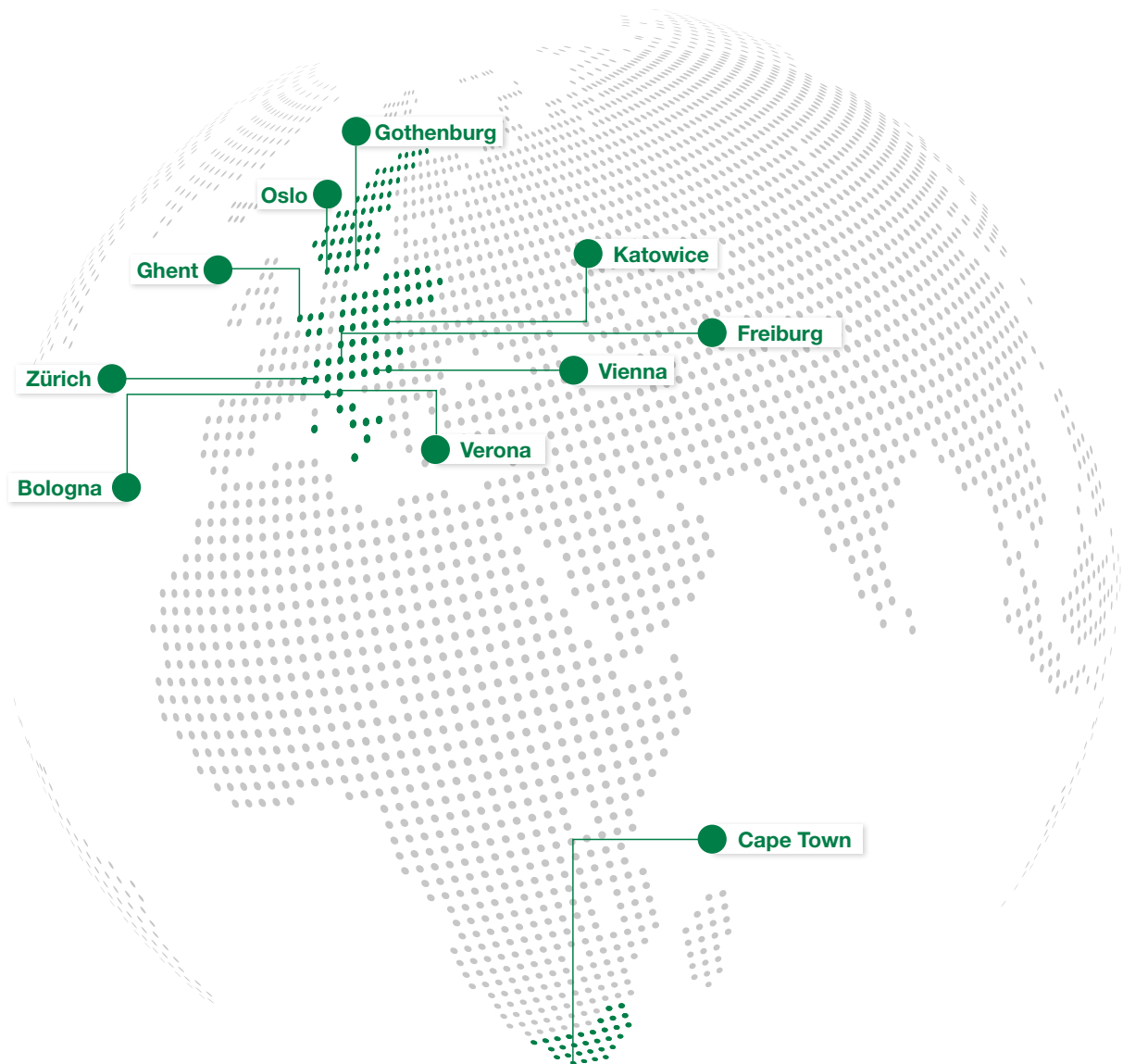


MaioRegen vs Microfracture

Clear Indications
proving
Clinical Superiority



Results from **LEVEL OF EVIDENCE 1**
MULTICENTER RANDOMIZED CONTROLLED TRIAL

MaioRegen

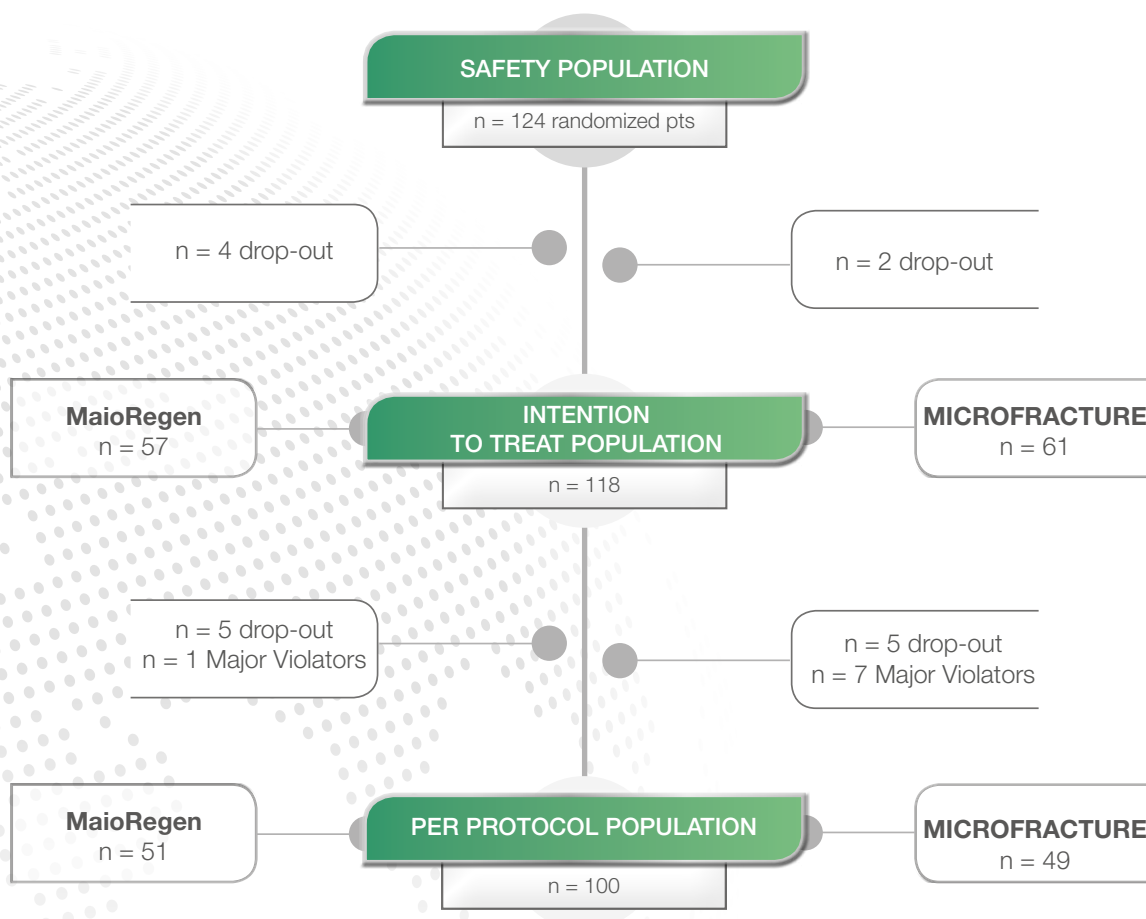
Biojoint System

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

CLINICAL SITES AND POPULATION

CLINICAL SITES

- **Istituto Ortopedico Rizzoli** - Bologna, Italy
- **Ospedale Sacro Cuore Don Calabria** - Verona, Italy
- **Kungsbacka Hospital** - Gothenburg, Sweden
- **Universitair Ziekenhuis Gent** - Ghent, Belgium
- **Schulthess Klinik** - Zürich, Switzerland
- **Universitätsklinik Wien** - Vienna, Austria
- **Albert Ludwigs Universität Freiburg** - Freiburg, Germany
- **Ullevål University Hospital** - Oslo, Norway
- **Samodzielny Publiczny Wojewódzki** - Katowice, Poland
- **Sport Science Orthopaedic Clinic** - Cape Town, South Africa

PATIENTS - BASELINE CHARACTERISTICS

Demographics (Per Protocol Population - n = 100)		MaioRegen (n = 51)	Microfracture (n = 49)
AGE (years)	mean ± SD	34.0 ±10.9	35.2 ±10.2
GENDER n (%)	male	36 (70.6%)	31 (63.3%)
	female	15 (29.4%)	18 (36.7%)

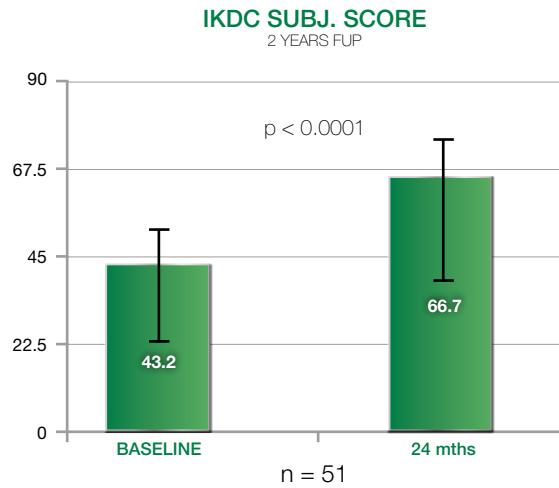
LESIONS - BASELINE CHARACTERISTICS

Demographics (Per Protocol Population - n = 100)		MaioRegen (n = 51)	Microfracture (n = 49)
LESION SIZE (cm ²)	mean	3.4±1.5	3.5±1.6
DEFECT LOCALIZATION n (%)	condyle	37 (72.6%)	23 (47.0%)
	throclea	2 (3.9%)	6 (12.2%)
	patella	12 (23.5%)	20 (40.8%)
ETIOLOGY n (%)	microtraumatic/degenerative	20 (39.2%)	24 (49%)
	OCD	15 (29.4%)	12 (24.5%)
	traumatic	13 (25.5%)	12 (24.5%)
	other	3 (5.9%)	1 (2%)
PRE-SURGERY ACTIVITY LEVEL n (%)	non-active	35 (68.6%)	38 (77.5%)
	sport active	16 (31.4%)	11 (22.5%)

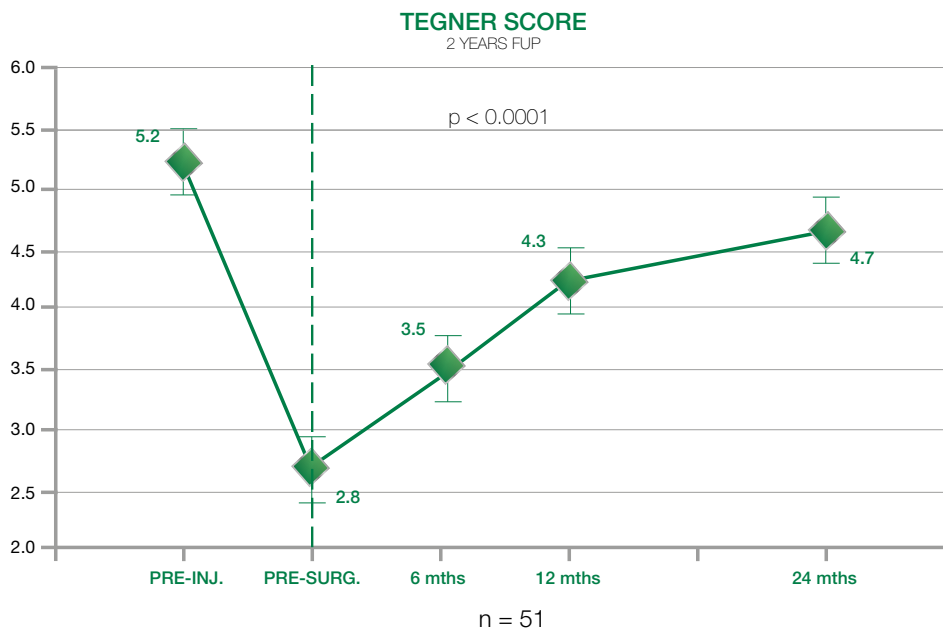
Baseline demographic data and lesions characteristics were similar in both treatment groups.

EVIDENCE OF MaioRegen EFFICACY

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.

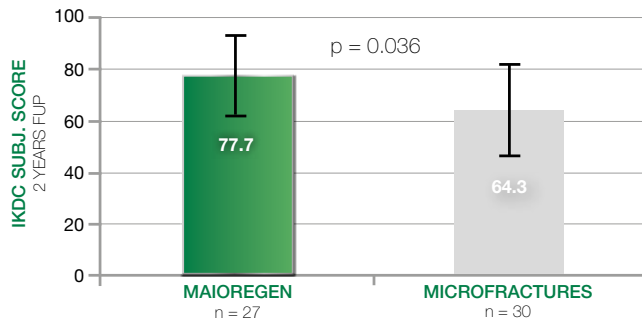


A statistical significant improvement from baseline to 2 years follow-up was achieved in both treatment groups for IKDC Subj, Tegner, KOOS and VAS pain scores.

EVIDENCE OF MaioRegen SUPERIORITY

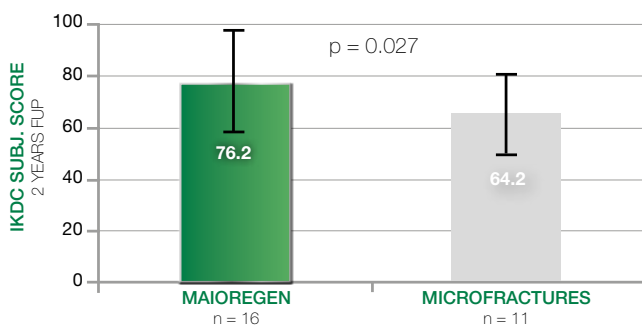
vs MICROFRACTURE

● Deep Osteochondral Lesions



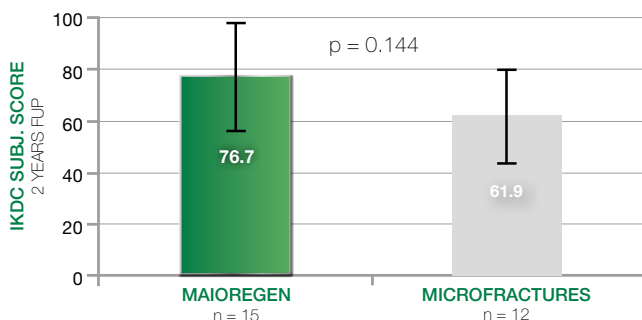
Statistically significant MaioRegen superiority: +12.4 points vs Microfracture in change from baseline of IKDC Subjective score.

● Sport Active Patients



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

● Osteochondritis Dissecans



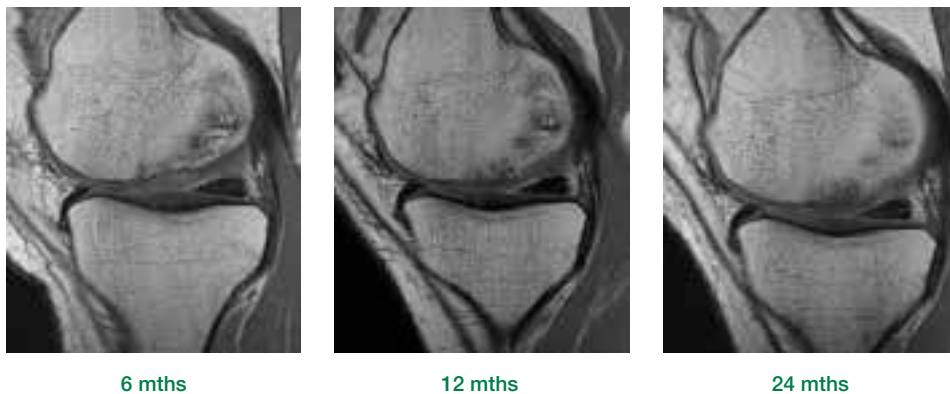
Clinically relevant improvement of MaioRegen: +12.0 points vs Microfracture in change from baseline of IKDC Subjective score.

Clear Clinical Indications: RCT analysis in above sub-populations confirms the superiority of MaioRegen compared to microfracture.

TISSUE REGENERATION AND SAFETY

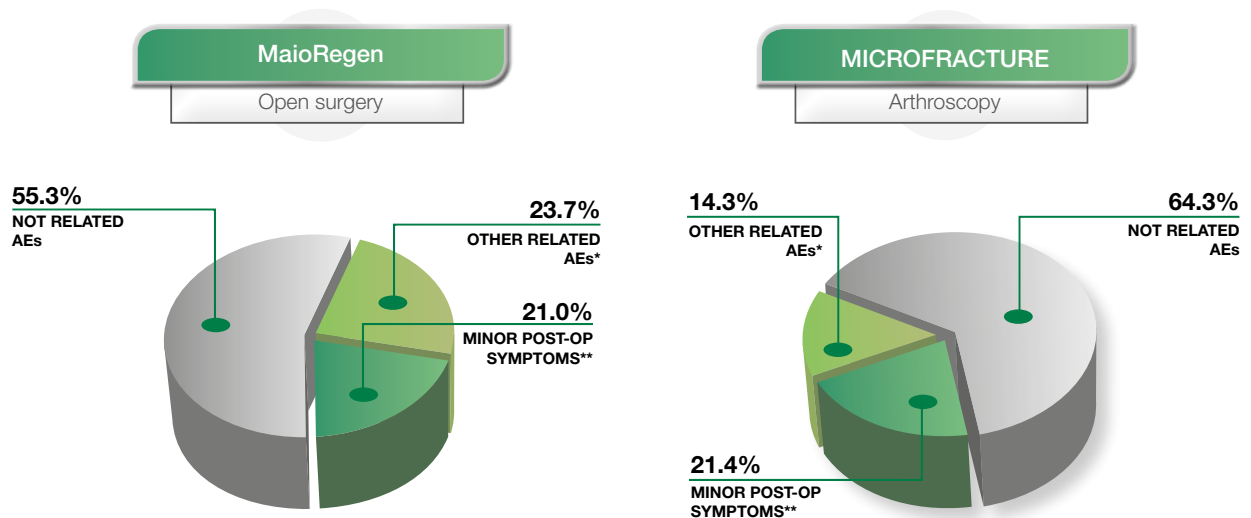
MRI Images

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.



Finceramica
regenerative surgery

manufacturer: **Fin-ceramica faenza spa**
manufacturing facility: via Ravegnana 186 - 48018 Faenza RA, Italia
registered office: via Granarolo 177/3 - 48018 Faenza RA, Italia
t +39 0546 607311 - f +39 0546 607312
info@finceramica.it - www.finceramica.it