Perceptie van kabel bedieningskrachten en verplaatsingen tijdens de bediening van een lichaamsbekrachtigde prothese

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22773

Source
Nationaal Trial Register

Brief title
Perception in BBP

Health condition

arm amputation, upper limb prostheses, body powered prosthesis, force perception, cable operation force and displacement

arm amputatie, hand prothesen, lichaamsbekrachtigde prothese, kracht perceptie, kabel bedieningskracht en -verplaatsing

Sponsors and support

Primary sponsor: Delft University of Technology
Source(s) of monetary or material Support: Fonds Nuts OHRA

Intervention

Outcome measures

Primary outcome

The experiment has two primary outcome measures relating directly to the quality of prosthetic control: 1. Force reproduction error, 2. Force variability.

Force reproduction error: The differences between the reference force/displacement and the reproduced force/displacement of the control cable indicates the capability of a subject to perceive and control the required force/displacement.

Force variability: the standard deviation of the reproduced force/displacement indicates the capability of the subject to control the required force/displacement.

Secondary outcome

Secondary outcome measures of the experiment are 1. Maximum voluntary contraction (MVC) and 2. questionnaires; NASA TLX and body map.

MVC: The maximum voluntary contraction indicates the physical capacities of a subject. This indicates design requirements for future prosthesis design.

Questionnaires: The Nasa TLX questionnaire and the colored body map documents the subjective feelings of the subject during the experiments. These data might help to explain and interpret the primary outcome measures.

Study description

Background summary

Rationale: Nowadays 20 - 40 % of the arm amputees decide not to wear a prosthesis. Of those who wear a prosthesis 40 -60% do not to use the full functionality the prosthesis offers. Users of a shoulder controlled body powered prosthesis complain about the shoulder harness cutting into the arm pit and about the tiresome use of the prosthesis. Recent research showed that the operating forces of commercially available prostheses are (too) high. Therefore, operation forces need to be lowered. On the other hand, operation forces getting too low may result in a loss of perception and of control. This research will investigate which operating forces can be perceived and controlled best by the users. Additionally the influence of different cable displacements on the best operating force will be investigated. Furthermore, the maximum operating forces will be measured to indicate whether the user's physical capacities will influence the preference of operating forces. The results of this study will be used as requirements for a new physiological prosthesis control system which will be

designed to match the capacities of the user to the demands the user puts on the prosthesis to enable execution of ADL (activities of daily living).

Objective: The main objective of this study is to find cable operation forces and displacements which can be perceived and controlled best by a prosthetic user. The secondary objective is to relate the physical capacities of the subjects/users to the outcome measures of the main objective. Furthermore the outcome measures of the main objective should be supported by subjective data from surveys.

Study design

The experiment of approximately 2 hours is conducted during one appointment with the subject.

Intervention

Subjects: A total of 25 subjects with a trans-radial deficiency will participate in the experiment.

Intervention: This experiment is designed to give insight into the quality of control of a body powered prosthesis and, more specifically, to determine the cable force and displacement associated with an optimal level of control, which are expressed as the primary outcome measures force reproduction error and force variability.
The experiment consists of a force reproduction task using a prosthetic simulator consisting of a hard socket and a shoulder harness which are connected by a Bowden cable. The hard socket end of the Bowden cable is connected to a spring. The spring can be exchanged with other springs of different stiffness to investigate different force- displacement-configurations in different trials.

Reference force levels vary between 10 and 40 N and are each presented in combination with a cable displacements ranging between 0 and 80 mm. First, subjects' maximum voluntary contraction level (MVC) will be determined. Next, the subjects performs a series of force reproduction trials. Each trial consists of (visually) matching a reference force shown on a laptop screen and repeating this without visual feedback. Between the trials, subject are requested to fill in a NASA TLX questionnaire and colour a body map at the places they might feel discomfort. Finally, another MVC measurement is taken.
Forces and displacement are measured at the control cable of the prosthesis simulator using a force and displacement sensors and provide the input for the primary outcome measures.

Duration of experiment: The experiment will last approximately 2 hours including breaks.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Amputation level: below elbow / trans radial

• Age: older than 18 years

• No co-morbidities interfering with study requirements, such as joint diseases, muscle diseases, pulmonary or cardiovascular diseases, or psychiatric diseases.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- younger than 18 years

- mentally incompetent

- Neurological problems concerning upper extremity or torso

- Motor problems concerning upper extremity or torso

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2013
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-06-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3875
NTR-old	NTR4072
Other	: METc 2012.251
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A