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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-37962
Status: Approved
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Approval Period: 6/27/2018 - 6/26/2019

Section Aa: Title & PI

A1. Main Title

AVEX FOOTBEAT--MICRO-MOBILE FOOT COMPRESSION DEVICE FOR REDUCING LOWER EXTREMITY EDEMA IN PATIENTS WITH DIABETES: A PROOF OF CONCEPT 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: AVEX HEALTH

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

BCM: Baylor College of Medicine
Baylor St. Luke's Medical Center (BSLMC)

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?
No

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. [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 the key for better clinical management of such patients. It is not uncommon for patients suffering from diabetes to have concomitant lower extremity edema or even venous insufficiency[2-4] and they subsequently may benefit from graduated compression[5-7]. However, because of the common association of peripheral arterial disease (PAD) in patients with diabetes[8-10], most clinicians are reluctant to apply compressive dressings in fear of exacerbating the symptoms of PAD and the possible resulting gangrene[11].

Unfortunately, this area has received comparatively little attention from industry, academia, or insurance providers. A novel micro-mobile intermittent pneumatic foot compression device (AVEX Footbeat, Inc.) offers alternative means providing lower extremity compression. This device is portable and can be used in ambulatory settings providing increased venous blood and relief from concomitant lower extremity edema.

Section D: Purpose and Objectives

The purpose of this study is to conduct an observational study with N=30 patients to assess whether this micro-mobile foot compression device can help reduce lower extremity in patients with both diabetes and lower extremity edema without compromising the vascular supply.

The main purpose of this study is to determine if the device lessens edema. This study will also evaluate a new research device to see if it may help prevent diabetic foot ulcers. Additionally, it may potentially help delay progression of foot disease and produce a better quality of life by providing a better blood flow to foot and ankle.

Primary Endpoints: Reduction in lower extremity edema at 4 weeks of continuous device usage. Peripheral edema will be measured at baseline, 48 hours, 1 week and 4 weeks. Peripheral edema will be directly measured by traditional volume change assessment and indirectly by skin perfusion pressure assessment.

Secondary Endpoints: 1) Improvement in balance and fall risk as measured at baseline and 4 weeks. 2) 48 Hours of continuous daily physical activity using a validated body worn sensor as measured at baseline and 4 weeks. 3) Gait assessment at baseline and 4 weeks.

Specific Aim and Hypothesis

Aim 1. To assess the effectiveness of a micro-mobile foot compression device that provides mild compression to help reduce peripheral edema as compeered to baseline in patients with both diabetes and lower extremity edema in a four-week observational clinical trial of 30 patients.

Hypothesis 1: The micro-mobile foot compression device will result in edema reduction when compared to baseline peripheral edema for the study population.

Aim 2. To assess the effect of micro-mobile foot compression device on the macro and micro lower extremity circulation as measured by Ankle Brachial Index (ABI) and Skin Perfusion Pressure (SPP) Measurements.

Hypothesis 2: The micro-mobile foot compression device will help improve macro and micro- circulation in the lower extremity of patients with diabetes and lower extremity edema as compared to baseline. We expect to see positive changes in ABI and SPP measurements.

Aim 3. To assess the effect micro-mobile foot compression device on the quality of life quantified using the validated, international qualify of life assessment survey SF12, fear of falling quantified by FES-I, and risk of falling assessment quantified by gait, balance and spontaneous daily physical activity of patients with diabetes and lower extremity edema.

Hypothesis 3. The micro-mobile foot compression device will improve the quality of life, lower the risk of falling, lower fear of falling, and improve activity level of patients as compared to baseline assessments.

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, 30 consecutive patients with diabetes and lower extremity edema will be recruited from the outpatient clinic at Baylor College of Medicine. Patients will be consented per the local Institutional Review Board's guidelines and approval for this study.

Inclusion Criteria:

a) Males or females age 18-90 years old with history of type 1 or 2 diabetes and the ability and willingness to provide Informed consent b) Patients at risk of developing 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 at 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 foot region c) Patients with active wound infection, or untreated osteomyelitis d) Patients currently on immunosuppressive drugs. e) Pregnant or breastfeeding females. (standard urine pregnancy done on women during physical exam procedures) 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 with major foot deformities which won't fit in the diabetic shoes

F2. Procedure

Following is a summary of study procedures:

Study Day 0 (initiation), Visit 1 The following baseline values will be assessed and documented.

Screening/ Baseline: Subjects will be screened to ensure that they meet the inclusion criteria of the study. The study will be fully explained and written informed consent will be 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. A score less than 26 could indicate cognitive impairment. Although it is not an exclusion criteria, a score less than 26 will require PCP permission. Written permission from the patient will be asked for in order to contact their PCP for approval to participate in the study.

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 or via volumetric water displacement.

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 (see the attached list of questionnaires/assessments for further explanation).

Physical Performance Tests - Gait assessment: Gait performance will be assessed using by a validated body worn sensors (LegSys™, Biosensics LLC, USA) [17-19]. 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 under 4 conditions: (1) walking at habitual speed (single task); (2) walking at habitual speed while counting backward from a random number (e.g. 83) (dual task); (3) walking at maximum speed (fast walking), (4) Timed Up and Go (TUG); and (5) alternative 8 step test

Upper Extremity Test: Investigators will measure arm motion from each participant by implementing a validated technology based on wearable sensor system named LegSys. This system will assess respectively spatio-temporal parameters of arm motion in a clinical setting. The LegSys system will be used with 2 sensors to capture arm motion, one placed at the subject's wrist and another at their elbow. While being at a comfortable position, the subject will be asked to flex and extend their arm for 20 seconds at a fast speed. Subject will also be asked to repeat this task but counting backwards as they flex and extend their arm (dual task). We may also add wrist weights (no more than 5 pounds) to increase the resistance of this task.

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.

Plantar Pressure Assessment: Plantar pressure will be examined using computerized pressure insoles® (Fscan®, TekScan, Boston, MA). Subjects will be asked to walk a distance of approximately 20 feet at habitual speed while wearing regular shoes with and without AVEX insoles.

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 Mini-Metal State Exam, the mobility-tiredness scale, Barthel Index, Depression Scale, fear of falling (Short-Falls Efficacy Scale – International)[25], quality of life (SF-12 Health Survey)[26], Fried Frailty Criteria, Foot Questionnaire, Pain Assessment, Fall Log and Contact Agreement, Physical activity log, follow-up questionnaire, and Shoe-fit test

AVEX insole: The AVEX insole will be given to the subject. The research personnel will adjust the clutching reel (BOA technology) in order to ensure a comfortable shoe fit. The research personnel will also provide device education to the subject and will answer any questions which may arise.

Study Day 1, Visit 2 48-hour follow up: 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) AVEX insole data will be downloaded to ensure operability and patient compliance; and (4) further device education will be provided in case any issues have risen

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) AVEX data download to ensure operability and patient compliance. Device education will be provided if needed. The subject will be asked to return the device at their next visit. Similar assessments performed during visit 1 may be performed again during this visit.

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, benefit and user-friendliness of the AVEX insoles and Boa Technology 'Clutch Reel' will be assessed using a questionnaire. The subject will return the device back to the research personnel.

Patients 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 Three month follow-up: All participants will be contacted by the study coordinator approximately three months post the last study visit (Visit 4) to document potential incident of diabetic foot ulcer or falls.

The researchers will take digital photographs of you and videotape you and your feet during the study to monitor progress or deterioration (worsening) due to intervention. This is done using a normal digital camera for visual images and a thermal (heal sensitive) camera for thermal images. Both these methods are non-invasive. **We will NOT blur your face out in the photographs/videos. While we do all our efforts to mask your face in some cases (for example. journal policy) this may not be practical. We will only use videos and photos of you for scientific presentations or scientific publications. Initial your decision below.

____I agree to have my photographs/videotape presented in scientific presentation or scientific publication

____I do NOT agree to have my photographs/videotape presented in scientific presentation or scientific publication

Please provide below your Emergency contact information:

Contact name: _____

Relationship: _____

Phone number: _____

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:

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?

Statistical Analysis - This study includes three hypotheses. To examine whether the proposed micro-mobile foot compression device will result in a edema reduction compared to the baseline (H1), we will use ANOVA and Fisher's exact tests for intra-subject rate of edema reduction using the outcome explained before. Multivariate and multiple linear regression test will be used for testing the effects of confounding factors including age, gender, BMI, foot insensitivity, etc. Additional, paired t-test will be used to examine whether amount of edema reduction at the end of study is significant compared to baseline. We will use Pearson correlation of coefficient and Fisher's exact tests to examine whether severity of neuropathy has any significant association with the rate of edema reduction. Finally, we will use multiple linear regression model to examine whether subject's level of activity, BMI, ABI, Skin perfusion pressure, and micro-mobile foot compression device are independent predictors for the rate of edema reduction.

To examine whether the proposed sock 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 socks 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:

The AVEX Footbeat insole is an investigational device, which has been designed to enhance blood flow to lower extremities via a Micro-Mobile Foot Compression Device. The compression component applied pressure under your foot arch. We will perform initial screening to ensure the safety of the device. But as any new insole, there is some risk that the insole caused some discomfort or cause development of foot ulcers. It is important to notify us if you feel discomfort on wearing the insoles or if you feel excessive pressure to your feet because of wearing the AVEX Footbeat insole.

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 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.

You must be willing to charge device battery daily. Otherwise they will not receive benefit from compression component during treatment.

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.

Please note that there is also the possibility for loss of confidentiality. The PI and the research team will minimize the possibility of for loss of confidentiality by keeping all the physical data locked in cabinets only accessible to the research team. The electronic data will be kept on network password protected institutional computers. And, subject PHI will be coded as much as possible to minimize the potential for loss of confidentiality.

H2. Data and safety monitoring plan

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

No

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.

There may be no direct benefit to you by being in this study. However, the device may improve blood flow and reduce the number of traumatic amputations.

Describe potential benefit(s) to society of the planned work.

What the researchers find out from this study may help other people with diabetes and history of foot ulcers. This research utilizes a new device to improve blood flow, which may help to prevent diabetic foot ulcer and enhance balance; it is part of a larger prevention initiative to reduce the high number of traumatic amputations associated with the diabetic foot disease.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

The risks involved with this study are very minimal. There is a possibility for a loss of confidentiality and some risks still remain unknown. There is also the possibility of minimal risks associated with use of the devices in this study. However, there is a chance that the device may provide some benefits. Therefore, the anticipated benefits outweigh the potential 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 will review our patient charts to determine and verify patient 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.

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.

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.

Patients will receive the same standard of care regardless to whether they participate or not. These patients will be clinic or established patients of the PI. Therefore, they already consent to a review of their charts at the time they are seen in clinic the first time and before they are even added to the PI's patient database.

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.

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 as subjects will receive the same standard of care regardless of whether or not they participate in the study.

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.

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 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):

No

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?
No

If No, explain why providing subjects additional pertinent information after participation is not appropriate.
Subjects will be provided the same standard of care whether or not they participate in the study. Therefore, providing additional information is irrelevant.

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.
Subjects will be recruited from the PI's own practice. He may get some referrals from his colleagues that work in the same clinic. We have included a Waiver of Partial Consent to cover our screening process. The PI 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.

Thomas A. Glazier Senior Education Center and the Jim and JoAnn Fonteno Senior Education Center will allow the research team to display information regarding the research study as well as provide the research team with a space to conduct consenting and assessments.

Please note that all subjects will be consented before any screening procedures are done.

Spanish speakers will be consented using a full Spanish version of the consent. We have Spanish speaking coordinators on staff that can translate the consent for the patients. The coordinator who translates the consent will sign off on the Translator signature line of the ICF.

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 #:
No

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?
All data will be kept at in our offices at our BCM McNair office building

How will such physical research data be secured?
All physical data will be kept in file cabinets that have a lock and key.

At what institution will the electronic research data be kept?
Electronic data will be kept on Network Severs that are password protected. The computers are in the McNair building.

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 be sent via secure and encrypted 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.

Participating in this study will take time and will not involve any direct cost to the subject. Subject medical insurance will not be billed for this purpose. All study procedures are research related and will be covered 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:

120

Distribution Plan:

By law, payments to subjects may be considered taxable income. You will receive $30 for each completed study visit, including a maximum of $120. If you do not complete the study, you will still be paid for the visits you have completed.

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

SAMPLE: Urine

What is the purpose of the sample collection?

Pregnancy test for women

For blood draws, specify the amount drawn, in teaspoons, at each visit and across the course of the subjects entire participation time.

We will be using a standard urine test. We will collect only what is required to perform the test.

Is there the possibility that cell lines will be developed with this sample?No

Sample will be obtained from:

Research Labs

Will the sample be stripped of identifiers?

No

If sample will be released outside the hospital:

Will sample be released to anyone not listed as an investigator on the protocol? Will the information be identifiable, coded or de-identified?

Sample will be coded along with all other study data collected.

Will sample material be sold or transferred to any third parties? Will the information be de-identified?

Sample not sold.

If sample will be banked for future use:

Where will the sample be banked and for how long?

Sample not banked.

Does the banking institution have an approved policy for the distribution of samples?

NA

If the entire sample will NOT be used during the course of this research study:

Will the remaining tissue be discarded? If not what will be done with the remaining sample after study completion and how long will the sample be kept?

NA

Will samples be made available to the research subject (or his/her medical doctor) for other testing?

No

If a subject withdraws from the study:

Will subject have the option to get the remaining portion of their sample back?

No

Will samples be destroyed? If not, will they be kept anonymously? What will happen to the sample if the subject revokes authorization?

Sample will be destroyed if subject withdraws consent.

Will data obtained from their sample be deleted? What will happen to the sample if the subject revokes authorization?

All data will be deleted and sample will be discarded if subject revokes authorization.

Will study data or test results be recorded in the subject's medical records?

Yes

Will results of specific tests and/or results of the overall study be revealed to the research subject and or his/her doctor?

Yes.

Please identify all third parties, including the subject's physician, to receive the test results.

The pregnancy tests information will be recorded in the patient's medical record and accessible by the research team and subject's doctor.

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: AVEX Health & Boa Technology `Clutch Reel'

Device 2: LegSys for Gait assessment

Device 3: BalanSens for Balance assessment

Device 4: Tekscan

Device 5: PAMsys

Section Q: Consent Form(s)

AVEX

Section R: Advertisements

Mode of Advertising: Other: Bullentin Board, Local Houston Churchs' Website, social media

Exact language of Advertisement:

Novel Shoes & Insoles for Adults with Diabetes and at Risk for Foot Problems

To enroll in this study, Contact Ana or Ivan (713) 798– 7537 or (713) 798– 7538

interdisciplinary Consortium on Advanced Motion Performance

Are you having pain in your feet due to diabetes? If yes, you may qualify for a unique study that could reduce: - pain in your feet, - numbness & tingling - swelling as well as possibly enhance your balance and walking performance.

Contact Baylor College of Medicine iCAMP at (713) 798-7537 or (713) 798– 7538 for more information.

Who we are

Bijan Najafi, PhD Principal Investigator Professor of Surgery Director, iCAMP Bijan.Najafi@bcm.edu

Ana Enriquez, BS Lab Manager iCAMP ana.enriquez@bcm.edu

Ivan Marin, BS Research Coordinator iCAMP Ivan.Marin@bcm.edu

Are you? Are you an adult who has diabetes ? If so... Are you interested in volunteering for “high-tech” studies targeted to reduce swelling in ankles, pain and numbness in feet and improve balance?

THEN… You are eligible to participate in a novel study that uses state-of-the-art technology to assess benefit of a novel footwear to improve the blood flow in your feet.

Objectives BCM iCAMP at the Department of surgery has been partnered with AVEX LLC to test an innovative insole device for improving blood flow, improving balance and reducing your feet problems. If proven effective, the technology could help enhance balance, reduce swelling and promote a strong and healthy life.

What exactly do I do? We will provide you with a new pair of shoes and insoles. We will study your walking and balance patterns and measure your numbness throughout a month long period. During this period you will ONLY be seen 4 times. Qualifying participants will be eligible to receive an innovative footwear to reduce numbness at NO cost.

Why participate? It could help you increase your circulation in your feet and ankles When there is numbness in the feet, a little cut could potentially become a troubling ulcer and you are at higher risk of falling It could help with reduction of swelling and pain. Need some extra cash? We compensate with $30 per visit. You will be helping scientist know more about these technologies which could help others with these problems!

Equipment

Special insoles with a pump that delivers a massage to the arch of your foot.

Innovative a wearable system using sensors attached to shins, thighs, and lower back to help assess your quality of walking and balance

Enroll now! In order to enroll, see the front side of this pamphlet for contact information

Mode of Advertising: Other: Bulletin Board, BCM Website, BCM Clinic waiting areas, distributed in the community, social media

Exact language of Advertisement:

Do you you have diabetes and concerns about falling?

Interested to try a revolutionary footwear that massages your feet at no cost to you? Be compensated up to $120!

*Are you an adult (50 years or older) who has diabetes? *Do you have pain in your feet? *Do you have numbness and tingling in your feet? *Do you have swelling?

If so, you may qualify for our study!

Benefits of participation include *Potential improvement of pain, swelling and numbness in your feet. *Potential improvement of balance and better walking performance *Advancement of scientific knowledge to help other

For more information please contact the research coordinator list in the following

Ivan Marin Research Coordinator 713-798-7538 ivan.marin@bcm.edu

Louie Morsy Research Coordinator 713-798-8714 louie.morsy@bcm.edu

AVEX Balance Study 713-798-7538

Michael E. DeBakey Department of Surgery 7200 Cambridge St. B01.529 Houston Texas Phone 713-798-7537; Fax 713-798-8460 www.bcm.edu/icamp

Mode of Advertising: Other: BCM Website, Social media, Community outreach

Exact language of Advertisement:

Video in section S shows testimony of participant regarding study device.