Stability and variability of prosthetic walking: The relation between the variability and stability of the gait pattern of amputees.

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In this study the differences in variability and stability of people walking with and without a limb prosthesis will be investigated. In addition, it will be studied which of the employed outcome measures will discriminate best between both groups....

| Ethical review | Approved WMO |
|-----------------------|----------------------------|
| Status | Pending |
| Health condition type | Bone and joint injuries |
| Study type | Observational non invasive |

Summary

ID

NL-OMON30195

Source ToetsingOnline

Brief title Stability and variability of of prosthetic walking

Condition

- Bone and joint injuries
- Bone disorders (excl congenital and fractures)
- Vascular injuries

Synonym lower limb amputation, lower limb prosthesis

Research involving

Human

1 - Stability and variability of prosthetic walking: The relation between the variab ... 2-05-2025

Sponsors and support

Primary sponsor: Vrije Universiteit Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: prosthesis, stability, variability, walking

Outcome measures

Primary outcome

Based on the 3D-acceleration pattern of the pelvis and the step times derived

from this signal, variability and stability will be calculated using different

(non-linear) techniques. Primary outcome measures will be: standard deviation,

Hurst exponent and Lyapunov exponent.

Secondary outcome

not applicable

Study description

Background summary

Learning to walk with a prosthesis is not an easy task. In order to adequately train this walking ability, it is of interest for patients and therapists to monitor changes their walking performance. These changes are difficult to monitor subjectively. Hence it is useful to use objective measures. Evaluation of walking ability can be done in terms of walking speed, symmetry or energy cost. However, also stability of the walking pattern will be an important outcome parameter.

Frequently, stability is measured based on the variability of the walking pattern in terms of standard deviation or coefficient of variance. Recent studies, however, have shown that the assumption underlying these conventional outcome measures, i.e. that the steps during walking are independent of each other, is not valid. Therefore, a possible structure and regularity in the variability is ignored. It was additionally shown that new (non-linear) approaches could better discriminate between the variability of different groups (for instance patients vs. healthy people or old vs. young people). Different pathologies have been studied based on these new approaches of variability and stability, however walking with a limb prosthesis has not deserved any attention. In this study the dynamics prosthetic of walking will be analyzed in order to find an adequate measure for monitoring the stability of walking.

Study objective

In this study the differences in variability and stability of people walking with and without a limb prosthesis will be investigated. In addition, it will be studied which of the employed outcome measures will discriminate best between both groups. Finally, the relation between variability and stability of walking in general will be analyzed.

Study design

Subjects perform four six-minutes walk under four conditions: 1) indoor, 2) indoor with cognitive dual task, 3) outdoor on regular surface, 4) outdoor on irregular surface. During walking the acceleration of the trunk will be measured using an ambulant accelerometer, worn around the pelvis. Walking velocity will be measured on several parts of the track. All tests for the subjects with a prosthesis will be performed at self selected walking speed. The control group, without prosthesis, will perform each condition twice; at self selected speed and at the speed of the matched prosthetic user. All tests will be performed at and around the Heliomare rehabilitation center

Study burden and risks

Burden and risk for the subjects will be low. Subjects will walk indoor on regular surface and outdoor on normal pavement and somewhat irregular pavement. In none of the conditions serious obstacles are met. The conditions do not deviate from the circumstances people meet in their normal daily life. The experimenter will always be close by, to assist when necessary.

Contacts

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3 - Stability and variability of prosthetic walking: The relation between the variab ... 2-05-2025

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- people with prosthesis after transfemoral amputation of knee exarticulation
- between 18-65 years of age
- able to walk without aids for at least four times six minutes

Exclusion criteria

- comorbities that effect walking ability
- current stump problems or problems with prosthtic fitting
- cognitive dysfunctions that effect execution of cognitive dual task

Study design

Design

| Study type: | Observational non invasive |
|---------------------|---------------------------------|
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

4 - Stability and variability of prosthetic walking: The relation between the variab ... 2-05-2025

| Control: | Active |
|------------------|------------|
| Primary purpose: | Diagnostic |

Recruitment

| NL | |
|---------------------------|-------------|
| Recruitment status: | Pending |
| Start date (anticipated): | 06-01-2006 |
| Enrollment: | 20 |
| Туре: | Anticipated |

Ethics review

| Approved WMO | |
|--------------------|--------------------|
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

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 CCMO **ID** NL12600.029.06