

# A Sound Solution to Tendonitis: Healing Tendon Tears With a Novel Low-Intensity, Low-Frequency Surface Acoustic Ultrasound Patch

Haim Moshe Adahan, MD, CM CCFP FRCPC(PM+R), Dep Sports Med, Hanania Sharon, BPT, Itzhak Siev-Ner, MD

The use of therapeutic modalities such as nitrous oxide; platelet-rich plasma therapy; stem cell transplantation; and low-intensity, low-frequency ultrasound (LILFU) to enhance tendon regenerative capacity in patients with tendinous insufficiency is in its early stages. Of those alternatives, only LILFU studies have provided level 1 evidence of efficacy in bone healing [1-4]. In vitro, low-intensity ultrasound, which exerts direct nonthermal effects on cell physiology, stimulates the expression of numerous genes involved in the healing process, including aggrecan, insulin-like growth factor, transforming growth factor, collagen, nitric oxide synthase, cytokines, and angiogenesis [5].

Ultrasound, which is a form of mechanical energy, is transmitted into biologic tissues as an acoustic pressure wave at extremely high frequencies. Traditionally, therapeutic ultrasound is in the 1-3 MHz frequency range and the 0.2-1 W/cm<sup>2</sup> intensity range. Long-duration ultrasound treatments can overheat tissues and cause injury and cavitation. Scientific studies of the effects of ultrasound on the acceleration of tissue healing have shown that treatment is beneficial when it is applied in a lower frequency and at a lower acoustic intensity (kHz) range, rather than in high-frequency (MHz) ranges [5].

## The PainShield Device

The PainShield (NanoVibronix Inc, Farmingdale, NY), which has been cleared by the U.S. Food and Drug Administration and by the European Union, is a portable, compact, battery-operated, LILFU diathermy device. It provides safe, low-level energy during the administration of therapeutic ultrasound for relatively longer treatment periods and creates a slow-release effect on the targeted area of injury. The surface acoustic waves provide a wide effective treatment zone and enable longer treatments while keeping the total energy exposure of the body at a safe level [5].

The PainShield generates, via a reusable or disposable adhesive patch, continuous-wave ultrasound at a frequency of 90 kHz, with an acoustic power output of 70 mW/cm<sup>2</sup> (0.07 W/cm<sup>2</sup>). The patch incorporates a thin, flexible transducer that directly couples the ultrasound energy to the underlying tissues without the need for a coupling agent in most cases.

## METHODS

In the following case reports, the PainShield device was used in a home-treatment regimen. The recommended use of the device is for 8 hours, usually during the night. Some patients preferred to add daytime hours of treatment. This was also an accepted regimen for treatment. The device was programmed to a cycle of 30 minutes on, 30 minutes off.

## CLINICAL CASES

### Case 1

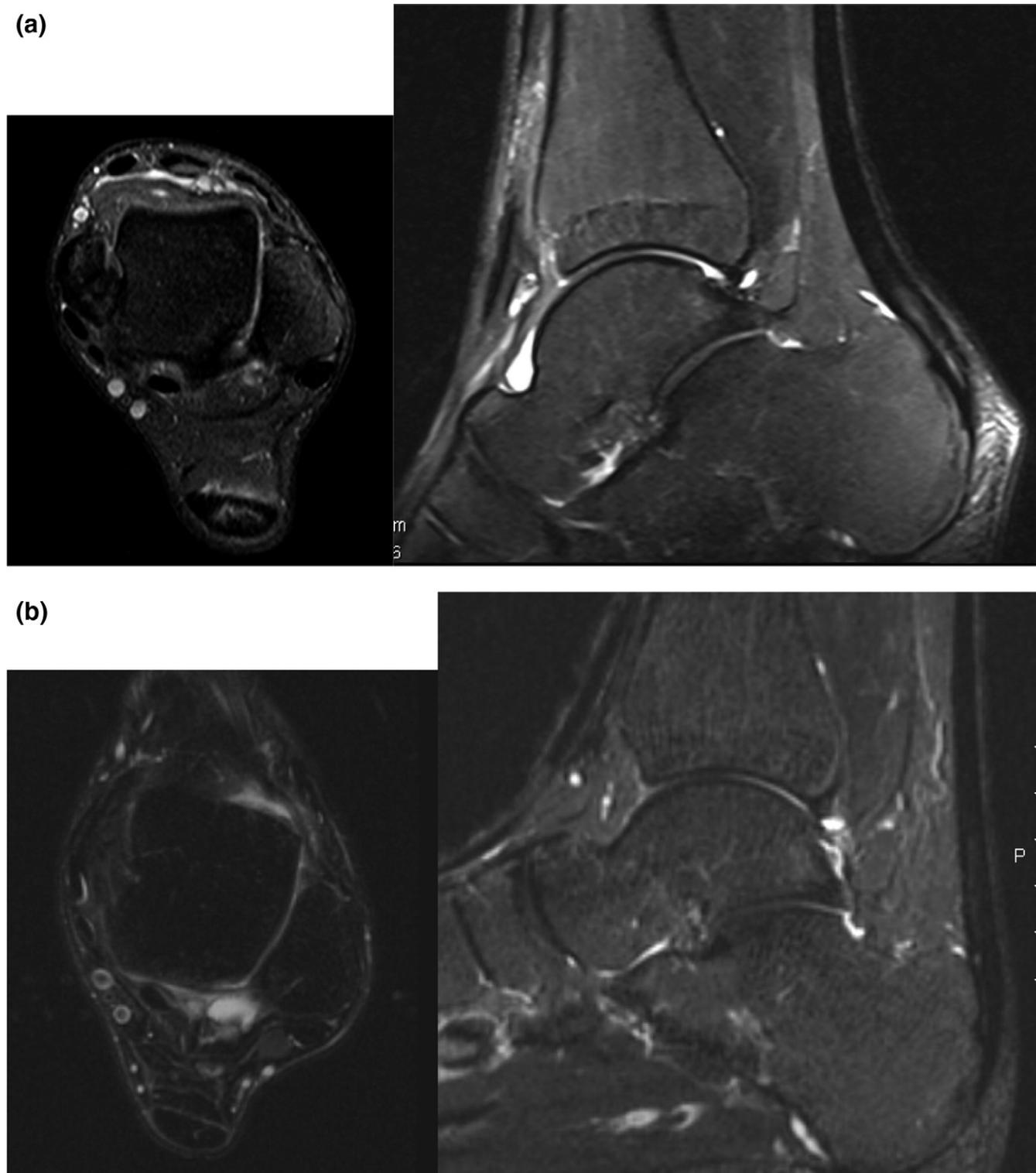
A 37-year-old triathlete presented with chronic left Achilles tendon insufficiency of 18 months' duration. Pretreatment magnetic resonance imaging (MRI) revealed a 2.5-cm

**H.M.A.** Division of the Orthopedic Rehabilitation Department, The Chaim Sheba Medical Rehabilitation Center, Ishpuz Yom Binyan Lechaim Office, No 19 Mercaz Hashikum (affiliated to the Tel-Aviv University, Sackler School of Medicine), Tel-Hashomer 52621, Israel. Address correspondence to: H.M.A.; e-mail: [haim.adahan@sheba.health.gov.il](mailto:haim.adahan@sheba.health.gov.il)  
Disclosure: 1B, NanoVibronix

**H.S.** Physical Therapy Department, The Chaim Sheba Medical Center, Tel Hashomer Hospital, Tel-Hashomer, Israel  
Disclosure: nothing to disclose

**I.S.-N.** Orthopedic Rehabilitation Department, The Chaim Sheba Medical Rehabilitation Center, Tel Hashomer Hospital, Tel-Hashomer, Israel  
Disclosure: nothing to disclose

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**Figure 1.** (A) Pretreatment T2 magnetic resonance image (MRI) of the Achilles tendon from Case 1, showing a 2.5-cm partial tear. (B) posttreatment T2 fat saturation. Sagittal and coronal MRI study of the Achilles tendon from Case 1 after 5 months of use of the Nanovibronix Painshield device for 16 hours a day.

partial tear (Figure 1A) that was refractory to conventional care. A daily 8-16-hour treatment regimen with the PainShield yielded a significant improvement within the first weeks of therapy. An interim MRI, which was performed 5 months after the initiation of treatment, showed almost complete resolution of the partial tear and a significant reduction in local edema (Figure 1B). The patient was pain free and exhibited no disability after 9 months of PainShield therapy.

## Case 2

A 69-year-old tour guide presented with an ultrasonographically diagnosed 2-cm partial tear of the extensor carpi radialis tendon at the proximal insertion. He had sustained the injury 29 months earlier, and it had not responded to conservative treatment. The patient applied the PainShield to the tendon 3 hours daily for 6 months and then 1.5 hours (divided into three 30-minute treatments) daily for the 7th month. A comparison of pretreatment and posttreatment Brief Pain Inventory Scale values showed a significant improvement in his condition and an 80% reduction in his overall pain level, both of which occurred during the first weeks of PainShield treatment. A post-treatment diagnostic ultrasonographic study revealed almost complete healing of the injured tendon.

## Case 3

A 32-year-old professional basketball player, presented with sudden onset pain in his left Achilles tendon of 6 months' duration. A MRI performed 4 months after the injury revealed a partial tear in that tendon that had failed to respond to conservative care. The patient remained symptomatic and experienced diminished power and endurance that greatly and adversely affected his athletic performance. Treatment consisted of the application of the PainShield for 8 hours daily overnight. Four days after the initiation of that therapy, the patient noted a significant improvement in the pain. Three weeks after the initiation of PainShield treatment, he stated that he was completely free of pain and disability caused by his Achilles tendon injury.

## DISCUSSION

The PainShield is the first medical device that uses the physical properties of surface acoustics to help deliver LILFU waves along the length of a tendon, thus ensuring a much wider treatment field than that offered by traditional therapeutic ultrasound devices. The unique physical properties of surface acoustic waves include their propensity to travel efficiently along elastic surfaces, such as tendons, by inducing the elliptic motion of surface points along the tendon surface [6].

## CONCLUSION

Physicians now have an innovative option for dispensing safe, home-based, inexpensive, slow-release ultrasound therapy for use in patients with painful tendinopathy. In light of the results of these case reports and the body of literature that suggests beneficial effects of ultrasound on tendinopathy, this novel technology merits further study.

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