CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

Information about the Research Study

A Robotic Hand Orthosis Providing Grasp Assistance for Patients with Brachial Plexus Injuries

Principal Investigators:

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The study staff will explain this study in detail to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends. Please keep in mind:

Please read this consent form carefully

INTRODUCTION

You are invited to participate in a research study under the direction of Dr. Pinhas Ben-Tzvi, Department of Mechanical Engineering, Virginia Polytechnic Institute and State University (Virginia Tech), and Dr. Cesar Bravo, Carilion Clinic Orthopedic Surgery. The study is being funded by a grant from the National Institute of Health. Before you can decide whether to take part in the research, you should be told about the possible risks and benefits with this study. This process is known as informed consent. Taking part in this research is entirely voluntary.

Your treatment at the Carilion Clinic ION facility will not be affected in any way should you choose not to participate or if you decide to withdraw from the study at any time. To participate in this study you be receiving treatment at the ION facility for brachial plexus injury.

Be aware that the role of the study doctor is different from the role of your personal doctor. Your personal doctor decides how to treat your specific problem in order to help you. The study doctor treats all subjects under a specific protocol to obtain general knowledge that may or may not benefit you. Be sure to ask your doctors questions to help you know more about these different roles.

PURPOSE

The purpose of this study is to determine whether a robotic exoskeleton glove designed by engineers from Virginia Tech in patients with a brachial plexus injury can help you better perform certain tasks and to obtain your feedback on the glove

PROCEDURES

You are eligibile for this study because you have a brachial plexus injury Both male and female subjects will be recruited. This research will include a recording of the movements in your fingers and wrist joints, your ability to complete tests from the Southampton Hand Assessment Procedure (SHAP), and the comfortability of the robotic glove.

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If you decide to participate, you will attend a single data collection session lasting approximately 2 hours. At this session your hand will be fitted with a glove-like device including several small rods and motors. You will then perform six different grasps: using lightweight objects followed by heavyweight objects. The procedure for each trial is for the subject to start the timer, pick up the object using the specified grasp from the rear slot in the experimental setup, move it to the front slot in the setup, and stop the timer.

You will also be asked to perform 14 activities of daily living (ADLs), starting and stopping a timer before and after the task is completed. This includes pick up coins, undoing buttons, simulate food cutting, page turning, opening a jar lid, pouring from a glass jug, pouring from a carton, lifting a filled jar, lifting an empty tin, lifting a tray, rotating a key, opening and closing a zipper, rotating a screw with a screwdriver, and rotating a door handle.

We will record you performing these tasks to analyze the device's effectiveness. Only your hand will be in the video. However, due to the nature of your injury it may be possible to identify you.

Afterwards, you will be presented with a survey in which you qualitatively evaluate the subject fit, the mechanical performance, the controller performance, and any thoughts you have on the effectiveness/usability of the device.

You may be asked to return for an additional session performing the same activities if the researchers determine it is needed and you are willing to return.

RISKS AND CONFIDENTIALITY

A potential risk is slight discomfort while using the device. Orthotic devices are usually customized to the individual but this study is using a single device for all subjects and it may not fit perfectly. The device itself will be designed so that it will allow normal human range of motion in the hand and is free of potential pinch points.

You will be closely monitored while using the device. If you feel uncomfortable at any time, you may request that research procedures be stopped and the device will be removed immediately.

Your hand motion will be video-recorded. Recordings will be reviewed and transcribed into a spreadsheet. The videos may be kept indefinitely.

The study may include risks that no one knows about yet.

The research records will be kept private on a password-protected computer in a locked office. All research data will be coded with a unique number. Your name will be linked to the code number on a master list of those who take part in the study. This master list will be kept separate from the research database and will be stored in a locked filing cabinet. This master list will only be used by the researchers or organizations that govern research quality and safety oversight. Your identity will not be used in any sort of published report.

The Carilion IRB, at telephone number (540) 853-0728, can provide further information about your rights as a research participant. Further information regarding this study may be obtained by contacting Dr. Pinhas Ben-Tzvi, PhD, Virginia Tech Principal Investigator, at (540) 231-6938, or Dr. Cesar Bravo, M.D., Carilion Principal Investigator, at telephone number (540) 510-6200.

BENEFITS

You will not benefit directly from your participation in the study. The benefits to science and humankind

that might result from this study are: improved knowledge of how the human hand functions during grip activities and the effectiveness of the designed and tested orthosis.

If results of this research study are reported in journals or at scientific meetings, the individuals who participated in this study will not be named or identified.

ARE THERE ANY OPTIONS TO BEING IN THIS RESEARCH STUDY?

You may choose not to participate.

WILL IT COST ME MONEY TO TAKE PART IN THIS RESEARCH?

Taking part in this research will not cost you any money.

WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

You will be provided a $60 gift card for participating in this research.

Payments made to you as compensation for your participation will be tracked by the research team. This information will be submitted to Carilion's financial department for central tracking. If you receive greater than $600 from Carilion in a calendar year, this is considered taxable compensation and will be reported to the Internal Revenue Service (IRS). You will be issued a 1099 tax form by Carilion if you meet this reporting threshold.

WHAT WILL HAPPEN IF I HAVE COMPLICATIONS OR IF I AM INJURED BY THIS RESEARCH STUDY?

If you have a medical problem that happens because you are in this study, you should alert the study doctor.

The treatment will be billed to you or your insurer at the usual charge. The study does not make any provisions for the payment of these costs. You will not receive any other financial compensation, nor payment for any wages you may lose due to your injury. However, you do not give up any legal rights to seek compensation for injury by signing this consent form.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION

There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act." Because of this law, your health information cannot be looked at, collected or shared with others without your permission.

Signing this consent and authorization form means you allow the Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share information that identifies you for the purposes of this research.

This is the information about you that researchers will use:

- Personal identifiers such as name, address, telephone number, or medical record number.
- Demographic information such as age, race, gender.
- Current and past medications or therapies.
- Family medical history.
- Results of physical exams, laboratory tests, x-rays and other diagnostic procedures.
- Tests and procedures that will be done in the study.
- Other personal health information that will be obtained from other sources to use in the research, including past medical history, tests or records from other sites

The investigator and research team may share information about you with:

- The Carilion Clinic Institutional Review Board or Virginia Tech Institutional Review Board, research protection groups that provide ongoing review of the research project.
- Authorized employees of Carilion Clinic who need the information to perform their duties to provide treatment, to ensure the integrity of the research or to do accounting and billing.
- Laboratories and other individuals and organizations that analyze your health information in connection with this research.
- The Food and Drug Administration or other government agencies that oversee research with humans.
- Committees that monitor research data and safety or other groups authorized to monitor the study.
- Researchers at the following non-Carilion facilities: Virginia Tech

Health information that could allow you to be identified is called protected health information or PHI. The investigator and research team will share only the PHI listed above with the individuals/agencies listed above. If the investigator needs to share other PHI or needs to share PHI to other individuals/agencies not listed above, then you will be asked for your permission in writing again.

Carilion Clinic and its affiliates are required under law to protect your PHI. However, the individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it. They could share your PHI with others without your permission, if permitted by the laws governing them.

You have the right to stop sharing your PHI. To end your permission to share your PHI, you must do so in writing to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your PHI for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study. Also, the FDA (if involved with your study) can look at your PHI related to the study even if you end your permission.

You may not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

ARE RESEARCHERS BEING PAID TO DO THIS STUDY?

The principal investigator received grant funding for the conduct of the research study.

IRB SURVEY:

The IRB committee is a group of people that reviews research to protect the rights of research subjects. One job of the IRB is to make sure the research is done in a way that is respectful to subjects. If you agree, the Carilion IRB may select you to receive a survey asking about your experiences while taking part in this research study. If your name and address are given to the Carilion IRB in order to mail the survey, the Carilion IRB will keep this information confidential. You do not have to put your name or other identifying information on the survey unless you choose to do so or request to be contacted regarding your experiences. You do not have to give permission to allow the Carilion IRB to send you this survey. Please check below whether you agree to allow the Carilion IRB to send you a survey:

_____Yes, I agree to Carilion IRB sending me a survey about my experiences while taking part in research

_____No, I do not want Carilion IRB to send me such a survey.

CONSENT DOCUMENT

If you agree to participate in the above research study, please sign below. The researchers will provide you with a copy of the signed consent form. Please keep it for your reference.

Your status at the Carilion Clinic will not, in any way, be affected should you choose not to participate in this study, or if you withdraw from the study at any time.

Should you decide to withdraw from the study, please notify the PI or study administrator, and you will be permitted to terminate your participation

DOCUMENTATION OF CONSENT

RESEARCH SUBJECT: The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and voluntarily. I may withdraw my consent at any time. I will receive a signed copy of this consent form.

_____
Printed Name of Research Subject (18 years or old

_____ _____
Subject's Signature Date

PERSON OBTAINING CONSENT: I certify I was present for the informed consent discussion. The subject had an opportunity to ask questions about and appeared to understand the information presented. The subject agreed to take part voluntarily in the research and I obtained his/her signature.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

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