Extended evaluation of a new powered knee prosthesis (Reboocon IntelLeg Knee) through musculoskeletal simulations

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

Summary

ID

NL-OMON52009

Source
ToetsingOnline

Brief title
Extended evaluation of IntelLeg Knee

Condition

- Other condition

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 Bionoics (medeverrichter naast de Universiteit Twente)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Musculoskeletal, Prosthetic, Simulation, Tranfemoral

Outcome measures

Primary outcome

The main study parameters for the first part of the study are joint kinetics and joint load and induced acceleration analyses, obtained through musculoskeletal simulations. Left-to-right symmetry mean and peak values and the timing of peak values will be evaluated between the prostheses, as well as comparing them to literature. For the second part of the study the study parameters are the same, now comparing the analyses only for level-walking for the IntelLeg Knee before and after subject specific parameter adjustment and gait instructions, using the daily prosthesis as reference.

Secondary outcome

Not applicable.

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 & 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 (Hafner & Askew, 2015; Simon et al., 2016; Wolf et al., 2012).

The company Reboocon Bionics B.V. has developed a new lightweight powered knee prosthesis, referred to as the IntelLeg Knee. This knee prosthesis is lightweight (2.4 kg including battery) and is actuated using a spindle mechanism. It is expected that transfemoral amputees may benefit from the IntelLeg Knee compared to their 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 et al., 2016). The injection of power can possibly decrease the load on, and work done by, the sound leg (Ingraham et al., 2016; Pasquina et al., 2017) during gait as well as reduce the level of asymmetry in muscle activation in the low back spinae regions and lower extremity muscles (Jayaraman et al., 2018). On top of that, the IntelLeg might be beneficial in particular when performing more energy-demanding tasks, such as getting up from a chair (Wolf et al., 2013), crossing over obstacles (Mendez et al., 2020) and also might be able to make a running gait possible (Shultz et al., 2015).

The proposed study extends earlier clinical evaluation (NL68471.044.18 - Evaluation of Reboocon IntelLeg Knee (ILK).) The previous study focussed on testing different movement controllers and compare the IntelLeg knee to the daily use prosthesis of subjects. The main study parameters were temporal-spatial and kinetic parameters as well as subjective evaluations.

This newly proposed study extends the evaluation in two ways. First, musculoskeletal simulations will be done for the walking gait which gives the possibilities to investigate joint kinetics and make joint load and induced acceleration analyses. This can give information on the loading of both legs, joint power generation and joint contact forces. It has been found that right now transfemoral amputees load their legs asymmetrical (Vrieling et al., 2008), which can lead to joint degeneration (Burke et al., 1978; Hurwitz et al., 2001) and lower back pain (Jayaraman et al., 2018; Shojaei et al., 2016). On top of that, induced acceleration analyses will be done to identify the effect of the muscles and prosthesis towards the center of mass trajectories. This can give the ability to find out if the prosthesis takes over the muscle function of the missing muscles (vasti, soleus and gastrocnemius) as well as to find gait compensatory mechanism.

Next to analysing regular walking gait, three other activities will be evaluated using the same techniques: sit-to-stand, stepping over an object and running. Stepping over an object and running were not evaluated in the previous study. The running gait will only be evaluated with subjects capable of already achieving a running gait with their current prosthesis. Next to using the results to give a better insight in the IntelLeg Knee performance, there is

either very little or no literature available on the proposed analyses with passive or powered prostheses, making this study contribute to the current scientific research.

The second part of the study evaluates the possibilities of improving gait with subject specific instructions as well as tweaking prosthesis parameters. This will be done based on the results gained through musculoskeletal simulations. The main goal is to make the subject use the full potential of the powered prosthesis which requires different gait strategies than with a non-powered prosthesis.

Study objective

The primary objective is to compare the IntelLeg Knee on the execution of a subset of daily activities for individuals with a transfemoral amputation to auto-adaptive or mechanical (non-powered) prosthetic knee via musculoskeletal simulation. The device will be evaluated using joint kinetics, joint load analyses and induced acceleration analysis analyses. The secondary objectives are exploring the possibilities of using results from musculoskeletal simulation to improve gait instructions and prosthesis parameters and make a useability analysis and design validation of the IntelLeg Knee.

Study design

The study consists of two main parts. The first part, focused on a subset of daily activities, is designed as an intervention study. The IntelLeg Knee is compared to the daily use prothesis of the subjects with unilateral transfemoral amputee. The second part of the study is designed as an A-B1-B2 study, effectively comparing results of the IntelLeg Knee at the beginning (B1) and end of the session (B2), using the daily use prosthesis as reference (A).

Intervention

Part I of the study is designed as an intervention study with A the baseline measurement (subject*s own prosthesis) and B the intervention (IntelLeg Knee). Part II of the study is designed as an A-B1-B2 study. In here B1 is the baseline measurement (IntelLeg Knee, beginning of session), B2 the intervention (IntelLeg Knee, end of the session) and A is used as reference (subject*s own prosthesis).

Study burden and risks

All experiments are non-invasive, in which participants are asked to perform activities of daily living. Both studies combined last 3 weeks with 3 measurement sessions of 2 hours. In the case that new subjects are recruited, the study last one week longer with an extra training session of 3 hours. Thus,

in 3-4 weeks the participants spend around 6-9 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 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 as well as contribute to the current scientific research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

(Preferably, the subjects have already participated in a previous study and are familiar with the IntelLeg Knee.)
- Aged between 18 and 65.
- Weight below 125 kg.
- Body length between 1.51 and 1.95 m.
- Unilateral transfemoral amputation or k nee disarticulation.
- Functional level from K2 to K4
o Level 2: The patient has the a bility 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 2 hours including breaks.
- At least one year after amputation.

Exclusion criteria

- Not willing to consent to partic ipate in the study.
- Other musculoskeletal problems influencing wal king ability.
- Stump problems/bad socket fitting

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):	21-09-2022
Enrollment:	7
Type:	Actual

Medical products/devices used

Generic name:	IntelLeg Knee
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-04-2022
Application type:	First submission
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	NL76303.091.22

Study results

Date completed:	13-02-2023
Actual enrolment:	2

Summary results
Trial ended prematurely