Use of ActiPatch™ for Treatment of Plantar Fasciitis

Principle Investigator:

Joel Brook, DPM, MS, FACFAS

Associate or Co-Investigators:

Morley A Herbert, PhD
Damien M. Dauphine DPM, FACFAS, CWS
Nicole D. Hancock, DPM
D. Jason Hancock, DPM
Jaryl G. Korpinen, D.P.M.

Study Co-coordinator:

Tracey Hawkins, RN

Table of Content

1. Executive Summary

a. Purpose

To assess whether patients using ActiPatch for treatment of plantar fasciitis have reduced usage of pain medications, while maintaining an adequate control of their pain.

b. Design

A double blind, randomized prospective study covering a 7 day treatment period.
Patients were trained in use of stimulator and supplied with data forms to record their pain level (VAS) upon awakening and at night. They also kept a log of medication used.
Study was approved by North Texas Institutional Review Board at Medical City Dallas in Aug 2008.

c. Analysis of Medication Usage

All medications were translated into 'doses' using multiples of the base concentration (ibuprofen 200 mg, acetaminophen 250 mg).

d. Results

70 patients have been enrolled, with 28 controls and 42 stimulator units. Repeated measures ANOVA is statistically significant for a difference in time response between the 'stim' and 'cont' groups ($p = 0.02$). The evening VAS shows no difference between groups.
There is a large clinically significant difference in pain medication usage. In the 'stim' group, no mediation was used on 82.3% (242/294) of the patient-days while no medication was used in 'cont' group on 68.4% (134/196) of the patient-days ($p < 0.001$). On days 3 and 4, there was a strong trend to reduced usage by the 'stim' group ($p=0.07$) while on day 7, the difference was larger ($p=0.06$).When total medication over days 1-4 is compared, the 'stim' group uses less than 1/2 that of the controls, while over the full 7 days, total medication usage drops by 55%. Large variances in usage preclude significant p-values with current enrollment levels.

No study related adverse events were reported by any patient.

e. Discussion

The study shows that using the stimulator at night leads to a steadily increasing reduction of morning pain even though the patients use less than 1/2 the medication doses of the control group.

2. Study Execution:

a. Study Design

- The study is a prospective randomized double-blind, placebo- and positive-controlled trial of PEMF versus placebo for pain in adult patients having diagnosed plantar fasciitis.
- 70 patients: 42 control and 28 active
- Control simulators will be identical but inactive as far as output signal.
- Patients will wear device nightly for 7 days with loop antenna placed adjacent to area of pain on the bottom of the foot.
- Patients given a Visual Analogue Scale (VAS) to fill out am and pm each day
- Patients given form to record pain meds used
- No new treatment to be started during study unless patient drops out
- Return filled out data forms to coordinator.
- All study personnel will be trained to use the stimulator and in the use of the VAS scores.

b. Inclusion/Exclusion Criteria

- All patients with diagnosis of plantar fasciitis agreeing to participate
- Over 18 years of age
- Able to wear unit and keep data up-to-date

c. Recruitment of Patients

Patients seen in clinician's office, discuss study, consent

d. Blinding

Blinding method was double blinding, all devices – active and control, were given numbers and packaged in the same type of box, without any sign on the package. The code for active/control stimulators was sent to Dr. Morley Herbert only after the entire data was collected, so he can analyze the data. Dr. Morley Herbert was the only investigator to receive the codes list. All devices (active and control) had the same physical appearance, wrapped in the exact same wrap and had red light when working. Since the stimulation could not be felt, there was no way to separate the groups.

e. Randomization

140 boxes (70 active and 70 control) were delivered to the center, and were tossed into cardboard boxes, mixing active and control devices together. Trial patients just picked one out of the box. The mixing process of the active and control together was probably not perfect, giving us a bit more patients on active device, then on control.

f. Adverse Events Reporting

As mentioned in the informed consent forms, all adverse events were reported to investigating physicians, where they needed to report adverse events to study Co-coordinator Tracey Hawkins. Patients were given phone numbers of their physician, the principal investigator and phone number of Tracy Hawkins.

g. **Administrative Section**

Here is the location and personnel of study related activities:

Study Activity	Location where done	Study personnel who did
Recruiting	-Medical city, 7777 Forest Lane, Dallas, TX -Baylor Plano, 4708 Alliance Blvd, Plano, TX -Complete Foot and Ankle Care of North Texas, 2817 S. Mayhill Rd. Denton, TX -500 N. Valley Pkwy. Lewisville, TX -6309 Preston Rd Plano, TX	Dr. Joel Brook Dr. Damien M. Dauphine Dr. Nicole D. Hancock Dr. Jason Hancock Dr. Jaryl Korpinen
Signing patients on informed consent	Same as recruiting locations	Dr. Joel Brook Dr. Damien M. Dauphine Dr. Nicole D. Hancock Dr. Jason Hancock Dr. Jaryl Korpinen
Treatment / Device and forms allocation	Same as recruiting locations	Dr. Joel Brook Dr. Damien M. Dauphine Dr. Nicole D. Hancock Dr. Jason Hancock Dr. Jaryl Korpinen
Data collection	3626 Lakeside Dr. Rockwall, TX	Tracy Hawkins, RN
Data Analysis	Dr. Herbert's Home Office- Dallas TX	Dr. Morley Herbert

h. **Data Collection**

Measurements were done by the patients who filled out daily log sheets recording morning and evening pain levels on the VAS line, and all daily pain meds used. The data was collected by Tracy Hawkins, RN (study coordinator) who transferred it to a spreadsheet and forwarded it on to Dr. Herbert Morley for analysis at the end. Seven data forms came back to her at the last minute and Dr. Herbert Morley entered the values himself.

3. **Statistical Analysis**

a. **Statistical Analysis**

Data was collected from the patients at the end of their participation. They had kept logs which included the VAS (Visual Analog Score) pain assessment, as rated upon first getting out of bed, and at night before going to bed. They also marked down all pain medication used including brand, strength and number of tablets.

The monitor copied the data from the individual sheets and placed it in a spreadsheet with 1 row per patient. Data was combined so that one column was used for each day. At the end of the study, the data was provided for analysis.
The data was read into SAS (V9.2, SAS Institute, Cary NC) by DDE link. The contents of the daily cells was parsed to create morning VAS, evening VAS and medication usage values. Medication was scored in units based on 200 mg of ibuprofen, 250 mg naproxen or 250 mg acetaminophen as 1 unit. One tablet of Celebrex was also scored as 1 unit.
Basic summary statistics were run for the medication usage, morning VAS and evening VAS by day. Means were plotted. Daily results were compared using Wilcoxon rank sums. Multivariate analysis of variance with repeated measures was used to examine the effect of group on the medication usage, morning and evening pain levels.

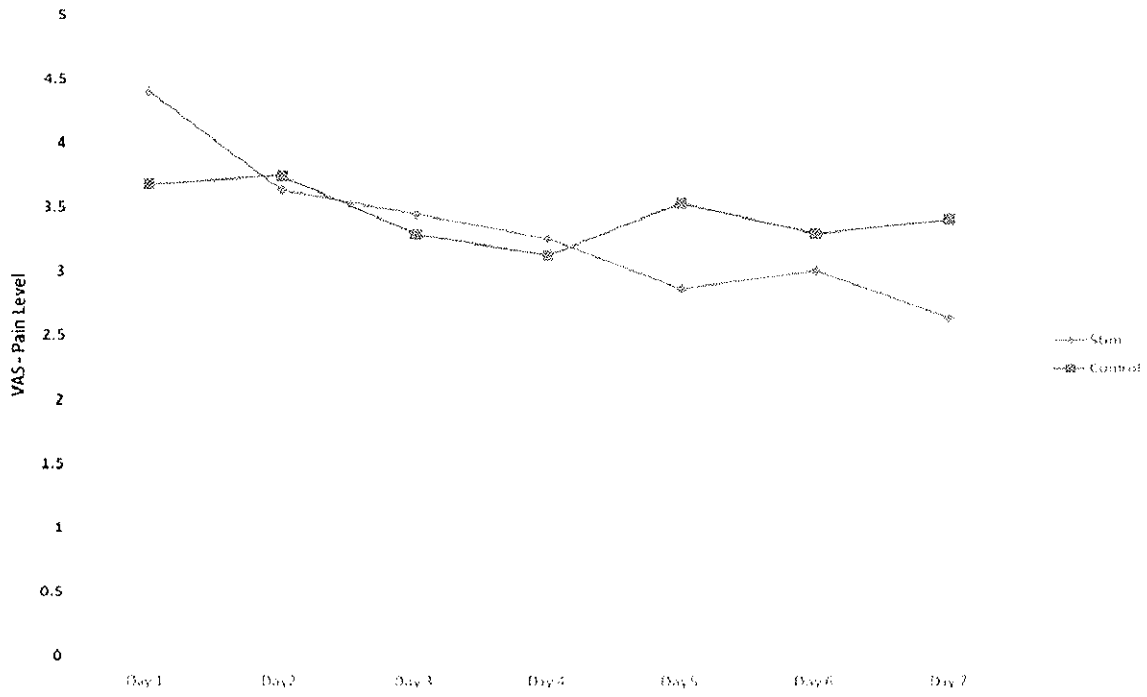
b. **Acceptance Criteria**

This study is acceptable because the results show a statistical significance in pain reduction using visual analog scale (VAS).

4. Results

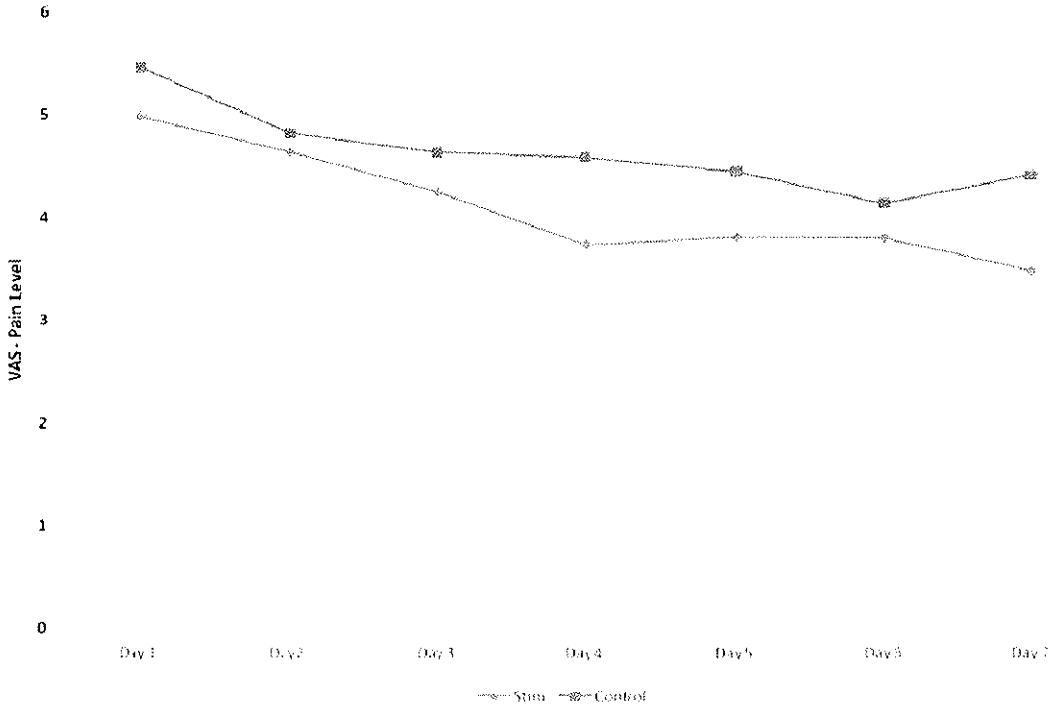
70 patients have been enrolled to date, with 28 controls and 42 stimulator units, with 21/28 (75%) females in the control group, and 31/42 (73.8%) in the stimulated.
Graph 1 shows the mean VAS at the start of the day while **graph 2** is the evening scores.

Graph 1: VAS- AM Values



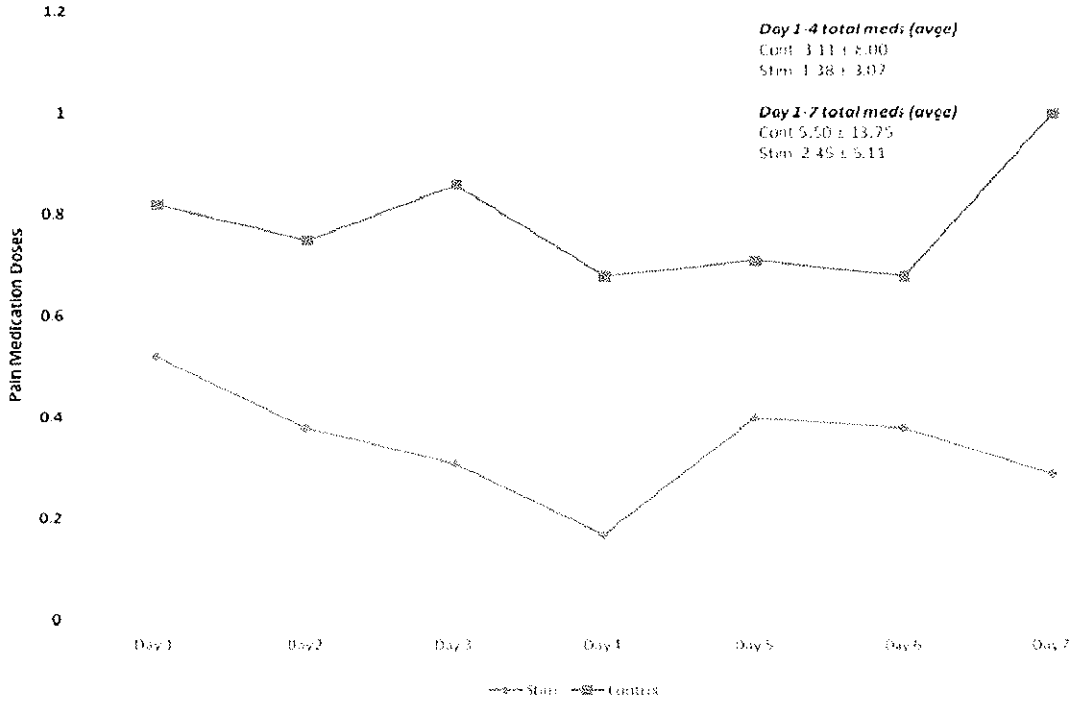
Repeated measures ANOVA is statistically significant for a difference in time response between the 'stim' and 'cont' groups (p =0.02). The evening VAS shows no difference between groups.

Graph 2: VAS - PM Values



Graph 3 shows medication doses for the two groups over the 7 days. There is a large clinically significant difference in usage. In the 'stim' group, no mediation was used on 82.3% (242/294) of the patient-days while no medication was used in 'cont' group on 68.4% (134/196) of the patient-days ($p < 0.001$). On days 3 and 4, there was a strong trend to reduced usage by the 'stim' group ($p=0.07$) while on day 7, the difference was larger

Graph 3: Medication Doses



(p=0.06).
When total medication over days 1-4 is compared, the 'stim' group uses less than 1/2 that of the controls, while over the full 7 days, total medication usage drops by 55%. Large variances in usage preclude significant p-values with current enrollment levels.
No study related adverse events were reported by any patient.

5. Discussion

Plantar fasciitis is an inflammatory disorder of the foot that results in pain. The heel of the foot has a musculoskeletal structure consisting of muscles, bones, tendons, nerves and vascular components.

Using ActiPatch at night leads to a steadily increasing reduction of morning pain even though the patients use less than 1/2 the medication doses of the control group. The results of this study show us that ActiPatch is an extremely safe, and an effective treatment for plantar fasciitis. The convenience of a simple, one dose use of the device at home, provides an excellent new treatment for plantar fasciitis, especially when you compare the treatment with ActiPatch to other over the counter treatments like NSAIDs and other pain medications that have worse safety profile.

6. Appendix

North Texas Institutional Review Board at Medical City
7777 Forest Lane, C-740 Dallas, TX 75230 972/566-6060 Phone 972/566-4715 Fax

July 16, 2009

David Genecov, MD
International Craniofacial Institute
7777 Forest Lane
Bldg. C-717
Dallas, TX 75230

Re: #08.042, Study Continuation, "Use of High Frequency Electrical Stimulation for Treatment of Plantar Fascitis in Adults"

Dear Dr. Genecov:

In accordance with the Federal Register Guidelines and our Institutional Review policies, the Institutional Review Board approved your request for continuation of study #08.042 at its meeting of July 15, 2009 for a one-year period. Please use the attached informed consent date stamped approved July 16, 2009 and destroy all other drafts and undated copies.

IRB and Federal regulations require that written consent be obtained from all human subjects in your studies. The consent form should be kept on file for a period of three years past completion of the study. Also, you must put a copy of the consent form in the subject's medical record. Investigators should keep the original, executed copy of the consent form and file it with their records of the protocol.

If you need further assistance, please contact Yvette King at (972) 566-6060.

Sincerely,

John H. Cissik, PhD
Executive Director, Clinical Research
Coordinator, Institutional Review Board

cyk

08042ctn

Protocol Summary Outline

Title:

Use of High Frequency Electrical Stimulation for Treatment of Plantar Fasciitis in Adults.

Sponsor:
BioElectronics Corporation

IND # or IDE # (if applicable)

Principal Investigator:
Joel Brook, DPM

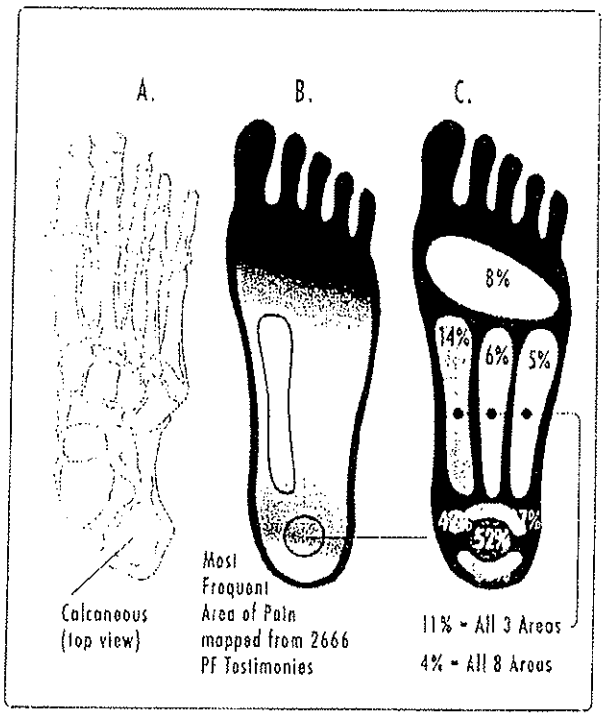
Associate or Co-Investigators:
David G Genecov, MD

I. Background (why the study is necessary)

Plantar Fasciitis

Plantar Fasciitis (PF) is a painful inflammatory condition caused by excessive wear to the plantar fascia of the foot or biomechanical faults that cause abnormal pronation of the foot. The plantar fascia is a band of connective tissue on the underside of the foot stretching from the heel to the toes. The illustration shows typical locations of the pain. Patients suffering from PF often have extreme pain on taking their first steps in the morning.

PF accounts for approximately 15% of all foot related complaints (Lutter, 1997, Med. J Allina. 6(2) http://www.allina.com) seen by clinicians.



While many different treatments have been effective, any relief may be slow in coming as it typically takes six to eighteen months to find a favorable resolution; overall plantar fasciitis has a generally good long-term prognosis. The mainstays of treatment are stretching the Achilles tendon and plantar fascia, resting, keeping off the foot as much as possible, discontinuing aggravating activity, cold compression therapy, contrast bath therapy, weight loss, arch support and heel lifts, and taping. Care should be taken to wear supportive and stable shoes. Patients should avoid open-back shoes, sandals, "flip-flops", and any shoes without a raised heel. To relieve pain and inflammation, nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin and ibuprofen are often used but are of limited benefit. Diclofenac is sometimes prescribed for ongoing problems. Patients should be encouraged to lessen activities which place more pressure on the balls of their feet because it increases tension in the plantar fascia. This is counter-intuitive because the pain is in the heel, and the heel is often sensitive to pressure which causes some patients to walk on the balls of their feet.

Local injection of corticosteroids often gives temporary or permanent relief, but may be painful, especially if not combined with a local anesthetic and injected slowly with a small-diameter needle. Recurrence rates may be lower if injection is performed under ultrasound guidance. Repeated steroid injections may result in rupture of the plantar fascia. This may actually improve pain initially, but has deleterious long-term consequences.

It is estimated that 25 million patients experience acute pain caused by trauma or surgical procedures each year. The most commonly prescribed analgesics for acute pain are NSAIDs, acetaminophen, and opioids; however in the peri-operative period NSAIDs are often contraindicated due to their anticoagulant effects. Acetaminophen is not the drug of choice except in a small number of patients in whom other drugs are contraindicated, due to its lack of an anti-inflammatory effect. Opioids, which are frequently used in the perioperative period[2] are problematic in ambulatory patients due to their CNS effects, and they also have no anti-inflammatory properties and thus do not minimize edema.

PEMF[1] in some form has been used or investigated since the work of Ginsberg in 1934 when he pulsed the emission of a medical diathermy machine to elicit a non-thermal biological effect Since this pioneering work, PEMF therapeutic applications have been reported for the reduction of post-traumatic and post-operative pain and edema in soft tissues, wound healing, burn treatment, and nerve regeneration (Pilla et al., 1993; Itoh et al., 1991; Ionescu et al., 1982; Raji and Bowden, 1983). Ten years ago, an NIH Consensus Conference Report on Electromagnetic Fields in Medicine (1998), entitled "An Assessment of Health Effect from Exposure to Power-Line Frequency Electric and Magnetic Fields" concluded in an over 500 page report (NIH Publication 93-3981, Washington, DC) that the one area where there was overwhelming evidence for beneficial effects of electromagnetic fields was the stimulation of bone healing in orthopedics. An Army study of ankle sprains showed that PEMF exposures are generally in a range of 15 to 45 minutes with significant reductions in pain and edema usually occurring during, or immediately after, treatment (Pennington et al., 1993; Wilson, 1974). The clinical outcome of effective treatment of pain and edema is a more rapid return to function post trauma, as well as enhanced healing of pathologies, such as ischemic ulcers (Hunt et al., 1986).

There is a large body of clinical experience that has led to the recognition of pulsed electromagnetic therapy as an effective treatment for all tissue trauma, both accidental and postoperative, especially during the early stages, for up to about a week. Thus all recent injuries, such as hand injuries and sprained ankles, as well as acute traumatic synovitis and muscle haematomas, are being treated immediately. Traditional pulsed electromagnetic energy equipment has used an 110 Volt plug-in unit requiring patients to go to the treatment site for therapy. Existing machines are expensive and require a trained operator.

How ActiPatch™ Therapy Reduces Edema and Promotes Healing

When a body receives an injury during surgery, or from trauma such as a sprain, there is little danger of infection. Nevertheless the body will react to the injury to prevent an infection. This response is referred to as the "inflammatory process" and consists of a rapid onset tissue destruction phase followed by a longer duration tissue repair phase. The initial destruction phase is evidenced by redness, heat, swelling, and pain in the tissue. These characteristics of inflammation result from the rapid dilation of blood vessels in the immediate vicinity of the injury and increased leakiness of these vessels. This rapid response permits fluid and protein to flow into the region, resulting in a disruption of communication among the cells of the tissue. This tissue disruption serves little purpose in non-infected trauma or aseptic post-surgical applications. In fact, for surgical wounds, inflammation is usually more damaging than helpful. To enhance the healing of non-infected injuries, the therapeutic goal is to induce the tissue to rapidly pass through, or bypass, the tissue-damaging phase of the inflammatory process and move to the mode of tissue repair. ActiPatch™ Therapy produces an induced electrical current in the injured tissue region that serves to inhibit swelling. The therapy has the following beneficial effects:

- Precludes or truncates the inflammation phase
- Restores a synchronization signal among the cells of the injured tissue
- Provides cell-cell "communication" over an area at least four times larger than the patch area
- Penetrates through the epidermis and dermis to involve the underlying musculature

ActiPatch Therapy causes measurable changes to the regional cell population. Cell communication is restored through the electrical interconnection of the cells. Because cells are reconnected and re-synchronized, normal cell function is rapidly restored and healing is accelerated. In untreated healing the formation of new cells is

[1] The following information about PEMF has been provided by the study sponsor

haphazard and chaotic. If the cells are aligned the wound healing is stronger. Uncontrolled collagen matrix accumulation leads to excess scarring. One of the visible effects of PEMF is to improve the physical alignment of the cells. Simultaneously, enhanced lymphatic flow cleans up the wound area. Dead cells are devoured by the macrophages and the bruising is removed. In the final stage of healing, remodeling, the cells gradually replace themselves in an ongoing process. The newly stabilized cells can regenerate faster through the calcium pumping mechanism. This activation and strengthening of the cell along with the increased oxygen supports the body's normal functions to rapidly accelerate healing.

The outcomes include accelerated healing and several other advantages:

- Reduced pain
- Reduced edema
- New matrix formation is organized, reducing scarring and enhancing tensile strength
- Lymphatic flow is enhanced, resulting in reduction of bruising

John Low (1992) in his textbook on Electrotherapeutic Modalities, suggests that for acute conditions a low average energy is beneficial. Acute conditions such as soft tissue injuries require a higher repetition with shorter (narrower) pulses.

Like other pulsed electromagnetic therapy devices ActiPatch Therapy functions at a frequency in the 27.1 MHz ISM band. The electromagnetic field has the (vector) form of the "near-field" produced by a loop antenna. Long-range transmission ("far-field" effect) is rendered negligible by the small antenna size, compared with one wavelength. The near field induces electric current in human tissue, oscillating at such a high frequency that it cannot be "felt" by our nervous system. The high frequency also limits penetration by way of the "skin-effect", resulting in a "skin depth" of approximately 10 cm. In addition, the geometry of the loop limits penetration to approximately one diameter, (or approximately, the width, in the case of the model 250). So antenna size dominates penetration over skin effect for the model 250 and 500.

The ActiPatch affixes onto patient for a convenient 24-hour treatment, with an "overnight" suggested minimum treatment time. Therapeutic efficacy requires consideration of the treatment time difference factor. ActiPatch Therapy Device produces a 24 hour absorbed energy of **630? mJ/cc** compared to traditional pulsed electromagnetic devices which produce a 15 minute absorbed energy in the range of **110 mJ/cc** at the 1.5 watt power setting This suggests that a 6 to 8 hour ActiPatch Therapy treatment is well within the range of efficacy for soft tissue injuries.

ActiPatch™ Therapy power density at the skin surface is between 14 and 73 $\mu W/cm^2$. It is reasonable to assume that 10% of the incident energy is absorbed in the first centimeter of tissue depth, or maximum energy absorption of up to 7.3uW/cm3 in skin. While that absorbed power appears to be a very low exposure level, in fact, this level is well above the threshold levels necessary to ensure non-thermal biological responses from electromagnetic field exposures. To understand this statement it is important to note that non-thermal effects of electromagnetic field exposure are due to the induced electric field in the tissue and not the magnetic field. ActiPatch produces an induced electric field of typically 10 milliVolt/cm. In a fibroblast/collagen wound healing model, field intensities as low as 30 $\mu V/cm$ rms were sufficient to significantly reduce protein excretion by cells (consistent with a reduction in edema and scarring) for exposure durations of 12 hours (McLeod, et a l. 1987). This field intensity corresponds to an induced power level of 10-11 Watts/cm3. More recently, investigations on other aspects of cell phenotypic expression related to the healing process, including differentiation, cell morphologic adaptation, and cell motility, suggest that even this very low exposure level can be further reduced

by extending the exposure time. In a study on morphologic adaptation of cells to induced electromagnetic fields, 3.5 μV/cm rms electric fields were found to be sufficient to induce significant morphologic changes if the exposure times were extended to 24 hours, corresponding to induced power levels of 10-13 Watts/cm3 (Lee & McLeod, 2000). Moreover, a study on regulation of differentiation in mesenchymal cells, utilizing exposure durations of up to 64 hours, showed that cells were capable of responding to induced field intensities as low as 0.7 μV/cm rms, corresponding to induced power densities of 5x10-15 Watts/cm3 (McLeod & Collazo, 2000). It is clear, therefore, that use of ActiPatch™ Therapy, resulting in adsorbed power levels in the range of **7.3 μW/cm3**, provides field exposure levels at the target tissue that are five to nine orders of magnitude above the thresholds which have been established for non-thermal electromagnetically induced biological effects at the cell and tissue level.

The ActiPatch™ has received FDA approval for use in reducing swelling after blepharoplasty. In Canada, Health Canada has approved it for relief of pain in musculoskeletal complaints. The system also has EU approval as a Class II pulsed electromagnetic medical device. On-going studies (including this one) will provide clinical data to support further applications for the device.

The purpose of this study is to investigate pulsed electromagnetic frequency (PEMF) for the treatment of pain in patients with diagnosed plantar fasciitis.

II. Specific Aims of the Study

Our hypothesis is that PEMF delivered via the Actipatch™ will ameliorate the inflammatory effects of edema and pain in humans with fewer adverse effects than typically experienced by standard pharmacologic means. Specifically, we will compare delivery of PEMF via the active (ActiPatch™) as compared to a placebo patch as control:

1. Assess changes in pain as measured by visual analogue scale (VAS) from baseline to 7 days
2. Analgesic intake over 7 days

We will also assess the frequency of adverse effects and patient satisfaction using patient self-reported surveys.

III. Study Design (how the study will be accomplished)

- The study is a prospective randomized double-blind, placebo- and positive-controlled trial of PEMF versus placebo for pain in adult patients having diagnosed plantar fasciitis.
- 120 patients: 60 control and 60 active
- Control simulators will be identical but inactive as far as output signal.
- Patients will wear device nightly for 7 days with loop antenna placed adjacent to area of pain on the bottom of the foot.
- Patients given a Visual Analogue Scale (VAS)[2] to fill out am and pm each day

[2] See Appendix A

- Patients given form to record pain meds used[3]
- No new treatment to be started during study unless patient drops out
- Return filled out data forms to co-ordinator.

IV. Inclusion/Exclusion Criteria

- All patients with diagnosis of plantar fasciitis agreeing to participate
- Over 18 years of age
- Able to wear unit and keep data up-to-date

V. Recruitment of Patients

Patients seen in clinician's office, discuss study, consent

VI. Potential Risks and Benefits

Benefits: reduced use of pain medication, reduced pain, improved function
Risk: skin irritation

VII. Special Precautions

None

VIII. Financial Compensation by an Outside Source (e.g., do researchers or their family have a financial interest in the research project such as major stock holdings or funding from the sponsor?)

Participating physicians may be compensated for their time and effort by stock grants from BioElectronics.

IX. Hospital Departments/Services to be assessed by the Research

None

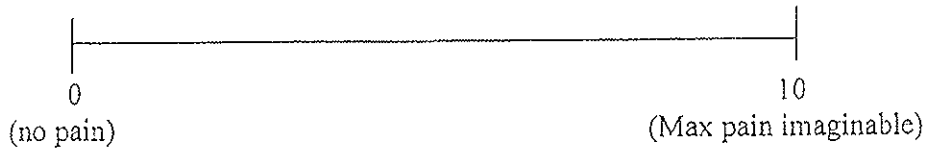
[3] See Appendix B

Appendix A

Patient ID #:
Date:

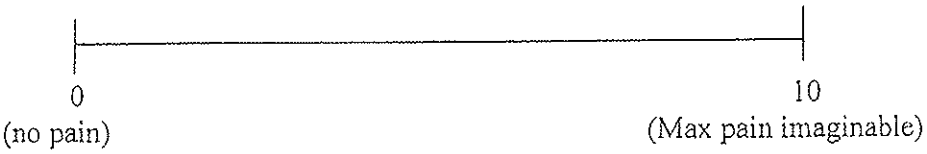
Morning Pain

Place a mark on the line representing the amount of pain you felt in the bottom of your foot when you awoke today.



Evening Pain

Place a mark on the line representing the amount of pain you felt in the bottom of your foot when you were preparing for bed today.



Appendix B

Patient ID #:
Date
Age
Sex
Diagnosis
Side

Time	Medicine	Strength	Number Tablets

PATIENT INFORMED CONSENT

Title:
Use of High Frequency Electrical Stimulation for Treatment of Plantar Fasciitis in Adults.

Sponsor:
BioElectronics Corp

Investigator:
Joel Brook, DPM, FACFAS

Phone:
(972) 566-7474

Associate or Co-Investigators:
Damien M. Dauphine DPM, FACFAS, CWS
Nicole D. Hancock, DPM
D. Jason Hancock, DPM
David G Genecov, MD

Study Co-coordinators
Tracey Hawkins, RN
Synergy Surgical

Participant: _____
(Last) (First) (Mi)

Address: _____

Phone #: _____

This consent form may contain words that you do not understand. Please ask Dr. Brook to explain any words or information that you do not understand.

Introduction
You are being invited to participate in a research study. This study is being sponsored by BioElectronic Corporation. We are testing a new miniature, wearable electrical stimulator that is designed to reduce pain and swelling after injury or surgery. You can not feel the treatment being given to you.

The study doctor is not being compensated to conduct this research trial. The purpose of this research is to determine whether this new treatment will reduce the pain in your foot and your need to take pain medication. Some patients will have units that do not stimulate so we can compare the groups. You will not know which group you are in, but you will be able to treat your pain in the manner you do now. The study sponsor makes and sells the ActiPatch™ stimulator. You may or may not be informed of the results of this study.

Procedures and Drugs

The following procedures or drugs will be used in this study.
At night when you prepare for bed, you will apply the ActiPatch™ to the sole of your foot as you were shown by the staff. Wrap the elastic bandage loosely around the unit to hold it in place. If you have been supplied with a half-sock, you may use that instead. Pull the tab to activate the unit. You may take any pain medication you have been using or has been prescribed by your doctor. Remember to fill out the data forms recording your pain level and any medicines used.

The proposed length of your participation in this study is 7 days; your treatment will take place at night while you sleep (approximately 8 hours/day). Approximately 120 total patients will be involved in this research study. This study is currently going on at this center only.

The following procedures or drugs which will be used are experimental- high frequency electrical for pain control.

Side Effects, Toxicities and Risks

The following risks, side effects or toxicities are possible: you may have skin problems under the device if you tighten the elastic wrap too much

In addition, this procedure may involve risks to you which are currently unforeseeable.

Extraordinary Costs

Your participation in this study will not require hospitalization. Unforeseen consequences of the experiment may require your hospitalization.

No funds for compensation for injuries associated with participation in this study have been set aside. You are free to contact the below listed investigator if you have questions and you may report research related injury to that investigator or to the Institutional Review Board which reviewed this study.

Alternatives

The following procedures or courses of treatment are available as alternates to the research procedure. If you decide not to participate, you have the option of using standard stretching, splinting icing therapy as previously recommended by your physician.

Benefits

The following are the direct and indirect benefits which you may derive from participation in this study: early relief of pain, reduced swelling and a reduced need for pain medicines.

Confidentiality

Your records will be held confidential by all parties involved in this research study and you will not be identified in any publication. However, the Food and Drug Administration has the right to access your medical/research records and identity, and may have the need to release this information. In addition, personal information may be disclosed if required by state or federal law.

Participation

Your being in this study is voluntary. You may refuse to be in the study without penalty to you or without loss

of any treatment rights. You may also leave the study at any time without penalty or loss of benefits.

Under the following circumstances the investigator may need to end your being in this study: none

New Findings
You will be told of anything new learned during this study which could affect your willingness to continue being in the study. Your physician, the sponsor or the Institutional Review Board has the right to terminate the study based on this information.

Questions
You have a right to have all questions about the study answered in away that you clearly understand the answer.

If you have any questions about the research or if you have any research related injuries, you may contact Dr. Joel Brook at (972) 566-7474 or Tracy Hawkins, RN 214-497-9246

If you have any questions about your rights as a research patient, you may contact John H. Cissik, PhD, IRB Coordinator, North Texas Institutional Review Board at Medical City at (972) 566-6060.

You will receive a signed copy of this consent form.

I understand and am satisfied with the above information, and I acknowledge having received a copy of this consent form.

_____ _____
Patient Printed Name and Signature Date

_____ _____
Witness Printed Name and Signature (if appropriate) Date

_____
Guardian Printed Name and Signature (if appropriate) Date

_____
Printed Name/Signature of Person Conducting Consent

North Texas Institutional Review Board
at Medical City
JUL 16 2009
APPROVED

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

You have a right to privacy. This means all information obtained as a part of this study will only be used

as described below. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used without your specific written permission. In addition, if photographs, audiotapes or videotapes are taken during the study, then you must give special written permission for their use. All information about you from this research project will be kept in a locked space.

By signing this Agreement you agree to allow Joel Brook, DPM, FACFAS and his/her staff (Researchers), the co-investigators and the study sponsor, BioElectronics (Sponsor), to use and disclose health information that identifies you for the purposes described below. You also agree to permit Medical City Dallas Hospital, its staff, your doctors, and other health care providers to disclose health information in your medical records to the Researchers and Sponsor for the purposes described below.

The Researchers and the Sponsor may use and share your health information to conduct the research. They may use your heath information as described in the informed consent. They may disclose your health information as required by law and to representatives of government organizations, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

If information that could be used to identify you has been removed, then the information that remains is no longer subject to this Authorization and may be used and disclosed by the Researchers and Sponsor as permitted by law. Once your health information has been disclosed to another party as indicated above, federal privacy laws may no longer protect it from further disclosure. However, the Researchers and Sponsor agree to protect your health information by using and disclosing it only as permitted by you in this Authorization. These limitations will continue even if you revoke (take back) your Authorization.

You do not have to give this permission and it is all right to refuse to sign this section of the consent form. Your doctor will still treat you even if you do not give your permission for this release of information. Your insurance will still pay your medical bills if you do not give your permission. However, since it is important for the people listed above to have access to your information, if you do not sign this Agreement, you cannot be in the research study.

While the research is in progress, you will not be allowed to see any health information that is created or collected. After the research is finished, you may see the information if you wish. Unless permission is specifically withdrawn, this permission will NOT expire at the end of the research study.

You will be given a copy of this Authorization after you have signed it.

_____ _____

Signature of Patient Date

_____

Printed Name of Patient

North Texas Institutional Review Board"
at Medical City

JUL 16 2009

APPROVED