Study Title:	Electrical stimulation as an adjunctive therapy to accelerate wound healing in people with Diabetic Foot Ulcers – A randomized controlled trial
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Purpose

This study is designed to test the efficacy of a novel electrical stimulation platform named the Tennant Biomodulator designed by AVAZZIA to accelerate wound healing, reduce pain and improve mobility in patients with diabetes and lower extremities ulcers/wounds after four weeks of therapy. In addition,

The objective of the study is to examine effectiveness of transcutaneous electrical stimulation (TENS) as an adjunct therapy to improve wound outcomes among people with plantar ulcers. Our hypotheses are:

H1: TENS is effective to relive pain in particular during night and during dressing change

H2: TENS is effective to increase skin perfusion

H3: TENS is effective to speed up wound healing weekly rate

H4: TENS is effective to improve mobility :

Table I: Patient Population

Inclusion Criteria	Able to provide informed consent 18-85 years old Clinically confirmed diabetes (ADA criteria) One or more active non-infected lower extremities ulcer or wound Subject or responsible caregiver is willing and to maintain the required offloading (as applicable the location of the ulcer) and applicable dressing changes and electrical stimulation application.
Exclusion Criteria	Subject has a demand-type cardiac pacemaker, implanted defibrillator or other implanted electronic device Is pregnant Is nursing or actively lactating Has history of seizures. Active wound infection Active Charcot Foot Non-ambulatory (Unable to walk 40 feet with or without assistive device) Bilateral AK/BK amputation Active drug/alcohol abuse (or history in the last year) Dementia or severe cognitive impairment Subjects with excessive lymphedema Subjects with osteomyelitis and/or gangrene Unable to comply with research appointments (e.g. long travel)

	Wide spread malignancy or systemically imumno-compromising disease Subject has a history of or any intercurrent illnesses or conditions that would compromise the safety of the subject according to judgement of a qualified wound specialist.

Background

Electrical stimulation may offer a unique treatment option to heal complicated and recalcitrant wounds, improve flap and graft survival, and even reduce the likelihood of ulceration. Electrical stimulation has been suggested to reduce infection, improve cellular immunity, increase perfusion, relieve pain, improve plantar sensation, and accelerate wound healing. At least five studies reported significant benefit of electrical stimulation on perfusion as measured by different tools able to measure cutaneous perfusion including laser Doppler flowometry, micro-vessel density, and measures of transcutaneous oxygen. While previous studies revealed that electrical stimulation could be effective to accelerate wound healing, prior studies limited to in-clinic and supervised use of electrical stimulation therapy and to our knowledge there is no randomized controlled trial examining potential benefit of in-home and daily use of electrical stimulation to accelerate wound healing.

Normal wound healing consists of regulated and integrated phases: hemostasis, inflammation, proliferation and tissue re-modelling. Oxygen plays a central role in each step of the healing process. Poor tissue perfusion caused by peripheral arterial disease (PAD) is highly prevalent among people with diabetes and interrupts this normal process by creating a system of localized hypoxia. PAD has its effects on the local wound environment by macro-vascular and microvascular processes. Macro-vascular disease is the sequelae of atherosclerosis on larger axial vessels. The earliest vascular change here begins with intimal thickening, which consists of increased smooth muscle cells and abnormal deposits of extracellular matrix within the tissue. Initially, blood flow is minimally affected but as the disease progresses there is increased disruption of flow and consequently the creation of an ischemic environment. Unlike ulceration from venous insufficiency, where disease usually arises in the distal leg or so called “gaiter” regions, arterial leg wounds typically affect the forefoot or toes, though wounds present at any spot distal to the arterial perfusion abnormality may suffer from non-healing regardless of original etiology. A compounding factor common in patients with diabetes is the effect of compromised mobility on their disease process. Diminished mobility can lead to prolonged periods of unrelieved pressure on the extremities resulting in increased shearing force applied to the skin and underlying tissues leading to a decrease in oxygen tension and eventual tissue necrosis.

Electrical stimulation could have positive effect on not only increasing skin perfusion in people with diabetes but also could improve mobility and balance via enhancing plantar sensation as demonstrated in our recent study. Thus, plantar stimulation not only may be beneficial to accelerate wound healing in people with diabetes but also may assist to improve mobility and reduce the likelihood of recurrence of ulcers. In this study, we proposed to examine effectiveness of daily home use of an innovative portable electrical stimulation platform (Tennant Biomodulator by AVAZZIA) to accelerate wound healing in people with diabetes. We

hypothesize that daily use of the Tennant Biomodulator for 4 consecutive weeks is effective to increase skin perfusion, accelerate wound healing, and improve balance and mobility in people with diabetes and plantar ulcers or wounds.

Study Design

We are proposing a clinical study at the Baylor College of Medicine, Division of Vascular Surgery and Endovascular Therapy, to test the efficacy of daily home use of a novel electrical stimulation platform named the Tennant Biomodulator designed by AVAZZIA to accelerate wound healing, relieve pain and improve mobility in people with diabetes and non-infected plantar ulcers or wounds. In addition, we will examine immediate benefit of electrical stimulation provided by the Tennant Biomodulator on increasing skin perfusion. Our specific aims are:

Aim1: Examine immediate benefit of lower extremity electrical stimulation to improve tissue perfusion (short term benefit)*:* We will recruit 40 eligible subjects (see table I for eligibility criteria). They will receive lower extremity electrical stimulation (at the shin level) for duration of approximately one hour using the Tennant Biomodulator Pro device. Skin perfusion before, at mid-point (approximately 30 min) and at the end of therapy will be measured. Skin perfusion will be assessed by Skin Perfusion Pressure (Sensilase, Vasamed Inc, MN, USA) and Kent Imaging. Other modalities such as HyperView Imaging (HyperMed Imaging, Inc., TN, USA) may be also used as comparator. Our hypothesis is:

H1: One-hour use of lower extremity electrical stimulation therapy will increase tissue perfusion.

Aim2: Examine long-term benefit of daily home use of lower electrical stimulation (long-term benefit)*:* Eligible participants will be randomized (ratio: 1:1) to either active (active group, n=20) or sham (sham group, n=20) therapy group. After receiving education, both groups will receive a home-based electrical stimulation system (Tennant Biomodulator device) for daily use at home up to 4 weeks. The duration of each treatment session per day will be one hour. The active group will receive an active electrical stimulation device. The control group will receive an identical device but without active electrical stimulation output. Participants and physicians who are treating the wound would be blinded to the type of device assignment. The study coordinator will be aware of assignment (active device or sham device). Each unit will be coded with a unique identification number. At the last visit, the study coordinator will reveal their group allocation. Since participating patients will have moderate-to-severe peripheral sensory neuropathy, they will be unable to determine via "feeling" whether or not they were receiving electrical stimulation. Patients will visit the clinic on weekly basis up to 4 weeks for assessing outcomes. The primary outcomes include changes in speed of wound healing and changes in plantar sensation. Secondary outcomes include patients self-report outcomes (e.g., pain, sleep quality, and quality of life), changes in mobility (e.g. physical activities and gait), and adverse outcomes (e.g., infection, amputation, etc.). Skin perfusion will be assessed similar to the method described in the Aim 1. Plantar sensation will be assessed using vibratory

perception threshold. Balance will be assessed using wearable sensors (BalanSENS, Biosensics LLC, MA, USA), mobility will be assessed using wearable sensors (PAMSys, Biosensics LLC, MA, USA), sleep quality will be assessed using PSQI questionnaire, and quality of life will be assessed using PROMIS Global.

Our hypotheses are

H2: Weekly speed of wound healing would be higher in the active group compared to the shame group

H3: Plantar sensation is improving in the active group in response to active therapy.

H4: Patient-reported outcomes and other secondary outcomes will be improved in the active group.

Study Device

BEST™ (Bio-Electric Stimulation Technology) devices produce unique microcurrent impulses transmitted through the skin to interface with the internal peripheral nervous system for the purpose of therapeutic intervention. The BEST microcurrent output stimulation is a train of high-voltage, pulsed-current, damped, sinusoidal and asymmetrical pulses. BEST devices react to the body's response to the microcurrent stimulus. With each response, the electrical properties of the tissue change. These changes in the tissue characteristics result in changes in the output. The device detects changes and indicates relative tissue reaction responses in a cybernetic feedback loop. BEST products are controlled by a high-performance microcomputer chip, which uses Avazzia proprietary software. These hand-held devices are FDA-cleared for the symptomatic relief and management of chronic, intractable pain and adjunctive treatment in the management of post-surgical and post-traumatic pain (available by prescription). These non-invasive neuro-stimulation devices allow patients to take control of their pain management. Avazzia BEST products feature a tissue reaction response indication, making them superior to traditional TENS units. BEST products work on different neural paths than a traditional TENS.

Avazzia BEST device technology and modes including the Tennant Biomodulator® devices have been FDA-cleared as transcutaneous electro-nerve stimulators for pain relief since 2007.

- K062641 clearance for BEST-AV1 family of micro current Rx devices with LED display for pain relief including reaction technology. The Tennant Biomodulator® device is a BEST-AV1 device. These devices are cleared for symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain (prescription required).

- K123099 clearance for BEST-AV2 professional family of Rx devices with LCD displays for pain relief including reaction technology. The Tennant Biomodulator PRO® device is a BEST-AV2 device. The difference between BEST-AV1 and BEST-AV2 is either LED display or LCD display of modes, power setting, timer, and reaction indications. The

BEST-AV2 devices have the same output specifications and technology as well as the same indications for use as the Rx devices in K062641.

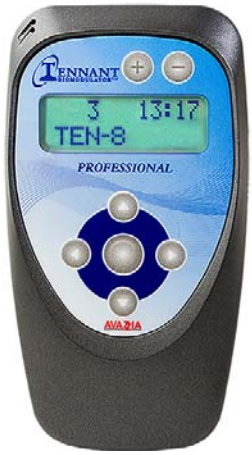
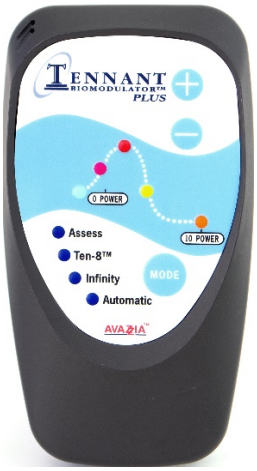
- K162392 clearance for BEST-AV1 family of microcurrent devices with LED display for pain relief including reaction technology for Over-the-Counter use. They have the same output specifications and technology. The difference between Rx and OTC labeling is indication for use for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities

The professional device with the LCD display will be used in the clinic, and patients will be issued the simpler device for home use.

Tennant Biomodulator PRO® designed by AVAZZIA
The candidate Tennant Biomodulator PRO® and the Tennant Biomodulator® devices designed by AVAZZIA are microcurrent transcutaneous electro-stimulation device with proprietary frequency sets specified by Jerry Tennant MD within the BEST platform control options. The devices are easy-to-use, handheld, AA battery-operated portable device for use in the home or clinic. They apply charge and power to the tissue through electrodes where maximum power delivered to the load is controlled and limited, and an automatic shut off is implemented. The user can passively place the electrodes where indicated and apply stimulation for a period of time. The user controls the output by selecting the preset mode and power setting. The device's controls and visual indicators are located on the upper side of the case and on the upper cover.

Both Tennant Biomodulator® devices designed by AVAZZIA are indicated for:

- symptomatic relief and management of chronic, intractable pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain

Tennant Biomodulator PRO® device	Tennant Biomodulator® device
	
Features: • LCD display • Over 50 present modes including Ten-8 and Infinity modes • User programmable control settings including frequency, pulses per packet, time between pulses, modulation, damping output.	Features: • LED display • For four present modes: Assess, Ten-8, Infinity and automatic.

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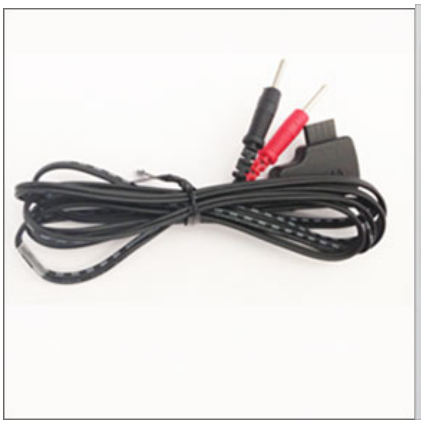

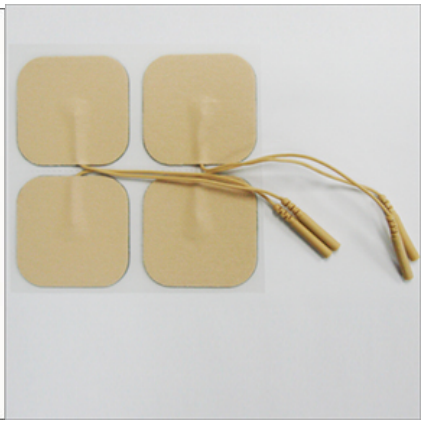

Randomization & Blinding

This study will be designed as a double-blind randomized clinical model. Both patients and the treating podiatrist will be blinded. The study coordinator will be aware of the assignment (active device or sham device) by a guide provided by the sponsor. The guide will identify which devices are active or inactive.

The control group will receive an identical device but without active electrical stimulation output. The physician treating the wound as well as patients will be blinded to the type of device. Only the study coordinator will be aware of assignment (active device or sham device). The study coordinator will reveal the group to the participant during the last visit. At that time, the coordinator will ask the participant if they would like to continue with the therapy. If they agree, participants will be instructed to contact Avazzia Inc. to receive a device after the completion of the study phone interview (12 weeks). .

Each unit will be coded with a unique identification number, and the study coordinator will reveal their status, placebo or electric stimulation, only at the end of data collection from the last patient. The PI and data analyzer will be able to match the status of the identification numbers with the corresponding units to analyze the data. Since participating patients will have moderate-to-severe peripheral sensory neuropathy, they will be unable to determine via "feeling" whether or not they were receiving electrical stimulation. Furthermore, the credibility of design is enhanced due to all enrolled patients being therapeutically naïve to the sensation of electrical stimulation.

Sample size estimation:

The estimated number of study subjects is 40. The sample size for the short-term effect (immediate changes in skin perfusion) was estimated to achieve 85% power when comparing to baseline values, using assumed rates of 50% and 10% improvement, respectively. A two-sided test of results in evaluable subjects (qualified for analyses of efficacy on immediate changes on skin perfusion) will provide the specified power at a 5% significance level. Sample size calculations resulted in a requirement for a total of 27 subjects. The sample size for long term benefit was estimated based on our previous study (Najafi et al, Diabetes Sci & Tech, 2017) in which effectiveness of daily use of electrical stimulation to improve balance was examined using a randomized controlled trial model. An effect size of greater than Cohen's d=1.35 was observed for improvement of mobility post plantar electrical stimulation intervention. In this study we will use a power of 80%, two –tailed t-test, and alpha level of 5% to observe a significant improvement in the intervention group receiving active stimulation compared to sham group (with nonfunctional stimulator), 18 subjects per group is required. Assuming a 10% drop out, the estimated sample size would be 20 subjects per arm. We recognize that this sample size may not be sufficient to validate all primary and secondary outcomes, but would be sufficient to estimate trend and estimate the sample size for follow up study. Upon approval of the sponsor, availability of budget, and based on initial results (first 20 subjects), the sample size may be increased as well.

Schedule of Events

Visit	Baseline assessment	Follow up				
#	0	1	2	3	4	12
Consent & HIPPA forms	X					
Screening (inclusion and exclusion criteria)	X					
Medical & Surgical History	X					
Gram Stain	X				X	
Neuropathy assessment (VPT)	X		X		X	
Immediate Skin Perfusion Pressure Response after one hour of BEST Therapy	X					
BEST Therapy	X	X	X	X	X	
Optional assessments		X			X	
Upper Extremity Test	X				X	
WiFi wound classification	X	X	X	X	X	
Vascular Assessments (SPP and HyperView/Kent Imaging)	X				X	
Wound Photos	X	X	X	X	X	
Thermal Images	X		X		X	
Wound Care (standard of care)	X		X		X	
Adverse Events Reporting	X	X	X	X	X	
Pain Questionnaire (VAS)	X	X	X	X	X	
Heart Rate Variability	X	X			X	
Health Questionnaires (MOCA, FESI, CES-D, PSQI, TSFI, Promis Global)	X				X	
Device Acceptability Questionnaire					X	
Phone Interview						X

Study Tasks:

Medical History: The presence of diabetes will be determined based on American Diabetes Association criteria. This will include: duration and type of diabetes, type of diabetes medication (insulin, oral, combination therapy, diet), previous history of foot ulcers, amputation (toe, foot), lower extremity bypass, lower extremity angioplasty, Coronary artery bypass surgery, cardiac angioplasty, arthritis, liver disease, osteoporosis, malignancy, and bone tumors. We will measure height and weight to determine body mass index (BMI). We will evaluate glycated hemoglobin, albumin and prealbumin at baseline. We will confirm PAD by measuring ABI.

Social Factors: We will evaluate the following factors: marital status, years of education, type of work, tobacco history (pack years, current smoker, current use of chewing tobacco, previous smoker, no tobacco history), drug history (current, previous history, or no history), and alcohol history.

BEST Therapy: The participant will be given an active Tennant Biomodulator PRO ® by the research staff. They will place the pads on the plantar area of the foot and provide therapy for one hour. At the end of the visit, the research staff will provide an active or sham Tennant Biomodulator ® to the participant for in-home therapy. The participant will have the ability of increasing/decreasing the intensity of the therapy with the Tennant Biomodulator ®. At each visit, the research staff will provide AA batteries to the participant for the device.

Peripheral Neuropathy: Neuropathy and its severity will be assessed using vibratory perception threshold (VPT) at the affected side. VPT will be evaluated at the distal great toe and fifth metatarsal head using a Biothesiometer.

Vascular Assessment: We will assess perfusion of the macro-circulation with arterial Doppler studies and microcirculation with Skin Perfusion Pressure measurements (SPP) at the affected side. We will use the SensiLase system (Väsamed) to measure SPP in mmHg. Ankle Brachial Index (ABI) will be also measured in the case of compressive vessel and if it was feasible (e.g. in non-hemodialysis patients) on the affected side. Additionally, we will use HyperView Imaging (HyperMed Imaging, Inc., TN, USA) or Kent Camera (Kent Imaging Inc., Calgary Canada) for surface tissue oximetry measurement.

Gram Stain: Bacteria levels will be assessed by collecting a samples and ordering a Gram Stain assessment, which provides an estimate of number of bacteria in the wound. A sample will be collecting before treatment and at 4 weeks.

Wound photo: A digital photo/video will be taken to record wound size.

Thermal Image: A Thermal camera will be used to obtain an image of the wound and observe inflammation.

Definition of Healed Wounds: A wound will be considered "healed" when it is fully epithelialized with no drainage. Only patients with non-infected wound will be recruited. *Infection* will be defined as a patient with three of six clinical signs of infection (erythema, heat, edema, pain, loss of function, purulence) or leukocytosis. We will use the Infectious Diseases Society of America's Diabetic Foot Infection guidelines to stratify the severity of infection. This guideline stratifies infections into four categories (none, mild, moderate, and severe) based on practical clinical and laboratory findings. Our group has shown this system to be predictive of morbidity.

Health Questionnaires: Quality of Life, Frailty Status, Fear of Falling, Sleep Quality, Depression and Mental Status and Device Acceptability: To evaluate functional status we will use well-accepted questionnaires, PROMIS for Quality of Life, Sleep Quality questionnaire (PSQI), MOCA for cognitive assessment, FES-I for fear of falling, CES-D for depression and TSFI for frailty status. During the last visit, we will ask an acceptability questionnaire.

Upper Extremity Assessment: Investigators will measure the participant's arm motion using a wearable sensor (LegSys, Biosensics LLC, MA USA). This sensor will be placed around the wrist. While being at a comfortable position, the participant will be asked to flex and extend their arm for 20 seconds at a fast speed. They will also be asked to repeat this task but counting backwards as the participants flex and extend their arm (dual task). (Measurement will be done at baseline and visit 4)

Heart Rate Monitoring: A comfortable chest worn sensor (BioStamp RC, MC10) will be used to measure physiological signs such as heart rate, skin temperature, and physical activity. This device will be comfortable placed on the chest attached either with two sticky electrodes or with elastic strap. Researchers will attach this device on the participant for the duration of the visit or during 24 hours. We will be assessing heart rate variability (HRV) as a surrogate of pain to determine magnitude of pain during dressing change and debridement process according to the protocol describe in Razjouyan et al (2017).

Phone Interview: Research staff will be contacting the subject to record any adverse events such as hospitalizations, ulceration falls and others.

Optional assessments – These may occur at any visit. However, they do not need to be performed.

Physical Exam: If they are able to stand and walk, the research staff will place 5 sensors named Legsys and Balanses (one on lower back, two on each upper thigh, and two on each shin) attached with elastic straps to test balance and record walking patterns. Research staff will ensure that the straps are not too tight to avoid poor circulation.

Physical activity: The research staff will provide the participant with a small sensor (Pamsys, Biosensics LLC, MA, USA) that will be measuring physical activity for 48 hours. It will record number of steps taken, duration of sitting, standing, walking, and lying. It will also record the number of transitions made from sitting to standing and vice versa. Researchers will provide a pre-paid envelope where the participants may use to return the device.

Informed Consent:

In order to recruit or identify subjects, we will screen our patient charts for eligible subjects.

The subject will be fully informed about the study, and will verbalize understanding and voluntarily agree to participate with the guidelines as stipulated in the informed consent. The subject will be informed if he/she can withdraw from the study at any time without loss of benefits. Consent forms will be signed and dated by the subject and by the Principal Investigator or Investigators. The original (with patient's signature) will be maintained per policy. A signed copy of the consent form will be provided to the patient. Informed consent will be obtained prior

to performance of any study procedures. Subjects are given as much time as needed to ask questions and read over the consent.

Subjects will be recruited from the Co-I's own practice. He may get some referrals from his colleagues that work in the same clinic such as Dr. Brian Lepow and other collaborators. We have included a Waiver of Partial Consent to cover our screening process. The Co-I will identify eligible subjects and alert the coordinator. The coordinator will review all the details of the study with the subject and/or their family. If the subject agrees to participate in the study, they will be screened and then enrolled into the study.

Spanish speakers will be consented using a full Spanish version of the consent. We have Spanish speaking coordinators on staff that can receive consent from Spanish speaking patients.

Withdrawal of Patients:

A Subject may withdraw from the study or be withdrawn from the study at any time and for any reason including but not limited to:

- Non-compliance with the visit schedule
- Non-compliance with the dressing change schedule and/or daily application of AVAZZIA
- Significant protocol violations
- Withdrawal of consent
- Serious adverse event
- Do not satisfy the entry criteria during wound healing process such as presence of infection or need for amputation.

Statistical analysis:

Continuous variables are expressed as mean +/- standard deviation (SD). Unpaired t-tests, Mann-Whitney U-tests, and Chi-square-tests will be used for baseline comparison according to the scale of the investigated variable and the distribution of the data. Repeated measures ANOVA tests will be used for examining the effect of intervention in each group after adjusting by age and BMI. Similar test will be used for short-term effect (i.e. changes in skin perfusion immediately after electrical stimulation) and long term benefit (i.e. changes in primary and secondary outcomes after 4 weeks). To account for missing data (prevent entire subject data removal due to lack of a data point), a linear mixed-effect model will be selected instead of univariate general linear model repeated measures analysis. T Chi-square-test will be used for comparing the incident of AE between groups. The effect size to discriminate between groups will be estimated using Cohen's *d* effect size and represented as *d* in the results section. Values ranging from 0.20 to 0.49 indicate small; from 0.50 to 0.79 indicate medium, from 0.80 to 1.29 indicate large, and above 1.30 indicate very large effects. Values less than 0.20 are considered as having no noticeable effect. Spearman correlation of coefficient will be used to examine association between changes in motor parameters and changes in skin perfusion and plantar sensation post intervention. All analyses will be performed using SPSS statistics (version 24; IBM, Armonk, NY, USA) , with a significance level of $p<0.05$.

Potential Risks/Discomforts:

As any new investigational device, there are some risks. Some of potential risks could be:

* Skin related discomfort, such as tingling
* Skin reaction to adhesive patch

If the tingling sensation is too intense for the participant, they have the ability to reduce the intensity for their best level of comfort.

Some of the study devices (LegSys, SensiLase, PAMSys, and Tennant Biomodulator®) and technology are completely non-invasive, safe, non-toxic and non-ionizing. The potential risks are minimal. However, like any battery powered systems, there is a minimum risk of sensor malfunctioning. In addition, the study devices are not waterproof, and although they use a low powered battery (similar to a cell-phone battery), in order to avoid any risk of shock the monitor should not be submerged or saturated with fluids during operations or cleaning. Participants will be instructed to remove all devices before showering or going swimming.

Participants will be instructed that while receiving the in-home therapy, they should be lying or sitting down with their foot elevated. They will be instructed to not walk or perform other activities while receiving therapy.

A vibration perception device will be used to monitor progress and diagnose severity of peripheral neuropathy in lower extremities. The vibration range will be from 0-50 Volts. Participants may feel slight discomfort from the vibration. This device is compliant with medical electrical device safety according to IEC 60601-1.

There is a minimal risk of interference from the Tennant Biomodulator® in the functionality of pacemaker/ICD devices. Therefore, to avoid any adverse events, it is recommend avoiding the use of this device on subjects with a pacemaker/IDC.

The safety of electro-stimulation devices for use during pregnancy, birth or while nursing has not been established. We will be excluding potential subjects with these conditions.

Subjects must be willing to change the batteries of the device. Otherwise, they will not receive benefit from treatment. The study coordinators will provide batteries at every visit to the participant for the study device.

Since personal information is obtained, there is a possibility for invasion of privacy. These risks are considered minimal as they have a low likelihood of occurrence. Confidentiality will be maintained by storing the data for analysis without names attached, using a numerical code. All written data will be stored in a locked filing cabinet. A master list will be kept separately to facilitate follow-up data collection. Subject identifiers will not be included in any computer files. Only staff with the permission of the PI will have access to the master list linking names to code numbers. All staff will be made fully conversant with relevant ethical principles, particularly around confidentiality. These procedures are expected to be highly effective in protecting subject confidentiality.

Potential Benefits:

There may be no direct benefit to the participant by being in this study. However, the information that will be gathered and analyzed from this research may help in development of a useful adjunct therapy program to improve wound healing and patient-centered outcomes including as pain and mobility among people with diabetic foot ulcers. It is part of a larger prevention initiative to reduce the high number of traumatic amputations associated with the diabetic foot disease.

The body of work in this area suggests opportunities for better patient care using a simple, inexpensive approach that has few adverse effects. There is a possibility of improving speed of wound healing and reducing associated pain.

Subject compensation:

Participants will be compensated with $50 per visit. For five completed visits a total of $250 may be compensated to the subject. We will be also providing parking validations.

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