Patch Based Ultrasound: A New Dimension in Therapeutic Ultrasound

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Introduction

Recently, the US Food and Drug Administration (FDA) granted 510K clearance to market PainShield™ MD (PSMD), a unattended hands free device used to treat pain. Functioning at 90 kHz with an acoustic power output of 0.4W, PSMD is the first portable, band aid sized, patch-based, "slow release" ultrasound device (figure 1). Its unique construction has expanded the domain of ultrasound therapeutic treatment for pain and soft tissue healing. It generates a low intensity, low frequency ultrasound wave (LILFU) which is propagated over the surface of the treatment area (Surface Acoustic Waves; SAW)[1]. Many new uses are described in the reviews below as well as unique solutions for traditional ultrasound.

Patch position for Achilles Tendinitis (tendinosis, tendinopathy)

Traditional Therapeutic Ultrasound (TTU)

Ultrasound in general is used primarily for its thermal effects, which promote tissue relaxation, reducing muscle tightness and spasms. It stimulates healing usually without irritation, speeds up metabolism, improves circulation, breaks up scars and adhesions, reduces inflammation and irritation to nerve roots and increases mast cells and collagen production. Ultrasound is used for phonophoresis as well, which delivers therapeutic medications (Acoustic Targeted Drug Delivery). PSMD's nonthermal effects (pulsed ultrasound) are from cavitation, microstreaming, acoustic streaming, alterations of membrane permeability, ionic concentration gradients, and cellular biochemical activity.[2] Like other physical modalities, it decreases healing time.

Unique Features of PainShield™ MD

While PSMD accomplishes much of the above, there are several unique features of the PSMD that have added considerably to its therapeutic effects when compared to TTU.

1) It stays in one position for 6 half hour treatments administered during the day or at night.

2) It operates at 90 kHz with acoustic intensity of 70mW/cm2, compared to TTU's 0.7 to 3.3 MHz, with acoustic intensity of 0.2-1 W/cm2 and utilizes a transducer that is only 3 mm in thickness and has a 6 cm2 diameter.

3) Patients can walk, work and perform daily activities while being treated throughout the course of the day.

4) It allows for the propagation of surface acoustic waves, which opens up new uses for the modality (noted below). A surface acoustic wave (SAW) is an acoustic wave traveling along the surface of a material exhibiting elasticity, whose amplitude decays with depth. The energy penetration depth ~2cm.

5) It has a self regulation feature which eliminates overheating. This maintains minimal mitochondrial degeneration.

It prevents the development of biofilm and increases antibiotic efficacy against biofilm bacteria yet maintains the general healing qualities of traditional ultrasound.[3]

Application of the PainShield™ MD

The band aid-like patch is adhered on the skin so that the ultrasonic transducer (the metal part in the center of the treatment patch) is over the pain source or next to it and in complete contact with the skin. The leads from the PainShield device are clipped onto the patch and turned on using a single operation button. The treatment session consists of several 30 minute LILFU treatments, each interrupted by a 30 minute pause. The device will turn itself off, automatically, at the end of the series of treatments. Some common applications include Morton's neuroma, plantar fasciitis, tarsal tunnel syndrome and various Achilles' issues.

Review of Literature: The Effect of a Novel Patch Based Therapeutic Ultrasound Device on the Healing of Diabetic Foot Ulcers[4]

Comment: This was an open label one week study evaluated by histological analysis.

The PSMD was shown to stimulate epithelialization of diabetic wounds. It also stimulated the precursors of dermal and epidermal growth including Glycoseaminoglycan (GAG's).

Healing of Tendon Tear with a Novel Low Intensity Low Frequency Surface Acoustic Ultrasound Patch[5]

Comment: Three successful case studies are presented along with several hypotheses on the mechanism of action. "…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 (improving the local microcirculation) and the expression of type I and type III collagen in a process that is possibly mediated by the up-regulation of TGF-b."

Patched Base Ultrasound...

Effective Prevention of Microbial Biofilm Formation on Medical Devices by Low-Energy Surface Acoustic Waves[6]

Comment: Infection associated with various kinds of indwelling medical devices (many of which are used in the podiatric profession) is caused by a buildup of biofilm which houses various bacteria and candida species. This paper presents evidence that LILFU prevents the development of these microorganisms, particularly Candida albicans, Proteus mirabilis, and E. coli.

Acoustic Waves Enhance Human Neutrophil Killing of Bacteria[7]

Comment: An in vitro examination of, "the immunological effects of acoustic waves on the capacity of neutrophils to phagocytose and eradicate S. epidermidis bacteria in fibrin gels" is presented. "SAW significantly promotes chemotaxis in response to chemoattractants such as LTB4 or to substances released by opsonized S. epidermidis." Other mechanisms are noted as well.

A Sound Solution for Trigeminal Neuralgia[8]

Comment: This 15 case study was an open label series where patients suffering from acute facial pain due to Trigeminal Neuralgia used PainShield for overnight treatments. 73% of the subjects experienced complete or near complete relief.

Independent In-Vitro Evaluations

NanoVibronix has placed data on its site from a number of independent laboratories that have examined the effect of its devices on various in-vitro and ex-vivo models. In the testing of ex-vivo human skin, skin regeneration was enhanced and cytokeratin 14, collagen 3, and Glycoseaminoglycan (GAG) expression was increased. Cell migration studies done at the University of Miami Skin and Wound Institute were reported to show a significant increase in cell migration, an important element in wound healing. Finally, it demonstrated that SAW technology increased the antibiotic efficacy of Gentamycin by almost 100% in biofilm bacteria.[9]

Discussion

While SAW were first described in 1885 and have found many commercial uses, the medical community has done relatively little to explore their value in therapeutic medicine.[10] Low frequency SAW, like traditional therapeutic ultrasound, produces mechanical stress resulting from a biophysical phenomenon which generates piezoelectric effects and electric potentials in bone.[11] In the last few years the medical community has utilized this phenomenon, which is effective in bone remodeling,[12] and has a dramatic healing effect on fractures. It seems that the propagation of SAW through bone adds to the healing dynamic of soft tissue surrounding the resonating bone.

SAW (kHz range) propagation in "soft" media, such as human skin and tissues, has not been previously investigated. NanoVibronix is the first to investigate and employ SAW propagation on human skin and tissues. Initial studies have shown that kHz range ultrasound is more beneficial than MHz range ultrasound in such treatments as: pain, chronic wound healing, transdermal drug delivery, and antibiotic penetration into biofilm. kHz range acoustic waves differ from those of traditional therapeutic ultrasound (MHz range) in frequency of molecular compression and rarefaction, which are phenomena that occur with the larger amplitudes characteristic of kHz range ultrasound. In addition, the wavelength of kHz ultrasound is longer, and therefore the treatment area is greater.

The PSMD utilizes SAW as well as traditional therapeutic effects of ultrasound for healing and is the first user-friendly modality enabling researchers and practitioners to explore the advantages of LFLIU. It prevents infection associated with catheter-related injury (soft tissue trauma and infection), one of the leading nosocomial complications.In podiatry we frequently use drainage tubes in wound care and pins during surgery which can cause nosocomial complications. PSMD is an important preventative tool in these cases.

Conclusion

This review has presented a number of papers demonstrating the efficacy of PSMD as an effective therapeutic healing device. The utilization of LILFU through PSMD has great potential in healing, especially in podiatry. This author is currently involved in a study at Rutgers University which employs PSMD for the treatment of injured athletes. Being an unattended device, it has improved the efficiency of trainers by reducing the time spent for one-on-one treatment with ultrasound. Rutgers University athletes have a demanding schedule that sometimes limits treatment time. By attaching the LILFU to the athlete's arm or leg, he or she is now able to leave the training room and attend class or catch up on needed rest, yet not interrupt the treatment.

For more information visit www.nanovibronix.com or *circle #160 on the reader service card.*

Dr. Sherman served as a team physician for Billy Jean King's "NJ Stars", World Team Tennis League (91-94). He was a researcher for USFSA/Olympic Training Center (89-90) and received the award of "Outstanding Physician Researcher of the Year" from Morristown Memorial Hospital twice (in 1998 & 2004).

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