Exoskeleton Optimization For Reducing Gait Variability For Patients With Peripheral Artery Disease

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ADULT CONSENT - NON-CLINICAL BIOMEDICAL
Exoskeleton optimization for PAD

Title of this Research Study
Exoskeleton optimization for reducing gait variability for patients with peripheral artery disease

Invitation and Summary

You are invited to take part in this research study. Participation in this research study is voluntary. You do not have to take part.

Here is a summary of the purpose, methods, risk, benefits, and alternatives to help you decide whether or not to take part in the research.

This study aims to develop new computational methods that will allow us to improve devices that help people walk better and easier, such as exoskeletons. The exoskeleton we want to improve is a robotic device that fits around your waist and thighs and can help you walk. Developing these new approaches can make these devices more helpful and more accessible to patient populations, such as patients with peripheral artery disease.

Your participation in this study will involve up to one hour for session 1 and up to 3 hours for session 2. During the first session, you will walk up to 20 minutes or less with a robotic hip exoskeleton (i.e., a robotic device that fits around your waist and upper legs).

During the second session, you will walk up to 15 minutes or less while the exoskeleton switches between different assistance modes after every 20s. Then you will complete two to four walking trials each lasting 5 or fewer minutes under different assistance modes. These assistance modes will be different in the forces that the exoskeleton applies to the wearer's legs. During the experiment, we will measure your movement using cameras that detect markers on your body. We will measure the energy you spend using a special breathing mask. The breathing mask looks like an oxygen mask used in airplanes, and it allows you to breathe the room air. We will measure your muscle activity using little sensors that stick to your skin with skin-friendly tape. We will measure the forces that your legs apply on the belt of treadmill with a force-measuring treadmill.

Possible risks of participating in the control group are discomfort and skin irritation because of wearing the exoskeleton, motion capture markers, muscle activation

sensors, and breathing mask. Walking on a treadmill could lead to elevated heart rate, fatigue and muscle soreness (similar to low-intensity walking exercises). Walking on a treadmill with an exoskeleton involves a risk of tripping and (partial) falls. The risks of (complete) falls onto the ground will be avoided with a safety harness attached to the ceiling.
Possible risks for the patients with peripheral artery disease in this study are the same risks as under healthy adult participants, plus the following additional risks:
Walking on a treadmill could also lead to shortness of breath and claudication pain similar to the pain experienced on a daily basis by patients with PAD.
Wearing the exoskeleton could also lead to the development of leg sores.

This research will help us improve assistive devices for patients with leg problems. Instead of being in this research study, you can choose not to participate.

Why are you being asked to be in this research study?
You are asked to participate in our control group if:
- You are relatively healthy, between 19 to 85 years of age (or currently 19 or 85 years) and have no problems affecting your walking

You may not participate in our control group
- You have a neuromotor disorder, abnormal gait or injury. Neuromotor disorders are diseases that affect the functioning of your muscles, joints and nervous system. Abnormal gait is when you are unable to walk in the usual way (deviation from normal walking).
- The exoskeleton that we use for our study does not fit
- You are pregnant.
- You have peripheral artery disease.
- You experience claudication (leg discomfort when walking) produced by blockages in the blood flow to your legs.
- You have unstable blood pressure and a stable level of fats, cholesterol, and sugar in your blood over six weeks.
- You have open foot sores or leg pain even when you are resting
- Your walking ability is limited disorders to the nervous system or disorders of your muscles and joints.
- You have an acute injury or pain or illness.
- You are unable to see clearly, or you are blind.
- You are unable to hear clearly, or you are deaf.

You are asked to participate in our group of patients with Peripheral Artery Disease

(PAD) if
- You are 19 to 85 years of age
- You experience claudication (leg discomfort when walking) produced by blockages in the blood flow to your legs.
- You have stable blood pressure and a stable level of fats, cholesterol, and sugar in your blood over six weeks.

You may not participate in our PAD group if
- Your PAD is too advanced and is producing open foot sores or leg pain even when you are resting
- Your walking ability is limited by diseases other than PAD, such as disorders to the nervous system or disorders of your muscles and joints.
- You have an acute injury or pain or illness.
- You are unable to see clearly, or you are blind.
- You are unable to hear clearly, or you are deaf.
- You are pregnant.

What is the reason for doing this research study?
The purpose of this study is to develop new approaches that will allow us to improve devices that help people walk better and easier, such as exoskeletons. Developing these new approaches can make these devices more helpful and more accessible to patient populations such as patients with peripheral artery disease.

What will be done during this research study?
As part of this study, you will visit the lab for two sessions. Your participation in this study will involve up to 1 hour for session 1 and up to 3 hours for session 2. You will be asked to fill out a brief health history form to ensure that it is safe for you to participate.

The hip exoskeleton consists of a segment that fits around your waist and segments that fit around your thighs. The exoskeleton is connected to a motor via a flexible transmission cable. The exoskeleton will provide assistive forces during walking based on sensors that detect when your feet touch the ground. The exoskeleton feels like as if someone is holding and moving your thighs while you are walking. In some of the conditions, this feeling will be more helpful. In other conditions, this will be less helpful. The assistive forces will be lower than the forces that your muscles exert during normal walking which means that you will still have to do most of the effort to walk.

During the experiment, we will conduct the following measurements:

Motion capture (using cameras that detect reflective markers on your body). You will be asked to change into a wrestling singlet before the testing in order to accurately place the markers.
Your energy expenditure via a breathing mask.
Your muscle activation using electrode sensors placed on your skin.
The forces that you exert on the treadmill with a force-measuring treadmill.

If you are part of the control group:
During a first session, you will walk up to 20 minutes with a robotic hip exoskeleton.
During a second session, you will:
- Walk up to 15 minutes while the exoskeleton switches between different assistance modes after every 20 seconds (The assistance modes will provide early or later assistance in your stride cycle with more or less force). During the 15 minutes, a computer algorithm will try to optimize the exoskeleton based on real-time measurements. This computer algorithm will be based on measurements of your gait variability.
Or:
- Four walking trials each lasting 5 minutes (three times with the exoskeleton in different assistance modes and one time without exoskeleton). During all the walking bouts, you will be secured with a harness attached to the ceiling.

If you are part of the group of patients with PAD:
During the first session, you will walk up to 10 times for 1 minute each time with a robotic hip exoskeleton, alternated with at least 2 minutes of rest.

During a second session, you will either:
- Walk ten times for 1 minute each time while the exoskeleton switches between different assistance modes after every 20 seconds. The assistance modes will provide early or later assistance in your walking cycle with more or less force. A computer program will try to improve the help provided by the exoskeleton based on real-time measurements.
Or:
- Walk two times until you experience calf pain or until a maximum duration of 6 minutes: one time while wearing the exoskeleton and another time without the exoskeleton.

What are the possible risks of being in this research study?
Possible risks for being in the control group are: walking on a treadmill could lead to

elevated heart rate, fatigue, and muscle tiredness (similar to low-intensity walking exercises).

Wearing the exoskeleton, motion capture markers, muscle activation sensors and a breathing mask (from calorimetry unit) could lead to discomfort and skin irritation.

Walking on a treadmill with an exoskeleton involves a risk of tripping and (partial) falls. The risks of (complete) falls onto the ground will be avoided with a safety harness attached to the ceiling.

There is a possible risk of loss of confidentiality.

Possible risks for the patients with peripheral artery disease in this study are: the same risks as under healthy adult participants, plus the following additional risks:
Walking on a treadmill could also lead to shortness of breath and claudication pain similar to the pain experienced on a daily basis by patients with PAD.
Wearing the exoskeleton could also lead to the development of leg sores.

It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

What are the possible benefits to you?
You are not expected to get any benefit from being in this research study.

What are the possible benefits to other people?
This research could make optimization of assistive devices more feasible in patient populations such as patients with peripheral artery disease.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to participate.

What will being in this research study cost you?
You will be responsible for travel to and from UNO for testing purposes.

Will you be paid for being in this research study?
If you are part of the control group:
You will receive one single $20 stipend for participation in the study. This will offset the cost of your travel to the Biomechanics Research Building and time during data collection.

If you are part of the group of patients with PAD:
You will receive a $60 stipend for the first session and $100 for the second session. This greater compensation (than the one for healthy participants) is to compensate for longer time required for preparations and resting time during conditions.

Per UNO accounting policy, in order to compensate you for your participation, we must ask you to provide your social security number. Should you decide you do not wish to provide this information, you may still participate in the research, but we will be unable to compensate you.

Dr. Philippe Malcolm, the principal investigator on this study is one of the inventors of the exosuit used in this study.

Who is paying for this research?
This research is supported by department funds of the Biomechanics Research Department, and the National Institutes of Health (NIH).

What should you do if you are injured or have a medical problem during this research study?
Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form. Emergency medical treatment for this injury or problem will be available at the Nebraska Medical Center. If there is not sufficient time, you should seek care from a local health care provider.

The Institution has no plans to pay for any required treatment or provide other compensation. If you have insurance, your insurance company may or may not pay the costs of medical treatment. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay for the medical treatment.

Agreeing to this does not mean you have given up any of your legal rights.

How will information about you be protected?
In the course of this study we will collect information about you. The information may include things that could be used to find out who you are (like your name, phone number, birthdate, address). This is called identifiable private information. During and after the research we will keep your research records as confidential as possible.

At some time in the future, we may take the identifiers off the information. It is possible that this information without identifiers could then be used for other research studies by us, or by another investigator, without asking you for your permission

Who will have access to information about you?
By signing this consent form, you are allowing the research team to have access to your research data. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.Your research data will be used only for the purpose(s) described in the section What is the reason for doing this research study?You are also allowing the research team to share your research data, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
    - The HHS Office of Human Research Protections (OHRP)
    - National Institutes of Health (NIH)

The research data will be maintained for a period of no less than 7 years after the completion of the study.

You may cancel your authorization for further collection of research data for use in this research at any time by contacting the principal investigator in writing. However, the information which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.This research is covered by a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality means that the researcher in most cases cannot reveal identifiable information about you to others without your permission. He or she can report things like potential child abuse or intent to hurt self or others. He or she can report contagious diseases, and can share information with agencies paying for the research or with the Food and Drug Administration. He or she can also share the information with other scientific researchers, as allowed by federal regulations protecting research subjects. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor

of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:

6160 University Drive South, Biomechanics Research Building Omaha, NE 68182

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your relationship with the investigator or the Institution. You will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop participating in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff. Deciding to withdraw will otherwise not affect your relationship with the investigator or this institution. You will not lose any benefits to which you are entitled. Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of "What Do I Need to Know Before Being in a Research Study?" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your rights as a research subject?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel

- Institutional Review Board (IRB)
  - Telephone: (402) 559-6463.
  - Email: IRBORA@unmc.edu
  - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
  - Telephone: (402) 559-6941
  - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject _____ Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent _____ Date _____

Authorized Study Personnel

Principal

* Malcolm, Philippe
alt #: 617-487-1148
degree: PhD

Secondary

* Pipinos, Iraklis

phone: 402-559-9549
alt #: 402-559-4000
degree: MD

Participating Personnel
* Razavi, Hiva
alt #: 402-554-3225
degree: BS

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "research surveys", "research questionnaires" or "scientific protocols." **Research** is an organized plan designed to get new knowledge about health, disease, behaviors, attitudes and interactions of, among and between individuals, groups and cultures. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is the research different than what will happen if I'm not in the research?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? How will it affect my status at the institution if I say **no**?

Can I **stop** being in the research once I've started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT ...

... to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

... to freely decide whether or not to take part in the research.

... to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

... to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

... to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

... to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

... to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.