Towards a smart and intuitive controlled MyLeg prosthesis: acquisition of intramuscular electromyography for motion intention detection. A pilot study.

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Primary Objective:Develop improved movement prediction for transfemoral amputees by application of iEMG (in comparison to sEMG), and moreover to determine to what extent TMR can contribute to this improvement.Secondary Objective(s):- Verify if the...

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

Summary

ID

NL-OMON49529

Source
ToetsingOnline

Brief title
MyLeg: motion intention detection based on intramuscular EMG and TMR

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
transfemoral amputation, upper leg amputation

Health condition

chirurgische en medische verrichtingen: zenuwstelsel therapeutische verrichtingen

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: EMG, Motion intention, Prosthesis, TMR

Outcome measures

Primary outcome

The main study parameters are the misclassification rates of a classifier, while varying the input (iEMG versus sEMG data, TMR versus non-TMR data). In addition, the corresponding confusion matrixes will provide insight in what the classification model is getting right (for instance the difference between walking and ascending stairs) and what types of errors it makes (for instance often confusing slow walking with walking on uneven terrain).

Secondary outcome

The secondary study parameters are:

- Average muscle activation pattern of the TMR site and the original site of innervation during a gait cycle of activities of daily life (normal walking, stair ascent, ramp descend, etc.).
- Muscle activation patterns of intramuscular TMR site and the reconstructed version from the multi-array sEMG (after extensive signal analysis).
- Bland-Altman plots and the Root Mean Square Error to estimate a goodness-of-fit for joint angles prediction based on sEMG and iEMG.

Study description

Background summary

The control of prosthetic legs is not intuitive. Where individuals without an amputation can flex and extend their joints voluntarily, individuals with an amputation cannot do that but have to use movements of the residual leg (stump) to control the movement of the prosthetic device. To realize intuitive control, researchers are working to incorporate muscle activity, as measured with surface electromyography (sEMG), in prosthetic leg control. By investigating muscle activity one can predict the activity somebody is (about to be) performing, like walking on a ramp or ascending stairs. Based on the activity that is about to be performed the prosthesis can be set to optimal biomechanical properties that are needed to successfully complete the activity. The state-of-the-art sEMG-based prediction, with a misclassification rate of 7.9% [1], has a high risk of stumble and falls. For this reason, it is still not good enough for clinical application. Therefore, this pilot study explores the use of intramuscular EMG (iEMG) and targeted muscle reinnervation (TMR) to improve prediction results. The hypothesis is that iEMG will improve prediction results because of the more consistent electrode sites, reduced crosstalk, and acquisition of signals from deeply located muscles. Further, TMR will provide additional muscle signals which is valuable extra information for movement prediction.

[1] L. J. Hargrove et al., *Intuitive control of a powered prosthetic leg during ambulation: A randomized clinical trial,* JAMA - J. Am. Med. Assoc., vol. 313, no. 22, pp. 2244*2252, 2015.

Study objective

Primary Objective:
Develop improved movement prediction for transfemoral amputees by application of iEMG (in comparison to sEMG), and moreover to determine to what extent TMR can contribute to this improvement.

Secondary Objective(s):
- Verify if the muscle activation patterns of the phantom lower leg (TMR sites) are similar to the activation patterns in a lower leg of an individual without an amputation.
- Investigate if TMR activation patterns, as derived from intramuscular TMR sites (located deep), can be extracted from the multi-array sEMG data.
- Explore the possibilities of direct control with both iEMG and sEMG, with presence of TMR.

Study design

Observational study (pilot).

Study burden and risks

The burden and risks associated with participation are limited to a minimum, since the activities which will be performed by the participants represent functional and familiar movements and the tasks are performed only within the scope of the subject*s ability. Furthermore, most measurements used in this study (kinematics, sEMG) are non-invasive and involve no risks to the participants in any way. The only invasive measure is the intramuscular EMG via fine-wires, which might cause minor discomfort but is routinely used in clinical studies. Participants will not directly 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

Transfemoral amputees with targeted muscle reinnervation:
- Aged 18 or above.
- Unilateral transfemoral amputation.
- At least one year after osseointegration implant surgery.
- At least six months after TMR surgery and visible contractions (by ultrasound) of the TMR sites.
- Functional level defined as Medicare Functional Classification Level 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 limited 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 1 hour including breaks.

Transfemoral amputees:
- Aged 18 or above.
- Unilateral transfemoral amputation.
- At least one year after osseointegration implant surgery.
- Functional level defined as Medicare Functional Classification Level K2 to K4 [12]; see description above.
- Able to perform low to moderate vigorous physical activity for a duration of 1 hour including breaks.

Able-bodied:
- Aged 18 or above.
- Able to perform low to moderate vigorous physical activity for a duration of 1 hour including breaks.

Exclusion criteria

Transfemoral amputees (with targeted muscle reinnervation):
- Not willing to consent to participate in the study.
- Other musculoskeletal problems influencing walking abilities.
- Stump problems: untreated skin conditions, wounds, infections, or problems affecting walking ability.

- Taking coumarin-derivatives and having an INR > 3.0. (Subjects with an INR * 3.0 or using NOACs will be included in the study, and informed about the slightly increased bleeding risk.)
- Have had amputation because of infection and/or bad wound healing.

Able-bodied:
- Not willing to consent to participate in the study.
- Musculoskeletal problems influencing walking ability.
- Taking coumarin-derivatives and having an INR > 3.0. (Subjects with an INR * 3.0 or using NOACs will be included in the study, and informed about the slightly increased bleeding risk.)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2021
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL75528.091.20
Other	nog onbekend