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CLINICAL EVIDENCE SERIES

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Long-term pain relief and functional recovery after one-step cartilage repair with Hyalofast plus BMAC - successful outcomes maintained up to 14 years post-surgery

Introduction

Articular cartilage injuries can severely impact joint function and overall quality of life. Left untreated, these lesions often progress to advanced degeneration requiring total joint replacement. Several techniques have been developed to preserve joint function, including bone marrow stimulation, osteochondral grafting, cell-free scaffolds, and cell-based regenerative techniques.[1, 2, 3] Although traditional regenerative options like ACI/MACI, demonstrated the ability to restore durable articular cartilage tissue, they involve multiple surgeries, high costs, and regulatory barriers due to cell culture requirements.

Hyalofast is a scaffold made of hyaluronic acid fibers which, combined with Bone Marrow Aspirate Concentrate (BMAC), offers a single-step regenerative alternative. Clinical studies have demonstrated promising outcomes for both knee and ankle cartilage repair.[4, 5] Imaging and histological data reveal the formation of hyaline-like cartilage tissue, suggesting long-lasting improvement in joint function and symptom relief.[6,7,8,9]

While short and mid-term evidence is encouraging, long-term outcomes are essential, especially for active patients undergoing surgery at a young age. Here we present main clinical findings showing sustained pain reduction and functional stability for up to 14 years post-treatment using the Hyalofast plus BMAC approach. The investigation was conducted by the OASI (Orthopedic Arthroscopic Surgery International) Bioresearch Foundation group (Milan, Italy) and published in two clinical peer-reviewed articles.[10, 11]

Key Highlights

Significant and Durable pain relief and improved joint function maintained over the long term
(mean follow-up of 14 years)

Kaplan-Meier survival analysis showed durable clinical results:

- 92% survival rate at 5 years
- 88% survival rate at 10 years
- 88% survival rate at 14 years

Overview

Hyalofast plus BMAC represents a reliable single-step cartilage repair technique for treating full-thickness knee cartilage lesions as described in previous studies, on the same patient population with effectiveness up to 8 years.[10]

Objective: assess the effectiveness of Hyalofast plus BMAC to provide a stable improvement over time.

Study Design: prospective case series with 26 patients treated between April 2007 and January 2012

Inclusion Criteria:

- Grade 4 knee cartilage lesion (ICRS criteria)
- Defect size ≥ 1 cm^2
- Age: 30–60 years old
- BMI (Body Mass Index): 20–30
- Active lifestyle (≥ 2 sport sessions/week)

Follow-Up Duration: 12–16 years (mean 14 years)

Clinical Evaluation Tools:

- KOOS (Knee injury and Osteoarthritis Outcome Score)[12]
- VAS (Visual Analogue Scale)

Study Results

Patients
26 (mean age 48.3)
Median lesion size 6.6cm²

Follow-up
Mean 14 years
Lost to follow-up:
4 pts

Pain Relief
VAS Pain decreased from 5.0 pre-op to 0.3 at 8 years, remaining almost stable at 14 years (0.6)
(P<.001) Table 1, Fig 1

KOOS
All subscales improved almost stable, when compared 14-year values to 8-year data
(P<.001) Table 1, Fig 2

Durability
Survival rate:
5 years: 92%
10-14 years: 88%
Fig 3

TABLE 1

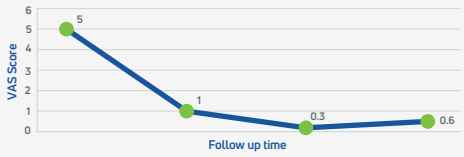
Comparison of clinical outcome scores at each follow up time point.[10, 11]

Score Type	Mean Score Values				P Value
KOOS	Pre-op (N=26)	2 years (N=23)	8 years (N=23)	14 years (N=22)	Pre-op vs 14 y
Sport	30	78	85	85	<0.001
Pain	57	94	94	92	<0.001
Symptoms	60	91	89	86	<0.001
ADL	65	95	99	96	<0.001
QOL	25	83	85	88	<0.001
VAS	5	1	0.3	0.6	<0.001

ADL activities of daily living; KOOS, Knee injury and Osteoarthritis Outcome Score; QOL, quality of life; VAS, visual analog scale.

FIGURE 1

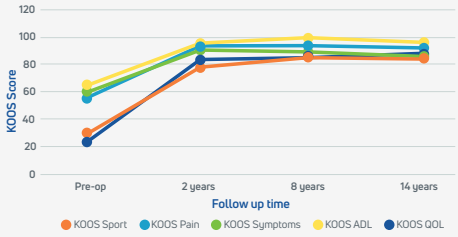
VAS from baseline to final mean follow-up (14 years)



VAS, visual analog scale

FIGURE 2

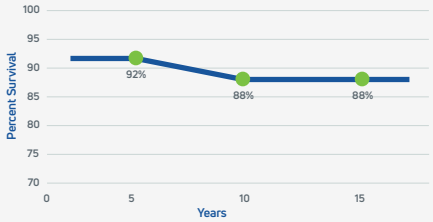
KOOS subscales from baseline to mean final follow up (14 years)



ADL activities of daily living; KOOS, Knee injury and Osteoarthritis Outcome Score; QOL, quality of life

FIGURE 3

Kaplan-Meier survival plot after treatment of full thickness knee chondral injury with Hyalofast scaffold and BMAC



Conclusion

One-step cartilage repair using Hyalofast combined with BMAC delivers proven, long-term successful clinical results for full-thickness knee chondral defects. Clinical outcomes demonstrated sustained pain relief and preserve joint function over an average follow-up of 14 years, underscoring the durability and stability of this regenerative treatment.

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