






Five-year outcomes from a multicentre knee repair randomised control trial (RCT): CARTIHEAL[◇] AGILI-C[◇] Cartilage Repair Implant compared with standard of care (microfracture or debridement)

Altschuler N, Zaslav KR, Di Matteo B, et al. Five-year follow-up of a multicentre randomised controlled trial comparing an aragonite-based scaffold with microfracture and debridement for chondral and osteochondral knee lesions. *Am J Sports Med.* Published online April 16, 2026. doi:10.1177/03635465261437781

Available at: [The American Journal of Sports Medicine](#)  

Compared with surgical standard of care (SSOC; microfracture or debridement), knee cartilage defects treated with the CARTIHEAL Implant demonstrated:

 <p>Significantly greater improvement* in KOOS overall score (p<0.001)</p>	 <p>81%</p> <p>Significantly lower relative risk of knee replacement or osteotomy (p=0.008)</p>	 <p>Click or scan the QR code</p>
 <p>2x greater reduction in pain as measured by KOOS pain sub-score (p<0.001)</p>	 <p>No difference in outcomes in both osteoarthritis (OA) and non-OA patients</p>	

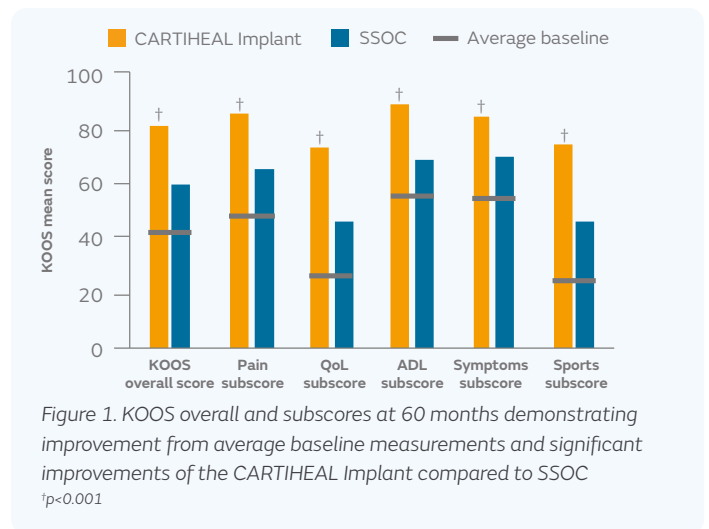
Study overview

- A five-year, prospective, multicentre RCT evaluated the clinical and safety outcomes of the CARTIHEAL Implant compared with SSOC in patients with knee cartilage defects
- Adults aged 21–75 years with up to three cartilage defects (ICRS grade 3A or higher) and a total treatable area of 1–7 cm²
- 251 patients were randomised, including patients with concurrent mild to moderate OA (Kellgren–Lawrence grade 0–3). The full analysis set included:
 - CARTIHEAL Implant (n=164)
 - SSOC (n=83)
- Primary outcome was the change in average overall Knee Injury and Osteoarthritis Outcome Score (KOOS) from baseline to 60 months
- Secondary outcomes included:
 - Change in KOOS subscales from baseline to 60 months (Symptoms, Pain, activities of daily living [ADL], Sports, Quality of Life [QoL])
 - Responder rate (≥30-point improvement in KOOS overall) at 60 months
 - Failure rate (re-intervention) and safety

Results

Compared with SSOC, patients who received the CARTIHEAL Implant demonstrated at 60 months:

- Significantly greater improvement in overall KOOS (mean score: 81.0 vs 59.1; p<0.001)
- Higher KOOS scores at all post-operative follow-up time points (p<0.001)
- A more than two-fold higher responder rate (≥30-point improvement in KOOS overall score) at 24 months, sustained at 60 months
- Significantly greater improvements across all KOOS subscales, including pain, symptoms, ADL, sports, and QoL (Figure 1)



*The Bayesian posterior probability of superiority was >0.999

Five-year follow-up: treatment failures and re-interventions

Compared with SSOC, knee cartilage defects treated with the CARTIHEAL[®] Implant demonstrated:



>50% lower incidence of treatment failure and re-intervention (surgery and/or injection; $p < 0.001$; Figure 2)

81%

Significantly lower relative risk of knee replacement or osteotomy ($p = 0.008$)

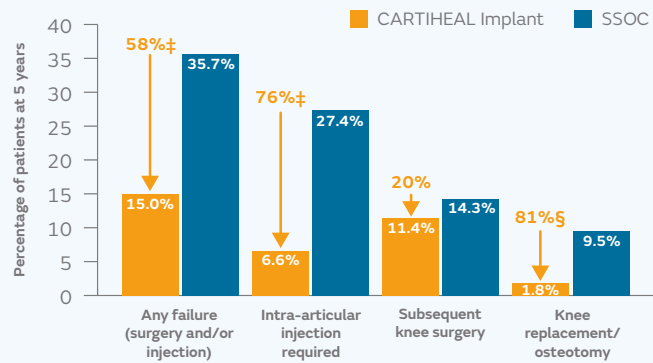


Figure 2. Percentage reduction: Treatment failures, intra-articular injections required, and need for knee replacement or osteotomy were significantly lower in patients who received the CARTIHEAL implant compared with SSOC, with a trend towards reduced subsequent knee surgery

[‡] $p < 0.001$. [§] $p = 0.008$

Five-year data demonstrated significant improvements for patients with OA, comparable to non-OA patients

In OA patients, the CARTIHEAL Implant group had greater mean improvements in all KOOS subscale scores between baseline to 60 months compared to those in the SSOC group ($p < 0.05$).[†]

In a prespecified subgroup analysis, patients who received the CARTIHEAL Implant with mild-to-moderate OA (Kellgren–Lawrence grade 2–3) experienced improvements in KOOS outcomes comparable to those observed in patients without OA (Kellgren–Lawrence grade 0–1).

Table 1. Comparison of the outcomes for the two OA subgroups in the CARTIHEAL Implant group

	KOOS change	Response rate at 5 years
Group 1, n=90 (Kellgren–Lawrence 0–1)	+39.4 points	74.7% (59/79)
Group 2, n=74 (Kellgren–Lawrence 2–3)	+39.8 points	74.6% (50/67)

[†]There was no evidence that superiority margin was based on degree of OA ($p = 0.842$).

Both subgroups demonstrated similar response rates (at least a 30-point improvement in KOOS overall score at 60 months), (Table 1).

Equivalent outcomes were observed between the subgroup who received the CARTIHEAL Implant regardless of OA status



- Sustained pain reduction
- Functional improvement
- QoL improvements
- Likelihood of a clinically important response

Conclusion



In a five-year multicentre randomised control trial, the CARTIHEAL Implant delivered durable, clinically meaningful improvements in pain, function and quality of life compared with surgical standard of care, with lower rates of treatment failure and fewer reinterventions. For patients with chondral/osteochondral knee lesions and mild-to-moderate osteoarthritis, CARTIHEAL Implant may be a suitable approach.

Abbreviations: KOOS = Knee Injury and Osteoarthritis Outcome Score; OA = osteoarthritis; RCT = randomised controlled trial; SSOC = standard of surgical care.

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