Feedback trough vibrotactile and electrotactile sitmulation for myoelectric forearm prostheses

Published: 09-05-2011
Last updated: 28-04-2024

The main objective of the separate studies of this study is the evaluation of grasping performance when electrotactile or vibrotactile feedback is provided compared to the non-feedback and only visual feedback situation. The main question to be...

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

Summary

ID

NL-OMON38006

Source
ToetsingOnline

Brief title
Feedback in forearm prostheses

Condition

- Other condition
- Congenital and hereditary disorders NEC

Synonym
amputation, loss of forearm

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: electrotactile, feedback, forearm prostheses, vibrotactile

Outcome measures

Primary outcome

Study 1 - position feedback

The main study parameter of study 1 will be the performance in grasping tasks. This performance will be expressed in the time needed to complete the grasping task. During one task several objects with different sizes have to be grasped and hold for 2 seconds. Because it will no longer be trial and error to reach the correct hand position, it is hypothesized that feedback will lower the time needed to complete a task. The percentage of incorrect hand positions and the mean deviation from the desired end position are also a main study parameters, because this describes the over- and undershoot of the grasping motion and therefore the accuracy in the grasping task.

Study 2 - force feedback

The main study parameter of study 2 is the performance of a force control task when holding an object, also expressed in the time needed to complete the task. During the task, an object has to be grasped and hold, while the support of the object will be removed. Errors made during the performance task are also the main study parameter. For this study the errors are the number of object slippages and the excess of force applied to hold the object.

Study 3 - combination of position and force feedback

As study 3 is the combination of the first two studies, the main study parameters are also the combination of the study parameters of those studies, namely the performance in the grasping and holding task, expressed in the time needed, the percentage incorrect hand positions, the deviations from the desired positions, the number of slipped objects and the excess of force applied during grasping. The challenge of this third study is the combination of the best options of the first two studies.

Study 4 - feedback for patients

The best options from the first three studies will be combined in one protocol that will be evaluated on amputee patients or patients with a congenital deficit to proof the working of the methods to provide feedback to possible prosthesis users. The main study parameters will therefore be a combination of the parameters of the first three studies, all related to the performance in a grasping task.

Secondary outcome

A possible confounder for these studies can be the gender of the subjects, because there may be some differences in psychophysical characteristics, like the perception and localization of stimuli. Furthermore, the order of the experiments can influence the performance, because the first experiments can serve as a training period for the following experiments. The order of experiments within one study will be randomized over the subject to cancel this training effect in the overall outcome of the study. However, an increase in performance caused by the training effect will be followed while measurements

are repeated during the experiment with the same conditions.

Study description

Background summary

An incomplete upper limb, due to amputation or a congenital cause, results in a great level of disability. A prosthesis should be able to take over the function of the missing hand, but in practice the mechanism of the human hand is very complex and cannot even be approached by a prosthesis. The development of externally powered (myoelectric) prostheses has improved the more natural control of the prosthesis, but at the cost of a large amount of non-visual feedback. The lack of sensory feedback is indicated as one of the most important factors in prosthesis rejection. Feedback of the applied grasping force and the position of the prosthesis hand/fingers is essential in subconscious prosthesis control according to representative users. In current prostheses, there still is some haptic information about loads and proprioceptive information of spatial orientation available, but no artificial feedback about force and position is available and users therefore completely have to rely on visual information. This drastically impedes the functionality of a prosthesis, because users have to continuously watch their prosthesis while grasping an object. Possible methods to provide artificial feedback are electrotactile or vibrotactile stimulation of the skin. However, these methods have rarely been used in prosthesis applications before.
Early research on methods to provide the feedback have mainly used electrotactile stimulation, but more recent research focuses on vibrotactile stimulation. Three large research projects aiming for the development of innovative forearm prostheses have experienced with vibrotactile stimulation to provide grasping force feedback. Although their evaluations showed positive results of the use of feedback, it is not being implemented in current prostheses, likely because of the lacking investigation of the optimal stimulation settings. Even less research is being performed on the application of position feedback. By Mann et al. phantom sensations (perceived sensations between stimulators) are used to provide vibrotactile feedback of the elbow angle of a Boston arm prosthesis. By Prior et al. feedback on the level of hand opening of a Utah arm prosthesis is provided by electrotactile stimulation. They used one electrode to provide position feedback (by pulse rate modulation) simultaneously with force feedback (pulse width modulation), which resulted to be not possible. However, they showed an increase in the performance in distinguishing object sizes when using a separate electrode for position feedback.

Study objective

The main objective of the separate studies of this study is the evaluation of grasping performance when electrotactile or vibrotactile feedback is provided compared to the non-feedback and only visual feedback situation. The main question to be answered is: Will grasping performance increase with artificial feedback? Grasping performance is defined as the time needed to complete a grasping and/or holding task and the number of errors made before reaching the desired position or deviations in the necessary force level.
Futhermore, another objective of these studies is to find the optimal stimulation settings to provide position feedback, force feedback and the combination of both types. This will be derived from the grasping performance during different feedback conditions. Within these conditions, at least the stimulation mode (vibrotactile or electrotactile), stimulation patterns and stimulator placements will be varied.

Study design

As the goal of the study is to compare the effect of feedback on grasping performance, grasping performance will be compared between situations with and without feedback. All subjects will experience all feedback conditions and therefore the study design will be a mono center experimental study.

Intervention

All subjects will receive feedback about the position of the hand and/or the gripping force of the hand through electrotactile and vibrotactile stimulation.

Study burden and risks

There are no serious risks involved in this study, but there might occur some skin problems, like redness or other irritations, after prolonged stimulation. Furthermore, electrotactile stimulation can provoke painful sensations, especially when determining the pain threshold or when the stimulus intensity has to be increased to oppose adaptation effects. These effects will be very short in duration and will not induce long term problems. Furthermore, the time needed to complete the total study (about 2 hours) may cause some mental burden to the subjects.

Contacts

Public
Universiteit Twente

Drienerlolaan 5
7522 NB Enschede

NL
Scientific
Universiteit Twente

Drienerlolaan 5
7522 NB Enschede
NL

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 years (healthy subjects and patients)
ability to control the experimental setup (healthy subjects and patients)
forearm stump of at least 10 cm. (patients)

Exclusion criteria

diminished sense of touch (healthy subjects)
experience with vibrotactile and electrotactile stimulation (healthy subjects and patients)
skin problems at the place of stimulation (healthy subjects and patients)
hypersensitivity of the skin of the stump (patients)
bilateral amputation or deficit (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):	01-06-2011
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO Date:	09-05-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	07-02-2012
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL36189.044.11