Vibrotactile feedback in forearm prostheses in daily life grasping tasks

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38759

Source
ToetsingOnline

Brief title
Vibrotactile feedback in daily life

Condition

- Other condition
- Congenital and hereditary disorders NEC

Synonym
amputation, upper limb loss

Health condition

amputatie van de onderarm

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: ministerie van economische zaken en provincie Overijssel (PIDON)

Intervention

Keyword: feedback, grasping tasks, myoelectric forearm prosthesis, vibrotactile stimulation

Outcome measures

Primary outcome

The main outcome parameter of this study is the performance in grasping tasks. Performance will be expressed by: (1) the time needed by the subjects to perform the grasping task, (2) the success in grasping (percentage of objects that is handled without object slippage or breakage), and (3) the Index of Functionality (IoF), which is the outcome parameter of the SHAP test, which is part of the test protocol.

Secondary outcome

The secondary outcome parameters will provide information about the performance of the separate feedback methods (hand opening en grasping force feedback). To evaluate the effect of hand opening feedback, the performance in situations with and without visual feedback will be compared (primary study parameters). The effect of grasping force feedback will be determined by the the number of trials needed by the subjects to succesfully perform the grasping task and the excess of grasping force that is applied to hold the objects. The combination of hand opening and grasping force feedback likely also provides information about the stiffness of an object. This effect will be evaluated with the percentage objects that is correctly identified (size, weigth and stiffness) by

the subjects.

Study description

Background summary

The number of myoelectric forearm prostheses that is being used on a daily basis is still quite low, while the functionality of these prostheses continuously increases. One of the main reasons for prosthesis abandonment is the lack of sensory feedback about the hand opening and the grasping force of the prosthesis. One of the possibilities to provide this missing sensory feedback to the prosthesis users is by vibrotactile stimulation. In earlier studies we already proved that the use of an array of coin motors (small vibrating elements) to provide hand opening feedback and a somewhat larger C2 tactor to provide grasping force feedback increases the performance in virtual grasping tasks. To really prove the usability of this feedback in daily life, we will evaluate the performance with the feedback in grasping tasks that are more related to daily life activities. Subjects will perform these tasks with and EMG controlled myoelectric prosthesis.

Study objective

The main goal of this study is to evaluate whether the performance in daily life grasping tasks, performed with a myoelectric prosthesis, increases when vibrotactile feedback about hand opening and grasping force is provided. Furthermore, the effect on performance will be evaluated for the feedback methods (hand opening and grasping force feedback) separately.

Study design

The main research question is: Will vibrotactile feedback about hand opening and grasping force increase the performance in grasping tasks in comparison to situations without vibrotactile feedback. Therefore, the performance in grasping tasks will be compared between situations with and without vibrotactile feedback. Furthermore, the performance in situations with and without visual feedback (in combination with and without vibrotactile feedback) will be investigated, because especially in situations without visual feedback, the hand opening feedback should be of additional value. The feedback configurations will be varied within three tests: (1) the SHAP test, which is a highly standardized test for the evaluation of performance with hand prostheses, (2) a grasping task where delicate objects, that can be found in daily life, have to be transferred and (3) a grasping task where abstract objects with varying weights, sizes and stiffness have to be hold. All subjects will experience the same feedback conditions and therefore this study can be

regarded a monocenter experimental study.

Intervention

While performing the grasping tasks, in some cases vibrotactile feedback about the hand opening and grasping force will be provided to the subjects through vibrotactile stimulation. Hand opening feedback will be provided via an array of small vibrating elements (coin motors), whereby activation of a single coin motor corresponds to a certain level of hand opening. Grasping force feedback will be provided by a somewhat larger vibrating element (C2 tactor), which amplitude of stimulation is related to the level of applied grasping force. All vibrators will be implemented in a sleeve (healthy subjects) or a prosthesis socket (patients), which will be worn by the subjects.

Study burden and risks

There are no serious risks involved in this study. Due to the long-term vibrotactile stimulation it is possible that the skin wil become irritated, but these effects will not be long lasting. The burden for the subjects will be mainly determined by the duration of the experiment. For both studies, the experiments will take about 2 hours (including instructions and other preparations). The healthy subjects of study 1 will get a training session of maximally 1/2 hour. For the patients of study 2, a user specific prosthesis socket will be made and therefore, the patients will be asked to come the RRT (Roessingh Revalidatie Techniek) some time before the experiments to take measures for this, which will take about 1/2 hour.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age between 18 and 65
able to control the measurement setup
forearm circumference between 24 and 28 cm (healthy subjects)
forearm stump of at least 8 cm (patients)
myolectric prosthesis user (patients)

Exclusion criteria

extreme skin problems at the forearm
mental problems (when they cannot understand the procedures)
self-reported diminished sense of touch (healthy subjects)
experience with vibrotactile stimulation (healthy subjects)
experience with EMG control of a prosthesis or other device (healthy subjects)
hypersensitivity of the skin of the stump (patients)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-07-2013
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	myoelectric forearm prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-04-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20497
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL44020.044.13
OMON	NL-OMON20497