

Ultrasound Therapy for Musculoskeletal Injuries: A Medgadget Interview with Michael Slayton, CEO of Guided Therapy Systems

Guided Therapy Systems (GTS), a company based in Mesa, Arizona, is at the forefront of ultrasonic therapy and imaging. Founded in 1994, GTS is the first company in the world that commercialized the combined use of ultrasound imaging with intense therapeutic ultrasound (ITU). Actisound, their latest product to be developed using ITU, is a low-cost, painless and easy to use device that can be used to treat musculoskeletal injuries. According to a 2016 report, one in two Americans present with some sort of musculoskeletal conditions that cost an estimated \$213 billion in treatment and through lost wages.

The two most popular treatments currently for musculoskeletal injuries are physiotherapy or surgical intervention, both of which can be expensive and rarely provide 100% relief. Actisound makes use of decades of technological innovations in the ultrasound space to create small lesions, or thermal injuries, in a controlled setting close to the area that is injured or inflamed. This lesion leads to a kick-off of immune and repair mechanisms by the body that recruit several types of healing cells to the lesion site, which is also close to the site of musculoskeletal injury. So far, the technology has been successfully tested in two clinical trials.

Medgadget had the opportunity to interview the CEO and founder of GTS, Michael Slayton, PhD, to find out more about the results of the trials and the use of the technology for different applications.

Rukmani Sridharan, Medgadget: How did you come up with this technology and how does it work?

Michael Slayton: For the past 12-14 years, high frequency ultrasound has been used for several applications, including cancer ablations, aesthetics and more recently by us for musculoskeletal injuries. Actisound non-invasively and very precisely creates small thermal lesions close to the site of musculoskeletal injury, which triggers the body's natural regenerative mechanism. This is the first step of repair and leads to the recruitment of immune cells, which is followed by a rapid second phase where the cells divide and lay down new matrix made up of collagen. In the third stage, this collagen converts into fibers and this entire process leads to the formation of new musculoskeletal tissue which replaces the damaged tissue found in the site of injury.

Medgadget: What kind of musculoskeletal injuries have been treated using Actisound?

Michael Slayton: So far, we have sponsored two clinical trials at the University of Arizona in Tucson and The Core Institute in Phoenix with Actisound. We focused on patients that had chronic injuries, so they had already

exhausted all other options for treatment. The first trial was for patients with chronic plantar fasciitis, commonly referred to as heel pain and affects 10% of the U.S. population. The study, which was double-blinded and sham-controlled, showed significantly positive results within 12 weeks of treatment in 81% of patients. In the study, they also carried out additional diagnostic imaging before and after treatment, and reported that the size of the injury is directly related to the pain experienced by the patient. This provides a quantitative measure of pain, which is usually considered a qualitative and provided using a scale of 1-10. The second trial explored the use of Actisound on lateral epicondylitis, commonly referred to as tennis elbow, which affects up to 3% of the population. Again, 83% of the 17 patients treated with Actisound reported improvements in pain management. In both cases, the use of Actisound reduced pain and inflammation within 48-72 hours and repaired the soft tissue injuries within 12 weeks. The potential applications for the technology extends far beyond the two injuries treated so far, and can be used to treat other musculoskeletal injuries as well.

Medgadget: Are there limitations with the device in terms of depth of injury?

Michael Slayton: As long as the injury is within line of sight without obstruction from impenetrable tissues like bone, depth is not a challenge. Tennis elbow injuries are generally only 3-4mm deep; however, heel pain injuries are usually 12-14mm deep and by tuning the frequency and intensity of the ultrasound, we can target any depth without challenges.

Medgadget: On your website you mention the use of ultrasound for drug delivery applications as well. Could you explain how that would work?

Michael Slayton: Yes. We have recently entered the field of drug delivery through the use of high frequency, high intensity ultrasound. We have published a few papers on the use of cavitation bubbles to increase the perfusion of tissues and thereby increase the spread of a drug that is delivered through topical delivery. While low frequency ultrasounds can be used to create stable caviations (small bubbles) that explode, high frequencies can be used to create inertial caviations which can implode. Creation of such small bubbles can greatly enhance the speed at which the drug is delivered through topical applications. If a patch takes 8 hours to deliver a drug, using inertial caviations, we can bring the time down to a minute or less. This has to be approached carefully as there are certain safety considerations with the use of caviations for delivering drugs and research into this is still ongoing.

Medgadget: What are the next steps for the company?

Michael Slayton: For the past 23 years, we have created several technologies based around the use of ultrasound imaging and therapeutic ultrasound. We are continuing innovation in this space to increase the number of applications for which therapeutic ultrasound can be used to help non-invasively treat patients.