



Orthovisc®-T

Relieve Pain + Restore Function

*Injectable viscoelastic sodium hyaluronate
for lateral elbow tendinopathy*

Anika. *Restore Active Living.™*



What is Lateral Elbow Tendinopathy?

The most common chronic musculoskeletal pain condition affecting the elbow causing significant pain, disability and lost productivity¹

Lateral elbow tendinopathy (LET), or tennis elbow, presents as pain due to tendinopathy of the common extensor tendon at the lateral epicondyle and considered to be the result of recurrent mechanical overuse or overloading at the lateral elbow. The ability of the tendon to repair itself is overwhelmed and ultimately fails.²

This leads to microscopic tears & degeneration of the tendon joining the forearm muscles to lateral epicondyle and an immature, abnormal reparative response leading to pain and tenderness on the outside of the elbow.²

LET is not simply inflammation^{3,4}

Tendinopathy is a general term used to describe chronic overuse tendon disorders encompassing a wide spectrum of histopathological changes including microscopic tears to the tendon. Tendinosis relates to these specific histological changes.²

The principal elements of tendinosis are abnormalities of the cellularity, vascularity, and collagen arrangement within the tendon.²

Current treatment options

Conservative	Corticosteroid injections	Surgery
66.5% of Patients ⁵	26% of patients ⁵	7.5% of patients ⁵
Bracing, physiotherapy, manual therapy, oral or topical NSAIDs	72% of patients treated with steroid injections experience a recurrence within 12 months ⁶ Physicians agree that the short-term effects of corticosteroids are outweighed by the longer-term consequences of their overuse in this condition ⁶	Usual indications include intractable & persistent symptoms despite conservative management (typically for at least 12 months) ⁶

The problem

Typical episode of lateral elbow tendinopathy lasts **6-to 24 months⁶** and **90%** will heal spontaneously in about **12 months⁶**. But 12 months is a **long time** to have constant elbow pain. It can have a significant effect on quality of life and can be a source of chronic pain if left untreated. With current treatment options long term results are poor: Over **50%** of patients attending general practice for their elbow pain report not being recovered at **12 months¹**. Follow-up of participants in a clinical trial of non-surgical treatments for LET identified that **20%** of respondents (27/134) reported ongoing pain after **3 to 5 years¹**

LET is not necessarily self-limiting and is associated with ongoing pain and disability in a substantial proportion of sufferers.¹

Orthovisc-T: The clinically proven solution to relieve pain + restore function



Orthovisc-T is an ultra-pure hyaluronic acid (HA) viscosupplement with a high concentration of 15 mg of HA per mL - a total dose of 30 mg HA per injection. It acts as a tissue lubricant, promoting tendon gliding and providing an ideal environment to support tendon healing. As a result, Orthovisc-T relieves pain and restores function.

Patient outcomes

Effective pain relief⁵

Restored physical function⁵

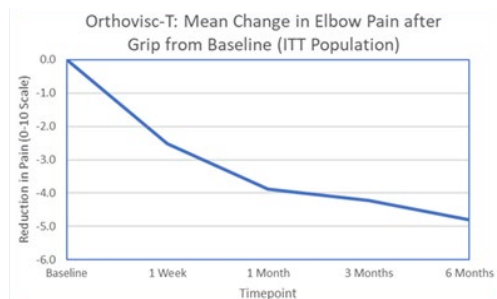
Low risk of adverse events⁵

Results of the Orthovisc-T OVT 16-03 Study⁵

A Prospective, Open-Label, Multi-Center Post-Market Clinical Follow-Up Study to Evaluate the Residual Risk of Orthovisc-T (OVT) in the Treatment of Chronic Lateral Epicondylitis (Tennis Elbow)

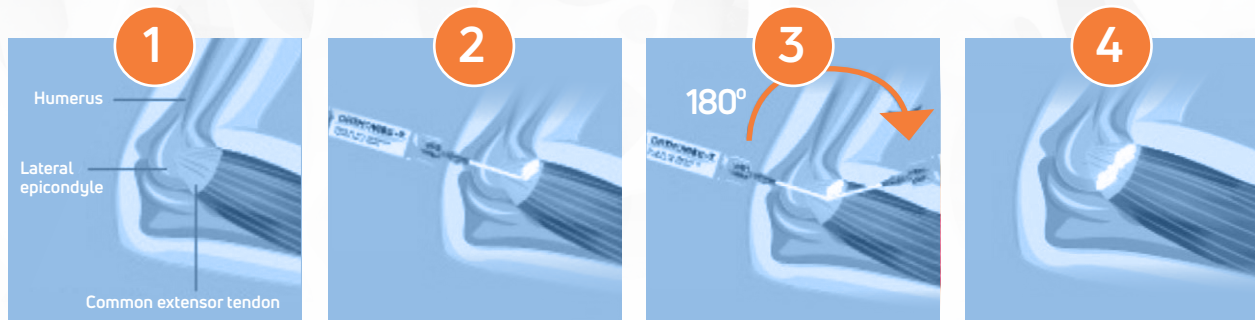
49 subjects with chronic lateral epicondylitis treated with two injections of Orthovisc-T, one week apart

- OVT effectiveness demonstrated through **6 months**.
- The study met all primary and secondary endpoints with **p<0.001** (strongly statistically significant).
- OVT achieved large percent improvements from baseline, e.g. **76% - 86%** in all measures at 6 months.
- ALL AE (**10/10**) were listed as unrelated or unlikely related to OVT, with very few mild adverse events.
- All subjects treated with OVT completed the study through to the 6 month visit and exited the trial demonstrating an improvement in the pain after grip compared to baseline and a statistically significant increase in the mean grip strength of **44.24%** at 6 months.



Recommended injection technique

Orthovisc-T is a single use medical device that should be used by a physician trained in periosteotendinous injections only.



1. Patient should be seated with elbow flexed and resting on a firm surface.
2. Mark injection spot at primary point of pain (often slightly anterior or lateral epicondyle over the common extensor tendon).
3. Clean skin thoroughly using a strict aseptic technique.
4. Inject needle (22 to 25 gauge) into the soft tissue 1 cm from the lateral epicondyle. DO NOT inject directly into the tendon.
5. Position needle to 45°, insert and retract as you inject half of the Orthovisc-T syringe contents over the tendon
6. Retract needle slightly but do not remove completely.
7. Re-orientate the syringe through 180°, insert slightly deeper again and retract as you inject the remaining Orthovisc-T to ensure the spread of Orthovisc-T across the tendon.
8. Remove needle completely.
9. After the injection procedure, patient should flex and extend the wrist five times slowly, then rotate into pronation and supination five times slowly to ensure proper distribution of Orthovisc-T across the tendon.

The Orthovisc-T device is intended to relieve pain and restore function in tendons affected by chronic lateral epicondylitis. It is not intended to be used for the treatment of first or second degree ankle sprain or symptomatic rotator cuff tendinopathy.

Directions For Use

For complete product information, reference to product IFU.

Orthovisc-T should be injected around the affected osteotendinous junction once a week for a total of two injections. Injections may be done under imaging guidance.

How Supplied

Orthovisc-T is supplied as a sterile viscoelastic preparation of sodium hyaluronate supplied in a disposable glass syringe. Each mL of Orthovisc-T contains 15 mg of sodium hyaluronate, 9 mg of sodium chloride and sterile water for injection (USP). Orthovisc-T is sterile filtered and aseptically filled. The contents of the syringe are sterile if the syringe is intact. The Orthovisc-T syringe is packaged in a pouch.

Storage

Orthovisc-T should be stored at 2°C to 25°C, and should be allowed to reach room temperature approximately 20-45 minutes prior to use. Protect from freezing.

Shelf life

The shelf life of Orthovisc-T is 24 months when stored at a temperature of 2°-25°C.

References

1. Leanne M Bisset, Bill Vicenzino, Physiotherapy management of lateral epicondylalgia, Journal of Physiotherapy, Volume 61, Issue 4, 2015, Pages 174-181, ISSN 1836-9553, <https://doi.org/10.1016/j.jphys.2015.07.015>.
2. Bhabra et al. Lateral Elbow Tendinopathy, Development of a Pathophysiology-Based Treatment Algorithm. The Orthopaedic Journal of Sports Medicine, 4(11), 2325967116670635 DOI: 10.1177/2325967116670635
3. Walz DM, N.J., Konin GP, Ross G, Epicondylitis: Pathogenesis, imaging, and treatment. Radiographics, 2010. 30; p. 167-184. (via OVT study Data on file)
4. Khan et al. Time to abandon the tendinitis myth. Editorials BMJ 2002;324:626 BMJ VOLUME 324 16 MARCH 2002 bmj.com
5. OVT 16-03 Clinical Study Report v1.0 08Jan2021 – Data on file
6. Luk et al. Lateral Epicondylalgia: Midlife crisis of a tendon Hong Kong Med J | Volume 20 Number 2 | April 2014 | www.hkmj.org

Anika Therapeutics, Inc.

32 Wiggins Ave, Bedford, MA
1-781-457-9000 · www.anika.com

©2021 Anika Therapeutics, Inc. | 01/21 | AML 900-169

Anika and Cingal are registered trademarks of Anika Therapeutics, Inc.
The information contained in this document applies exclusively to territories outside of U.S.A.