Gross Efficiency of cyclists with a TransTibial Amputation and the effects of positioning on the Bike: a pilot study

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Primary Objective: This study aims to analyze cycling gross efficiency, pedalling power symmetry, and hip, knee, ankle kinematics in adults with a transtibial amputation in different foot positions and seat heightsSecondary Objective(s): The second...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49072

Source
ToetsingOnline

Brief title
GETTaBike

Condition

- Other condition
- Muscle disorders

Synonym
leg amputation, transtibial amputation

Health condition

lower limb amputation

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: Amputees, Bicycling, Efficiency

Outcome measures

Primary outcome

Outcomes are gross efficiency, pedalling power symmetry, and kinematics of

lower limb in people with a transtibial amputation.

Pedaling power on each foot during the last minute of cycling (of each

condition) will be used to calculate pedaling power symmetry.

Hip, knee and ankle angles of each limb during the last minute of cycling will

be recorded through 2-dimensional kinematic assessment with a video camera.

Secondary outcome

The secondary outcome is the asymmetry index

Study description

Background summary

Cycling is one of the activities people with a lower limb amputation do in free time or choose as a mode of transportation [6,9]. People with a transtibial amputation due to trauma are the largest group of cyclists with an amputation [6,9]. Able-bodied cyclists generate 12 to 21% of their power by the ankle [3,4]. Although the ankle joint contribute less than the knee and hip joints, people with a transtibial amputation have lost this contribution [12-14]. Consequently, cyclists with a transtibial amputation may cycle less efficiently. Even though changing the foot positions on a pedal does not affect the efficiency of competitive able-bodied cyclists (4,5), it may improve the efficiency in cyclists with a TTA who use a passive device as prosthetic foot. Prostheses are generally designed to mimic walking but are often also used for

recreational cycling. The range of motion in prosthetic feet varies [15,16], but is usually smaller than the ankle range of motion of able-bodied during cycling [15,16]. Hence, there is a need of hip and knee compensation. As a result, kinematics of prosthetic and sound limb are not symmetrical. Besides, prosthetic components or knee/hip contractures could prevent people with a transtibial amputation to compensate for the reduced motion of the ankle. For example, a socket can limit the ability to flex the knee [3] or contractures could prevent the knee to extend. To accommodate with the individuals* condition, raising or lowering the bicycle seat height might be helpful. Moreover, an appropriate seat height could reduce the knee injury and increase cycling efficiency [1,2].
Different seat heights affects cycling gross efficiency [1,2] and lower limb kinematics in able-bodied cyclists [2]. Adjusting the seat height enables cycling in people with a transtibial amputation [3]. Though foot positions did not affect cycling economy in competitive able-bodied cyclists without the amputation [4,5], it could affect gross efficiency differently in cyclists with a transtibial amputation. There is limited knowledge about gross efficiency in recreational cyclists with a transtibial amputation although 47% of them cycle [7].

Study objective

Primary Objective: This study aims to analyze cycling gross efficiency, pedalling power symmetry, and hip, knee, ankle kinematics in adults with a transtibial amputation in different foot positions and seat heights
Secondary Objective(s): The second aim is to compare cycling gross efficiency, pedalling power symmetry and lower limb kinematics between people with a transtibial amputation and able-bodied adults in different foot positions and seat heights. Third aim is to assess the relationship between kinetics symmetries and gross efficiency, and kinematics symmetries and gross efficiency in both groups.

Study design

This is a pilot study with repeated measures design. In total 12 adult people with a transtibial amputation and 12 able-bodied cyclists matched for gender and age will be recruited.

Intervention

The interventions are cycling foot positions and seat height. There will be no interventional product/treatment.

Study burden and risks

Both groups of participants will visit lab two times and the total time for the

first and second visit will be about 30 and 90 minutes respectively. Participants* maximal oxygen uptake (VO2max) will be determined. On visit 2, participants will ride an ergometer for 6 trials. Each trial consists of a 6-minute submaximal cycling and 5-minute resting. Lower limb movement will be filmed for kinematic analysis. Tools and protocols have been performed safely in healthy individuals and people with a TTA in earlier research without any report of adverse effects. For safety, the test will be terminated when the subject fails to conform to the exercise test protocol, experiences adverse signs or symptoms, requests to stop, or experiences an emergency situation [8].

Contacts

Public
Universitair Medisch Centrum Groningen

CB41, PO Box 30001 30001
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

CB41, PO Box 30001 30001
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible for this study, a person must meet all of the following

criteria and give the written informed consent:
For persons with a transtibial amputation:
• Have been amputated more than 1 year ago
• History of cycling in the past 6 months with a prosthesis
• Unilateral TTA due to non-vascular disease
• age 18-65 years old
For able-bodied cyclists:
• History of cycling in the past 6 months
• age 18-65 years old

Exclusion criteria

For both groups, a potential subject who meets any of the following criteria will be excluded from participation in this study:
* People with impairment of cognitive function that limit communication ability, visual limitation, muscular (not related to the amputation) or neurological conditions, a history of cardiovascular diseases and lung diseases, lower limb motion and cardiorespiratory function.
* People with hip, knee, and ankle contractures.
* People who are or have been the professional cyclists.
* People with beta-blockers or other medication influencing heart beats

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	24

Type:	Anticipated

Ethics review

Approved WMO Date:	20-05-2020
Application type:	First submission
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	NL72943.042.20