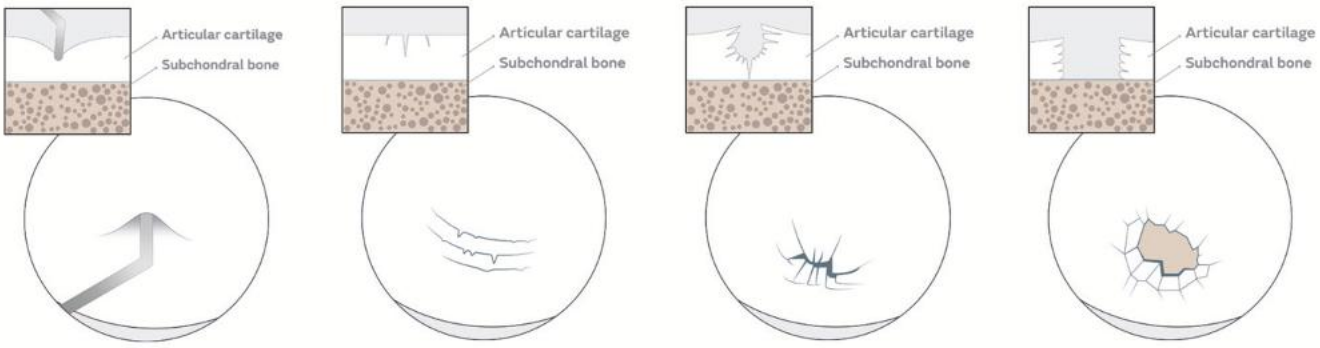
The + in Bone Marrow Stimulation

Joint+rep®

Target patients

The status quo for cartilage repair

- Microfracturing represents the most common cartilage repair technique.[1]
- 63% of arthroscopies reveal the presence of asymptomatic cartilage lesions.[2]



ICRS Grading Scale*

Grade I	Grade II	Grade III	Grade IV
Cartilage with softening and swelling	Partial thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5cm in diameter	Fissuring to the level of subchondral bone in an area with a diameter more than 1.5cm	Exposed subchondral bone

Bone marrow stimulation (BMS) + JointRep®

PROS OF MFX

- Easy to apply with no specific infrastructure needed
- Single-step, easy to apply arthroscopically/mini-open
- Safe with relatively lower cost (when compared to culture cell-based and grafting solutions)

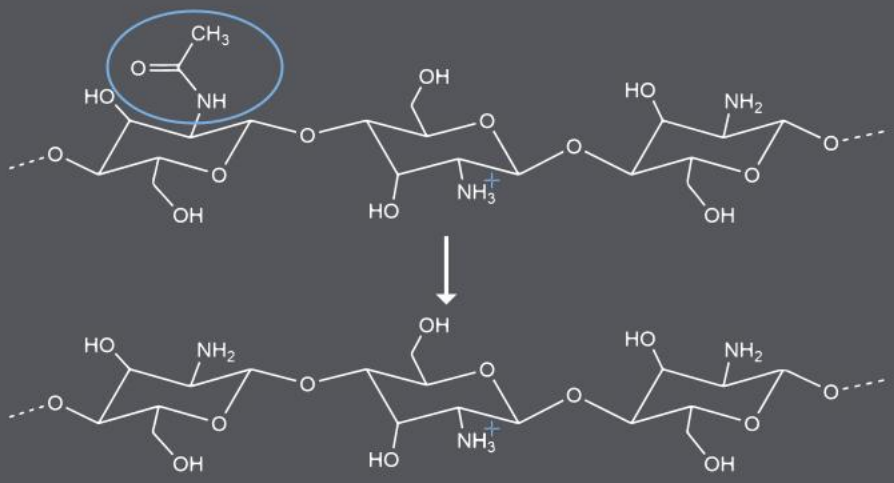
Could we improve the results of MFX alone?

- Risk of retraction and/or disruption of the blood in the cartilage lesion.[3]
- Inconsistent quality of the resulting healing tissue.[4]
- Eventual deterioration of knee function on the medium/long term.[5]

Chitosan

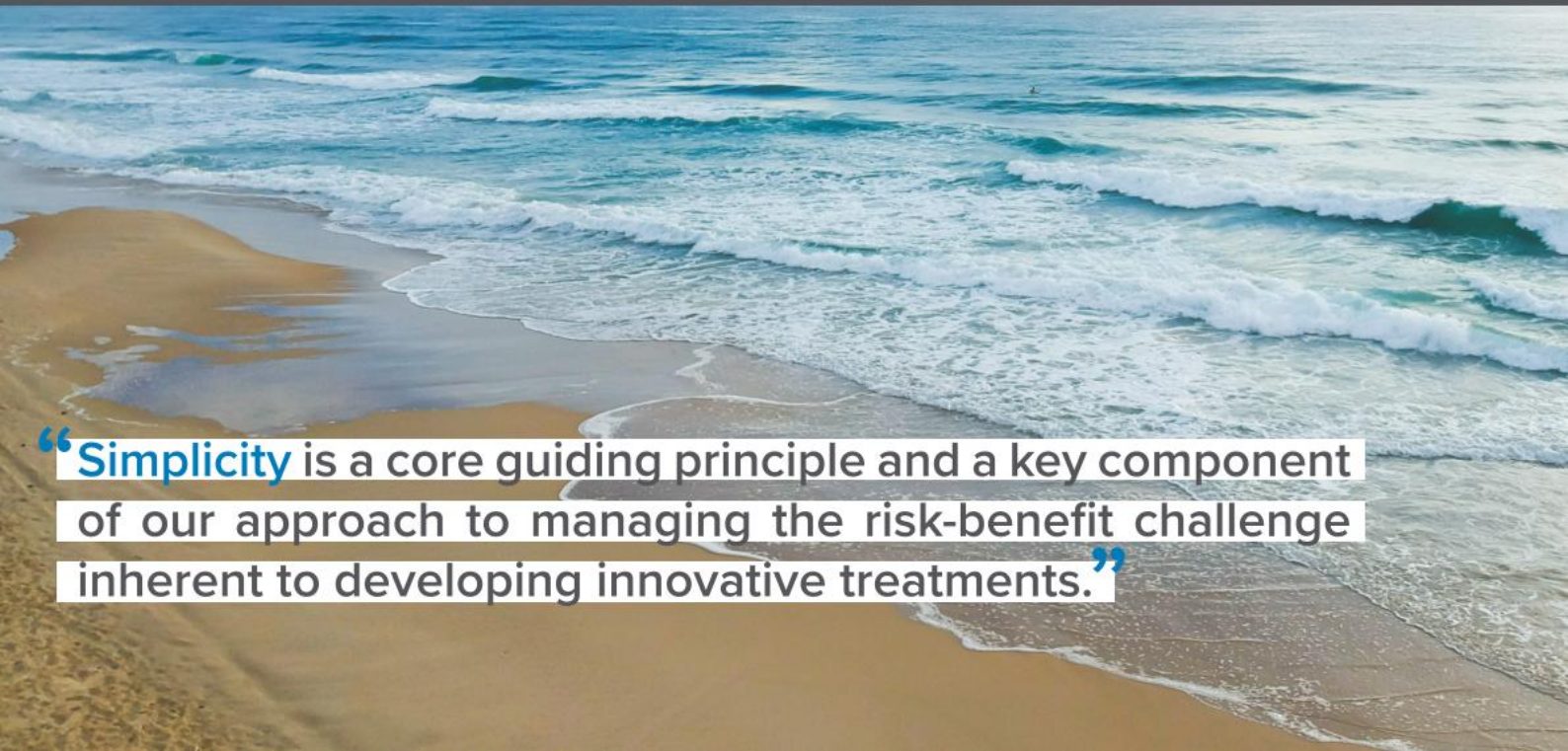
A polyglucosamine polymer

- has strong uses for biomedical applications such as wound healing and is one of the most abundant polysaccharides in nature.
- is a particularly suitable polymer base for a cartilage repair scaffold due to its good biocompatibility and chemical similarity to native joint macromolecules.
- enjoys a unique status as a natural cationic polysaccharide, which confers its bioadhesive property.



The JointRep® matrix is composed of completely deacetylated chitosan, also known as polyglucosamine.

At physiological pH, chitosan is partially cationic, which results in its bioadhesive property.



"**Simplicity** is a core guiding principle and a key component of our approach to managing the risk-benefit challenge inherent to developing innovative treatments."

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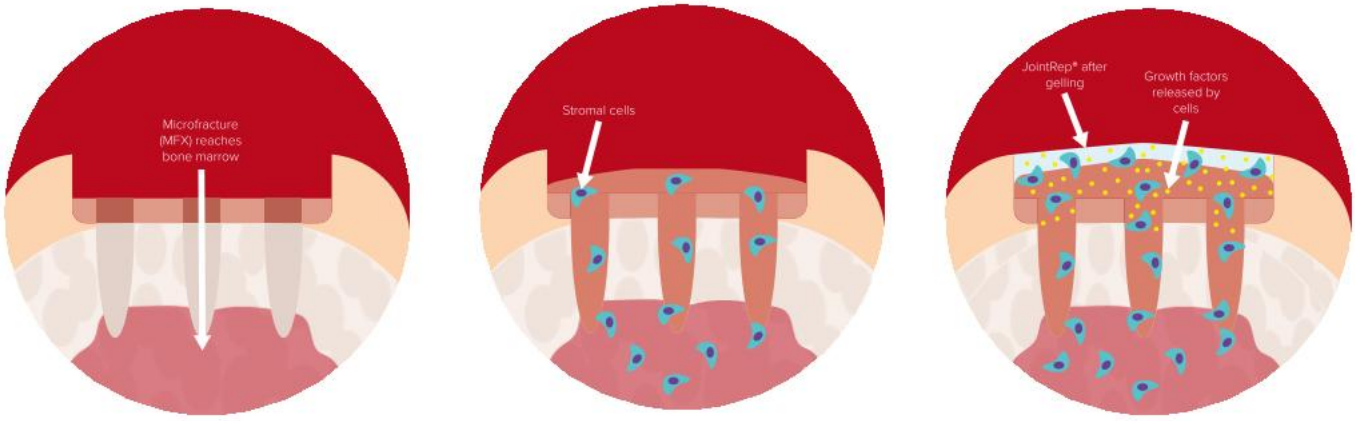
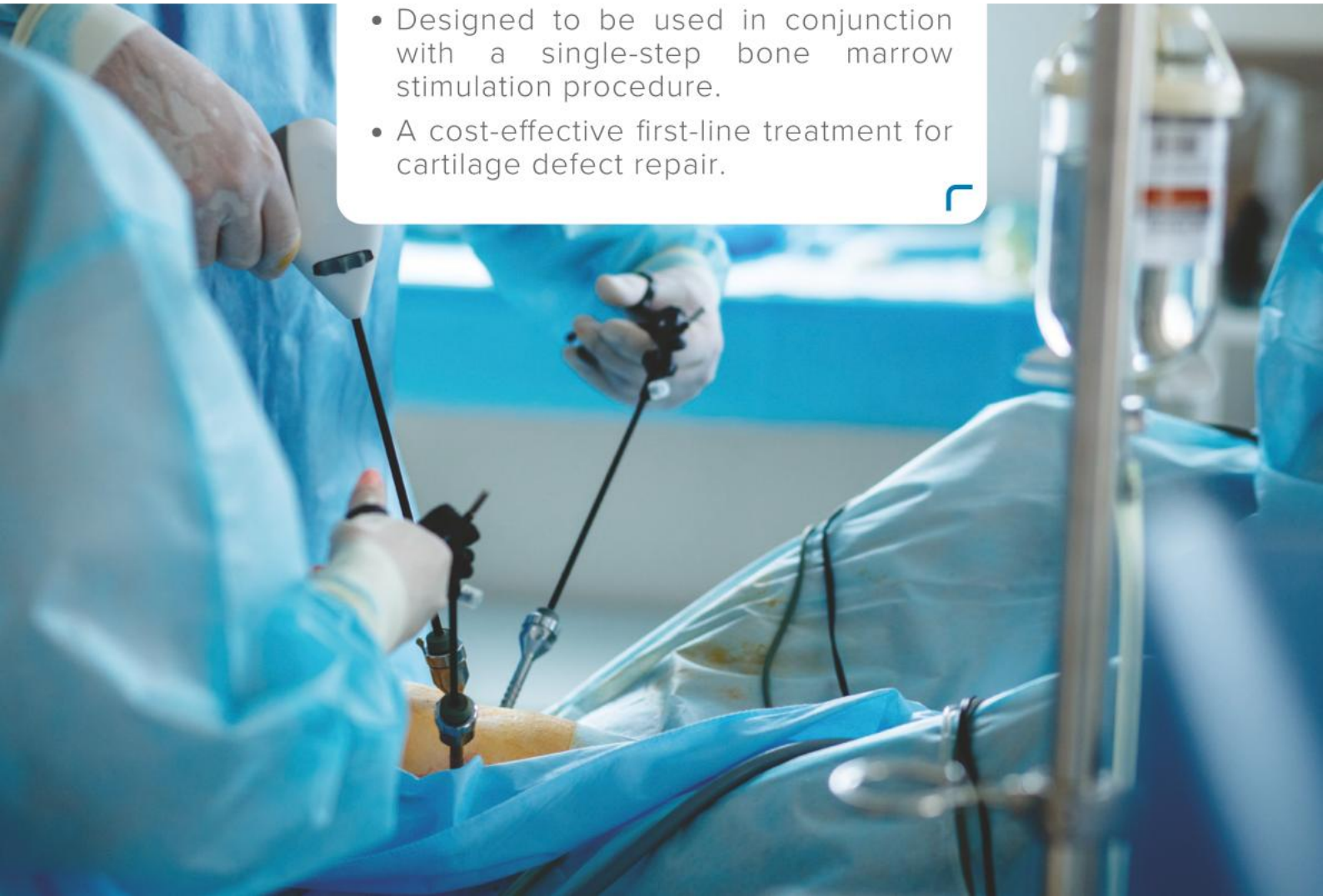


Transversal view: Joint+rep® protects the blood clot and acts as a bioscaffold for the stromal cells.

WHAT

- A second generation chitosan-based, easy to use arthroscopically-delivered bioscaffold.[6]
- Designed to be used in conjunction with a single-step bone marrow stimulation procedure.
- A cost-effective first-line treatment for cartilage defect repair.



WHY

Simplicity: Prepared in under one minute, JointRep® is an off-the-shelf solution injected to fill any shape defect (single or multiple lesions) with no wait time after implantation to begin closing.

Safety: Isotonic with neutral pH, non-toxic and highly biocompatible, JointRep® has been used in more than 7000 clinical cases as of 2021.

Efficacy: Improved consistency in clinical outcomes (vs MFX) through protection of the blood clot.

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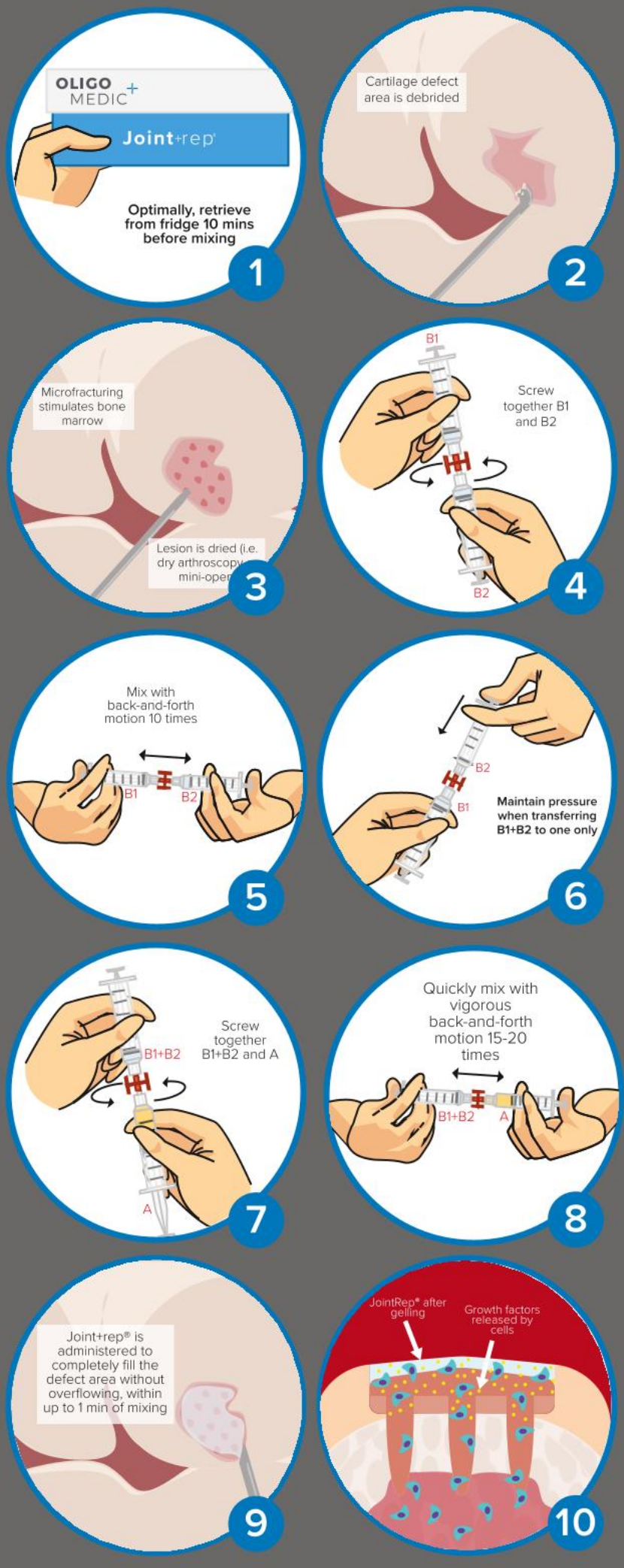
HOW

- Once mixed, JointRep® forms a flowable viscous gel and can be applied arthroscopically until the defect is filled up to every edge, easily adapting to any lesion shape, size and contour.[7]

  In adapting itself to the lesion (and not vice versa), JointRep® can preserve healthy cartilage from unneeded debridement.

- Adheres firmly to the lesion surface and surrounding cartilage rim due to its cationic nature.
- Helps to stabilize and protect the BMS generated clot, forming a "hybrid clot" and allowing for optimal healing outcomes in a BMS procedure.



Clinical Data

Microfractures and hydrogel scaffolds in the treatment of osteochondral knee defects: A clinical and histological evaluation, Pipino et al (2019)

A controlled post-market clinical study (Bologna University, Italy / LUdeS HEI, Switzerland / Stanford University, USA) comparing microfracture with JointRep (test group) versus standard arthroscopic microfracture alone (control group).

A total of 69 patients (46 test, 23 control) aged 18-75 having Outerbridge grade III or IV knee joint cartilage damage were enrolled.

01

Patient Inclusion

- No restriction on lesion size
- Associated conditions such as previous partial meniscectomy, cruciate ligament lesions or previous failed microfracture
- 18-75 year old patients

02

Primary Endpoint

- Clinical improvement assessed by the Western Ontario and McMaster Universities Arthritis Index (WOMAC) at 6, 12 and 24 months post-op
- Safety assessed by the recording of Adverse Events

03

Microfracture Technique

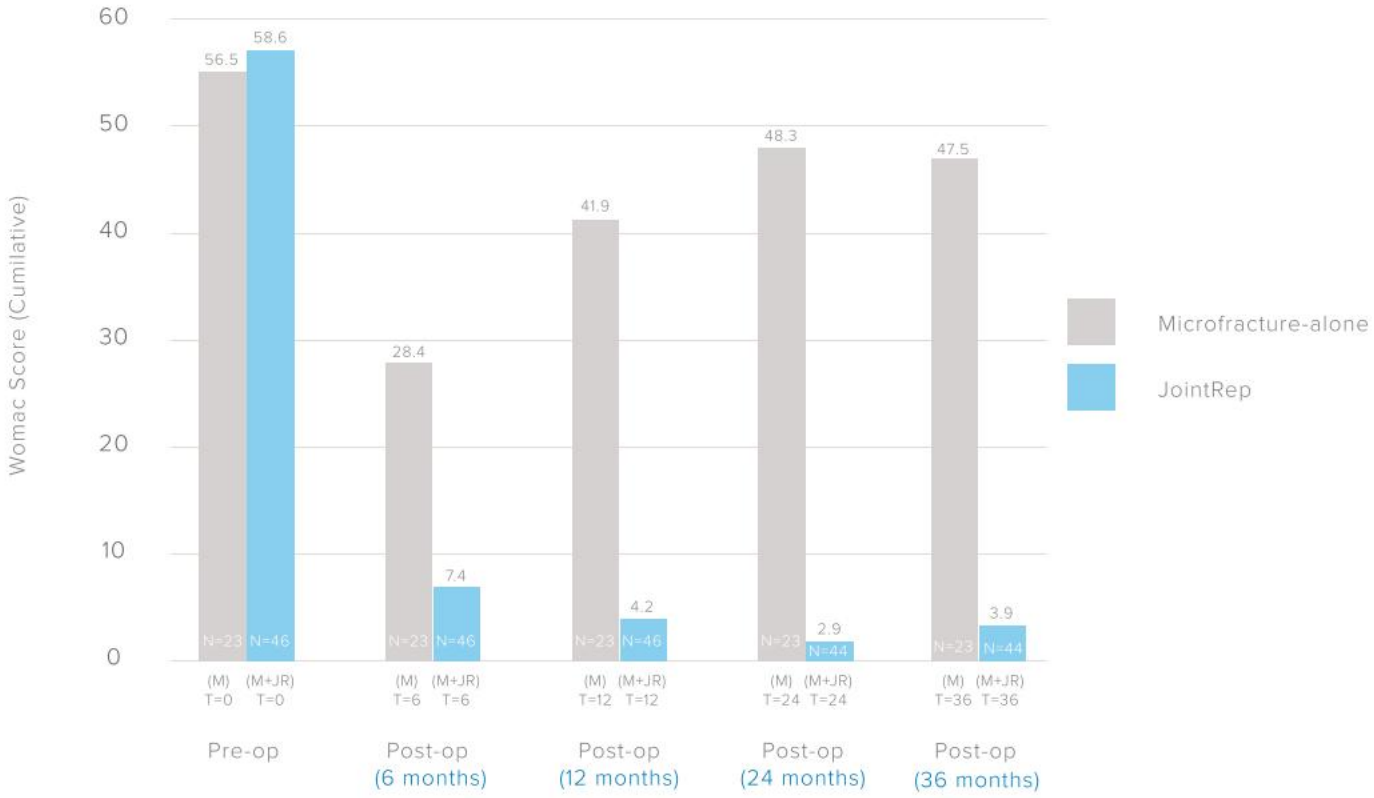
- Standard Steadman arthroscopic microfracture
- No autologous materials mixed with the device
- No special instruments utilised for administration of JointRep

04

Rehabilitation Program

- Following arthroscopy, all patients were first allowed to weight bear as tolerated (WBAT) immediately after the surgery: the use of a contralateral cane for 5-7 days postoperatively was suggested
- On day 15 post-op, the patients were allowed to start formal standard physical therapy, including quadriceps electro stimulation, swimming, and the use of a stationary bike for a reduced period of 3 weeks only.

Improved clinical outcomes for the JointRep Group at 6, 12, 24 and 36 months post-operation*



***up to 90%+ improvement in clinical outcomes sustained up to 36 months[6, 8]**

Patient Statistics and Defect Size

Patient Statistics				
	Study Group (JointRep + Microfracture)		**Control Group** (Microfracture alone)	
Total number of patients	N=46		N=23	
Patients, age	54.5 ± 9.5 (26 - 72)		56.6 ± 7.6 (44 - 70)	
Patients, gender	Male 29 (63%)	Female 17 (37%)	Male 11 (47.8%)	Female 12 (52.2%)
Treated knee	Right 25 (54.3%)	Left 21 (45.7%)	Right 19 (69.6%)	Left 4 (30.4%)
Grade (outerbridge)	III 10 (23%)	IV 36 (78%)	III 6 (39%)	IV 17 (61%)
Associated lesions	Lesion of Meniscus 98%	Patello-femoral 2%	Leison of Meniscus 100%	Patello-femoral 0%
Previous microfracture	1	0	0	0
Average defect size	2.8 cm^2	2.5 cm^2	2.7 cm^2	2.5 cm^2

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Case Study

Patient

- 23 y.o. male
- Isolated full thickness chondral lesion on lateral femoral condyle
- 5 cm^2 after debridement
- JointRep implanted after BMS

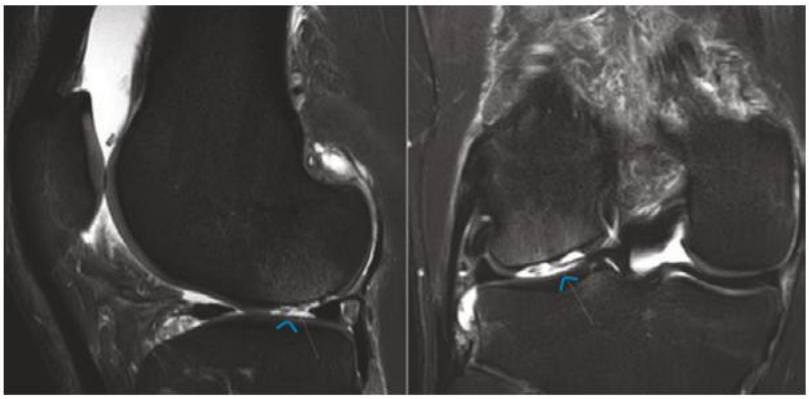
Surgeon

- Dr Mark Clatworthy
  Auckland Bone and Joint Surgery

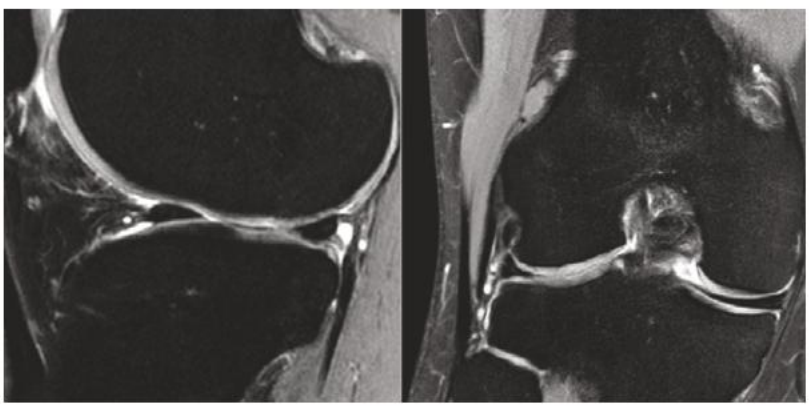
9 Month post-operative MRI

- Complete filling of lesion
- No bone marrow reaction beneath treated lesion

Pre op MRIs



Post op MRIs



JointRep®

- An off-the-shelf, 2nd generation chitosan-based hydrogel prepared in under one minute to complement a single-step bone marrow stimulation procedure that can be injected arthroscopically, filling even odd shaped defects (single or multiple lesions) with no wait time before closing.
- Helps to stabilize and protect the bone marrow stimulation-generated clot, forming a “hybrid clot” and allowing for optimized tissue healing within a properly prepared articular cartilage defect.
- Published clinical data demonstrating improved pain and functional outcomes VS microfracture-alone.

References

1. Medina J, Garcia-Mansilla I, Fabricant P, Kremen T, Sherman S, Jones K. Microfracture for the Treatment of Symptomatic Cartilage Lesions of the Knee: A Survey of International Cartilage Regeneration & Joint Preservation Society. Cartilage. 2020;00(0):1-8. doi:10.1177/1947603520954503

2. Widuchowski W, Widuchowski J, Trzaska T. Articular cartilage defects: Study of 25,124 knee arthroscopies. Knee. 2007;14(3):177-182. doi:10.1016/j.knee.2007.02.001

3. Furukawa T, Eyre D, Koide S, Glimcher M. Biochemical studies on repair cartilage resurfacing experimental defects in the rabbit knee. The Journal of Bone & Joint Surgery. 1980;62(1):79-89. doi:10.2106/00004623-198062010-00012

4. Frisbie D, Oxford J, Southwood L et al. Early Events in Cartilage Repair After Subchondral Bone Microfracture. Clin Orthop Relat Res. 2003;407:215-227. doi:10.1097/00003086-200302000-00031

5. Mithoefer K, Williams R, Warren R et al. The Microfracture Technique for the Treatment of Articular Cartilage Lesions in the Knee. The Journal of Bone & Joint Surgery. 2005;87(9):1911-1920. doi:10.2106/jbjs.d.02846

6. Pipino G, Risitano S, Alviano F et al. Microfractures and hydrogel scaffolds in the treatment of osteochondral knee defects: A clinical and histological evaluation. J Clin Orthop Trauma. 2019;10(1):67-75. doi:10.1016/j.jcot.2018.03.001

7. Please refer to the Instructions for Use (IFU) for a complete list of indications and contraindications

8. Pipino G, Vaccarisi D, Mardones R, Indelli PF. Articular Cartilage Lesion of the Knee: 3 Years Follow-up. 20th EFORT Annual Congress, Lisbon, Portugal. June 6th, 2019. Poster #2378.

OLIGO MEDIC+ was founded in 2010 by pioneers of chitosan as a material for biomedical applications, with over 25 years of experience developing medical devices

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