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30-Day Ligament/Tendon Lesion Closure: A 24-horse Case Report Study

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Abstract

This paper describes an electromagnetic method and technique to treat severe equine tendon and ligament lesions, close those injured tissue lesions and then guide them to a healthy state. The signal applied in this method is derived from SQUID (Superconductive Quantum Interference Device) magnetometer signals of healthy and injured soft and dense tissues. A study that enrolled 24 thoroughbred horses in states of Florida, New York and California demonstrates an average 23.5 day Level 4 lesion to Level 1 closure with the SQUID-derived signals, while conventional closure rates range up to 6-18 months. Hi-definition ultrasound administered by licensed veterinarians is used to monitor the lesion closure with final evaluation using two evaluation modalities: image segmentation analysis and acoustoelastic strength evaluation.

Take-Home Message

A new electromagnetic field equine therapy technology is being developed which demonstrates a reliable closure of severe equine lesions of the SDFT or DDFT in less than four weeks. A follow-on imaging technology is being refined which will demonstrate the replacement tissue is healthy instead of scar tissue.

Introduction

Tendon and ligament foreleg lesions are a frequent and career-ending condition for race horses. Many race horses that injure a tendon or ligament will not race again. Others may not return to their previous level of performance.

Injuries to the equine SDFT (Superficial Digital Flexor Tendon) have been the bane of the trainer and frustration for the veterinarian, who have for decades sought means to manage such injuries. Having a large variability for recovery, injuries can take up to 18 months for recovery.[1-3] Whitcomb and Vaughan from the University of California, Davis stated: “It is important to be aware that treatments are thought to improve healing quality and do not reduce the rehabilitation period. Long term success rates have not been proven for individual treatment options, and some studies offer conflicting information.” [4]

The structure of the SDFT consists of a hierarchal collection of fiber bundles surrounded by loose connective tissue called endotenon. Equine activities frequently stress this system to 95-100% of breaking strength (although for a short period of time), but the high stress often produces severe and career-limiting injuries revealed as lesions. These interior cavities may occupy 25-33% of the tendon CSA (Cross Section Area) and are very slow to heal.

Most injuries occur in the foreleg which bears almost 70 percent of the weight. The most common injury occurs to the Superficial Digital Flexor Tendon (SDFT), one of the major tendons on the back of the foreleg, followed by injury to the deep digital flexor tendon (DDF) and suspensory ligament. Each has similar findings at the cellular level and require almost identical treatment regimes.

Tendon injuries come in all sizes and degrees. They are usually so small that they cannot be detected without ultrasound or they may be a complete tendon rupture.

In a tendon injury, both fibers and blood vessels tear. The tendon fibers disrupt and separate and blood and fluid may leak into the tendon lesion. Bleeding ultimately causes a clot to form and within three to four weeks it usually became scar tissue.

A tendon injury usually is accompanied with swelling, hemorrhaging into the lesion and tendon edema (internal swelling of the tendon) from inflammation. Fluids and debris leak into the tendon and, along with blood, separate and weakens the remaining normal fibers. The body tries to clean up the damaged tissue by releasing enzymes, called hydrolytic enzymes that help the breaking of carbohydrate chains. In other words, they would normally chew up damaged tissue into smaller sizes that can be carried away by the circulation. In excess, they can cause further damage to the collagen fibers and the glue that holds the fibers together: the interfibrillar matrix.

The tendon injury initiates an inflammatory process which is an important component of healing. Various cells and enzymes migrate to the tendon's damaged area to clean out the damaged tissue over time. Blood vessel dilation, swelling, heat, pain and an increase of inflammatory blood cells are all signs of beginning inflammation. However, the inflammation should not be allowed to go unchecked, because it might cause damage in healthy tissue. Therefore, it is important to control the inflammation during therapy.

From this point of view, a modality that could offer a variation in the treatment parameters to counter the complex changes at the injury site is the most plausible in treatment of tendon injury. One such modality, using a SQUID based electromagnetic field, is the subject of this paper.

Many practitioners consider that time is the most important factor in recovery. We should point out, however, that the critical factor is the right therapy at the right time. Choosing the right treatment is essential in ensuring that the injury heals as fast as possible. Since the healing is a complex process that involves different cell types at different stages, it is important to select the therapeutic modality that provides an opportunity for change during the healing period.

The therapy technology proposed herein appears to dilate the interfascicular linings of the tendon proper, thus permitting the interior lesion fluids to escape within 30 days, instead of the normal 6-18 months.[5] Once that lesion area has flushed out the tendon CSA, however, subsequent processes are not well understood. It is accepted by the equine community that these former lesion areas will frequently be occupied by scar tissue which is relatively disorganized and not connected properly with regular tendon fibers.

Hi-definition ultrasound is used to monitor the lesion during the treatment process up to closure. However, it is well known that the evaluation of tendon and ligament repair is a difficult and complex process using B-Mode ultrasound. The Hi-definition program described later uses the same ultrasound signal that is commonly accepted in the equine practice, but seeks to remove unwanted noise components.

Materials and Methods

We initiated a study of 24 race horses at race tracks Gulfstream and Calder (Florida), Belmont (NY), Santa Anita (CA) and in certain stables in Delray Beach, Ocala, and Wellington (FL) from December 2012 through February 2014. We look at classical SDTF lesions, both in transverse and longitudinal view and the closure of lesions seen at both views.

This study also uses three physical methods in evaluating the treatment modality discussed here: ultrasound inspection by the veterinarian, image segmentation and acoustoelasticity.

The treatment consisted of an application of an electromagnetic field with a waveform experimentally determined by direct measurement of biological responses from external stresses as recorded by a SQUID (Superconducting Quantum Interference Device) installed at Alexandropoulos, Greece under the direction of Prof. Photios Anninos [6,7]. SQUID magnetometers are capable of detecting extremely weak magnetic fields emitted by normal and injured tissues which are two orders of magnitude weaker than signals recorded by electrocardiograms. The SQUID was originally developed in 1962 by Nobel Prize winner British physicist Brian David and has been used extensively by NASA for extremely weak signal detection. In our case, we use the SQUID to record the signals the body gives off when healing an injury. These minute signals are thought to represent the actual body responses to an injury[8].The signals were specified 15 minutes for inflammation reduction, followed by 45 minutes for tendon/ligament tissue stimulation as delivered by a custom electromagnetic field generator specified by Richard Parker and manufactured by CytoWave LLC of Jupiter, FL*[1] with the waveforms pre-programmed into the device. The signals were applied to the equine foreleg by means of a quasi-Helmholtz coil configuration moulded so as to conform to the horse leg and positioned over the SDF tendon (Figure 1). Magnetic field intensities were up to 50 gauss and up to 60 cycles, which signals in no way adversely affected the health of the treated tissues.

Fig. 1: Placing coils on leg boots

The principal difference between this therapy technique and all others proposed is that the signals used are derived from the actual measured signals from the living organism, recorded and stored into the generating device, then amplified and re-admitted to the injury pathology in such a manner that the recovery process is greatly accelerated.

Ultrasound images were performed using a Sonosite Edge or M-Turbo device with a 7.5 MHz linear probe by licensed veterinarians. Most scans were performed by Jonathan Allen DVM.

Equipment design practice was guided by FCC part 15b, UL and GMP (good manufacturing practices) to ensure safety and comfort for animals during the treatment.

Treatment was applied daily for 60 minutes per session. Lesion closure was typically defined as a change from Type 4 to a Type 1 lesion (definition as provided by the AAEP 2000), or as seen in Figure 2 and 3:

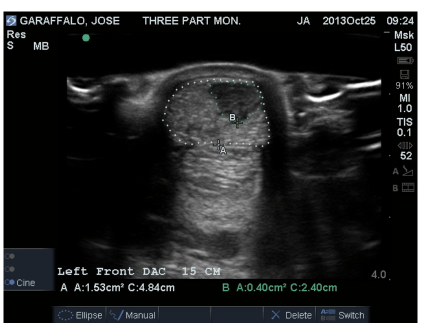


Fig. 2: T/L US @ 15 cm *before* (10/25/13) Type 4 lesion

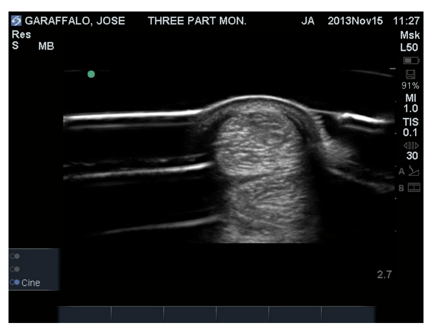


Fig. 3: T/L US @ 15 cm DAC *after* (11/15/13) Type 1 lesion

Results

During the above mentioned period 24 horses were treated by using SQUID based signals, and a complete set of data that is a subject of statistical analysis was obtained for 19 subjects. For these animals the following statistical data were received:

* CytoWave, LLC, 1201 Jupiter Park Drive, Jupiter, FL 33458

Average healing time D and standard deviation SD are

$$D \pm SD = (23.5 \pm 1.2) \text{ days}$$

- It should be noted that for one horse the closure of tendon lesion was reached at day 45. For four horses the closure occurred within 31 days. This represents 22% of the cases.
- The tendon lesion was closed for 21 days in 8 horses which represent 44% of all cases.
- If we consider the closure interval of 20-30 days, it includes 12 horses (67%) of all cases.
- This does not include two remarkable cases: one closure for 12 days and one closure for 7 days.

If the statistical analysis is complete for all horses, it is remarkable to average 23.5 days for complete closure for 94% of the studied cohort.

Discussion

It is well known that after any injury the body mobilizes the systems responsible for repairs. In a tendon injury, the tendon's fibers and blood vessels tear and regional blood/fluid and debris leak into the injured tendon. Therefore, the first process is to mobilize the action of the lymphatic system in order to drain the injury area. Usually this function is attributed to the immune system.

Since we were unable to find appropriate data for the effects of electromagnetic fields in equine therapy, we looked at human medicine. Soft-tissue healing is considered as a complex process involving the interactions of multiple cell types and a variety of molecules[9]. Cytokines, the humeral mediators of inflammation, are induced within minutes to hours after tissue damage, and serve as signals to engulf damaged tissue, destroy infectious agents, and clear the wound bed for healing[10].

A recent paper[11] clearly demonstrated the efficiency of a correctly selected electromagnetic field in the therapy of postoperative wounds and pain. The model of modulation of calcium binding to calmodulin, with subsequent enzyme activation, was proposed. Calmodulin-dependent activation of nitric oxide synthase to produce nitric oxide and its subsequent stimulation of various tissue repair processes is considered in this model.

Neutrophils, the first cellular responder in the inflammatory phase of tissue repair, produces cytokine IL-1 which, in turn, can up-regulate inducible nitric oxide synthase activity, resulting in proinflammatory amounts of nitric oxide to be released into the injury site. Selected electromagnetic fields have been found to stimulate activity of most of anti-inflammatory component.

In our study, we should consider the EMF (ElectroMagnetic Field) stimulation of fibroblast, cytokine and growth factor activity. Then angiogenesis should be considered in the process of regeneration of tendon fibers. It is known that the angiogenesis provides new vascular conduits for oxygen, nutrients, and hormones, and numerous studies indicate that certain electromagnetic fields can have a significant impact on angiogenesis both in vitro and in vivo[12,13].

In all 24 case studies, EMF stimulation was found to promote closure of tendon lesions without formation of the scar tissue, although we cannot demonstrate this as clearly as we would prefer absent histology. Seeking clarification of this unique characteristic, our next research will employ Image Segmentation and Acoustoelasticity to clarify the ultrasound image. However, we may still feel confident about our current approach, as this is in good agreement with the practice of EMF stimulation in bone unification and wound healing. It has been reported that when bone unification was performed within EMF there was no callus formation in the site of unification[13]. The application of EMF in wound healing, despite surgical or result of injury has been reported to lead to closure of wounds without formation of scar tissue[11,15]. These examples are a good conformation to the observation in all our treated animals that the tendon repair occurs without formation of the scar tissue. We hypothesize that this particular EMF stimulation not only significantly accelerates recovery process, but also provides organized tendon tissue after end of the therapy. It is in sharp contrast with the fact that most other modalities used today in the equine practice not only require 6-18 months for therapy, but also form scar tissue[16].

In preparing this paper, the authors could not find another reference which used SQUID signals in the manner as specified herein, so this work appears to be original. All other references the authors encountered resembled simple signals based on trial and error.

Conclusion and Further Plans

We have seen that this system, applied over a wide geographical area by numerous trainers and veterinarians, has achieved a reliable and consistent performance in closing tendon and ligament lesions.

We now address our concerns to the obvious next step, but one which has been lacking in these types of investigations: monitoring and guiding the development of healthy tissue subsequent to lesion closure.

Absent histology, the speckle noise of B-Mode ultrasound is too prominent to achieve a reliable tissue characterization. Many attempts have been made to interpret the data in the ultrasound image and filter out the non-contributory elements in order to determine the true nature of the fiber bundle density before the lesion, during the lesion experience, and after the applied treatment.

We offer two promising technologies which may serve us well in this investigation: Acoustoelasticity[17] and Image Segmentation[18]. Acoustoelasticity offers the promise of determining whether a given region has healthy tissue or scar tissue[19]. Segmentation offers the unique means of a picture of the tendon in 3D mode, which has resolutions similar to that of an MRI. We picture such a high-resolution display of Case Report #29 here (Figure 4), where the lesion is clearly evident among the healthy tissue. This image was directly obtained from the field ultrasound picture using a Sonosite M-Turbo device by Jonathan Allen DVM. In subsequent images later in time, you can observe the lesions disappear with further treatment.

Fig. 4: 3D tendon and lesion as shown in Figure 2

This investigation seeks to make informed decisions absent histology. A recent (unpublished) paper has found that Image Segmentation employing a specific algorithm was equivalent to histology with a very high degree of confidence[20].

When this technology is perfected and is complementary to the therapy technology discussed herein, we feel that the combination will offer to the investigator or trainer and veterinarian a unique low-cost means to diagnose, treat and then guide recovery of severe equine tendon and ligament lesions with a substantial increase in performance and savings in time.

Appendix

We offer Case Report #29 of the horse which was treated by the electromagnetic field SQUID technology as discussed above, and analysed by the Segmentation Technology.

Field Ultrasound and Therapy Report	Report RPT-REL-029
Horse: EQH-029	Location: Gulfstream. Hallandale, FL
Age: 4 years	Owner: EQO-029
Gender: Gelding	Trainer: Jose Garafolo

History: The Superficial Digital Flexor Tendon (SDF) was severely injured September 2013 with a massive set of lesions that extended 40% the length of the tendon. Treatment started on 10/25/13 with proximal lesion closure by 11/15/13 and distal lesion closure three weeks later. **DVM:** Jon Allen, DVM

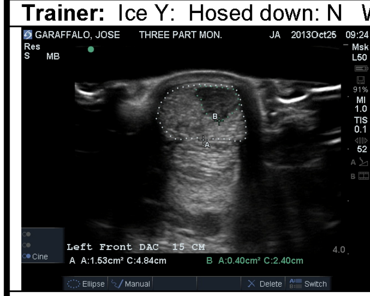
Summary: lesions at 15 and 20 cm were observed by high-definition ultrasound initially on 10/25/13 and again 20 days later on 11/15/13 whereby the 15 cm lesion appeared to be 90% resolved. The horse treatment continued and the next ultrasound on 12/19/13 also shows closure.

Vet Discussion: This subject presented with a massive Type 4 lesion located 15 and 20 cm below the accessory carpal bone. Other lesions are below this study. Closure was 100% by 12/19/13 on these lesions. The subject was treated with a specialized electromagnetic signal developed by CytoWave LLC as part of a field study.

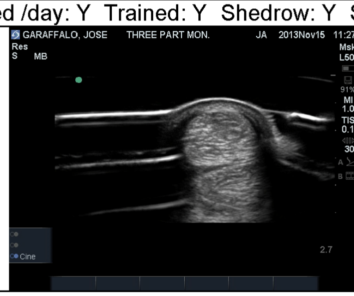
The equipment was applied and administered by personnel reporting to the trainer, applied for an initial period of 7 days for a period of 60 minutes per day on the track and continued. The SDF exhibited an organized filling in of the anechoic lesion seen in the longitudinal fibers which appeared on the longitudinal ultrasound exam as parallel lines. Following the treatment series, the 12/19/13 ultrasound demonstrated a Type 1 lesion (AAEP definition), or full lesion closure.

NOTE**:** there are many other lesions in this case not discussed herein.

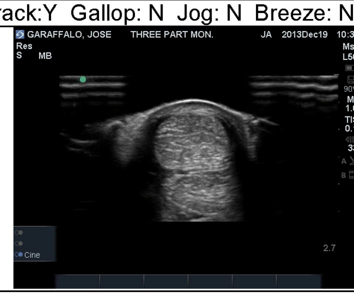
Trainer: Ice Y: Hosed down: N Walked /day: Y Trained: Y Shedrow: Y Saw track:Y Gallop: N Jog: N Breeze: N



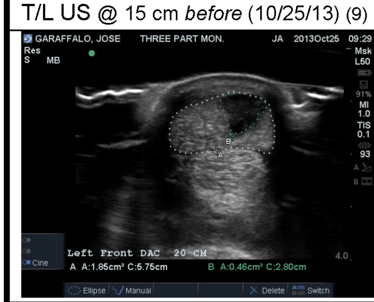
T/L US @ 15 cm *before* (10/25/13) (9)



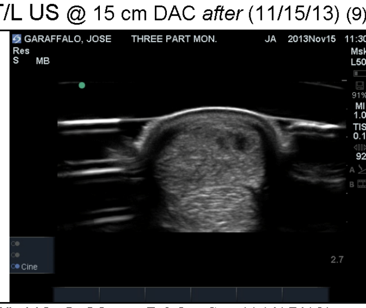
T/L US @ 15 cm DAC *after* (11/15/13) (9)



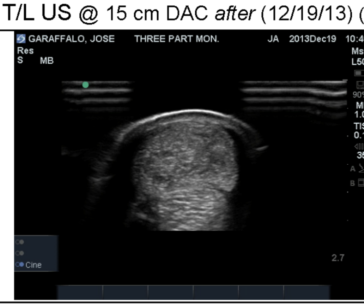
T/L US @ 15 cm DAC *after* (12/19/13) (9)



T/L US @ 20 cm *before* (10/25/13) (19)



T/L US @ 20 cm DAC *after* (11/15/13) (19)



T/L US @ 20 cm DAC *after* (12/19/13) (19)

CYTOWAVE

Performed and subscribed by Jon Allen, DVM:

_______________ (sig.)

1201 Jupiter Park Drive
Jupiter, FL 33458

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