

CELL-FREE BIOMIMETIC OSTEOCHONDRAL SCAFFOLD FOR THE TREATMENT OF KNEE ARTICULAR SURFACE LESIONS: CLINICAL OUTCOMES DIFFER BASED ON PATIENT AND LESION CHARACTERISTICS

Knee Surgery Sports Traumatology Arthroscopy, 2024 July 14, doi: 10.1002/ksa.12402

(<https://pubmed.ncbi.nlm.nih.gov/39101253/>)

Material: MaioRegen line of resorbable and implantable medical devices is indicated for the treatment of chondral and osteochondral joint lesions.

The devices are provided as a three-dimensional porous and multilayered matrix, consisting of:

- a layer of type I collagen fibres (equine origin);
- one or two composite layers consisting of type I collagen fibres (equine origin) and magnesium-enriched hydroxyapatite crystals.

Type I collagen and magnesium-enriched hydroxyapatite are biomimetic biomaterials that are physiologically present in the body and therefore do not alter the joint biochemical balance. The particular chemical composition enables the MaioRegen devices line to mimic the extracellular matrix of cartilage and osteocartilaginous tissue. The devices high porosity and good hydrophilicity favour the rapid absorption of the biological liquids (and related cellular components) with which they come into contact during implantation, facilitating their adaptation to the lesion site.

Intended Use IFU: Osteochondral defects, ICRS grade 3 and 4.

Keywords paper: biomimetic osteochondral scaffold, cartilage, knee, OCD.

	Purpose A cell-free biomimetic osteochondral scaffold was developed to treat cartilage knee lesions, with positive clinical results documented in small case series. However, clear evidence on patient and lesion characteristics that might affect the outcome is still lacking. The aim of this study is to analyze a large cohort of patients treated with this scaffold to investigate factors that could influence the clinical outcome.
	Methods Two hundred and three patients (mean age 30.7 ± 10.9 years) treated with this scaffold were prospectively evaluated at baseline, 6-, 12- and 24-month follow-up. The clinical outcome was analysed using the International Knee Documentation Committee (IKDC) score, and the activity level was assessed with the Tegner score. The influence of patient and lesion characteristics on clinical outcomes was analysed.
	Results Mild and severe adverse reactions were found in 39.0% and 1.5% of patients, respectively. The failure rate was 2.0%, increasing to 12.3% when including also clinical failures. The IKDC subjective score increased from 43.3 ± 15.9 to 61.0 ± 16.2 at 6 months, 68.3 ± 18.5 at 12 months and 73.8 ± 18.3 at 24 months ($p < 0.0005$). The Tegner improved from 2.5 ± 1.7 to 4.2 ± 1.7 at 24 months ($p < 0.0005$), without reaching the pre-injury level (6.0 ± 2.2) ($p < 0.0005$). The IKDC objective score changed from 68.5% normal and nearly normal knees before the treatment to 90.1% at 24 months. At 24 months, age showed a correlation with the IKDC subjective score ($r = -0.247$; $p < 0.0005$), women had a lower score ($p < 0.0005$), as well as patients with patellar lesions ($p = 0.002$). Previous surgery correlated with lower results ($p = 0.003$), while better results were found in OCD compared to degenerative lesions ($p = 0.001$). Significant improvement was observed over time in all scores but worsened at the final follow-up. The IKDC subjective score improved from 46.9 ± 16.2 to 79.8 ± 16.4 at 3 years ($p < 0.0005$) and then decreased to 64.5 ± 21.4 ($p = 0.001$) at 12 years. A similar trend was confirmed for VAS and Tegner scores. Only two patients subsequently underwent knee arthroplasty, and nine more patients were considered clinical failure, for a cumulative surgical and clinical failure rate of 28.2% at the final follow-up.
	Conclusion This cell - free biomimetic scaffold is a safe and effective treatment for cartilage knee lesions, offering positive clinical results at 2 years with a low failure rate. Better outcomes were observed in younger patients, in lesions of the femoral condyles and in OCD, while joints affected by patellar lesions, patients who underwent previous knee surgery, and women may expect lower results.

	Take home messages: MaioRegen Prime large cohort study. OCD, traumatic, degenerative knee lesions.
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Study design: Cohort study; Level of evidence, 3.