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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-37713
Status: Approved
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Approval Period: 9/5/2017 - 9/4/2018

Section Aa: Title & PI

A1. Main Title

NOVEL OFFLOADING FOR DIABETIC FOOT ULCERS WITH PULSEFLOW DF®: A PROSPECTIVE STUDY

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Organization: DIABETIC FOOT COMPANY, LTD

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine
Baylor St. Luke's Medical Center (BSLMC)
HCHD: Harris County Hospital District Ben Taub
U.S. Renal Care- Baylor Scott Street Dialysis Center

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
Yes

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Diabetic foot ulceration (DFU) is a common and largely preventable complication of diabetes. [1] While most of these ulcers can be treated successfully, some will persist and become infected. Ultimately, nearly one fifth of patients with infected lower-extremity diabetic ulcers will require amputation of the affected limb, resulting in staggering costs for both the patient and the healthcare system. Prevention by identifying people at higher risk is key for better clinical management of such patients. It is not uncommon for patients suffering from diabetes to have concomitant lower extremity edema or venous insufficiency and they subsequently may benefit from graduated compression. However, because of the common association of peripheral arterial disease (PAD) in patients with diabetes, most clinicians are reluctant to apply compressive dressings in fear of exacerbating the symptoms of PAD and possibility of gangrene.

Unfortunately, this area has received comparatively little attention from industry, academia, andinsurance providers. A novel low voltage, battery powered medical device, PulseFlow DF® (The Diabetic Boot Company, Ltd. UK) has endeavoured to assist in the treatment of Diabetic Foot Ulcers. The device provides hybrid functionality i.e. mobile air bladder pump at plantar arch and offloading boot. The air bladder inflates to 160mmHg for approx. 1 second then deflates back to atmospheric pressure, allowing the plantar vessels sufficient time to refill. The offloading boot design holds the foot and lower leg in a position that reduces shear and friction forces and provides a reduction in plantar pressure.

The PulseFlow DF is designed to record how many hours of blood pumping it has delivered. This data will be downloaded at each clinic visit. The boot cannot pump blood around your foot unless fitted correctly and the battery is charged up overnight.

Please note that this study is a proof of concept study.

Section D: Purpose and Objectives

The purpose of this study is to conduct an observational study with N=15 diabetic subjects with active foot ulcers to assess whether PulseFlow foot compression device can help improve lower extremity perfusion, whilst improving balance and spatio-temporal parameters of gait.

Primary Endpoints: 1. Lower Extremity Perfusion: Measurement of lower extremity perfusion at 4 weeks of continuous device usage. Peripheral perfusion will be measured at baseline, 48 hours, 1 week and 4 weeks. Ankle Brachial Index (ABI) and Skin Perfusion Pressure (SPP) will be used to evaluate perfusion status for all study participants.

2. Plantar Pressure: Measurement of plantar pressure compared to the standard (non-PulseFlow DF) offloading boot.

Secondary Endpoints:

The following secondary effectiveness endpoints will be evaluated but success will not be required for determining success of the study. 1) Balance: Improvement in balance and decrease in fall risk as measured using a validated body worn sensor system at baseline and 4 weeks. 2) Activity Measurement: Activity measurement during 48 hours of continuous daily physical activity using a validated body worn sensor system, measured at baseline and 4 weeks. 3) Gait assessment using validated wearable technology at baseline and 4 weeks.

Primary Safety Endpoints: 1) The occurrence of adverse events during the four (4) weeks of the study treatment that are possibly related, probably related, or definitely related to PulseFlow DF (e.g. deterioration in wound condition such significant increase in wound size, infection, etc, falls, serious adverse events) will be properly reported.

Other assessments: 1) Usability assessment 2) Patient perception of benefit and level of comfort (Scoring System); 3) Adherence to use of offloading boot; and 4) Others: Quality of life, fear of falling, frailty, etc.

The key goals of the proposed project are to test whether a specially designed compression device can improve lower extremity perfusion, whilst also simultaneously improving the balance and walking performance. We envision the use of this specially designed offloading device with compression capability will help reduce the incidence of diabetic foot ulcers in high-risk diabetic patients. In addition, we assumed the proposed device might enhance daily physical activity as well as walking performance. We will conduct a prospective clinical study to validate these hypotheses. Potential changes in walking and spontaneous daily physical activities will be assessed using validated technologies that include walking analyzer system, balance assessment using body worn sensors, and computerized pressure insoles.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 2: Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English, Spanish

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E5. Children

Will children be enrolled in the research?

No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

In this proof of concept, intent to treat trial, 15 consecutive patients with diabetes and risk for lower extremity ulcers will be recruited from all study sites. Patients will be consented per the local Institutional Review Board's guidelines and approval for this study.

Inclusion Criteria:

a) Males or females age 18-80 years old with history of type 1 or 2 diabetes and the ability and willingness to provide Informed consent b) Patients with diabetic foot ulcers c) Patient is willing to participate in all procedures and follow up evaluations necessary to complete the study. d) Patients who have undergone lower extremity surgery / amputation may be enrolled into the study to the clinical judgment of the Investigator

Exclusion Criteria:

a) Patients with severe peripheral vascular disease (ABI or ankle brachial systolic pressure index <0.5) b) Patients with diabetic foot ulcers in the plantar surface of the medial longitudinal arch of the foot c) Patients with active wound infection, or untreated osteomyelitis d) Patients currently on immunosuppressive drugs. e) Pregnant or breastfeeding females. f) Acute fractures of the foot g) Acute heart failure h) Participation in an interventional Study within the last 30 days i) Non-ambulatory or unable to stand without help or walk a distance of at least 6 feet without assistance. k) Patients with major foot amputation. j) Patients who are unable or unwilling to participate in all procedures and follow up evaluations h) Patients who do not fit to available PulseFlow® sizes (UK 5-11, US 7-10.5) provided by the Diabetic Boot Company

F2. Procedure

Following is a summary of study procedures:

Study Day 0 (initiation), Visit 1 The following baseline values will be assessed and recorded. In needed assessments, the podiatric physician will examine the patient providing standard of care treatment.

Screening/ Baseline: Subjects will be screened to ensure that they meet the inclusion and exclusion criteria. The study will be explained and written informed consent obtained from each patient prior to the initiation of screening procedures.

Cognitive assessment: The Montreal Cognitive Assessment (MOCA) is a series of questions used to assess cognitive status.

Physical exam: Physical exam will be conducted, including vascular, dermatological, and neurological, as part of a regular care visit.

Medical History: A detailed medical history will include: previous medical history, location and duration of previous ulcers, amputation (toe, foot, below knee, above knee), lower extremity bypass, lower extremity angioplasty, CABG, cardiac angioplasty, last visit by physician (in weeks), and current/past use of special shoes or insoles.

Neurological Evaluation: The Neurological assessment will consist of Vibratory Perception Threshold testing (VPT) using the technique described by Young [12], and the 10 gram Semmes-Weinstein monofilament using the criteria described by Armstrong and Lavery[13]. The presence of sensory neuropathy will be identified as vibratory perception threshold greater than 25 volts or inability to accurately perceive a 10 gram Semmes-Weinstein monofilament at 1 or more of 10 test sites on the sole and dorsum of the foot[14], which is a standard clinical measurement in diabetic patients.

Vascular Assessment: The vascular assessment will consist of palpation of the dorsalis pedis and posterior tibial arteries and non-invasive Doppler studies. Ankle Brachial Index (ABI) will be determined for both extremities [14, 15]. ABI ratios less than 0.5 will indicate severe vascular disease. These patients will be eliminated from the study per exclusion criteria.

Additionally, skin perfusion pressure (SPP) monitor will be used to assess vascular status for all patients. SPP offers a non-invasive and real-time assessment of critical limb ischemia. It indicates the pressure at which blood flow resumes in capillaries. SPP is unaffected by falsely elevated systolic blood pressures, calcified arteries and peripheral edema. Typically SPP readings are obtained by photoplethysmography (cuff occlusion and re-appearance of pulsatile blood flux) or laser Doppler (cuff occlusion/thermal hyperemia and movement of red blood cells).

Edema Assessment – Peripheral edema will be assessed at baseline, using clinical signs and circumference

measurements at foot, calf and ankles.

Wound Assessment: We use acetate tracings, digital photos and a laser scanning measurement tool (SilhouetteMobile™ ARANZ Medical, Christchurch, New Zealand) to measure wound area and volume before and after debridement. This technique has been shown to be reproducible (72). A wound will be considered “healed” when it is fully epithelialized with no drainage

Physical Performance Tests - Balance assessment: Balance will be quantified using validated body worn sensors (BalanSens™, Biosensics LLC, USA). The system measures ankle and hip motion in three dimensions (3D), 2D COM sway as well as RCI in ML and AP directions [16]. Balance will be assessed according to Romberg protocol during eyes-open and eyes-closed condition during double, semi-tandem, and full tandem stances.

Physical Performance Tests - Gait assessment: Gait performance will be assessed using by a validated body worn sensors (LegSys™, Biosensics LLC, USA). The device uses five sensor modules respectively attached to right and left anterior shins, right and left anterior thighs, and posteriorly to the lower back. Based on the subject’s height and using a two-link inverse pendulum model the following spatio-temporal gait parameters will be estimated: velocity, stride length, stride time, double support, single support, stride-to-stride variability, and gait initiation [20]. In addition, the COM range of motion during walking will be calculated by using the data from the sensor attached to lower-back. Gait will be assessed over a distance of 20 meters while wearing PulseFlow DF® under 2 conditions: (1) walking at habitual speed (2) walking at maximum speed (fast walking). In addition, the above tests will be repeated while wearing removable cast walker (RCW), which is a standard offloading device.

Plantar Pressure Assessment: The efficacy of PulseFlow DF® to reduce plantar pressure will be examined using computerized pressure insoles® (Fscan®, TekScan, Boston, MA). Subjects will be ask to walk a distance of approximately 20 feet at habitual speed while wearing a standard offloading boot and then while wearing PulseFlow DF®. In addition, to ensure that PulseFlow DF® is providing a comparable offloading to a standard offloading device, plantar pressure during standing (approximately 30 seconds) will be assessed while wearing a standard offloading device (e.g. Aircast Walker) and results will be compared while wearing PulseFlow DF®.

Objective assessment of physical activity: Spontaneous daily physical activities as well as the risk of falling during activity of daily living are quantified using a validated body worn sensor named PAMSys™ (Biosensics, LLC, USA). PAMSys is a small long-term recording movement sensor which is unobtrusively inserted into a comfortable shirt (PAMshirt™). The system contains inertial sensors with software developed to identify postural positions and movements such as walking, standing, sitting, or lying during a measuring period of 48 hr. It has proven to be sensitive (87–99%) and specific (87–99.7%)[21, 22] for postural position and detection of walking in different samples of older adults and patient groups.

Assessment of user friendliness, acceptability, and perception of need: We will use a questionnaire tailored to the topic of this study to evaluate the perception of the target population in receiving benefit from the proposed technology. Subjects are asked to answer the questionnaire at the end of study. The questionnaire includes 11 items and allows assessing how target population perceives the need of such technology in management of their problem.

Other assessments: Other relevant assessments are Demographic/Health questionnaire, the Montreal Cognitive Assessment, the mobility-tiredness scale, Barthel Index, Depression Scale, fear of falling (Short-Falls Efficacy Scale – International), quality of life (Promise Global General Health Questionnaire), digital photography, Fried Frailty Criteria, Foot Questionnaire, Pain Assessment, Fall Log and Contact Agreement, Physical activity log, follow-up questionnaire, Shoe-fit test , subject’s perception assessment compared to standard shoe and RCW assessed using a 10 point Likert scale questionnaire.

PulseFlow DF: The PulseFlow device will be given to the subject. The research personnel will make sure that the subject is comfortable with the device and the device itself provides the offloading that is needed. The research personnel will also provide device education to the participants and will answer any questions that may arise.

Study Day 1, Visit 2 48-hour follow: All participants will be asked to return to clinic approximately 48 hours after visit 1. In this visit, (1) any adverse events will be assessed; (2) activity measurement (body sensor) will be returned; (3) PulseFlow DF data will be downloaded to ensure operability and patient compliance; and (4) further device education will be provided in case any issues have risen. We will take digital photographs of the participants feet and collect edema information.

Study Day 2, Visit 3 1-week follow-up: All participants will be asked to return to clinic approximately 1 week after visit 1. In this visit, (1) any adverse events will be assessed; and (2) PulseFlow DF data will be downloaded to ensure operability and patient compliance. Device education will be provided if needed. The participant will be asked to return the device at their next visit. We will take digital photographs of the participants feet and collect edema information.

Study Day 3, Visit 4 4-week follow-up: All participants will be asked to return to clinic approximately 4 weeks after visit 1. In this visit, outcome assessment using similar assessments described for Study Day 0 will be performed. In addition, perception of benefit and user-friendliness of the PulseFlow DF® will be assessed using a questionnaire. We will take digital photographs.

Participants will be asked to wear a comfortable shirt which holds a small activity monitor (PAMSys) for a period of 48 Hours (2 days). Patients will be requested to return this device via a pre-paid FEDEX envelope

Study Day 4, Visit 5 Follow-up up to three months: Some participants may be contacted by the study coordinator approximately up to three months post the last study visit to document success of wound healing if they continue to use PulseFlow DF after 4 weeks as well as potential incident of re-ulceration, or incident of falls.

We will ask participants to provide an Emergency Contact.

We will ask participants if they would like to be contacted for further studies they may be eligible for.

*****Please note that the protocol attached to Section S is from the University of Arizona. The PI initially established this protocol at U of A as it is an investigator initiated study. We have ensured that we have not included any references to U of A in this BCM protocol********

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 50 Worldwide: 50

Please indicate why you chose the sample size proposed:

We intend to employ a simple minimal risk research protocol to capture data required to realize the goals of this study. The results from this study will help us understand the real clinical needs and optimize the device specifications and form factor to fulfill these needs.

This is an initial proof of concept pilot study. The results of this study will allow for the calculation of an appropriate sample size for a larger proof of superiority (over current standard of care) trial.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

This study includes three hypotheses. To examine whether the proposed PulseFlow DF will provide comparable offloading as compared to removable cast walkers measured through a repeated measures study design for in shoe pressures (H1), we will use ANOVA and Fisher's exact tests for intra-subject reduction of peak pressures, pressure time integrals and Dynamic Plantar Loading Index.

To examine whether the proposed PulseFlow DF will help improve macro and micro-circulation in the lower extremity of patients (H2), we will use the similar analytical plan explained above by considering change in Skin perfusion pressure and ABI as dependent variables. For identifying the predictors, we will use multiple linear regression model and Anova (n-way). The independent variables will be severity of neuropathy quantified using Semmes Weinstein Monofilament, the level of activity, BMI, and age.

To examine whether the proposed PulseFlow DF will improve the activity level and quality of life (H3), we will use ANOVA multivariate test. The dependent variables will be number of total steps per day, duration of walking and standing, duration of longest episode of walking (i.e. continuous walking without stop), number of walking episode, duration of sit-to-stand and stand-to-sit postural transition, and SF12. We will use multiple linear regression model and multi-variant test to examine the effect of confounding parameters such as weather condition, BMI, age, etc.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

Some of potential risks could be discomfort, insufficient offloading, and uncomfortable level of compression to your plantar arch. It is important to notify us if you feel discomfort on wearing PulseFlow DF or if you feel excessive pressure to your feet because of wearing the PulseFlow DF.

You should always inspect the wound at each dressing change and comply with instructions providing by your doctor or wound care provider. You should immediately notify us or contact clinic, your doctor, or care provider if you feel the condition of your wound has been deteriorated. The signs of wound deterioration will be discussed with you by your doctor or care provider who treats your wound.

PulseFlow DF is an adjunct to standard wound healing therapies for the treatment of diabetic foot ulcer. You must comply with the procedures provided by your doctor or care provider for treating your diabetic foot ulcer.

The study device and technology is completely non-invasive, safe, non-toxic and non-ionizing. The potential risks to you are minimal. However, like any battery powered systems, there is a minimum risk of device 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 or shock the provided devices including activity monitor should not be submerged or saturated with fluids during operations or cleaning.

The assessments described above are expected to be minimal risk and probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

The duration of this study is 4 weeks and thus the treatment using PulseBoot DF will be terminated at 4 weeks. If subject's foot ulcer has not fully healed at 4 weeks, or is deemed not to be responding, they will be switched to standard of care and a different treatment method as instructed by subject's doctor or care provider. Based on subject's preference and advice of subject'/s doctor or care provider, participants may continue to use PulseFlow DF for up to 12 weeks.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?
Yes

NOTE: The answer to the questions in H2 requires the completion of the form: 'Section H – Data and Safety Monitoring Plan' as an attachment in Section S.

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?
No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?
No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.
It would stand to reason, that if proven useful the Device could be used for enhancing skin perfusion, which in turn may accelerate wound healing process and reduce risk of re-ulceration. In addition, the proposed compression device may reduce lower extremity edema, gait, balance, and thus quality of life.

Describe potential benefit(s) to society of the planned work.
Furthermore, the offloading component provided by PulseFlow DF®, may provide a wound healing environment to allow natural healing to occur in patients with active foot ulcer. This may reduce the need for amputations.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.
This study is minimally invasive and does have the potential to be beneficial. Therefore, the benefits outweigh the risks.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?
Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)
We are applying for a partial waiver of consent to cover the screening of our patient charts to identify patients and verify eligibility.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.
The PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.
Regardless of whether or not the subject participates in the study, they will receive the same quality of care.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted

without access to and use of the protected health information.

If we are not allowed to search our patient's records, we cannot identify and recruit the patients that are eligible for the study. This research will not affect the subject's care as they are receiving the standard of care.

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

We will destroy identifiers at the earliest opportunity consistent with conduct of the research absent a health or research justification for retaining them or a legal requirement to do so. The use or disclosure of PHI involves no more than minimal risk to the individuals and the waiver will not adversely affect the privacy rights and the welfare of the individuals. PHI is not disclosed to any other person or entity except for the authorized oversight of the research study by the PI and the clinical database administrator. The Division uniformly adheres to all patient and patient data security and confidentiality rules and regulations set forth by the College.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

A plan exists such that only the PI and clinical database administrator have access to these password-protected identifiers, which are subsequently removed when sharing data with co-investigators, analyzing data, and reporting or disseminating aggregate outcome data (often reported as rates) in scholarly publications and scientific presentations. The use or disclosure of PHI involves no more than minimal risk to the individuals and the waiver will not adversely affect the privacy rights and the welfare of the individuals.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

The PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):

Yes

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

Yes

Other:

No

Will additional pertinent information be provided to subjects after participation?

Yes

If Yes, explain how subjects will be provided additional pertinent information after participation.

Subjects will be able to get information about the study once it has been completed.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

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, will verbalize understanding, and voluntarily agree to participate with the guidelines as stipulated in the informed consent. The study coordinator or designee will introduce the study, present the written consent form, and spend as much time as necessary to ensure the potential subject completely understands the protocol. Emphasis will be placed on the voluntary nature of participation and the subject will be assured that his/her care will not be compromised in any way whether or not they choose to participate. The subject will be informed s/he can withdraw from the study at any time without loss of benefits. Consent forms will then be signed and dated by the subject and individual obtaining consent (PI, co-PI, study coordinator, or designee). Once written consent is obtained, the protocol may begin immediately or a follow-up appointment may be made.

The individual (PI, co-PI, study coordinator, or designee – interns) obtaining consent will be given a thorough training of the process and go through several mock consent scenarios. The training consists of understanding the study and being able to fully explain it to the participant providing all pertinent information (procedures, risks, benefits, alternatives to participant), giving sufficient time to the participant to consider whether or not they would like to participate, and answer any questions which the subject may have. The training will have a strong emphasis on subject comprehension of the research study by asking open-ended questions to the subject.

The patient will be informed that their participation is strictly voluntary and their choice will not affect future care with their care providers. We will also inform them that they are free to withdraw consent and discontinue participation in the project at any time, even after signing the informed consent document. At the end of the meeting, a signed informed consent form will be given to the patient for their records. Once the subject is providing his/her own consent for medical care and procedures, he/she will be asked for permission to continue to participate. The consent will be presented and discussed just as any initial consent process. The subject will then be given adequate time to read and discuss the study and make an informed decision about continuing to take part.

Patients will be referred by Co-PIs' practices including Wound Care Center at Southwest Memorial.

Please note that we will submit a Spanish consent for approval once the English one has been approved.

We also have attached the English questionnaires to Section S. We are not translating the questionnaires as we have Spanish speaking coordinators on staff to provide translation in these situations.

Are foreign language consent forms required for this protocol?

Yes

Which of the following ways will you document informed consent in languages other than English?

A full-length informed consent document

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Other:
No

At what institution will the physical research data be kept?
The physical research will be kept in our BCM offices located in the Neurosensory building in Methodist.

How will such physical research data be secured?
The physical data will be kept under lock and key in file cabinets.

At what institution will the electronic research data be kept?
All electronic research will be kept on network password-protected computers in our BCM offices in the Neurosensory Building of Methodist.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
Yes

Such electronic research data will be secured via Other:
No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research

data?

No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

Transmissions will only occur via secure email.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

Please note that there is an adequate plan in place to destroy identifiers at the earliest opportunity consistent with conduct of the research absent a health or research justification for retaining them or a legal requirement to do so.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

There is no costs to patients in this study except for their time. The device is provided by the sponsor.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

150

Distribution Plan:

Each subject will receive $25 for each completed study visit. If the subject does not complete the study, he or she will be compensated for the visits that have were completed. The subject will be requested to fill out a payment reimbursement form in order to capture their SSN number and address and issue a Check Request through Baylor College of Medicine. Subject’s information will be kept in a locked cabinet to protect privacy.

Since this is a pilot study, we may not foresee some minimal technical issues with the device (e.g. difficulty to charge device). If these problems happen during subject's participation in the study, we will schedule an extra visit in order to address and resolve the issue. We will compensate up to two extra visit (total:$50) per subject as agreed by the sponsor.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?
No

O1. Current Drugs

Is this study placebo-controlled?
No

Will the research involve a radioactive drug that is not approved by the FDA?
No

Section P: Device Studies

Does this research study involve the use of ANY device?
Yes

Device 1: PulseFlow DF

Section Q: Consent Form(s)

PulseFlow DF

Section R: Advertisements

None