Measuring plantar pressure during total contact softcast offloading versus conventional total contact cast offloading: a pilot study

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Primary objective: Investigation of mean peak plantar pressure at the location of the diabetic foot ulcer and at 6 plantar regions of the foot (i.e. hallux, digits, first metatarsal, second to fifth metatarsals, midfoot, and heel) during total...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON52242

Source
ToetsingOnline

Brief title
MOVE pilot study

Condition

- Musculoskeletal and connective tissue disorders NEC
- Skin vascular abnormalities
- Skin and subcutaneous tissue therapeutic procedures

Synonym
diabetic foot ulcers. Foot ulceration. A wound on the foot in a person with diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: BSN medical GMBH

Intervention

Keyword: Diabetic foot ulcer, Offloading, Plantar pressure, Total contact softcast

Outcome measures

Primary outcome

Peak plantar pressure during a minimum of 12 midgait steps with the affected

foot

Secondary outcome

Patient comfort, expressed using a visual analoge scale.

Study description

Background summary

Diabetic foot ulcers are a major health problem. Adequate offloading is paramount for the treatment of diabetic foot ulcers. Irremovable, knee-high total contact casts are recommended for plantar diabetic foot ulcers on the forefoot or midfoot. However, these are infrequently used due to poor patient acceptance because of negative impacts on lifestyle and mobility. Recently, several hospitals in the Netherlands have used non-rigid cast materials for offloading cast treatments, named 'total contact softcast offloading'. The key difference with conventional total contact cast offloading is that total contact softcast offloading allows some mobility of the ankle which could reduce the negative impacts on lifestyle and mobility. In clinical practice, good experiences have been reported. But total contact softcast offloading has practically not been investigated. Therefore, we designed a cross-over observational pilot study to investigate peak plantar pressure and patient comfort. Our hypothesis is that mean peak pressure at the diabetic foot ulcer is lower during total contact softcast offloading than it is during mobilization in the patient*s own footwear. We expect that this reduction in mean peak pressure is non-inferior to the reduction found during total contact cast offloading.

Study objective

Primary objective: Investigation of mean peak plantar pressure at the location of the diabetic foot ulcer and at 6 plantar regions of the foot (i.e. hallux, digits, first metatarsal, second to fifth metatarsals, midfoot, and heel) during total contact softcast offloading, conventional total contact cast offloading and whilst wearing own footwear.

Secondary objectives:
1) Investigation of mean peak plantar pressure at 6 plantar regions of the foot (i.e. hallux, digits, first metatarsal, second to fifth metatarsals, midfoot, and heel) during total contact softcast offloading, conventional total contact cast offloading and whilst wearing own footwear.
2) Investigation of patient comfort during total contact softcast offloading, conventional total contact cast offloading and whilst wearing own footwear using a Visual Analogue Scale.

Study design

Cross-over observational study pilot.

Study burden and risks

We will perform the study procedures at a single session during a clinical visit 1-8 weeks after the start of the casting treatment, which will require approximately 90 minutes in addition to the time needed for cast replacement as part of the standard treatment. We will assess peak plantar pressure on a non-invasive manner using an insole with pressure sensors, and patient comfort as a patient-reported outcome measure. The risks of these study procedures are negligible, since casts are applied once for approximately 20 minutes, and mobilization whilst wearing the casts is supervised by medical personnel.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Age 18 years or older
2) Diagnosed with diabetes mellitus
3) A plantar diabetic foot ulcer on the forefoot or midfoot for which offloading by total contact softcast or total contact cast is indicated

Exclusion criteria

1) Inability or unwillingness to provide a written declaration of informed consent.
2) Unable to mobilize weight-bearing
3) moderate or severe diabetic foot infection, as defined by the international working group on the diabetic foot / infectous diseases society of America (IWGDF / IDSA).
4) Moderate or severe limb ischemia, as defined in the Wound, Ischemia, foot Infection (WIfI) classification.
5) The combination of mild limb ischemia and mild infection, defined in accordance with the WIfI classification and IWGDF / IDSA definitions, respectively.
6) Severe foot deformities (e.g. Charcot neuroarthropathy-related deformity, ankle arthrodesis, partial calcanectomy) which lead to increased pressure and friction on the site of the DFU and thereby make adequate TCSO or TCCO impossible, as judged clinically by the treating physician

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-04-2022
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Delta cast soft
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-03-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL77689.042.21