+ Evidence in focus
Publication summary

Smith+Nephew

CARTIHEAL◊ AGILI-C◊ Cartilage Repair Implant for the treatment of joint surface lesions in mild-to-moderate osteoarthritic knees: two-year outcomes

Kon E, Di Matteo B, Verdonk P, et al. Aragonite based scaffold for the treatment of joint surface lesions in mild to moderate osteoarthritic knees. *Am J. Sports Med.* 2021;49(3):588–598.

Available at: American Journal of Sports Medicine

Key points

Compared to baseline, patients with **osteoarthritis (OA),** treated with the CARTIHEAL Implant demonstrated:

Significant improvement in **KOOS overall, KOOS subscales*** and **IKDC subjective score** (p<0.001) at 24 months

Significant increase in defect area **covered by cartilage (up to 78.7%±25.3%; p<0.001 vs 6 months)**

Histology showed **newly formed hyaline cartilage,** rich in collagen type II, **integrated with adjacent native tissue**†

Overview

- A prospective multi-centre (8 European centres) case series evaluated the clinical, functional and radiological outcomes of patients treated with the CARTIHEAL Implant.
  - 86 patients (mean age 37.4 years)
  - Mild-to-moderate OA (KL grade 2–3)
  - Up to three chondral or osteochondral joint surface lesions (ICRS grade 3–4)
  - Mean defect size 3.0 cm²
  - Defects located on the femoral condyles and/or trochlea
- Patients were followed for 24 months, with outcomes assessed using Knee Injury and Osteoarthritis Outcome Score (KOOS), International Knee Documentation Committee (IKDC) subjective score, and magnetic resonance imaging (MRI) for defect fill
- The primary endpoint of the study was the change in the KOOS value from baseline to 24 months
- Failure was defined as implant removal for any reason during the follow-up period

Results

Compared to baseline, measures at 24 months follow-up, patients reported:

- Clinically meaningful improvement in knee function, with KOOS overall increasing from 41.5 at baseline to 71.4 (p<0.001)
- Significant improvement across all KOOS subscales (Pain, Symptoms, ADL, Sport, QoL) compared with baseline (Figure; all p<0.001
- Significant improvement in IKDC subjective score, increasing from 37.8 to 65.8 (p<0.001)
- Progressive cartilage defect fill on MRI, reaching a mean 78.7% surface coverage
- Comparable clinical improvements in patients with KL grade 2 and grade 3 OA
- A treatment failure rate of 9.3% (implant removal) was observed

Histological evaluation (single explanted specimen) demonstrated:

- Hyaline cartilage rich in collagen type II
- Restoration of subchondral bone architecture
- Evidence of osteoconduction and osteotransduction

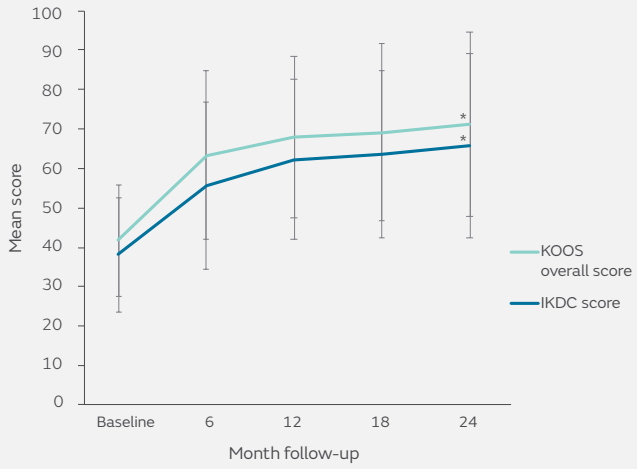


Figure. Continued improvement of overall KOOS and IKDC subjective scores at baseline, 6, 12, 18 and 24-months follow up
**Significant improvement compared to baseline (p<0.001).*

Conclusions

In a difficult-to-treat patient population, treatment with the CARTIHEAL Implant resulted in meaningful clinical improvement in patient-reported outcomes as early as 6 months and continued through 24 months. MRI demonstrated ongoing CARTIHEAL Implant integration and defect filling over time, consistent with regeneration of the osteochondral unit.

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*KOOS subscales: pain, symptoms, ADL, QoL and sport. †Histology of an explant specimen from one patient.
Abbreviations: ADL = activities of daily living; ICRS = International Cartilage Repair Society; IKDC = International Knee Documentation Committee; KL = Kellgren Lawrence; KOOS = Knee Injury and Osteoarthritis Outcome Score; MRI = magnetic resonance imaging; OA = osteoarthritis; QoL = quality of life.

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