

## **Information for Potential Participants in “An Investigation of Ankle Joints for Ankle Foot Orthoses (AFOs)”**

VA Chicago Motion Analysis Research Laboratory  
Northwestern University Prosthetics Research Laboratory  
& Rehabilitation Engineering Research Program

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Sponsor: Department of Veterans Affairs

### **INTRODUCTION/PURPOSE**

We are investigating the effect ankle joint configuration within an Ankle Foot Orthosis (AFO) may have on walking in persons with hemiplegia following stroke. An AFO is an orthosis that controls ankle motion for the purpose of providing stability during walking. You are being invited to participate in this study because, as the result of a stroke, you normally walk with an AFO. The purpose of this research study is to evaluate the effectiveness of different ankle joint configurations at restoring the function of the ankle-foot complex when wearing an Ankle Foot Orthosis (AFO).

### **PARTICIPANT CRITERIA**

We are interested in recruiting people between the ages of 40 and 70 years, who had a stroke a minimum of 24 months previously, and who normally wear a jointed AFO to assist with their walking. You must have normal function in the opposite arm and leg and be able to walk without an assistive device, such as a cane, indoors.



Example of a ‘test’ AFO.

### **PROCEDURES**

Participation in this study requires a minimum of five visits (over approximately eight to ten weeks) to the VA Chicago Motion Analysis Laboratory (VACMARL) within the Northwestern University Prosthetics Research Laboratory (NUPRL) located on the 14<sup>th</sup> floor of the Rehabilitation Institute of Chicago (RIC). During the first two visits, study participants are cast and custom-fitted with three ‘test’ AFOs by a qualified orthotist. The test AFOs are worn along with shoes supplied by us full-time for two weeks each. While wearing the ‘test’ AFOs, study participants undergo three walking evaluations at two-week intervals. After each gait analysis, the AFO is exchanged and the next ‘test’ AFO worn for the next two weeks. You will be responsible for your transportation to and from the RIC.

For the evaluations, you should bring shorts and a t-shirt. All of the measurements made during the analyses will be external to the body. Positions of the legs and trunk will be determined from reflective markers that are placed on the body using hypoallergenic double-sided tape. Forces

between the feet and the ground will be measured from force platforms that are built into the walkway. We also record electrical activity from leg muscles using electrodes that attach to the surface of the skin with double-sided non-allergic tape. Placement of these electrodes may require shaving small patches of skin to ensure it is free of hair as it causes interference with the signal being recorded from the muscle. Some clinical measurements of joint range of motion and muscle strength are also made. You should arrange your schedule to allow for a minimum of two hours per session. Comparisons of the data obtained during each walking analysis will enable the effects on walking of different ankle joint configurations to be determined.

You will be videotaped and photographed during the analysis sessions for our records. You may choose whether or not to let us use pictures and videotapes of you in medical or scientific publications and presentations. We may publish and present pictures and videos of you including (or not including) your face. In the event these photographs are used in a public presentation your face may be shown, but we will not reveal your identity or any personal information about you.

### **POTENTIAL RISKS**

Your participation in this study involves the same risks as those that you would experience when walking on level ground in your regular AFO. The double-sided tape used to attach the markers and electrodes to your body will not cause skin problems.

### **BENEFITS**

There may be no direct benefit to you by your participation in this research study. Results from this research will enable orthotists to better understand how ankle joint configurations in AFOs effects the way people who have had a stroke walk. Our work may lead to the development of more functional walking aids, or for the design of more advanced orthotic components.

### **FINANCIAL INFORMATION**

You will be paid \$30 in cash at the completion of each session, a total of \$150 for participating in all five sessions. If you drive and park at the Huron-St Clair Parking Garage (222 E. Huron Street), your parking ticket will be validated.

### **SUBJECT RIGHTS**

You have the option to withdraw from this study at any time.

### **CONTACT DETAILS**

If you are interested in participating in this project, please contact the Project Director, Dr Stefania Fatone, on (312) 238 6538, Monday to Friday, between 9am and 5pm.