Pressure Alternating Shoes for Prevention of Diabetic Foot Ulcers

NCT06026813

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Title of Study: Pressure Alternating Shoes (PAS) for Prevention of Diabetic Foot Ulcers

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center

Key Information about this Study

You are voluntarily being asked to take part in a research study because you are healthy or have diabetes and have been diagnosed with diabetic neuropathy (DN). Your participation in this study is completely voluntary. You do not have to participate if you choose not to.

In this study, researchers will test pressure-alternating shoes (PAS), which will relieve pressure on the soles of the feet. This may help prevent foot sores in people with diabetic neuropathy (DN), who are at high risk for them. Subjects will be healthy or diagnosed with DN and will walk on a treadmill at their own pace for 5 minutes in special diabetic shoes with pressure-alternating insoles. Insole plantar pressures will be assessed using a pressure mapping system. Body-worn sensors will be worn to measure balance while walking in a hallway in a straight path. Researchers will then measure tissue perfusion and temperature in the soles of the feet with special cameras.

This study will include one visit and will take about 2 hours of your time. There may be no benefit to you for taking part in this study, but this study may help DN patients prevent pressure ulcers in the future. The most significant risk is falling while walking on the treadmill. The treadmill has safety features to help prevent falls. The alternative to taking part in this study is to decide not to participate.

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Your doctor may or may not be a research investigator in this study. If your doctor is a research investigator in this study, s/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Lawrence A. Lavery, DPM, MPH, Department of Plastic Surgery at the University of Texas Southwestern Medical Center at Dallas.

Funding
The National Institute on Aging, part of the National Institute of Health, a federal agency that promotes scientific research, is funding this study. This organization is providing money to UTSW so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

You are asked to participate in a research study that compares the effectiveness of Pressure-Alternating Shoes (PAS) against your usual daily shoes, in reducing pressure on the sole of the foot. Pressure on the sole of the foot is associated with foot ulcers. These shoes are referred to as "off-loading" devices since their purpose is to reduce pressure in the location of the ulcers. These shoes are custom made for the treatment and/or prevention of diabetic foot ulcers. The researchers hope to learn the effectiveness of these devices.

Investigational Use of Device
This study involves the use of an investigational device called Pressure-Alternating Shoes (PAS). "Investigational" means that the PAS device have not yet been approved by the U.S. Food & Drug Administration (FDA) for preventing foot ulcers.

This study will help find out what effects, good and/or bad, the PAS have. The safety of this device in humans has been tested in a prior research study at UNT; however, some side effects may not yet be known.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are either healthy or have been diagnosed with diabetic peripheral neuropathy with or without ulceration or history of foot surgery.

How many people are expected to take part in this study?
This study will enroll approximately 40 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend one visit with the researchers or study staff. This visit will take approximately 2 hours.

Study Procedures - as a participant, you will undergo the following procedures:

- Standard biomechanical exam to measure for range of motion and assess for deformity
- Physical exam to measure level of neuropathy
- Walk on a treadmill for 2 minutes in your usual daily shoes.
- Walk on a treadmill for 5 minutes in standard diabetic shoes, which we will provide, that have the custom insole along with an insole that measures pressure.
- Measure the pressure of different parts of your feet by the insole
- Body-worn sensors to measure balance will be worn while walking in a hallway in a straight path
- A specialized camera will take pictures of your feet at a set distance away from your feet to see how much oxygenated blood is present and will not contact the subject.
- A specialized camera will take pictures of your feet at a set distance away from your feet to measure the temperature and will not contact the subject.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician.

Risks – "What are the risks of participation in the research?"

Risks from the research
The investigators have designed this study to learn how well the new custom insoles reduce pressure on the soles of the feet. We will compare your foot pressures in regular shoes and in the custom insoles.

Risks from the specific research procedures (interventions or procedures)
The risk during this study is falling while on the treadmill or while the sensors are attached to the subject. The treadmill has safety features to prevent falling. There may be a risk of skin irritation or ulceration from walking in a custom insole. Participating in research may involve a loss of privacy and the potential for a breach in confidentiality.

There are not any anticipated risks of imaging with the infrared camera.

For more information about risks, ask one of the researchers or study staff.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Are there Risks related to withdrawing from the study?

There are no risks related to withdrawing from the study. If you wish to withdraw from the study early, please discuss your decision with the principal investigator.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you have an injury or illness from the study device, taking the study drug, or the procedures required for this study, medical care will be provided. Depending on the circumstances, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the principal investigator and study sponsor, if applicable, have decided that the injury/illness is directly related to the study drug, device, or procedures and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions

of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

We have no plans to give you money if you are injured. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

You may not receive any personal benefits from being in this study. We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

There are other options available to you. Your other choices may include:
Getting treatment or care without being in a study or taking part in another study.

Payments – Will there be any payments for participation?

You will be compensated a one-time payment of $100 for your time and travel costs related to this study. Compensation will be provided at the end of the study. If you are unable to complete this study because eligibility as self-reported during the phone screening is not verifiable at the time of the study, you will not be compensated. If you are unable to complete this study because you or study personnel are concerned about your safety as related to application of the devices and/or your ability to move about and conduct tests without falling, then you will still be provided with full compensation for your participation.

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of the study visit. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. Your social security number is needed to process your payments. Study payments are considered taxable income and are reportable to the IRS. Should you decide not to provide your social security number, or your social security number does not match the name on file with the IRS, your study participation payment will be decreased in accordance with the current IRS tax rate. All information will be stored in a secure fashion.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Certificate of Confidentiality:
To help us further protect your information, the investigators will obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

Your personal information collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- Demographics, such as birthdate, sex, race, and ethnicity.
- Medical History.
- Shoe size.
- Foot exam results
- Vital signs, such as height and weight.
- Results from research, such as data from the insole, perfusion and temperature results from the special camera.

We will get this information by asking you questions, having you fill out a questionnaire, and by testing you as described above.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center.
- The Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?

The records of this study will be kept private, and stored in a locked cabinet. Your records and health information will be kept as confidential as possible under current local, state and federal laws. However, the Office of Human Research Protections, possible other federal regulatory agencies, and the Institutional Review Board may examine your research records. In the case that the final results of this study should be published, no individual results will be reported, and your name will not appear in any published material. Data will be shared with research personnel only. When the study is completed, any identifying information that has not already been removed from the study documents will be removed. If you give permission for us to contact you for other studies, we will only keep your name and contact information on file. If you do not provide permission, your name and contact information will not be retained once the study has been completed.

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the School of Health Professionals for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?

You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Lawrence Lavery, DPM, MPH at 5323 Harry Hines Blvd., Dallas, TX 75390-8560. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?

By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Lawrence A. Lavery, DPM, MPH can be reached at 214-399-5381.

If primary is not available, contact
Debby Noble can be reached at 214-648-8686.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Witness / Interpreter Signature Section

Interpreter/witness (Interpreter signature required per hospital policies when physically present.)

I attest that I have interpreted the information in this consent form and it was explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of Interpreter	Signature of Interpreter	Date	Time AM PM

Witness Signature (required when interpreter is not physically present-e.g., Language Line is used):

By signing below:

I attest that the information in the consent form was accurately explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of witness	Signature of witness	Date	Time AM PM

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:

By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM