

Title: Virtual Neuroprosthesis: Restoring a Sense of Touch to Amputees

Clinical Trials number: NCT03581448

Informed Consent

August 18, 2021

INFORMED CONSENT TO PARTICIPATE IN SCIENTIFIC RESEARCH

1) Title of Research Study: Virtual Neuroprosthesis

2) Investigator(s): Erik D. Engeberg, Ph.D., Emmanuelle Tognoli, Ph.D.

3) Purpose: The purpose of this experiment is to study manipulation of a robotic hand and how it is affected by the sensation of touch.

4) Procedures: The experiment will take place at the Laboratory for BioRobotics, Florida Atlantic University - Boca Raton. It consists of a session lasting at most 2h, and with numerous breaks to prevent fatigue. During the session, you will perform simple, non-strenuous actions using a robotic hand.

PARTICIPATION IS VOLUNTARY - YOU ARE FREE TO REFUSE TO PARTICIPATE

If this box is checked, the study will include an electroencephalogram (EEG), which measures your brainwaves. For this purpose, you will be equipped with an electrode cap that collects the miniature currents created by the brain. A cream will first be applied on your scalp to remove the greasy layer on the skin that impedes the recording of a clear signal from your brain. Then a gel will be used to maintain the contact between your scalp and the electrodes. Those products are standard for EEG recording, are harmless, and are easily removed afterwards with hair washing. EEG monitoring is painless, consisting only of "hearing" the small currents naturally produced by your brain. All materials that you will be exposed to during the placement of the electrode cap are disposable, sterile or decontaminated, in order to guarantee your protection against germs.

If this box is checked, the study will include an electromyogram (EMG), which measures your level of arm muscle exertion. For this purpose, you will be equipped with a set of skin-surface electrodes on your arm. EMG monitoring is painless, consisting only of recording the small currents naturally produced by your muscles.

If this box is checked, the study will include a soft inflatable armband will be placed on the upper part of your arm. This armband will be inflated relative to the grip forces exerted by the robotic hand. In this way, you will have an ability to sense the forces applied by the robotic hand, even if you are not looking at it.

Next, you will learn to control the robotic hand in a computer simulation or in person. Then, you will perform a series of trials using the robotic hand to accomplish simple actions such as transporting objects or reaching, grasping and moving. In some trials, you will perceive how much pressure the robotic hand experiences, but not in others.

If you are a student at FAU, you will not receive any negative grades or side-effects as a result of participation in this research, regardless of the results. If you complete the experimental protocol, you will receive a \$80 stipend.

If you check this box, you agree that we can contact you again to propose a follow-up experiment which repeats the same protocol as above. You will be free to accept or refuse to participate in the follow-up experiment, irrespective of your consent to the present experiment. If you accept a follow-up experiment, you will sign a new consent form like this one. At completion of the follow-up study, you will be compensated with an additional \$80 stipend.

5) Risks: This study involves no more risk than encountered during routine medical, psychological examination or during daily life. Application of EEG electrodes and arm sensors present a small risk of skin irritation that is extremely rare and usually disappears within a day or two. Every effort is made to render the inflatable armband comfortable, but you could feel some tightness at times. We will ask your help to calibrate the pressure and avoid such discomfort. Robotic control tasks are designed to minimize strain and fatigue. There are small risks of tension or fatigue in the muscles; of visual fatigue while concentrating on the computer screen or robotic hand; and of general mental fatigue. Experimenters are present at your side at all time, and you are free to interrupt a session at any time.

6) Benefits: This experiment is not a health intervention, and you will not receive direct health benefit from your participation. However, your participation is important for science and engineering and for society. It will lead to increased understanding on the control of robotic hands and how touch contributes to it. It will lead to improvements in the design of prosthetic arms, to the benefit of amputees and limb-absent people who use prosthetic hands or disabled individuals who rely on robotic assistants. There are others who could benefit from this research as well, for example, doctors who perform robot-assisted surgery and their patients, or people having suffered from neurotrauma.

7) Data Collection & Storage: Any information collected about you will be kept confidential and secure and only the people working with the study will see your data, unless required by law. All identifiable material will be kept for 4 years in a locked cabinet or password-protected computer in Dr Engeberg's office. After 4 years, paper copies will be destroyed by shredding and nominative electronic data will be deleted. We aim to publish what we learned from this study. It is customary in Engineering and Science publications that subjects' names or identities are carefully kept confidential and results only present aggregate outcome from multiple subjects. We will not let anyone know of your name/identity in publications and scientific publications, unless rare, extraordinary circumstances that would require that we successfully reach to you and you give us explicit, written permission.

8) Contact Information:

- If you have questions about the study, you should call or email the principal investigator(s), Erik Engeberg at (561) 297-0530; email: eengeberg@fau.edu
- If you have questions or concerns about your rights as a research participant, contact the Florida Atlantic University Division of Research, Research Integrity Office at (561) 297-1383 or send an email to researchintegrity@fau.edu .

9) Consent Statement:

*I have read or had read to me the preceding information describing this study. All my questions have been answered to my satisfaction. I am between 18 and 65 years of age and freely consent to participate. I understand that I am free to withdraw from the study at any time without penalty. I have received a copy of this consent form.

Signature of Participant: _____ Date: _____

Printed Name of Participant: First Name _____ Last Name _____

Signature of Investigator: _____ Date: _____