# + Evidence in focus

**Publication summary** 

# **Smith**Nephew

Patients treated with the CARTIHEAL AGILI-C Cartilage Repair Implant demonstrated significantly better clinical and radiographic outcomes, compared to standard of care (SOC), in a randomised controlled trial (RCT) of chondral and osteochondral lesions

Altschuler N, Zaslav KR, Di Matteo B, et al. Aragonite-based scaffold versus microfracture and debridement for the treatment of knee chondral and osteochondral lesions. Results of a multicenter randomised controlled trial. Am J Sports Med. 2023;51(4):957–967.

Available at: The American Journal of Sports Medicine



## Key points

Compared with SOC, treatment of chondral and osteochondral lesions treated with CARTIHEAL AGILI-C Implant at 2-year follow-up demonstrated:







#### Overview

- Multicentre RCT comparing the clinical and radiographic outcomes of CARTIHEAL AGILI-C Implant with SOC (microfracture or debridement)
- 251 patients affected by joint surface lesions of the knee, including patients with concurrent mild to moderate osteoarthritis (OA), were randomised to receive either:
  - CARTIHEAL AGILI-C Implant (n=167)
  - SOC (n=84) microfracture or arthroscopic debridement

- No differences in pre-operative patient characteristics
- Primary outcome was Knee Injury and Osteoarthritis Outcome Score (KOOS) overall, assessed at 6, 12, 18 and 24 months
- Secondary outcomes were KOOS subscales (Pain, Quality of Life [QoL], Activities of Daily Living [ADL]), responder rate (+ ≥30 KOOS overall) International Knee Documentation Committee (IKDC) score, MRI to assess defect fill grade assessed at 12 and 24 months, and failure rate (defined as any intervention in the treated joint, regardless if related or unrelated to the original treatment)

### Results

Compared to SOC, patients that received the CARTIHEAL AGILI-C Implant demonstrated:

- Post-operatively, KOOS overall showed a greater increase at all time points, with an increasing difference over time (Figure)
  - Greater post-operative change in KOOS pain, QoL and ADL
- Significantly higher IKDC scores than the minimal clinically important difference (MCID) at each time point (p<0.001)
- Significantly greater defect fill at 2-years
  - >75% defect fill: 88.5 versus 30.9% (p<0.0001)
  - >50% defect fill: 98.7 versus 50.0% (p<0.0001)
- Higher responder rate (77.8 vs 33.6%)
- Significantly lower failure rate overall (7.2 vs 21.4%; p=0.002)
- Greater improvement regardless of age (≥50 and <50 years), lesion size ( $\leq 3 \text{ vs} > 3\text{cm}^2$ ) and OA (KL 0-1 or 2-3)

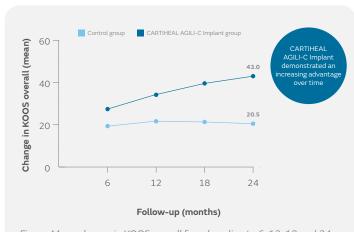


Figure. Mean change in KOOS overall from baseline to 6, 12, 18 and 24 months follow-up

## **Conclusions**

In a randomised controlled trial, patients with knee joint surface lesions treated with the CARTIHEAL AGILI-C Implant had significantly better clinical radiographic outcomes regardless of age, lesion size or presence of osteoarthritis, compared to patients treated with standard of care.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith+Nephew representative or distributor if you have questions about the availability of Smith+Nephew products in your area. For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.