Tuning ankle foot orthoses using a standardized protocol

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23537

Bron
NTR

Verkorte titel
TBA

Aandoening

People with a chronic neurological condition

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: OIM Orthopedie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- GRF in relation to the knee joint
- Knee angle and moment

- Shank-to-Vertical Angle (SVA)

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

Measurements will be performed at one measurement day.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2021
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-11-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9864
Ander register	METC Arnhem Nijmegen : 2021-13171

Resultaten