Informed Consent to Participate in Research

Principal Investigator: Ann Marie Virts

Study Title: *Analysis of Exoskeleton-Use for Enhancing Human Performance*

Study Site(s): NIST Gaithersburg, MD, Engineering Mechanics Building 202, rooms 130 and 138.

Introduction

You are being asked to take part in a research study. Research studies include only people who choose to take part. This document is called an informed consent form. Please read this information carefully and take your time making your decision. Ask the researcher or study staff to discuss this consent form with you, please ask him/her to explain any words or information you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are provided below.

The person who is in charge of this research study is Ann Marie Virts**.** This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge.

Purpose of the study

The purpose of this study is to begin developing measurement methods to evaluate performance of exoskeletons in two key areas: 1) the fit and movement of the exoskeleton device with respect to the users' body and 2) the impact that using an exoskeleton has on the performance of users executing tasks that are representative of activities in industrial settings.

Why are you being asked to take part?

We are asking you to take part in this research study because: 1) you are physically fit to perform the tasks (i.e., you can: wear an exoskeleton that weighs approx. 30.3 Lbs (13.7 kg), you can perform knee bends, position tools, and apply forces many times using tools (e.g., up to the approx. weight of 3 gallons of milk), 2) you are at least 18 years old, and 3) you fit within the exoskeleton manufacturers specification for height (5' 0" to 6' 1") and weight (108 Lbs to 225 Lbs). Subjects that are near the height and weight extremes of the exoskeleton may not fit, in which case may not be able to participate in the study.

Study Procedures:

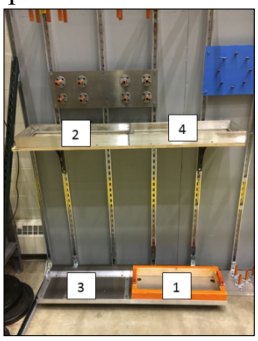
If you agree to participate in this research study, you will be asked to sign this consent form. This study will involve video recording you as you perform the tasks described below. If you agree to allow us to use your images in future publications or presentations, we will also ask you to provide your permission for this at the end of the form. Background information will be collected to explain the variation in acquired data (e.g., a subject with a replaced knee may perform

Research 1 – Task test

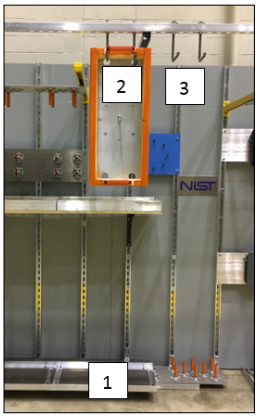
During these tests, we will ask you to wear the full exoskeleton suit. We will also measure heart rate to allow us to track how your heart rate increases during the tests and then returns to normal after the test.

There are 6 different tasks where one of the tasks will be chosen for you to participate in this part of the study. Each task is summarized below. Each task may take up to 45 minutes. You will be asked to perform each task with and without the exoskeleton 30 times.

Task 1: Load positioning – pick up and move a load onto a tray.

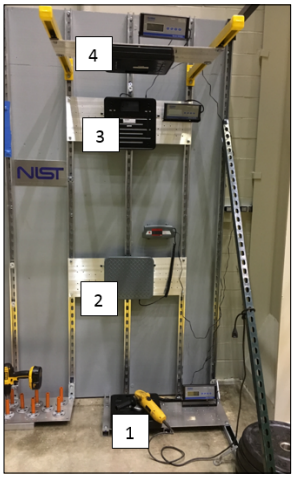


Task 2: Load hanging – pick up the load from the tray and hang it on hangers and then move it to other.

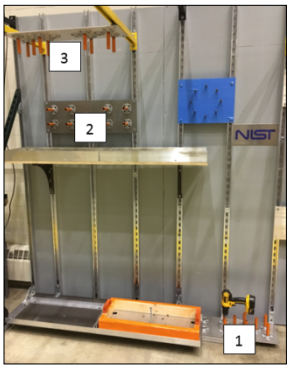


Task 3: Load alignment – pick up the load and hang it at an angle.

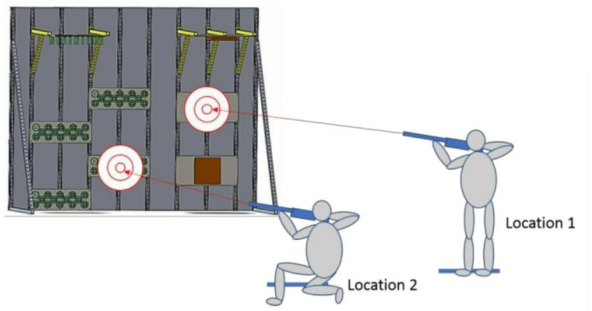
Task 4: Force applied - grab a grinder tool from the holder as if attempting to use it with both hands to grind and apply a force of at least 10 Lbs. with the grinder onto 4 different force plates.



Task 5: Peg-in-hole – contact - grab a drill tool from the holder as if attempting to use it with both hands to drill and insert the blank drill bit into a series of tubes located on the floor, wall, and above.



Task 6: Peg-in-hole – non-contact - grab a laser tool, align the tool with the target, and move the switch when the target is acquired. This task will be performed standing and crouching.



Research 2 - Knee test (approximately 45 minutes)

1. You will be asked to put on the lower extremity (leg/hip) exoskeleton according to manufacturer specifications with help from the research team. You may already be wearing the exoskeleton and simply walk to the knee test measurement lab for this test.
2. The research team will attach markers to you and the exoskeleton so that we can measure how the exoskeleton moves as you move through tests.
3. Knee test, part 1 steps (Stand/Crouch-Static):

a. You will be asked to stand still in an upright position and remain still during data collection.
b. You will be asked to bend your legs to full crouched position (if necessary, while holding onto a chair for support), to stand still in a crouched position and to remain still during data collection. A full crouched position will include touching your back upper leg to your back lower leg.

4. Knee test, part 2 steps (Stand/Crouch-Dynamic):

a. You will be asked to stand vertical and bend down to full crouch position and to stand back up. You will be asked to perform this bending and crouching several times.

After you complete the Task and/or Knee test(s), we will ask you to complete a questionnaire about the tests and the exoskeleton.

This study will publish and present raw data. Raw data is the data that is specific to you for each of the tests, observations and questionnaires in this study. It is individual data. However, aggregate data will also be published as needed to combine the individual subject data with others for an overall test method development result. The summary results will also be published in publications or presentations

Raw data in this study could include individual data, based on study observations (e.g., task performance, exertion), survey questionnaire (e.g., age range, previous injury, right or left handedness), physiological response data (e.g., heart rate) pictures and videos. Pictures and videos are taken of task performance and exoskeleton fit only. Names are not recorded or mentioned in the protocol or data collected. The physiological response data (e.g., heart rate) and other subject information (e.g., age range, previous injuries) you provide will be used to correlate operator performance of a task with and without wearing the exoskeleton. The availability of raw data may enable further processing and analysis by other researchers for future studies that are not a part of the NIST research team, be made public within and outside of NIST and may also be used independently and/or compiled into aggregate results.

Your identity will not be included in this set of raw data, however it's possible that someone may be able to identify you from the raw data. The raw data will be published in publications or presentations. The raw data will be used to summarize the results of this study.

Total Number of Participants

Up to 200 individuals will take part in this study at NIST.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study.

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study. Decision to not participate will not affect your job status or student status.

If at any time you choose to withdraw from the test(s), inform the PI and/or research team and the test will immediately end. If the subject withdraws, their data will be destroyed and not used in additional analyses. The PI and/or research team may also end the test(s) prior to completion at any time and providing notice of ending the test to the subject at the stop time or prior.

Benefits

You will receive no benefit(s) by participating in this research study.

The potential benefits of participating in this research study include helping NIST researchers develop methods for measuring the performance of the exoskeleton.

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study. There is also a very small risk that someone who is not authorized could get access to the data we have stored about you. However, we describe how we will protect your privacy and confidentiality in a later section of this consent form. The following risks may occur:

- Lifting and maneuvering loads up to 30 Lbs may cause body strain. Chances of this are minimal and depend on the physically fit individual's capability to lift, carry, and position light loads several times.
- Bending arms and legs to normal angles while wearing an exoskeleton may cause bruising, slight pain, or muscle fatigue. Chances of this are minimal and depend on the individuals skin irritation similar to wearing loose fitting and weighted garments (e.g., tool belt, snorkel gear, harness, etc.).

- Falling due to the subject not being familiar with wearing an exoskeleton.
- Rubbing of exoskeleton or NIST artifact devices attached to the body may cause skin irritation. Chances of this are minimal and depend on the individuals skin irritation similar to wearing loose fitting and weighted garments (e.g., tool belt, snorkel gear, harness, etc.).
- Wearing of the Vo2 Master Oxygen Expiration Sensor may cause some subjects to feel claustrophobic or a feeling not being able to catch their breath. This sensation is similar to using a snorkel or dive regulator.
- Possibility of re-identification once raw data is made publicly available. If you agree to let us use your images and data (raw or aggregate) in presentations or publications, then there is a chance that someone may recognize you. Your name will never appear in any presentations or publications. The data and recordings will be studied and analyzed by the research team and made available to the public for research.

If, at any point while you are completing the tasks, you experience any pain or fatigue that is more than just minor fatigue or discomfort, stop doing the task immediately and tell a member of the research team.

Sanitation of Exoskeleton and equipment

All equipment will be sanitized per the recommendation of the manufacturer and OSHE. We will also take the extra steps to fully clean the exoskeleton by using an ozone cleaning system, Sani Sport. This system is used by law enforcement, professional sport teams and several manufacturers to clean their PPE and equipment. The Vo2 Master Oxygen Expiration Sensor will be fitted with a new filter for every subject.

Compensation

You will receive no payment or other compensation for taking part in this study.

The findings from this research may result in the future development of products (e.g., test methods) that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

Costs

There will be no additional costs to you as a result of being in this study. Because the study involves minimal risk, there is little likelihood that you would be injured during your participation. If, however, an injury occurs, you would follow the process for reporting any NIST workplace injury because you will be participating in the study as part of your official duties with your manager's approval.

Privacy and Confidentiality

We will keep your study records private and confidential. The research team will store the records on password protected computers and encrypted disks, hard drives and locked facilities with access by the PI and research study team only. Every attempt to keep the data private from others outside of the research team will be enforced as described here. Certain people may need

to see your study records. Anyone who looks at your records must keep them confidential. These individuals include:

- The code key/master list will be kept separate from participant identifiers. The code, a random number is assigned to the participant instead of using the name or contact information of the participant. Only the Principal Investigator and research staff will have access to the code key or master list. The PI and research team include engineers, computer scientists, and mathematicians.
- Certain government people who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
- Any agency of the federal, state, or local government that regulates this research, including the NIST Research Protections Office.

Your identity will be protected to the extent permitted by law, including the Freedom of Information Act. Total confidentiality cannot be guaranteed, since all security measures have vulnerabilities and may be compromised.

Future use of research data

Raw and aggregate data, information, photos and images collected from you for this current study may be shared with other researchers in the future. The raw and aggregate data will be publicly available for research in journal articles, presentations and posters. Identifiers will not be provided, and your name will never appear in any article, presentation or publication.

Once the data is released to the public, we (NIST) no longer have control of the data and it would not be able to be removed/destroyed. All data internal to NIST shall be destroyed after five years according to NIST's record retention policy.

You can get the answers to your questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, or experience an unanticipated problem, or research-related injury, call Ann Marie Virts at 301-975-5068.

If you have questions about your rights as a participant in this study, or have complaints, concerns or issues you want to discuss with someone outside the research team, call the Human Subjects Protection Office at (301) 975-5445.

You will receive a copy of this signed consent form.

Consent to Take Part in this Research Study

I freely give my consent to take part in this study. I understand that by signing this form I am agreeing to take part in research. I agree that I have the ability to physically and safely complete the tasks. I have my employer's permission to perform study activities in the course of my work

duties. I am at least 18 years of age; and have spoken to one of the study researchers, who answered any questions I had about this study.

_____ _____

Signature of Person Taking Part in Study Date

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Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

_____ _____

Signature of Person obtaining Informed Consent Date

_____

Printed Name of Person Obtaining Informed Consent