The science behind injectable, flexible stabilization.

Novobrace is a revolutionary new tissue revitalization technique based on NEXT (Nonsurgical EXogenous crosslink Therapy) technology. Novobrace is particularly effective in treating repair-challenged load-supporting tissues such as ligaments and tendons. Novobrace’s mission is to bring to market the NEXT technology for treatment of various musculoskeletal injuries and diseases in horses and other animals, and the purpose of this document is to introduce and explain the underlying science behind this ground-breaking new product.

Our patented technology, Novobrace, is a chemically made internal brace formed by injection of a crosslinking agent directly into the tendon or ligament, immediately adding mechanical support to the injury. This newly formed brace prevents further propagation of the lesion, provides better stronger healing, and results in the horse returning to full work significantly faster.

Research Supports the Use of Novobrace Technology
Over sixty horses have been successfully injected with Novobrace to date. Numerous articles have been published on Novobrace technology, Nonsurgical EXogenous crosslink Therapy. Several studies have been performed testing the product on equine tendons. Both in the lab and in the field, Novobrace has shown efficacy with minimal side-effects. (Refer to Literature for more details).

Clinical Case Studies
Ten horses with SDFT lesions and one with chronic SDFT tendinitis treated with Novobrace at multiple geographic locations.

- Horses began exercising at accelerated pace (as little as 7-days post-treatment)
- No signs of significant lesion enlargement or propagation noted
- Horses were able to exercise with lesions still visible by ultrasound with no rebowing
- Chronic tendinitis case showed dramatic improvement in fiber pattern within 40 days

Findings submitted to JAVMA.

Biocompatibility
Uninjured SDFTs injected with Novobrace in three healthy horses. Injection resulted in slight lameness due to transient inflammation but gait rapidly returned to normal (7-10 days) as assessed by wireless-computer-based gait analysis system (left). Histology of injected tendons (below) showed that the treated collagen fibers were straighter, reflecting the change in the mechanical properties Otherwise the cells and matrix appeared normal.

Toxicology
Studies conducted to date include: in vitro cytotoxicity experiments, subcutaneous injection studies (rats & horses with clinical observation, blood chemistry, histopathology of injection site, 2-day, 15-day), intratendinous (rabbit Achilles, horse SDFT), and neurotoxicity (epidural worst case injections in rats, 2 hour, 72 hour, with a battery of functional observational evaluations). These tests showed satisfactory results, temporary inflammation, “no treatment related changes”, similar to other studies in the literature.

Literature
Publications and studies on Novobrace technology, Nonsurgical EXogenous crosslink Therapy:
Novobrace is the right technology...for the horse. Novobrace will immediately strengthen and stabilize the tissue, by creating a chemically made internal brace, preventing re-injury or tearing, while supporting normal biomechanics as the tissue heals.

Overview

Unlike cell-based therapies such as stem cells and conventional tissue engineering, Novobrace repairs and stabilizes the degraded tissues in a matter of minutes and hours rather than weeks or months. Novobrace uses a biomimetic injectable approach that replicates and augments a naturally occurring repair mechanism in fibrous collagenous tissues. Long lasting covalent bonds called crosslinks are formed in and between collagen fibers of the tissue matrix using an organic non-toxic agent in a buffered solution. The NEXT (Nonsurgical EXogenous crosslink Therapy) technology that is the basis of Novobrace is currently being investigated for several clinical applications in both animals and humans, including lower back pain, sleep apnea, surgical dehiscence, knee (and stifle joint) meniscus injuries and dorsal displacement of the soft palate (DDSP).

Resistance to Degradation

NEXT technology increased soft tissue resistance to degradation from normal, repetitive mechanical loading. Treatment resulted in a three-fold reduction in fatigue-induced mechanical degradation of bovine disc tissue, a fibrous collagenous tissue with a similar molecular composition to tendons and ligaments.

Compromised soft tissues are thus protected from further degradation induced by repetitive loading and unloading.

Increased Tear Resistance

Slits were cut into strips of bovine spinal disc tissue and the amount of force and energy required to propagate the tear measured for both native tissue and tissue treated with the NEXT technology at the heart of Novobrace.

NEXT technology increased tear resistance by 40%.

Independent Verification

An independent academic laboratory confirmed our own results (Fessel et al., 2012) and showed that treatment of artificially damaged equine SDFTs with the NEXT reagent leads to recovery of normal tissue strains and fatigue failure properties. Treatment increased the number of fatigue cycles taken to achieve tendon failure and came close to restoring injured tendons to uninjured levels (right).

Tissue Strength and Toughness

Novobrace dramatically increased both the strength and toughness of equine superficial digital flexor tendons (SDFT). Chemically-induced core lesions were created in the laboratory and subsequent Novobrace injection raised core strength, stiffness and toughness by between 43% and 130% (left). The Novobrace treatment effect is almost immediate and resists ligament or tendon re-injury during the normal healing process.

Increasing Strength While Retaining Flexibility

To visualize Novobrace’s dramatic mechanical effects on soft tissues, an equine SDFT was clamped into place and laid horizontally onto an aluminum block. At 0, 2, 4, 6 and 24 hours post-injection (four applications of 0.2 ml every 2 cm) the block was temporarily removed and the amount of gravitational sagging recorded. After 24 hours, the tendon was removed and bent by hand to demonstrate its maintained flexibility. Note the blue color that is characteristic of the Novobrace reagent reaction with proteins.