BS Structured Summary

Article: Safety and Survival of the Biomimetic Osteochondral Knee Scaffold

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Structured Summary: Safety and Survival of the Biomimetic Osteochondral Knee Scaffold

Original Article: Safety and Survival Rate of a Biomimetic Osteochondral Scaffold for the Treatment of Lesions of the Knee Articular Surface

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INTRODUCTION / BACKGROUND

Lesions of the knee articular surface represent a frequent pathology, affecting more than 60% of patients undergoing knee arthroscopy. When not adequately treated, they can lead to chronic symptoms such as joint effusion and pain, and favor early osteoarthritis development. Over the decades, multiple therapeutic strategies have been developed: bone marrow stimulation techniques (microfracture), osteochondral autograft or allograft transplantation, and autologous chondrocyte-based procedures (ACI/MACI). Each option carries important limitations — variable repair tissue quality, donor-site morbidity, restricted availability, inability to treat the entire osteochondral unit, two-stage procedures, and high costs, with clinical results that are not always satisfactory.

Cell-free osteochondral scaffolds emerged as an attempt to overcome these limitations, offering a biodegradable three-dimensional structure that promotes tissue growth and, ideally, regeneration of the osteochondral unit. Published clinical results suggest good outcomes through long-term follow-up, with low failure rates even in complex lesions — large defects, challenging locations, and early osteoarthritis. Despite this, postoperative adverse events (AEs) after cell-free scaffold implantation have been reported in more than 30% of patients in some series.

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Systematic tracking of AEs and failures is a regulatory requirement for medical device companies and a critical tool for surgeons to understand specific risk factors, develop preventive measures and safety protocols. The existing literature on AEs after cell-free scaffold implantation is characterized predominantly by small series with short- to medium-term follow-up. The incidence of minor self-resolving complications — frequently underestimated but relevant for early postoperative quality of life — is rarely accurately evaluated. Nor is it possible, with current literature, to identify patient-specific risk factors that allow treatment to be tailored to each case's individual profile.

This study from the Istituto Ortopedico Rizzoli group addresses this gap by analyzing a post-market pharmacovigilance regulatory database of the MaioRegen device (Finceramica), in a large series with extended follow-up — up to 180 months.

OBJECTIVE

To analyze the incidence of adverse events and failures at long-term follow-up and investigate their association with patient and lesion characteristics, in a large series of patients undergoing cell-free osteochondral scaffold implantation for the treatment of knee articular surface lesions.

METHODS

Case series study based on the regulatory safety database collected by the scaffold manufacturer (Finceramica Faenza spa). The European Medical Device Regulation (2017/745; EU) establishes clinical follow-up of marketed medical devices as a continuous process of updating the device's clinical evaluation, with periodic proactive vigilance activities. The total initial population consisted of 1,397 patients with 1,486 lesions treated with the MaioRegen cell-free biomimetic scaffold.

Inclusion criteria: patients with clinical symptoms related to chondral or osteochondral lesions involving the femoral condyles, trochlea, patella, or tibial plateau, undergoing scaffold implantation between January 2007 and January 2024, with at least 6 months of follow-up. AEs were classified as (1) surgery-related, (2) treatment-related, or (3) not related to surgery or treatment; and divided into serious or mild.

The MaioRegen scaffold is a three-layer, three-dimensional structure composed of equine type I collagen and hydroxyapatite (HA), mimicking osteochondral anatomy. Three formulations were analyzed: "Prime" (6 mm depth, cartilaginous layer of type I collagen, intermediate layer 60% collagen + 40% HA, and bone layer 30% collagen + 70% HA); "Slim" (4 mm, double layer, for shallower lesions); and "Chondro+" (2 mm, designed for purely chondral lesions with minimal subchondral bone involvement).

All patients underwent scaffold implantation by a standardized and previously described surgical technique. Under tourniquet, the surgical approach was determined by lesion location (medial or lateral parapatellar incision), via arthrotomy. The lesion was prepared by removing damaged osteochondral tissue to create a defect of suitable depth. The scaffold was sized to match the prepared area and implanted by press-fit technique. Fibrin glue was optionally applied per surgeon preference.

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Statistical analysis: descriptive analyses with arithmetic mean, median, standard deviation; life table method to estimate probability of survival without surgical failure; Fisher exact test for individual risk factors; logistic regression for multifactorial approach. Analyses performed in SAS Statistical Software.

MAIN RESULTS

From the total population of 1,397 patients, 704 (50.4%) met the minimum 6-month follow-up criterion and were included in the analysis. Characteristics of the included population: male predominance (487 men vs. 194 women), mean age of 34.1±12.1 years, mean lesion size of 3.7±2.0 cm^2, mean follow-up of 44.8 months (range 6-180; median 24). Distribution by location: medial femoral condyle (320), lateral femoral condyle (118), patella (138), trochlea (121) and tibial plateau (23). Etiologies: traumatic (145), degenerative (278), osteochondritis dissecans (158), osteonecrosis (10), other (43). Concomitant knee surgery was performed in 292 of 704 patients (41.5%).

Adverse events: 177 postoperative AEs in 170 patients (24.1%). Of these, surgeons considered 104 surgery-related and 73 treatment-related. Additionally, 52 AEs in 45 patients (6.4%) were considered unrelated to the procedure and excluded from analysis. Mild AEs were reported in 93 patients (13.2%) and included mainly minor persistent postoperative symptoms (fever, pain, swelling, difficulty of movement) in 82 patients (11.6%), joint inflammation (4 cases), crepitus (3), and loose body (1).

Serious AEs were reported in 66 patients (9.4%) and included: early or persistent postoperative symptoms in 54 patients (7.7%), joint inflammation in 6 (0.9%), arthrofibrosis in 3 (0.4%), crepitus in 1, loose body in 1, patellar tendinitis in 1, and early resorption in 1. Most AEs concentrated in the first months: 81.3% in the first 6 months, 7.5% between 7-12 months, 6.7% between 13-24 months, and only 4.5% after 24 months.

Implant survival rate: 93.1% up to 180 months of observation by the life table method — the study's central finding. A total of 31 surgical failures were recorded: 22 before 24 months, 6 between 24 and 60 months, and only 3 between 60 and 180 months. Time-interval analysis demonstrates the survival curve stabilizes after the second year: 97% at 12-24 months, 95% at 36-48 months, and 93% at 120-180 months.

Risk factors: no demographic or clinical characteristic evaluated — sex, age, combined surgeries, etiology, lesion location, lesion size — significantly influenced the risk of AEs or implant failure. This "homogeneity of risk" finding has important clinical implication: the scaffold can be considered across heterogeneous patient profiles without any subgroup presenting differential complication or failure risk.

AUTHORS' CONCLUSION

Implantation of the cell-free biomimetic osteochondral scaffold for the treatment of knee articular surface lesions presents a high survival rate of 93.1% at long-term follow-up (up to 180 months). Mild AEs (13.2%) and serious AEs (9.4%), as reported by surgeons in the database, consisted mainly of pain and postoperative symptoms. Patient demographic and clinical characteristics did not influence the risk of postoperative AEs or failures. These results can

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help surgeons improve clinical decision-making and patient counseling regarding expectations related to the implantation of an osteochondral scaffold to treat chondral and osteochondral knee lesions.

💬 BS DISCUSSION

This paper deserves special attention because of its scale — 704 patients included from a total base of 1,397, with follow-up extending to 15 years. For a treatment area like osteochondral regeneration, where the literature is dominated by small series and short follow-ups, this is a relevant contribution. The central data — 93.1% survival up to 180 months — confirms and extends previous findings, and gives the surgeon a concrete number to discuss with patients: "in long-term studies, more than 9 out of 10 implants were not explanted at 15 years."

For BS practice, three points deserve attention. First, the temporal distribution of AEs: 81.3% occur in the first 6 months. This means clinical surveillance and close follow-up in the first two postoperative trimesters are fundamental. If the patient gets through the first semester without intercurrences, the probability of later adverse events drops dramatically. This information can reorganize how we structure post-cartilage follow-ups at BS: more frequent visits in the first semester, progressive spacing from the second year on.

Second, the finding that no demographic or clinical factor significantly influenced AE or failure risk is provocative — and potentially liberating for indication. Traditionally, larger lesions (>4 cm^2) were considered less suitable for scaffold, with preferential indication for osteochondral autograft or ACI. The authors cite a recent ICRS consensus (Filardo et al. 2021) that broadened scaffold indications even for larger lesions. This work reinforces that expansion: lesion size was not a risk factor. Equally important is the finding that concomitant surgeries (in 41.5% of cases — osteotomy, meniscal transplant, ligamentous) did not increase risk. This validates what many of us already do: scaffold in "complex knees" as part of an integrated joint preservation strategy, especially in young patients with early osteoarthritis.

Third, a word on the most prevalent event: persistent postoperative symptoms (pain, swelling, stiffness) in 11.6% of cases as mild AE and 7.7% as serious AE. This is an expressive number that demands honest patient counseling. As the authors themselves comparatively point out, chronic pain after knee arthroscopic procedures ranges from 6 to 25% at 1-2 years, and after ACL reconstruction reaches more than 20%. That is, post-cartilage pain is not deviant from what is observed in other knee procedures — but is frequent enough that the patient should know upfront, avoiding frustration and a perception of "treatment failure" when the final clinical outcome will be good. The authors also cite prior evidence (De Marziani et al. 2025) showing these early symptoms, although delaying recovery, do not compromise the 2-year outcome. Message for consultation: "it is common, manageable, and does not compromise final outcome."

Important limitations must be clearly mentioned. This is a case series based on a regulatory database — there are no systematic PROMs (IKDC, KOOS, Lysholm) nor

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imaging data (MOCART) available. The definition of "failure" was surgical (need for explant), and may underestimate clinical failures where the patient lives with symptoms without surgical revision. The proportion of patients with adequate follow-up is relatively low (50.4% of the total treated population), introducing risk of selection bias — patients with worse evolution may have been lost to follow-up. There is also significant clinical heterogeneity (etiology, size, location, age). Finally, there is clear conflict of interest to consider: one author (R. Miale) works for the scaffold manufacturer. Despite these limitations, the study delivers an essential data point — safety and durability profile of the scaffold at a scale no other series has provided so far. For BS Papers, the recommendation stands: include this paper as reference whenever we discuss cartilage at BS Summit and labs, and use the numbers to structure our preoperative counseling narrative.

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