Integrating control and feedback into a trans-femoral prosthesis

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

Summary

ID

NL-OMON34125

Source
ToetsingOnline

Brief title
Integrating control and feedback into a trans-femoral prosthesis

Condition

- Other condition

Synonym
missing upper leg, trans-femoral amputation

Health condition

(bovenbeen) amputaties

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: STW,Ossur

Intervention

Keyword: control, feedback, prosthetics, trans-femoral amputation

Outcome measures

Primary outcome

: Firstly, EMG measurements are used to design an algorithm which can detect

the intention of the subject and timings of certain events during ADL (e,g,

push-off during walking) to control a prosthesis. The algorithm is then tested

and improved using healthy subjects and TFA. Secondly, feedback experiments

will provide us with a method of giving feedback to the subject on the state of

the prosthesis without conscious attention of the subject. Finally the

optimalized EMG algorithm will be combined with the best functioning feedback

modality to form a controlled TFP.

Secondary outcome

nvt.

Study description

Background summary

In the day to day life of a trans-femoral amputee (TFA) a stumble or a fall is
not uncommon, mainly due to the lack of feedback and control of the
prosthesis[23, 22]. Proprioception and motor control are essential for all
motor tasks, but that is exactly what a TFA is missing in the prosthetic leg.
The ultimate goal of this project is to allow TFA to control their prosthesis
and to give them feedback, where necessary, during activities.

Study objective

There are multiple objectives to this study. First, we want to find a way of controlling the prosthesis using electromyography (EMG) of the muscles left in the stump. Secondly, we want to find a way to give feedback to the human during certain *states* of the prosthesis. Finally we want to combine the control and feedback to form a closed-loop system.

Study design

For this study multiple experiments will be performed on healthy subjects (students), for initial testing, and TFAs, for testing and finalizing the setup. First, to determine EMG patterns, for the design of an algorithm to control the prosthesis. Secondly, to find the optimal way of giving feedback to the TFA (vibrotactile and electrotactile stimulation). Finally, evaluation experiments in TFAs to test the closed loop system.

Intervention

For the EMG measurements the subjects will receive EMG electrodes on several muscles and they will be asked to perform activities of daily life (ADL). For the feedback experiments the subjects will receive vibrotactile or electrotactile stimulation during ADL. For healthy subjects either no further intervention takes place or they will walk with a TFP-simulator designed for non-amputees (TFP-sim). The amputees will use their own socket to which either their own prosthesis or another (controllable) prosthesis will be attached. For the combined experiments both EMG electrodes and vibrotactile and / or electrotactile stimulation will be applied during ADL.

Study burden and risks

For the healthy subjects participating in the EMG experiments the burden will lie in the time it takes to prepare and perform the experiments. Some will have to learn to walk with the TFP-sim, but fall prevention will be provided, so no risk of falling is involved. For the feedback experiments the same holds, together with slight discomfort the feedback may give at some stages during the tests (i.e. during threshold determination slight pain might be felt), but there is no risk of skin damage or other injuries. For the TFAs EMG experiments are similar, they are all used to walking with a prosthesis so no risks are expected there. When providing them with another prosthesis than their own they will receive proper training and support where necessary. For the feedback experiments the burden is similar to that in healthy subjects, or less due to a better developed feedback method. TFA are needed for testing of the system, no other (patient) group can replace them, their direct benefit will be negligible although eventually they might profit from a controlled prosthesis.

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

Healthy: no lower extrimity disorders
Trans-femoral amputees: can walk by themself with prosthesis

Exclusion criteria

Healthy: neurodegenerative diseases, skin conditions legs, mental illnesses
Trans-femoral amputees: skin conditions stump, neurodegenerative diseases, mental illnesses

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):	14-11-2010
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	12-07-2010
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

No registrations found.

In other registers

Register	ID
Other	Candidate number NTR 8173
CCMO	NL32677.044.10