Kevin Wilk PT, DPT
Champion Sports Medicine
Andrews Sport Medicine & Orthopaedic Center
Director of Rehabilitative Research

"The ZetrOZ sam® ultrasound device is a very useful and efficacious modality. The sam® unit is a long duration wearable ultrasound that we have found to be very effective for the treatment of various musculoskeletal lesions. This unit will change the delivery of ultrasound in the future."

---

**Faster Collagen Synthesis**
- Ultrasound treatment increased the synthesis of hydroxyproline, a constituent of the collagen fibers of the tendon.
- Synthesis was increased by 200% over placebo after 5 days and 100% after 21 days.

Data from Fu et al. (2010) and Jackson et al. (1991).

**Stronger Tendon Tissue**
- Across 5 studies, ultrasound treatment increased the rupture strength of the tendon.
- The average increase in rupture strength was 20% after 5 days and 50% after 42 days when compared to placebo treatment.

Data from Demir et al. (2004), Enwenmeka et al. (1990), Fu et al. (2008), Jackson et al. (1991), Jeremias et al. (2011), Yeung et al. (2005).

---

**RECOVER**
**FASTER STRONGER**

*Sustained Acoustic Medicine*

RECOVER
Sustained Acoustic Medicine
Tendons Are Difficult To Treat

Tendon injuries pose several distinct barriers to recovery:

- Limited vascularization-poor blood and nutrient supply
- Slow cellular proliferation and migration
- The synthesis and deposition of collagen fibers to replace damaged tendon tissues are slow processes which are easily interrupted
- Tendons are subject to chronic overuse and are often re-injured which can prolong inflammation and delay recovery

sam® is Biology Accelerated™

sam® is the first FDA cleared 4 hr continuous ultrasound therapy device. sam® is a wearable technology that aids in recovery and accelerates the body's natural processes.

Injured Tendon
- Poor circulation
- Slow collagen synthesis
- Inflammatory cytokines

Faster & Stronger Recovery with sam® Therapy
- Increased circulation
- Improved collagen fiber organization
- Reduced inflammatory cytokines

Back in the Game
- Ultrasound increases tensile strength 20% to 60% over placebo, reducing likelihood of re-injury to tendon
- Ultrasound increases collagen production and fiber organization 100% - 200% over placebo
**Faster Collagen Synthesis**

- Ultrasound treatment increased the synthesis of hydroxyproline, a constituent of the collagen fibers of the tendon
- Synthesis was increased by 200% over placebo after 5 days and 100% after 21 days

Data from Fu et al. (2010) and Jackson et al. (1991)

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Data from Demir et al. (2004), Enwenmeka et al. (1990), Fu et al. (2008), Jackson et al. (1991), Jeremias et al. (2011), Yeung et al. (2005)
Sustained Deep Penetrating Therapy

**sam®** is the first:
- 3 MHz long duration ultrasound system
- >4°C mean temperature increase at 1.5 cm depth after three hours
- 2-3°C mean temperature increase at 3 cm depth after three hours
- Long duration ultrasound delivers greater total ultrasonic energy than traditional ultrasound

---

**Sustained Mechanisms of Action**

*For Faster Recovery*

**Increased Local Circulation**
- Mechanical interaction of ultrasound with tissue generates deep therapeutic heat and increased circulation. As a result of the increased local circulation, more oxygenated blood reaches the injured tissue, facilitating delivery of nutrients and the elimination of metabolic waste.
- Stable cavitation and convection streaming provide a mechanical energy level capable of altering cell membrane activity to promote soft tissue healing.

**Anti-Inflammatory Response**
- Ultrasound decreases inflammatory cytokines, disrupting the chemotactic gradients that trigger the inflammation cascade. This accelerates the transition to recovery and increases fibroblast migration into the site of injury.

**Mechanotransduction**
- Cell receptors respond to shear forces and compression/rarefraction of the ultrasonic field, stimulating protein production and increasing cellular proliferation.
- Mechanical stimulation promotes fibroblast migration and collagen synthesis.

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1. Rigby JH, Draper DO (2014)
The **sam** Ultrasonic Diathermy Device is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as the relief of pain, the relief of muscle spasms, the treatment of joint contractures, and the local increase in circulation.

The **sam** ultrasonic diathermy device is a prescription use device. The device should only be administered and monitored by a licensed healthcare practitioner.

**CITATIONS**


**Contraindications**

For the use of ultrasound include over an area of the body where a malignancy is known to be present, over the eyes, over or near growth centers until bone growth is complete, over the reproductive organs, over the pregnant uterus, over a healing bone fracture, on the thoracic area if the patient is using a cardiac pacemaker, over an active implanted medical device such as an implanted deep brain stimulation device, on the brain, spinal cord, or large subcutaneous peripheral nerves, ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.

---

**sam® vs. Traditional Ultrasound**

<table>
<thead>
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<th>Energy Delivered (Joules)</th>
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<th>10,000</th>
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</tr>
</tbody>
</table>

**Competitive Comparison**

- **TENS**
- **Traditional Ultrasound (15 minutes)**
- **Laser**

<table>
<thead>
<tr>
<th>Feature</th>
<th>TENS</th>
<th>Traditional Ultrasound</th>
<th>Laser</th>
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<tr>
<td>Increased Circulation</td>
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<td>Increased Cellular Transport</td>
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<td>Reduced Inflammation</td>
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<td>Multi-hour Enhancement</td>
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Abstracts

Ultrasound therapy for calcific tendinitis of the shoulder


Although ultrasound therapy is used to treat calcific tendinitis of the shoulder, its efficacy has not been rigorously evaluated. We conducted a randomized, double-blind comparison of ultrasonography and sham ionization in patients with symptomatic calcific tendinitis verified by radiography. Patients were assigned to receive 24 15-minute sessions of either pulsed ultrasound (frequency, 0.89 MHz; intensity, 2.5 W per square centimeter; pulsed mode, 1:4) or an indistinguishable sham treatment to the area over the calcification. The first 15 treatments were given daily (five times per week), and the remainder were given three times a week for three weeks. Randomization was conducted according to shoulders rather than patients, so a patient with bilateral tendinitis might receive either or both therapies. We enrolled 63 consecutive patients (70 shoulders). Fifty-four patients (61 shoulders) completed the study. There were 32 shoulders in the ultrasound-treatment group and 29 in the sham-treatment group. After six weeks of treatment, calcium deposits had resolved in six shoulders (19 percent) in the ultrasound-treatment group and decreased by at least 50 percent in nine shoulders (30 percent), as compared with respective values of zero and three (10 percent) in the sham-treatment group (P=0.003). At the nine-month follow-up visit, calcium deposits had resolved in 13 shoulders (42 percent) in the ultrasound-treatment group and improved in 7 shoulders (23 percent), as compared with respective values of 2 (8 percent) and 3 (12 percent) in the sham-treatment group (P=0.002). At the end of treatment, patients who had received ultrasound therapy had greater decreases in pain and greater improvements in the quality of life than those who had received sham treatment; at nine months, the differences between the groups were no longer significant. In patients with symptomatic calcific tendinitis of the shoulder, ultrasound treatment helps resolve calcifications and is associated with short-term clinical improvement.

The biomechanical effects of low-intensity ultrasound on healing tendons


The effect of low-intensity ultrasound on the healing strength of tendons was studied in experimentally tenomized, repaired and immobilized right tendo calcaneus (Achilles tendon) of 24 rabbits. Ten tendons were sonicated in continuous waves at a space-averaged intensity of 0.5 W cm⁻² for 5 min every day. The remaining 14 tendons were mock-sonicated as controls. After nine consecutive treatments, the tendons were excised under anesthesia and compared for differences in tensile strength, tensile stress and energy absorption capacity. Sonication at 0.5 W cm⁻² induced a significant increase in the tensile strength (p < .02), tensile stress (p < .005) and energy absorption capacity (p < .001) of the tendons. These findings suggest that high-intensity sonication may not be necessary to augment the healing strength of the tendons and that sonication at similarly low intensities may enhance the healing process of surgically repaired human tendon calcaneus.

Therapeutic ultrasound improves strength of Achilles tendon repair in rats


The purpose of this study was to evaluate the effects of therapeutic ultrasound on structural properties and functional performance of Achilles tendon healing. Thirty Sprague-Dawley rats with surgical hemitransected Achilles tendons were studied. Ten were treated daily with 1 MHz continuous ultrasound at 1.0 W/cm² for 4 min, 11 at 2.0 W/cm² for 4 min and nine served as control without treatment. Achilles functional index (AFI) was recorded preoperatively and postoperative days 3, 10 and 30. On day 30, the rats were sacrificed and Achilles tendons were tested for load-relaxation, stiffness and ultimate tensile strength (UTS). Results showed that UTS of both low-dose (p = 0.023) and high-dose (p = 0.002) groups was significantly greater than in controls. No significant differences in AFI (p = 0.179), load-relaxation (p = 0.205) and stiffness (p = 0.842) were found among groups. These findings suggest that both low and high-dose therapeutic ultrasound accelerate the healing process of ruptured tendon.

In vivo low-intensity pulsed ultrasound (LIPUS) following tendon injury promotes repair during granulation but suppresses decorin and biglycan expression during remodeling


To determine if the effects of low-intensity pulsed ultrasound (LIPUS) on matrix synthesis change at different stages of tendon healing. LIPUS is effective in promoting tendon healing by stimulation of matrix synthesis. The timing of initiation and duration of LIPUS treatment have been shown to affect its effectiveness to promote tendon healing, suggesting a change of tissue responses to LIPUS stimulation. Understanding how the cellular responses to LIPUS stimulation change during tendon healing is thus important. In a rat model of patellar tendon donor site injury, a single sonication of LIPUS or mock-sonication was delivered to the injured knee of the rats on the fourth, 14th or 28th day postinjury. Tendon samples were harvested at 4 hours and 24 hours after sonication and the mRNA expression of COL1A1, COL3A1, decorin, biglycan, and TGF-beta1 was analyzed. The results showed that a single sonication of LIPUS increased COL1A1 and COL3A1 mRNA in healing patellar tendons when administered on the fourth or 14th day postinjury; but not when administered on the 28th day postinjury. Both decorin and biglycan mRNA were decreased by treatment with LIPUS on the 28th day postinjury. Our results showed that LIPUS enhanced collagen synthesis in vivo only during the granulation phase. Matrix remodeling may be affected by LIPUS with the suppressed expression of decorin and biglycan. Our findings suggest that LIPUS should be applied during the granulation phase but not during the remodeling phase, to promote tendon healing.

Effect of ultrasound therapy on the repair of Achilles tendon injuries in rats


The purpose was to determine the effects of selected regimens of ultrasound therapy on the rates of repair of injured Achilles tendons of rats. Specific dependent variables examined were tendon breaking strength and rate of collagen formation. A puncture technique was used to induce injuries to both Achilles tendons of rats. Continuous ultrasound was administered to the left tendon for 4 min per treatment session at an intensity of 1.5 W/cm². Rats were sacrificed at 2, 5, 9, 15, and 21 d following injury for measurement of tendon breaking strength and 3 and 5 d post injury for analysis of collagen synthesis. Breaking strength was defined as the minimum force required to completely rupture the tendon. Collagen synthesis was indicated by the conversion of labeled proline to hydroxyproline. The breaking strengths of the treated tendons were greater than strengths of the untreated tendons 5, 9, 15, and 21 d post injury. Collagen synthesis was increased in the treated tendons compared to the untreated tendons 5 d post injury. The results indicate that ultrasound treatment increases the rate of repair of injured Achilles tendons of rats. The results are also consistent with an association between increased collagen synthesis and greater breaking strength during tendon repair.
Abstracts

The effect of therapeutic ultrasound intensity on the ultrastructural morphology of tendon repair

This study evaluated the effects of ultrasound intensity on the ultrastructural morphology of Achilles tendon healing. Twenty Sprague-Dawley rats with surgically hemi-transected Achilles tendons were randomly assigned into four groups of 0, 0.5, 1.2 and 2 W/cm² for ultrasound treatment, with five rats in each group. The treatments were administered with 1 MHz continuous ultrasound daily starting from day 5 after injury. On day 30, ultrathin slides of the Achilles tendons were prepared and examined with transmission electron microscopy. Results showed that the mean collagen fibril size of all treatment groups was higher than the control (p < 0.05). There was no significant difference in the collagen fibril size among the treatment groups. These findings suggest that therapeutic ultrasound can enhance the maturation of collagen fibrils of repairing tendons, and this was not dependent on the intensity of ultrasound applied.

Low-intensity pulsed ultrasound accelerates healing in rat calcaneus tendon injuries

To evaluate the effect of low-intensity therapeutic ultrasound on the murine calcaneus tendon healing process. Therapeutic ultrasound promotes formation and maturation of scar tissue. Calcaneus tendon tenotomy and tenorrhaphy was performed on 28 Wistar rats. After the procedure, the animals were randomly divided into 2 groups. The animals in the experimental group received a 5-minute ultrasound application, once a day, at a frequency of 1 MHz, a spatial average temporal average intensity of 0.1 W/cm², and a spatial average intensity of 0.52 W/cm² at a 16-Hz frequency pulse mode (duty cycle, 20%). Data for the injured side were normalized in relation to the data from the contralateral healthy calcaneus tendon (relative values). The animals in the control group received sham treatment. After a 28-day treatment period, the animals were sacrificed and their tendons surgically removed and subjected to mechanical stress testing. The parameters analyzed were cross-sectional area (mm²), ultimate load (N), tensile strength (MPa), and energy absorption (mJ). A significant difference between groups was found for the relative values of ultimate load and tensile strength. The mean SD ultimate load of the control group was 3.5% ± 0.52% compared to 33.3% ± 2.8% for the experimental group (P = 0.005). The mean tensile strength of the control group was 47.7% ± 7.1% compared to 28.1% ± 24.1% for the experimental group (P = 0.019). No significant difference was found in cross-sectional area and energy absorption. Low-intensity pulsed ultrasound produced by a conventional therapeutic ultrasound unit can positively influence the calcaneus tendon healing process in rats.

Comparative study of the efficacy of the topical application of hydrocortisone, therapeutic ultrasound and phonophoresis on the tissue repair process in rat tendons

The purpose of this study was to compare the treatment efficacy of topical application of hydrocortisone, therapeutic ultrasound (US) and phonophoresis on the rats Achilles tendon (tendo calcaneus) repair process after tenotomy. The two treated groups with US were made in a pulsed mode. The irradiation of US was performed at a frequency of 1 MHz and an intensity of 0.5 W/cm² (SATA), for 5 min each session. The tendons were analyzed using the polarized light microscopy. The results showed that the treated group with the topical application of hydrocortisone has not been delivered transdermally and that the molecule of collagen responds to the ultrasonic stimulation. The treatment with phonophoresis was the more efficient method. These findings allow us to conclude that the US stimulates the acceleration of tissue repair processes and induces the transdermal delivery of hydrocortisone in a therapeutic concentration on the tendon.

Comparison of the effects of laser, ultrasound, and combined laser + ultrasound treatments in experimental tendon healing

Therapeutic ultrasound (US) and laser (L) treatments accelerate and facilitate wound healing, and also have beneficial effects on tendon healing. This randomized control study was designed to evaluate the effects of low-intensity US and low-level laser therapy (LLLT) on tendon healing in rats. Eighty-four healthy male Swiss-Albino rats were divided into three groups consisting of 28 rats, the left Achilles tendons were used as treatment and the right Achilles tendons as controls. The right and left Achilles tendons of rats were traumatized longitudinally. The treatment was started on postinjury day one. We applied the treatment protocols including low-intensity US treatment in Group I (US Group), Sham US in Group II (SUS Group), LLLT in Group III (L Group), Sham L in Group IV (SL Group), US and LLLT in Group V (USL Group), and Sham US and Sham L in Group VI (USpSL Group). The US treatment was applied with a power of 0.5 W/cm², a frequency of 1 MHz, continuously, 5 minutes daily. A low-level Ga–As laser was applied with a 904 nm wavelength, 6 mW average power, 1 J/cm² dosage, 16 Hz frequency, for 1 minute duration, continuously. In the control groups, the similar procedures as in the corresponding treatment groups were applied with no current (Sham method). The treatment duration was planned for 9 days (sessions) in all groups, except the rats used for biochemical evaluation on the 4th day of treatment, which were treated for 4 days. We measured the levels of the tissue hydroxyproline for biochemical evaluation on the 4th, 10th, and 21st days following the beginning of treatment and the tendon breaking strength on the 21st day following the beginning of treatment for biomechanical evaluation. Seven rats in each group were killed on the 4th, 10th, and 21st days for biochemical evaluation and on the 21st day for biomechanical evaluation. The results showed that the mean collagen fibril size of all treatment groups was higher than the control (p < 0.05). There was no significant difference in the collagen fibril size among the treatment groups. These findings suggest that therapeutic ultrasound can enhance the maturation of collagen fibrils of repairing tendons, and this was not dependent on the intensity of ultrasound applied.
Placement Protocol

sam Placement:

• Always consult user manual when applying sam therapy
• sam bandages are single-use only
• Place sam coupling bandage over the injured area
• Actual bandage placement may vary depending on the condition and/or injury

• sam may be applied utilizing one or two applicators
• Do not overlap sam coupling bandages when applying two applicators
• Do not apply the sam coupling bandages on a boney protrusion
• Additional sam coupling gel may be added if necessary
sam® is an ultrasonic diathermy device that provides a therapeutic solution that aids in the recovery process. sam®'s intended use is to provide therapy to both acute and chronic conditions. Proper placement of applicator/bandage and adherence to treatment regime will ensure the user’s successful recovery.

**Treatment Regime**

**General Guidelines**  
**sam®** should be used multiple times per week

**RECOMMENDED APPLICATIONS**  
4 times per week minimum

**ACUTE CONDITIONS**  
See chart below

**CHRONIC CONDITIONS**  
See chart below  
Continuous and daily use of **sam®** ultrasound therapy is not contraindicated.

**Dosage Calibration**  
Begin the use of **sam®** with incremental treatments to gauge patient sensitivity to treatment.

*This regime will indicate the user’s tolerance level, determine skin sensitivity and maximum dosage of each treatment.

*Dosage is determined by user’s maximum tolerance. The maximum tolerable dosage is suggested for each treatment.

<table>
<thead>
<tr>
<th>Day</th>
<th>Maximum Dosage</th>
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<td>1</td>
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<td>3</td>
<td>3 Hour maximum</td>
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<tr>
<td>4</td>
<td>4 Hour maximum</td>
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<td>5+</td>
<td>4 Hour maximum</td>
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**Number of ** **sam®** Applicators**

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<td>Achilles</td>
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<td>Lateral or Medial Epicondylitis</td>
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<td>Patellar</td>
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<td>Post-Operative (Partial/Full Thickness Tear or Debridement)</td>
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<td>1 or 2 (depending on size of treatment area)</td>
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<td>Tendonosis</td>
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**Treatment duration in weeks**

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<th>Acute</th>
<th>Chronic</th>
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<tbody>
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<td>4 – 6</td>
<td>6 – 8</td>
</tr>
<tr>
<td>Chronic Tendonopathy</td>
<td>2 – 4</td>
<td>6 – 12</td>
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**Post-Symptomatic Resolution**

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<th>Chronic</th>
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<td>Acute Tendonitis</td>
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<td>1</td>
</tr>
<tr>
<td>Chronic Tendonopathy</td>
<td>2</td>
<td>2</td>
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</table>

*Recommended treatment period following resolution of pain related symptoms.

**Proper Placement**

When using one applicator, place the applicator close to the injured site. The second applicator should be placed as close as possible without overlapping the coupling bandages.
### sam® Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
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<tbody>
<tr>
<td>Maximum Acoustic Power Output</td>
<td>0.65W ±20% for one applicator</td>
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<td></td>
<td>1.3W ±20% for two applicators</td>
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<tr>
<td>Maximum Intensity</td>
<td>0.132 W/cm² ±20%</td>
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<tr>
<td>Frequency</td>
<td>3MHz ±20%</td>
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<tr>
<td>Duty Cycle</td>
<td>100% - continuous wave</td>
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<tr>
<td>Beam Form</td>
<td>wide beam–5 degree diverging lens</td>
</tr>
<tr>
<td>Individual Transducer Dimension</td>
<td>5 cm² emitting surface area (circular)</td>
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<tr>
<td>BNR</td>
<td>&lt;5:1</td>
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<tr>
<td>ERA</td>
<td>6 cm² ±20%</td>
</tr>
<tr>
<td>Maximum Treatment Duration</td>
<td>4 hours</td>
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### sam® closed loop continuous temperature monitoring maximizes the safe and effective delivery of the long duration continuous ultrasound

### sam® patented integrated coupling bandage standoff allows for the safe delivery of multi-hour ultrasonic energy

### sam® graduated treatment protocol allow for the evaluation of individual tolerances to ascertain maximum dosimetry

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**DEVICE**

**The sam® Power Controller**

**The sam® Applicator**

**The sam® Coupling Bandage**
sam® Usability and Safety Data

sam® is drug free, easy to use, wearable ultrasound treatment for your patients

94% surveyed practitioners thought sam® was easy to use (n=17)

100% surveyed practitioners would use sam® again (n=17)

90% patients reported a positive experience with sam® (n=60)

FDA Safety Study

- Histological analysis after four hours of therapy found no evidence of tissue damage from sam® treatment
- sam® overlapping ultrasound treatment zones do not create hot spots
- sam® applicator prevents standing wave formation at bone and connective interfaces

Human Clinical Research

- sam® therapy has been tested clinically and results have been published in 11 peer-reviewed research articles and proceedings
- sam® clinical research is funded by the National Institutes of Health, the Department of Defense and NASA
- The sam® team remains committed to empowering patients and improving healthcare outcomes. Ongoing clinical research involving sam® can be found at clinicaltrials.gov
Kevin Wilk  PT, DPT  
Champion Sports Medicine  
Andrews Sport Medicine & Orthopaedic Center  
Director of Rehabilitative Research  

“The ZetrOZ sam® ultrasound device is a very useful and efficacious modality. The sam® unit is a long duration wearable ultrasound that we have found to be very effective for the treatment of various musculoskeletal lesions. This unit will change the delivery of ultrasound in the future.”

Tom Best  MD, PhD  
The Ohio State University  
Professor & Chair Division of Sports Medicine  

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