Aflastende fodkirurgi versus Standard sårbehandling for Voksne med diabetiske fodsår

Review information

Authors

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Citation example: S. Aflastende fodkirurgi versus Standard sårbehandling for Voksne med diabetiske fodsår. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Characteristics of studies

Characteristics of included studies

Allam 2006

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Overall ● *Age, mean (SD)*: 55 (11) ● *BMI, mean (SD)*: 35 (3) ● *mean duration of diabetes (years) SD*: 20 (11) ● *mean duration of the foot ulcer (months) range*: 42 (10-72) **Included criteria:** diabetic patients with plantar forefoot ulceration **Excluded criteria:** no exclusion criteria
Interventions	**Intervention Characteristics** Intervention ● *Description*: patients were treated by local ulcer care and Achilles tendon lengthening (ATL). The ankle was kept in slight dorsiflexion witha posterior plaster splint.The patients remained non-weight bearing forone week and the leg was placed in a walker witha heel lift for further 5 weeks then the patientswere allowed to weight bear after the 6th postop-erative week. The sole ulcer was dressed daily and local careof the ulcer continued till complete healing. ● *duration*: active treatment for 6 weeks, until healing ● *followup*: 2 years Kontrol ● *Description*: patients were managed by local wound care and total contact cast alone (TCC). Below knee cast was applied with awindow for daily dressing of the ulcer. Both groups the ulcer w as debrided anddressed while systemic antibiotic w as given ac-cording t o culture sensitivity results: ● *duration*: until healing ● *followup*: 2 years
Outcomes	*Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: DichotomousOutcome ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint *Sårheling, længste follow-up (op til 1 år)* ● **Outcome type**: DichotomousOutcome ● **Unit of measure**: n/N ● **Direction**: Higher is better ● **Data value**: Endpoint *Bivirkninger (DVT, lungeemboli, komplikationer i relation til operationssår), længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint *Transfersår, Længste follow-up (op til 1 år)* ● **Outcome type**: DichotomousOutcome ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** no funding **Country:** egypt **Setting:** Twenty nine diabetic patients with plantar forefoot ulceration were randomized into two groups: TCC og ATL at a university hospital **Authors name:** abdel mohsen allam **Institution:** The Department of General Surgery, Plastic & Reconstructive Surgery Unit, Tanta University. **Email:** no email **Address:** The Department of General Surgery, Plastic & Reconstructive Surgery Unit, Tanta University. El-Gharbia Govenorate,Tanta . El-Gash st. Medical Campus The Faculty of Medicine
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "forefoot ulceration. MATERIAL AND METHODS Twenty nine diabetic patients with plantar forefoot ulceration were randomized into two groups: ● Group I (GI): 14 patients were managed by local wound care and total contact cast alone (TCC). ● Group II (GII): 15 patients were treated by local ulcer care and Achilles tendon lengthening (ATL). Postoperatively, the patients were followed" Quote: "There were no significant differences in age, sex, or the duration of the plantar forefoot ulcerations between the studied groups." Judgement Comment: No information about randomisation method.
Allocation concealment (selection bias)	High risk	Judgement Comment: Not described. Likely no efforts made to conceal allocation.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No blinding of participants. No information about blinding of the personnel.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No description of blinding of outcome assessors. Likely no efforts made to blind.
Incomplete outcome data (attrition bias)	Low risk	Quote: "29 diabetic patients with plantar forefoot ulceration were allocated in two groups" Judgement Comment: No information about drop outs. Alle participants informed outcomes of interest for all time points.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: Only early complications reported for ATL group. No protocol
Other bias	Unclear risk	Judgement Comment: Only one author. No information about funding etc...

Mueller 2003

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Female, N (%)*: 5 (16.13) ● *Age, mean (SD)*: 56.6 (9.2) ● *BMI, mean (SD)*: 33.3 (7.8) ● *Type 2 diabetes, N (%)*: 26 (83.87) ● *Duration of diabetes (years)*: 17.1 (10.8) ● *HbA1c, %*: 8.8 (1.9) ● *Peripheral neuropathy, N (%)*: 31 (100) Kontrol 1 ● *Female, N (%)*: 10 (3.03) ● *Age, mean (SD)*: 56.2 (10.1) ● *BMI, mean (SD)*: 30.5 (6.8) ● *Type 2 diabetes, N (%)*: 22 (66.67) ● *Duration of diabetes (years)*: 19.6 (12.6) ● *HbA1c, %*: 8.8 (1.7) ● *Peripheral neuropathy, N (%)*: 33 (100) **Included criteria:** Patients were considered for inclusion in the study if they had ahistory of diabetes mellitus, loss of protective sensation (unableto sense the 5.07 Semmes-Weinstein monofilament on at leastone location on the plantar aspect of the foot), limitation of an-kle dorsiflexion to ≤5°, a palpable ankle pulse, and a recurrentor nonhealing ulcer on the forefoot (Grade II according to theWa g n e r s c a l e21). A limitation of 5° of ankle dorsiflexion waschosen because most authors believe that ≥10° is required fornormal walking ability22. A recurrent or nonhealing ulcer wasdefined as two or more occurrences of a plantar ulcer or the fail-ure of a plantar ulcer to heal with conservative treatment (i.e.,dressing changes and footwear modifications). **Excluded criteria:** Patients were excluded from the study if they had a neurologi-cal problem complicating the rehabilitation, had a history ofCharcot fractures of the hindfoot, were unable to tolerate theanesthesia required for Achilles tendon lengthening, or if itwas thought that they would not benefit from an Achilles ten-don lengthening (i.e., they were not able to walk). We did notexclude individuals with a Charcot deformity of the midfootor forefoot or a partial foot amputation if they met the aboveinclusion criteria.
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: All necrotic tissue and callus surrounding the ulcer were sharplydébrided. The ulcer was covered with a dry gauze dressing. Thesubjects who were randomized to the Achilles tendon lengthen-ing group were placed supine on the operating table, and intra-venous sedation was administered. After sterile preparation,local anesthesia was injected along the subcutaneous border ofthe Achilles tendon as a field block. Three hemisections weremade in the Achilles tendon with use of the Hoke triple he-misection technique26. Then the surgeon firmly pushed on theplantar aspect of the forefoot, dorsiflexing the ankle in a con-trolled manner to allow the Achilles tendon to lengthen alongthe course of its weakened fibers until the foot could be brought into 10° of dorsiflexion. Excessive force that might cause com-plete transection or overlengthening of the tendon was carefullyavoided. No sutures were used to close the three tenotomy sites,and a dry gauze dressing (4 by 4 in [10 by 10 cm]) was appliedand held in place with a sterile cotton wrap.After the Achilles tendon lengthening, a total-contactcast was applied as described previously27, except that the dis-tal end of the toe box was left open and a standard rocker castshoe was used rather than a walking heel. The cast was appliedto the leg with the ankle joint in a neutral position. The castwas initially changed after one week and was subsequentlychanged every two to three weeks for at least six weeks or untilthe forefoot ulcer had completely healed. The patient was al-lowed partial weight-bearing immediately after application ofthe total-contact cast and progressed to full weight-bearing af-ter the first week but was asked to limit his or her activities asmuch as possible. After application of the cast, the involvedfoot was placed in a padded diabetic pressure-relief walkingboot (DH Pressure Relief Walker; Royce Medical, Camarillo,California) for one to four weeks until the subject felt stableenough to walk with the extra-depth shoes with custom-molded inserts that ● *Duration*: 7 months ● *Dose*: one time surgery, +tcc changed every 2-3. week Kontrol 1 ● *Description*: Subjects who were randomly assigned to the total-contactcast group were treated with a total-contact cast with use ofmethods identical to those used in the Achilles tendon length-ening group except that the patients were allowed full weight-bearing immediately after the initial application of the cast.The ankle was positioned as close to neutral as possible, andthe cast was changed every two to three weeks until the plantarulcer was healed. Subjects then were instructed to wear the ex-tra-depth shoes with custom-molded inserts28.After treatment, all subjects were instructed in a home-exercise program by a physical therapist with use of a Thera-Band (Hygenic, Akron, Ohio) to provide resistance to themusculature around the ankle. The

	exercise program includeduse of a red Thera-Band, progressing to a green one to resistankle plantar flexion, dorsiflexion, inversion, and eversionmovements. Exercises were completed in three sets with tenrepetitions in each set, one time per day, for three, four, or fivedays per week ● *Duration*: 7 months ● *Dose*: tcc changed every 2-3. week
Outcomes	*Helbredsrelateret livskvalitet, længste follow-up (op til 1 år)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: SF 36, General Health ● **Range**: 0-100 ● **Unit of measure**: Point ● **Direction**: Higher is better ● **Data value**: Endpoint *Selvrapporteret funktion, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: SF-36 Physical functioning ● **Range**: 0-100 ● **Unit of measure**: Point ● **Direction**: Higher is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** funding from the National Center for Medical Rehabilitation Research and the National Institutes of Health RO1 HD 36802. **Country:** USA **Setting:** Sixty-four subjects were randomized into two treatment groups, immobilization in a total-contact cast alone orcombined with percutaneous Achilles tendon lengthening, with measurements made before and after treatment, at theseven-month follow-up examination, and at the final follow-up evaluation (a mean [and standard deviation] of 2.1 ± 0.7years after initial healing). **Authors name:** Michael J Mueller **Institution:** Washington University School of Medicine, St. Louis, Missouri **Email:** muellermi@msnotes.wustl.edu **Address:** Program in Physical Therapy, Box 8502, 4444 Forest Park Boulevard, St. Louis, MO 63018.
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "were randomized into the Achilles tendon lengthen- ing group or the total-contact cast group with use of a prear- ranged schedule generated by a computer program."Quote: "Randomization methods were successful as there were no differences between the groups with respect to any subject characteristic (p > 0.05)."Quote: "There were no differences between groups (p > 0.05) for any of these characteristics."Judgement Comment: No baseline differences
Allocation concealment (selection bias)	Unclear risk	Quote: "were un- likely to meet. The orthopaedic surgeon (J.E.J.), who screened all patients for eligibility into the study, was blind to the prear- ranged schedule. Once the subject agreed to participate, he or she was referred to the patient coordinator for the study who assigned the subject to a treatment group according to the prearranged schedule and arranged all testing sessions. Subject Characteristics Sixty-four subjects met"Judgement Comment: Unclear how the patient coordinator concealed the allocation for patients and personnel until after testing sessions.
Blinding of participants and personnel (performance bias)	High risk	Quote: "Because we anticipated a much higher rate of reulceration in the total- contact cast group compared with that in the Achilles tendon lengthening group 6, and we wanted subjects to have the op- portunity to cross over to the Achilles tendon lengthening group if treatment with a total-contact cast alone was not suc- cessful, the prearranged schedule was planned to enroll two times as many subjects in the total-contact cast group as in the Achilles tendon lengthening group. Subjects who had a reul- ceration after treatment with a total-contact cast were then al- lowed to enter the Achilles tendon lengthening group."Judgement Comment: Personnel not blinded. No sham surgery
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: Not blinded outcome assessors however, only objectively assessed outcomes.
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Low attrition however, per protocol analysis (No ITT or description of drop outs)
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No protocol available. Only reporting self-reported data from participants with follow-up data from all time points in seperate publication. Thorough reporting of relevant outcomes.
Other bias	Low risk	Quote: "8233, St. Louis, MO 63110 In support of their research or preparation of this manuscript, one or more of the authors received grants or outside funding from the National Center for Medical Rehabilitation Research and the National Institutes of Health RO1 HD 36802. None of the authors received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated. "Judgement Comment: No reason to suspect other sources of bias

Mueller 2004

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Female, N (%)*: 3 (21.43%) ● *Age, mean (SD)*: 54.8 (9.5) ● *BMI, mean (SD)*: 33.6 (6)

	• *Type 2 diabetes, N (%)*: 11 (78.57%) • *Duration of diabetes (years)*: 19.9 (10.2) • *HbA1c, %*: 8.7 (1.8) • *Peripheral neuropathy, N (%)*: 14 (100%) Kontrol 1 • *Female, N (%)*: 4 (28.57%) • *Age, mean (SD)*: 54.3 (9.9) • *BMI, mean (SD)*: 31.8 (6.8) • *Type 2 diabetes, N (%)*: 9 (64.29%) • *Duration of diabetes (years)*: 17.9 (13.9) • *HbA1c, %*: 8.9 (2) • *Peripheral neuropathy, N (%)*: 14 (100%) **Included criteria:** Inclu-sion criteria were a diagnosis of diabetes,inability to sense a 5.07 (10-g) SemmesWeinstein monofilament on at least onelocation on the plantar surface of the foot(indicating loss of protective sensation), arecurrent (i.e., two or more episodes)Wagner grade II ulcer (3) on the plantarforefoot or toes, and5°of passive dor-siflexion range of motion at the talocruraljoint as measured using a goniometerwith the knee extended. **Excluded criteria:** Patients were ex-cluded from participation in the study ifthey were nonambulatory, had a historyof rear foot Charcot fractures, had im-paired circulation indicated by an ankle-arm index0.45, or reported a history ofsignificant health problems that renderedthem medically unfit for surgery or post-surgical rehabilitation
Interventions	**Intervention Characteristics** Intervention 1 • *Description*: After wound debridement, subjectsassigned to the ATL group underwent apercutaneous ATL procedure before ap-plication of a TCC using a modified Hoketriple hemisection technique (8). Thefirsthemisection was on the medial side of thetendon above its insertion into the calca-neus. The second hemisection was also onthe medial side of the tendon but belowthe musculotendinous junction. Thefinalhemisection was on the lateral side of thetendon midway between the two medialcuts (8). A slow controlled force was ap-plied to the forefoot to rotate the anklejoint into10°of dorsiflexion range ofmotion (8). A TCC was applied as de-scribed above, and patients were pro-gressed from partial to full weight bearingin the cast 1 week after surgery. A paddedpressure-relief walking boot (DH Pres-sure Relief Walker; Royce Medical, Cam-arillo, CA) was prescribed for 1–4additional weeks after cast removal, untilsubjects regained sufficient stability towalk with extra-depth shoes and custom-molded inserts • *Duration*: 8months • *Dose*: ATL surgery, TCC change every 2-3 week Kontrol 1 • *Description*: TCC was performedas described previously (6), with the ex-ception that the distal end of the toe boxwas left open and a standard rocker castshoe was used. Casts were removed forwound assessment and reapplied after thefirst week of casting and then every 2–3weeks until complete epithelializationwithout drainage was observed. All sub-jects were instructed to limit their weight-bearing activity during treatment withTCC, and subjects were provided with ex-tra-depth shoes and custom-molded in-serts after cast removal according topublished recommendations (7). Addi-tionally, a physical therapist instructed allsubjects in a home exercise program toperform active ankle plantarflexion, dor-siflexion, inversion, and eversion exer-cises 3–5 days per week (three sets of 10repetitions), using appropriate Theraband(Hygenic Corporation, Ipoh, Malaysia) toprovide resistance. No supervised therapywas provided beyond this instruction • *Duration*: 8 months • *Dose*: TCC change every 2-3 week
Outcomes	*Underekstremitets amputationer, længste follow-up (op til 1 år)* • **Outcome type**: AdverseEvent • **Reporting**: Fully reported • **Unit of measure**: Events • **Direction**: Lower is better • **Data value**: Change from baseline *Recidiv af sår, længste follow-up (op til 1 år)* • **Outcome type**: DichotomousOutcome • **Reporting**: Fully reported • **Unit of measure**: Events • **Direction**: Lower is better • **Data value**: Change from baseline *Mobiliseringsgrad, efter endt behandling* • **Outcome type**: ContinuousOutcome • **Reporting**: Fully reported • **Direction**: Higher is better • **Data value**: Endpoint *Sårheling (total sårlukning), længste follow-up (op til 1 år)* • **Outcome type**: DichotomousOutcome • **Reporting**: Fully reported • **Unit of measure**: n/N • **Direction**: Higher is better • **Data value**: Change from baseline *Sårareal, længste follow-up (op til 1 år)* • **Outcome type**: ContinuousOutcome • **Reporting**: Not reported • **Data value**: Endpoint *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* • **Outcome type**: AdverseEvent • **Reporting**: Fully reported • **Unit of measure**: n/N • **Direction**: Lower is better • **Data value**: Change from baseline *Bivirkninger (DVT, lungeemboli, komplikationer i relation til operationssår), længste follow-up (op til 1 år)* • **Outcome type**: AdverseEvent • **Reporting**: Fully reported

	● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Change from baseline *Transfersår, længste follow-up (op til 1 år)* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Change from baseline
Identification	**Sponsorship source:** Funding was provided by the National Center for Medical Rehabilitation Research, the National Institutes of Health Grant RO1-HD-36802. **Country:** USA **Setting:** Prevention and Control Research Core of the Washington University Diabetes Research Training Center, **Authors name:** Michael J Mueller **Institution:** Applied Biomechanics Laboratory, Program in Physical Therapy, Washington University Schoolof Medicine, St. Louis, Missouri **Email:** muellerm@wustl.edu **Address:** P.O. Box 8502, 4444 ForestPark Blvd., St. Louis, MO 63108
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The groups were not signifi- cantly different with regard to age, eth- nicity, BMI, duration of diabetes, HbA 1c, sex composition, or the proportion of subjects with type 1 and type 2 diabetes (Table 1)."Quote: "Subjects were randomly assigned to treatment with an ATL procedure fol- lowed by TCC (ATL group; n 31) or treatment with TCC alone (TCC group; n 33)."Judgement Comment: From other publication: "Subjects were randomized into the Achilles tendon lengthen- ing group or the total-contact cast group with use of a prear- ranged schedule generated by a computer program." No baseline differences
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information about allocation concealment
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information about blinding, likely particpants and personnel are unblinded
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No blinded of participants, self-reported outcomes.
Incomplete outcome data (attrition bias)	Unclear risk	Quote: "n 14; TCC, n 14). The number of subjects reported in the analyses varies (see Tables 2 and 3) because not all data were available on all 28 subjects. The groups were not signifi-"Quote: "A smaller subset of subjects agreed to additional testing as described in this study. Therefore, the analyses de- scribed in this study include only those subjects who completed testing on all three test occasions (ATL, n 14; TCC, n 14)."Judgement Comment: of 64 participants, only 28 completed SR measures (all time points) unclear attrition. PP analysis.
Selective reporting (reporting bias)	High risk	Judgement Comment: No protocol available. Only reporting data from participants with follow-up data from all time points.
Other bias	Low risk	Judgement Comment: No reasons to suspect other sources of bias

Piaggesi 1998

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age, mean (SD)*: 65.53 (9.87) ● *BMI, mean (SD)*: 28.12 (13.04) ● *Type 2 diabetes, N (%)*: 19 ● *Duration of diabetes (years)*: 16.84 (10.62) ● *HbA1c, %*: 8.9 (2.2) ● *Peripheral neuropathy, N (%)*: 21 ● *Wound diameter (cm), mean (SD)*: 4.32 (1.95) Kontrol 1 ● *Age, mean (SD)*: 63.24 (13.46) ● *BMI, mean (SD)*: 27.71 (9.43) ● *Type 2 diabetes, N (%)*: 17 ● *Duration of diabetes (years)*: 18.20 (8.41) ● *HbA1c, %*: 9.5 (3.8) ● *Peripheral neuropathy, N (%)*: 20 ● *Wound diameter (cm), mean (SD)*: 4.25 (2.35) **Included criteria:** Inclusion criteria were: diabetes mellitus (DM), eitherType 1 or Type 2, of at least 5 years' duration; presenceof one or more painless foot ulcers with clinicalcharacteristics of neuropathy (symptomatic peripheralneuropathy assessed with the Michigan NeuropathyScreening Instrument (MNSI), absence of ankle reflexes,and abnormal vibration perception threshold(VPT.25 V) at malleolus and first toe, according to themethodology described by Younget al.8,9) **Excluded criteria:** Exclusion criteria were: presence of symptomaticclaudication or absence of foot pulses, recent keto-acidosis, renal failure as suggested by creatinine higherthan 177mmol l−1, presence of infection as indicated byperilesional oedema and erythema, or presence of pus,systemic symptoms like fever or leukocytosis. In casesof doubt, a wound swab was sent for bacteriologicalassessment and no suspicious case was enrolled. Patientswith congenital foot deformities or diabetic neuroarthro-pathy, body mass index (BMI).30 kg m−2, clinicalhistory of stroke, cardiac failure, cancer, HIV positivityor history of mental illness were also excluded.To exclude the possibility of subclinical macroangio-pathy, a Doppler study was performed in any case ofreduced peripheral pulses. An ankle-brachial pressureindex (ABPI) less than 0.9 excluded patients from thestudy. Osteomyelitis was suspected in any case in whichthe bone or the

	joint could be probed through the ulcer.In such cases an X-ray of the foot was examined forsigns of osteomyelitis; doubtful cases were excluded
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Group B patients were scheduled for outpatient surgery,after pre-operative evaluation including basal ECG, chestx-ray, blood cell count, plasma chemistry, and virologicalscreening. On the day of surgery, patients had theircapillary glucose monitored and controlled with intra-venous infusion of 5 % glucose solution with insulinthroughout the operation, in order to maintain plasmaglucose between 5.5 and 11.1 mmol l−1. Surgical oper-ations were all carried out with local or regionalanaesthesia, patients were observed for 3–4 hours afterthe intervention and then discharged home.13Surgery consisted of the removal of the ulcer throughconic ulcerectomy, which removes both the walls andthe bottom of the lesion; moreover, in the presence ofvisible bone segments under the ulcers, or in caseswhere bone segments might interfere with the closureof the margins of wound, their debridement or removalwas performed with scalpels or a rong. To verify thepossible presence of osteomyelitis, any resected bonefragments were cultured for microbial or fungal infection.The surgical wound was closed with single stitches anda drain, which was removed after 48 h. The closedwound was covered with sterile gauze and the limb waspositioned in slight anti-orthostatic position for 48 h.Then the wounds were treated with antiseptic solution(povidone iodine 50 %+saline 50 %) twice a week.Stitches were removed after 3 weeks. Patients wereallowed to walk with crutches and fitted shoes(Podiabetes□; Buratto, Treviso, Italy) for the first week,and 4–6 weeks after the operation they were allowed towalk with orthsis and moulded shoes only ● *Duration*: 6 months ● *Dose*: change of bandage ywice a week, suregry only one time Kontrol 1 ● *Description*: Both treatments were performed on an outpatientbasis, in the foot clinic of our metabolic department bytrained physicians and personnel. Ulcers in group Apatients, after initial debridement of lesions and elimin-ation of surrounding hyperkeratosis, were dressed withsaline-moistened sterile gauze and patients were advisedto change the dressing every 24 h, helped by a specificallytrained relative if necessary. They were given specialshoes (Podiabetes□; Buratto, Treviso, Italy) with a custom-413SURGICAL THERAPY FOR NEUROPATHIC ULCERS□1998 John Wiley & Sons, Ltd.Diabet. Med.15: 412–417 (1998)made orthosis to relieve weight from the lesions, andwere asked to stand on their feet as little as possible,helping themselves with crutches.12They were seentwice a week as outpatients for inspection and controlof orthosis. On these occasions lesions were irrigatedwith an antiseptic solution (povidone iodine 50 %+saline 50 %) and then covered again with saline-moistened gauze. No other medications were used. Afterhealing, patients were provided with a definitive orthosisand moulded shoes. The whole treatment course ofgroup A patients from initial debridement to follow-upvisits was performed by physicians and nurses unawareof the participation of patients in the study, and did notdiffer from the standard protocol of treatment of non-complicated neuropathic ulcerations in our foot clinic ● *Duration*: 6 months ● *Dose*: change of bandage every day
Outcomes	*Helbredsrelateret livskvalitet, længste follow-up (op til 1 år)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: Global satisfaction ● **Range**: 0-10 ● **Unit of measure**: Point ● **Direction**: Higher is better *Underekstremitets amputationer, længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Reporting**: Fully reported ● **Unit of measure**: Events ● **Direction**: Lower is better ● **Data value**: Change from baseline *Recidiv af sår, længste follow-up (op til 1 år)* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: Events ● **Direction**: Lower is better ● **Data value**: Change from baseline *Mobiliseringsgrad, efter endt behandling* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Direction**: Higher is better ● **Data value**: Endpoint *Sårheling (total sårlukning), længste follow-up (op til 1 år)* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Higher is better ● **Data value**: Change from baseline *Sårareal, længste follow-up (op til 1 år)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Not reported ● **Data value**: Endpoint *Infektion (positiv dyrkning, eller klinisk (rødme, pus, lugt, hævelse, smerte)), i interventionsperioden* ● **Outcome type**: AdverseEvent ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Change from baseline *Bivirkninger (DVT, lungeemboli, komplikationer i relation til operationssår), længste follow-up (op til 1 år)* ● **Outcome type**: AdverseEvent ● **Reporting**: Fully reported ● **Unit of measure**: n/N

	● **Direction**: Lower is better ● **Data value**: Change from baseline *Transfersår, længste follow-up (op til 1 år)* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Unit of measure**: n/N ● **Direction**: Lower is better ● **Data value**: Change from baseline
Identification	**Sponsorship source:** no sponsors **Country:** italy **Setting:** To test the efficacy of surgical treatment of non-infected neuropathic foot ulcers comparedto conventional non-surgical management, a group of diabetic outpatients attending ourdiabetic foot clinic were studied. Group A received conservative treatment, consisting of reliefof weight-bearing, regular dressings; group B underwent surgical excision, eventualdebridement or removal of bone segments underlying the lesion and surgical closure **Authors name:** Alberto Piaggesi **Institution:** Cattedra di Malattie del Metabolismo, Istituto di Clinica Medica II,Universita`di Pisa, Pisa, Italy **Email:** no email **Address:** Unita`Operativa Malattiedel Ricambio, Azienda Ospedaliera Pisana, Via Paradisa 2, 56100Pisa, Italy
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "After having obtained their informed consent, patients were randomized into two groups according to a table of randomization:"Judgement Comment: Unclear how a RANDOM randomization was performed however, no apparent baseline differences between groups (ANOVA analysis not shown)
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Ni information about who performed the sequence generation and if the allocation was concealed.
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Efforts made to blind personnel. No efforts to blind described participants, No sham surgery.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: No information about blinding however, primarily objectively assessed outcomes
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: 20/21 randomised. NI about drop outs or missing data.
Selective reporting (reporting bias)	Low risk	Judgement Comment: No protocol registered however, anticipated outcomes thoroughly reported
Other bias	Low risk	Judgement Comment: No reasons to suspect other sources of bias

Footnotes

Characteristics of excluded studies

Resch 2004

Reason for exclusion	Wrong study design

Richter 2012

Reason for exclusion	Wrong intervention

Footnotes

Characteristics of ongoing studies

Finestone 2018

Study name	Surgical offloading procedures for diabetic foot ulcers compared to best non-surgical treatment: a study protocol for a randomized controlled trial
Methods	RCT
Participants	Diabetic foot ulcers
Interventions	Surgical offloading procedures vs best non-surgical treatment
Outcomes	Outcome criteria will be time to healing of the primary ulcer (complete epithelization), time to healing of surgical wound, recurrence of ulcer, time to recurrence and complications
Starting date	2018
Contact information	asff@inter.net.il
Notes	Protocol registration: https://my.health.gov.il/CliniTrials/Pages/MOH_2017-08-10_000719.aspx

Footnotes

References to studies

Included studies

Allam 2006

Allam, A. M.. Impact of Achilles tendon lengthening (ATL) on the diabetic plantar forefoot ulceration.. 2006;30(Journal Article):43-8. [DOI:]

Mueller 2003

Mueller, M. J.; Sinacore, D. R.; Hastings, M. K.; Strube, M. J.; Johnson, J. E.. Effect of Achilles tendon lengthening on neuropathic plantar ulcers. A randomized clinical trial. The Journal of bone and joint surgery.American volume 2003;85(8):1436-1445. [DOI:]

Mueller 2004

Mueller M.J.; Sinacore D.R.; Hastings M.K.; Lott D.J.; Strube M.J.; Johnson J.E.. Impact of Achilles tendon lengthening on functional limitations and perceived disability in people with a neuropathic plantar ulcer. Diabetes care 2004;27(7):1559-1564. [DOI: http://dx.doi.org/10.2337/diacare.27.7.1559]

Piaggesi 1998

Piaggesi A; Schipani E; Campi F; Romanelli M; Baccetti F; Arvia C; Navalesi R. Conservative surgical approach versus non-surgical management for diabetic neuropathic foot ulcers: a randomized trial.. Diabet Med 1998;15(5):412-7. [DOI: 10.1002/(SICI)1096-9136(199805)15:5<412::AID-DIA584>3.0.CO;2-1]

Excluded studies

Resch 2004

Resch, Sylvia. Corrective surgery in diabetic foot deformity. Diabetes/metabolism research and reviews 2004;20 Suppl 1(Journal Article):S34-6. [DOI:]

Richter 2012

Richter, Martinus; Zech, Stefan. Four-stage regimen for operative treatment of diabetic foot ulcer with deformity - a results of 300 patients. Foot and ankle surgery : official journal of the European Society of Foot and Ankle Surgeons 2012;18(4):247-54. [DOI: https://dx.doi.org/10.1016/j.fas.2012.03.001]

Ongoing studies

Finestone 2018

Finestone, Aharon S.; Tamir, Eran; Ron, Guy; Wiser, Itay; Agar, Gabriel. Surgical offloading procedures for diabetic foot ulcers compared to best non-surgical treatment: a study protocol for a randomized controlled trial. Journal of foot and ankle research 2018;11(Journal Article):6. [DOI: https://dx.doi.org/10.1186/s13047-018-0248-3]

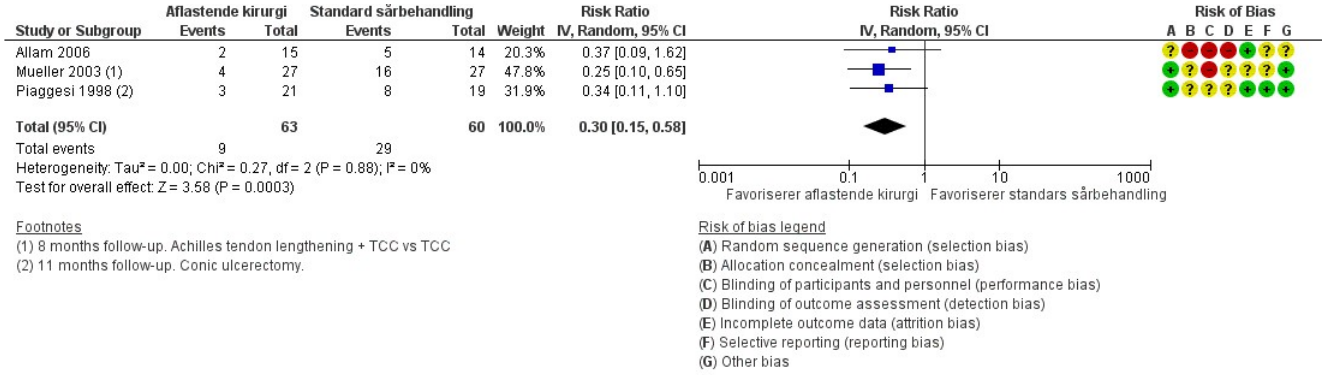
Data and analyses

1 Aflastende kirurgi vs standard sårbehandling

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Recidiv af sår, længste follow-up (op til 1 år)	3	123	Risk Ratio (IV, Random, 95% CI)	0.30 [0.15, 0.58]
1.2 Underekstremitets amputationer, længste follow-up (op til 1 år)	2	105	Risk Ratio (IV, Random, 95% CI)	0.34 [0.04, 3.12]
1.3 Sårheling (total sårlukning), længste follow-up (op til 1 år)	3	138	Risk Ratio (IV, Random, 95% CI)	1.08 [0.99, 1.17]
1.4 Transfersår, længste follow-up (op til 1 år), risk ratio	2	93	Risk Ratio (IV, Random, 95% CI)	6.75 [0.86, 53.13]
1.5 Transfersår, længste follow-up (op til 1 år), risk difference	2	93	Risk Difference (IV, Random, 95% CI)	0.13 [0.02, 0.24]
1.6 Infektion, i interventionsperioden	2	110	Risk Ratio (IV, Random, 95% CI)	0.79 [0.10, 6.03]
1.7 Bivirkninger, længste follow-up (op til 1 år), risk ratio	3	134	Risk Ratio (IV, Random, 95% CI)	1.28 [0.36, 4.57]
1.8 Bivirkninger, længste follow-up (op til 1 år), risk difference	3	134	Risk Ratio (IV, Random, 95% CI)	1.28 [0.36, 4.57]
1.9 Selvrapporteret funktion, efter endt behandling	1	25	Mean Difference (IV, Fixed, 95% CI)	3.70 [-2.46, 9.86]
1.10 Helbredsrelateret livskvalitet, længste follow-up (op til 1 år)	1	25	Mean Difference (IV, Random, 95% CI)	3.80 [-4.41, 12.01]
1.11 Sårareal, længste follow-up (op til 1 år)	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.12 Mobiliseringsgrad, efter endt behandling	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable

Figures

Figure 1 (Analysis 1.1)

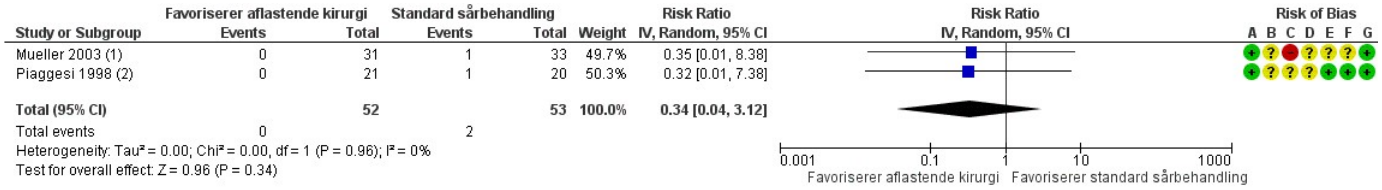


Footnotes
(1) 8 months follow-up. Achilles tendon lengthening + TCC vs TCC
(2) 11 months follow-up. Conic ulcerectomy.

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 Aflastende kirurgi vs standard sårbehandling, outcome: 1.1 Recidiv af sår, længste follow-up (op til 1 år).

Figure 2 (Analysis 1.2)

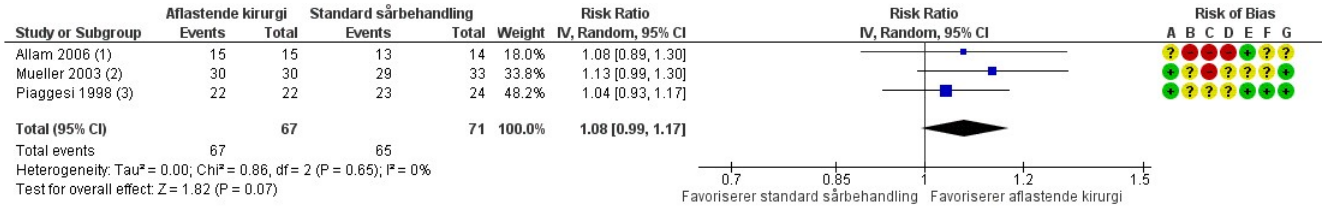


Footnotes
(1) 8 months follow-up. Achilles tendon lengthening + TCC vs TCC
(2) 11 months follow-up. Conic ulcerectomy.

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 Aflastende kirurgi vs standard sårbehandling, outcome: 1.2 Underekstremitets amputationer, længste follow-up (op til 1 år).

Figure 3 (Analysis 1.3)

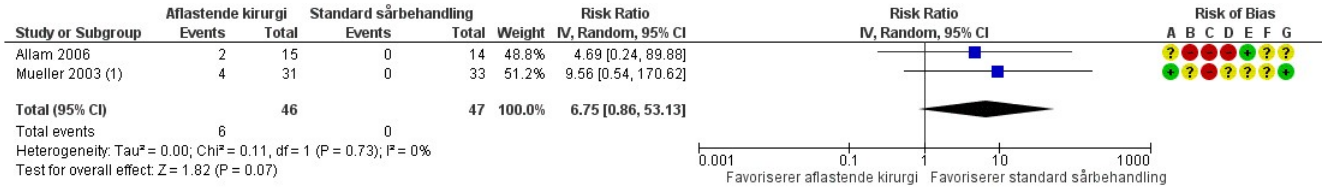


Footnotes
(1) 12 months follow-up. Achilles tendon lengthening vs TCC
(2) 8 months follow-up. Achilles tendon lengthening + TCC vs TCC
(3) 11 months follow-up. Conic ulcerectomy.

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 Aflastende kirurgi vs standard sårbehandling, outcome: 1.3 Sårheling (total sårlukning), længste follow-up (op til 1 år).

Figure 4 (Analysis 1.4)

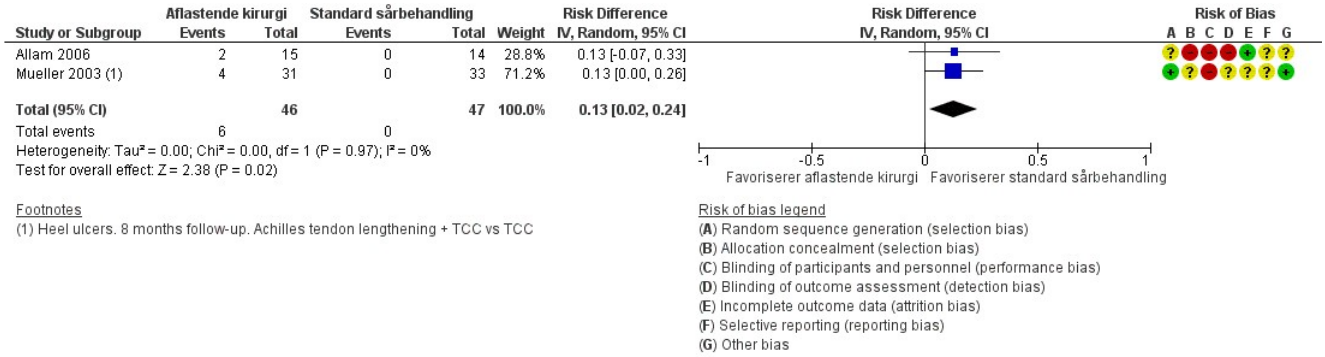


Footnotes
(1) Heel ulcers. 8 months follow-up. Achilles tendon lengthening + TCC vs TCC

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

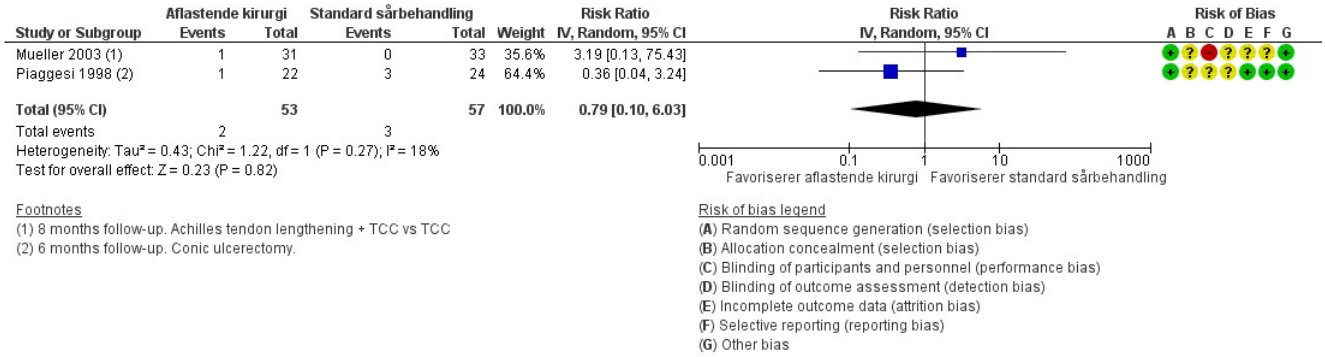
Forest plot of comparison: 1 Aflastende kirurgi vs standard sårbehandling, outcome: 1.4 Transfersår, længste follow-up (op til 1 år), risk ratio.

Figure 5 (Analysis 1.5)



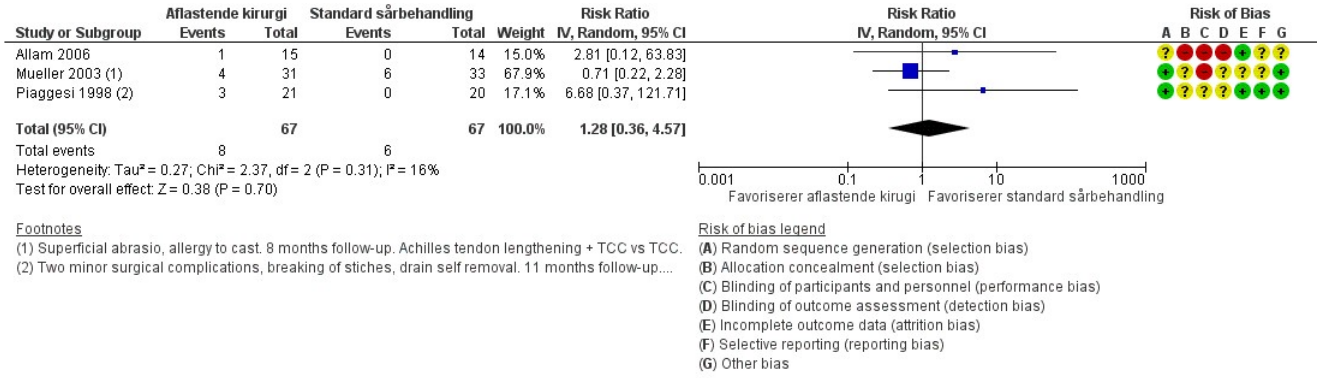
Forest plot of comparison: 1 Aflastende kirurgi vs standard sårbehandling, outcome: 1.5 Transfersår, længste follow-up (op til 1 år), risk difference.

Figure 6 (Analysis 1.6)



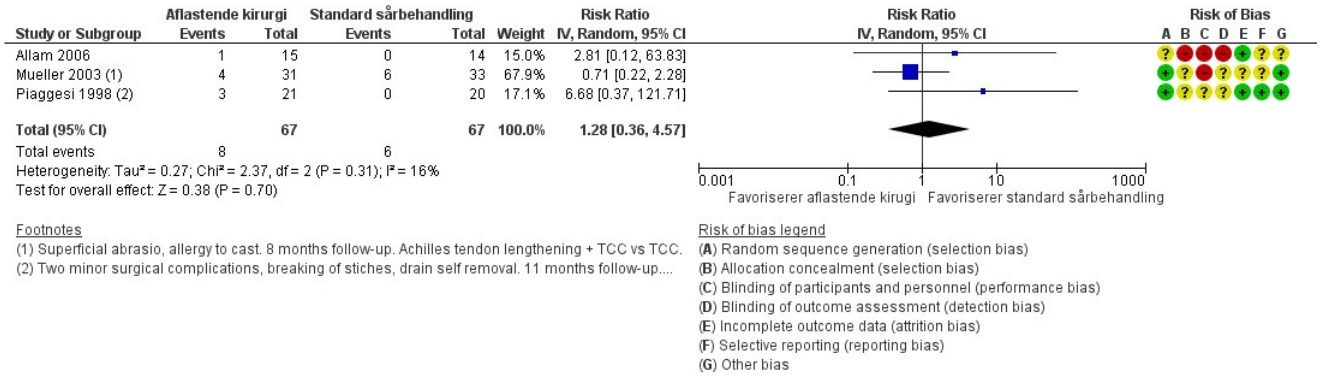
Forest plot of comparison: 1 Aflastende kirurgi vs standard sårbehandling, outcome: 1.6 Infektion, i interventionsperioden.

Figure 7 (Analysis 1.7)



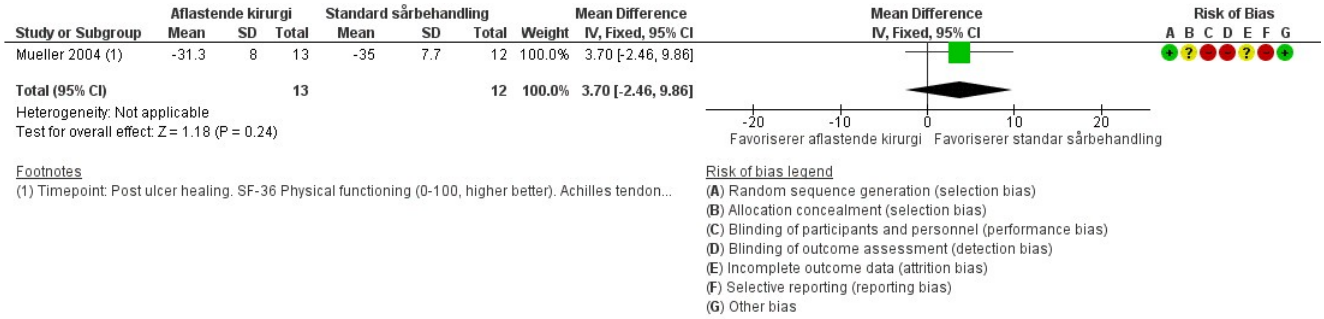
Forest plot of comparison: 1 Aflastende kirurgi vs standard sårbehandling, outcome: 1.7 Bivirkninger, længste follow-up (op til 1 år), risk ratio.

Figure 8 (Analysis 1.8)



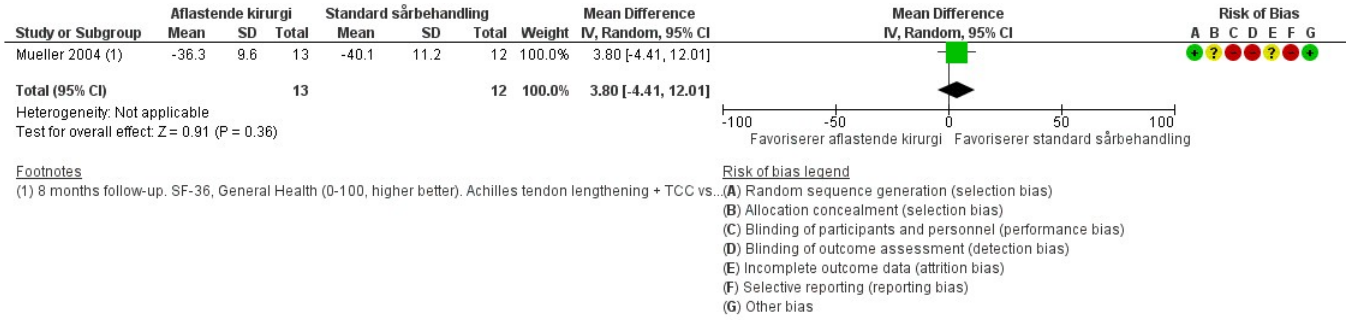
Forest plot of comparison: 1 Aflastende kirurgi vs standard sårbehandling, outcome: 1.8 Bivirkninger, længste follow-up (op til 1 år), risk difference.

Figure 9 (Analysis 1.9)



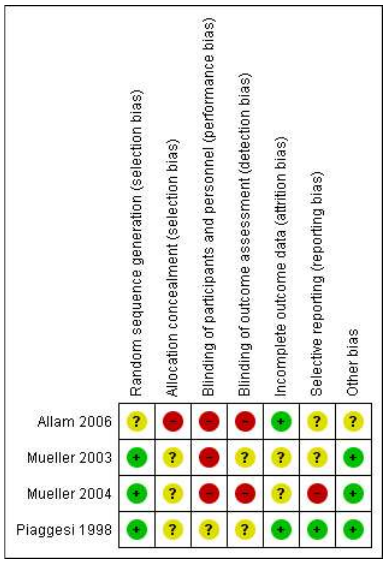
Forest plot of comparison: 1 Aflastende kirurgi vs standard sårbehandling, outcome: 1.9 Selvrapporteret funktion, efter endt behandling.

Figure 10 (Analysis 1.10)



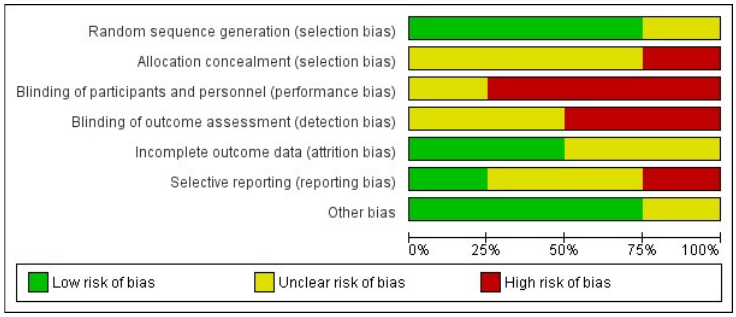
Forest plot of comparison: 1 Aflastende kirurgi vs standard sårbehandling, outcome: 1.10 Helbredsrelateret livskvalitet, længste follow-up (op til 1 år).

Figure 11



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

Figure 12



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