

Total contact versus Total contact Softcast in treatment neuropathic plantar ulcers.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	-

Summary

ID

NL-OMON29630

Source

NTR

Health condition

Diabetic foot, forefoot ulcers, Total Contact Cast , Total Contact Softcast, offloading.
Diabetische Voet, voorvoet ulcus,

Sponsors and support

Primary sponsor: UMCG Groningen

Hanzeplein 1

9700 RB Groningen

Source(s) of monetary or material Support: geen

Intervention

Outcome measures

Primary outcome

Results of ulcer-healing equally well for TCS, as compared to TCC? When looking AT THE PERCENTAGE OF ULCER-HEALING AT 12 WEEKS FOLLOW UP.

Secondary outcome

Time to wound healing

validated Quality of life score.

Study description

Background summary

A Total Contact Softcast (TCS) is a new alternative treatment for patients with a forefoot ulcer.

An increasing number of Hospitals in the Netherlands use a TCS or the Total Contact Cast (TCC):

the golden standard for off-loading. Patients have a better comfort in a TCS instead of a TCC, resulting in an easier walking pattern. Cast technicians observe adequate healing of the wounds.

A comparison between both techniques was never made (to our knowledge). A TCS relieves multiple possible causes prohibiting mobilization. It may shorten the treatment duration and increase the quality of life.

The impact of excessive pressure on the sole of the foot in the pathogenesis of neuropathic plantar ulcers, is well established. It is also known that complete relief of pressure from the ulcerated area is the key to effective healing. A non-removable Total Contact Cast is the golden

standard for off-loading ulcers located at the forefoot or midfoot. Patients walk for weeks or several months with a TCC: After 12 weeks resulting in 90% healing of the patients' wounds.

This non-removable knee-high device, including ankle joint immobilization, reduces the activity

level with a potential risk of falls and knee or hip complaints due a provoked asymmetry in walking. Early discontinuation because of inconvenience of the TCC was seen in 21% of the patients. The use of a TCC is contraindicated, in patients with infection or critical ischemia.

A relative contraindication is found in elderly, patients with visual or equilibrium problems, and

patients with a contra lateral foot ulcer or varicose veins. Other reasons for discontinuation are

pressure points and joint problems in 7% of the patients. Also ankle stiffness and lower back pain

disturb the walking pattern.

In a Total Contact Softcast the ankle is wrapped in a semi-rigid stretch bandage allowing movement of the ankle joint. The sole is constructed of a rigid cast. This allows a normal walking

pattern combined with off-loading of pressure points of the wounds. The World Health

Organization (WHO) defines disability as one of the problems an individual may experience in functioning. This may be positively influenced by the accomplishment of a physically active lifestyle with a semi-rigid cast: A TCS.

Study objective

A TCS is comparable to TCC and an effective treatment in neuropathic forefoot ulcer,

Study design

patients visit the outpatient clinic weekly for a cast change and wound inspection by a wound nurse.

Intervention

Total Contact Cast

Contacts

Public

Europaweg-Zuid 1

B.P. Vierhout

Assen 9401 RK

The Netherlands

0592-325211

Scientific

Europaweg-Zuid 1

B.P. Vierhout

Assen 9401 RK

The Netherlands

0592-325211

Eligibility criteria

Inclusion criteria

age >18 years old, mental competence and understanding of the Dutch language

Diagnosis: Neuropathic ulcers without sign of ischemia, ability to walk more than 20 meters, wound depth tissue loss grade D1 and D2 according to PEDIS I1 and I2

Exclusion criteria

patients with a Charcot deformity, excessive edema of the lower leg, immobility (<20 meters)

an ankle brachial pressure index <0.9 and clinical signs of wound infection. (wound classification according to PEDIS Classification)

Study design

Design

Intervention model: Other

Masking: Single blinded (masking used)

Control: Active

Recruitment

NL

Recruitment status: Pending

Start date (anticipated):	31-01-2017
Enrollment:	76
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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	NL5978
NTR-old	NTR6142
Other	ABR-nummer : 61960

Study results