Feedback about hand position and gripping force through stimulation of the skin to be used in forearm prostheses.

No registrations found.

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

Summary

ID

NL-OMON28194

Source
NTR

Brief title
Myopro feedback

Health condition

feedback
forearm amputation
amputatie van de onderarm
electrotactile stimulation
vibrotactile stimulation

Sponsors and support

Primary sponsor: Twente University
Source(s) of monetary or material Support: ministry of economic affairs and the province Overijssel (PIDON)

Intervention

Outcome measures

Primary outcome

Time needed to perform grasping tasks;

2. Errors made during the grasping tasks.

Secondary outcome

Effect of training over the different tasks.

Study description

Background summary

Feedback, directed to the user, about hand position and grasping force is missing in current myoelectric forearm prostheses, which impedes the subconscious control of the prostheses. In this study, the use of electrotactile and vibrotactile stimulation to provide this feedback will be evaluated. The study is splitted in four parts. In part 1 position (hand opening) feedback is studied, in part 2 (grasping) force feedback and in part the combination of position and force feedback. These three parts will be performed on 15 healthy subjects per study. In part four of the study, the optimal stimulation settings will be evaluated on amputation patients. For all studies, the task to be performed is a grasping task in which a virtual hand is controlled by the scroll function of a mouse and feedback is provided by electrotactile or vibrotactile stimulation on the same (fore-)arm. Feedback conditions (modality, placement of stimulator, presence of visual feedback) will be varied over the different tasks.

Study objective

Feedback about hand position and gripping force will improve the control of forearm prostheses by reducing the time needed to perform grasping tasks and the errors made during these tasks.

Study design

1 day (everything is measured on the same day).

Intervention

All subjects will be asked to perform, as accurate and fast as possible, several grasping tasks. A (virtual) hand will be shown on a computerscreen and the level of hand opening and/or the grasping force can be controlled by the computermouse. During the task, the level of hand

opening and/or the grasping force will be fed back to the subjects arm through vibrotactile or electrotactile stimulation. Stimulation parameters (number of stimulators, placement of the stimulators), feedback method (electrotactile or vibrotactile) and the presence or not of visual feedback will be varied over the different tasks. Every subject will experience the same set of tasks (although in random order presented) and the duration of the whole experiment will be 2 hours.

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Eligibility criteria

Inclusion criteria

1. Age between 18 and 65 (healthy subjects and patients);

2. Able to control the experimental setup (healthy subjects and patients);

3. Forearm stump of at least 10 cm (patients).

Exclusion criteria

1. Diminished sense of touch (healthy subjects);

2. Experience with vibrotactile or electrotactile stimulation (healthy subjects and patients);

3. Skin problems (healthy subjects and patients);

4. Mental problems (healthy subjects and patients).

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):	01-05-2011
Enrollment:	55
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-03-2011
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	NL2302
NTR-old	NTR2831
Other	CCMO / METC University Twente : 36189 / P11.15
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A