Tuning ankle foot orthoses using a standardized protocol

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23537

Source
Nationaal Trial Register

Brief title
TBA

Health condition

People with a chronic neurological condition

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: OIM Orthopedie

Intervention

Outcome measures

Primary outcome

- GRF in relation to the knee joint
- Knee angle and moment
- Shank-to-Vertical Angle (SVA)

Secondary outcome

- Spatiotemporal parameters (e.g. walking speed, step length, step width)
- Centre of Pressure (CoP)
- Satisfaction on a VAS scale

Study description

Background summary

Ankle-foot-orthoses (AFOs) are commonly prescribed to improve the walking ability of patients with neurological diseases. However, the AFO effectiveness depends on several factors, of which alignment of the AFO is highly important. Optimal alignment is achieved by making fine adjustments to the AFO footwear combination (AFO-FC), which is often referred to as tuning. In clinical practice, the tuning process is performed by observation of gait (observational gait analysis) and alignment is optimized by trial and error. However, observational gait analysis has shown to be ineffective and unreliable, and could therefore result in incorrect AFO alignment. Moreover, incorrect AFO alignment can result in a suboptimal walking pattern and the development of pressure sores, which negatively affects the patient's walking ability, satisfaction and treatment adherence. Furthermore, inadequate AFO tuning may influence the clinical process, as it could result in more tuning adjustments and more return visits before reaching optimal alignment. An alternative to observational gait analysis is 2D gait analysis using cameras and a force plate or the use of Inertial Measurement Units (IMUs) and/or pressure plate. With 2D gait analysis, the ground reaction force vector can be displayed in a video (force vector overlay), visualizing the GRF in relation to the joints. IMUs can measure movements of body segments and joints, while the pressure plate can measure the GRF in relation to the footprint. With the use of these measuremnt instruments, AFO alignment can be quatified more objectively. However, the use of a standardized protocol for AFO tuning has never been investigated.
Objective: Investigate the use of a standardized protocol for AFO tuning.
- Investigate the effect of wedges under the heel and forefoot on the GRF in relation to the knee joint
- Investigate the effect of wedges under the heel and forefoot on knee angle and knee moment
- Investigate the effect of wedges under the heel and forefoot on the Shank-to-Vertical Angle
- Validate the use of force vector overlay to estimate the GRF in relation to the knee joint centre
- Validate the use of IMUs to estimate the knee angle
- Validate the use of a pressure plate to estimate the GRF in relation to the footprint
- Estimate the inter-rater reliability of the assessment of the GRF in relation to the knee joint

Study objective

The GRF in relation to the knee joint, knee angle and moment and the SVA change when wegdes are placed under the heel and forefoot. Furthermore, these parameters and changes can be measured accurately with force vector overlay (2D gait analysis), IMUs and/or a

pressure plate.

Study design

Measurements will be performed at one measurement day.

Intervention

AFO tuning following a standarized protocol using wedges under the heel and forefoot.

Contacts

Public
Sint Maartenskliniek
Lysanne de Jong

0243272564
Scientific
Sint Maartenskliniek
Lysanne de Jong

0243272564

Eligibility criteria

Inclusion criteria

- Between 18 and 80 years old
- Provided with a custom-made AFO
- AFO with minimal dorsal and plantar flexion
- Able to walk 10 meters without a walking aid

Exclusion criteria

- Abnormal knee extension and dorsal flexion movement
- Knee extensor weakness (MRC < 3)
- Surgery on the lower extremities less than a year ago
- Spasticity treatment during or less than 4 months prior to the study
- Neuropathic and/or orthopedic comorbidities influencing walking ability

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-11-2021
Application type:	First submission

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
NTR-new	NL9864
Other	METC Arnhem Nijmegen : 2021-13171

Study results