

Healing Of Tendon Tear With A Novel Low Intensity Low Frequency Surface Acoustic Ultrasound (LILFU) Patch

Haim-Moshe ADAHAN, Hanania SHARON, Itzhak SIEV-NER

Pain Rehabilitation Center, The Chaim Sheba Medical Center, Tel-Hashomer, Israel

Correspondence: Dr Haim Moshe ADAHAN Tel: +972 (03) 530 5933 Fax- +972 (03) 530 5179 Email: Haim.Adahan@sheba.health.gov.il

Introduction

Several biological mechanisms have been proposed to explain the influence of LILFU on the acceleration of the tissue repair process, most involve the induction of conformational changes in cell membranes which alter ionic permeability and second messenger activity which then lead to downstream alterations in the expression of certain proteins vital to tissue healing. There has also been evidence that ultrasound helps stimulate nitric oxide [NO] synthase thereby improving the local microcirculation which are thought to help tendon healing. Further ultrasound stimulates the expression of type I and type III collagen in a process that is possibly mediated by the up-regulation of TGF- β .

LILFU treatment to a tendon for prolonged daily treatment sessions has never been available for clinical assessment in humans before. The PainShield is a FDA and EU approved device that is a portable, battery operated, low intensity low frequency ultrasound (LILFU) device that generates continuous surface acoustic wave ultrasound at 90 kHz with a power output of 0.4W. The surface waves provide a large effective treatment zone, for longer periods of treatment time, despite keeping the total amount of energy exposure of the body well below the noxious level, as per the guidelines of the American Institute of Ultrasound in Medicine (AIUM).

Method

We used a PainShield (NanoVibronix Ltd.) device in a domiciliary regimen of overnight use during sleep. The device was programmed to a cycle of 30min on -30min off.

Clinical Cases

Case 1

A.H., a 37 yo triathlete came to our clinic, suffering from chronic left Achilles tendon insufficiency with an MRI proven partial tear of 18 months duration. Patient was refractory to conventional conservative care including - megahertz ultrasound, LASER, NSAIDs and 1 year of rest. A pre-treatment MRI revealed a 2.5cm partial tear of the tendon (fig 1 a, b). On initial evaluation, he was unable to walk, without discomfort. He was started on a daily treatment regimen of the PainShield device; yielding a significant improvement within the first weeks. Interim MRI [after 5 months] shows near complete resolution of the partial tendon tear and significant reduction in local edema (fig 1c). He became pain and disability free, after 9 months of treatment.

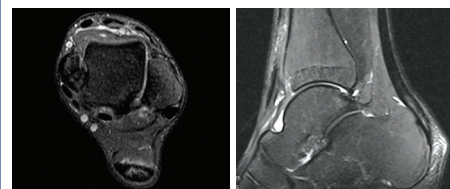


Figure 1a: pre-treatment T2 MRI of the Achilles tendon in A.H. showing a 2.5 cm partial tear ■

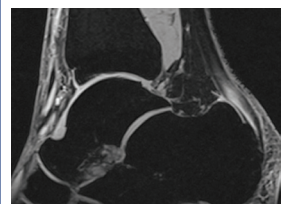


Figure 1b: pre-treatment T1 Post Gadolinium injection pre-treatment MRI study of the Achilles tendon in A.H. showing marked local chronic inflammatory reaction at the site of the tear ■

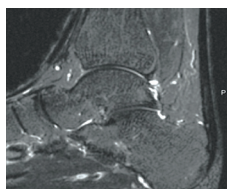


Figure 1c: post-treatment T2 Fat saturation. Sagittal and coronal MRI study of the Achilles tendon in A.H. after 5 months of use of the Nanovibronix PainShield device for 16 hours a day ■

Case 2

S.B, a 69 YO tour guide with an ultrasound confirmed painful 2cm extensor tendon [ECR] at the Elbow(fig 2), due to lifting heavy luggage, 29 months prior to his first visit to our service. He came to us, to avoid surgery, after failing to respond to maximal conservative treatment, which included multiple injections and traditional megahertz ultrasound.

The patient applied the PainShield to the tendon for about 3 hours of daily use for 6 months, followed by 1.5 hrs[3 x 0.5 hrs] daily for the 7th month.

Comparison of pre- and post treatment BPI measures showed a significant improvement in his condition, and indicated an 80% reduction in his overall pain, starting within the first weeks of PainShield treatment. Post-treatment diagnostic ultrasound study (fig 2) revealed near complete healing of the injured ECR tendon.

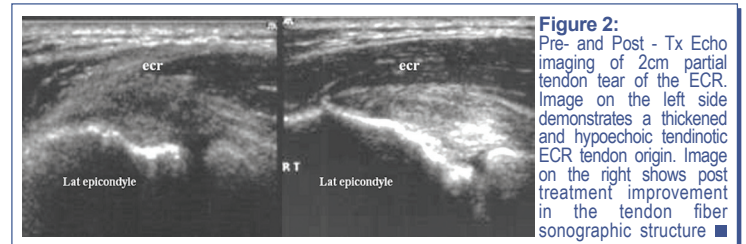


Figure 2: Pre- and Post - Tx Echo imaging of 2cm partial tendon tear of the ECR. Image on the left side demonstrates a thickened and hypoechoic tendinotic ECR tendon origin. Image on the right shows post treatment improvement in the tendon fiber sonographic structure ■

Case 3

O.S, a 32-year-old professional basketball player, described sudden onset pain in his left Achilles tendon, that occurred in the course of a game, 6 months prior to initial consultation with our treatment team, which failed to respond to maximal usual conservative care, including LASER and MHZ ultrasound. MRI performed 4 months after the injury, showed evidence of a partial tear of the left Achilles tendon. The patient remained symptomatic, with diminished power and endurance, which greatly affected his athletic performance, and resulted in his being completely sidelined from basketball, for 3 months after his injury.

We treated the patient with the PainShield device, for 8 hours daily overnight. Four days after starting this regimen, the patient had noted significant improvement. Three weeks after the nightly treatment, he reported to be completely free of any pain or disability related to Achilles tendon injury.

Conclusion

The presented therapeutic results of these case reports, and the significant body of basic science literature, showing many possible mechanisms of beneficial effects of ultrasound on painful tendinopathy, are important indications, that this novel, safe, practical, and economical FDA cleared technology definitely merits further study.

