

Participant Information Sheet

Name of department: Biomedical Engineering

Study title: A study of the effectiveness of a leg splint during walking.

Introduction

We would like to invite you to take part in a research study. The study is part of a PhD project undertaken by Mrs Amneh Alshawabka. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

During standing or walking, bodyweight is transmitted through lower limb joints. This transmitted weight is called load and can be measured. This study aims to gain a thorough understanding of ankle joint load during walking and the effects of wearing leg splint on this load. Therefore, a sensor has been designed to record the loads in the splint during walking. The results of this study may influence clinical decision making in choosing splint design and material that best matches the patient needs.

Why have you been invited to take part?

You have been invited to take part because you have had a stroke, and you meet all of the following inclusion criteria:

- ✓ Over 18 years of age
- ✓ Able to walk 10-15 steps on the treadmill which correspond to 10 meters, without walking aids.
- ✓ No spasticity or with mild to moderate spasticity
- ✓ No hip or knee muscle shortening.
- ✓ Not pregnant.
- ✓ Using lower leg splint (Ankle foot orthosis).

If you have had any major surgery on the lower limbs, suffer from motion sickness, have musculoskeletal or neurological or balance conditions other than the stroke you will be excluded from the study.

Do I have to take part in the study?

No, it is up to you to decide whether or not to take part, since participating in this study is completely voluntary and you may withdraw at any time. Also, even after agreeing to participate in our study, you are still free to withdraw at any time and without giving a reason. However, your anonymised data (i.e. data which do not identify you personally) cannot be withdrawn once they have been included in the study.

If you decide not to participate or to withdraw from the study, your ongoing treatment will not be affected in any way. You will continue to receive your standard clinical care. The leg splint will be fitted with a sensor to measure the load. Therefore, it will not be delivered to you and it will be used only during the walking trials.

What will you do in the project?

If you decide that you would like to take part in the study, please contact the researcher (contact details are at the end of this sheet), who will arrange an appointment time to check your suitability for the study and to answer any questions you may have.

You will be invited to attend **three sessions** for no longer than 2 hours each at the National Centre for Prosthetics and Orthotics (NCPO) at the University of Strathclyde. **The first session** will be a quick screening session to determine whether you can be included in the study, if so a plaster of Paris cast of your lower leg will be taken. **The second session** (one week later) will be to check the splint fitting, comfort and function. **The third session** (two weeks later) will be to record your walking.

In the first visit, you will be asked to sign a consent form. If you match all the selection criteria, a research team member will take a Plaster of Paris cast of your lower leg. The cast will be removed after it dried, approximately 10 minutes. Then, you will be free to leave. This cast will be used to make a splint which will be fitted after one week.

In the second visit, once the splint has been made, you will be invited to visit the NCPO for checking the fitting, comfort and function of the splint. A heel wedge will be inserted under the splint to achieve a better posture for your lower legs. Additionally, another heel wedge will be placed under the other foot in order to equalise the leg length. Then, you will be free to leave. A load sensor will be attached to the splint before you third visit, Figure (1).

In the third visit, after one week from your second visit, you will be invited to visit the laboratory at the NCPO. This laboratory is fitted with a treadmill and other equipment to record your walking patterns, Figure (3). You will need to wear close-fitting shorts (like cycling shorts, Figure 4) so that accurate motion of your legs can be recorded (appropriate clean laundered shorts will be provided to you by the department, if necessary, but you may feel more comfortable wearing your own clothes). You will have the opportunity to become familiar with the splint which you will wear with a long sock underneath. Also, you will wear standard shoes which will be provided to fit all sizes, the shoes will be sterilised before and after the test session using a Sterilising Spray. It is important to note that the splint will only be used within the building in which the movement laboratory is housed.

Reflective markers will be attached at various points on your legs and pelvis. These markers will be attached to your skin using non-allergenic adhesive tape as shown in Figure (2). Other markers will be attached to plastic pads. These plastic pads will be attached to various parts of your leg using elastic strap. Additionally, to measure the electrical activity of your knee muscles, electrical sensors -called electrodes- will be placed on your skin (Figure 2). For secure attachment of these electrical sensors, any hair on their locations will be removed using a standard disposable safety razor, and the shaved skin will be cleansed with gel mild abrasive and alcohol wipe.

Before the walking test commences, a supportive harness will be fitted around your chest and shoulders. The harness is a set of bands hung from the ceiling and tightened comfortably around your chest and shoulders with the aim of eliminating the risk of falling off the treadmill. Afterwards, you will be asked to walk on the treadmill where your walking will be recorded. You will be asked to walk at different speeds, all within a range that is comfortable to you. Three tests will be performed in random order:

Test 1: Standard shoe – you will be asked to walk while wearing standard shoes with no splint.

Test 2: Standard shoe with splint – you will be asked to walk while wearing the splint.

Test 3: Standard shoe with splint and heel wedge – you will be asked to walk while wearing the same splint in test 2 with a heel wedge.

What are the potential risks to you in taking part?

1. Removing the plaster of Paris cast from your leg may cause mild skin abrasion, however, the casting will be done by an experienced clinician.
2. There is a slight chance that you may experience discomfort from the splint. However, this will be made by an experienced orthotist and the test will be stopped if any discomfort is being experienced.
3. The testing requires markers and electrodes to be attached to the skin with non-allergenic adhesive tape. Occasionally this can cause a mild irritation to the skin. This should only be a temporary irritation since the markers and the electrodes will only be in place for a short time and we will be very careful when we take the markers off. If you develop a reaction to the tape, we will remove them immediately. Removing the reflective markers and the electrodes attached with tape may cause mild discomfort, but these will be removed very carefully, or if you prefer, you can remove them yourself.
4. To reduce the risk of tripping or falling, you will be fitted with a supportive harness attached to the ceiling and tightened comfortably around your chest and shoulders to prevent possible trips or falls from the treadmill. Moreover, if this happens the researchers will stop the treadmill immediately.
5. You will not be active throughout the entire session. Rest breaks are built in between tests while equipment is prepared. Moreover, you will be able to rest as required and refreshments will be provided. You will not be asked to perform any activity which causes distress to you.

What happens to the information gathered during the project?

The consent form will be kept confidential, in a secured locked cabinet of the chief investigators office in the Department of Biomedical Engineering and will be only used as instructed in University Data Management Plan. Consent forms will be retained indefinitely and will not be destroyed. The researcher will use a unique code for each individual who participates in the study so that the results of the tests will be kept anonymous. All anonymous data will be stored

on secure university website, Strathcloud, with access only by the named researchers. Its access and destruction will be in accordance with the University Data Management Plan. The anonymization code will be destroyed at the completion of the study (18 months).

None of your personal details (name, contact details and other identifiable personal information) will be used in any publication related to the study. Consent will be obtained to use images in publications and for teaching if needed. Facial and other identifying features will be obscured from the images, so that you will not be identified. The University of Strathclyde is registered with the Information Commissioner's Office who implements the General Data Protection Regulation (GDPR). All personal data on participants will be processed in accordance with the provisions of the GDPR.

What happens next?

If you are happy to take part in this study, please e-mail Amneh Alshawabka using the details below. If you decide to take part and if you are considered suitable for participation in the study, Mrs Alshawabka will contact you to schedule suitable appointment dates and times. The consent form can be handed to any of the investigators/researchers at the first visit.

In the case that you do not wish to be involved in the project, then the investigators of this study would like to take the opportunity to thank you for taking an interest in this research project.

Once the study is over, a summary of the results can be provided to you, if requested, by contacting any of the investigators on the contact details given below.

Researcher contact details:

Thank you for reading this information – please ask any questions if you are unsure about what is written here. If you have any questions about this study you can talk to one of the researchers organising it:

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This investigation was granted ethical approval by the University Ethics Committee. If you have any further questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed, or further information may be sought from, please contact:

Secretary to the University Ethics Committee
Research & Knowledge Exchange Services
University of Strathclyde, Graham Hills Building
50 George Street, Glasgow, G1 1QE
Telephone: 0141 548 3707
Email: ethics@strath.ac.uk

Appendix A



Figure (1): the instrumented leg splint

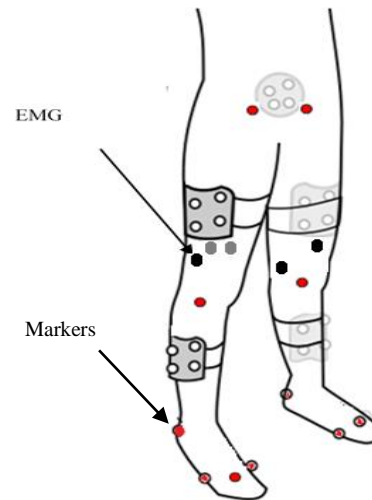


Figure (2): Marker and electrodes positions

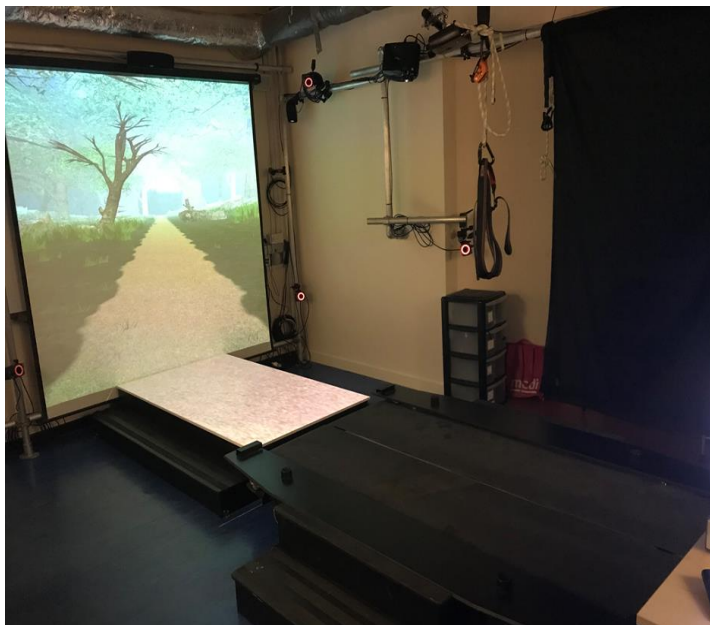


Figure (3): The Motek lab



Figure (4): participant wearing appropriate clothing