enrolled and underwent implantation of the scaffold. Some patients had multiple lesions treated. Twenty-five out of 30 patients were analyzed prospectively at 6, 12, 24, 36, 48, and 60 months using the Cartilage Standard Evaluation Form, as proposed by ICRS, and a high resolution MRI. The sites of the defects were: 6 medial femoral condyles, 5 lateral femoral condyles, 10 patellae, 7 trochleae, and 2 lateral tibial plateaus. The average size of the defects was  $2.9 \pm 1.3$  cm<sup>2</sup>. Etiology was traumatic in 5 cases, microtraumatic/degenerative in 14 cases, and 6 patients were affected by osteochondritis dissecans.

#### Results:

Twenty-five patients were evaluated up to 60 months of follow-up. We detected a statistically significant clinical improvement and function recovery with respect to pre-operative assessment. Mean pre-op IKDC subjective score was  $40.0 \pm 14.7$ . The trend was positive since the 12 months f-up and the results were confirmed at the following evaluations. At final evaluation mean IKDC-subjective was  $78.0 \pm 17.9$ , thus showing a statistically significant improvement, stable over time. Mean pre-injury Tegner score was  $5.0 \pm 2.5$ , whereas at pre-treatment evaluation it was  $2.0 \pm 1.0$ . A significant increase was registered at 12 months f-up with a mean value of  $4.0 \pm 1.7$ , with a further, statistically not significant, rise at 36 months f-up, and good results confirmed even at 5 years evaluation ( $4.3 \pm 2.1$ ). These results show a statistically significant improvement ( $p < 0.05$ ) from pre-op level, even if the final sport activity

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level is lower than the pre-injury one. MRI evaluation revealed a good integration of the scaffold and a satisfactory filling of the defect.

### Conclusion:

This new minimally invasive one-step surgical approach seems to be an easy and effective procedure. The results registered are very encouraging and this procedure shows satisfactory outcomes even in large osteochondral lesions or complex cases. These data, both clinical and radiological, suggest that this particular one step surgical approach could be successfully performed in knee chondral or osteochondral lesions. By the way, further studies with longer term follow-up and a higher number of patients are still needed to confirm the efficacy showed by this procedure.