CLINICAL STUDY OVERVIEW

Healvisco® Tendon in Rotator Cuff Tendinopathy

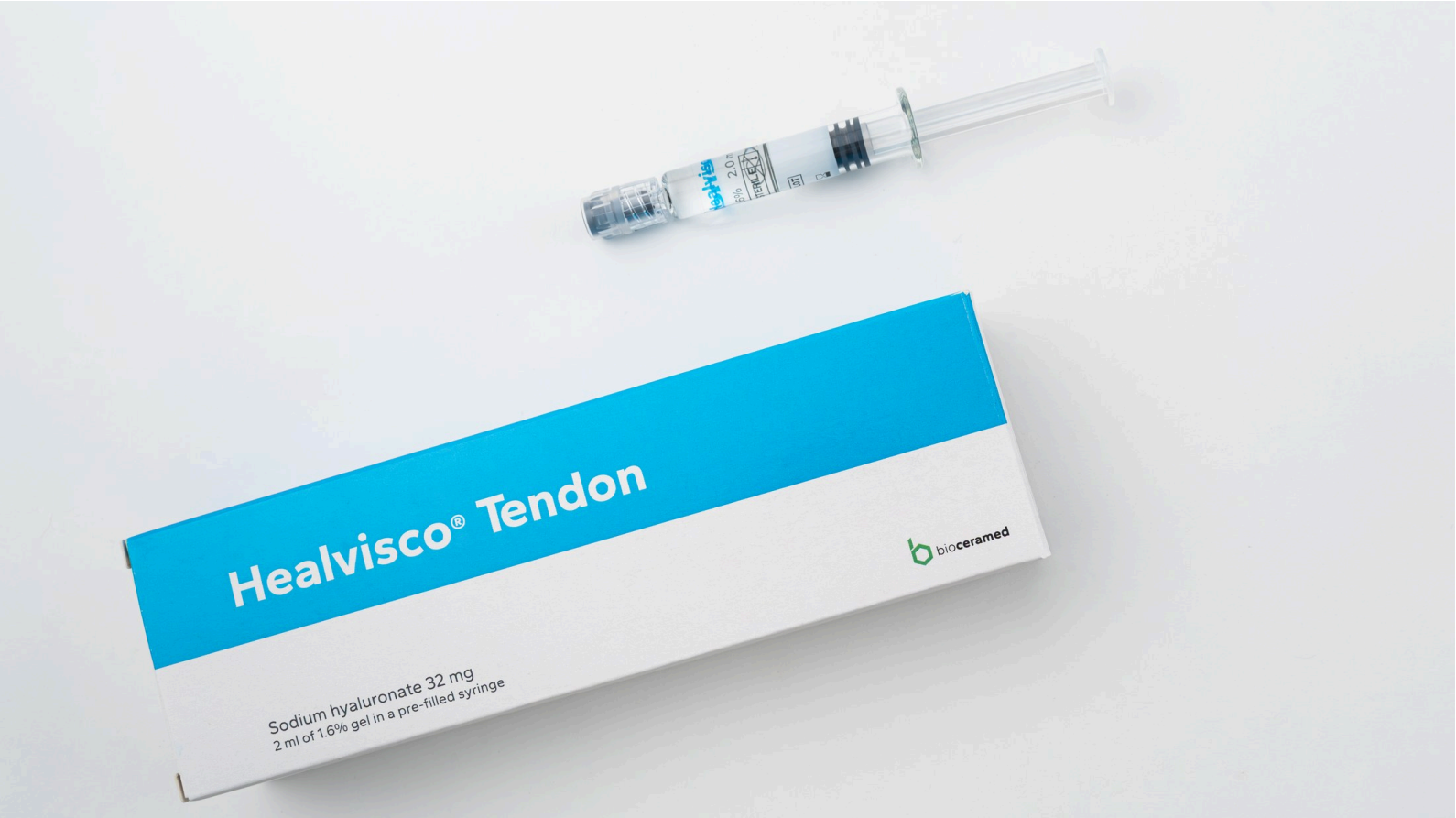
Twelve-month results from a prospective study of two peritendinous hyaluronic acid injections in patients with shoulder pain due to rotator cuff tendinopathy.

STUDY DEVICE

Biolevox™ HA TENDON, manufactured by Biovico Sp. z o.o. and distributed by Bioceramed as Healvisco® Tendon.

STATUS

Completed, follow-up to twelve months. Single centre, 10 patients enrolled.



01 • AT A GLANCE

Two Injections.
Twelve Months of Follow-Up.

Ten patients with rotator cuff tendinopathy received two peritendinous injections of 1.6% sodium hyaluronate, seven days apart. Pain and upper limb function were assessed across seven time points over one year.

FOLLOW-UP

12 months

Assessments at 1, 2, 3, 6, and 12 months after the second injection.

TREATMENT

2 HA injections

Peritendinous, seven days apart. No further injections during follow-up.

SAFETY

0 AEs

No adverse events, serious adverse events, infections, or allergic reactions were reported.

OUTCOME

VAS (Visual Analogue Scale) and DASH (Disabilities of the Arm, Shoulder and Hand questionnaire) scores both decreased already after the first injection, one week after the first administration. Both improved significantly from 60 days onward, and the paired comparison between baseline and 360 days remained statistically significant for both scales.

COMPLETION

7/10

Patients completed follow-up. Three were lost after declining further contact.

Read this alongside the study design. This was a single-arm study in ten patients at one centre, with no comparator group. The full set of limitations is set out in section 08.

02 • CONTEXT

The Shoulder That Does Not Settle

Shoulder pain is described in the literature as the third most common musculoskeletal complaint. Rotator cuff tendinopathy (RCT) is one of its most frequent causes, presenting with pain and weakness during external rotation and arm elevation.

The condition is often resistant to treatment. Its causes are considered multifactorial, combining extrinsic mechanical compression with tendon overuse or overload from repetitive overhead movement. Published data report that a substantial proportion of patients do not respond to exercise-based conservative therapy.

Injectable hyaluronic acid has been investigated in this setting, with reported attention to pain reduction and functional improvement. This document summarises the twelve-month results of one prospective study in that context.

THE DEVICE

Healvisco® Tendon

A sterile, non-pyrogenic, viscoelastic, transparent injectable hyaluronic acid gel for single use. Sodium hyaluronate of non-animal origin, obtained by biofermentation.

Presentation	32 mg sodium hyaluronate
Volume	2 mL of 1.6% gel
Format	Pre-filled syringe, single use
Classification	Class III, MDD 93/42/EEC, Annex IX Rule 8
Manufacturer	Biovico Sp. z o.o., Gdynia, Poland

INDICATION FOR USE

Healvisco® Tendon is indicated for pain and reduced mobility in tendon disorders caused by injury, such as tendon strain, or by overload changes, such as tennis elbow and rotator cuff tendinopathy. Duration up to six months. Refer to the Instructions for Use for full indications, contraindications, warnings, and precautions.

03 • METHOD

Study Design

Design	Prospective, single-centre, single-arm study
Population	10 patients with shoulder pain due to rotator cuff tendinopathy (RCT)
Site	Trauma and Orthopedic Surgery Clinic, Kielce, Poland
Treatment protocol	Two peritendinous injections at a seven-day interval. 2 mL per administration, applied around the injured site using a fanning technique
Product parameters	2 mL of 1.6% sodium hyaluronate, molecular weight 1400 to 1600 kDa
Follow-up	1, 2, 3, 6, and 12 months after the second administration
Pain endpoint	Visual Analogue Scale (VAS)
Function endpoint	Disabilities of the Arm, Shoulder and Hand questionnaire (DASH)
Safety	All patients monitored for adverse events related to the treatment
Statistics	Results presented as column bar graph and scatter plot, as mean values with standard deviation. Analysis performed in GraphPad Prism v.9.0.0 using the Friedman test and the Wilcoxon test

PATIENT PROFILE

Median age 59 ± 8.1 years. Half of the cohort was female. All patients presented with shoulder pain attributed to rotator cuff tendinopathy.

FOLLOW-UP

Three of the ten enrolled patients were lost during the follow-up period after declining further contact. Seven patients completed the twelve-month schedule.

The two scales measure different things. VAS captures pain intensity as reported by the patient. DASH captures physical function and symptoms in the upper limb, so it reflects what the shoulder can actually do.

04 • RESULTS

Pain and Function Across One Year

Both scales decreased after the first injection. Statistical significance against baseline was reached from 60 days onward and was maintained at every later assessment.

VAS · PAIN INTENSITY

Baseline	7 days	30 days	60 days	90 days	180 days	360 days
1st injection	not significant	not significant	p<0.05	p<0.05	p<0.01	p<0.05

DASH · UPPER LIMB FUNCTION

Baseline	7 days	30 days	60 days	90 days	180 days	360 days
1st injection	not significant	not significant	p<0.05	p<0.01	p<0.001	p<0.05

All values are comparisons against baseline. Assessments at 60, 90, and 180 days come from the multiple comparison analysis across the full follow-up. The 360-day value comes from a separate paired comparison between baseline and one year.

Reading the timeline. Scores fell as early as one week after the first injection, but that early change did not reach statistical significance. The significant separation from baseline appears at 60 days and holds through the twelve-month visit.

ON THE NUMBERS

The source report presents the absolute VAS and DASH values graphically, as mean with standard deviation, rather than as a table. The mean values behind each time point are available from the manufacturer on request.

05 • ONE YEAR

What Held at Twelve Months

A separate paired analysis compared each patient's baseline value with their value at 360 days.

VAS AT 360 DAYS

p<0.05

Statistically significant improvement in pain intensity compared with baseline, one year after therapy.

DASH AT 360 DAYS

p<0.05

Statistically significant improvement in upper limb function compared with baseline, one year after therapy.

A sustained effect. In the patients who completed follow-up, pain and upper limb function at one year remained significantly better than at baseline. The study report describes this as a sustained therapeutic effect lasting up to one year. Study design and limitations are set out in section 08.

06 • SAFETY

Safety Profile

All included patients were monitored for adverse events connected with the treatment across the full twelve-month period.

ADVERSE EVENTS

0

Adverse events or discomfort in relation to the injections were reported by any patient.

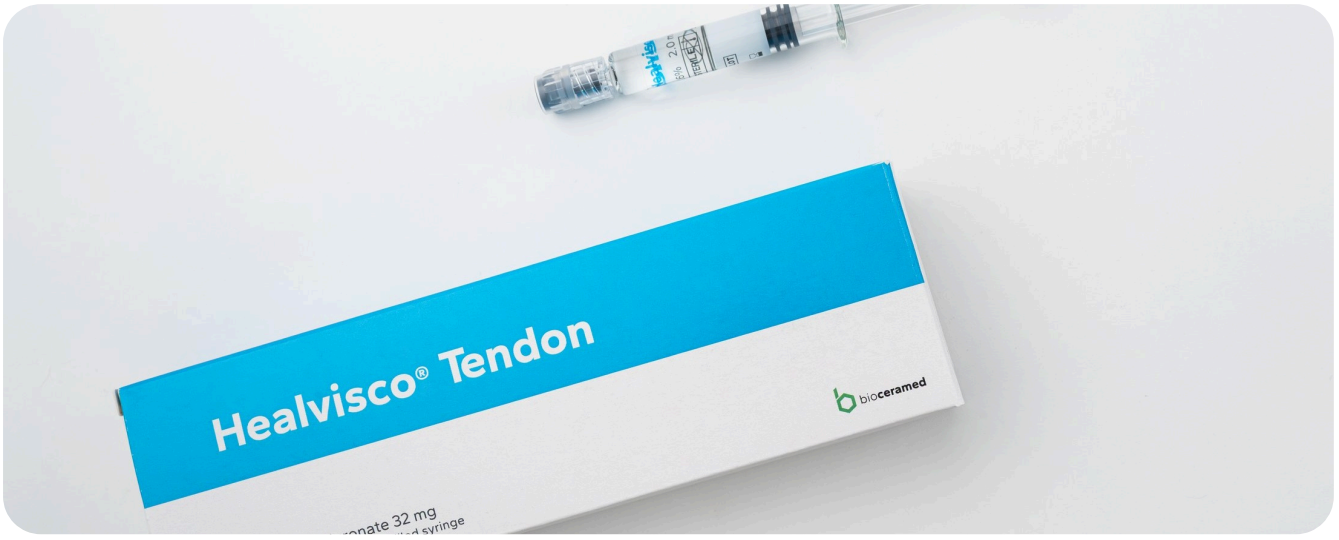
SERIOUS EVENTS

0

Serious adverse events, intra-articular infections, or allergic reactions were reported.

IN CONTEXT

Published reviews report that injection-site pain is consistently the most common adverse event during hyaluronic acid injection in tendinopathy. No such reports were recorded in this cohort.



The report's safety conclusion. The study report states that the safety assessment performed during the study confirmed the double-injection therapy to be safe, with no adverse events related to the hyaluronic acid administrations recorded. Any serious incident occurring in relation to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user is established.

07 • PRACTICAL CONSIDERATIONS

How the Protocol Was Applied

The regimen was short. Two visits, seven days apart, one pre-filled syringe each, followed by twelve months of observation with no further injection.

ROUTE

Peritendinous injection around the injured site, using a fanning technique rather than a single deposit.

DOSE

2 mL of 1.6% gel per administration, corresponding to 32 mg of sodium hyaluronate.

SCHEDULE

Two injections, seven days apart. Follow-up visits at 1, 2, 3, 6, and 12 months.

TWO STUDIES, ONE PROTOCOL

The same two-injection regimen at a seven-day interval was applied in a separate study of patellar tendinopathy and lateral epicondylitis, conducted at Puerta del Mar Hospital in Cádiz, Spain, with sixty patients and six months of follow-up. Between the two studies, the same treatment schedule has been applied at the patellar tendon, the lateral epicondyle, and the rotator cuff.

PATIENT SELECTION IN THIS STUDY

Patients presented with shoulder pain attributed to rotator cuff tendinopathy. The report does not specify additional inclusion or exclusion criteria. The population studied does not replace the contraindications listed in the Instructions for Use, which should be consulted before use.

08 • LIMITATIONS

Where This Evidence Ends

Presented in full, because evidence is only useful when its boundaries are visible.

01 **Ten Patients**

Ten patients were enrolled and seven completed the twelve-month schedule. This is a small exploratory cohort. The report itself notes that data from a larger number of participants would be desirable.

02 **No Comparator Group**

Single-arm design with no control. The outcomes cannot be attributed to the device in isolation, and no comparison can be drawn against physiotherapy, corticosteroid injection, or any other hyaluronic acid product.

03 **Single Centre**

All patients were recruited and treated at one clinic in Kielce, Poland.

04 **Clinical and Patient-Reported Endpoints**

Outcomes were measured with VAS and DASH. No imaging endpoint was included, so no structural change in the tendon was assessed.

05 **One Tendon Site**

All patients presented with rotator cuff tendinopathy. The results do not extend to other shoulder pathologies or to other tendon sites.

06 **Device Identity**

The study was conducted with the device under the manufacturer's Biolevox™ HA TENDON brand. Healvisco® Tendon is the same 32 mg, 2 mL, 1.6% sodium hyaluronate device supplied by Biovico Sp. z o.o. and distributed by Bioceramed.

09 • IN PRACTICE

What Twelve Months of Follow-Up Show

In this cohort, two peritendinous injections were associated with reduced pain, improved upper limb function, and no reported adverse events across one year.

EFFECT ONSET

Scores fell after the first injection. Significant separation from baseline appeared at 60 days.

EFFECT DURATION

The improvement in pain and function remained significant against baseline at the twelve-month assessment.

TOLERABILITY

No adverse events, serious adverse events, infections, or allergic reactions were reported in this cohort.

FROM THE STUDY REPORT

The report concludes that the two-injection treatment provided an immediate and long-lasting therapeutic effect, bringing pain relief and improvement of physical function for patients with rotator cuff tendinopathy, and that the therapeutic effect was sustained up to one year. It further states that the safety assessment confirmed the double-injection therapy to be safe, with no related adverse events recorded during the study.

Healvisco® Tendon is supplied as a pre-filled syringe containing sodium hyaluronate of non-animal origin, obtained by biofermentation. Full indications, contraindications, warnings, and precautions are set out in the Instructions for Use.

CONTINUE THE CONVERSATION

Request More Information

Our clinical and technical teams can support product selection, case planning, and training. Contact us for the Instructions for Use, the technical data sheet, and distribution enquiries.

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SOURCE

Biovico Clinical Report Series, Volume III, Issue 105. "Peritendinous treatment of rotator cuff tendinopathy with Biolevox™ HA TENDON brings sustain clinical effectiveness up to 1 year."

Study site: Trauma and Orthopedic Surgery Clinic, Kielce, Poland.

Product parameters as stated in the report: 2 mL of 1.6% sodium hyaluronate, molecular weight 1400 to 1600 kDa.

MANUFACTURER

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EXCLUSIVE DISTRIBUTOR

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SELECTED REFERENCES

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Lewis J, McCreesh K, Roy JS, Ginn K. Rotator cuff tendinopathy: navigating the diagnosis-management conundrum. J Orthop Sports Phys Ther. 2015;45(11):923–937.
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