Evaluation of a new powered knee prosthesis (Reboocon IntelLeg Knee)

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

Summary

ID

NL-OMON49303

Source
ToetsingOnline

Brief title
Evaluation of Reboocon IntelLeg Knee

Condition

- Other condition
- Joint disorders

Synonym
'Amputation' and 'Lower limb loss'

Health condition

Transfemorale amputatie (als gevolg van bijvoorbeeld trauma of diabetes)

Research involving
Human

Sponsors and support

Primary sponsor: Reboocon Bionics (medeverrichter naast de Universiteit Twente)
Source(s) of monetary or material Support: Reboocon Holding B.V.;Hendrik Tollensstraat 84;2624 BJ;Delft

Intervention

Keyword: Control, Intention detection, Prosthesis, Transfemoral

Outcome measures

Primary outcome

The main study parameters/ endpoints of part I are the comparison of kinematics to normative data (Winter, 1984), the Borg-Scale (rate of perceived effort) for different control algorithms and different activities and are all sensory data from the IntelLeg Knee. These parameters will be used to determine the optimal controllers for the IntelLeg Knee.

The main study parameter/ endpoints of part II are comparisons between baseline and intervention measurements, such as self-selected preferred walking speed, fastest walking speed, metabolic energy consumption during walking, uphill walking and stair negotiation, Borg-Scale (rate of perceived effort), relevant subscores of the Prosthesis Evaluation Questionnaire, the Hill Assessment Index, the Stair Assessment Index, the time to complete the L-test, TUG-test and time to complete the Four Square Step Test.

Secondary outcome

The secondary study parameters/ endpoints of part I are videos recorded during the measurements.

The secondary study parameters/ endpoints of part II are all sensory data from the IntelLeg Knee, classification accuracy of intent recognition algorithms

using the IntelLeg Knee, kinematics (including left-to-right symmetry) and

muscle activity (to assess significant changes between subject*s daily use

prosthetic knee and the IntelLeg Knee)

Study description

Background summary

As of now, the commercial market remains mostly exclusive to passive, auto-adapative knee prostheses (e.g. Össur Rheo Knee, Otto Bock C-Leg/ Genium, Freedom Innovation Plie, Blatchford Orion). Only one powered, motorized knee prosthesis is available, the Össur Power Knee. Unfortunately, the first generation of the Power Knee (as introduced in 2006) was not well received, as it was expensive, bulky, heavy, noisy and had a short battery life of around 6 hours (Edelstein and Moroz 2011). As a matter of fact, there is no agreement in scientific literature on the benefits of the Power Knee with respect to passive knee prostheses. Although some research find that the active knee prosthesis improves symmetry and reduces load of the intact leg for some tasks (Wolf, Everding et al. 2012, Simon, Fey et al. 2016), Hafner and Askew (Hafner and Askew 2015) report that the Össur Power Knee (second generation) *significantly limited users laboratory based mobility and overall daily activity* and that *active knee control, as it is implemented in the Power Knee II, may not be ideal for middle-age or older persons with TFA*.
The start-up company Reboocon Bionics B.V. has developed a new lightweight powered knee prosthesis, referred to as the IntelLeg Knee. This knee prosthesis is lightweight (2.5 kg including battery) and is actuated using a spindle mechanism. It is expected that transfemoral amputees may benefit from the IntelLeg Knee compared to the their passive, auto-adaptive or mechanical daily use prosthesis. The IntelLeg Knee provides full control of the knee joint and is able to inject energy into the system, allowing for active promotion of stance knee flexion during gait (Creylman, Knippels et al. 2016) and performing more energy-demanding tasks with less effort, such as getting up from a chair (Wolf, Everding et al. 2013), step-over-step stair ascent (Young and Hargrove 2016, Ledoux and Goldfarb 2017) or upslope walking (Sup, Varol et al. 2011). As becomes clear from the study of Hafner and Askew (Hafner and Askew 2015), the type of active control used is of key importance for the performance of the IntelLeg Knee. Therefore, this study is focussed on developing and evaluating different controllers for a relevant subset of activities, including algorithms which are concerned with identifying the intent of the user, to be evaluated using the IntelLeg Knee.

Study objective

The primary objective is to evaluate the added value of the IntelLeg Knee on the execution of activities of daily living for individuals with a transfemoral amputation when compared to the use of an auto-adaptive or mechanical (non-powered) prosthetic knee. The second objectives are to develop control algorithms to restore natural movement of the knee for different activities of daily living and to develop unambiguous, robust and natural transitioning between different activity modes.

Study design

The study consists of two main parts. The first part, concerned with developing control algorithms for different activities and transitioning between activity modes, is designed as an iterative usability study. The second part, concerned with comparing the IntelLeg Knee to other passive prostheses in individuals with a unilateral transfemoral amputee, is designed as a comparative study. In this study, measurements with the participants' daily use prosthesis and IntelLeg Knee will be done within the same session, allowing for direct comparison between both knees.

Intervention

Not applicable

Study burden and risks

All experiments are non-invasive, in which participants are asked to perform activities of daily living. Study one entails 10 weekly usability sessions, each requiring about 2 hours of active participation (20 hours in total). Part II of the study), lasts 6 weeks with 2 measurements sessions (3 hours) and 4 training session (2 hours). A separate session to fit the IntelLeg Knee to the subject will require about 1 hours. Thus, in these 6 weeks, participants spend about 15 hours of active participation. All participants can take rest during the experiments and participate at their own pace.
The risks for the subjects participating in this study are small. All experiments are performed wearing a fall prevention system (the ZeroG system, CE-marked), which will prevent any injury and prevent the subjects from falling. This creates a safe and controlled environment for all activities investigated in this study.
The study does not lead to any direct benefits for the subjects, but may lead to improved control or insights to the added benefit of the IntelLeg Knee.

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

Individuals without an amputation
- Aged between 18 and 65.
- Body length between 1.20 and 1.95 m.
- Weight below 125 kg.
- Able to perform low to moderate vigorous physical activity for a duration of 3 hours including breaks., Individuals with an amputation
- Aged between 18 and 65.
- Weight below 125 kg.
- Body length between 1.20 and 1.95 m.
- Unilateral transfemoral amputation or knee disarticulation.
- Auto-adaptive or mechanical prosthesis user
- Functional level from 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 3 hours including breaks.
- Has finished rehabilitation and uses own prosthesis at home for more than 3 months.
- Willing to commit to a series of 4 training sessions to get adjusted to the IntelLeg Knee.

Exclusion criteria

Individuals without an amputation:
- Not willing to consent to participate in the study.
- Musculoskeletal problems influencing walking ability., Individuals with an amputation:
- Not willing to consent to participate in the study.
- Other musculoskeletal problems influencing walking ability.
- Stump problems/bad socket fitting, Only for study I (for both individuals with and individuals without amputation):
- For the second and third individual with amputation, subject*s weight differs more than 15 kg of already included subject(s) or subject*s length differs more than 15 cm of already included subject(s).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	02-02-2019
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	IntelLeg Knee
Registration:	No

Ethics review

Approved WMO Date:	21-05-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-03-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25551
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68471.044.18

Register	ID
OMON	NL-OMON25551