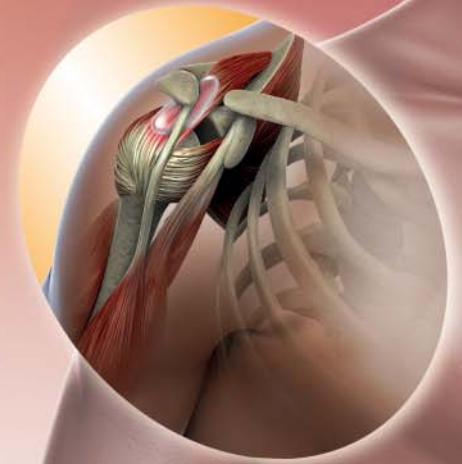




*TendoVis*TM

Keeping active people active

*Designed for soft
tissue injuries*



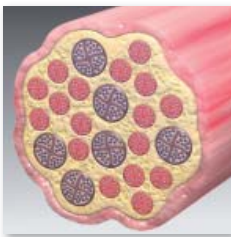
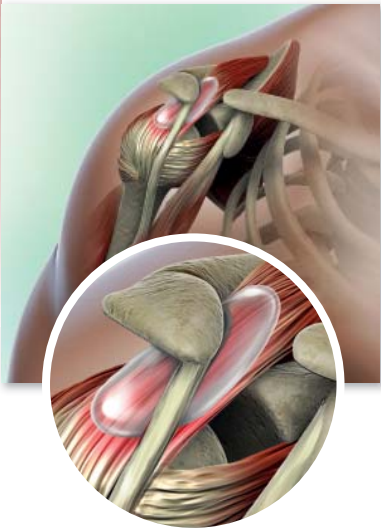
Contains **STABHA**TM
Soft Tissue Adapted Biocompatible Hyaluronic Acid

TENDOVIS™ in ROTATOR CUFF TENDINOPATHY

2 injections, 14 days apart

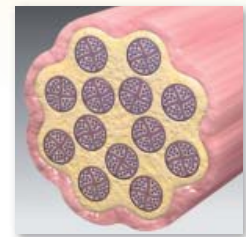
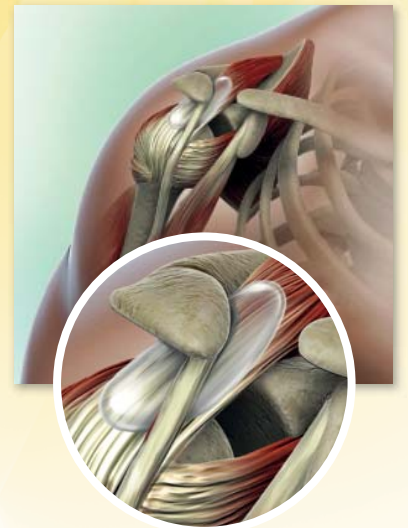
STABHA™ for shoulder strains

- 1 - Reduced scar tissue formation
- 2 - Restored strength and function
- 3 - Earlier return to mobility
- 4 - Pain relief
- 5 - Proven efficacy



- A - ECM degeneration and lower quality of ECM produced (less proteoglycans)
- B - Decreased collagen production
- C - Excess fibrosis

ECM : *Extra Cellular Matrix*

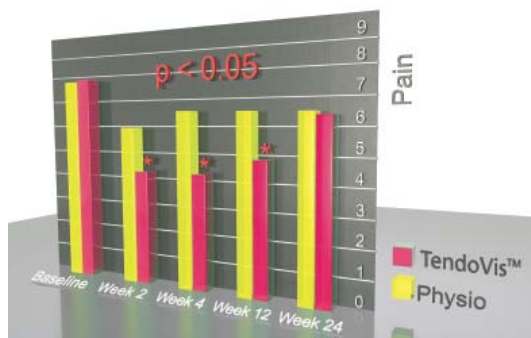


- A - ECM regeneration functional proteoglycans restored)
- B - Increased collagen production
- C - Restored tendon structure (less scar tissue)

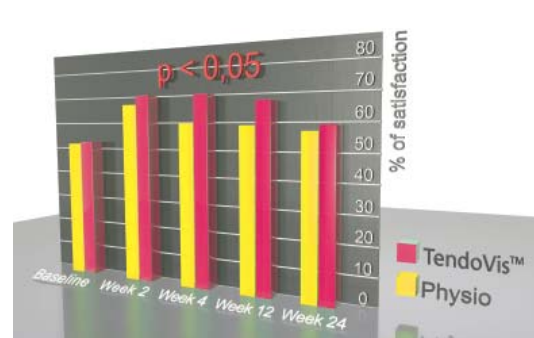
CLINICAL STUDY

Ultrasound-guided subacromial injections of sodium hyaluronate for the management of rotator cuff tendinopathy: a prospective comparative study with rehabilitation therapy. Merolla et al. *Musculoskelet Surg* (2013) 97 (Suppl 1) : S49–S56.

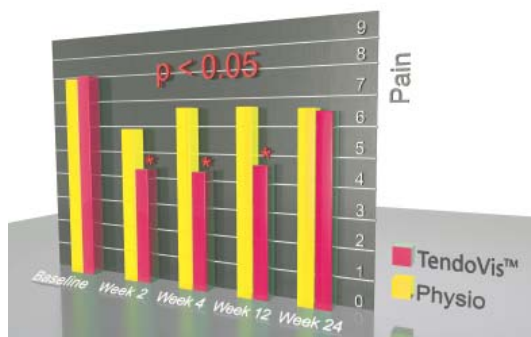
50 PATIENTS RECRUITED > 25 in *TendoVis™* Group
> 25 in *Physio* Group



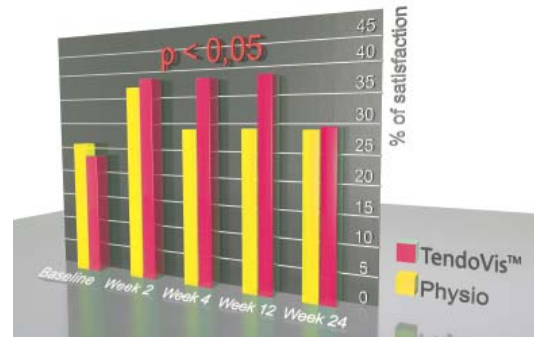
Pain at rest



Constant Murley Score



Pain with activity



Oxford Shoulder Score

REFERENCES

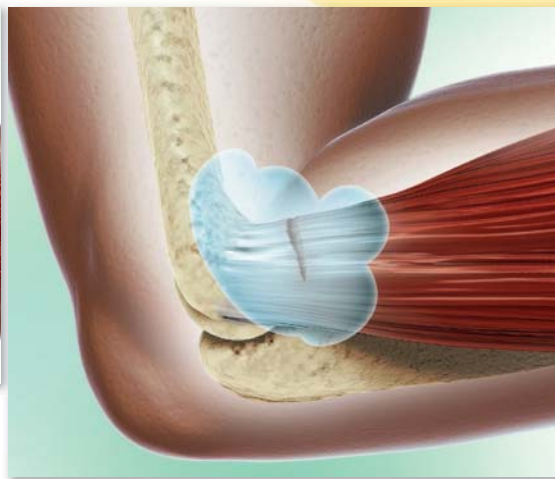
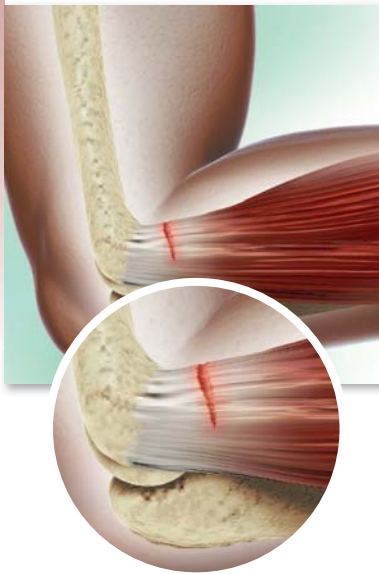
1. Ultrasound-guided subacromial injections of sodium hyaluronate for the management of rotator cuff tendinopathy : a prospective comparative study with rehabilitation therapy. Merolla et al. *Musculoskelet Surg* (2013) 97 (Suppl 1) : S49–S56.
2. Effects of repetitive injections of hyaluronic acid on peritendinous adhesions after flexor tendon repair: a preliminary randomised, placebo-controlled clinical trial. Ozgenel et al. *Turkish Journal of Trauma and Emergency Surgery* 2012 Jan ; 18(1) : 11-17.
3. Involvement of proteoglycans in tendinopathy. Parkinson et al. *J Musculoskelet Neuronal Interact*. 2011 Jun ; 11(2) : 86-93.
4. Tendon: biology, biomechanics, repair, growth factors, and evolving treatment options. James et al. *J Hand Surg Am*. 2008 Jan ; 33(1) : 102-112.
5. Collagen structure of tendon relates to function. Franchi et al. *www.thescientificworld.com* 2007 Mar ; 7 : 404-420.
6. Tendon proteoglycans : biochemistry and function. Yoon et al. *J Musculoskelet Neuronal Interact*. 2005 Mar ; 5(1) : 22-34.
7. Effect of hyaluronic acid on the excursion resistance of tendon grafts. A biomechanical study in a canine model in vitro. Nishida et al. *J Bone Joint Surg (Br)*. 2004 Aug ; 86(6) : 918-924.
8. Glycosaminoglycans of human rotator cuff tendons : changes with age and in chronic rotator cuff tendinitis. Riley et al. *Ann Rheum Dis*. 1994 Jun ; 53(6) : 367-376.
9. Tendon degeneration and chronic shoulder pain : changes in the collagen composition of the human rotator cuff tendons in rotator cuff tendinitis. Riley et al. *Ann Rheum Dis*. 1994 Jun ; 53(6) : 359-66.

TENDOVIS™ in LATERAL EPICONDYLALGIA

2 injections, 7 days apart

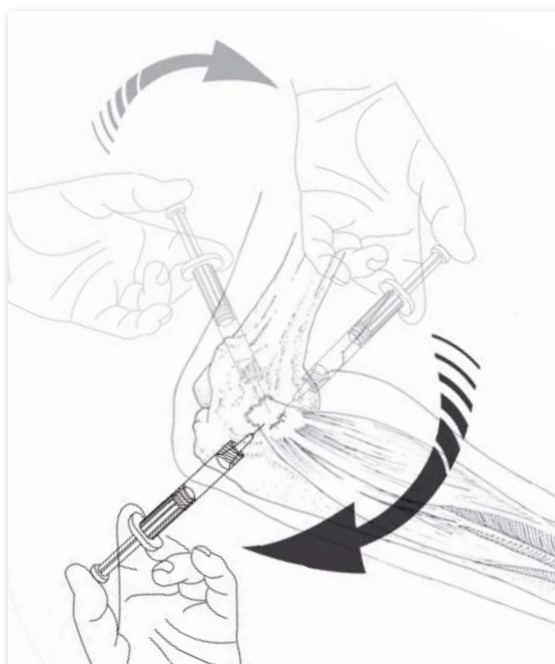
STABHA™ for elbow strains

- 1 - Proven efficacy
- 2 - Accelerated healing
- 3 - Increased tensile strength
- 4 - Reduced pain
- 5 - Quicker return of strength



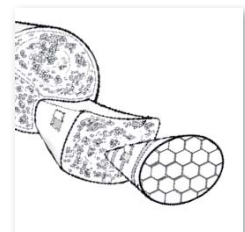
Misalignment of fibres

- Pain
- Loss of movement



Realignment of fibres

- No pain
- Return of motion



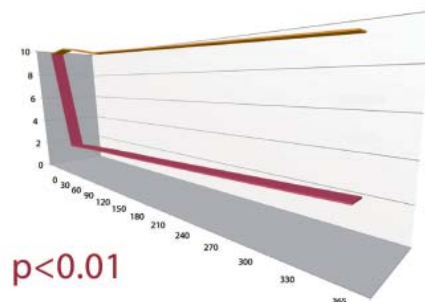
CLINICAL STUDY

Management of tennis elbow with sodium hyaluronate periarticular injections. Petrella et al. Sports Medicine, Arthroscopy, Rehabilitation, Therapy and Technology. 2010,2;4:1-6

331 PATIENTS > 165 patients treated with TendoVis™
> 166 patients treated with placebo

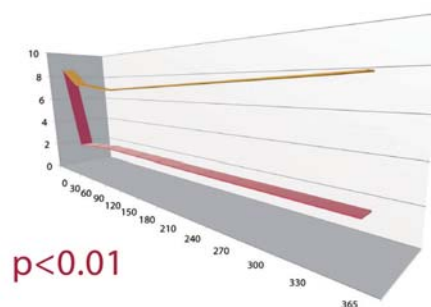
*Patients injected with TendoVis™
experienced less pain when gripping*

■ TendoVis™ ■ placebo



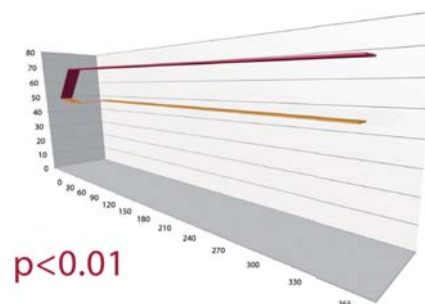
*Patients injected with TendoVis™
experienced less pain at rest*

■ TendoVis™ ■ placebo



*Patients injected with TendoVis™
had better grip strength*

■ TendoVis™ ■ placebo



REFERENCES

1. Chronic tendon pathology: molecular basis and therapeutic implications. Riley G. Expert Rev Mol Med. 2005 Mar 24 ; 7(5) : 1-25.
2. Collagen fibres of the spontaneously ruptured human tendons display decreased thickness and crimp angle. Tero et al. J Orthop Res. 2004 Nov ; 22 : 1303-1309.
3. Biomechanics of tendon injury and repair. Lin et al. J Biomech. 2004 Jun ; 37 : 865-877.
4. Tendon lesions and soft tissue rheumatism--great setback or great opportunity? Cawston et al. Ann Rheum Dis. 1996 Jan ; 55(1) : 1-3.
5. The role of proteoglycans in maintaining collagen fibril morphology. Dell'Orbo et al. Histol Histopathol. 1995 Jul ; 10(3) : 583-8.
6. Hyaluronic acid modulates proliferation, collagen and protein synthesis of cultured fetal fibroblasts Mast et al. Matrix. 1993 Nov ; 13(6) : 441-6.
7. Management of tennis elbow with sodium hyaluronate peri-articular injections Petrella et al. Sports Medicine, Arthroscopy, Rehabilitation, Therapy and Technology. 2010,2 ; 4 : 1-6.
8. Efficacy and safety of corticosteroid injections and other injections for management of tendinopathy : a systematic review of randomised controlled trials, Coombes et al. The Lancet. Volume 376 ; Issue 9754 : 1751-1767.
9. Comparative Effectiveness of Injection Therapies in Lateral Epicondylitis. A Systematic Review and Network Meta-analysis of Randomized Controlled Trials, Krogh et al. The American Journal of Sports Medicine. Vol. 20(10) : 1-12.

SUPPLEMENTING THE ECM FOR BETTER HEALING

ELBOW STRAINS



- > *Quicker recovery*
- > *Increases tensile strength*
- > *Reduces pain*



SHOULDER STRAINS

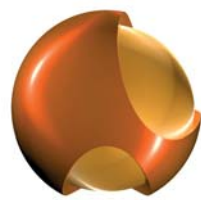


- > *Restores strength*
- > *Earlier return to mobility*
- > *Relieves pain*



- STABHA™** > *Reduces scar tissue formation*
- > *Proven Efficacy*
- > *Biocompatible*

FOR BETTER MANAGEMENT OF STRAINS



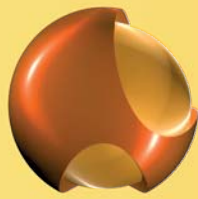
TendoVis™
Keeping active people active

- > *The only Sodium Hyaluronate for peri-articular injections for tendons*
- > *TendoVis™ contains STABHA™*
- > *STABHA™ - Soft Tissue Adapted Biocompatible Hyaluronic Acid*

STABHA™ - Proven treatment for tendinopathy

EXTRA READING

1. Therapeutic effects of hyaluronate injections in patients with chronic painful shoulder: A meta-analysis of randomised controlled trials Saito et al. *Arthritis Care Res (Hoboken)*. 2010 Jul ; 62(7) : 1009-1018.
2. Modulation of the formation of adhesions during the healing of injured tendons. Khan et al. *J Bone Joint Surg (Br)*. 2000 Sep ; 82-B : 1054-1058.



TendoVis™

Keeping active people active

TO RELIEVE PAIN AND PROMOTE FUNCTION IN DAMAGED TENDONS AND LIGAMENTS.

> Presentation

TendoVis™ is a clear solution of sterile 1% sodium hyaluronate in a phosphate buffered saline contained in a pre-filled syringe for peri-articular injection into the soft tissue surrounding tendons and ligaments.

Sodium hyaluronate is a long chain polysaccharide made up of repeating disaccharide units, which occurs naturally in the body. **TendoVis™** has a pH and osmolality biocompatible with the soft tissue.

1.2ml of **TendoVis™**, sterilised by filtration, is enclosed within a glass, ready to use, disposable syringe. The syringe is packed within a blister pack and an outer cardboard carton.

> Uses

TendoVis™ is intended to relieve pain and optimise recovery of tendons and ligaments damaged by acute or chronic injury.

TendoVis™ sodium hyaluronate augments the sodium hyaluronate naturally present in the soft tissue surrounding damaged tendons and ligaments and provides support, lubrication and hydration to the affected site thereby providing the ideal environment for healing of the damaged tissue.

TendoVis™ has been demonstrated to relieve pain and optimise recovery in the ankle following first or second degree sprain, to relieve chronic pain and disability of the elbow with lateral epicondylalgia and to relieve pain in patients with symptomatic rotator cuff tendinopathy.

> Contra-indications

Patients with known sensitivity to sodium hyaluronate.

> Dosage and Administration

Peri-articular injection of **TendoVis™** should only be made by a Healthcare Professional trained in the specific peri-articular injection technique.

The contents of the syringe are sterile and should be injected using a sterile needle of an appropriate size for the injection site.

The area to be treated should be disinfected before injection.

Discard the syringe and needle after single use.

> Ankle Sprains

One 1.2ml peri-articular injection of **TendoVis™** preferably within 48 hours of the first or second degree ankle sprain and a second injection 2 to 3 days following the first injection, 27 gauge needle is recommended. Peri-articular injections should be delivered during a single penetration along the anterior talofibular ligament using clinical landmarks. The injection is delivered along 3 planes from antero-posterior, medial and lateral to the proximal ligamentous landmark.

> Lateral Epicondylalgia

One 1.2ml peri-articular injection of **TendoVis™** at the lateral elbow epicondyle site followed by a second injection at the same site one week after the first injection, 27 gauge needle is recommended.

Identify the tenderest point of the epicondyle by gentle palpation.

Position the needle at 45 degrees to the point of maximal pain of the lateral epicondyle. After puncture of the skin, angle the needle parallel to the skin and insert it towards the point of maximal pain on the lateral epicondyle. Inject half the contents as the needle is withdrawn to the skin without exiting the skin.

Rotate the needle 180 degrees (opposite direction) and insert the needle parallel to the skin towards the point of maximal pain on the lateral epicondyle. Inject the remaining contents on withdrawing of needle. Remove the needle from the skin.

Flex and extend the elbow five times and then internally and externally rotate five times.

> Rotator Cuff Tendinopathy

One 1.2ml peri-articular injection of **TendoVis™** into the subacromial space of the shoulder just above the tendon followed by a second peri-articular injection after 14 days, 22 gauge needle is recommended. Seat the patient in an upright position, arm relaxed at the side and externally rotated. Use of an ultrasound probe positioned on the lateral shoulder directed in the plane of the supraspinatus tendon to guide the injection is recommended.

Locate the acromion, greater tubercle, head of the humerus and subacromial cleft. Introduce the needle into the cleft 1cm posterior and 2cm distal to the antero-lateral acromial edge. Advance the needle horizontally and in a partly medial direction under the acromion process. When no resistance to the plunger is felt inject **TendoVis™** over the head of the humerus into the subacromial space taking great care not to inject into the tendon.

> Warnings and Precautions

TendoVis™ should only be injected by a Healthcare Professional trained in the procedure. **TendoVis™** pre-filled syringes are single use. The contents of the syringe should be used for one injection only. Any remaining sodium hyaluronate should be discarded. If a syringe is retained for a subsequent injection there is a risk of contamination resulting in the possible infection of the patient and/or foreign body reaction. **TendoVis™** should not be re-sterilised as the device performance may be compromised which could cause serious harm to the patient's health and safety. **TendoVis™** must not be injected into blood vessels because sodium hyaluronate has the potential to occlude the vessels, which could result in embolism or infarction. **TendoVis™** should not be injected into a haematoma. Direct injection into tendons should be avoided as this can lead to rupture. Use of an ultrasound probe to guide the injection will minimise this risk. Do not inject into the soft tissue of patients if the area of the injection site is infected or where there is evidence of acute or chronic skin disease. Sodium hyaluronate is manufactured by fermentation of *Streptococcus equi* and rigorously purified. However, the Healthcare Professional should consider the immunological and other potential risks that can be associated with the injection of any biological material. There is a risk of infection at the injection site as with any peri-articular procedure. There is no evidence of the safety of **TendoVis™** in human pregnancy and lactation. The safety and effectiveness of **TendoVis™** has not been tested for children below 18. Follow national or local guidelines for the safe use and disposal of needles. Obtain prompt medical attention if injury occurs. Do not use if packaging has been damaged. Do not use after the expiry date.

> Adverse Reactions

Mild erythema that should resolve with time.

> Incompatibilities

TendoVis™ has not been tested for compatibility with other substances for peri-articular injection. Therefore the mixing or simultaneous administration with other peri-articular injectables is not recommended.

> Storage

Store between 2°C and 25°C. Do not freeze. Protect from light. Do not use if sterile packaging has been damaged. Do not use after expiry date.

