Towards MY smart and intuitive controlled LEG prosthesis: acquisition of electromyography for motion intention detection

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Primary Objective: The primary objective is to develop supervised algorithms for the classification of motor intentions for different activities of daily living. These algorithms are developed for both bipolar surface electromyography as well as...

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

Summary

ID

NL-OMON55509

Source
ToetsingOnline

Brief title
MyLeg: motion intention detection based on EMG

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
Amputation, Individuals without an amputation

Health condition

N.v.t.

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Europese Unie H2020-2017-ICT-25

Intervention

Keyword: Electromyography, Machine learning, Motion intention, Prosthesis

Outcome measures

Primary outcome

The primary study parameter is the misclassification rate of a classifier.

The misclssification rate of the classifier that is based on biplor EMG and

HD-EMG will be compared. In addition, misclassification rates of classifiers

developed with different techniques will also be compared.

Secondary outcome

Secundary study parameters are:

- The misclassification rate for unsupervised algorithms Unsupervised

algorithms will also be compared to supervised algorithms. To determine - - The

effect of repeated measurements on the robustness of the classifier and

regressor

- The effect of additional sensor information on misclassification rate by

using the raw IMU sensor data from the Xsens suit. This information is recorded

during measurements anyway, as Xsens uses this information in their

biomechanical model to reconstruct movements.

- The effect of prosthesis type on the robustness of the classifier

Study description

Background summary

The control of prosthetic knees is not intuitive. Where individuals without an amputation can flex and extend their knee voluntarily, individuals with an amputation cannot do that but have to movement of the residual leg (stump) to control the movement of the prosthetic knee. To realize intuitive control, researcher are working to incorporate muscle activity, as measured with electromyography, in prosthetic knee control. By investigating muscle activity one can predict the activity somebody is (about to be) performing. Based on the activity that is being performed, the prosthetis can be set to optimal settings that are needed to successfully complete the activity. There are several ways to obtain muscle activity, including bipolar (using two electrodes) and high-density EMG (HD-EMG; using a grid of electrodes). Classifiers based on HD-EMG might be superior to classifiers based on HD-EMG because with HD-EMG more data is obtained and it is less sensitive to electrode placement. The use of HD-EMG, however, has not been studied before in the context of prosthetic knee control.

Study objective

Primary Objective:
The primary objective is to develop supervised algorithms for the classification of motor intentions for different activities of daily living. These algorithms are developed for both bipolar surface electromyography as well as High-Density electromyography (HD-EMG).

Secondary Objective(s):
The secondary objectives are:
- Comparison of different methods that can be used to classify motor intentions in terms of accuracy of correct classification of the activity of daily living.
- Investigate the added value of additional (non-electromyography) sensors such as inertial magnetic units on the accuracy of the methods for the classification of motor intentions.
- Determining the consistency of the electromyography signal over the course of several measurements conducted on different days.
- Development of unsupervised algorithms for classification of motor intentions
- Development of regression algorithms to estimate joint angles
- Development of classifiers which are robust for prosthesis type

Study design

Observational study with a single measurement (n=60) and repeated (up to four) measurements (n=15) and measurements on a subgroup of individuals with an

amputation (n=5) getting an intervention (active prosthesis).

Intervention

Subgroup of individuals with an amputation (n=5) will be walking on an active prothesis during train and measurement sessions. This group also takes the prothesis home between the trainingsessions for additional practice.

Study burden and risks

The burden and risk associated with participation is considered low. The activities that are studied are activities that are routinely performed during daily life. In addition, the measurements do not interfere with the execution of daily life therefore not putting an additional strain on subjects to execute the activities. Participants do not benefit from participation.

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

Individuals without an amputation
- Aged 18 or above.
- Able to perform low to moderate vigorous physical activity for a duration of 3 hours including breaks. , Individuals with an amputation
- Aged 18 or above.
- Unilateral transfemoral amputation or knee disarticulation.
- Functional level from K2 to K4.
o Level 2: The patient has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the community ambulator.
o Level 3: The patient has the ability or potential for ambulation with variable cadence. Typical of the community ambulatory who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
o Level 4: The patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.
- Able to perform low to moderate vigorous physical activity for a duration of 3 hours including breaks.
- At least one year after amputation.

Exclusion criteria

Individuals without an amputation
- Not willing to consent to participate in the study.
- Musculoskeletal problems influencing walking ability., Individuals with an amputation:
- Not willing to consent to participate in the study.
- Other musculoskeletal problems influencing walking ability.
- Stump problems/bad socket fitting

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):	14-12-2018
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	13-12-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-03-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-09-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-03-2021
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL67247.044.18