Gait stability on slopes and lateral inclines in transtibial and transfemoral amputees.

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To deliver:data to be used as part of a reference database for the EUROBENCH-framework.To assess:- to what extent transfemoral and transtibial amputees are able to adapt to standing and walking on slopes and laterally inclined surfaces in terms of...

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

Summary

ID

NL-OMON49022

Source
ToetsingOnline

Brief title
Walking with a prosthesis: ups and downs

Condition

- Other condition

Synonym
Leg amputation, Leg cut-off

Health condition

Beenamputatie

Research involving
Human

Sponsors and support

Primary sponsor: Militair Revalidatie Centrum 'Aardenburg'
Source(s) of monetary or material Support: Ministerie van OC&W,Deel van het EUROBENCH-framework;European Union□s Horizon 2020 grant agreement No 779963,OIM Orthopedie

Intervention

Keyword: Amputation, Gait, Slopes, Stability

Outcome measures

Primary outcome

Standing stability measures for each slope:

- mean center of pressure (COP) velocity

- COP anteroposterior sway

- COP mediolateral sway

Gait stability measures for each slope:

- local divergence exponents

- foot placement coordination

- margins of stability

Secondary outcome

Spatiotemporal gait parameters: step length, step width and step frequency.

Hip, knee and ankle joint kinematics (movements) and kinetics (moments).

Anthropometric data (height, weight, age, segmental circumferences).

Study description

Background summary

This study is part of the Dutch UDBenchmark-project, which is part of the European EUROBENCH-framework (eurobench2020.eu).

EUROBENCH aims to create the first framework for the application of benchmarking methodology on robotic systems. The framework, specifically focused on bipedal robotic technologies (humanoids and exoskeletons), will include methods and tools to measure System Ability Levels on a rigorous, quantitative and replicable way, both during stance and during gait.

The UDBenchmark-project is a collaboration between the VU University, Amsterdam, The Netherlands, Military Rehabilitation Center 'Aardenburg', Doorn, The Netherlands and Heliomare, Wijk aan Zee, the Netherlands. The goals of this project are to deliver:
(1) a minimal and flexible measurement protocol, ...
(2) data analysis software, ...
(3) a reference database ...
to assess how exoskeletons and humanoids perform while walking on slopes and lateral inclines.

The measurements for which approval is requested can be used to assess:
- to what extent transfemoral and transtibial amputees are able to adapt to standing and walking on slopes and laterally inclined surfaces in terms of standing and walking stability and
- how this stability is related to different prosthetic components

Using a more extensive variant of this protocol we measured 20 healthy subject over a range of walking speeds, slopes and lateral inclines, both with and without an extension limiting knee brace or mobility limiting ankle brace. The protocol of this study was evaluated and approved by the Scientific and Ethical Review Board of the Faculty of Behavioral and Movement Sciences from the VU University, Amsterdam, The Netherlands.

Study objective

To deliver:
data to be used as part of a reference database for the EUROBENCH-framework.

To assess:
- to what extent transfemoral and transtibial amputees are able to adapt to standing and walking on slopes and laterally inclined surfaces in terms of standing and walking stability and
- how this stability is related to different prosthetic components

Study design

Quasi Experimental

Intervention

During the experiment, subjects stand or walk on a treadmill at a pace of 0.6 (m/s) (2.16 km/h), while the slope of the treadmill increases in steps of 3 degrees from 0 to a maximum of 15 degrees in anteroposterior or lateral direction. Transtibial amputees will undergo this protocol on a carbon fibre prosthetic foot and a glass fiber prosthetic foot.

All combinations of these conditions and prosthetic components will be offered as individual trials, resulting in a total of 2 (standing/walking) x 2 (slope/lateral incline) = 4 trials for transfemoral amputees and 8 trials (4 trials x 2 prosthetic feet) in transtibial amputees.
If the subjects feel or appear unable to continue standing or walking on a given slope, the trial will be stopped.

Study burden and risks

The duration of this protocol is up to 120 minutes for transfemoral amputees and up to 180 minutes for transtibial amputees. Since all subjects will be recruited from the Netherlands, and measurements take place in Doorn, maximal travel time is estimated 4 hours (2 hours from and to Groningen or Maastricht).
The tests will be performed in an unfamiliar virtual reality laboratory, that can be somewhat intimidating to the subjects.
The amplitudes of imposed slopes could be larger than the maximal capacity of transtibial amputees and probably is larger than the maximal capacity of transfemoral amputees, which could result in a fall if the subject or researcher does not decide to stop in time. To prevent negative consequences as a result of a fall, all subjects will wear a safety harness.
The gait lab (CAREN: Computer Assisted Rehabilitation ENvironment) of the military rehabilitation center is used on a daily basis to improve patients' ability to walk on varying slopes as part of a multidisciplinary rehabilitation program. These patients include transtibial and transfemoral amputees.
The military rehabilitation center has worked with this system for more than 10 years. Dr. M.R. Prins, who will be present at all the measurements, is registered in the BIG-registry as a physiotherapist and has been working fulltime at the VR rehabilitation department of the rehabilitation center for 10 years (and
still works there fulltime). Therefor, we estimate the chance of unforeseen risks as 'low'.

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

Uni-lateral transtibial (n<=10) or transfemoral (n<=5) amputation;
Wearing a prosthesis for at least 1 year;
Able to walk without assistive walking aid on flat surfaces and mild slopes (3 degrees)
At least 18 years old;

Exclusion criteria

Use of a computer assisted foot;
Stump problems;
Cognitive or communicative disorders;
Visual impairments.
Any condition (other than leg amputation) that might interfere with gait (e.g. neurodegenerative disease, peripheral vascular disease)
Any condition that renders unfit to be tested (e.g. severe cardiovascular conditions)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2020
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL72723.028.20

Study results

Date completed:	23-03-2022
Actual enrolment:	15