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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27003

Source
NTR

Brief title
AOFAS-DLV

Health condition

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

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Department of Surgery
Erasmus Medical Center, Medical Research Ethics Committee (MREC)
Source(s) of monetary or material Support: N.A.

Intervention

Outcome measures

Primary outcome

Content validity

Secondary outcome

Reliability (i.e., internal consistency, test-retest reliability, measurement error); Smallest detectable change; Floor and ceiling effect; Responsiveness.

Study description

Background summary

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.

Study objective

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).

Study design

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.

Intervention

Not applicable, this is a questionnaire study.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2014
Enrollment:	378
Type:	Actual

Ethics review

Positive opinion

Date:	05-01-2016
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	NL5469
NTR-old	NTR5613
Other	: MEC-2014-215 (METC Erasmus MC)

Study results

Summary results
- 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.