Individualized Optimization of a tuneable prosthetic foot to lower the metabolic cost of walking for transtibial amputees

Published: 03-10-2023
Last updated: 07-03-2025

The aim of the current project is to evaluate the effect of a prosthetic foot, which can be individually optimized using human in the loop optimization, on metabolic cost of walking for transtibial amputees. We want to investigate both the effect of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON53194

Source
ToetsingOnline

Brief title
Individualized optimization of a tuneable prosthetic foot

Condition

- Bone and joint injuries
- Bone disorders (excl congenital and fractures)

Synonym
onderbeengamputeerde, Transtibial amputees

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Human-in-the-loop optimization, Prosthetic foot, Walking

Outcome measures

Primary outcome

Metabolic cost of walking.

Secondary outcome

- Kinetics and kinematics of the lower extremities

- Optimal joint stiffness and alignment settings for every individual

participant

Study description

Background summary

People after lower-limb amputation often experience reduced quality of life. The reduction in quality of life is to a great extent the consequence of the diminished mobility. To improve mobility, people after lower-limb amputations are provided with an artificial limb that imitates the biological ankle-foot function. However, current prostheses do not succeed to fully compensate for the normal foot-ankle system and people with an amputation prefer a lower self-selected walking speed. Altogether, this results in a 35% increase of metabolic cost of walking compared to able bodied controls at similar walking speeds.
To lower the metabolic cost of walking and improve mobility of lower-limb amputees, the natural foot roll over function and push-off needs to be restored. However, problems with the timing of energy return of the prosthetic foot have been observed and the importance of prescribing individually-tailored prosthetic components was already highlighted. Due to the difficulties in individual tuning of prosthetic components, the effectiveness of current state of the art assistive devices stays behind expectations.
A potential method to overcome these challenges is human-in-the-loop optimization, in which the human is included *in vivo* in the control loop and device parameters are systematically varied using an intelligent optimization algorithm in response to a defined and directly measured cost function to optimize human (-machine) performance. By means of this method, the parameters can be tuned to biomechanical properties of the individual while taking into

account the natural adaptive behaviour of humans who simultaneously optimize coordination patterns with respect to locomotor performance.

Study objective

The aim of the current project is to evaluate the effect of a prosthetic foot, which can be individually optimized using human in the loop optimization, on metabolic cost of walking for transtibial amputees. We want to investigate both the effect of the change in foot properties (i.e. joint stiffness and alignment) as well as the effect of motor learning during this process on the final reduction in metabolic cost after human-in-the-loop optimization.

Study design

Pre-posttest quasi experimental repeated measures design.

Intervention

Participants will use a passive prosthetic foot with a manually tuneable joint stiffness and alignment. During the optimization period, we will aim to optimize the joint stiffness and alignment of the prosthetic foot to minimize the metabolic cost of walking. The joint stiffness and alignment will be changed manually by changing the position of the joint slider and the 'tendon' length of the prosthesis. The settings that resulted in the lowest metabolic cost of walking will be selected as optimal settings and will be compared with the tuneable prosthetic foot with standard settings (reference joint stiffness from participant*s personal prosthetic foot and neutral alignment), and the participant*s personal prosthetic foot.

Study burden and risks

Participants (transtibial amputees) will be invited twice to the GRAIL lab of the Center for Rehabilitation of the UMCG, Beatrixoord. During the visits the participants will be asked to walk on the treadmill on self-selected walking speed, while data for breathing gas exchange, kinematics and kinetics are collected. The burden for the participants is that they have to spend about 4 hours in the lab and have to walk for almost one hour (with intermediate brakes) during each session at self-selected comfortable submaximal walking speed.
During the visits, the participants will wear a prosthetic foot with manually tuneable joint stiffness and alignment. Although fitted by a certified prosthetist, use of this prototype can cause some discomfort. Walking with the new prototype can feel uncomfortable, mostly at the beginning of practice with the prosthesis. Getting used to a new prosthesis, like this prototype, may also cause muscle strain. However, these effects are not different from when the patient is provided with a new prosthesis as part of regular clinical

management. Although the prosthetic prototype has been extensively tested for safety and use, the unlikely event that the prototype may break could cause a participant to fall. However, when using the prototype, the participants will always wear a safety-harness, which will prevent them from harm in the event of a fall. In addition, the researcher will always be present and next to the participant to support the participant and prevent a fall from happening.

Contacts

Public
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1 1
Groningen 9713AV
NL
Scientific
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1 1
Groningen 9713AV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Aged >= 18 years
- Shoe size 42-44
- Have a unilateral transtibial amputation
- Underwent the amputation more than 1 year ago

- Able to walk independently

Exclusion criteria

- Any vascular, neurological or musculoskeletal conditions affecting balance or gait
- Use of drugs or other medication negatively affecting balance or gait
- Use of orthopaedic footwear for the intact leg
- Body mass >= 100 kg
- Current problems with the alignment or fit of their prosthesis or socket
- Use of an osseointegrated implant

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-03-2024
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Tuneable prosthetic foot
Registration:	No

Ethics review

Approved WMO Date:	03-10-2023

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-02-2025
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL84819.042.23