NKR - 02 for Udredning og behandling af diabetiske fodsår

Review information

Authors

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Characteristics of studies

Characteristics of included studies

Armstrong 2001

Methods	**Study design:** **Study grouping:**
Participants	**Baseline Characteristics** Intervention 1 (RCW) ● *Female, N (%)*: 2 ● *Distal blood pressure (mmHg), mean (SD)*: 62.0 (16.3) ● *Wound area (cm2), mean (SD)*: 1.4 (1.4) ● *Peripheral neuropathy, N (%)*: 100% Intervention 2 (Half-Shoe) ● *Female, N (%)*: 4 ● *Distal blood pressure (mmHg), mean (SD)*: 58.6 (10.4) ● *Wound area (cm2), mean (SD)*: 1.3 (1.2) ● *Peripheral neuropathy, N (%)*: 100% Kontrol 1 (TCC) ● *Female, N (%)*: 5 ● *Distal blood pressure (mmHg), mean (SD)*: 60.7 (9.0) ● *Wound area (cm2), mean (SD)*: 1.3 (0.8) ● *Peripheral neuropathy, N (%)*: 100% **Included criteria:** The diag-nosis of diabetes had been made before enrollment and was confirmed either by communication with primary care providers or by reviewing medical records. All patients had clinically significant loss of protective sensation (.25 V) as measured with a biothesiometer (BiomedicalInstrument, Newbury, OH) (18,19), at least one palpable foot pulse or a transcutaneous oximetry (TcPO2) measurement higher than 40 mmHg at the level of the dorsum of the forefoot, and a neuropathic plantar diabetic foot ulcer corresponding to grade 1A (superficial, not extending totendon, capsule, or bone using the University of Texas Diabetic Foot Wound Classification System) (20). Neuropathy was defined as the inability to sense the 10-g Semmes-Weinstein monofilament and a vibration perception threshold.25 V (18,19,21). If patients had more than one plantar wound, the largest wound was used as the index ulcerfor inclusion in this study. **Excluded criteria:** Patients who had ac-tive infection, were unable to walk with-out wheelchair assistance, had wounds in locations on the heel, rear foot, or area other than the plantar aspect of the foot,or had severe peripheral vascular disease (diagnosed by the criteria listed above) were excluded from the study.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: RCWs and half-shoes were applied using the directions dispensed with the original packaging. All patients were in-structed to use the devices at all times during ambulation ● *Duration*: 12 w ● *Dose*: All patients were followed on a weekly basis for device inspection,wound care, and wound debridement. Kontrol 1 ● *Description*: TCCs were applied using amodification of the technique described by Kominsky (22). The modification to this technique included the use of a castboot in lieu of the rubber cast walker and plywood platform. TCCs were changed on a weekly basis or as clinically necessary. ● *Duration*: 12 w ● *Dose*: All patients were followed on a weekly basis for device inspection, wound care, and wound debridement.
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Længste follow-up *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks) *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported ● **Direction**: Lower is better

	● **Data value**: Endpoint *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks) *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported ● **Direction**: Higher is better ● **Data value**: Endpoint *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Længste follow-up *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** This study was fundedby the U.S. Department of Veterans Affairs'Rehabilitation R&D Merit Award GrantA2150RC and the Aircast Research Founda-tion. **Country:** USA **Setting:** 63 patientswith superficial noninfected, nonischemic diabetic plantar foot ulcers were randomized to one ofthree off-loading modalities: TCC, half-shoe, or RCW **Authors name:** David G. Armstrong **Institution:** Department of Surgery, SouthernArizona Veterans Affairs Medical Center **Email:** armstrong@usa.net **Address:** Department of Surgery, SouthernArizona Veterans Affairs Medical Center, 3601 South Sixth Ave., Tucson, AZ 85723.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "are listed in Table 1. No significant differences were observed in any of the characteristics evaluated, in- cluding age, sex, duration of diabetes, size or location of wounds, or duration of plantar wounds. With the numbers avail- able," Quote: "Patients were randomized through a computerized randomization schedule. Randomization was performed after the initial screening."
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Not feasible to blind however, no information about blinding of participants.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: No information however, only objectively measured outcomes of interest.
Incomplete outcome data (attrition bias)	Unclear risk	Quote: "Of an initial enrollment pool of 75 patients, 12 failed to complete the course of study. Reasons for this included discomfort (four TCC, three RCW), insta- bility (one half-shoe), or failure to return for follow-up appointments and data- collection visits (two TCC, two RCW)." Judgement Comment: Low attrition rate however, not balanced drop outs (n=6 TCC and 1 from half-show group). Per protocol analysis.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol available. Limited reporting of relevant outcomes.
Other bias	Low risk	Quote: "This study was funded by the U.S. Department of Veterans Affairs' Rehabilitation R&D Merit Award Grant A2150RC and the Aircast Research Founda- tion." Judgement Comment: No description of the roles of the funding parties. Likely limited to funding.

Armstrong 2005

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 64.6 (9.8) ● *Female, N (%)*: 3 (88.9) ● *BMI, mean (SD)*: 33.5 (6.2) ● *HBA1C, mean (SD)*: 8.0 (1.4) ● *Wound area (cm2), mean (SD)*: 2.0 (1.1) ● *Peripheral neuropathy, N (%)*: 27 Kontrol 1 ● *Age, mean (SD)*: 66.9 (10.1)

	● *Female, N (%)*: 3 (87) ● *BMI, mean (SD)*: 33.3 (6.8) ● *HBA1C, mean (SD)*: 8.5 (1.5) ● *Wound area (cm2), mean (SD)*: 2.7 (1.3) ● *Peripheral neuropathy, N (%)*: 23 Overall ● *Age, mean (SD)*: 65.6 (9.9) ● *BMI, mean (SD)*: 33.4 (6.4) ● *HBA1C, mean (SD)*: 8.2 (1.4) ● *Wound area (cm2), mean (SD)*: 2.3 (1.2) ● *Peripheral neuropathy, N (%)*: 50 **Included criteria:** All patients had experienced the loss of protective sensation (25 V) as measured with a vibration perception threshold meter (Xilas, SanAntonio, TX) (12,13), at least one palpable foot pulse, and a neuropathic plantardiabetic foot ulcer corresponding to grade 1A (superficial, not extending to tendon,capsule, or bone, according to the Univer-sity of Texas Diabetic Foot Wound Classification System) (14,15). Wound size was evaluated by measuring the maximum length by the maximum width. If patients had more than one plantar wound, the largest wound was used as the index ulcer for inclusion in this study. **Excluded criteria:** Patients with active infection; unable towalk without a wheelchair; with wounds in locations on the heel, rearfoot, or a location other than the plantar aspect of thefoot; or with severe peripheral vasculardisease (diagnosed by the criteria listed above based on the absence of both footpulses on the affected extremity) were excluded. **Pretreatment:** wound size was nearly greater in the iTCC group (2.71.3 vs.2.01.1 cm2,P0.07)
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: an RCW (Ac-tive Offloading Walker; Royce Medical,Camarillo, CA) ● *Duration*: 12 w ● *Dose*: followed on weekly basis Kontrol 1 ● *Description*: an RCW (Ac-tive Offloading Walker; Royce Medical,Camarillo, CA) or the same devicewrapped entirely in a cohesive bandage(iTCC). ● *Duration*: 12 w ● *Dose*: followed on weekly basis
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks) *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks) *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported
Identification	**Sponsorship source:** This work was sup-ported by U.S. Department of Veterans Affairs,Health Services Research and DevelopmentAward IIR 20-059 and the Rehabilitation Re-search and Development Merit AwardA2150RC. **Country:** USA **Setting:** randomly assigned 50 patients withUniversity of Texas grade 1A diabetic foot ulcerations into one of two off-loading treatmentgroups: an RCW or the same RCW wrapped with a cohesive bandage (iTCC) **Authors name:** DAVID G. ARMSTRONG **Institution:** Center for Lower Extremity Ambulatory Research, the Dr. William M. Scholl College of PodiatricMedicine at Rosalind Franklin University of Medicine, Chicago, Illinois **Email:** E-mail: armstrong@usa.net **Address:** Scholl College of Podiatric Medicine at Rosalind Franklin University of Medicine and Science, 3333 GreenBay Rd., North

	Chicago, IL 60064
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly assigned through a computerized randomization schedule. Randomization was performed after the initial screening,"
Allocation concealment (selection bias)	Low risk	Quote: "Randomization was performed after the initial screening, with allocation provided to the treating clinician by a sin- gle study coordinator via telephone."
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No blinding
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: No information about blinding. Outcomes of interest are objectively measured.
Incomplete outcome data (attrition bias)	Low risk	Quote: "Of an initial enrollment pool of 50 patients, 4 failed to complete the course of study. Reasons for this included discomfort/ weight of the device (one RCW, one iTCC) or failure to return for follow-up appoint- ments or data collection visits (two RCW). These patients were considered treatment failures (nonhealers) for the purpose of the intent-to-treat analysis."
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol.
Other bias	Low risk	Judgement Comment: No reasons to suspect other sources of bias.

Caravaggi 2000

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 59.2 (9.9) ● *Female, N (%)*: 8 ● *BMI, mean (SD)*: 27.3 (2.5) ● *Current smoker, N (%)*: 10 ● *Distal blood pressure (mmHg), mean (SD)*: 1.03 (0.8) ● *Wound area (cm2), mean (SD)*: 431.7 ● *Peripheral neuropathy, N (%)*: 25 Kontrol 1 ● *Age, mean (SD)*: 60.5 (10.7) ● *Female, N (%)*: 8 ● *BMI, mean (SD)*: 27 (1.6) ● *Current smoker, N (%)*: 5 ● *Distal blood pressure (mmHg), mean (SD)*: 1.00 (0.7) ● *Wound area (cm2), mean (SD)*: 587.3 ● *Peripheral neuropathy, N (%)*: 25 **Included criteria:** diabetic patients with neuropathic plantarulcers. All the subjects were insensitive toSemmes-Weinstein 5.07 monofilament andhad a vibration perception threshold of 25 V,measured on the malleolus with a biothe-siometer (Neurothesiometer; S.L.S., Notting-ham, U.K.). **Excluded criteria:** The exclusion criteria were theclinical presence of deep or superficial tissueinfection or underlying osteomyelitis (boneexposure or X-ray of the foot), transcuta-neous PO2(30 mmHg and/or ankle-brachialindex [ABI] of 0.6), severe problems inmaintaining equilibrium, severe visualdeficit, skin lesions of the foot (other than the ulcer under study) or leg, amputation ofa limb, or plantar bilateral ulcerations.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: .In this study, we used a cloth therapeuticshoe with a rocker-bottom sole and a rollingpoint that is situated beside the metatarsalarch during walking. The shoe is predis-posed (extra depth) for lodging an8 - mm–thick cushioned elastic insole madeof plastazote (alkaform) on which an area ofunloading is prepared in the area of theplantar ulcer. The unloading area must be5–8 mm larger than the perimeter of theulcer. The shoe is opened dorsally with vel-cro straps that permit the dressing to stay inplace (Fig. 3). All patients used the sametype of shoe, with a plantar insole but noarea of unloading, for theunaffected foot. ● *Duration*: 30 days ● *Dose*: change every 2. day Kontrol 1 ● *Description*: Two types of fiberglass bandages were usedfor the construction of the pressure-reliefapparatus. The first type of bandage (Softcast3M; 3M Health Care, St. Paul, MN) wascomposed of fiberglass imbued with apolyurethane resin with characteristics offlexibility and resistance. The other bandage(Scotchcast 3M; 3M Health Care) was com-posed of fiberglass imbued with apolyurethane resin of two different concen-trations that confers high resistance to load-ing. Before using both types of bandages, atubular stockinet was placed onto the lowerlimb, which was first covered with Germancotton to protect the skin adequately, espe-cially on bony protrusions. To further protectbony protrusions, such as the malleolus andtibial crista, some pieces of protective rubberfoam (Microfoam 3M; 3M Health Care) werealso applied. The plaster bandages wereapplied so that the boot conformed to theshape of the leg as much as possible.The first two layers were applied usingthe Softcast bandage. The structure wasthen reinforced with a stick made with aScotchcast bandage placed in the middle ofthe two malleoli, extending beyond themfor at least 20 cm, giving rigidity to the cast.The same material was used to build a rigidplantar sole. The number of layers appliedto construct the sole depended on theweight of the patient (range 3–8 layers).The final structure was reinforced withmore Softcast bandages.An aluminum stirrup or rubber heelwas anchored to the structure as a support toallow walking (Fig. 1). The side supportswere secured with an outer layer of Softcast.The choice of using the stirrup or the rubberheel as a support for walking depends on theposition of the ulcer. The stirrup is used ifthe ulcer is localized in the midfoot region.This support leaves the entire plantar surfaceof the boot free from pressure and permitsthe construction of an opening precisely inthe ulcerated region. Therefore, examina-tion and changes of dressing to the ulcer canbe performed as frequently as needed. Arubber heel is used when lesions are locatedon the forefoot, the plantar surface of thetoes, or the heel because it allows an openwindow directly above the ulcer (Fig. 2).The rubber heel is positioned in the center ofthe plantar surface to allow comfortablewalking. In all subjects, the sole of the unaf-fected foot's shoe was elevated to ease walk-ing.

	● *Duration*: 30 days
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported ● **Direction**: Lower is better ● **Data value**: Længste follow-up *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Direction:** Higher is better ● **Data value:** End point (30 days.) ● **Scale:** Subject satisfaction (VAS 0-100). *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (30 days weeks) *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (30 days) *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (30 days) *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (30 days)
Identification	**Sponsorship source:** no funding **Country:** Italy **Setting:** Fifty diabetic patients with neuropathicplantar ulcers were consecutively enrolled and randomized to one of two treatment groups. Ofthe 50 patients, 24 were treated with a specialized cloth shoe with a rigid sole and an unload-ing alkaform insole (shoe group), and 26 patients were treated with a nonremovable off-bear-ing fiberglass cast (cast group **Authors name:** Carlo Caravaggi, **Institution:** the Center for the Study and Treatment of Diabetic Foot Pathology, Ospedale di Abbiategrasso (C.C.,R.D.G., E.S., C.P.); Internal Medicine Unit (E.F., M.M., A.Q., M.G.), Policlinico Multimedica, Sesto S. Gio-vanni (Milan); and the Institute of Medical Stat **Email:** cara@mail3.telnetwork.it **Address:** Centro per la Cura e lo Studio delPiede Diabetico, Pz Mussi 1, Abbiategrasso (Milano) 20080, Italy.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomization required that a patient was assigned to the shoe or cast group by calling the Biometrics Institute, University of Milan, Milan, Italy, where a table of ran- dom numbers was consulted." Quote: "No noteworthy differences were found between the two groups with respect to clinical characteristics (Table 1). There was no statistical difference in ulcer area at enrollment between the two study groups (431.7 [391.7 mm 2] in the shoe group and 587.3 [587.7 mm 2] in the cast group, P = 0.415)."
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: concealed by a phone call of the patients to an office in italy with a random table of numbers for allocation
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information and blinding not feasible.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No information about blinding. Outcomes of interest are objectively measured except patient acceptance.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: LIkely no attrition

Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol.
Other bias	Low risk	Judgement Comment: No reasons to suspect other sources of bias.

Caravaggi 2007

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Peripheral neuropathy, N (%)*: 29 Kontrol 1 ● *Peripheral neuropathy, N (%)*: 29 **Included criteria:** All participants had peripheral neu-ropathy, as highlighted by insensitivity to10 g monofilament and vibration percep-tion threshold measured by biothesiom-eter at malleolus of at least 25 volts, andpresented with a neuropathic ulcer on thewhole part of the plantar surface of thefoot, including ulcers correlated withCharcot neuroarthropathy deformities **Excluded criteria:** We excluded patients with superficialtissue infection, osteomyelitis, TcPO2(transcutaneous PO2)30 mmHg, anklebrachial index0.6, severe visual deficit,severe problems of equilibrium, amputa-tion of the controlateral limb, and bilat-eral plantar ulcers.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: The Aircast Pneumatic Walker (XP Dia-betic Walker) is an off-loading device. Itskey elements include a semi-rigid plasticshell surrounding the limb, a removablefront panel allowing easy access to the in-jured site, four individual internal aircellsinflated with manometer at 20 −30 mmHgto hold the limb, a specifically designedrocker sole for improved off-loading, anda dual-density insole. A hole was made onthe insole at the ulcer site in order to off-load the ulcer ● *Duration*: 90 days Kontrol 1 ● *Description*: Fiberglass off-loading castIn previous literature, we describe twotypes of fiberglass bandages of differentrigidity that were used in the constructionof a pressure-relief device (7). Before us-ing both types of bandages, a tubularstockinet was placed onto the lower limb,which was first covered with German cot-ton to adequately protect the skin, espe-cially bony protrusions. A walking stirrupwas used for support when the ulcer waslocalized in the midfoot region, whereas arubber heel was used when lesions werelocated on the forefoot, the plantar sur-face of the toes, or the heel. ● *Duration*: 90 days
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (90 days) *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (90 days) *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Higher is better ● **Data value**: Endpoint (90 days) *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (90 days)
Identification	**Sponsorship source:** no funding **Country:** italy **Setting:** 60 consecutive dia-betic patients with neuropathic plantarulcers were seen and randomly assignedto two groups: group A, using an AircastPneumatic Walker (XP Diabetic Walker);and group B, using the fiberglass off-loading cast

	Authors name: CARLO CARAVAGGI **Institution:** Department of Diabetic Foot Pathology, Ospedale di Abbiategrasso, Milan, Italy **Email:** carlo.caravaggi@fastwebnet.it. **Address:** Ospedale di Abbiategrasso, DiabeticFoot Pathology, Pz Mussi 1, Abbiategrasso (Milano) 20080, Italy.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "No statistical difference was seen between groups in the positioning of the ulcer on the plantar surface of the foot." Quote: "and bilat- eral plantar ulcers. Clinical characteristics (age, sex, type of diabetes, and duration of diabetes) of both groups were compara- ble. The mean area of the ulcer was 3.4 3.0 cm 2 in group A and 3.9 3.4 cm 2 in group B (NS). No statistical difference was seen" Quote: "January 2005 and October 2005, 60 consecutive dia- betic patients with neuropathic plantar ulcers were seen and randomly assigned to two groups: group A, using an Aircast Pneumatic" Judgement Comment: Unclear sequence generation
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information about blinding, likely unblinded.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: No information about blinding however all outcomes of interest are objectively measured.
Incomplete outcome data (attrition bias)	Low risk	Quote: "One patient from each group was ex- cluded due to noncompliance."
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol available.
Other bias	Low risk	Judgement Comment: No reasons to suspect other sources of bias.

Chakraborty 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 53 (13.19) ● *BMI, mean (SD)*: 23.51 (4.18) ● *HBA1C, mean (SD)*: 8.09 (1.16) ● *Wound area (cm2), mean (SD)*: 7.85 (3.70) Kontrol 1 ● *Age, mean (SD)*: 51.40 (12.84) ● *BMI, mean (SD)*: 22.7 (4.34) ● *HBA1C, mean (SD)*: 8.21 (1.08) ● *Wound area (cm2), mean (SD)*: 10.02 (4.58) **Included criteria:** To be eligible for the study, participants should be ambulatory, have solitary neuropathic plantar ulcer grade 1A or 2A using the University of Texas scale, and unilateral foot involvement. The grade was based on clinical examina-tion and evaluation of a plain digital radiograph **Excluded criteria:** Patients unable to walk indoors, with significant comorbidities, infected ulcers and/or osteomyelitis, ankle brachial index (ABI) < 0.9, and Charcot osteoarthropathy were excluded.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Preparation of PRAFO was a bit complicated. At first cast was taken by maintaining the ankle at neutral position. Once the cast was set, it was removed from the extremity and filled with liq-uid POP. At that time modifications were done to get proper clearance of malleoli to avoid pressure over the malleoli. Further adjustments were made to keep the toe in hyperextension (for getting the toe rocker), keep the ankle at 90 degrees and make the arch in proper shape. A build-up of 3 mm thickness was made around the ulcerate area to offload the ulcer. Ankle joints were incorporated to provide ankle motion. Pelite sheet was molded over the planter aspect of the foot and a 3 mm polypro-pylene sheet was draped over the modified mold. Once it was completely set, it was gently removed with the necessary trim lines. Velcro closures were provided and the required trials were carried out over the patient. After the required trials, the brace was well padded off (Figure 2) ● *Duration*: 4 w Kontrol 1 ● *Description*: TCC was done by plaster of Paris (POP) cast and a simple rubber insole was incorporated between the sole of the patient and the POP cast (Figure 1). Before incorporating the insole, the area of the insole overlying the ulcer was removed from its plantar aspect (that is from that part of insole, which is in contact with the POP cast) to avoid pressure on the ulcer. The cast was allowed to dry and it became irremov-able. The patients were asked to come after 2 weeks. The gait parameters were taken and the TCC was removed. The limb was inspected, the wound was cleaned with normal saline, and a new TCC was put on for another 2 weeks ● *Duration*: 4w
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Sårheling (total sårlukning (ja/nej)), efter endt behandling*

	● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Direction:** Higher is better ● **Data value:** End point (4 weeks) ● **Scale:** Percentage surface area reduction 0-100 *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported
Identification	**Sponsorship source:** no funding **Country:** india **Setting:** Thirty adult diabetic patients attending the foot clinic with neuropathic plantar ulcers irrespective of sex, age, duration and type of diabetes were randomly assigned to 1 of 2 off-loading modalities (TCC and PRAFO **Authors name:** Partha Pratim Chakraborty **Institution:** Department of Endocrinology and Metabolism, **Email:** sayantan.ray30@gmail.com **Address:** Institute of Post Graduate Medical Education & Research (IPGMER) and SSKM Hospital, Kolkata, West Bengal, India
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The mean age, duration of diabetes, BMI, and glycemic sta- tus of the patients at study entry were statistically insignifi- cant between the 2 groups. The mean surface areas of the plantar ulcers between the groups were also not significant at the baseline (Table 1)." Quote: "Patients were randomly allocated to 1 of 2 off-loading proce- dures using the randomization table:"
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information about allocation concealment.
Blinding of participants and personnel (performance bias)	High risk	Quote: "Wound care and wound debridement was carried out by a single podiatrist blinded to treatment mode. Tissue" Judgement Comment: Patients not blinded, participants likely blinded.
Blinding of outcome assessment (detection bias)	Low risk	Quote: "The area of the wound was then calculated by counting the number of squares in the graph paper and was expressed as cm 2. Photographs were taken of each ulcer." Judgement Comment: No information about blinding of outcome assessors. Wound size was the only outcome of interest and were objectively measured.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: likely no attrition
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol available.
Other bias	Low risk	Quote: "The author(s) received no financial support for the research, author- ship, and/or publication of this article."

Faglia 2010

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 61.7 (10.4) ● *Female, N (%)*: 7 ● *BMI, mean (SD)*: 30.3 (1.1) ● *HBA1C, mean (SD)*: 7.5 (1.1) ● *Wound area (cm2), mean (SD)*: 2.2 (2.2) Kontrol 1 ● *Age, mean (SD)*: 59.0 (8.5)

	● *Female, N (%)*: 8 ● *BMI, mean (SD)*: 32.3 (4.5) ● *HBA1C, mean (SD)*: 9.1 (2.1) ● *Wound area (cm2), mean (SD)*: 1.4 (1.2) **Included criteria:** Study inclusion criteria were the presence of a neuropathic plantar forefoot ulcer with an area graded IA according to the University of Texas Classification of Dia-betic Wounds (11). Peripheral neuropa-thy was diagnosed based on insensitivity to a 10-g Semmes-Weinstein monofila-ment in more than six of nine areas of the foot and by a vibration perception thresh-old measured by biothesiometer (Neu-rothesiometer SLS, Nottingham, U.K.) at the malleolus of 25 V. **Excluded criteria:** Exclusion criteria were the presence of an ankle-brachialpressure index 0.9 and/or transcutane-ous oxygen tension 50 mmHg tested on the dorsum of the foot and clinical signs of infection. Both the probe-to-bone maneuver and standard X-ray examination of the foot were required to be negative for osteomyelitis (12). Additional exclusion criteria included use of steroids or antimitotic drugs, the presence of visualproblems that could impair balance, anactive ulcer on the contralateral foot, previous major amputation of the contralateral limb, previous or current deep venous thrombosis of the leg, or mental disorder interfering with patient compliance.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Stabil-DThe Stabil-D device is composed of a spe-cifically designed rigid, boat-shaped, andfully rocker bottom sole: its rounded ex-tremities (at the heel and tiptoe) facilitategait, and its middle section improves themid-stance phase. The insole height (24mm) avoids excessive lifting of the con-tralateral limb during walk, thus loweringthe barycenter and favoring more stablewalking. The cover is made of Elastam(Lycra), a yarn composed of polyurethanesegments and block copolymers that con-fer high transparency and stability to thesystem, mixed with polyethylene glycolsegments with the characteristic of elas-ticity. At the ankle, the cast is providedwith removable, lateral stabilizer insertsmade of ABS, which ensure stability to thetibiotarsal joint and/or adequate supportduring gait. Moreover, a rigid brace madeof a thermoformable polymer materialproperly supports the Achilles tendonand contributes to stability during rollingsteps; such a brace can be adapted to thefoot deformity using a hot air gun andmalleolar forceps. The cast is closed dor-sally with Velcro wrap placed over theforefoot to relieve skin pressure and Vel-cro straps with self-fitting rings placedagainst the instep to secure perfect fasten-ing, provide foot stability, and ensure aperfect fit of the heel in the rigid brace.Finally, more Velcro straps are placed orsecured with rings against the tibia to pro-vide a secure fit. ● *Duration*: 90 days Kontrol 1 ● *Description*: TCC— Patients in the TCC group were casted according to the technique de-scribed previously by Caravaggi et al.(13). All casts were made by personnelwith particular expertise in the use of thisdevice (W.V. in Sesto San Giovanni andD.S. in Milan). Two types of fiberglassbandages were used for construction ofthe pressure-relief apparatus. The firsttype of bandage (Softcast3M; 3M HealthCare, St. Paul, MN) was composed of fi-berglass imbued with a polyurethaneresin with characteristics of flexibility andresistance. The other bandage(Scotchcast3M; 3M Health Care) wascomposed of fiberglass imbued with apolyurethane resin of two different con-centrations that confers high resistance toloading. A bandage with German cottonand tubular stockinet was placed on thelimb. To further protect bony protru-sions, such as the malleolus and tibialcrista, pieces of protective rubber foam(Microfoam 3M; 3M Health Care) werealso applied. The structure was then rein-forced with a stick made of a Scotchcastbandage placed in the middle of the twomalleoli, extending beyond them for atleast 20 cm to give rigidity to the cast. Thesame material was used to build a rigidplantar sole. The number of layers appliedto construct the sole depended on theweight of the patient (range 3– 8 layers).An aluminum stirrup was anchored to thestructure as a support to allow walking.The side supports were secured with anouter layer of Softcast3M. After very brieftraining, all patients were able to walkproperly without crutches ● *Duration*: 90 days
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (90 days) *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Direction:** Higher is better ● **Data value:** 4 weeks ● **Scale:** Cm2 change from baseline *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (90 days) *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported

	Frafald, alle årsager, efter endt behandling ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: End point (90 days)
Identification	**Sponsorship source:** We acknowledge thecontribution of Podartis, Montebelluna, Tre-viso, Italy, manufacturers of the Stabil-D walk-ers used in this study **Country:** italy **Setting:** Forty-five adult diabetic patients with non-ischemic, noninfected neuropathic plantar ulcer were randomly assigned for treatment with anonremovable fiberglass off-bearing cast (total contact cast [TCC] group) or walker cast (Stabil-Dgroup). **Authors name:** EZIO FAGLIA **Institution:** diabetic foot center, Milan **Email:** iacomo.clerici@multimedica.it. **Address:** Diabetic Foot Center, Istituto di Ricovero e Cura a Carattere Scientifico Multimedica, Sesto SanGiovanni, Milan, Italy
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were ran- domly assigned to one of the two treat- ment groups by opening randomization codebreak envelopes containing one of the two options. Separate randomization was performed for each center," Judgement Comment: Likely random however, unclear how randomisation was performed
Allocation concealment (selection bias)	Unclear risk	Quote: "Patients were ran- domly assigned to one of the two treat- ment groups by opening randomization codebreak envelopes containing one of the two options. Separate randomization was performed for each center, and a copy of all randomization envelopes was kept at the statistical department of the Multi- medica center."
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No blinding.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: No blinding however, only obectively assessed outcomes.
Incomplete outcome data (attrition bias)	Low risk	Quote: "however, 2 patients in the TCC group and 1 patient in the Stabil-D group did not complete the study and were considered dropouts." Judgement Comment: <10% drop out. Per protocol analysis.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol.
Other bias	Unclear risk	Quote: "to provide TCCs. Acknowledgments — We acknowledge the contribution of Podartis, Montebelluna, Tre- viso, Italy, manufacturers of the Stabil-D walk- ers used in this study. No other potential conflicts of interest rele- vant to this article were reported. References 1. Boulton AJ. The" Judgement Comment: No description of Padartis role in the study however, likely limited to funding only.

Ganguly 2008

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Female, N (%)*: 9 Kontrol 1 ● *Female, N (%)*: 9 **Included criteria:** pt with DFU **Excluded criteria:** osteomyelitis and any other contraindication of total contact casting
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: sharp debridement, dressing of normal saline and gauze ● *Duration*: complete healing or 6 months ● *Dose*: change every 2. day Kontrol 1 ● *Description*: sharp debridement, dressing of normal saline and gauze and an applied TCC ● *Duration*: complete healing or 6 months
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: 6 months *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better

	● **Data value**: Endpoint (6 months) *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (6 months) *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (6 months)
Identification	**Sponsorship source:** no funding **Country:** india **Setting:** Total contact casting is one such method of offloading, and this study attempts to investigate the advantages of the above method as compared to conventional dressings in the physiatric management of the depth--ischaemia grades 1A, 1B, 2A, 2B neuropathic plantar ulcers in a diabetic patient. **Authors name:** Ganguly S **Institution:** Department of physical medicine and rehabilitation, institute of postgraduate mediacal education and research, kolkata **Email:** no email **Address:** Department of physical medicine and rehabilitation, institute of postgraduate mediacal education and research, kolkata, 700020
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: Unclear randomisation schedule. Annotation: "The selected patients were randomly allocated into category(...)"
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Not feasible to blind participants. No information about blinding of personnel.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: No information about blinding of assessors however, only objectively measured outcomes.
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: 3 vs 0 drop outs from standard dressing and TCC respectively, without reported reasons. Per protocol analysis
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol available. Reporting of critical outcome (amputations and wound healing).
Other bias	Low risk	Judgement Comment: No reasons to suspect other sources of bias.

Lavery 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Female, N (%)*: 12 ● *Type 2 diabetes, N (%)*: 25 (92.6) ● *Distal blood pressure (mmHg), mean (SD)*: 1.11 (0.32) ● *Wound area (cm2), mean (SD)*: 2.3 (4.1) Kontrol 1 ● *Female, N (%)*: 7 ● *Type 2 diabetes, N (%)*: 20 (87) ● *Distal blood pressure (mmHg), mean (SD)*: 1.11 (0.19) ● *Wound area (cm2), mean (SD)*: 2.2 (3.5) **Included criteria:** Diabetic patients with grade UT1A or UT2A forefoot ulcers(the University of Texas Ulcer Classification System) (18) onthe sole of the foot were enrolled. If more than one ulcer waspresent, the largest ulcer meeting all the eligibility criteria wasselected as the index ulcer. Other ulcers were treated in thesame manner as the study ulcer. **Excluded criteria:** Patients were excluded based on the following criteria: inability to care for their ulcer during the study period (e.g.

	because of vacation, hospitalisation anddisability), widespread malignancy, systematically immune-compromising disease, severe peripheral vascular disease (ABI < 0·60 or transcutaneous oxygen < 25 mm/Hg), alcoholor substance abuse within 6 months, untreated osteomyelitisor Charcot arthropathy with residual deformity that was too severe to allow proper fit of the removable walking boot,and patients with postural stability that was not adequateto safely ambulate in a TCC or walking boot.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: shear reducing walker ● *Duration*: 12 w Kontrol 1 ● *Description*: TCC ● *Duration*: 12 w
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Direction:** Higher is better ● **Data value:** End point (12 weeks) ● **Scale:** Patient acceptance of treatment (VAS 0-10) *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks) *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Direction:** Lower is better ● **Data value**: Endpoint (12 weeks) wound size (cm2) *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks) *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks) *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Higher is better ● **Data value**: Endpoint (12 weeks) *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse event ● **Reporting**: Not reported *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks)
Identification	**Sponsorship source:** a grant from the national institute of health **Country:** usa **Setting:** 12 week singleblinded rct consisting of 73 pt divided in three groups. TCC vs walker vs sandals **Authors name:** Lawrence a lavery **Institution:** Department of surgery, university of texas **Email:** larry.lavery@utsouthwestern.edu **Address:** University of texas southwestern medical center
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement Comment: A computer-generated list
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Unclear concealment however, computer generated sequence generation.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information, likely unblinded

Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: Blinding not feasible likely influencing self-reported rating of ability to perform daily activites and compliance with device. Other outcomes of interest are "objective"
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Patients completing study 78% and 56% in TCC and walker group respectively. Adequate ITT and per protocol analysis. Unbalanced drop outs.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol.
Other bias	Low risk	Judgement Comment: No reasons to suspect other sources of bias.

Mueller 1989

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 55 (12) ● *Female, N (%)*: 5 ● *Type 2 diabetes, N (%)*: 13 ● *Wound area (cm2), mean (SD)*: 2.8 (3.4) ● *Peripheral neuropathy, N (%)*: 19 Kontrol 1 ● *Age, mean (SD)*: 54 (10) ● *Female, N (%)*: 8 ● *Type 2 diabetes, N (%)*: 16 ● *Wound area (cm2), mean (SD)*: 1.8 (2.5) ● *Peripheral neuropathy, N (%)*: 21 **Included criteria:** Criteria for inclusion in the study were that the patienthad been diagnosed with diabetes mellitus and currently had a plantar ulcer **Excluded criteria:** No evidence of gross infection (no significant edema or drainage), osteomyelitis (deter-mined by radiograph or radionuclide scans), or gan-grene (visibly discolored or necrotic tissue).
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: All subjects had the option to discontinue treatmentat any time. Subjects refusing to receive treatment fromtheir assigned treatment group before complete woundclosure were considered not healed. Ulcers that becamegrossly infected, increased in size, or showed no im-provement after 6 wk were considered not healed. Ul-cers were considered healed if they showed completeskin coverage and no drainage. ● *Duration*: 6w ● *Dose*: change 2-3 times each day Kontrol 1 ● *Description*: Casts were applied by a physical therapist on the ini-tial visit as described elsewhere (7,8). Briefly, the ulcerwas covered with one thin layer of gauze. Cotton wasplaced between the toes to prevent maceration, and astockinette was applied to the lower leg with Vb-inch feltpads applied to the malleoli and anterior tibia and afoam pad placed around the toes. A total contact plastershell was then molded around the lower leg. The shellwas reinforced with plaster splints, and a walking heelwas attached to the plantar surface. A fiberglass roll wasapplied around the plaster for extra durability and toallow bearing weight sooner than would be allowedwith plaster alone. Patients were given a written list ofprecautions and instructed to limit ambulation to 33%of their usual activity (7). Assistive devices (walkers orcrutches) were provided to patients requiring them.Casts were removed after 5-7 days, and the ulcer andskin inspected. If there were no complications (i.e., ad-ditional skin breakdown, deterioration of the ulcer, orpatient refusing additional casting), the cast was reap-plied and changed every 2-3 wk until the ulcer wascompletely healed ● *Duration*: 6w ● *Dose*: changed every 2w
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint (6 weeks) *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Higher is better ● **Data value**: Endpoint (6 weeks) *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Scale**: Wound infection ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint (6 weeks) *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported

	● **Scale**: Proportion of induced wounds ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint (6 weeks) *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reportede *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse Event ● **Reporting**: Not reported *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse Event ● **Reporting**: Not reported *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Unit of measure**: Drop outs, all causes ● **Direction**: Lower is better ● **Data value**: Endpoint (6 weeks)
Identification	**Sponsorship source:** This study was supported by a grant from the Foun-dation for Physical Therapy. **Country:** USA **Setting:** Fortypatients with diabetes mellitus and a plantar ulcer butwith no gross infection, osteomyelitis, or gangrene wererandomly assigned to the TCC group (n = 21) or TDTgroup (n = 19). **Authors name:** Michael |. Mueller **Institution:** Irene Walter Johnson Rehabilitation Institute, Program in Physical Ther-apy, and Division of Orthopedic Surgery, Department of Surgery, WashingtonUniversity School of Medicine,st. louis, Missouri **Email:** no email contact **Address:** Washington University School of Medicine, Box8083, 660 South Euclid Avenue, St. Louis, MO 63110
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "As shown in Table 1, there was no significant difference in distribution of subject characteristics between the two groups (P > .05)." Quote: "The study was approved by the human studies committee at Washington University School of Medicine, and all patients participating in the study were randomly assigned to either the TCC or TDT group." Judgement Comment: No information about specific sequence generation. Likely difference in ulcer size.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information about concealment
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information about blinding, likely no blinding (not feasible)
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: No information about blinding of outcome assessors. However "objectively" measured outcomes.
Incomplete outcome data (attrition bias)	Low risk	Quote: "Five of 19 (26%) patients in the TDT group showed serious foot infection that required admission to a hospital. Two of these patients required a forefoot am- putation." Judgement Comment: Likely all 40 patients contributed with outcome data thus no attrition reported.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol.
Other bias	Low risk	Quote: "This study was supported by a grant from the Foun- dation for Physical Therapy." Judgement Comment: no competing interests or other bias' No reasons to suspect other sources of bias.

Najafi 2017

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 54.8 (7.3) ● *Female, N (%)*: 1 ● *BMI, mean (SD)*: 27.8 (5.4) ● *HBA1C, mean (SD)*: 10.3 (2.8) ● *Wound area (cm2), mean (SD)*: 10.13 (12) Kontrol 1 ● *Age, mean (SD)*: 52.1 (8.2) ● *Female, N (%)*: 3 ● *BMI, mean (SD)*: 30.8 (6.6) ● *HBA1C, mean (SD)*: 10.3 (1.7) ● *Wound area (cm2), mean (SD)*: 6.46 (8.48) **Included criteria:** Forty-nine eligible subjects with confirmed diabetes and PN, age 18 or older with noninfected, non ischemic, plantar neu-ropathic foot ulcers.If subjects had noncompressible vessels (ABI > 1.2), we measured toe pressures to determine a toe brachial index (TBI). A TBI > 0.65 was required for enrollment.

	Excluded criteria: Subjects with major foot amputation, active Charcot arthropathy, ankle brachial index (ABI) of 0.5 or less,27 history of alcohol or substance abuse within 6 months, or unable to keep research appointments were excluded. In addition, we excluded those patients, who could not be accommodated in a standard removable cast walker or were unable to walk a distance of minimum 20 minutes with or without an assistive device.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Removable cast walker (RCW, DH Offloading Walker, Ossur, Reykjavik, Iceland) ● *Duration*: 12 w Kontrol 1 ● *Description*: instant total contact cast (iTCC, the same RCW wrapped with a cohesive bandage, rendering it irremovable; Figure 1 ● *Duration*: 12 w
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks) *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Higher is better ● **Data value**: Endpoint (12 weeks) *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: Decrease in wound surface area ● **Direction**: Higher is better ● **Data value**: Endpoint (12 weeks) *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Scale**: Wound infection ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks) *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse Event ● **Reporting**: Not reported *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse Event ● **Reporting**: Not reported *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse Event ● **Reporting**: Not reported *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Unit of measure**: Drop outs, all causes ● **Direction**: Lower is better ● **Data value**: Endpoint (12 weeks)
Identification	**Sponsorship source:** The project described was supported in part by a grant from the Qatar National Research Foundation (Award Number NPRP 4-1026-3-277, http://www.qnrf.org/). The content is solely the responsibility of the authors and does not necessarily represent the official views of the Qatar National Research Foundation. None of the authors employed or contracted by the fund **Country:** USA **Setting:** Forty-nine people with diabetic foot ulcers were randomized to wear either a removable cast walker (RCW) or an irremovable instant total contact cast (iTCC). **Comments:** **Authors name:** Bijan Najafi **Institution:** Interdisciplinary Consortium on Advanced Motion Performance (iCAMP) **Email:** najafi.bijan@gmail.com **Address:** Department of Surgery, Baylor College of Medicine, One Baylor Plaza, MS:BCM390, Houston, TX 77030, USA.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Using a computer generated randomization list, partici- pants were assigned to one of the two off-loading modalities; removable cast walker (RCW, DH Offloading Walker, Ossur, Reykjavik, Iceland) and instant total contact cast (iTCC, the same RCW wrapped with a cohesive bandage, rendering it irremovable; Figure 1)."
Allocation concealment (selection bias)	Low risk	Quote: "Sequentially numbered, opaque envelopes that contained the study group assignment were provided to each site. At the time of randomization, an enve- lope was opened by the study coordinator to identify the study group assignment."
Blinding of participants and personnel (performance bias)	High risk	Quote: "predictors to successful wound healing. The person who analyzed the data was blind to the type of intervention. The collected physical activity data" Judgement Comment: Not feasible to blind patients and investigator not blinded.
Blinding of outcome assessment (detection bias)	Low risk	Quote: "ensure the absence of infection. At each study visit the study coordi- nator took photographs of the wound, which were planimet- rically measured using a 3-D imaging system (Silhouette, ARANZ Systems, Christchurch, New Zealand) and assessed by a clinician unaware of specific study allocation. This pro- vides measures of wound area, length and width. Pre and post treatment photos were taken. Areas of new epithelium or" Judgement Comment: Only objective outcomes likely blinded..
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: All randomised received group intervention. n= 4 and 2 excluded from analysis in iTCC and RCW respectively. Per protocol analysis.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol available.
Other bias	Low risk	Quote: "The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The project described was supported in part by a grant from the Qatar National Research Foundation (Award Number NPRP 4-1026-3- 277, http://www.qnrf.org/). The content is solely the responsibility of the authors and does not necessarily represent the official views of the Qatar National Research Foundation. None of the authors employed or contracted by the funder." Judgement Comment: No reasons to suspect other sources of bias.

Piaggesi 2016

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 62.3 (9.2) ● *Female, N (%)*: 20 (45%) ● *BMI, mean (SD)*: 29.7 (3.3) ● *HBA1C, mean (SD)*: 8.4 (1.0) Kontrol 1 ● *Age, mean (SD)*: 61.4 (9.7) ● *Female, N (%)*: 20 (40%) ● *BMI, mean (SD)*: 30.2 (3.9) ● *Type 2 diabetes, N (%)*: ● *HBA1C, mean (SD)*: 8.1 (0.9) **Included criteria:** type 1 or type 2 diabetes lasting for at least 5 years; presence of a forefoot plantar ulcer wider than 1 cm2, staged IA or IIA according to the University of Texas Diabetic Wound Classification,1 last-ing at least 6 weeks; ankle-brachial pressure index ≥0.9 with 2 palpable pulses in the affected foot. **Excluded criteria:** Exclusion cri-teria were the presence of infection according to the crite-ria of the Infectious Disease Society of America guidelines20; surgical procedure in the previous year on the affected foot; inability to actively dorsiflex the affected foot; involvement of deeper foot structures, that is, probe-to-bone negative; presence of other lesions in the same or contralateral foot; diagnosis of acute or chronic Charcot foot, either in the affected or contralat-eral foot; lower limb edema; chronic renal insufficiency as demonstrated by creatinine >2 mg/dL; previous minor or major amputations in the affected or contralateral limb; nonambulatory; body mass index >35; visual impairment; metabolic decompensation with HbA1c >10%; cancer; HIV-positive; or any local or systemic conditions that may impair tissue repair. In cases of suspected osteomy-elitis, a radiograph of the foot and a magnetic resonance imaging was performed in order to confirm the diagnosis and justify exclusion from the study.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: RWD; accommo-dative offloading was obtained by cutting a hole in the intermediate layer of the 3-layered insole of the device, corresponding to the lesion, in order to reduce the pressure in the area. ● *Duration*: 90 days Kontrol 1 ● *Description*: The TCC was made using fiberglass material (Scotchcast longuettes and Softcast rolls; 3M Health Care, St Paul, MN) with padding put over the ulcer, according to the pro-cedure previously described by Petre eta ● *Duration*: 90 days
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported

	● **Scale**: Able to perform normal daily activities (VAS 0-10) ● **Unit of measure**: Points ● **Direction**: Higher is better ● **Data value**: Endpoint (90 days) *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Higher is better ● **Data value**: Endpoint (90 days) *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: wound area cm2 ● **Direction**: Lower is better ● **Data value**: Endpoint (90 days) *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Tryksår, i interventionsperioden* ● **Outcome type**: AdverseEvent ● **Reporting**: Not reported *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Not reported *Venetrombose, i interventionsperioden* ● **Outcome type**: AdverseEvent ● **Reporting**: Not reported *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Reporting**: Not reported *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: Drop outs, all causes ● **Direction**: Lower is better ● **Data value**: Endpoint (90 days)
Identification	**Sponsorship source:** he author(s) received no financial support for the research, authorship, and/or publication of this article **Country:** italy **Setting:** 60 patients with DFUs, randomly assigned to 3 different offloading modalities: TCC (group A), walking boot rendered irremovable (i-RWD; group B), and removable walking boot (RWD; group C). Patients were followed up weekly for 90 days **Comments:** **Authors name:** Alberto Piaggesi **Institution:** Sezione Dipartimentale Piede Diabetico, Dipartimento di Area Medica, Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy **Email:** piaggesi@immr.med.unipi.it **Address:** Sezione Dipartimentale Piede Diabetico, Azienda Opspedaliero-Universitaria Pisana, Via Paradisa 2, 56124 Pisa, Italy
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The patients were then randomized, by means of a remote telephone computer-generated randomization into one of the following 3 groups:"
Allocation concealment (selection bias)	Unclear risk	Quote: "The patients were then randomized, by means of a remote telephone computer-generated randomization into one of the following 3 groups: group"
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: no blinding
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Then the patients were evaluated by an investigator blinded to the offloading device adopted for the patient. A photograph and tracing of the lesion were taken, and the local conditions were assessed in order to check for possible complications or signs of infection."
Incomplete outcome data (attrition bias)	Unclear risk	Quote: "The 65 remaining patients were enrolled and randomized in the 3 groups; 3 patients in group A and 2 in group B did not com- plete the study. Of the patients who interrupted the study, all the patients in group A withdrew consent as did one in group B, whereas the other one was lost to follow-up. All the patients who withdrew consent were treated as per stan- dard of care and all healed within the follow-up period." Judgement Comment: 3 drop outs from Group A (control) and 0 drop outs from intervention group. Unbalanced drop outs, no information about the three participants.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol available. Reporting relevant outcomes of interest.
Other bias	Low risk	Quote: "The author(s) received no financial support for the research, authorship, and/or publication of this article." Judgement Comment: No reasons to suspect other sources of bias.

VanDeWeg 2008

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 58.1 (11.1) ● *Female, N (%)*: 2 (10%) ● *HBA1C, mean (SD)*: 8.7 (2.2) ● *Distal blood pressure (mmHg), mean (SD)*: 0.65 (0.21) ● *Wound area (cm2), mean (SD)*: 3.0 (3.1) Kontrol 1 ● *Age, mean (SD)*: 64.8 (10.8) ● *Female, N (%)*: 7 (32%) ● *HBA1C, mean (SD)*: 7.8 (0.3) ● *Distal blood pressure (mmHg), mean (SD)*: 0.69 (0.25) ● *Wound area (cm2), mean (SD)*: 4.2 (3.1) **Included criteria:** Inclusion criteria were confirmed diabetes, sensory neuropathy tested by a quantitativesomatosensory threshold test using the Semmes-Weinstein 5.07 (10 g) monofilament (on firstand fifth metatarsal heads, medial and lateral midfoot and heel), and a plantar ulcer Grade 1or 2 using the Wagner scale (Wagner 1981). The grade was based on clinical examination andevaluation of a plain radiograph; the location of the ulcer and pre-trial ulcer duration wererecorded. **Excluded criteria:** Patients unable to walk indoors, with dementia or life-threatening co-morbidity,ankle/brachial index50.4 and/or osteomyelitis (determined by plain radiograph) wereexcluded.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: CTF. The CTF was custom-made of felt and supplied with a rigid leather socketstiffened with Rhenoflex, a composite of rubber and plastic with thermoplasticproperties. This ensures that movement of the foot in the shoe is restricted to anabsolute minimum. The height of the shoes is twice the distance from the foot base tothe lateral malleolus. The custom full-length insoles were made from cork and aplastazote and PPT (polyethylene foam and polyurethane) covering. Extra depth wasprovided in the inlay for the ulcer. To ensure maximal relief of pressure under theMTPs, the pivot point of the rocker bar was placed proximal to the MTPs and theoutsole stiffened to facilitate the distribution of forces exerted on the foot. A plastic trialcast was always made for a test fitting to check the last measurements, innersoleaccommodation and balance before the shoe was completed. Patients were instructed towear their footwear at all times whilst out of bed. Detailed instructions regarding routinecare of the cast and shoes were given to all patients. All patients were advised to decreasetheir activity levels considerably (i.e., to one-third of their pre-morbid level). To avoidparticipation bias patients in the CTF group were relied upon to wear their shoes ● *Duration*: 16w Kontrol 1 ● *Description*: TCC. A well-moulded and minimally padded non-removable below-knee cast thatmaintains contact with the entire plantar aspect of the foot and lower leg was used. TCCwas applied by a cast technician with at least five years experience using the Kominskytechnique (Kominsky 1991). Prior to casting, a single layer of cast padding was applied.After debridement, the wound was dressed with aquacell (565 cm Hydrofiber [sodiumcarboxymethylcellulose] wound dressing with moisture-resorbing properties). Adhesivefoam was used over bony prominences. Cast shoes with a polyphasic rocker weresupplied; patients with poor postural stability were advised to use a crutch/cane tomaintain balance. The cast was changed on a weekly basis for the duration of the trial(i.e., a maximum of 16 weeks) ● *Duration*: 16w ● *Dose*: Change every week
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: Adverse Event ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint (16 weeks) *Patientrapporteret helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Not reported *Sårheling (total sårlukning (ja/nej)), efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Sårareal, efter endt behandling* ● **Outcome type**: Continuous Outcome ● **Reporting**: Fully reported ● **Scale**: Decrease in wound size (cm2) ● **Direction**: Higher is better ● **Data value**: Endpoint (16 weeks) *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Tryksår, i interventionsperioden* ● **Outcome type**: Adverse Event ● **Reporting**: Not reported *Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Not reported *Venetrombose, i interventionsperioden* ● **Outcome type**: Adverse Event ● **Reporting**: Not reported

	Recidiv af sår, længste follow-up (op til 1 år) ● **Outcome type**: Adverse Event ● **Reporting**: Not reported *Frafald, alle årsager, efter endt behandling* ● **Outcome type**: Dichotomous Outcome ● **Reporting**: Fully reported ● **Unit of measure**: Drop outs, all causes ● **Direction**: Lower is better ● **Data value**: Endpoint (16 weeks)
Identification	**Sponsorship source:** This study was supported by a grant from Convatec Netherlands and the OFOM(Ontwikkelingfonds Orthopedisch Maatschoeisel) **Country:** the netherlands **Setting:** 43 patients with plantar ulcer Grade 1 or 2 (Wagner scale) wererandomized to one of two off-loading modalities: TCC or CTF. **Authors name:** F. B. VAN DE WEG **Institution:** Rehabilitation Centre Amsterdam, **Email:** f.b.vandeweg@olvg.nl **Address:** Ambachtsheerensingel 22, 1393 RE Nigtevecht, The Netherlands
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly allocated to one of two off-loading procedures: Total contact cast (TCC) or custom-made temporary footwear (CTF)." Quote: "An independent person prepared a randomization list in advance with an equal number of treatment assignments (5/5) per block of ten to ensure approximately equal numbers of patients in each treatment group (Pocock 1991)." Quote: "Differences between both groups were observed with respect to gender and baseline wound surface." Judgement Comment: OBS: baseline differences
Allocation concealment (selection bias)	Low risk	Quote: "Allocation was concealed using opaque, sealed envelopes."
Blinding of participants and personnel (performance bias)	High risk	Quote: "All patients attended the out-patient department regularly for device inspection. Wound care and wound debridement was carried out by a podiatrist blinded to treatment mode, and antibiotics dispensed if necessary." Judgement Comment: Participants not blinded.
Blinding of outcome assessment (detection bias)	Unclear risk	Quote: "Wound measurement was undertaken by a research assistant blinded for the treatment; patients were instructed not to discuss the treatment with the investigator. The secondary outcome measure was time to wound healing in days.The exact moment of wound closure was identified by a patient's self-report." Judgement Comment: Patients not blinded however primarily objective outcomes.
Incomplete outcome data (attrition bias)	Low risk	Quote: "The analysis of effectiveness was done according to the intention-to-treat principle." Judgement Comment: 2 drop outs from TCC including deviation from intended intervention, however ITT.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol
Other bias	Low risk	Quote: "This study was supported by a grant from Convatec Netherlands and the OFOM (Ontwikkelingfonds Orthopedisch Maatschoeisel). Neither was involved in the handling of data in any way or in the publication of this manuscript." Judgement Comment: No reasons to suspect other sources of bias.

Footnotes

Characteristics of excluded studies

Agas 2006

Reason for exclusion	Wrong intervention

Birke 2002

Reason for exclusion	Wrong study design

Bus 2018

Reason for exclusion	Wrong comparator

Bus 2018a

Reason for exclusion	Wrong comparator

deOliveira 2015

Reason for exclusion	Wrong study design

Elraiyah 2016

Reason for exclusion	Wrong study design

Hastings 2012

Reason for exclusion	Wrong setting

HealthQualityOntario 2017

Reason for exclusion	Wrong study design

Jeffcoate 2017

Reason for exclusion	Wrong comparator

Johnson 2018

Reason for exclusion	Wrong intervention

Johnson 2018a

Reason for exclusion	Wrong comparator

Katz 2005

Reason for exclusion	Wrong comparator

Lewis 2013

Reason for exclusion	Wrong study design

Miyan 2014

Reason for exclusion	Wrong comparator

Morona 2013

Reason for exclusion	Wrong study design

Nabuurs Franssen 2005

Reason for exclusion	Wrong comparator

Nube 2006

Reason for exclusion	Wrong comparator

Piaggesi 1998

Reason for exclusion	Wrong intervention

Piaggesi 2007

Reason for exclusion	Wrong comparator

Sahu 2018

Reason for exclusion	Wrong intervention

Udovichenko 2006

Reason for exclusion	Wrong comparator

Zimny 2003

Reason for exclusion	Wrong comparator

Footnotes

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Armstrong 2005

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Data and analyses

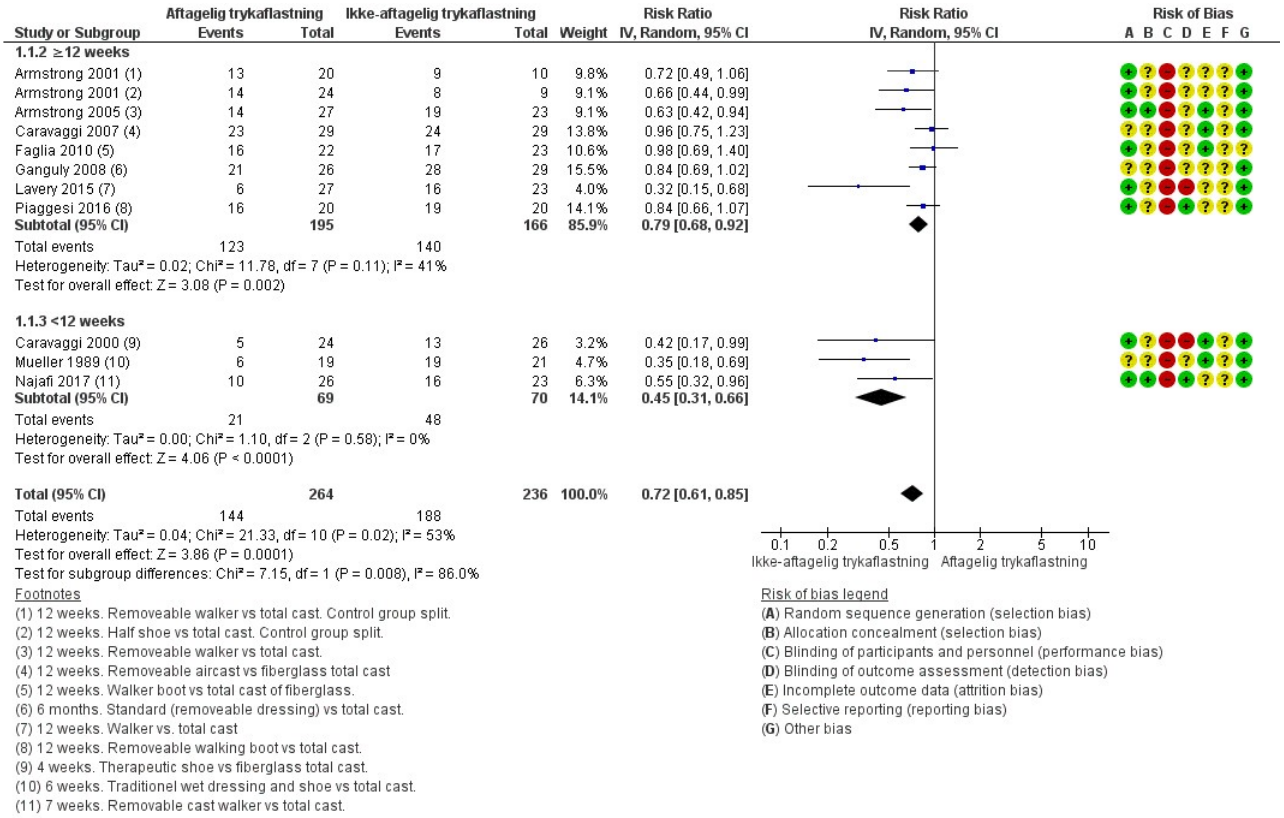
1 Aftagelig vs ikke-aftagelig trykaflastning

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Sårheling (total sårlukning (ja/nej)), efter endt behandling	10	500	Risk Ratio (IV, Random, 95% CI)	0.72 [0.61, 0.85]
1.1.2 ≥12 weeks	7	361	Risk Ratio (IV, Random, 95% CI)	0.79 [0.68, 0.92]
1.1.3 <12 weeks	3	139	Risk Ratio (IV, Random, 95% CI)	0.45 [0.31, 0.66]
1.2 Underekstremitets amputationer (total sårlukning (ja/nej)), længste follow-up (op til 1 år), risk ratio	4	178	Risk Ratio (IV, Random, 95% CI)	0.99 [0.17, 5.87]
1.3 Underekstremitets amputationer (total sårlukning (ja/nej)), længste follow-up (op til 1 år), risk difference	4	178	Risk Difference (IV, Random, 95% CI)	-0.01 [-0.06, 0.05]
1.4 Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden	8	397	Risk Ratio (IV, Random, 95% CI)	1.54 [0.87, 2.74]
1.5 Tryksår, i interventionsperioden, risk ratio	3	169	Risk Ratio (IV, Random, 95% CI)	2.57 [0.11, 60.24]

1.6 Tryksår, i interventionsperioden, risk difference	3	169	Risk Difference (IV, Random, 95% CI)	0.01 [-0.04, 0.06]
1.7 Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence	2	108	Risk Ratio (IV, Random, 95% CI)	0.96 [0.86, 1.07]
1.8 Frafald, alle årsager, efter endt behandling	10	508	Risk Ratio (IV, Random, 95% CI)	0.94 [0.47, 1.85]
1.9 Sårareal, efter endt behandling, mean difference	5	224	Std. Mean Difference (IV, Random, 95% CI)	0.20 [-0.11, 0.50]
1.10 Sårareal, efter endt behandling, std. mean difference	6	254	Std. Mean Difference (IV, Random, 95% CI)	0.62 [-0.07, 1.31]
1.11 Helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling	1	50	Mean Difference (IV, Random, 95% CI)	-0.12 [-2.01, 1.77]
1.12 Recidiv af sår, længste follow-up (op til 1 år)	0		Risk Ratio (IV, Random, 95% CI)	No totals
1.13 Venetrombose, i interventionsperioden	0		Risk Ratio (IV, Random, 95% CI)	No totals

Figures

Figure 1 (Analysis 1.1)

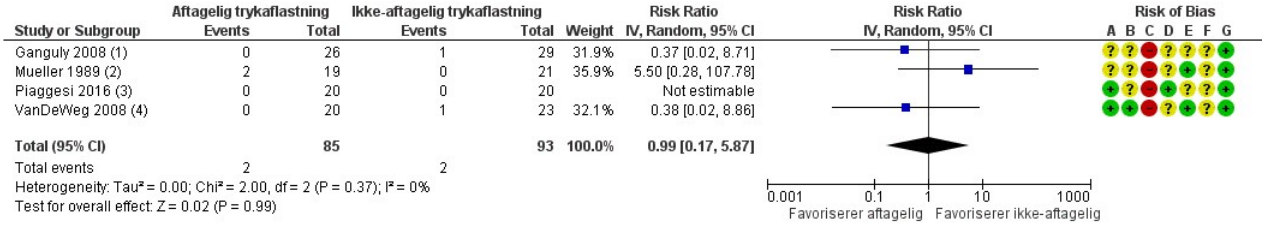


Footnotes
(1) 12 weeks. Removeable walker vs total cast. Control group split.
(2) 12 weeks. Half shoe vs total cast. Control group split.
(3) 12 weeks. Removeable walker vs total cast.
(4) 12 weeks. Removeable aircast vs fiberglass total cast
(5) 12 weeks. Walker boot vs total cast of fiberglass.
(6) 6 months. Standard (removeable dressing) vs total cast.
(7) 12 weeks. Walker vs. total cast
(8) 12 weeks. Removeable walking boot vs total cast.
(9) 4 weeks. Therapeutic shoe vs fiberglass total cast.
(10) 6 weeks. Traditionel wet dressing and shoe vs total cast.
(11) 7 weeks. Removable cast walker vs total cast.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.1 Sårheling (total sårlukning (ja/nej)), efter endt behandling.

Figure 2 (Analysis 1.2)

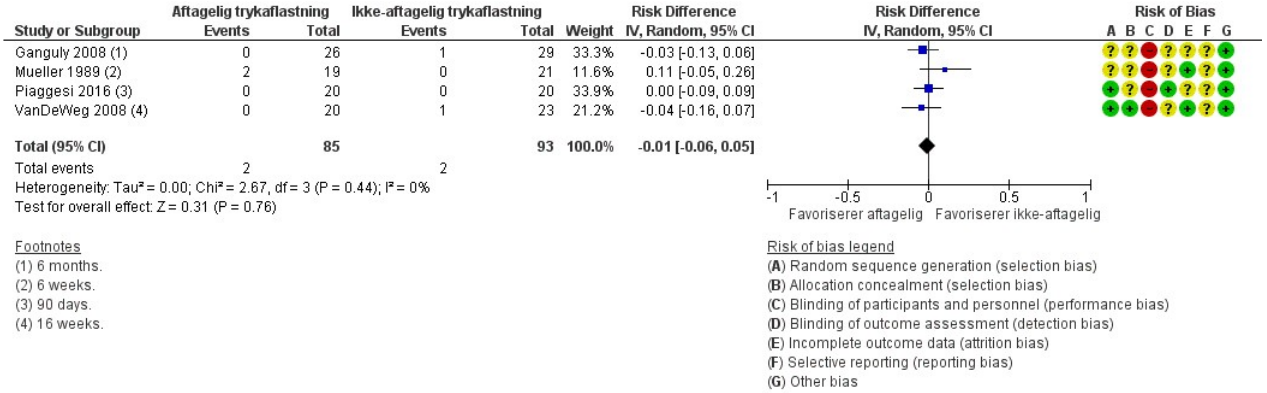


Footnotes
(1) 6 months.
(2) 6 weeks.
(3) 90 days.
(4) 16 weeks.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.2 Underekstremitets amputationer (total sårlukning (ja/nej)), længste follow-up (op til 1 år), risk ratio.

Figure 3 (Analysis 1.3)

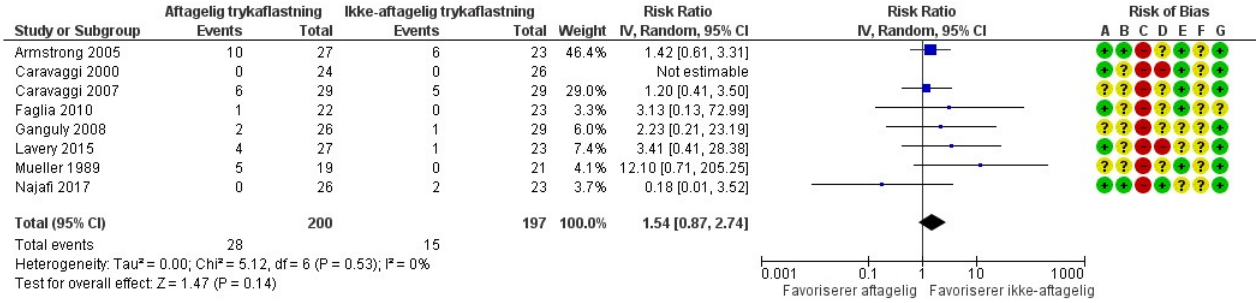


Footnotes
(1) 6 months.
(2) 6 weeks.
(3) 90 days.
(4) 16 weeks.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.3 Underekstremitets amputationer (total sårlukning (ja/nej)), længste follow-up (op til 1 år), risk difference.

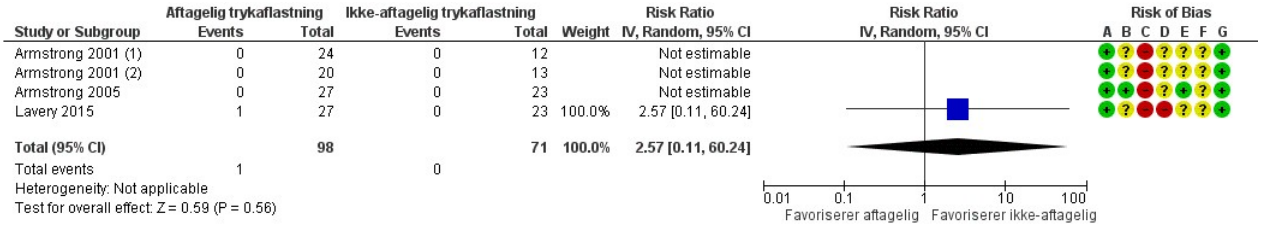
Figure 4 (Analysis 1.4)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.4 Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden.

Figure 5 (Analysis 1.5)

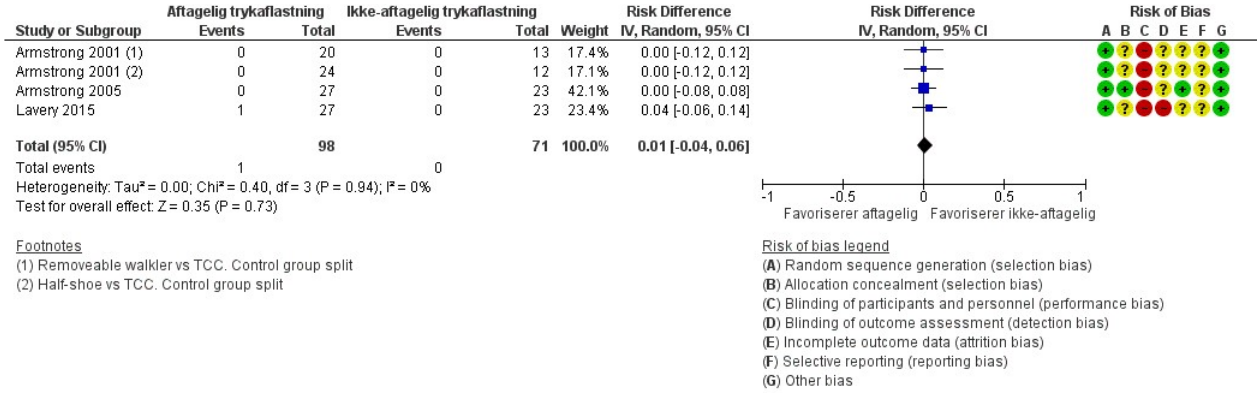


Footnotes
(1) Half-shoe vs TCC. Control group split
(2) Removeable walkler vs TCC. Control group split

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

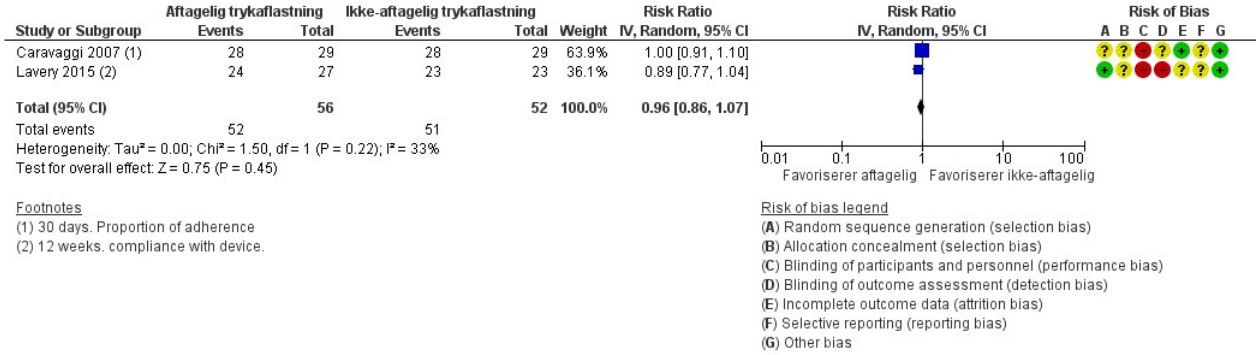
Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.5 Tryksår, i interventionsperioden, risk ratio.

Figure 6 (Analysis 1.6)



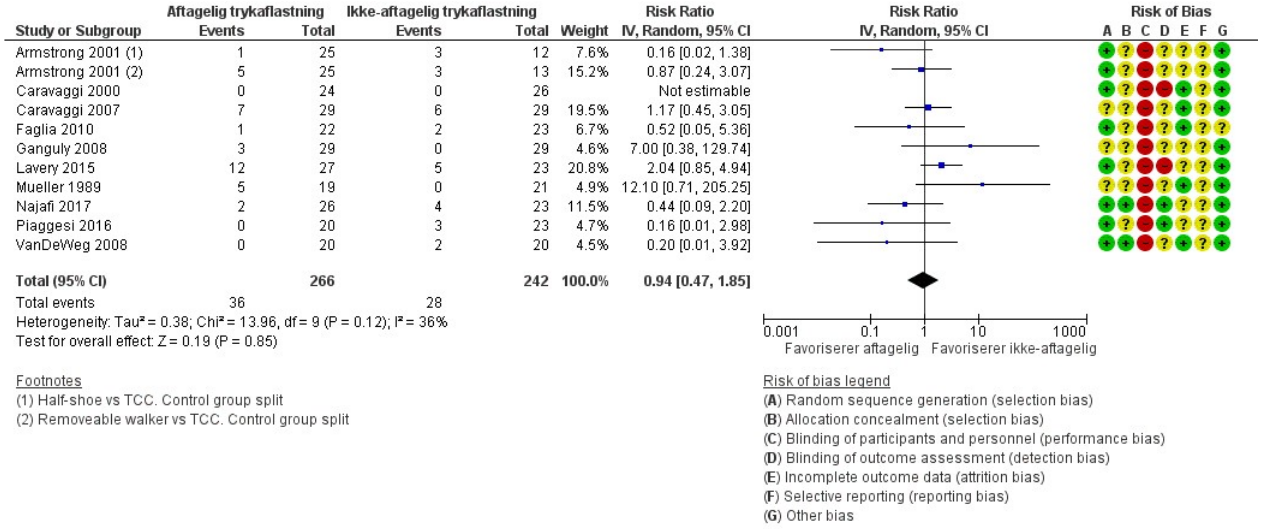
Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.6 Tryksår, i interventionsperioden, risk difference.

Figure 7 (Analysis 1.7)



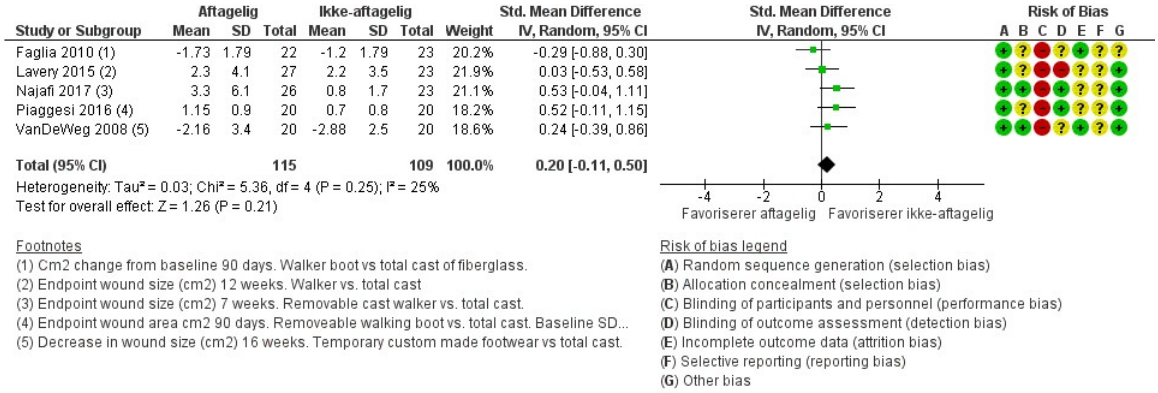
Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.7 Behandlings adherence/ kompliance, i interventionsperioden, proportion of adherence.

Figure 8 (Analysis 1.8)



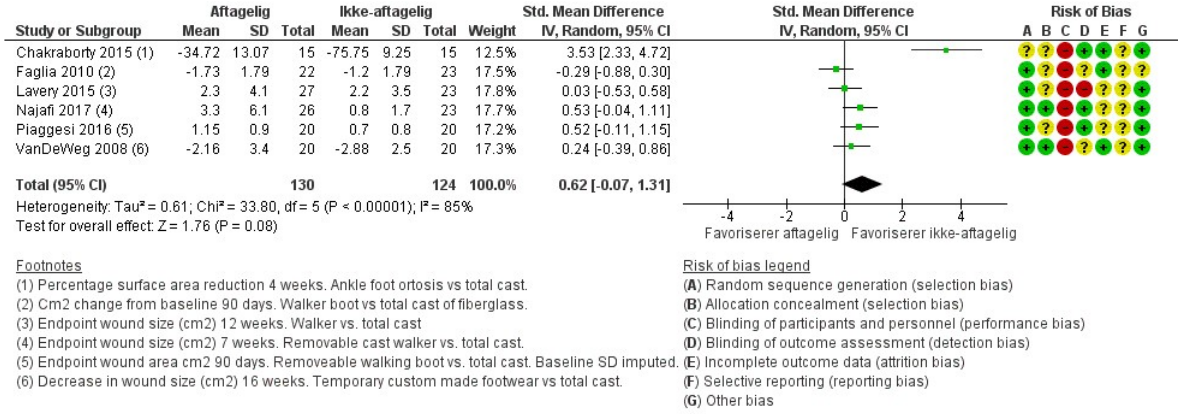
Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.8 Frafald, alle årsager, efter endt behandling.

Figure 9 (Analysis 1.9)



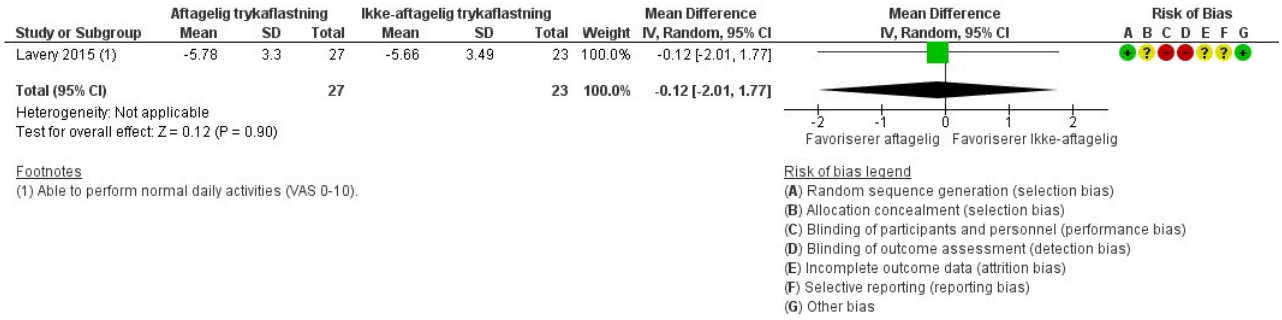
Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.9 Sårareal, efter endt behandling, mean difference.

Figure 10 (Analysis 1.10)



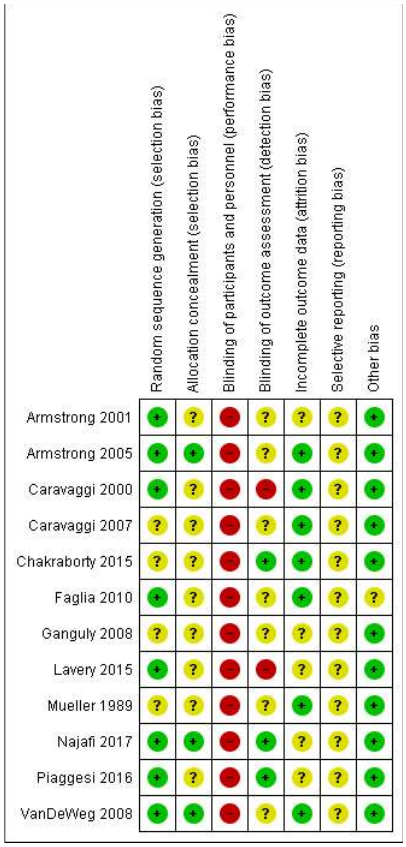
Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.10 Sårareal, efter endt behandling, std. mean difference.

Figure 11 (Analysis 1.11)



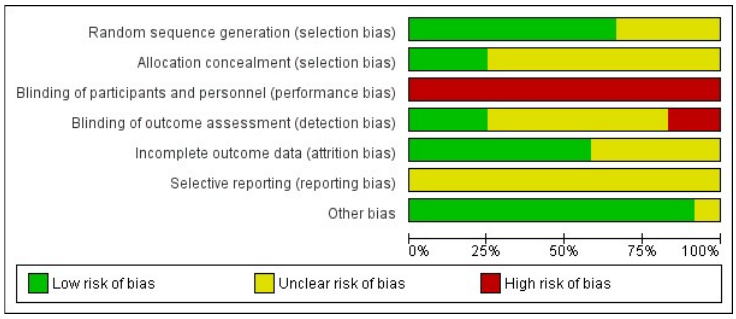
Forest plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.11 Helbredsrelateret livskvalitet målt med standardiseret spørgeskema, efter endt behandling.

Figure 12



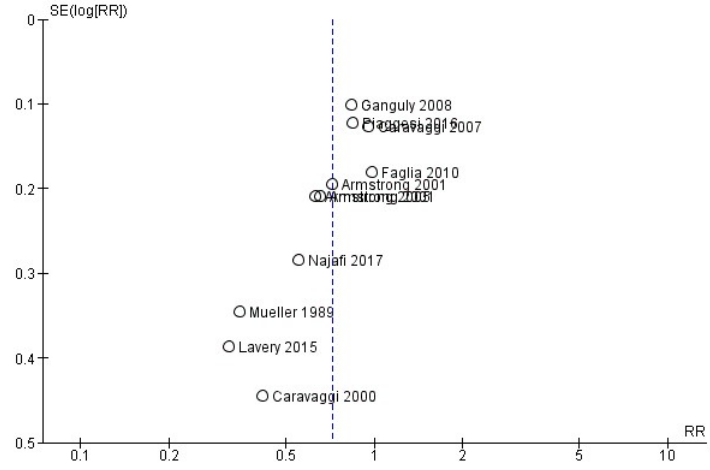
Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Figure 13



Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 14 (Analysis 1.1)



Funnel plot of comparison: 1 Aftagelig vs ikke-aftagelig trykaflastning, outcome: 1.1 Sårheling (total sårlukning (ja/nej)), efter endt behandling.