Can we find the optimal Ankle Foot Orthoses (AFO)?

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1. To determine whether AFO stiffness can be optimized for individual patients in terms of minimizing the energy cost of walking. 2. To asses whether the optimal AFO in terms of energy cost of walking matches the AFO at which the most energy can be...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON33390

Source
ToetsingOnline

Brief title
OPTAFO

Condition

- Movement disorders (incl parkinsonism)

Synonym
Multiple Scleroris, partial spinal cord injury, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Anna Fonds (indien gehonereerd)

Intervention

Keyword: Ankle, Gait, Orthotics

Outcome measures

Primary outcome

a) The functional benefit of the AFOs

- The Energy Cost of walking with the AFOs, compared to walking without an AFO

b) The biomechanical effects of the AFOs

- The amount of energy stored in the AFOs

- The push-off power produced around the ankle whilst wearing the AFOs

c) The optimal AFO stiffness

- According to the regular prescription by the rehabilitation physician

- As objectively measured in this study

Secondary outcome

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Study description

Background summary

Energy storing carbon composite Ankle Foot Orthoses (AFO) are frequently prescribed to compensate for a reduced push off power in patients with Stroke, Multiple Sclerosis (MS) and partial Spinal Cord Injury (SCI). From a mechanical point of view it can be reasoned that the amount of energy that can be stored and returned by the AFO, and thereby the functional benefit of the AFO, depends on the mechanical characteristics of the AFO, particularly the AFO stiffness. However, this remains to be proven because the mechanical AFO characteristics have rarely been quantified. Ahead of this study we developed a measurement device to reliably quantify the mechanical AFO stiffness. By varying the AFO stiffness, the effect of AFO stiffness on gait performance can be investigated, which is likely to result in an optimal AFO stiffness. Furthermore, evaluation of the walking patterns with biomechanical gait analysis, will reveal how the

stiffness of the AFO must interact with the impaired ankle function in order to result in an optimal walking performance. In addition, the current AFO prescription process can be evaluated by comparing an AFO for which the stiffness is determined by the rehabilitation physician and orthothist, to the measured most optimal AFO stiffness.

Study objective

1. To determine whether AFO stiffness can be optimized for individual patients in terms of minimizing the energy cost of walking.
2. To asses whether the optimal AFO in terms of energy cost of walking matches the AFO at which the most energy can be stored in the AFO, and at which the highest peak push off power around the ankle joint during the pre-swing phase of gait is obtained.
3. To evaluate how the stiffness of an AFO prescribed by a rehabilitation physician relates to the objectively measured most optimal AFO stiffness.

Study design

1. To determine whether AFO stiffness can be optimized for individual patients in terms of minimizing the energy cost of walking.
Controlled intervention study in which the functional benefit of walking with 5 different AFOs is compared to walking without an AFO.
2. To asses whether the optimal AFO in terms of energy cost of walking matches the AFO at which the most energy can be stored in the AFO, and at which the highest peak push off power around the ankle joint during the pre-swing phase of gait is obtained.
Observational study in which it will be determined whether the benefit of walking with 5 AFOs can be related to the biomechanical aspects of walking with each of these 5 AFOs.
3. To evaluate how the stiffness of an AFO prescribed by a rehabilitation physician relates to the objectively measured most optimal AFO stiffness.
Comparative study in which the regular (subjective) manner of AFO prescription is compared to the objectively measured most optimal AFO prescription.

Intervention

All 12 patients will walk with five AFOs with different stiffnesses. The gait whilst wearing each of these AFOs will be compared to the control condition, i.e. walking without an AFO. Subsequently, these results will be compared to walking with a 6th AFO, that is prescribed according to the regular procedures.

Study burden and risks

Patients are measured during intake at the VUmc movement laboratory. This takes approximately 3 hours. After the intake, the patients will visit the VUmc on

three separate days. The measurements during each of these days will take approximately 2 hours per day. The risk for the patients in this study is negligible. The load for patients is slightly higher than in a common gait analysis that is regularly performed at our department to support clinical decision making. With the current protocol the patients* gait can be studied in a more reliable and objective manner, which will result in the best AFO prescription for the patient. In order to make the load for patients as low as possible, bouts of (seated) rest periods are planned in between the different parts of the experiment and between the trials. The patients may benefit from the study, because the optimal AFO will be prescribed to the patient after the study. (If this AFO differs form the regularly prescribed AFO).

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

- Gait related problems due to a clinically observed lack of push-off power.
- Patients diagnosed with Stroke, MS or partial SCI
- Time since diagnosis is more than one year
- The ability to walk independently for 6 minutes without walking aids
- Age: 18-75

Exclusion criteria

- The use of other walking aids than the AFO
- The bilateral use of AFOs
- Walking speed lower than 0.5 m/s
- Severe spasticity
- Previous orthopaedic interventions of the lower extremities
- Severe contractures
- Any disorder apart from MS, Stroke or partial SCI that may influence gait

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-03-2010
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Ankle Foot Orthoses
Registration:	No

Ethics review

Approved WMO Date:	14-09-2009
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	ID
CCMO	NL27855.029.09