Evaluating Mobility Interventions in the Real World

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University of Wisconsin-Madison

CONSENT TO PARTICIPATE IN RESEARCH
and
AUTHORIZATION TO USE PROTECTED HEALTH INFORMATION FOR RESEARCH

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Summary

This study compares the effects of different prosthetic feet and different orthotic solutions for drop-foot on the quality of walking movement. You will use multiple different prostheses or orthoses for up to several weeks. You will participate in laboratory studies of your movement such as walking on level ground, ramps and stairs, and standing still. During at-home use you will wear a set of advanced wearable sensors that monitor your movement and location. The researchers will use this information to determine how different prostheses or orthoses can best help improve mobility for different people.

Some important considerations for your participation are:

1. You will be required to use several different prosthetic feet or orthotic solutions for drop-foot (braces or electrical stimulators) for up to three weeks each (up to 10 weeks total).
2. You may perform testing with each prosthesis/orthosis in a biomechanics laboratory, in which we measure your movement. This testing may include: walking on level ground, stairs, ramps, uneven ground, and stationary or moving treadmills; standing on platforms that move to challenge your balance; and breathing through a mask that samples your breath to measure your energy consumption.
3. You will be required to wear several movement sensors on one or both legs during both lab testing and take-home testing. These sensors will be mounted on the prosthesis/orthosis and possibly other parts of your legs.
4. These sensors will include GPS and other location sensors, which will record where you are at all times.
5. We will use the location information to focus on how you move in the most common places you go. If the data will be used for publication, researchers will modify this information to obscure the real-world location.

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6. You will complete a variety of questionnaires, including questions about your mobility, participation, and use of each prosthesis/orthosis, and related topics.
7. Your data will be stored for long-term use in future research. This future research will probably focus on human movement, prosthetics/orthotics, and the use of wearable sensors, but it may include other topics we have not thought of yet. At a future date after the study is complete, information linking your data to you will be removed so you are no longer identifiable. The resulting "de-identified" data may still be used for future research.
8. If you give permission, we will take photos and videos of your movement in which you may be identifiable, and we may show these images at scientific conferences, in papers or on websites to explain the study to others. If you do not give permission for identifiable images, we will take only photos or videos in which you cannot be identified.

These considerations and the risks to you from this research are described in more detail in the following sections.

1. PROTOCOL TITLE:

Evaluating Mobility Interventions in the Real World

You may be eligible to take part in this research study. This form gives you important information about the study, including how the study will use your health information.

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

Please tell these researchers if you are taking part in another research study.

You do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty.

Your decision will not affect your future care at the University of Wisconsin-Madison (UW-Madison), its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation), or the U.S. Military health care system.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you use a prosthesis or orthosis to help you walk. The purpose of this research study is to learn about the best ways to help people walk better using prostheses and orthoses. From prior research, we know that standard prostheses and orthoses do not typically restore full function, and that it is difficult for practitioners to choose what devices to provide to each individual. This study uses biomechanical analysis and

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advanced wearable sensors to compare different prostheses and orthoses to determine their effects on movement.

If you are eligible and decide to take part, you will be in the study for up to 12 weeks including up to five (5) visits to the laboratory and up to ten (10) weeks of monitoring during everyday life. The duration of each laboratory visit is up to five (5) hours. During the study, you may have about 3 to 5 visits with researchers in the Biomechanics laboratory and/or the Orthotics and Prosthetics Clinic. You may need to return to UW-Madison every 3 weeks. In certain circumstances, you may be asked to participate without a visit to the lab at UW-Madison, in a take-home-only version of the study. For participants in the orthotics portion of the study, you will be contacted about 1 month after study completion, by email, to complete one final survey regarding how your participation may have impacted your plan of care regarding orthotic choices.

There will be about 60 people taking part in the study at the University of Wisconsin-Madison, over a period of three years.

There will be about 85 people taking part in this study overall, with about 25 participants to be enrolled at Walter Reed National Military Medical Center, over a period of 3 years.

This study is looking at how different features of foot prostheses (including adjustable ankle resistance and computer-controlled resistance, or activity-specific design) and different orthotic treatments for drop-foot (ankle braces or functional electrical stimulation) affect people's movement in everyday life. These interventions have been studied in laboratories, but they have not been compared in everyday use before. This means that the use of these prostheses and orthoses is considered experimental for this scientific study.

At the end of this research study the clinical results, including research results about you, will not be shared with you. Results will be published in the scientific literature to help improve future management of amputation and drop-foot.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process". Screening for this study consists of listening to a description of the study and answering several questions about your health and any health conditions you have, including amputation or drop-foot (the conditions addressed in this study) or other health conditions that may affect your ability to participate. You may have completed the screening process at the time you were recruited to participate in the study.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will perform a variety of typical activities using one or more prostheses or orthoses. These activities may include:

standing on one or both legs
standing on a platform that disturbs your balance
walking at different speeds, according to your comfort level

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walking up, down and across slopes,
walking on uneven ground indoors or outdoors
ascending and descending stairs
walking while leaning your torso to different angles
wearing sensors on different parts of your body during laboratory testing
wearing sensors on different parts of your body during everyday life

In-Laboratory Studies:

You may perform these activities both inside a laboratory and outside it. Inside the laboratory, you may perform the activities while standing still on force plates, walking across a room, or walking on a treadmill. Locations outside the laboratory may include buildings and outdoor spaces on or near the campus of the University of Wisconsin-Madison.

Test Activities:

You will perform standing trials and walking trials at various speeds. You may perform some tests with your usual shoes, or with a custom set of shoes we supply. You may also perform some tests while wearing one or more prosthetic or orthotic devices, as well as the sensors listed below.

For quiet standing, you will stand as still as you can with your feet on force-measuring platforms. You may stand directly on force platforms, or on top of a piece of soft foam. You may also stand with your eyes closed or on one leg for comparison.

For standing trials with disturbances, you will stand as still as you can on platforms that can be moved by the test machine, possibly with walls around you that can also move. The test machine will move the floor and/or walls to disturb your balance. The machine will record the forces under your feet to determine how you balance.

For trials in the laboratory, you will walk either "overground" or on a treadmill. For "overground" trials, you will start from a marked location on the floor, move at a steady speed through the room across the force platforms, stop at the other side of the room, and walk back. You may also climb and descend stairs or ramps. For treadmill trials, you will walk on a raised treadmill at a controlled speed for up to 6 minutes at a time. In some conditions the treadmill may move in different directions, and may include a large screen surrounding you to display video that looks like walking through an imaginary environment. In both kinds of trials, the sensors will record data on how you move.

Field Studies

For trials outside the laboratory, you will walk on sidewalks, grass, slopes, and other typical surfaces while wearing wearable sensors that record your body movement, forces and/or location. Sensors will be similar to those under the Take-Home Studies section, below.

Take-Home Studies:

For some participants, the study involves testing prostheses or orthoses for extended periods of time during your everyday life. For these tests, you may visit the laboratory several times to be

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Figure 1: Examples of prostheses that may be compared in the experiment: energy storage-and-return prostheses (ESR, left); ESR with passive hydraulic ankle (PHA); and ESR with microprocessor-controlled ankle (MPA). Examples shown are Endolite Esprit, Echelon, and Élan. Specific prostheses from multiple manufacturers will be chosen in the course of the research.

fitted with different devices, and you may use each of them for up to three weeks. You should continue with all your normal activities during this period. Alternatively, for some participants, you may use only the prostheses you already have and you may not be required to come to campus for any visits. In this case, the research team will meet with you elsewhere to set up sensors on your prosthetic legs and teach you how to use them, and you will remove and return them at the end of the study.

You will wear one or more movement sensors on different parts of your body such as your feet, legs and/or waist. You will also wear or carry a means of logging location data – this could be a GPS, Bluetooth, or Wifi receiver or a cell phone application. You will wear or carry these sensors for the duration of the take-home study. You will have to charge them each night and restart them each morning.

You may also be asked to place one or more electronic location beacons in any common indoor locations where you frequently spend long hours, such as your workstation or desk. This beacon will help improve the measurement of your location.

Test Activities:

You may perform any of the Test Activities described in the In-Laboratory Studies section above. During the home-based portion of the study, you should simply follow your ordinary routine and perform all your usual activities. You will be expected to use the device under test as much as possible for the whole duration of the take-home test. Exceptions are allowed for special activities that require a different device or shoe (such as a designated prosthesis or shoe for running or athletic activity).

Test Devices:

The devices to be tested (prosthetic foot-ankle systems and orthotic solutions for drop-foot) will include common commercially-available devices. Example prosthetic systems are shown in Figure 1**.**, including different levels of features. Example orthotic devices are shown in Figure 2, including orthotic braces and functional electrical stimulation (FES) neuro-orthoses.

Clothing and Sensors:

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Figure 2: Orthotic drop-foot aids for potential use in the experiment: an ankle-foot orthosis (left); WalkAide FES Neuroorthosis (left) and BioNess FES Neuroorthosis (right). Both FES devices sense leg motion and stimulate the peroneal nerve during swing phases of gait, causing the dorsiflexor muscles to lift the foot for improved ground clearance.

During laboratory testing, you may wear special clothing and several kinds of sensors so experimenters can record your motion. The special clothing is athletic clothing, which consists of form-fitting shorts or athletic briefs and a shirt and/or sports bra, intended to allow attachment of the various sensors. The sensors may include:

small reflective spheres, which will be tracked by motion capture cameras in the laboratory
pressure-sensing shoe insoles, to record the forces under your feet
electrodes taped to your skin, to record how your muscles activate
wearable movement sensors on your feet, legs, trunk, arms and/or head
a face mask or mouthpiece and gas sensor unit, to record the oxygen and carbon dioxide in the air you breathe
force sensors installed with the foot prosthesis, if applicable
wearable location sensors based on GPS, Bluetooth and/or Wifi signals, and/or a location tracking app installed on your cell phone
voice recorder or voice recording app on your cell phone

Details of these sensors are given below:

Motion Capture:

For trials involving motion capture in the laboratory, we will attach reflective spheres to your body using double-sided tape (preferred) or cyanoacrylate glue, Velcro (on the clothing), and/or straps holding pre-assembled clusters of 3-5 spheres in place. We will palpate (feel with the fingers) to locate specific points on the bones of your body, and place the spheres on these points and/or in other locations. If necessary, we will gently rub your skin with an alcohol wipe to help the spheres stick better. Spheres may also be placed on any of the devices you are testing.

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Muscle Activity Measurements (Electromyography, EMG):

For trials involving electromyography (EMG), we will apply EMG electrodes to your skin, located above different muscles in your legs. The electrodes are used to measure the activity in those muscles. To apply the electrodes, we will:

Palpate (feel with the fingers) the muscles of your leg, to determine good electrode locations
Mark these locations on your skin with a permanent marker
Shave any hair at these locations
Gently rub your skin with an alcohol wipe
Place electrodes using either conductive gel or disposable electrode stickers.
Run wires from the electrodes to a measurement box (wireless electrodes may also be used)

Pressure Insoles:

For trials involving pressure insoles, we will insert the insoles in your shoes, either on top of your existing insoles or instead of them. The wires that protrude will be held in place with straps or stockings and routed to a data collection pack on a belt.

Wearable Motion Sensors:

For trials involving wearable motion sensors, you will wear the sensors on your feet and other body segments, attached with snug straps. These sensors, some similar in size to a wristwatch and some slightly larger or smaller, record the acceleration and rotation of your body segments. For take-home studies, you will be asked to charge these sensors nightly.

Respiratory Gas Sensors:

For trials involving the respiratory gas sensors, you will wear a torso harness holding the sensor box on your back, as well as a face mask or mouthpiece for sampling your breath gases. These trials will take up to 6 minutes of constant activity per condition. Please tell the experimenters right away if 6 minutes of constant activity is too long for you.

Force Sensors in the Prosthetic Leg:

For trials with prostheses, we may install a force sensor between your prosthetic foot and socket, to measure the forces you apply to the ground. This sensor will add some weight, but will not otherwise interfere with your movement.

Wearable Location Sensors:

For take-home studies, you will be asked to wear a sensor that tracks your location. This sensor may be a GPS location receiver, a Bluetooth beacon receiver, and/or a Wifi signal receiver. These receivers may be integrated with other wearable sensors, or may be standalone devices. A cell phone app that records equivalent data may also be used. If a cell phone app is used, you will be asked to ensure the cell phone remains with you (in a pocket, holster or your hand) at all times. An instruction sheet will be assigned to you with detailed information on how and when to turn on/off and charge sensors as well as some restrictions on the activities during the test. You

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should read this instruction sheet and discuss it with the researchers to ensure you understand it before agreeing to participate in the study.

Voice Recorders:

During your laboratory session(s), you may be asked to wear a voice recorder around your neck, to record any comments you make. These comments are helpful to the study team when making design adjustments or interpreting data. During take-home research, you may be asked to use a voice-recording application on a cell phone to record important events that occur related to your movement and balance (such as slips, trips, falls, or unusual activities).

Photographs and Videos:

During your laboratory sessions, we will record images of you, such as photographs of how the sensors and equipment are attached to your body and videos of how you move during the experiment. In some images you will not be identifiable (such as equipment photos), and these images are required for the study. In other images you will be identifiable (such as photos or videos of your movement), and these images are optional. More information about images is provided later in this document.

Questionnaires and Experimenter Questions:

In addition to the physical tests, you may complete questionnaires and answer verbal questions, to assess your use of different prostheses or orthoses. You will also complete a health questionnaire including questions on social habits and physical activity. These questionnaires may be performed at the beginning and end of the study and at any laboratory visits. We may also ask you questions about the specific devices you test. We may also ask you questions not included in the questionnaires, in order to understand aspects of your movement observed during the study.

Safety and Comfort:

The safety and comfort of participants is of paramount importance. If at any time you are uncomfortable performing an activity in the experiment, please inform your experimenter. Any activity can be skipped or possibly altered, or you can withdraw from the study without penalty (you will still be compensated for the time you participated). In addition to these policies, several precautions are in place to ensure your well-being.

Breaks/Rest:

You may take breaks during the training exercises and assessments whenever you need them. If you get tired or want to stop at any time before testing is finished, the researcher will stop the activity and allow you to have a break. You may also decide to withdraw from the study at any time.

Treadmill Safety:

The treadmill is equipped with a hand-rail, which you can use anytime you feel unsteady or uneasy, although if possible you should not use it while the sensors are recording your movement. The treadmill also has an emergency stop switch, which will stop it quickly. You

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should feel comfortable using this feature any time you need it. If you do stop the training exercise, you will be given an opportunity to rest and to provide feedback on any necessary adjustments to the system or the exercise before continuing. In some of the facilities, an overhead harness may be available; if you would prefer to use a harness, ask your experimenter if it is available.

Information Collected:

In addition to movement data, we will collect health and demographic information about you for this research study, which can help explain the findings.

Demographic information (gender, age, race, ethnicity, handedness) and your responses to the questions on the screening script will be collected.
We may also ask you questions about your medical history, physical exam findings, any prescription for a prosthesis or orthosis or other medical device, and past procedures related to the causes of your use of these devices.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there are several risks to be aware of:

Risks from the Test Devices:

For tests with prostheses or orthoses, there is a risk of skin irritation or abrasion due to contact between the device and the limb. The fit of any devices used will be checked repeatedly throughout the experimental sessions. Subjects using prostheses will wear their daily-use prosthetic socket in order to ensure proper fit. For take-home tests, the risk may slightly increase due to the change of equipment; you should watch for signs of such problems and contact the research team immediately if these problems occur.

Risks from the Equipment and Sensors:

For tests with EMG or respiratory gas exchange measurements, the equipment itself may be uncomfortable. This equipment will be attached to the body and adjusted as comfortably as possible, and attention will be paid to subject-specific adjustments to prevent unnecessary strain or load on the body.

For the tests with EMG electrodes and motion capture, you could experience an unpleasant glue smell, skin irritation, or mild discomfort associated with placing, wearing, and removing electrodes on the leg.

Risks from the Experimental Tasks:

The risks due to the walking tasks are similar to those in any exercise program. These risks include muscle soreness, joint soreness, a feeling of exertion, and being out-of-breath.

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There is a risk of falling associated with using different devices to walk. In treadmill trials, there are handrails available to minimize this risk. In overground trials, the risk is similar to normal everyday activities, with some increased risk because the devices are unfamiliar.

As with any device, there is a risk of malfunction or failure. The treadmill, if used, is equipped with emergency stops to be used in this event. If a failure occurs in the test devices (prostheses or orthoses), tests will be stopped until repairs or re-tuning are performed.

Risk of Being Identified:

For any tests performed outside the laboratory, you will be in public spaces. It is possible that someone who knows you may identify you while you are participating in the study. This risk is elevated compared to everyday life, as any novel devices or sensors will be more visible than standard prostheses or orthoses.

If you are having sensors installed at an off-campus location, especially a public place, this procedure increases the risk of being identified because it will take time and involve conversations and use of tools and multiple prostheses. By providing your Consent to participate, you acknowledge and accept this risk.

Risk of Breach of Confidentiality

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you. Precautions undertaken to prevent such breach of confidentiality are described in Section 16.

Risks due to Pregnancy

The risk of harm due to a fall is greater if you are pregnant.
You may not participate in the study if you are pregnant or planning to become pregnant during the course of the study. If you do become pregnant during the course of the study, you must inform the study team and provide an estimate of how long you have been pregnant. After a certain point in pregnancy, you may not continue participation, for safety reasons.

Risk to Privacy through Location Data

During the take-home studies, your location will be recorded continuously by a combination of GPS, IMU, Bluetooth and Wifi sensors. This means the data will contain a record of any place you have visited and how long you stayed there, including your home and workplace. This is comparable to the information a typical smart phone sends to Google or Apple. Your location data will only be used to find the most frequently repeated paths during the test, with the purpose of studying your movement under specific conditions.

We will treat your location information as personally identifiable information and store these data in a password protected file on a computer. Only our research team will have

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access to your location data. If we need to publish information containing your location, for example, some of your walking paths, we will make sure the absolute latitude/longitude/altitude are removed or altered so that the location cannot be identified from a map.

Risk to Privacy through Location Tracking Apps

During the take-home studies, the location tracking may be performed through a location tracking application installed on your cell phone. Installing such an application involves a privacy risk because (a) the company that manages your cell phone apps may receive notification that you have installed it, and (b) you may have to create an account with the app's vendor. The app vendor may then have access to your identity and location data.
If a cell phone app is used, we will attempt to mitigate this risk. We may use a custom app installed separately from the Google or Apple app stores, to overcome the need for any account. Alternatively, if a standard app must be used, we may create the account with dedicated credentials that are not linked directly to you.
You should know that complete anonymity may be impossible when using any smartphone app. If this risk to your privacy is unacceptable to you, you should not enroll in the study.

Other Risks

There may also be other risks of taking part in this study that we do not yet know about. Should any new information be discovered that potentially puts you at risk, you will be informed.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

This study is not intended to benefit you directly. You may receive small benefits from improved biomechanical function and mobility due to use of different prosthetic or orthotic devices during the take-home portions of the study. Any such benefits are not guaranteed and are expected to end when you complete the study. You may be able to use the experiences from this study to help your own providers improve your future care.

There are no other direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. The possible benefits to others are improved management of amputation and drop-foot by helping us learn more about how prostheses and orthoses can be improved to help people stand, walk more effectively.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes.

Participants in short-term in-laboratory studies will be compensated at a rate of $20 per hour. Participants living more than 15 miles from the test site will be compensated for travel time at the same rate. Parking will be reimbursed or paid directly.

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Participants in the orthotics study will be paid $40 per week for your participation in the at-home study. If you complete the whole study, including all laboratory visits, you will be paid the full weekly stipend (up to $210 depending on the duration) plus a $90 study completion bonus.

Participants in the prosthetics study will be paid $90 per week of your participation in the at-home study. If you complete the whole study, including all laboratory visits, you will be paid the full weekly stipend (up to $360 depending on the duration) plus a $90 study completion bonus. Parking will be reimbursed or paid directly. Payment will be processed after you return all take-home equipment.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

There will be no cost to you for the laboratory tests, the prostheses or orthoses you will use, the wearable sensors, or any procedures that are performed for research purposes only and are not part of your regular care.

You will have to pay for basic expenses like any childcare, food, or transportation related to study activities.

9. WHO IS CONDUCTING THIS RESEARCH?

Researchers at the University of Wisconsin-Madison and researchers at Walter Reed National Military Medical Center are conducting this research in collaboration. The principal investigator is Peter G. Adamczyk, Ph.D., at the University of Wisconsin-Madison.

10. STUDY SPONSOR

The study is sponsored by the Professor Peter Adamczyk at the University of Wisconsin-Madison. Prof. Adamczyk is a Sponsor-Investigator for this research, meaning he initiated the study and is also managing the study.

11. SOURCE OF FUNDING:

The study is funded by the United States Department of Defense under the Congressionally-Directed Medical Research Program, administered by the US Army Medical Research and Materiel Command. The award number is W81XWH-19-2-0024. Activities at Walter Reed National Military Medical Center are funded by a subaward.

12. PRINCIPAL INVESTIGATOR

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13. LOCATION OF THE RESEARCH:

There are four potential sites for UW-Madison participants in this study:

The UW Mechanical Engineering Building (1513 University Ave., Madison, WI 53706)
The Badger Athletic Performance Laboratory (McClain Athletic Facility/Sports Medicine Center)
The UW Neuromuscular Biomechanics Lab at Research Park (621 Science Dr., Madison, WI 53711)
The UW Health Orthotics and Prosthetics Clinic (6220 University Ave. Suite 103, Middleton, WI 53562)

Other participants will be enrolled at Walter Reed National Military Medical Center (4494 North Palmer Road, Bethesda, MD).

Participants not required to come to the laboratory will meet with a member of the research team in a convenient public place for installation of the sensors for take-home-only tests.

Transportation to each site and from one site to another is your responsibility. We will arrange parking at the on-campus locations; parking at the Research Park facility is freely available.

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

No members of the research team have financial relationships or personal arrangements with the agencies funding the study.

The investigators for this research may develop technology related to the wearable sensors and the prosthetic and orthotic devices being tested. They may benefit financially if these devices prove to be effective in improving movement.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Researchers at the University of Wisconsin-Madison (UW) are required to get written permission to use identifiable health information from the people taking part in a research study. This permission is called a "HIPAA Authorization" because it authorizes researchers to access health information that is protected under the Health Insurance Portability and Accountability Act (HIPAA). This information is called Protected Health Information (PHI). In order to take part in this research study you must sign this form to provide HIPAA Authorization so we can access your PHI for research purposes..

The research team will keep your research records. These records may be looked at by staff from the University of Wisconsin-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation), Walter Reed National Military Medical Center, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected.

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Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Federal privacy laws (e.g., HIPAA) may not apply to some people outside of UW who are not health care providers or health care insurers who can share your health information without your permission. We may have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss. Procedures to protect the confidentiality of the data in this study include several security considerations. First, all information will be stored in a locked file cabinet or in password protected files on a computer. Information collected from tests and intervention sessions will be coded so that it is not personally identifiable (a code will be used instead of your name). The only link between your name and your data will be this consent form, which will be stored in a locked file cabinet in a locked office accessible only to authorized study personnel. Data transmitted between locations will use approved, secure transfer methods and will not include your name.

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 results. You can search this Web site at any time.

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data, except identifiable photographs or videos if you agree to allow them (see permission release later in this document). Location data will be presented only in modified form that does not allow identification of your home or workplace.

The information collected from you during this study will be used by the researchers and research staff of the UW-Madison and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) for this study. It may also be shared with others at UW-Madison and outside UW-Madison as follows:

Others at UW-Madison and its affiliates who may need to use your health information in the course of this research:

UW-Madison regulatory and research oversight boards and offices

Accounting and billing personnel at the UW-Madison

Others <u>outside</u> of UW-Madison and its affiliates who may receive your health information in the course of this research:

United States Department of Defense (DOD)

- The U.S. Department of Defense is funding the study and DOD personnel are collaborating on the study. They may receive information about you to help analyze the data from the study.
- The U.S. Department of Defense may access research records about you as part of its human subjects protection oversight activities.

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- As the agency funding this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

Other agencies that may fund this study in the future could access study records for similar purposes.

U.S. Office for Human Research Protections (OHRP)

The U.S. Food and Drug Administration (FDA)

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

16. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. If you agree to be contacted for future studies, we will keep a record of your identity for purposes of recruiting for future studies. This information will be kept in a locked file cabinet or password protected file on a computer. We will also keep the data measured from your participation for further analysis, and for comparison against future participants or other studies. These data will be labeled with a code instead of your name, and only members of the study team will be able to link the code to your identity. Your identifying information will be retained for 5 years following the completion of the study.

After that time, your identifying information will be destroyed, and the data measured from your participation can no longer be linked with you. These "de-identified data" will be retained indefinitely, and may be published, used for future research studies or distributed to other researchers to help with future research without additional informed consent from you or any legally authorized representative. This future research may be in the same area as the original study or it may be for a different kind of study.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

17. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you are injured or get sick because of this study, medical care is available to you through your regular care health provider, or emergency services, as it is to all sick or injured people.

If it is an emergency, call 911 right away or go to the emergency room.

For non-emergency medical problems, contact your regular health care provider.

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Call the Lead Researcher, Peter G. Adamczyk, at 608-263-3231 to report your sickness or injury, even if you believe it is not because of the study.

18. WHAT WILL HAPPEN TO YOUR INFORMATION AFTER THIS RESEARCH HAS ENDED?

During this study you will not be asked to provide any biological specimens; only your health information and data recorded from your movement and location will be obtained. These data will be retained for future use according to the procedures in Section 17, *Long-term Use of Data*. Unless you withdraw your permission in writing to stop the use of your information, there is no end date for its use for this research study. Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used.

19. WHAT HAPPENS IF YOU WITHDRAW FROM THIS RESEARCH?

Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

If you choose to leave the study, you must inform the researchers. We will ask you to come in for a final study visit to return equipment and receive your participation payment.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your HIPAA Authorization for researchers to use your protected health information (PHI) does not have an end date. However:

You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.

If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.

If you take back your authorization, you will not be able to take part in the research study.

To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher:

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Peter G. Adamczyk, PhD
1513 University Ave., Mechanical Engineering Room 3039, Madison, WI 53706
email: peter.adamczyk@wisc.edu

20. VOLUNTARY PARTICIPATION:

The decision to take part in this research study is completely voluntary on your part. You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

21. CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Peter G. Adamczyk
Phone: 608-263-3231
Email: peter.adamczyk@wisc.edu
Mailing Address:
1513 University Ave., Mechanical Engineering Rm. 3039, Madison, WI 53706

Questions about research subjects' rights

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact UW Hospitals and Clinics Patient Relations Representative at 608-263-8009.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

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IDENTIFIABLE VIDEOTAPING/PHOTOGRAPHY

We will record videos and photographs of you while you participate in this study. The video recording/photographs may be used in the following ways:

As part of the study documentation, for example as a record of how sensors and other equipment were attached to your body

At lab meetings to discuss your progress and ways to improve testing

In research presentations with collaborators, at conferences, on web pages, and in publications to show examples of subjects performing the tasks in this research study

Some of these videos and photos are required, such as non-identifiable images of sensor mounting and the experimental setup. If you do not agree to these non-identifiable images, you should decline to be in the study.

We would also like to record videos and images in which you are identifiable. Your name will not be associated with the videos/photographs, but it is possible that you will be recognizable in the videos/images themselves. These images help us illustrate and explain the study to others. Identifiable videotaping/photography is not a requirement for study participation and you can decline permission to record these identifiable images below.

If you do consent for identifiable videotaping/photography, you will be told before any videotaping/photography starts and you will have the opportunity to decline if you change your mind. Please check below whether or not you consent to allow us to record identifiable videos/photographs of you.

_____YES, I give consent for identifiable videos and photographs to be recorded, but realize that I can change my mind at any time, including while videotaping/photography is taking place.

_____NO, I do not want identifiable videos/images to be recorded.

We may also want to share study videotape clips/photographs with the media when we talk about the research that we are doing at the University of Wisconsin. We would invite you to sign a separate media release form before we would use the videos/photographs in this way.

RECRUITMENT FOR FUTURE STUDIES

This study is one of many research activities, which continually need volunteers. Please indicate whether we may contact you again regarding future studies for which you may be eligible.

_____YES, I agree that study team members may contact me again about possible future studies. My contact information may not be shared outside the study team without my prior consent.

_____NO, please do not contact me again about possible future studies.

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EMAIL AND TEXT-MESSAGE COMMUNICATION

We are requesting your email address and cell phone number so we can communicate you about this study and future studies, including links to surveys you will need to complete for this study. Email and text-messaging are not secure ways to communicate about your health as there are many ways for unauthorized users to access email and text-messages. You should avoid sending sensitive, detailed personal information by email and by text-message. Email and text-messages should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the Principal Investigator listed on the front page. Please note that in addition to email and text-messaging, we may also call you if needed with study information.

_____YES, you may use email and text-messaging to contact me.

My email Address is: _____

My cell phone number is:_____

AGREEMENT TO PARTICIPATE IN THIS STUDY & PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this Informed Consent and HIPAA Authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study, and you give your Informed Consent to participate.
- You give authorization for your protected health information to be used and shared as described in this form.

_____
Printed Name of Research Participant

_____
Signature of Research Participant Date

_____
Name of Person Obtaining Consent and Authorization Date

_____
Signature of Person Obtaining Consent and Authorization Date

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