

Sensor Validity

No registrations found.

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

Summary

ID

NL-OMON22890

Source

NTR

Health condition

healthy individuals

Sponsors and support

Primary sponsor: University Medical Center Groningen

Source(s) of monetary or material Support: OntwikkelingsFonds voor Orthopedisch Maatschoen-technisch bedrijf (OFOM)

Intervention

Outcome measures

Primary outcome

use of footwear in hours per day based on sensor

use of footwear in hours per day based on camera

Secondary outcome

n.a.

Study description

Background summary

BACKGROUND: Orthopedic footwear is frequently prescribed to a wide variety of patients. Adherence of use of orthopedic footwear is a prerequisite of their effectiveness, but has mostly been assessed using methods, like questionnaires, interviews or diaries, with poor accuracy and reliability. A recent study has shown that temperature can be used to assess orthopedic footwear adherence, however, the sensor used could only collect data over a short period of time and had relatively large dimensions. A new technology is available, comprising a temperature sensor that is small and capable of long-term data collection (>100 days).

AIM: To assess the validity and feasibility of a new temperature sensor for measuring footwear use and nonuse in healthy individuals.

METHOD: In ten healthy volunteers, the validity of a new temperature sensor to discriminate between time periods of use and nonuse of footwear over a period of 48 hours was assessed. Footwear use measured with the sensor was compared to footwear use measured with a 1-minute time-lapse sports camera secured to the shoelace and focused on the lower leg. The correlation coefficient between footwear use based on the sensor and camera was calculated. The ease of the installation of the sensor in the insole and the data collection and analysis were assessed as feasibility criteria.

RESULTS: Mean footwear use measured with the camera was 8.10 (± 2.46) hours per day, and measured with the sensor 8.16 (± 2.37) hours per day. There was a strong correlation between footwear use assessed by camera and by sensor, $r = 0.995$.

DISCUSSION & CONCLUSION: The temperature sensor is valid and feasible for adherence monitoring in (orthopedic) footwear. The installation of the sensor, in the insole of the subjects' preferred footwear, and the data collection were performed easily.

Study objective

Asses the validity and feasibility of a temperature sensor for adherence monitoring in orthopedic footwear

Study design

footwear use was determined over a period of 48 hours with both sensor and camera

Intervention

n.a

Contacts

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Eligibility criteria

Inclusion criteria

healthy individual

shoe size between 37 and 45

in possession of a shoe with shoe laces

Exclusion criteria

n.a.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	01-08-2016
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion	
Date:	19-12-2016
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	NL6185
NTR-old	NTR6341
Other	University Medical Center Groningen : METC 2016.323

Study results