Application of external socket reaction moments to quantify uni-lateral transtibial prosthetic alignment

Published: 17-12-2014
Last updated: 21-04-2024

The primary objective of this study is to investigate whether computer assisted prosthetic alignment can influence the average external socket reaction moments in the frontal plane during stance phase for transtibial amputees. The secondary…

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

Summary

ID

NL-OMON41216

Source
ToetsingOnline

Brief title
ESRM to quantify transtibial prosthetic alignment

Condition

- Other condition

Synonym
below knee amputation, transtibial amputation

Health condition

amputatie en prothesiologie

Research involving
Human

Sponsors and support

Primary sponsor: Militair Revalidatie Centrum Aardenburg
Source(s) of monetary or material Support: Militair Revalidatie Centrum Aardenburg;Doorn;the Netherlands

Intervention

Keyword: Alignment, Amputee, Prosthetic, Quantification

Outcome measures

Primary outcome

The mean-root-squared external socket reaction moment (ESRM) at the base of the socket after dynamic alignment and the mean-root-squared external socket reaction moment after computer-assisted alignment.

Secondary outcome

The spatiotemporal gait parameters and the socket comfort score during both alignment conditions.

Study description

Background summary

Alignment of the prosthesis is currently an un-quantified iterative process, based on observation and communication between certified prosthetist and patient. Inadequate alignment results in compensatory mechanisms of the amputee. Assessment of symmetrical walking by exclusively looking at kinematic gait deviations, excludes the adaptability of the human body. Recently the moments working at the base of the socket are used in an effort to quantify prosthetic alignment, with promising results. There is a necessity for evidence-based clinical practice in relation to prosthetic alignment and quantification, enabling prosthetists to provide evidence based clinical interventions.

Study objective

The primary objective of this study is to investigate whether computer assisted

prosthetic alignment can influence the average external socket reaction moments in the frontal plane during stance phase for transtibial amputees. The secondary objective is to investigate whether an external socket reaction moment can be altered to an standardized mean external socket reaction moment during stance for different amputees.

Study design

The patient*s comfortable walking speed will be determined on their daily prosthetic and used for further testing. A certified prosthetist (CP) will receive all the prosthetic components, i.e. prosthetic foot, tube, adapter, Intelligent Prosthetic Endo-Skeletal Component System (iPecs-system), pin-system, prosthetic socket, shoes and will be asked to do a bench alignment. Where after, a prosthetic dynamic alignment will be preformed. Gait data will be measurement by the Gait Real-time Analysis Interactive Lab (GRAIL) and iPecs. After dynamic alignment the real-time external socket reaction moment (ESRM) will be shown on the GRAIL*s screen. The CP will fine-tune the prosthetic alignment by the mean external socket reaction moment during stance phase.

Study burden and risks

The burdens or risks associated with this research are not different from the risks and burdens of patients normally visiting a Prosthetics and Orthotics facility. A better understanding of alignment and achieving a more quantifiable approach will result in a more reliable alignment session inside prosthetic facilities. Where after, evidenced based alignment could reduce the risk on secondary condition, associated with a wrong alignment.

Contacts

Public
Militair Revalidatie Centrum Aardenburg

Korte Molenweg 3
Doorn 3941 PW
NL
Scientific
Militair Revalidatie Centrum Aardenburg

Korte Molenweg 3
Doorn 3941 PW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Uni-lateral transtibial amputees;
Wearing a prosthetic for at least 1 year;
Able to walk without assistive walking aid during measurements;
At least 18 years old;
Using a prosthetic leg with a pin-suspension;
No restrictions are being made due to: gender or ethnic background.

Exclusion criteria

Use of a computer assisted foot;
Stump problems;
Cognitive or communicative disorders;
Visual impairments.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Prosthetic limb
Registration:	No

Ethics review

Approved WMO Date:	17-12-2014
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	NL50704.028.14