MaioRegen vs Microfracture
Clear Indications proving
Clinical Superiority

Results from LEVEL OF EVIDENCE 1
MULTICENTER RANDOMIZED CONTROLLED TRIAL

MaioRegen
STUDY PROFILE

RCT STUDY

- Level of Evidence 1
- CRO trial management
- International, multicenter, randomized, controlled
- Central blinded MRI evaluation
- Carried out according to ethical and regulatory guidelines
- Primary Endpoints: IKDC Subjective, incidence and gravity of Adverse Events

PATIENTS FLOW CHART

STUDY GROUPS

- **MaioRegen**: implantation of MaioRegen 3-layer scaffold - Open Surgery
- **MICROFRACTURE**: marrow stimulation technique (microfracture, drilling) - Arthroscopy
Baseline demographic data and lesions characteristics were similar in both treatment groups.
A statistical significant improvement in IKDC Subjective Score for patients treated with MaioRegen from baseline to 2 years follow-up.

A statistical significant improvement from baseline to 2 years follow-up in Tegner Score was achieved in MaioRegen Group.

A statistical significant improvement from baseline to 2 years follow-up was achieved in both treatment groups for IKDC Subj, Tegner, KOOS and VAS pain scores.
EVIDENCE OF MaioRegen SUPERIORITY
vs MICROFRACTURE

Deep Osteochondral Lesions

Statistically significant MaioRegen superiority: +12.4 points vs Microfracture in change from baseline of IKDC Subjective score.

Sport Active Patients

Statistically significant MaioRegen superiority: +16.0 points vs Microfracture in change from baseline of IKDC Subjective score.

Osteochondritis Dissecans

Clinically relevant improvement of MaioRegen: +12.0 points vs Microfracture in change from baseline of IKDC Subjective score.

Clear Clinical Indications: RCT analysis in above sub-populations confirms the superiority of MaioRegen compared to microfracture.
MRI Images
A decrease in edema and effusion was observed in the subchondral bone, even if some bone tissue remodelling was observed at 2 years follow up. The analysis of structural outcomes, evaluated through MOCART score, showed similar results between treatment groups for defect filling and integration.

Safety Analysis
Most of related Adverse Events in MaioRegen group are minor post-operation symptoms that resolved within few weeks. Although MaioRegen group presents a higher rate of total AEs (open surgery vs arthroscopy), the percentage of re-operation in patients with related AEs is lower. Failure rate is comparable to other open joint surface surgeries.

*OTHER RELATED AEs: pain, joint adhesions/instability, loose body, inflammation.
**MINOR POST OPERATION SYMPTOMS: fever, swelling, hemarthrosis
STUDY HIGHLIGHTS

● CLINICAL SUPERIORITY
  About two-thirds of patients treated with MaioRegen show a statistically significant superiority in IKDC Subjective compared to Microfracture.

● CLEAR INDICATIONS
  Statistically and clinically significant subgroups for IKDC Subjective in favour of MaioRegen: Deep Osteochondral Lesions, OCD and Sport-Active Patients.

● TREATMENT SAFETY
  AEs in MaioRegen subgroups are mainly minor post-op symptoms and failure rate is comparable to other open-joint implantations, according to state-of-the-art scientific literature.