The American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot and Midfoot Scores; Translation and Validation of the Dutch Language Versions

Gepubliceerd: 05-01-2016 Laatst bijgewerkt: 18-08-2022

We expect that the Dutch language versions of the AOFAS Ankle-Hindfoot and the AOFAS Midfoot score will have adequate measurement properties (e.g. reliability and validity).

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27003

Bron
NTR

Verkorte titel
AOFAS-DLV

Aandoening

Ankle, hindfoot, or midfoot fracture or (fracture) dislocation

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Department of Surgery
Erasmus Medical Center, Medical Research Ethics Committee (MREC)
Overige ondersteuning: N.A.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Content validity

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND
Patient-Reported Outcome Measures (PROMs) are increasingly used in order to measure (functional) recovery over time from a patient's perspective. The AOFAS Ankle-Hindfoot Score is the most commonly used PROM for measuring outcome of treatment in patients who sustained a complex ankle or hindfoot injury. Similarly, the AOFAS Midfoot Score is a commonly used PROM for measuring outcome of treatment in patients who sustained a midfoot fracture or (fracture) dislocation. A valid, Dutch version of these instruments is currently not yet available. Such translated and validated PROMs will allow objective comparison across hospitals and with shown validity and reliability it may become a quality of care indicator in future.

AIM
1) To translate and culturally adept the AOFAS Ankle-Hindfoot Score and AOFAS Midfoot Score questionnaires into Dutch according to international guidelines, 2) to evaluate the measurement properties of the AOFAS Ankle-Hindfoot Score-Dutch Language Version (DLV) in patients with a unilateral ankle or hindfoot fracture or (fracture) dislocation, and 3) to evaluate the measurement properties of the AOFAS Midfoot Score-DLV in patients with a unilateral midfoot fracture or (fracture) dislocation.

STUDY DESIGN
Multicenter, prospective observational study.

POPULATION
Adult patients (18 years or older) presenting to the Emergency Department with a unilateral ankle, hindfoot, or midfoot fracture or (fracture) dislocation.

INTERVENTION
Not applicable, this is a questionnaire study.

ENDPOINTS
Measurement properties of the AOFAS Ankle-Hindfoot Score-DLV and the AOFAS Midfoot Score-DLV will be determined. Primary outcome measure is the content validity. Secondary outcome measures include the reliability (i.e., internal consistency, test-retest reliability, measurement error), smallest detectable change, floor and ceiling effect, and responsiveness.

RECRUITING COUNTRIES
The Netherlands.

Doel van het onderzoek

We expect that the Dutch language versions of the AOFAS Ankle-Hindfoot and the AOFAS Midfoot score will have adequate measurement properties (e.g. reliability and validity).

Onderzoeksopzet

Test-retest analysis:

1)7-9 months (ankle or midfoot) or 6-24 months (hindfoot) after injury

2) 2-3 weeks after first completion.

Responsiveness analysis:

1) between 6 weeks and 3 months (ankle or midfoot) or between 3 and 6 months (hindfoot) after injury

2) 5-6 months after first completion.

Onderzoeksproduct en/of interventie

Not applicable, this is a questionnaire study.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Group 1 (test of pre-final version):

1) Patients with a unilateral ankle, hindfoot, or midfoot fracture or (fracture) dislocation

a. Ankle-Hindfoot: ankle fracture, calcaneal fracture, talar fracture, subtalar dislocation, tibiotalar dislocation, or Chopart's fracture dislocation

b. Midfoot: cuboid fracture, navicular fracture, cuneiform fracture, or Lisfranc (fracture) dislocation

2) Age 18 years or older

3) Provision of informed consent by patient.

Group 2 (validity and (test-retest) reliability):

1) Patients with a unilateral ankle, hindfoot or midfoot fracture or (fracture) dislocation

a) Ankle: ankle fracture

b) Hindfoot: calcaneal fracture, talar fracture, subtalar dislocation, tibiotalar dislocation, or Chopart's fracture dislocation

c) Midfoot: cuboid fracture, navicular fracture, cuneiform fracture, or Lisfranc (fracture) dislocation

2) Treatment started between seven and nine months (ankle and midfoot) or between six and 24 months (hindfoot) prior to the start of the study

3) Age 18 years or older

4) Povision of informed consent by patient.

Group 3 (validity and responsiveness):

1) Patients with a unilateral ankle or hindfoot fracture (as defined for group 2 above)

2) Treatment started between six weeks and three months (ankle and midfoot) or between three and six months (hindfoot) prior to the start of the study

3) Age 18 years or older

4) Provision of informed consent by patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Multiple trauma patient (if additional injury limits function at time of enrolment)

2) Pathological fracture

3) Severe physical comorbidity (ASA ¡Ý3)

4) Patient was non-ambulatory prior to the injury

5) Insufficient comprehension of the Dutch language to understand and complete the questionnaires

6) Patients with expected problems of maintaining follow-up

For testing the pre-final version of the Dutch AOFAS Ankle-Hindfoot or Midfoot Score (group 1), only exclusion criteria 5 and 6 will apply.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2014
Aantal proefpersonen:	378
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-01-2016
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	NL5469
NTR-old	NTR5613
Ander register	: MEC-2014-215 (METC Erasmus MC)

Resultaten

Samenvatting resultaten
- Van Lieshout EMM, De Boer AS, Meuffels DE, Den Hoed PT, Van der Vlies CH, Tuinebreijer WE, Verhofstad M.H.J. The American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score; a Study Protocol for the Translation and Validation of the Dutch Language Version. BMJ Open. 2017 Feb 27;7(2):e012884.

- De Boer AS, Tjioe RJC, Van der Sijde F, Meuffels DE, Den Hoed PT, Van der Vlies CH, Tuinebreijer WE, Verhofstad MHJ, Van Lieshout EMM, AOFAS study Group. The American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Score; Translation and Validation of the Dutch Language Version for ankle fractures. BMJ Open. 2017 Aug 3;7(8):e017040.

- De Boer AS, Meuffels DE, Van der Vlies CH, Den Hoed PT, Tuinebreijer WE, Verhofstad MHJ, Van Lieshout EMM, AOFAS study Group. Validation of the American Orthopedic Foot and Ankle Society Ankle-Hindfoot Scale Dutch Language Version in Patients with Hindfoot Fractures. De Boer AS, et al. BMJ Open 2017;7:e018314.