**+ Evidence in focus**
**Publication summary**

Smith+Nephew

# The CARTIHEAL◊ AGILI-C◊ Cartilage Repair Implant demonstrated significantly better outcomes at 4 years for knee cartilage defects regardless of lesion location compared to surgical standard of care (SSOC)

Conte P, Anzillotti G, Crawford DC, et al. Differential analysis of the impact of lesions' location on clinical and radiological outcomes after the implantation of a novel aragonite-based scaffold to treat knee cartilage defects. *Int Orthop*. 2024;48(12):3117–3126.

Available at: International Orthopaedics

## Key points

In a RCT conducted for FDA approval, compared to SSOC, CARTIHEAL AGILI-C Implant at 4 years demonstrated:

**Significantly greater improvement** in KOOS overall score, **regardless of lesion location** and **absence** or **presence** of OA

**Significantly greater improvement in PROMs** across each lesion location

**87%** Significantly **lowers risk** of TKA or osteotomy

## Overview

- Multicentre randomised controlled trial (RCT) treating cartilage defects in the femoral condyles and trochlea comparing the clinical and radiographic outcomes of the CARTIHEAL AGILI-C Implant with SSOC
- 247 patients, including patients with concurrent mild to moderate osteoarthritis (OA; Kellgren-Lawrence grade 0–3) were randomised to receive either:
  - CARTIHEAL AGILI-C Implant (n=164)
  - SSOC (n=83; microfracture or debridement)
- Primary outcome was the change in Knee Injury and Osteoarthritis Outcome Score (KOOS) overall from baseline to last follow-up (48 months)
- Secondary outcomes included patient-reported outcomes (PROMs): KOOS subscales (Symptom, Pain, Function, Sport, Quality of Life [QoL]), International Knee Documentation Committee (IKDC) score, responder rate (>30 point improvement in KOOS overall), failure rate (defined as any secondary intervention, including injections, TKA and osteotomy) all at 48 month follow-up and defect filling on MRI at 12 and 24 months
- Sub-analysis of outcomes by lesion location; condylar (n=137), trochlear (n=48) and mixed lesions (n=62)

## Results

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

- Significantly higher KOOS overall score in condylar defects, trochlear defects and mixed-lesions at 48 months (all p<0.05; Figure)
  - The absense or presence of OA did not affect the greater performance of CARTIHEAL AGILI-C Implant
- Significantly higher IKDC scores in all lesion locations at 24 and 48 months (all p≤0.001)
- Significantly superior imaging outcomes at 24 months showing ≥75% defect fill:
  - 93.9% in condylar defects (vs 39.0%; p<0.0001)
  - 62.5% in trochlear defects (vs 18.2%; p=0.012)
  - 97.6% in mixed lesions (vs 18.8%; p<0.0001)
- Significantly higher responder rate in all lesion locations at 24, 36 and 48 months (all p≤0.004)
- Significantly lower failure rate in condylar defects and mixed lesions at 48 months (p=0.001 and p≤0.017, respectively)
  - Numerically lower, but not statistically significant, failure rate in trochlear defects
- Significantly fewer patients required a TKA or osteotomy at 48 months (1.2% vs 9.5%; p=0.003)

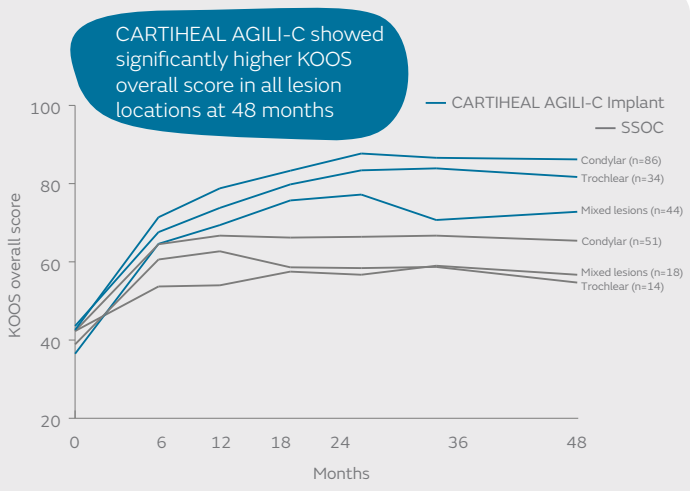


*Figure. KOOS overall scores for condylar, trochlear, and mixed lesions from baseline to latest follow-up*

## Conclusions

In a randomised controlled trial, patients with knee cartilage defects treated with the CARTIHEAL AGILI-C Implant had significantly better clinical and radiographic outcomes regardless of lesion location or presence of osteoarthritis, compared to patients treated with microfracture or arthroscopic debridement at 4 years post-operatively.



Sports Medicine, Smith & Nephew, Inc., 150 Minuteman Road, Andover MA, 01810, USA.
46599-en V1 02/25. February 2025. 

Developed by Evidence Communications, Global Clinical & Medical Affairs
www.smith-nephew.com