University of Illinois at Chicago

Research Information and Consent for Participation in Biomedical Research

Effect of Alternating Pressure Overlay on Weight Bearing Tissue Tolerance in People with SCI

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

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Sponsor: Dabir Surfaces Inc.

Why am I being asked?

You are being asked to be a subject in a research study that will assess the newly-developed low profile alternating pressure (AP) overlay (by Dabir Surfaces Inc.) in preventing pressure ulcer development in people with spinal cord injury (SCI).

You have been asked to participate in the research because you are 18-64 years of age, have had a spinal cord injury for more than a year, and do not currently have a pressure ulcer.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago. **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

Approximately 20 subjects may be involved in this research at UIC.

What is the purpose of this research?

People with SCI are at extremely high risk for developing pressure ulcers (bed sores). Approximately 50-80% of the SCI population will develop one pressure ulcer throughout their lifetime. Pressure ulcers are hard to treat and the recurrence rate is high. New technologies are needed to help prevent such complications.

The purpose of this study is to test if the Dabir alternating pressure overlay could be used to increase your skin's ability to tolerate pressure when lying in bed for an extended period of time (40 minutes). The AP overlay is a thin pad that can be used on top of any mattress, and it is composed of multiple cells (compartments) that can inflate and deflate alternatively to allow reduction in pressure when you lie on top of it.

We want to see if the pressure underneath your lower back and heel areas will be smaller when you are laid on top of the Dabir AP overlay as compared to a standard operation room (OR) overlay. For this study, the AliMed® standard OR overlay will be used. We also want to see if your skin blood flow (the amount of blood flowing through your blood vessels that supplies oxygen and nutrients to skin) will increase at your lower back and heel areas when you are laid on top of the Dabir AP overlay as compared to the standard OR overlay. Findings of this study will help us determine the protective effect of using the Dabir AP overlay as compared to the standard OR overlay.

Lastly, we will test your blood for factors that may potentially predict the outcome or development of an ulcer, as well as bank any left over blood for future research.

What procedures are involved?

This research will be performed at the Applied Health Sciences Building at University of Illinois at Chicago located at 1919 W. Taylor St. in room 272. You will need to come to the study site only once. The visit will take approximately **6 hours** of your time.

The following procedures will take place during the visit:
1) Face-to-face screening (30 minutes), 2) experimental procedures (4 1/2 hours), vascular control measures (30 minutes), and a single blood draw (15 minutes).

You will be asked to fast (refrain from eating food) and smoking for 4 hours prior to and during the study visit, as well as refrain from consuming any caffeinated foods/drinks for 12 hours prior to the visit.

1) Face-to-face screening:
To further determine your eligibility for this study, you will undergo a face-to-face screening procedure. Your resting heart rate and blood pressure will be measured using a heart rate monitor and blood pressure cuff, respectively. Your remaining motor function, sensation, and autonomic function will be examined just like they are when you go to the doctor's office. To test your remaining sensation, we will touch your skin lightly just below the injury level to see if you feel anything. To test your remaining motor function, we will ask you to perform movements using your arms and legs (such as kick out your legs and flex your elbows). To document your remaining autonomic function, we will ask you questions regarding your ability to: sweat, sense changes in temperature, control your bladder, bowel movements, and sexual function. If you demonstrate normal heart rate and blood pressure, you will proceed with the

study procedures below. In addition, if you are female of childbearing age, you will be asked to complete a urine pregnancy test using a test strip. If you are pregnant, you will not be eligible to participate in this study. If you are not eligible to participate for any reason, you will be compensated for your time accordingly.

Experimental Procedures:

During the study visit, you will undergo two protocols: the alternating pressure (AP) protocol and the Control protocol. The order of the protocols will be randomly assigned (by drawing from a pool of envelopes). A 30-minute resting period will be provided to you between the two protocols.

For both protocols, two flat silicone sensors will be taped to your skin (one at your sacrum or lower back and one at each of your heels). The two flat silicone sensors will be used to collect your skin blood flow non-invasively (from outside your skin) throughout the duration of the testing. A flat and flexible mat that contains pressure sensors will be placed between you and the overlay to monitor the amount of pressure generated while you lie on the overlays.

- *AP protocol (2 1/2 hours):* During this protocol, you will be asked to lie on your side for 10 minutes without any overlay, so we can collect your baseline blood flow. Then you will be asked to lie on the AP overlay, first on your back for 40 minutes, then on your side for 30 minutes. Last, you will be asked to lie on the regular OR overlay, first on your back for 40 minutes and then on your side for 30 minutes.

- *Control protocol (1 1/2 hours):* During this protocol, you will be asked to lie on your side for 10 minutes without any overlay, so we can collect your baseline blood flow. Then, you will be asked to lie on the regular OR overlay, first on your back for 40 minutes and then on your side for 30 minutes.

2) Vascular Control Measures:

- *Mild heating:* While you are still lying on your side, a probe (a heating instrument about the size of a penny) will be applied to your sacrum and one of your heels. The probe will be mildly heated to approximately 106 °F for approximately 7 minutes at each location. This procedure will take up to 15 minutes.

- *Mild electrical simulation:* You will be placed in a semi-reclined position. We will then apply a mild electrical stimulation procedure on your skin at two different sites, including your forehead and your abdomen (belly). We will deliver 5-8 stimuli (pulses) randomly at each site. The intensity of the stimuli is very low so it will not trigger any pain or muscle movements. This procedure will take up to 15 minutes.

3) Wheelchair Pressure mapping :

We will have you sit in your wheelchair. We will place the same mat that contains the pressure sensors between you and your seat cushion, so we can measure the amount of pressure generated while you are seated.

4) Blood Draw:
We will collect a blood sample by putting a needle into a vein in your arm. Approximately 1-2 tablespoons of blood will be taken to test for HbA1c (hemoglobin), blood sugar (indicators of diabetes), and cholesterol.

5) Blood Banking:
As a required part of this study, we will bank any blood that is left over after testing. The blood will be stored for up to five years for further research, since the latest trend in research shows that metabolic syndromes (disorders such as early signs of diabetes) after SCI may affect pressure ulcer formation. We will further analyze your blood samples once the test methods become available. Your blood will be stored coded (without any direct identifiers) in a laboratory freezer at UIC. Only Dr. Tzen and her research team will have access to the blood. After the analyses are complete, any unused blood will be destroyed.

The following information will be stored with your blood sample: your age, sex, pressure ulcer history, diagnosis of SCI, duration of SCI, and remaining sensation, motor function, and autonomic function.

What are the potential risks and discomforts?

The procedures performed in this study are unlikely to cause any damage to your body. Unless specified, the overall risks including pain and discomfort are considered rare (less than 1 out of 100 people). The risks associated with this study include:

1. Emotional stress caused by our screening procedures:
   You may feel uncomfortable during screening answering the personal health related questions or while you are undergoing the sensation, motor and autonomic function examinations. You do not have to answer the questions or complete the examinations if you don't want to. In addition, you may feel added emotional stress if you are female and your pregnancy test results are positive and you were unaware that you were pregnant.

2. Discomfort caused during blood pressure measurement:
   You may feel slight discomfort (squeezing) when the blood pressure cuff is inflated. The discomfort should be temporary. You will feel relief within minutes once the cuff is deflated.

3. The light pressure generated on your skin while lying on the overlays is similar to that when you lie on a mattress or sit on a cushion, and the duration of the pressure (40 minutes) is shorter than that which you would experience during daily activities. The risk of skin breakdown associated with the light pressure is very low (less than 1 out of 100 people).

4. The mild heating applied on your skin is very low (106°F) and will be applied only for a short period of time (5 minutes). The temperature and duration are far lower and shorter than when you use a hot pack to relieve muscle pain in the clinic or at home (113-129°F for more than 10 minutes). In addition, the mild heating used in our study will only be applied on a very small area of your skin (about the size of a penny), so this is unlikely to cause any discomfort or damage.

5. The mild electrical stimulation applied on your skin is far lower and shorter as compared to that used in the clinic to stimulate your nerve function and reduce pain in people with spinal cord injury. The risk of skin or muscle damage caused by the mild electrical stimulation is unlikely as well.
6. There is the rare risk of skin damage caused by the device that measures skin blood flow. The amount of energy used for these measurements is similar to that of ordinary daylight and of a bar code scanner.
7. The risks associated with the blood draw include: mild pain, bleeding, bruising and swelling at the site where the needle goes in. This is the same standard method that you will experience during a doctor's visit to obtain blood for tests. There is also a rare risk that you could feel dizzy or faint. The risk of an infection is very rare.
8. Some of the locations for the bare skin measurements are private areas, such as your lower back, so you may feel a little embarrassed. So that you are comfortable, you will be provided with a bed sheet to cover any other areas you do not want to expose.
9. A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).

Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Are there benefits to taking part in the research?

You will not directly benefit from participation in this research. However, the knowledge gained from this research may benefit others with spinal cord injury in the future.

What other options are there?

You have the option to not participate in this study.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research team. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects monitors the research or consent process) or if required by law.

Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research by:

- Dabir Surfaces, Inc., the funding agency

- UIC Office for the Protection of Research Subjects and State of Illinois Auditors.

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research. To protect your identity, all study data and blood collected will be stored coded using a subject ID number instead of using your name or any other direct identifier. For female subjects only who provide a urine sample for pregnancy testing, any sample that remains after the testing will be destroyed. Only Dr. Yi-Ting Tzen will have access to the key to the code which links to your identity. The key to the code (and any remaining blood samples and corresponding health information) will be stored up to five years and then destroyed. The data collected in this study will be shared with the study sponsor, Dabir Surfaces, Inc. When it is shared, it will be shared coded.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

What if I am injured as a result of my participation?

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Tzen at telephone number 312-996-1506.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What are the costs for participating in this research?

There are no costs to you for participating in this research.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will receive $75 for completing the study visit. You will be paid in cash at the end of the visit. If you do not finish the study, you will be paid $10/hour. If you fail the face to face screening, you will be compensated at the hourly rate listed.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at UIC.

You have the right to leave this study at any time without penalty.

The researchers and sponsor also have the right to stop your participation in this study without your consent if your vital signs become unstable during the visit or if they believe it is in your best interest.

In the event you withdraw or are asked to leave the study, you will still be compensated as described above.

Who should I contact if I have questions?

Contact the researcher Dr. Yi-Ting Tzen at (312) 996-1506 or email address tzenyt@uic.edu:

- If you have any questions about this study or your part in it,
- If you feel you have had a research-related injury (or a bad reaction to the study treatment), and/or
- If you have questions, concerns or complaints about the research.

What are my rights as a research subject?

If you have questions about your rights as a research subject or concerns, complaints, or to offer input you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research.

Remember:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject:

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

_____ _____

Signature Date

_____

Printed Name

_____ _____

Signature of Person Obtaining Consent Date (must be same as subject's)

_____

Printed Name of Person Obtaining Consent