Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of two different prosthetic suspension systems on lower limb amputee's gait performance and satisfaction.

Protocol summary

Summary

The objective of this study was to compare the effects of the two different prosthetic suspension systems namely: Seal-In Liner and Dermo Liner (both are considered silicone liners) on lower limb amputee's gait performance and satisfaction. This study aims to: To obtain kinematics and kinetics of trans-tibial amputees gait using locking liner and Seal-in liner by using motion analysis approach. To evaluate the biomechanical characteristics of each of the suspension systems (locking and seal-in) in terms of comfort, function and satisfaction in traumatic or diabetics amputees. 15 unilateral transtibial amputees were found eligible to participate in this study. Ethical approval was obtained from the University of Malaya Medical Centre Ethics Committee. All the subjects were required to sign a written consent form. The inclusion criteria for the study consisted of unilateral transtibial amputation, walking without walking aids, steady limb volume during the previous year, pain- and ulcer-free stump, and stump length of more than 11 cm. The latter was considered optimal for use of the Seal-In transtibial liner, as stated by the manufacture. A single registered prosthetist designed and aligned two transtibial prostheses for each subject to prevent any bias in the results. Only the suspension systems were different while all other components including feet were similar for both prostheses. A four-week acclimation period was allocated for each prosthetic leg. Following this, each subject completed five gait trials at a self-selected pace for each suspension system.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012816395N1**
Registration date: **2014-02-16, 1392/11/27**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-02-16, 1392/11/27

Registrant information

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Hossein Gholizadeh
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Malaysia
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Recruitment status

Recruitment complete

Funding source

This study was supported by Malaysia UM/MOHE/HIR (project number: D000014-16001). The prosthetic components were donated by Össur (Reykjavik, Iceland).

Expected recruitment start date

2011-01-01, 1389/10/11

Expected recruitment end date

2013-01-01, 1391/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of two different prosthetic suspension systems on lower limb amputee's gait performance and satisfaction.

Public title

prosthetic suspension system

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria for the study consisted of person with trans-tibial amputation, walking without walking aids, steady limb volume during the previous year, pain- and ulcer-free stump, and stump length of more than 11 cm.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Malaya Medical Centre Ethics Committee

Street address

Lembah Pantai, Kuala Lumpur, Malaysia, 59100

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Postal code

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Approval date

2010-07-27, 1389/05/05

Ethics committee reference number

799.7

Health conditions studied

1

Description of health condition studied

Lower limb amputation

ICD-10 code

S88.1

ICD-10 code description

Amputation at level between knee and ankle

Primary outcomes

1

Description

Ambulation

Timepoint

4 weeks after use

Method of measurement

kinematic & kinetic gait analysis

Secondary outcomes

1

Description

Interface pressure

Timepoint

4 weeks after use

Method of measurement

Pressure mapping

Intervention groups

1

Description

Transtibial prosthetic suspension system (Dermo liner with pin lock)

Category

Rehabilitation

2

Description

Transtibial prosthetic suspension system (Seal-in liner with valve)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Malaya (Hospital)

Full name of responsible person

Street address

City

Kuala Lumpur

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

UM/MOHE/HIR grant (project no: D000014-16001)

Full name of responsible person

Prof. Dr. Noor Azuan Abu Osman

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Deputy Dean office, Faculty of Engineering, Kuala Lumpur, Malaysia, 50603
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
UM/MOHE/HIR grant (project no: D000014-16001)

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty