DESIGN OF REAL-TIME NEUROMUSCULOSKELETAL MODELS FOR INTUITIVE AND ROBUST POWERED ANKLE PROSTHESIS CONTROL

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON56131

Source
ToetsingOnline

Brief title
Real-time musculoskeletal model prosthesis control

Condition

- Other condition
- Bone and joint injuries

Synonym
limb loss, lower limb amputation

Health condition

amputations

Research involving
Human

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: Marie Sk□odowska-Curie Actions (MSCA) Innovative Training Networks (ITN) H2020-MSCA-ITN-2019 - 860850 - SimBionics (Neuromechanical Simulation and Sensory Feedback for the Control of Bionic Legs),Otto Bock BV

Intervention

Keyword: ankle prosthetic, control, lower limb, neuromusculoskeletal model

Outcome measures

Primary outcome

The main study parameters are comparisons between measurements performed with

different controllers of the EMPOWER to evaluate their effect:

• Gait kinematics (a), obtained from patients

Comparison with the default controller

Left-to-right asymmetry

• Peak of the joint torque and timing of joint torque (a)

Comparison with the default controller

Analysis between the sound side and the prosthetic side

• Ankle and knee power (a)

Comparison with the default controller

Analysis between the sound side and the prosthetic

side

• Differences between control input (e)(b)(a)

• Data from all sensors are used to evaluate the step length, step height,

speed estimation, loading of the prosthesis, foot placement, healthy and

prosthetic joint torques, and evaluate correct switching between different

speeds

• COM, COP and GRF signals (a) to evaluate the balance strategies (recovery)

Secondary outcome

The secondary study parameters are:

• Joint compression load at the ankle and knee (a)

Comparison with the default controller

Analysis between the sound side and the prosthetic side

• Joint torque and timing of joint torque (a)

Comparison with the default controller

Analysis between the sound side and the prosthetic side

• Output from the prosthesis

• Work at the ankle joint on the prosthetic side

• Muscle activity (b) to evaluate changes in the use of different controllers

Study description

Background summary

Powered ankle prosthetics have the potential to improve the mobility of patients supporting individuals to walk better reducing energy consumptions thanks to the support they give during push off phase compared to non-powered prosthesis. However, the control of such devices has still weaknesses that prevent the user to perform various activities in a natural and safe manner and regain balance after perturbations. Creating a new interface between the powered prosthetic for the lower limb and the patient could overcome these before mentioned problems.

This study proposes three different control approaches that implement a control system that mimics the muscle dynamics and motor control strategies in humans. The goal of this research is to assess a neuro-mechanical model able to online control a prosthetic ankle joint according to subject-specific and motor task-specific properties. We will test an EMG-driven model-based controller, a synergies-driven model-based controller, and an enhanced reflex-driven model-based controller. ln comparison with the default controller of the Empower prosthetic foot from Ottobock, which already includes a neuromuscular reflex-based model.

Study objective

The primary objective of the current project is to develop and test a real-time accurate neuro-mechanical model-based controllers of the lower limb The hypothesis are that the synergy-driven approach would adapt to changes in speed, the enhanced reflex-driven approach with additional feedback pathways would support balance, and the EMG-driven controller would improve voluntary control of the prosthesis especially to execute movement that are not accounted for in the previous mentioned models, like ascending and descending stairs/ramps.
The secondary objective is to assess the mechanical loads on the healthy side comparing each system to the default one.
Additionally, the difference in adaptation rate and preferences of patients to the device are going to be investigated by a qualitative questionnarie.

Study design

Observational study in which a maximum of ten transtibial amputees will perform different session walking on the treadmill to compare three different controllers: an EMG-driven model, a synergy-driven model , and a reflex-driven model.
Patients will undergo the following measurements in two days:
On the first day, the subject is included in the study (model calibration) and he/she will interface the prosthesis device with the default control of the empower and test the first developed enahnced reflex-driven controller including perturbed walking trials to evaluate balance recovery. On the second day, thesynergy-driven controller and EMG-driven controller would be tested. There will also be a third day of trials , which is optional.

Study burden and risks

The patients will not have any personal benefit from participation.
The risks for the subjects participating in this study are small. All experiments are performed wearing a fall prevention system (safety harness or the ZeroG system, which is CE-marked). This creates a safe and controlled environment for all activities investigated in this study.

There are no immediate risks of physical harm associated with the proposed study.
• Measurement equipment: The used measurement equipment, is certified for its use, and at most causes discomfort for the subject: The EMG electrodes and motion capture markers can cause skin irritation (shaving, cleaning or removal or tape).
• Experimental equipment: A potential risk might be unexpected behaviour of the prosthetic ankle. Participants will use a safety harness in the Rehabilitation Lab or the ZeroG system, which is CE-marked, in the Wearable Robotics Lab. In case the prosthetic ankle acts differently than expected, the user can regain balance using either the safety harness or the handlebars around the treadmill. Moreover, the treadmill is safe to use. The treadmill can be stopped with an emergency button at any time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

Person is minimum 18 and maximum 60 years old.
Person has unilateral transtibial amputation
Person is able to walk with everyday prosthesis
Person with a body weight of less than 120 kg and BMI in the range from 18.5 to 29.9 kg/m^2 (normal to overweight)
Person who is willing and able to independently provide informed consent
Person who is willing to comply with study procedures
Person who finished rehabilitation trajectory and using own prosthesis at home for > 3 months.
Person who has an adequate, well-fitted socket
Functional level from K3 to K4 (even if balance issues occurs more for K2, for the current protocol that includes walking sessions on the treadmill it is better to exclude them to be able to complete the trial):
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.
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.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Pregnant women
* Person with conditions that would prevent participation and pose increased risk (e.g. unstable cardiovascular conditions that preclude physical activity such as walking)
* Person with weakened bones (e.g. osteoporosis)
* Person with a history of chronic skin breakdown of the residual limb
* Person who falls at least once a week for reasons that are not related to prosthetic use (e.g. problems with vestibular system)
* Person who has life-threatening medical condition (e.g. terminal cancer, severe heart disease)
* Person who is using under arm axillary crutches or walker
* Person in an emergency, life threatening situation
* Person who underwent osseointegration operation

* Person who is allergic to band aids or glue

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-11-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Empower
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-01-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-11-2023
Application type:	Amendment
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	NL81380.091.22