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CLINICAL EVIDENCE SERIES

Real-world evidence, real-world impact.

Long-term outcomes: Hyalofast plus BMAC for osteochondral lesions of the talus

Durable results maintained for a minimum of 10 years

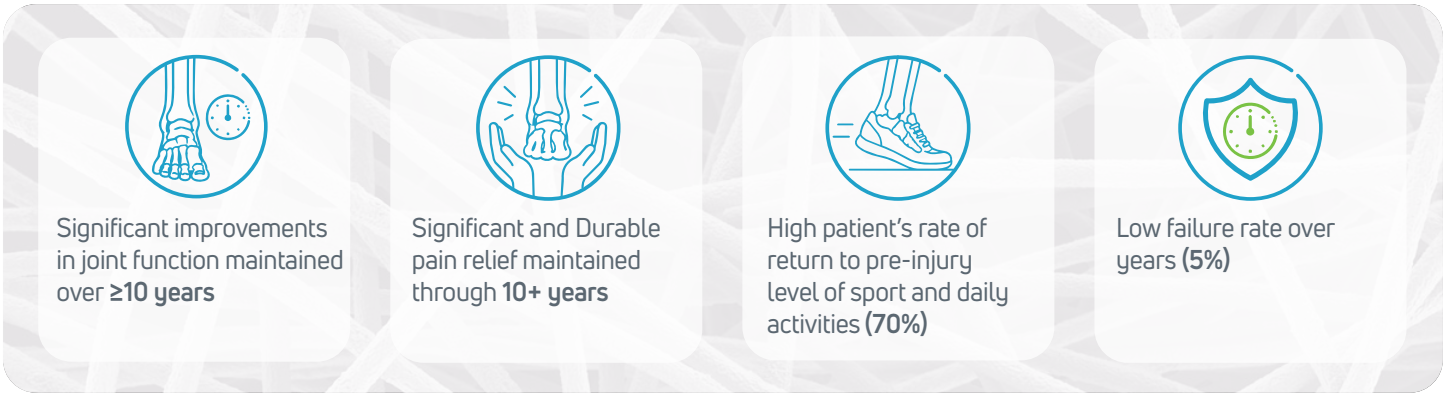
Introduction

Osteochondral lesions of the talus (OLT) can cause chronic ankle pain, instability, and progressive joint degeneration. Traditional approaches such as bone marrow stimulation, osteochondral grafting, or cell based techniques can provide relief but carry limitations, including compromised repair tissue quality, the need for multiple surgeries and high costs and regulatory barriers due to cell culture requirements[1,2,3].

Hyalofast® is a hyaluronic acid-based non-woven scaffold which, combined with Mesenchymal Stem Cells (MSCs), offers a single-step regenerative alternative. While short and mid term evidence for this technique has shown promising results in ankle lesions[4,5,6,7,8], long-term outcomes are essential for OLT treatments since patients undergoing surgery are often young and are expected to maintain an active lifestyle for many years.

Here we present main clinical findings, up to a minimum of 10 years follow-up, of OLTs treated using the Hyalofast plus BMAC approach. The clinical investigation was conducted at the Rizzoli Orthopedic Institute (Bologna, Italy) and published in 2023 in a clinical peer-reviewed article by Dr. F. Vannini et al[9].

Key Highlights



Overview

Objective: Assess the long-term effectiveness of using Hyalofast plus BMAC application for the treatment of OLTs to provide a significant improvement stable over time.

Study design: Prospective case series

Population: 120 consecutive patients affected by symptomatic OLTs, enrolled from 2006 to 2012

Exclusion criteria

- Patients younger than 12 years and patients older than 60 years
- Patients with moderate/severe osteoarthritis
- Patients with kissing lesions
- Patients with rheumatoid arthritis

Follow-up duration: Patients were evaluated at baseline, at 2 years, 5 years, and at a minimum of 10 years after treatment

Clinical evaluation tools

- AOFAS (American Orthopaedic Foot & Ankle Score) for functional outcome
- NRS (Numeric Rating Scale) for pain
- TEGNER score for the sports activity level at baseline and at the last follow-up
- PATIENT SATISFACTION LEVEL: collected at final follow-up
- FAILURES: a Kaplan–Meier survival analysis was performed to check the survival to failure up to the final follow-up

Study Results

Patients

- **101 patients** followed for a mean of **12.5** years (minimum 10 years)
- Mean age **33 years**
- Mean lesion size **2.2 cm²**

Pain Reduction (NRS)

- Pain **decreased significantly** at all follow-up stages compared to the baseline evaluation: (Fig. 1, table 1), going from **7.0 pre-operatively** to **3.9 at final follow-up**
- Significant improvement maintained through **10+ years**

Functional Recovery (AOFAS)

- Ankle functionality **significantly improved** (Fig. 2, table 1) from **59.6** at baseline to **82.3** at the final follow up
- Significant functional improvement is maintained through **10+ years**

Patient satisfaction

- **85%** of patients considered their health status "satisfactory" at the final long-term follow-up

Failure Rate

- **5%** failure rate over a minimum of **10 years**. (Fig. 3): 3 patients required ankle replacement (at 8, 10, and 11 years) while 2 patients had to repeat the same surgical procedure (at 14 months and at 10 years)

Return to Sport / Activity Level

- At the last follow-up, **70%** of patients returned to their pre-injury activity level
- Tegner activity score at the final follow-up improved significantly versus baseline ($p < 0.0005$)

TABLE 1 **Comparison of clinical outcome scores at each follow up time point**

Score Type	Score Values				P Value
	Pre-op	2 years	5 years	≥10 years	Pre-op vs ≥10 y
AOFAS	59.6	88.1	84.1	82.3	<0.0005
NRS Pain	7	3.4	2.8	3.9	<0.0005

Fig.1 NRS Pain from baseline to final mean follow-up (12.6 years)

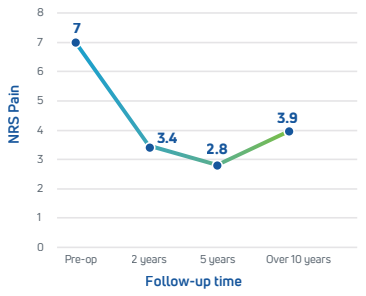


Fig.2 AOFAS Score from baseline to final mean follow-up (12.6 years)

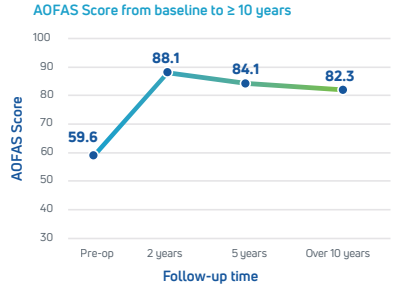
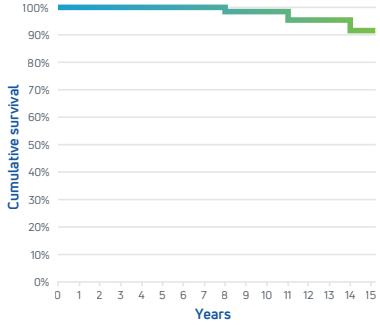


Fig.3 Kaplan–Meier curve for failure survivorship



Conclusion

One-step Hyalofast scaffold transplantation combined with BMAC yields highly satisfactory long-term outcomes and a low failure rate for patients with osteochondral lesions of the talus (OLT). Although a slight clinical decline is observed over time, partially due to the natural reduction of physical activity associated with aging[10–13], 85% of patients remained highly satisfied, and their overall clinical status at the final follow-up was still significantly better compared to their preoperative baseline.

Ultimately, these results are comparable with those obtained in a population of 15 patients with OLT treated with matrix-induced autologous chondrocyte implantation (MACI) and evaluated at 12 years of follow-up[14]. This further confirms the benefits of Hyalofast technique, with the advantages of a one-step approach and satisfactory results demonstrated in a large patient population.

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