PROTOCOL

TITLE: STUDY TO EVALUATE THE SAFETY, EFFICACY AND TOLERANCE OF INTENSE THERAPUETIC ULTRASOUND (ITU) FOR THE TREATMENT OF LATERAL EPICONDYLOSIS

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CONFIDENTIAL

Approval of the Protocol

I have thoroughly read and reviewed the study protocol. This study will be conducted in compliance with the protocol, the Declaration of Helsinki, principles of Good Clinical Practice and any applicable regulatory requirement(s).

PRINCIPAL INVESTIGATOR

Signature: ..... Date: .....

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SPONSOR - GUIDED THERAPY SYSTEMS

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INTRODUCTION

Acute and Chronic pain of the Common Extensor Tendon (CET) region, or lateral epicondylitis/lateral epicondylalgia, or tennis elbow is a common pathology of both athletes and non-athletes affecting 1 to 3 % of the population at large.[1,2] The prevalence of chronic problems caused by overuse in tennis players can be as high as 40%.[15] Elbow tendinopathy represents an important set of pathologies that account for lost recreation time, decreased quality of life, and work-related disability claims. As an example, medial and lateral epicondylitis was responsible for 11.7% of work-related injury claims in Washington State from 1987 to 1995, resulting in an average direct workers' compensation cost of $6,593 per case.[16] Elbow tendinopathy has widespread social, financial, and clinical implications. Walker-Bone et al[2] assessed the effect of medial and lateral epicondylitis on workplace absences in a cross-sectional sample of 9,696 working-aged adults. Five percent of patients reported taking a sick day due to their elbow pain within the preceding year.

This condition is most often associated with overuse or a repetitive stress, as opposed to an acute inflammatory reaction. The lack of pathological evidence of inflammation in these types of injuries has lead most authors to now refer to this condition as an Epicondylosis, abandoning the mislabelled "itis".[3–5]

Diagnostic Ultrasound has been used to evaluate musculoskeletal anatomy and pathology since the early 1990's. Ultrasound imaging can be used to evaluate the structure of the Common Extensor tendons, evidence of microtears, partial and full ruptures, and hypoechoic lesions in and about the tendon and peritendinous lesions[9]. Common Extensor Tendon thickness can change with age[10], and should be a useful tool in tracking tendon improvement during a long treatment period.

Conservative treatment of the Epicondylitis or osis is recommended as the initial strategy by most authors. This strategy includes identification and correction of possible etiological factors, and a symptom-related approach. Generally, the initial treatment consists of a multifactorial approach that may include a combination of rest (complete or modified activity), medication (NSAIDs for Epicondylitis), stretching and strength training[9].

Intense Therapeutic Ultrasound (ITU) is a novel potential treatment for CET Tendinosis. ITU is a highly focused ultrasound wave that delivers enough energy intensity to disrupt soft tissues within a controlled up to 1 mm^3 volume, while sparing surrounding tissue structures. Much like a laser is formed by focusing light to concentrate energy over a small area, ultrasound can emit sound waves that can propagate through tissues to deliver selective thermal coagulative changes while leaving the surrounding tissue unaffected.[11,12,13]

ITU has been used clinically for treating the facial soft tissue for the past decade and it has received FDA approval for non-surgical brow and submental lifting. Over 300,000 treatments have been performed with this technology. Clinical studies in 2005/2006 (IRB#'s 05-06-032, 1253-014) using intense therapeutic ultrasound (ITU) on facial soft tissue whereby the energy is focused underneath the skin tissue to achieve controlled coagulative necrosis (~1 mm^3) were performed. Seventy subjects were involved in the studies and 84% of subjects showed an improvement in facial lifting with no significant pain, erythema,

inflammation, or scarring[11,12]. Slight edema and erythema were noted on some subjects, all resolving within 30 minutes after treatment.

Histologically, it has been proven that ITU induces greater dermal collagen with thickening of the dermis and straightening of elastic fibers in the reticular dermis[11-15]. Due to the proven clinical performance, there is current ongoing research that is specifically designed to determine whether ITU can improve healing of damaged Achilles tendon in a rabbit model[15]. The main goal of the project was to determine if ITU accelerates the healing process, and/or promotes a response that leads to superior structural and mechanical properties of tendon. Preliminary results from the rabbit research at day 4 post treatment showed an increase in Vascular Endothelial Cell Growth Factor A (VEGFa), Tumor Necrosis Factor Alpha (TNFα), Interleukin 1-Beta (IL-1β), and Transforming Growth Factor Beta 1 (TGFβ1) and a decrease in Collagen Type 1 Alpha 1(COL1α1), and Collagen Type 1 Alpha 2(COL1α2) in the damaged and ITU treated legs.

At 14 days post treatment PCR showed an increase in Collagen Type 1 Alpha 1 (COL1a1) and Collagen Type 1 Alpha 2 (COL 1a2), as well as an increase in Vascular Endothelial Cell Growth Factor A (VEGFa), Tumor Necrosis Factor Alpha (TNFα), Interleukin 1-Beta (IL-1β), and Transforming Growth Factor Beta 1 (TGFβ1), in the injured rabbit tendon treated with ITU compared to injured, untreated rabbit tendon[15]. These results led us to explore the possibility of performing a clinical trial assessing the effectiveness of ITU in actual patients with CET Tendinosis.

The purpose of this trial is evaluate the tolerability and efficacy of an ITU device to treat CET tendinosis as measured by Subject Self-assessment survey of pain[17], function, and activity (Patient Rated Tennis Elbow Evaluation (PRTEE[18]), Diagnostic Ultrasound Imaging, to evaluate tendon thickness, homogeneity, and gross anatomy/pathology, and physical examination.

ULTRASOUND THERAPY BACKGROUND

i. Historical Background

Ultrasound is an energy modality that can propagate to deeper layers of tissue while sparing the skin surface. The energy created from intense focused ultrasound (ITU) can be focused into deep tissue layers to achieve controlled coagulative necrosis (≤ 1 mm^3).

ii. Previous Ultrasound Research

Ulthera® Studies

Clinical studies in 2005/2006 (IRB#'s 05-06-032, 1253-014) using intense therapeutic ultrasound (ITU) on facial soft tissue whereby the energy is focused underneath the skin tissue to achieve controlled coagulative necrosis (~1 mm^3) were performed. Seventy subjects were involved in the studies and 84% of subjects showed an improvement in facial lifting with no significant pain, erythema, inflammation, or scarring[10,11].

In addition, more than 300,000 patients worldwide have been treated with the Ulthera device with no reportable adverse events.

For these clinical studies, highly focused sources were used at 4.4 and 7.5 MHz, at source power levels of 20 – 60 W. This sharply focused intense field was capable of achieving selective coagulative necrosis in sub-epidermal skin tissue and resulted in substantial improvement of the skin with no side effects.

The Ulthera device has received FDA clearance for non-invasive lifting of the eyebrow, neck and submental regions (K121700).

Pre-clinical

Therapeutic application of ultrasound energy in skin tissue, has been extensively investigated by our group[10-13]. The selective thermal coagulation of skin tissue with directive ultrasound energy was demonstrated *in vitro* as well as *in vivo*. In order to comprehensively understand the ultrasound energy-skin tissue interaction, a wide range of ultrasound source geometries and source conditions were investigated during the pre-clinical research. The source frequencies investigated ranged from 4 – 10 MHz, whereby the source acoustic power ranged from 5 – 80 W.

A summary and scope of the various pre-clinical studies is provided in the **Table** below.

Table: Summary results of multiple exposures and effect on skin tissue using UltraSite ST™ System

Institute	Tests	Number of Exposures	Goals Accomplished
MEEI, Harvard Med. School, M White, MD, R. Gliklich, MD	6 Human cadavers 7.5 and 4.4 MHz probes	>1000 exposures placed in facial skin tissue At least 200 sample shots assessed (NBTC + H&E staining)	-- Define clinical procedure steps (skin marking, lesion identification, etc.) -- Verify treatment control, maximum depth, and dose response
Wellman Labs, MGH, H.J. Laubach, MD	*Ex vivo* human torso/back skin 7.5 and 10 MHz probes	>150 exposures All shots assessed (NBTC and Eosin counter-stain)	-- Understand basic skin tissue effect (depth, dimension, control, etc.) with ultrasound -- Understand biophysical processes – selective thermal ablation and its predictability
UC San Diego, R. Fitzpatrick, MD	6 Human cadavers 7.5, 4.4 and 10 MHz probes	>1000 exposures placed in facial skin tissue At least 300 samples assessed (H&E and Trichrome-Masson staining)	-- Validate clinical treatment logistics (skin marking, lesion identification, etc.) -- Validate visual (clinical) effect of tissue shrinkage -- Verify treatment depth, control, and dose response -- Identify Trichrome-Masson stain as a potential predictor of thermal damage with UltraSite ST™ System

Ulthera, Inc., I.R.S. Makin, MD. PhD, PG. Barthe, PhD, MH. Slayton, PhD	*Ex vivo* porcine skin 8 *in vivo* porcine abdominal skin experiments 7.5, 4.4 and 10 MHz probes	>1000 exposures placed in porcine skin (***in vivo*** and ***ex vivo***) At least 70% of samples assessed histological (NBTC and H&E)	-- Device and application development -- Correlate experiment with numerical simulations -- Understand skin-ultrasound biophysics -- Confirm dose response

In summary, safety and efficacy for the described above studies performed with intense therapeutic ultrasound (ITU) was demonstrated.

STUDY OBJECTIVES

To evaluate the tolerance, efficacy and safety of an ultrasound therapy device to treat CET tendinosis as measured by:

- Subject survey of pain, function, and activity: Patient Rated Tennis Elbow Evaluation (PRTEE).
- Diagnostic Ultrasound Imaging, to evaluate tendon thickness, homogeneity, and gross anatomy/pathology.
- Subject self-assessment of improvement, satisfaction and treatment tolerability.
- Physician physical examination.

STUDY DESIGN

This will be a single center, controlled study involving a total of twenty-five (25) subjects with CET tendinosis (figure 2). Subjects will receive two treatments. Each treatment will be up to ten minutes (10 minutes) in duration.

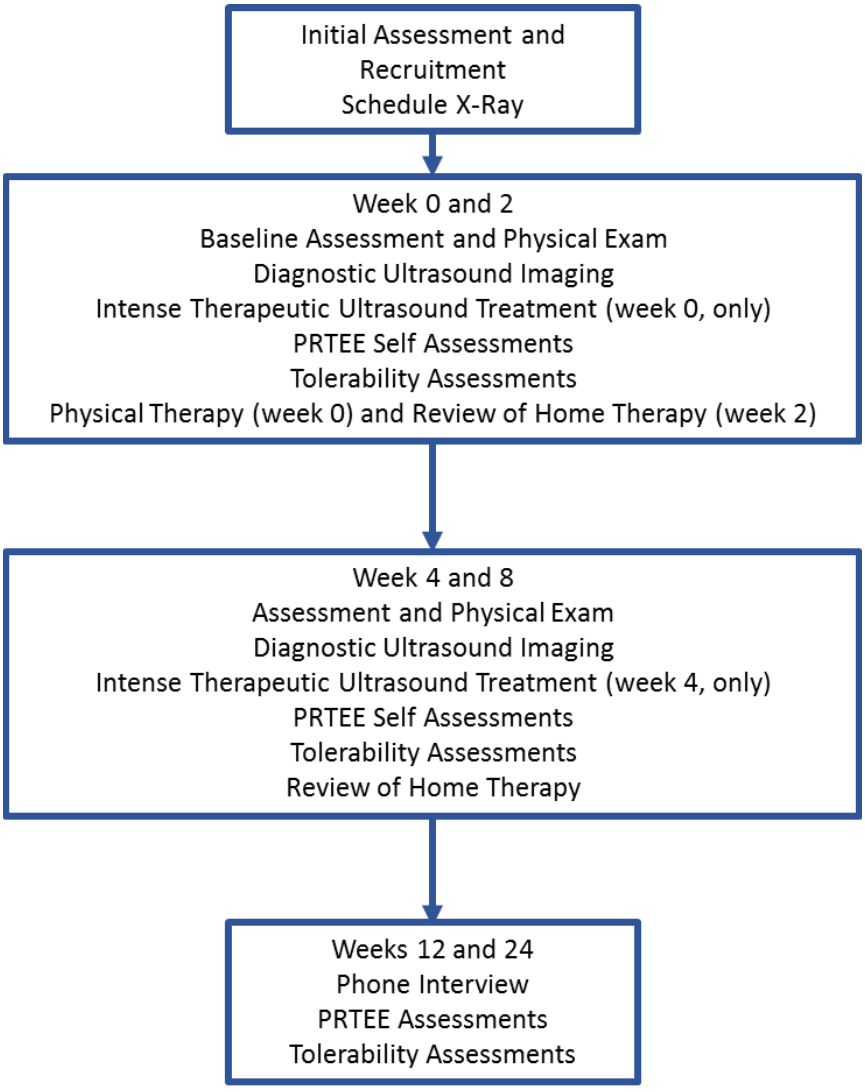


Figure 1. Study Design.

STUDY OUTLINE

This study will be approximately 2 months in duration plus 2 telephone surveys at 12 and 24 weeks. Subjects who meet the criteria and provide written consent to be in the study will be included in the study.

Subjects will receive conservative standard of care treatment plus two ITU treatments (week 0 and week 4) on the affected CET (figure 2) using the ultrasound therapy device. Treatments will be up to 10 minutes in duration. A 2, 4, and 8 week follow up period will be included to monitor the effects of the therapy post treatment. A 12 and 24-26 week telephone assessments for the primary objectives will also be included. Telephone assessments will consist of the subjects answering the survey questions over the phone.

Subject self-assessments will be conducted before the treatment phase and during the follow-up period. Physical exams will be completed by a physician. Physical therapy will completed by a therapist. ITU treatment and diagnostic ultrasound will be performed by Guided Therapy personnel as shown in the full schedule of events (Appendix 1).

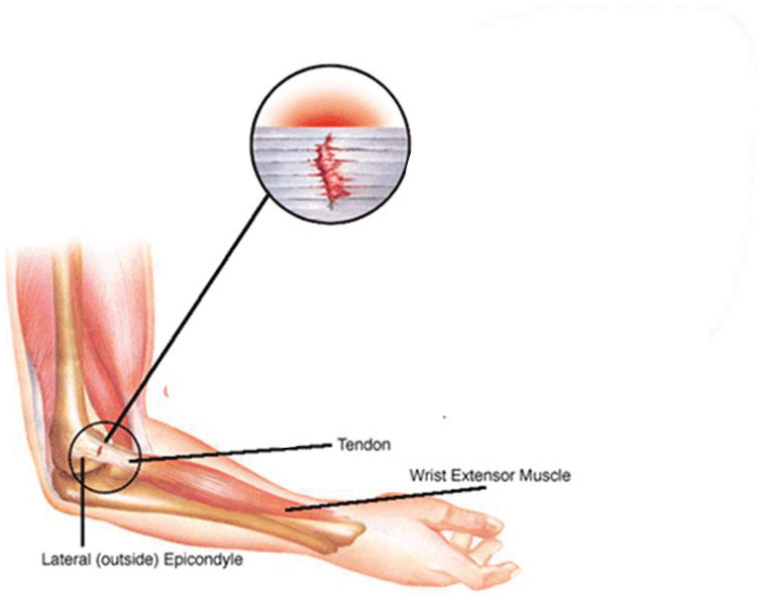


Figure 2: Treatment Area

SELECTION OF SUBJECTS

Planned number of subjects

The study population will consist of up to 25 subjects with unilateral CET tendinosis defined as pain lasting more than 3 months with little or no improvement following conservative standard of care alone.

The selection of suitable subjects will be made according to the inclusion and exclusion criteria described in the following sections.

Inclusion Criteria

1. Subjects who are in general good health and are willing to cooperate and participate by following study requirements for the duration of the study, and to report any adverse symptoms immediately;
2. Subjects who have provided written and verbal informed consent;
3. At time of enrollment subjects are between the ages of 21 and 65 years
4. Subjects literate in English and able to complete all patient self-assessment questionnaires;

5. Subjects is willing to refrain from beginning any additional treatment during the duration of the study;

6. Subjects is willing to refrain from changing physical activity during the duration of the study;

7. Subjects diagnosed with unilateral CET tendinosis defined as pain lasting more than 3 months with little or no improvement following conservative standard of care alone.

8. Subjects with BMI ≤ 35 or at the discretion of the PI.

9. Subjects must be able to sit in a chair with their arm on an appropriate table for the treatment and diagnostic ultrasound imaging.

10. Subject must be able and willing to complete the at home therapy regimen.

Exclusion Criteria

Subjects with any of the following conditions are not eligible for participation:

1. Subjects currently enrolled in any other device, or IND (Investigational New Drug) clinical trial, or who have participated in a clinical study involving the CET, thirty days prior to study initiation;
2. Subjects who have participated in any other clinical study involving an investigational product 30 days prior to enrollment that, in the opinion of the Principal Investigator, could affect the outcome of this study;
3. Subjects who have received any previous treatment in the symptomatic limb in the past 30 days timeframe (not including standard of care treatment);
4. Subjects diagnosed with bilateral CET tendinopathy.
5. Subjects who have had any previous difficulties or problems with wound healing, bruising, scarring or procedures involving medical devices;
6. Subjects with diagnosed uncontrolled metabolic diseases, such as diabetes, hypertension, hyperthyroidism, and hypothyroidism as determined by the initial paperwork;
7. Subjects known to be pregnant or nursing as determined by the initial paperwork;
8. Subjects currently taking medications which, in the opinion of the Investigator, may interfere with the study (e.g., statins, prescription steroids, prescription anti-inflammatory drugs, etc.). Subjects who have been on a stable dose of medication for a minimum of 3 months prior to the study start, and who agree to continue that dose of medication for the duration of the study may be allowed to participate at the Investigator's discretion
9. Subjects who have taken quinolone antibiotic in the past 3 months;
10. Subjects with a diagnosed auto-immune disorder;
11. Subjects with diagnosed fibromyalgia;
12. Subjects with diagnosed peripheral neuropathy;
13. Subjects that will not be available for on-site follow-ups as noted in the schedule.
14. Subjects with previous CET tendon rupture in the symptomatic limb.
15. Subjects with BMI > 35 or at the discretion of the PI

Individuals will be admitted to study at the discretion of the investigator or designate based on medical history (eligibility paperwork) and findings of the pre-study interview and examination.

Subject Restrictions

Subjects must not change their physical activity during the course of the study.

Subjects' BMI must not increase to > 35 or at the discretion of the PI

WITHDRAWAL OF SUBJECTS.

Subjects may discontinue from the clinical study at any time. In addition, the Principal Investigator (PI) or designee has the right to withdraw a subject for any reason that is in the best interests of the subject. The subject must inform the Investigator immediately if they intend to withdraw. Subjects may be asked to come to the study facility to complete some end of study procedures.

The Investigator can remove the subject from this study without their consent for any reason, including, but not limited to:

- His/her judgment that any condition or circumstance may jeopardize their welfare or the integrity of the study.
- Their failure to follow the instructions of the investigator(s) (protocol non-compliance)
- Subject BMI exceeds ≥35 during the courses of the study.
- If the study is stopped by GTS and/or Principal Investigator of the study prior to completion.

CLINICAL ASSESSMENTS

Assessment of Efficacy

Primary:

The primary endpoint(s) for efficacy and tolerability will be the total score of the PRTEE questionnaire (Appendix 2), subject self-assessment of improvement and satisfaction (SROM-Appendix 3-B), and Visual Analog Scale for Pain (VAS) or Universal Pain Assessment Tool (Appendix 3-C).

Secondary:

The secondary endpoint for efficacy will be a measured reduction in tendon thickness by diagnostic ultrasound, and a physical examination.

PRTEE Questionnaire

The PRTEE questionnaire **(Appendix 2)** evaluates three domains clinically relevant to patients (pain, function, and activity) and was specifically developed to assess the clinical severity of CET tendinopathy. It is composed of 15 questions that cover 3 domains of pain (questions 1 through 5), function for specific activities (questions 6 through 11), and general activities (questions 12 through 15). All questions are scored 0 – 10. Higher scores indicate more severe CET tendinopathy. The PRTEE questionnaire has been validated and shows good test-retest reliability[18]

Physical Examination

Medical History: Review patient's medical history questionnaire. Review any diagnostic imaging, tests, or work up listed under longitudinal medical record and centricity. Ask about possible trauma or history of injuries to the symptomatic arm. Review athletic history (tennis, golf, etc) and subject's pre-study exercise regimen (if any). Height, Weight (BMI) will also be documented.

History of Present Illness: Most common complaint is of elbow pain.

Social Hx: Frequently found those involved in racquet sports.

Medications: non-steroidal anti-inflammatory medications and corticosteroids.

Pain: measured on the VAS scale; note activities that increase symptoms, decrease symptoms, and the location of symptoms.

Examination protocol is simple and will consist of the following:

a. Skin examination (note any rashes, lesions, areas of skin irritation over the lateral elbow region)
b. Palpation over the lateral epicondyle of affected side, note presence of tenderness to palpation vs. no tenderness to palpation
c. Check range of motion of elbow in flexion, extension, pronation, and supination (may use normative template data that is in EMR under elbow exam)
d. Check provocative tests for lateral epicondylitis and note whether or not these elicit pain that refers into the common extensor tendon. The 2 provocative tests will be: 1. Resistance to active wrist extension. 2. Resistance to active middle finger extension

Ultrasound Imaging

Ultrasound images will be collected from test sites on both the affected and unaffected CET using the Spark® High Frequency Ultrasound System. CET tendon thickness, homogeneity and gross assessment of the CET tendon and surrounding tissue will be conducted.

Assessment of Safety

Recording of Adverse Events or any other significant event will take place at all visits. Adverse events will be monitored throughout the study. (Appendix 5)

ASSESSMENTS AT EACH VISIT

An overview of the assessments to be conducted at each study visit are presented in a Table in Appendix 1.

Subjects will be treated at Visit 1 and Visit 3. Imaging will occur, before the treatments, and at visits 2, and 4. The PRTEE questionnaire will be administered, prior to the first treatment at visits 1 and 3, and at visits 2, and 4. An additional telephone follow-up, where answers to the questionnaires will be recorded, will occur at 12 and 24 weeks post treatment one (1) per the schedule in Appendix 1.

The study will last approximately two (2) months with a follow-up phone call at three (3) and six (6) months.

Visit 0 (Recruitment): Screening and Enrollment

1. Candidate subjects will read an informed consent (which includes a confidentiality agreement) and will sign (along with a witness) after all questions about the study have been answered. Individuals will be issued a temporary screening number.
2. Eligibility paperwork will include documentation of pregnancy status and pertinent medical history.

If a subject meets all the inclusion/ exclusion criteria, they will be enrolled onto the study, issued a subject number and an X-ray will be scheduled.

Visit 1 and 3: (Weeks 0 and 4) Study treatments

1. Record AEs, con meds and other events
2. Administer PRTEE-A questionnaire (Appendix 2)
3. Subject self-assessment questionnaire (Appendix 3)
4. Focused Physical Evaluation
5. Diagnostic Ultrasound images taken
6. ITU treatment, and VAS assessment of treatment tolerability.
7. Physical Therapy will be performed as described (Appendix 4 – Visit 1 only)
8. Home Cold Pack & Stretching Program review and Log (Appendix 6-A and 6-B)

Visit 2, and 4: (Weeks 2 and 8) Diagnostic Ultrasound, Self-Assessments, Physical Examination

1. Record AEs, con meds and other events;
2. Administer PRTEE-A questionnaire (Appendix 2)
3. Subject self-assessment questionnaire (Appendix 3)
4. Diagnostic Ultrasound image taken;
5. Home Cold Pack & Stretching Program review and Log (Appendix 6-A and 6-B)

Phone/Online Interviews at 3 and 6 months post treatment

1. Record AEs, con meds and other events;
2. Follow-up phone interview PRTEE-A verbally administered (Appendix 2).
3. Subject self-assessment questionnaire (Appendix 3)

STUDY TREATMENT

ITU will be performed by a trained technologist, using a clinical prototype (Ulthera FDA cleared in Sept. 2009) GEN II or GEN III designed Guided Therapy Systems, LLC. Mesa, AZ USA (Appendix 7-A).

Subjects will be treated seated with their arm resting on a structure that is comfortable for the subject and technologist. Transdermal application of ITU therapy: An average energy up to 3 joules (0.5 to 3 J) will be administered to the affected CET tendon longitudinally until the maximum number of lines (12) are reached. Each line will include individual thermal zones, less than 1 mm^3 in volume, centered at a depth between 2 – 6 mm, up to 2 mm apart (figure 3).

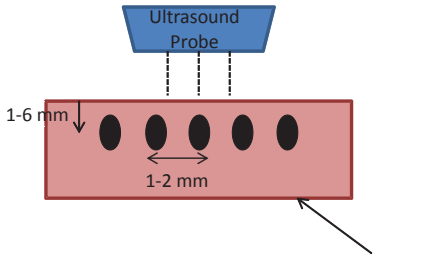
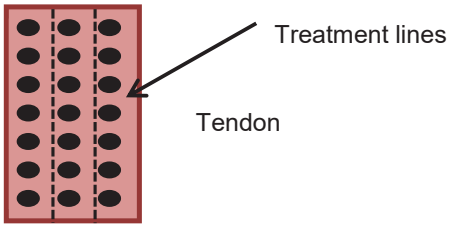


Figure 3. Zone pitch, and depth.

Treatment pattern:



Acoustic Coupling Gel will be applied every 3-5 lines.

Figure 3-1. Zone pitch, and depth.

The study treatment will be a 10 minute session using the ultrasound therapy device with coupling gel. Subjects will be treated seated with their arm resting on a structure that is comfortable for the subject and technologist.

DIAGNOSTIC ULTRASOUND IMAGING

Diagnostic Ultrasound Imaging will be performed by a trained Sonographer using the Spark® Imaging System, manufactured by Ardent Sound, Inc., Mesa, AZ USA (Appendix 7-B)

Subjects will be imaged seated with their arm resting on a structure that is comfortable for the subject and sonographer.

PolySonic® or AquaSonic® Gel will be applied by the sonographer as required to maintain adequate acoustic coupling. (Appendix 7-C)

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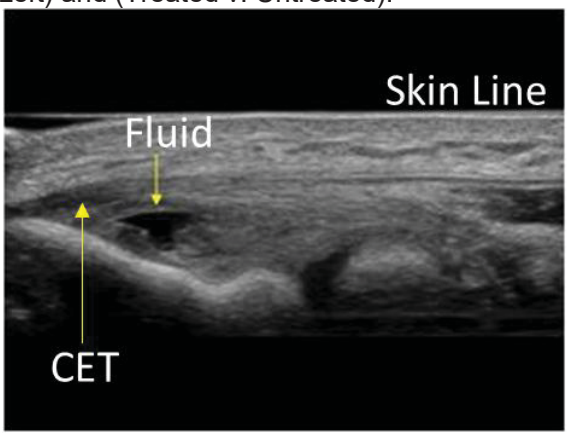
Images will be preserved with the following notations:

- Protocol ID
- Right vs. Left CET Tendon
- Treated vs. Untreated

Long Axis and Short Axis (if necessary) images will be stored at the Sonographer's discretion, to demonstrate and track the applicable anatomy/pathology in the peri-CET area.

Sonographer will also measure the thickness of the CET tendon in each applicable image.

Sonographer will scan the contralateral CET tendon in the same manner noting the change in the tendon (Right v. Left) and (Treated v. Untreated).



Common Extensor Tendon

Figure 4: representative long axis ultrasound images

Outcome measures

Subjects will complete subject reported outcome measures at 0, 2, 4, 8, 12, and 24 weeks and will undergo a focused physical examination and diagnostic ultrasound at 0, 2, 4, and 8 weeks. Adverse events will be recorded at each visit. Treatment tolerability will be assessed immediately after each treatment using the Visual Analog Scale for Pain (VAS) or Universal Pain Assessment Tool (Appendix 3-B). The VAS will be used for 2 different assessments: 1. Pain related to physical activity of the symptomatic arm before treatments and at follow-up visits and phone surveys. 2. Pain tolerance of the therapy treatment. Each of these assessments will be documented and evaluated separately.

Aim 1: reported outcomes

The principal aim of this study is to assess the efficacy of treatment and time course of response to treatment using validated subject reported outcome measures assessing pain, function and level of activity. Subjects will complete validated subject reported outcome questionnaires assessing pain, function and level of activity prior to initiating treatment and at

0, 2, 4, 8, 12, and 24 weeks after starting treatment (Appendix 2 and 3A).

Clinical Pain and Treatment Tolerance will be assessed using the Visual Analog Scale for Pain (VAS) or Universal Pain Assessment Tool (Appendix 3-B).

Function will be assessed using three validated response forms: PRTEE - An index of the severity of CET Tendinopathy[18] (Appendix 2), Self-Reported Outcome Measures (SROM)[16].

Level of Activity will be assessed using the activity subscale of PRTEE[18] (Appendix 2). This subscale scores quantitatively the level of difficulty subjects face when they perform basic activities of daily living. It has shown to be an accurate and reliable predictor of the activity level while performing day-to-day activities.

Statistical analysis
Data will be assessed for variance homogeneity and normality. PRTEE[18], and Visual Analog Scale for Pain (VAS) or Universal Pain Assessment Tool (Appendix 3-B) scores will be assessed before and after intervention. The VAS will be used for 2 different assessments: 1. Pain related to physical activity of the symptomatic arm before and after treatment. 2. Pain tolerance of the therapy treatment. Each of these assessments will be documented and evaluated separately.

Aim 2: CET Tendon thickness

Diagnostic ultrasound imaging will be performed with an FDA approved ultrasound scanner (Spark® System, Ardent Sound, Inc. – Mesa, AZ, see Appendix 7-B using a coupling gel (Polysonic®, or AquaSonic®, Parker Laboratories, Inc., Fairfield, NJ, see Appendix 7-C) by a trained sonographer or physician. Subjects will be treated seated with their arm resting on a structure that is comfortable for the subject and technologist.

CET Tendon thickness is measured before treatment(s) and at each documented assessment (Appendix 1). Paired t tests are used to compare the CET Tendon thickness means between pre- and post-treatment between the symptomatic and treated arm and the asymptomatic and untreated arm. $P<0.05$ is considered to be statistically significant. Any peri-CET pathology will also be documented.

Aim 3: Assessment of safety and tolerability

Subject self-assessments of treatment tolerability will be conducted immediately after treatments, and at each follow-up visit and phone survey using a 10-point visual analog scale VAS, (Appendix 3-B). The subject will be asked to report their current level of pain and the maximum level of pain experienced since the last treatment. The surveyor will remind the subject of the VAS criteria and record their reply. The VAS is the standard for assessing pain for both clinical and research purposes[22].

Recording of adverse events will take place at all visits (see adverse event reporting form Appendix 5). Adverse events will be monitored throughout the study.

A treatment will not be administered if there is residual pain/discomfort experienced by the subject from the previous treatment.

ACCOUNTABILITY

Treatment administered to the subjects will be documented by the operator and tracked on the Case Report Form (CRF).

BREAKING THE CODE IN AN EMERGENCY

Treatment codes and allocation of treatment per subject will be accessible by the Principal Investigator of the study.

SAFETY MONITORING

ADVERSE EVENT

An adverse event (AE) is any untoward medical occurrence in a subject, whether or not related to study product or study procedures. Adverse events include any occurrence that is new in onset, an exacerbation of a pre-existing condition and clinically significant laboratory values.

Exceptions

The following medical occurrences will not be reported as AEs;

- Pre-treatment Adverse Events; Any medical occurrence that occurs after informed consent, but before first administration of ITU treatment or first study procedure is considered as medical history and only recorded as an AE if it worsens during the study.
- Pre-existing medical condition; Events that occur with comparable frequency and severity to the subject's baseline condition are reported as medical history, not AEs unless they become exacerbated during the study.
- Pregnancy; This is not an AE however the PI must report any pregnancies to The Guided Therapy and the Institutional Review Board (IRB) for advice regarding the appropriate course of action.

Study Specific Expected Adverse Event

The following AEs are expected due to the use of these study products and/or procedures and for this specific study, they will not be regarded as AEs;

- Transient erythema may be expected as a result of the study treatment which is expected to subside after a few hours. This will not be recorded as an AE unless persistent after 24 hours.
- Subjects may experience mild-moderate tingling, warming, pain or discomfort during the study treatments. These will not be recorded as AEs unless persistent after 24 hours or if they increase to severe/unbearable sensations.

The following AEs may be expected due to the use of these study products and/or procedures and for this specific study, they will be regarded and recorded as AEs;

- While trained personnel will administer the study treatments, there is a possibility for operator error that may result in a burn or high skin irritation response. These will be recorded as AEs.

SERIOUS ADVERSE EVENT

A serious adverse event (SAE) is an AE that results in any of the following outcomes: death; a life-threatening event; in-patient hospitalization; prolongation of existing hospitalization; a persistent or significant disability/incapacity; a congenital anomaly or birth defect. Any other important medical event may be considered a SAE when the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed previously. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, or convulsions that do not result in in-patient hospitalization. Just as a stable pre-existing condition is not an AE, hospitalisation for elective treatment (e.g. cosmetic or dental procedure) of a pre-existing condition that did not worsen from baseline is not an SAE.

SEVERITY AND RELATEDNESS OF ADVERSE EVENTS

An AE will be recorded only once, with the most extreme severity. Severities are defined as:

Mild	Awareness of symptoms which require minimal or no treatment and do not interfere with daily activity
Moderate	Discomfort or low level of interference which is enough to interfere with but not prevent daily activity and may require treatment
Severe	Interrupted or unable to perform usual daily activity and usually requires treatment.

The likelihood that the AE was related to the study product or study procedure is defined as;

Not Related	The AE is clearly due to an alternative cause, even if this cannot be definitely identified. Alternative causes include disease, concomitant medications, or environmental factors.
Uncertain	A connection between the AE and the study product or procedure cannot be ruled out with certainty.
Definitely	The AE is clearly related to the study product or procedure.

REPORTING OF ADVERSE EVENTS

All AEs will be recorded in the CRF and submitted to the IRB at the end of the study treatment phase and at the end of the regression phase. The site staff must maintain source documents to fully record all AEs.

Additionally SAEs must be reported immediately to the IRB Title with 24 hours of the site staff becoming aware of the event. The contact details for reporting any expedited AE are given in the Contacts section of this protocol.

In the event that the percent of study related AEs is ≥25% for a specific AE symptom, the IRB Title should be notified within 24 hours.

FOLLOW-UP OF ADVERSE EVENTS

If an AE is ongoing at the end of the study, follow-up will be performed until the AE has resolved. Follow-up may take the form of subject visits, a referral to another specialist, site telephone calls to the subject or letters from the treating physician.

The PI or designee must comply with the specific reporting requirement(s) of the ethics committee.

PREGNANCY

Females may not participate in this study if they are pregnant, breastfeeding, were pregnant or gave birth within the last three months or are planning a pregnancy during the course of the study.

If the subject thinks they have become pregnant during the study it is important that they inform the study doctor immediately. If the subject becomes pregnant or thinks that they may be pregnant, they will be removed from the study.

STATISTICAL CONSIDERATIONS

SAMPLE SIZE CALCULATION

Up to 25 subjects will be enrolled onto the study to ensure a minimum of 25 subjects complete.

STATISTICAL METHODS

A sample size of 25 per protocol subjects will be required to demonstrate statistical significance (two-sided alpha=0.05; 80% power). Descriptive statistics will be calculated for comparison to the values noted in the existing literature.

MONITORING

The PI agrees that the site will permit, if required, study-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.

Sponsor personnel, or their designees, may monitor the study. The monitor has the responsibility to familiarise the PI and the entire centre staff involved in the study with Therapy procedures. The monitor can visit the clinical study centre on a regular basis such as before the first subject has been enrolled, during the course of the study, and at study completion. The monitor must maintain the confidentiality of the study documents. Regular visits may be made to monitor clinical procedures throughout the study duration.

DATA HANDLING AND RECORD KEEPING

Measurement and questionnaire data and images will be acquired by or sent to GTS for analysis. All clinical data will be collected/recorded by clinical site and reported to the GTS within two (2) weeks after the completion of the initial phase of the study (Week 8). Final, QA-approved raw data in SAS or Excel format (where applicable) will be sent to GTS for analysis within 2 weeks following completion of each phone survey.

There will be at least one CRF for each subject randomised into the study. It is the responsibility of the PI to ensure the completeness and accuracy of the CRF and to authorise only trained members of staff to complete the CRF.

The CRF must be completed legibly, using a black ballpoint pen. Erroneous values and/or text must not be obliterated. Instead, the error must be crossed out with a single line, the correct value/text added, and the correction signed or initialled and dated. At the end of the study, the original CRFs will be sent to The TBD Title and copies held at the study site.

All site staff must ensure that the subject's anonymity will be maintained. On all documents that are to be submitted to GTS or external laboratory, subjects must be identified only by an identification code and not by their names. The PI or designee must keep a separate confidential enrollment log that matches identifying codes with the subject's names and addresses. The PI or designee must maintain these documents at the site.

It is the responsibility of the PI or designee to maintain adequate clinical study records. Copies of all clinical study material must be archived for a period of at least 15 years after the end of the study (or more as legally required) or until informed by GTS that the documents can be destroyed. All documents must be archived in a secure place and treated as confidential material.

QUALITY STANDARDS

It is the responsibility of the PI to ensure that the study is conducted in accordance with the principles of Good Clinical Practice, the 2008 version of the Declaration of Helsinki and according to applicable local laws and regulations concerning studies conducted on human subjects which are outside of the definition of a medicinal product or medical device.

Quality assurance audits may be performed by the clinical site, GTS or any ethics committee or regulatory authority during the course of the study or at study completion.

The clinical trial will be conducted in accordance with the approved protocol and protocol amendments (if applicable). However, in the unlikely event of a major protocol deviation (i.e., those deviations which affect the integrity of the study or the safety of subjects) a protocol deviation form will be completed by the Principal Investigator (or designee) and submitted to the GTS and IRB for review and approval. The GTS will review the deviations and determine if the deviation(s) would significantly affect the results, and if deemed necessary, not include such data in the analysis. All other minor deviations should be recorded throughout the study and submitted to the GTS Title on a monthly basis.

ETHICS AND INFORMED CONSENT

The PI or designee must submit a copy of the protocol, informed consent form and all supporting documents to an Independent Ethics Committee or Institutional Review Board who must provide written approval before study specific procedures commence. The IEC/IRB must also approve any other information that is given to subjects such as advertisements and may require other documents such as study product documentation.

Any modification to the agreed protocol must be agreed by both GTS and the PI and approved in writing by the IEC/IRB. Written approval must be obtained from the IEC/IRB before any amendment is implemented, unless immediate change is required to eliminate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the study (e.g., change of monitor(s), telephone number(s)).

The PI or designee must obtain informed consent from each subject participating in the study, after explanation of the aims, methods, benefits and potential hazards of the study. The consent must be obtained before any study-specific procedures are performed. It must be made completely and unambiguously clear to each subject that they are free to refuse to participate in the study, or that they can withdraw their consent at any time and for any reason, without incurring any penalty or withholding of treatment. The subject must be given their own copy of the information sheet and signed consent form. The original signed informed consent must be kept on file by the PI or designee.

REPORTING AND PUBLICATION POLICY

Statistical analysis will be performed by GTS.

The Investigator or designee will issue a final report of the results of the study following completion of data collection and quality control. The report will include the following: tabulations, a summary of adverse events, a description of the study, the study number, dates the study was conducted, the number of subjects who participated in the study as well as demographics (age, gender, ethnicity) and a summary of deviations. All IRB documentation/approvals must be included in the report. A complete report (electronic is acceptable) will be provided to the Sponsor within four weeks after completion of the 12 week follow-up. A final report will be submitted with four weeks of the 24 week follow-up phone call.

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Appendix 1- Calendar of Events

Procedures	Visit 0 Recruitment -14 to 0 Days	Visit 1 Baseline Assessment Week 0	Visit 2 Week 2	Visit 3 Week 4	Visit 4 Week 8	Phone Survey Week 12	Phone Survey Week 24	Responsibility
IC, eligibiltiy paperwork, exam for inclusion criteria	X							PI/Clinical Coordinator (CC)
X-Ray Scheduled	X							PI or Outside
Ultrasound Imaging		X	X	X	X			GTS
ITU Treatment		X		X				GTS
Focused Physical Exam & Clinical Grading for Epicondylosis severity		X	X	X	X			PI or CC
Subject Patient Rated Tennis Elbow Evaluation		X	X	X	X	X	X	Panelist Week 2 -8 / PI or CC Weeks 12 and 24
Self-Assessment Questionairres: Satisfaction & Improvement		X	X	X	X	X	X	Panelist Week 2 -8 / PI or CC Weeks 12 and 24
Physical Therapy		X						PI or CC
Home Heat/Cold & Stretching Program Review		X	X	X	X			PI or CC
Telephone Survey						X	X	PI or CC

Appendix 2 – PRTEE (attachment)

PATIENT-RATED TENNIS ELBOW EVALUATION

Name _____ Date_____

*The questions below will help us understand the amount of difficulty you have had with your arm in the past week. You will be describing your **average** arm symptoms **over the past week** on a scale 0-10. Please provide an answer for all questions. If you did not perform an activity because of pain or because you were unable ,then you should circle a "10". If you are unsure please estimate to the best of your ability. Only leave items blank if you never perform that activity. Please indicate this by drawing a line completely through the question.*

1. PAIN in your affected arm

*Rate the average amount of pain in your arm **over the past week** by circling the number that best describes your pain on a scale from 0-10. A **zero** (0) means that you **did not have any pain** and a **ten** (10) means that you had **the worst pain imaginable.***

RATE YOUR PAIN: No Pain											Worst Imaginable
When your are at rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with repeated arm movement	0	1	2	3	4	5	6	7	8	9	10
When carrying a plastic bag of groceries	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its least	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its worst	0	1	2	3	4	5	6	7	8	9	10

2. FUNCTIONAL DISABILITY

A. SPECIFIC ACTIVITIES

*Rate the **amount of difficulty** you experienced performing each of the tasks listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. A zero (0) means you did not experience any difficulty and a **ten (10)** means it was **so difficult you were unable to do it at all**.*

No Difficulty											Unable To Do
Turn a doorknob or key	0	1	2	3	4	5	6	7	8	9	10
Carry a grocery bag or briefcase by the handle	0	1	2	3	4	5	6	7	8	9	10
Lift a full coffee cup or glass of milk to your mouth	0	1	2	3	4	5	6	7	8	9	10
Open a jar	0	1	2	3	4	5	6	7	8	9	10
Pull up pants	0	1	2	3	4	5	6	7	8	9	10
Wring out a washcloth or wet towel	0	1	2	3	4	5	6	7	8	9	10

B. USUAL ACTIVITIES

*Rate the **amount of difficulty** you experienced performing your **usual** activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities that you performed **before** you started having a problem with your arm. A **zero** (0) means you did not experience any difficulty and a **ten** (10) means it was so difficulty you were unable to do any of your usual activities.*

1. Personal activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
2. Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
3. Work (your job or everyday work)	0	1	2	3	4	5	6	7	8	9	10
4. Recreational or sporting activities	0	1	2	3	4	5	6	7	8	9	10

Comments:

Appendix 2 – PRTEE (attachment), continued

Scoring Instructions

Minimize non-response by checking forms when patients complete them. Make sure that the patient left an item blank because they could not do it, that they understand that should have recorded this item as a "10". If patients are unsure because they have rarely performed an activity in the past week, then they should be encouraged to estimate their average difficulty. This will be more accurate than leaving it blank. If they never perform an activity they will not be able to estimate and should leave it blank. If items from a subscale are left blank, then you can substitute the average score from that subscale.

Pain Subscale- Add up 5 items.	Best score= 0; Worst score =50
Specific Activities- Add up 6 items	Best Score= 0; Worst Score = 60
Usual Activities – Add up 4 items items	Best Score= 0; Worst Score = 40
Function Subscale- (Specific Activities + Usual Activities)/2-	Best score= 0; Worst score =50
Total Score = Pain Subscale + Function Subscale	Best Score= 0 Worst Score = 100 (pain and disability contribute equally to score)

Reliability of subscales and total score are sufficiently high that both subscales and total are reportable.

Appendix 3-A; Self Reported Outcome Measures

SROM 1.

Compared to your initial visit:

_____I feel BETTER OFF than before treatment
_____I feel THE SAME as before treatment
_____I feel WORSE than before treatment

SROM 2.

Compared to your initial visit, describe your heel pain now:

_____I have NO PAIN
_____I have LESS PAIN than before the treatment regimen
_____I have THE SAME PAIN as before the treatment regimen
_____I have MORE PAIN than before the treatment regimen

SROM 3.

What percent improvement in heel pain have you experienced since starting the study?

_____None
_____1 to 25%
_____26 to 50%
_____51 to 75%
_____76 to 99%
_____100%

SROM 4.

How do you rate your heel pain since the start of the study treatment?

_____All better
_____Much better
_____Slightly better
_____Unchanged
_____Worse

SROM 5.

What percent improvement in overall daily function including work and/or recreational activities have you experienced since starting the study?

_____None
_____1 to 25%
_____26 to 50%
_____51 to 75%
_____76 to 99%
_____100%

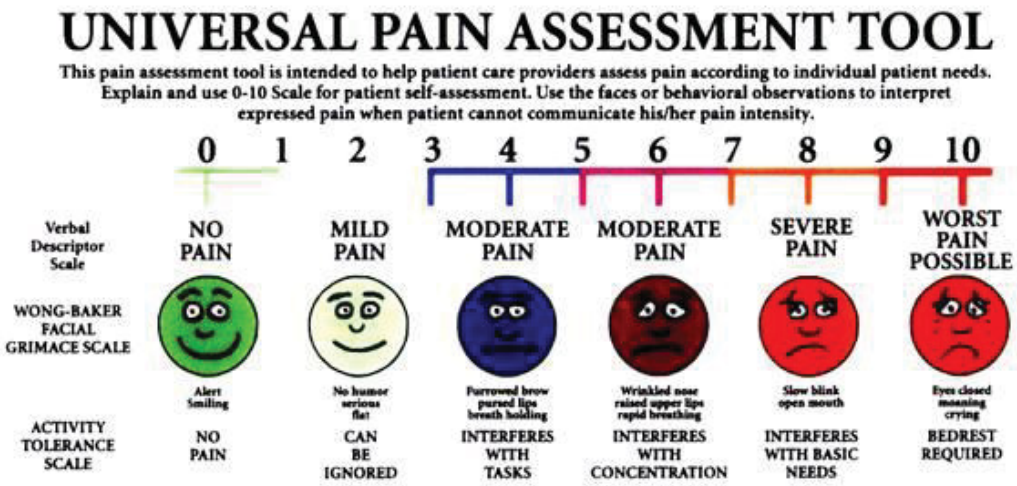
SROM 6.

Regarding the treatment that you received:

_____I am TOTALLY SATISFIED with the treatment
_____I am SATISFIED with MINOR RESERVATIONS with the treatment
_____I am SATISFIED with MAJOR RESERVATIONS with the treatment
_____I am DISSATISFIED with the treatment

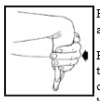
Appendix 3-B – Subject Self-Assessment Questionnaire, continued:

VAS: Visual Analog Scale for Pain or Universal Pain Assessment Tool.



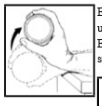
Rehab For Tennis Elbow: The Super 7

The "super 7" exercises are an important part of treatment for tennis elbow. They are designed to strengthen the muscles in the forearm and increase flexibility through stretching. In most cases te these exercises will help relieve elbow pain in about 4 to 6 week Each stretching exercise is held for 15 seconds and repeated 2 or 3 times. This pattern is repeated 5 times a day.

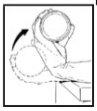


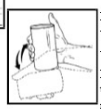
Exercise 1. Stretching the muscles that extend the wrist (extensor muscles): Straighten the arm out fully and push the palm of the hand down so you feel a stretch across the top of the forearm.

Exercise 2. Stretching the muscles that flex the wrist (flexor muscles): straighten the arm out fully (palm side up), and push the palm downward to stretch. Strengthening exercises are performed twice a day following the stretching exercises. To perform these exercises, the patient sits in a chair with the elbow supported on the edge of a table or on the arm of the chair the wrist hanging over the edge. Use a light weight such as a hammer or soup can when performing the strengthening exercises. Repeat the exercises 30 to 50 times, twice a day, but do not push yourself beyond the point of pain.



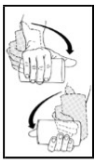
Exercise 3. Strengthening wrist extensor muscles: Hold the weight in the hand with the palm facing down. Extend the wrist upward so that it is pulled back. Hold this position for 2 seconds and then lower slowly.
Exercise 4. Strengthening wrist flexor muscles: Hold the weight in the hand with the palm up. Pull the wrist up, hold for 2 seconds and lower slowly.





Exercise 5. Strengthening the muscles that move the wrist from side to side (deviator muscles): Hold the weight in the hand with the thumb pointing up. Move the wrist up and down, much like hammering a nail. All motion should occur at the wrist.

Exercise 6. Strengthening the muscles that twist the wrist (pronator and supinator muscles): Hold the weight in the hand with the thumb pointing up. Turn the wrist inward as far as possible and then outward as far as possible. Hold for 2 seconds and repeat as much as pain allows, up to 50 repetitions.



Exercise 7. Massage is performed over the area of soreness. Apply firm pressure using 2 fingers on the area of pain and rub for 5 minutes.

If exercise aggravates any of your symptoms, contact a physician or physical therapist These exercises can be used to prevent or rehabilitate injuries in people who play sports or in those who do repetitive forearm work.

Tim L. Uhl, P.T., A.T.,C.

Appendix 5: Adverse Events Report
Sample AE Form

	AE Term	Serious Yes/ No	Severity, Relationship, Action Taken	Treatment of Event (if medication report CM)		Outcome
1			Severity: _____ Relationship: _____ Action taken: _____	○ 01 ○ 02 ○ 03 ○ 04 ○ 05 (specify) _____	Onset date: _____ End date: _____	_____
2			Severity: _____ Relationship: _____ Action taken: _____	○ 01 ○ 02 ○ 03 ○ 04 ○ 05 (specify) _____	Onset date: _____ End date: _____	_____

Severity	Relationship	Action Taken	Treatment of Event:	Outcome:
Mild Moderate Severe	01= Not Related to treatment 02=Probably related to treatment 03=Definitely related to treatment	01=None 02=Treatment interrupted 03=Treatment stopped	01=None 02=Pharmacological Treatment (report CM) 03=Non-Pharmacological Treatment 04=Hospitalization 05=Other	01=Recovered 02=Recovered w/ Sequelae 03=Recovering 04=Not Recovered 05=Fatal 06=Unknown

Investigator Signature: _____ Date:_____/_____/_____

Appendix 6-A: Home Treatment example. (PI may suggest other exercise protocols)

Subjects will apply ice or cold pack to the affected area for (times and duration to be confirmed with Clinical Site/PI)

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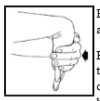

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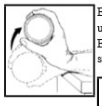

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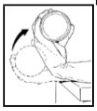

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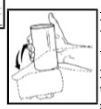

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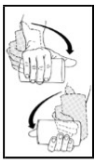

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Appendix 6-B: Home Treatment Log

	Sets per Day							
	CET Stretch (exercise 1 & 2)					Strenthening (Exercise 3 & 4)	Strenthening (Exercise 5 & 6)	Massage (Exercise 7)
	Set 1	Set 2	Set 3	Set 4	Set 5	Set 1	Set 1	Set 1
1/12/2015								
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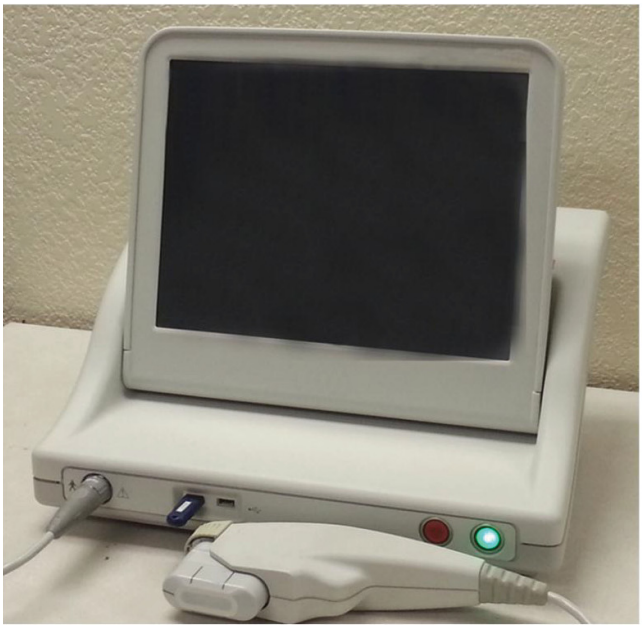
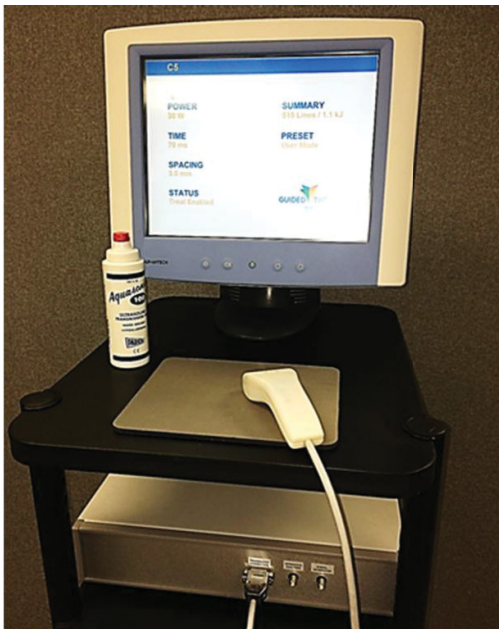
Appendix 7 – Marketed Materials Information

Appendix 7-A – ITU Systems





Clinical Prototype Systems Gen II and Gen III

Power: 3-100 Watts

Frequency: 3 – 10MHz

Energy/Zone: up to 3 Joules (tech. mode)

Appendix 7-B – Diagnostic Ultrasound Imaging System

SPARK®

Point of Care Ultrasound for Superficial Applications such as Musculoskeletal, Skin, and Breast

The affordable approach to ultra-high resolution and deep penetration of the superficial layer.

CHALLENGE

How many times in your practice have you wished that there was a way for you to run a quick scan of something in a patient's superficial layer? How many times have you suspected that a patient had torn cartilage in their knee, a dislocation of a thumb or shoulder, or an early-stage growth on a breast or testicle? Instead of being able to confirm your suspicion on the spot, you were forced to delay diagnosis and treatment while the patient scheduled and underwent comprehensive imaging—often times to confirm what you already knew.

High quality ultrasound for superficial applications have to this point been unaffordable and impractical for Point of Care practices. Requiring large pieces of proprietary equipment and systems, these systems have been cost prohibitive. Until now.

SOLUTION

Spark® is a vital breakthrough in Point of Care imaging for superficial structures. Offering unprecedented sensitivity and ultra-high resolution not found on traditional units 10x or more its price point, Spark is revolutionizing ultrasound for front-line physicians with its performance, price, and value. Highly portable, adaptable, and upgradeable, Spark is powered by a standard PC or laptop and can rapidly integrate with your Patient Information System. Spark is a standardized interface peripheral device that connects to your PC via a standard USB connection; it's as easy to install as connecting a mouse (and almost as simple to use).

Appendix 7-B – Diagnostic Ultrasound Imaging System, continued

Features and Benefits

Excellent Image Quality

- Superb Detail and Contrast Resolution
- Wide Bandwidth Architecture
- ArdentView Image Filters
- Capable of imaging from 5.0MHz - 21MHz (transducer dependent)
- High Frame Rate: up to 139fps

Research

- Human: RF Out Capabilities
- Small Animal:
  - RF Out Capabilities
  - 1KHz M-Mode PRF

Clinical Utility

Superficial Structures

- High Frequency Linear: 5mm - 30mm
- 12MHz Linear Array: 15mm - 45mm

WE CALL IT "PLUG AND KNOW"

1. Simply attach the Interface to your computer via a Standard USB (Universal Serial Bus) cable
2. Automatically install the software Suite from a CD-ROM
3. Immediately gain deeper insights into your patients' condition to improve and accelerate your decision making and/or treatment at the Point of Care

Wide interoperability via USB 2.0

Technical Specifications

Physical Characteristics

- Height: 10.75 in (273 mm)
- Width: 4.75 in (121 mm)
- Length: 19.00 in (483 mm)
- Weight: 22 lbs (10 kg)

Transducer Options

- 5.0 - 8.0 MHz Convex Endo
- 9.0 - 14.0 MHz Linear Array
- 14.0 - 21.0 MHz Linear Array

Imaging Modes

- B-Mode
- B-M Mode
- M Mode
- Zoom (Pan)

Measurement Tools

- Distance
- Circumference
- Area
- Volume
- Beats/Minute (m-mode)

Image Storage & Cine

- Dicom Compatible
- Stores Images and Cine as Raw Data
- Export Images as bmp or jpg
- Export Cine as AVI
- Back-up Database to internal or external Hard Drive, CD, DVD or Network

Power: 100-240 VAC 50-60 Hz input

Minimum Computer Requirements

Windows XP OS: USB 2.0 Port, 256 MB RAM, 1 GB Available Hard Drive Space

Windows7/ Vista OS: USB 2.0 Port, 500 MB RAM, >1 GHz Duo-Core Processor*, 1 GB Available Hard Drive Space

*assumes Windows7/ Vista Home OS. More Advanced Versions of Vista may require a faster processor and more RAM

CONTACT INFO

To learn more or purchase Spark, please contact Ardent Sound at 480-649-1806 or sales@ardentsound.com.

ARDENT SOUND

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Protected by US Patents: 6440071, 6049159, 6120452, 6213948 others pending

Appendix 7-C – Acoustic Coupling Gel – Polysonic or similar

POLYSONIC® Ultrasound Lotion

The best cosmetic quality lotion for medical ultrasound

Polysonic® Ultrasound Lotion

When tough injuries call for gentle treatment, POLYSONIC® Ultrasound Lotion combines the pleasing appeal of a fine cosmetic with superior soundwave transmission. It transmits ultrasonic waves more efficiently than most gels, and is acoustically correct for medical ultrasound procedures.

The rich, moisturizing formulation of POLYSONIC® Ultrasound Lotion is the ideal medium for therapeutic ultrasound when followed with massage. It's kind to your skin as well as to your patients... and won't damage your equipment.

Our multi-purpose lotion, **also available with aloe vera**, is recommended for all medical ultrasound procedures... Another world-class quality product from Parker, a company dedicated to quality.

ISO 13485:2003

PARKER Parker Laboratories, Inc. | The sound choice in patient care.™ 973.276.9500 www.parkerlabs.com

POLYSONIC® ULTRASOUND LOTION

Multi-purpose ultrasound lotion with superior coupling efficiency in a pleasing, cosmetic-quality base. Recommended for all ultrasound procedures when a lotion is preferred. Also available, Polysonic Ultrasound Lotion with Aloe Vera.

FEATURES

- Rich, moisturizing formula
- Comfortable and pleasing to patient and ultrasound practitioner
- Acoustically correct for the broad range of frequencies used
- Will not damage equipment or stain clothing
- Hypoallergenic, bacteriostatic
- No formaldehyde

Product #	Package Size
21-08	250 ml (8.5 fl. oz.) dispenser, 12 per box
21-28	3.8 liter (1 US gallon) with dispenser, 4 per case (Dispenser pump not included)
21-50	POLYPAC® contains: 4 Polysonic gallons, 2 dispensers and 1 pump
20-08 with Aloe Vera	250 ml (8.5 fl. oz.) dispenser, 12 per box
20-28 with Aloe Vera	3.8 liter (1 U.S. gallon) with dispenser, 4 per case (Dispenser pump not included)
20-50 with Aloe Vera	POLYPAC® contains: 4 Polysonic with Aloe Vera gallons, 2 refillable dispensers and 1 pump

ISO 13485:2003

PARKER Parker Laboratories, Inc. The sound choice in patient care.™ 973.276.9500 www.parkerlabs.com