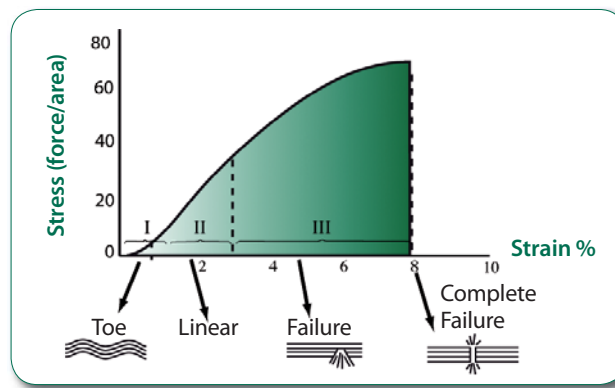


EPICONDYLITIS - THE FACTS

Common affection with an obscure exact aetiology.

Symptoms:

- Pain
- Discomfort
- Potential impairment



Stress-strain curve demonstrating the basic physical properties of a tendon.

Incidence/prevalence

- No gender distinction
- Persistence of 18 to 24 months
- Up to 50% of racquet sport players
- Affects up to 3% of any population

Damaged tendons often progress into chronic cases.

ECM / Ground substance – required for the healing process:

- Contains proteoglycans which are essential for the formation of fibrils.
- Hyaluronic Acid interacts with fibronectin to create a scaffold for cell migration.

Hyaluronic Acid: an important component of the biological recovery process.

SportVis™

To relieve pain and optimise recovery of the ankle following first or second degree sprain.

To relieve chronic pain and disability of the elbow with lateral epicondylalgia.

Presentation:

SportVis™ is a clear solution of sterile 1% sodium hyaluronate in a phosphate buffered saline contained in a pre-filled syringe for:

- a series of two peri-articular injections into the soft tissue of the ankle; one peri-articular injection preferably within 48 hours of the injury and a second peri-articular injection 2 to 3 days following the first injection.
- a peri-articular injection in the elbow epicondyle followed by a second injection as may be required one week after the first injection.

Sodium hyaluronate is a long chain polysaccharide made up of repeating disaccharide units, which occurs naturally in the body.

SportVis™ has a pH and osmolality biocompatible with the soft tissue.

1.2ml of SportVis™, 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.

Dosage and Administration:

Peri-articular injection of SportVis™ should only be made by a Healthcare Professional trained in the technique.

The dosage regimen is:

- one peri-articular injection preferably within 48 hours of the first or second degree ankle sprain and a second injection 2 to 3 days following the first injection.
- one peri-articular injection at the lateral elbow epicondyle site followed by a second injection at the same site one week after the first injection.

The contents of the syringe are sterile and should be injected using a sterile needle of an appropriate size (27 gauge needle is recommended).

The area to be treated should be disinfected before injection.

Ankle Sprains

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.

1.2ml of SportVis™ is injected preferably within 48 hours of the injury and a second injection of 1.2ml is given 2 to 3 days after the first injection.

Lateral Epicondylalgia

Peri-articular injections identify the tenderest point of the epicondyle by gentle palpation.

Insert the needle at 90 degrees to the point of maximal pain on the lateral epicondyle. After insertion to the epicondyle, angle the needle at 45 degrees (or thereabout) and inject half the contents as the needle is withdrawn to the skin (without exiting the skin).

Insert the needle to 45 degrees in the opposite direction to the epicondylar point of maximum pain and inject the remaining contents on withdrawing of the needle outward. The needle is removed from the skin.

The elbow is flexed and extended five times and then internally and externally rotated five times.

Discard the syringe and needle after single use.

Uses:

SportVis™ is intended to relieve pain and optimise recovery of the ankle following first or second degree sprain.

SportVis™ is intended as well to relieve chronic pain and disability of the elbow after lateral epicondylalgia.

SportVis™ sodium hyaluronate augments the sodium hyaluronate naturally present in the soft tissue of the ankle joint or elbow tissue thereby providing the ideal environment for healing of the damaged tissue.

Contra-indications:

Patients with known sensitivity to sodium hyaluronate.

Warnings and Precautions:

SportVis™ should only be injected by a healthcare professional trained in the procedure.

SportVis™ 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.

SportVis™ must not be injected into blood vessels because sodium hyaluronate has the potential to occlude the vessels, which could result in embolism or infarction.

Do not inject into the soft tissue of patients if the area of the injection site is inflamed, 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 SportVis™ in human pregnancy and lactation. Administration during pregnancy and lactation is at the discretion of the healthcare professional.

The safety and effectiveness of SportVis™ has not been tested for children. Administration to children below 18 is at the discretion of the healthcare professional.

SportVis™ should not be injected into a haematoma.

Needles should not be reused because SportVis™ may become turbid due to precipitation in the presence of cationic agents such as benzalkonium chloride or detergents residual in the needle following re-sterilisation.

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.

Adverse Reactions:

Mild erythema that should resolve with time.

Incompatibilities:

SportVis™ 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. Sterile product for single use only. Do not use after expiry date.

Manufacturer: Hyaltech Ltd

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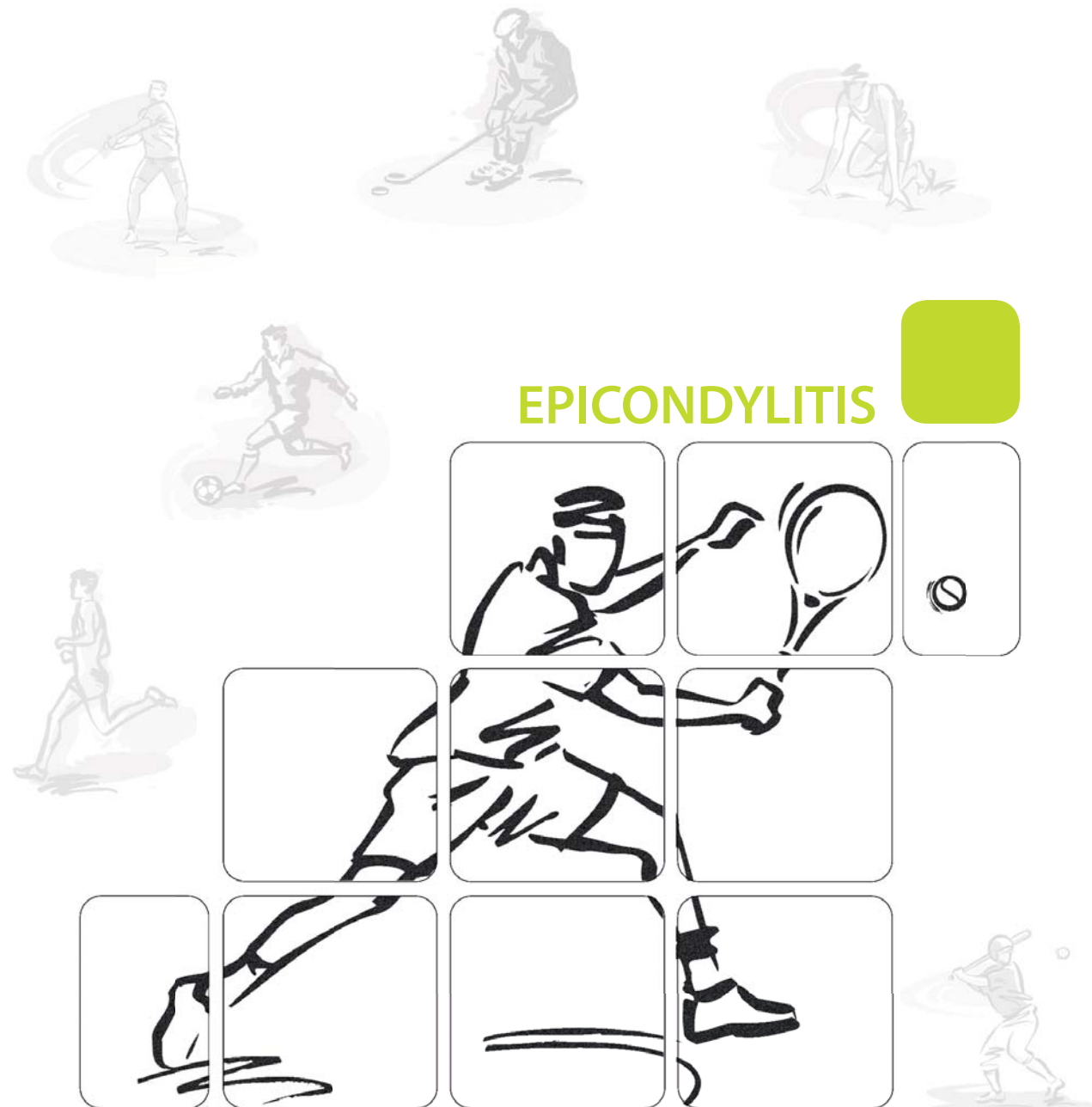
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EPICONDYLITIS

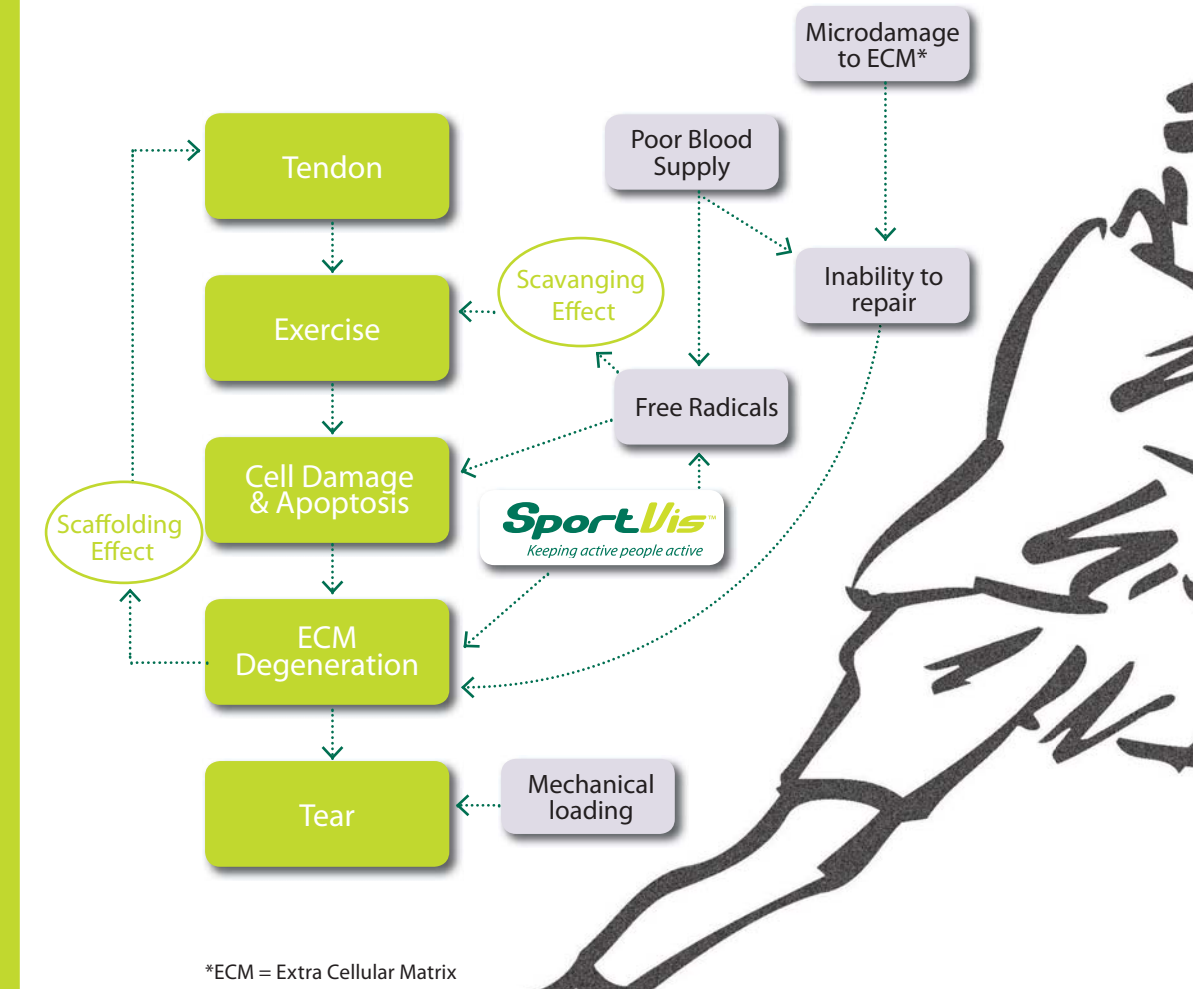
A NEW CLINICAL TREATMENT OPTION



MDT Int'l s.a.
Switzerland
www.sportvis.eu

EPICONDYLITIS - THE CYCLE

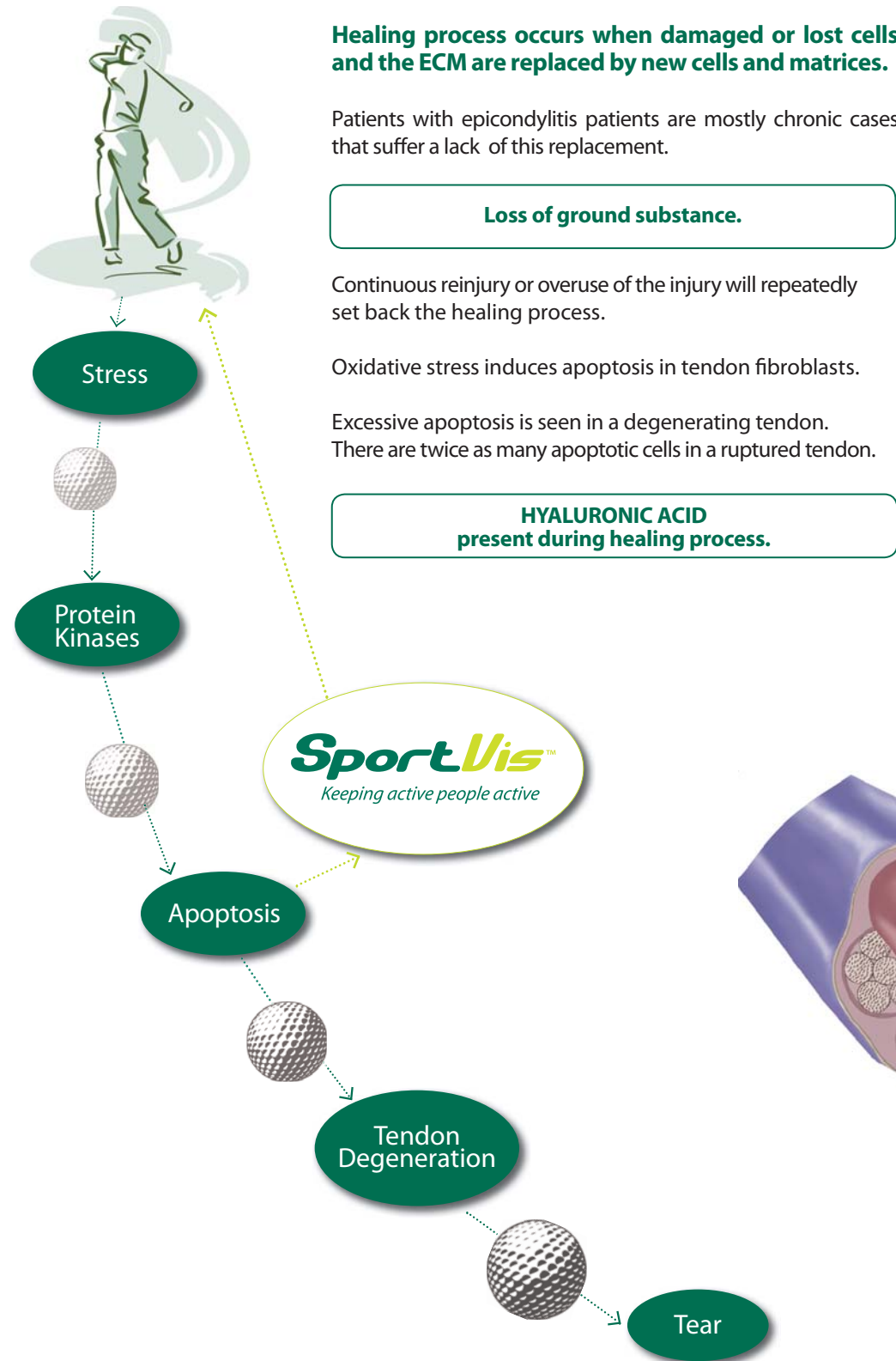
SportVis™ is able to limit the damage and help patients recover from chronic epicondylitis.



*ECM = Extra Cellular Matrix

ECM (Ground Substance) is essential for support. It is highly viscous and lubricating.

EPICONDYLITIS - THE EVENTS



EPICONDYLITIS - THE ROLE OF HYALURONIC ACID (HA)

At injury site:

- HA negative charges and hydrophilic nature helps **organise fibrils in fibres and fascicles.**
- HA electrostatic charges help to restore collagen fibres into normal parallel arrangement.

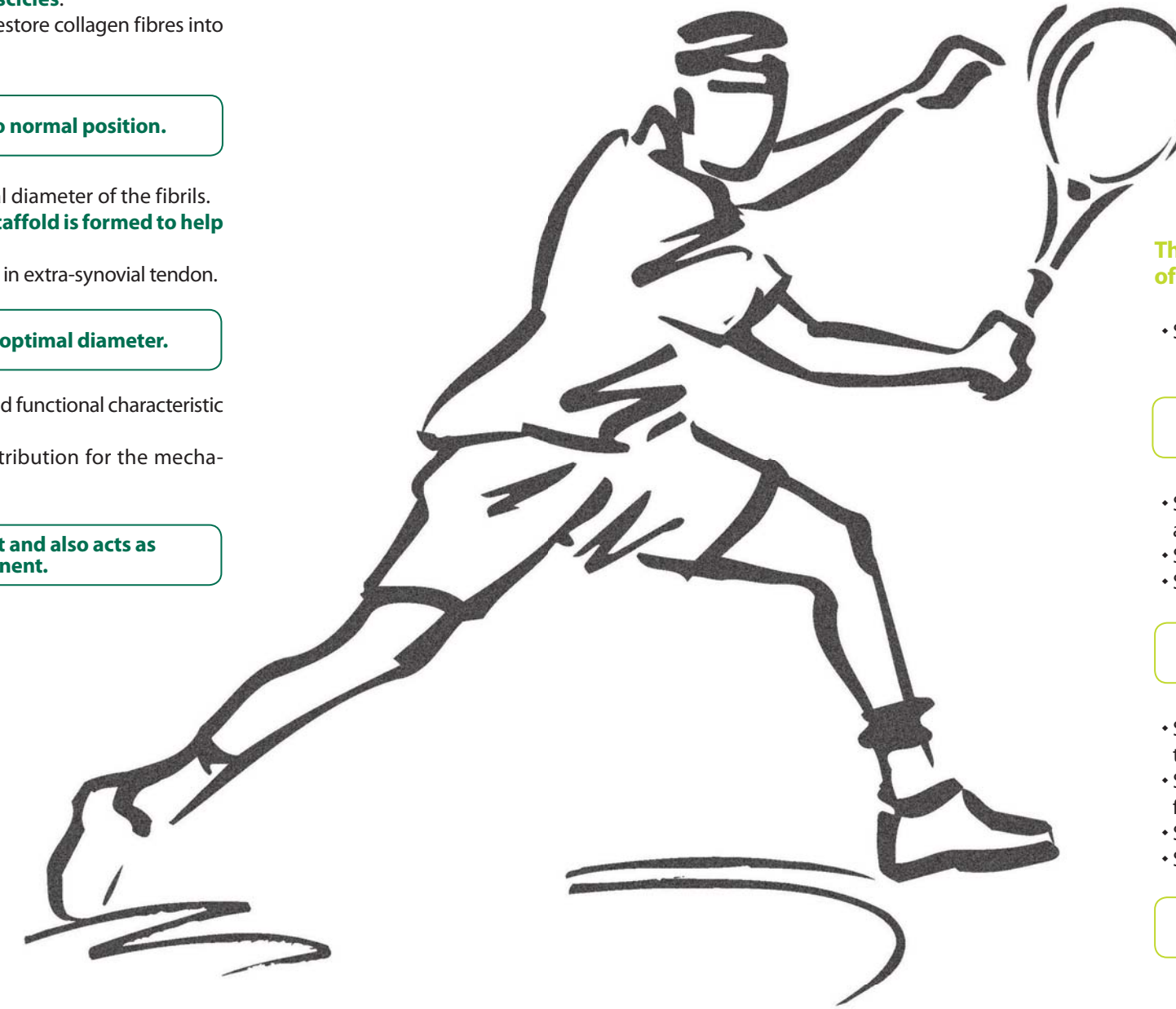
HA helps arrange fibres into normal position.

- HA helps in achieving the optimal diameter of the fibrils.
- HA interacts with fibronectin: **A scaffold is formed to help in cell migration.**
- HA helps reduce gliding resistance in extra-synovial tendon.

HA aids fibres in achieving optimal diameter.

- HA helps restore morphological and functional characteristic of the tendon structure.
- HA provides a fundamental contribution for the mechanism of tendon repair.

HA gives structural support and also acts as healing component.



SportVis™ - Ensures sufficient supplemented HA at the injury site for the repair process.

SPORTVIS™ - THE EFFECTS

SportVis™ contains STABHA™ (Soft Tissue Adapted Biocompatible HA)

The advantages of using SportVis™ for the treatment of epicondylitis are numerous:

- SportVis™ (STABHA™) may maintain required levels of HA content for healing.

Introduces the necessary HA needed for the healing.

- SportVis™ may contribute to accelerate spontaneous healing and reduce immobilisation.
- SportVis™ may help myofibroblast functions.
- SportVis™ may increase tensile strength.

Protects against free radicals.

- SportVis™ may protect against damage to cells by free radicals that are formed.
- SportVis™ may reduce adhesion formation within collagen fibres.
- SportVis™ may act as a mechanical barrier for better healing.
- SportVis™ may reduce repetitive strain injuries.

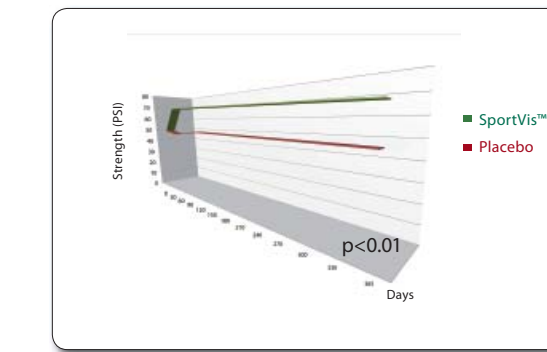
Increases strength and limits further injury.



SPORTVIS™ - THE CLINICAL RESULTS

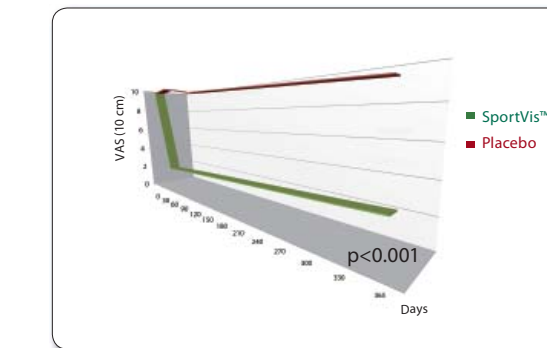
SportVis™ has shown efficacy up to 1 year in a large clinical trial.

GRIP STRENGTH



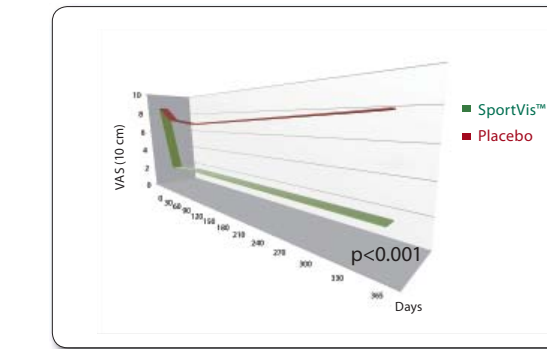
SportVis™ patients have increased grip strength compared to patients in placebo group.

VAS GRIP



SportVis™ patients feel less pain when gripping.

VAS REST



SportVis™ patients have better pain relief at rest.

Management of tennis elbow with sodium hyaluronate periarticular injections

Petrella et al. Sports Medicine, Arthroscopy, Rehabilitation, Therapy & Technology 2010, 2:4

331 Patients with chronic lateral epicondylitis:

Design - Prospective randomized clinical trial in primary care sport medicine.

- 165 patients treated with SportVis™.
- 166 patients treated with placebo.