

Optimizing gait with bidirectional tuning of the ankle-foot orthosis (AFO) stiffness in people with lower leg muscle weakness*

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Ethical review	Approved WMO
Status	Pending
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON56679

Source

ToetsingOnline

Brief title

Bidirectional tuning of the AFO stiffness

Condition

- Neuromuscular disorders

Synonym

flaccid paresis; neuromuscular disorder

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: bedrijf (Fior & Gentz orthopedie}, Fior & Gentz orthopedie

Intervention

Keyword: Ankle-foot orthosis, Bidirectional stiffness optimization, Lower leg muscle weakness, Walking.

Outcome measures

Primary outcome

The main outcome parameters will be the maximal ankle plantarflexion angle, ankle angular velocity and knee flexion angle during the loading response.

Secondary outcome

Secondary outcomes will include ankle power, walking energy cost, walking speed, standing balance, perceived walking safety, fatigue and stability, perceived functioning, and experiences with study participation and with the NEURO SWING AFO.

Study description

Background summary

Many neuromuscular diseases cause weakness of the ankle dorsiflexors and plantarflexors, resulting in an altered gait pattern. The primary treatment to improve walking ability in dorsiflexor and/or plantarflexor weakness is the provision of ankle-foot orthoses (AFOs). In case of dorsiflexion weakness, a relatively low AFO stiffness towards plantarflexion is required while for plantarflexor weakness, the required stiffness towards dorsiflexion is much higher. The required stiffness in both directions maximally normalizing the gait pattern varies between patients due to differences in characteristics, like the severity of weakness, body mass and patient activity. Consequently, to maximize treatment outcomes in case of lower leg weakness, the optimal AFO stiffness needs to be individually determined. Individual optimization of the stiffness can be performed with a spring-hinged AFO. An advantage of spring-hinged AFOs is that the stiffness can be separately optimized in the directions of dorsiflexion and plantarflexion, which is not possible in

spring-like AFOs without hinge. This separate tuning of the stiffness towards plantar- and dorsiflexion potentially leads to a more natural gait kinematics and kinetics in loading response and pre/swing. However, little is known about the benefits of individualizing the stiffness in plantar- and dorsiflexion separately (i.e. bidirectional stiffness tuning) in a spring-hinged AFO.

Study objective

The objective of this pilot study is to evaluate the effects of separate individualization of the AFO stiffness towards plantar- and dorsiflexion in a spring-hinged NEURO SWING AFO compared to a spring-like AFO without hinge (3 types) having the same stiffness in both directions on walking, as assessed by gait kinetics and kinematics, walking energy cost, walking speed, standing balance and posture, satisfaction and perceived walking ability.

Study design

A pilot study with a pre-post design

Intervention

Participants will be fitted with a new, custom-made spring-hinged AFO with the NEURO SWING® system ankle joint (Fior & Gentz). The stiffness of the ventral and dorsal compartment of this spring-hinged AFO will be individualized using a previously developed optimization algorithm. The spring-hinged AFO with optimal stiffness settings will be used at home for 6-weeks. For comparison, we will test the effect of three different prefabricated spring-like AFOs without hinge with different stiffness levels (but which have a similar stiffness towards plantar and dorsiflexion) of 2.8, 1.4 and 0.6 Nm/degrees, respectively.

Study burden and risks

Participants will visit the hospital four times for 3 hours per visit. During each visit, patients will undergo a 3D gait analysis and 6MWT. During the first visit, the spring-hinged NEURO SWING AFO will be casted and tests without AFO will be performed, during the second visit, tests with the 3 prefabricated spring-like AFOs are performed, during the third visit the spring-hinged NEURO SWING AFO is optimized based on a gait analysis and 6MWT, and the fourth visit is the follow up visit 6 weeks after AFO provision. For evaluation purposes, we will contact participants 6 weeks after completion of the study to ask about their experiences with study participation, and to inform if the NEURO SWING AFO is still used and if there are any complaints.

Possible burdens are fatigue due to the extensive protocol and physical discomfort due to walking with new AFOs. A potential benefit of participating in the study is that if separate individualization of stiffness towards plantar-

and dorsiflexion in spring hinged AFO is successful, patients receive an AFO better matched to their individual impairments and this may improve their walking ability more.

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

- Age 18 years or older;
- Presence of plantar flexor weakness in at least one leg, determined as a score lower than 5 on the manual muscle testing scale (Medical Research Council- MRC) and/or inability to perform three single heel rises, with or without dorsiflexion weakness;
- Indicated for or using an AFO;

- Able to walk 6-minutes consecutively (with assistive device, if necessary).

Exclusion criteria

- When wearing the AFO, not able to walk short bouts of 10m without walking aids, such as a walker;
- Foot deformities that do not fit in the prefab spring-like AFOs;
- Weakness of the knee extensor muscles, for which a knee-ankle foot orthosis is indicated

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-01-2024
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Ankle foot orthosis (AFO) with NEURO SWING ankle joint
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-04-2024
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	NL85684.018.23