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Surgical versus conservative interventions for treating ankle fractures in adults (Review)

Donken CCMA, Al-Khateeb H, Verhofstad MHJ, van Laarhoven CJHM



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[Intervention Review]

Surgical versus conservative interventions for treating ankle fractures in adults

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ABSTRACT

Background

The annual incidence of ankle fractures is 122 per 100,000 people. They usually affect young men and older women. The question of whether surgery or conservative treatment should be used for ankle fractures remains controversial.

Objectives

To assess the effects of surgical versus conservative interventions for treating ankle fractures in adults.

Search methods

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register, the Cochrane Central Register of Controlled Trials (*The Cochrane Library*, 2012 Issue 1), MEDLINE, EMBASE, CINAHL and the WHO International Clinical Trials Registry Platform and Current Controlled Trials. Date of last search: 6 February 2012.

Selection criteria

Randomised and quasi-randomised controlled clinical studies comparing surgical and conservative treatments for ankle fractures in adults were included.

Data collection and analysis

Two review authors independently performed study selection, risk of bias assessment and data extraction. Authors of the included studies were contacted to obtain original data.

Main results

Three randomised controlled trials and one quasi-randomised controlled trial were included. These involved a total of 292 participants with ankle fractures. All studies were at high risk of bias from lack of blinding. Additionally, loss to follow-up or inappropriate exclusion of participants put two trials at high risk of attrition bias. The trials used different and incompatible outcome measures for assessing

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function and pain. Only limited meta-analysis was possible for early treatment failure, some adverse events and radiological signs of arthritis.

One trial, following up 92 of 111 randomised participants, found no statistically significant differences between surgery and conservative treatment in patient-reported symptoms (self assessed ankle “troubles”: 11/43 versus 14/49; risk ratio (RR) 0.90, 95% CI 0.46 to 1.76) or walking difficulties at seven years follow-up. One trial, reporting data for 31 of 43 randomised participants, found a statistically significantly better mean Olerud score in the surgically treated group but no difference between the two groups in pain scores after a mean follow-up of 27 months. A third trial, reporting data for 49 of 96 randomised participants at 3.5 years follow-up, reported no difference between the two groups in a non-validated clinical score.

Early treatment failure, generally reflecting the failure of closed reduction (criteria not reported in two trials) probably or explicitly leading to surgery in patients allocated conservative treatment, was significantly higher in the conservative treatment group (2/116 versus 19/129; RR 0.18, 95% CI 0.06 to 0.54). Otherwise, there were no statistically significant differences between the two groups in any of the reported complications. Pooled results from two trials of participants with radiological signs of osteoarthritis at averages of 3.5 and 7.0 years follow-up showed no between-group differences (44/66 versus 50/75; RR 1.05, 95% CI 0.83 to 1.31).

Authors’ conclusions

There is currently insufficient evidence to conclude whether surgical or conservative treatment produces superior long-term outcomes for ankle fractures in adults. The identification of several ongoing randomised trials means that better evidence to inform this question is likely to be available in future.

PLAIN LANGUAGE SUMMARY

Surgical versus conservative treatment for ankle fractures in adults

Each year, one in every 800 people break (fracture) their ankles. Such injuries typically happen to young men and older women. Ankle fractures can be treated surgically or conservatively (non-surgically). Surgery involves an operation to expose the fracture to reposition the broken parts of the bone and then fix them in place using wires, pins, screws and other devices. Treatment after surgery varies but may also include the use of a plaster cast. Conservative treatment involves repositioning of the fractured bone by manipulating it through the skin, followed by immobilisation of the ankle in a plaster cast for several weeks. This review aimed to find out whether surgery or conservative treatment gives a better long-term outcome for people with these injuries.

This review included four trials, involving a total of 292 participants. All four trials had flawed methods that could affect the reliability of their findings. No data could be pooled for long-term measures of function or pain. The largest trial found no evidence of differences between surgery and conservative treatment in patient-reported symptoms or walking difficulties at seven years follow-up. The second trial found better results for the surgical group for function but not pain at 27 months, while the third trial reported no difference between the two groups in clinical outcome at 3.5 years. In all four trials, there were some patients in the conservative treatment group who were treated surgically because the repositioning of the fractured bone was judged unsuccessful. Otherwise, there were no significant differences between the two groups in any of the reported complications nor in radiological signs of osteoarthritis.

Overall, there was not enough reliable evidence to draw conclusions about whether surgery or conservative treatment is more appropriate for treating broken ankles in adults.

BACKGROUND

Description of the condition

The ankle joint is made up of three bones: the tibia ('shin bone'), the fibula (the other lower-leg bone) and the talus ('ankle bone'). The distal (lower) ends of the tibia and fibula form a 'saddle shaped' joint on top of and around the talus. The specific part of the tibia

that curves down and articulates with the inside facing part of the talus is called the medial malleolus. The posterior malleolus, which is also part of the tibia, is at the back of the ankle joint. The lateral malleolus forms the distal end of the fibula and articulates with the lateral (or outside facing) part of the talus. Situated just above the ankle joint is the 'syndesmosis', which is the joint between the distal tibia and fibula held firmly together by ligaments. Together with the many ankle ligaments, the three malleoli help to keep the ankle joint stable during movement.

A broken ankle or ankle fracture is when one or more parts of the distal tibia or fibula that form the ankle joint are fractured or broken. There will often be associated soft-tissue injuries, particularly to the ankle ligaments. Most ankle fractures are closed injuries, in that the overlying skin remains intact. Around 2% are open fractures (Court-Brown 1998). An epidemiological study of 1500 ankle fractures in adults attending Edinburgh Royal Infirmary during 1988 to 1991 reported an annual incidence of 122 fractures per 100,000 persons (Court-Brown 1998). Of these, 52% occurred in men. The age distributions of fractures in men and women differed. The 58% of fractures that resulted from a simple fall or twisting injury tended to occur in elderly women. Conversely, sports injuries, mainly from soccer accidents, typically occurred in young men.

Court-Brown 1998 reported that the 70% of fractures were isolated malleolar fractures (predominantly of the lateral malleolus), 23% were bimalleolar (often of the medial and lateral malleoli) and 7% were trimalleolar (all three malleoli fractured). As well as categorising ankle fractures by location and the number of malleoli involved, various fracture classification systems have been devised to describe the different fracture patterns and help inform treatment decisions. Three commonly used classification systems for ankle fractures are the Lauge-Hansen system (Lauge Hansen 1942), the Weber system (Weber 1972) and the AO classification system (Müller 1969; Müller 1990). The Lauge-Hansen system classifies injuries by the position of the foot and direction of force at the time of injury (Lauge Hansen 1942). The anatomical classification system of Danis and Weber (Danis 1949; Weber 1972) subgroups fibular fractures as A (below the syndesmosis), B (at the syndesmosis) or C (above the syndesmosis) depending on the relationship of the fracture to the syndesmosis. The AO classification system is based on fracture patterns alone. Clinical decisions are, however, often made without considerations of these formal classification systems and will take into account also other aspects such as the damage to soft-tissues and the general health of the patient.

Description of the intervention

Following closed manipulation to achieve reduction of any displaced fractures, conservative management of ankle fractures generally comprises immobilisation in a below-knee cast for several weeks. This is to stabilise the fracture and allow it to heal. Vari-

ous methods of immobilisation include casts (plaster or synthetic material), walking casts and functional braces. A Cochrane review on the rehabilitation of ankle fractures includes comparisons of different methods of immobilisation (Lin 2008).

Surgical treatment involves the reduction (if displaced) of the fractured parts and fixation using various devices such as metal plates, screws, tension bands or external fixation. These operative techniques aim to provide anatomical restoration and immediate stability, which facilitates earlier mobilisation. However, all surgery carries the risk of complications such as wound infection, pulmonary embolism, implant or fixation failure, mortality, amputation and reoperation (SooHoo 2009). For an evaluation of post-surgical rehabilitation interventions, see Lin 2008.

How the intervention might work

Healing of the bone takes at least several weeks and consists of five major phases: induction, inflammation, soft callus formation, ossification and remodelling (Koval 2002). For conservative treatment, immobilisation of the fractured parts is generally considered to be important for bone healing. However, immobilisation can lead to muscle atrophy, cartilage degeneration, and a stiff, painful and swollen joint. Also, conservative treatment can lead to secondary displacement, which generally requires surgery (Dietrich 2002), painful nonunion (Walsh 2004) and prolonged immobilisation.

With early mobilisation and postoperative exercises these adverse effects may be prevented. If surgical treatment can protect or accelerate the bone healing process by securely stabilising the fracture, it can also reduce recovery and 'back-to-work-time' and therefore indirect costs to society. This may not be the case for older people with osteoporosis because the porosity of their bones may increase the risk of fixation failure and thus preclude early mobilisation (Salai 2000a).

Anatomical restoration of displaced fractures is more likely to be achieved using surgical methods. A lateral talar dislocation of only one millimetre results in an average reduction of 42% of the contact area between talus and tibia (Ramsey 1976), which results in severe peak loads. It is assumed that such peak forces lead to secondary loss of cartilage, which in turn increases the risk of post-traumatic osteoarthritis. The better anatomical stabilisation achieved via surgery might reduce lateral talar dislocation more effectively than immobilisation alone and thus lessen the risk of long-term post-traumatic osteoarthritis. However, as well as the additional risks generally associated with surgery and anaesthesia, patients with conditions such as diabetes and peripheral vascular disease are at increased risk of complications and an unsatisfactory outcome. Moreover, there is evidence that not all fractures need perfect anatomical repair for a satisfactory outcome. Conservative treatment with closed reduction and cast immobilisation can yield good results for certain less severe fracture types (Bauer 1985a; Herscovici 2007; Kristensen 1985). Displaced fractures can be

treated successfully with closed reduction and plaster cast (Rowley 1986a; Wei 1999). If immobilisation alone gains equal results easily for certain fractures types, surgical interventions should be considered as over-treatment.

Why it is important to do this review

In current practice, most Weber A fractures are treated conservatively and most Weber C fractures are treated by open, anatomical reduction and internal fixation. The remainder (roughly 50%) of all ankle fractures consists of Weber B fractures, which are treated both surgically and conservatively. Some clinicians think conservative measures are adequate in ankle fractures, but others consider exact anatomical reconstruction is essential to prevent predisposition for post-traumatic osteoarthritis. The rate of surgical interventions increases with the number of malleoli fractured, but depending on location, a wide range (14% to 72%) in the rate of surgical interventions has been reported in the USA (Koval 2005). There is also controversy in the treatment of older people with osteoporotic bones and other comorbidities that increase the risk of surgical complications (SooHoo 2009). Additionally, the Lauge-Hansen and Weber classification systems are not able to assess the intrinsic stability of all ankle fractures, which is considered an important determinant for the type of treatment. To compare the outcome of both treatment modalities for ankle fractures in adults, a systematic evaluation of benefits and harms is needed.

OBJECTIVES

To assess the effects (benefits and harms) of surgical versus conservative interventions for treating ankle fractures in adults.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised and quasi-randomised (method of allocating participants to a treatment which is not strictly random; e.g. by date of birth, hospital record number, alternation) controlled clinical studies comparing surgical and conservative treatments for ankle fractures in adults were included.

Types of participants

Studies including adult participants with ankle fractures who underwent a surgical or conservative intervention were included. Trials containing adults and children were included if the proportion of children was clearly small (< 5%), or if separate data for adults could be obtained. Similarly, we excluded studies in which participants with more extensive fractures of the distal third of the tibia (pilon or tibial plafond fractures) or studies that included more than 5% fractures with delayed presentation, unless separate data for acute ankle fractures could be obtained. Studies evaluating surgical revision of displaced fractures were excluded.

Types of interventions

Studies comparing any type of surgical treatment with any type of conservative intervention were included. The following procedures were compared:

- Any kind of fracture stabilisation with osteosynthesis (lag screw, plates, tension bands, bridge plating, external fixation or internal fixation)

versus

- Any kind of fracture stabilisation with non-invasive interventions (plaster cast immobilisation, walking cast, orthosis, any kind of removable type of immobilisation).

Types of outcome measures

Primary outcomes

The primary outcome measures were functional outcome, pain and major adverse events. Preference was given to validated outcome measures, including visual analogue scale readings for pain. Examples of validated outcome measures included the physician-completed Olerud Molander Ankle Score (Olerud 1984), patient-rated functional outcomes such as the Lower Extremity Function Scale (Binkley 1999), and appropriate components of generic quality of life measures (e.g. SF36, SF12, and EQ-5D).

Major adverse events were generally considered as those related to the fracture or intervention that required secondary intervention (i.e. the need for surgery or further surgery; or prolonged intensive rehabilitation). Adverse events included insufficient primary osteosynthesis, soft tissue necrosis and any infection, osteitis, post-traumatic thrombosis, delayed union, nonunion, secondary fracture displacement, re-fracture, joint stiffness, muscular atrophy, tendinous insufficiency, sensory deficit, tarsal tunnel syndrome, and complex regional pain syndrome type 1 (also known as Sudeck's dystrophy or reflex sympathetic dystrophy) (Stanton-Hicks 1995).

Secondary outcomes

The secondary outcome measures sought included measures of recovery such as time to resume normal activities or return to work, range of motion, measures of functional impairment, anatomical result (x-ray) and radiologically-defined osteoarthritis.

Search methods for identification of studies

Electronic searches

The search was conducted in two stages. We initially searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (to 4 June 2010), the Cochrane Central Register of Controlled Trials (*The Cochrane Library*, 2010 Issue 2), MEDLINE (PubMed, 1965 to 4 June 2010), EMBASE (Elsevier, 1974 to 4 June 2010) and CINAHL (EBSCO, 1981 to 4 June 2010). We also searched the [WHO International Clinical Trials Registry Platform](#) (to 4 June 2010) and [Current Controlled Trials](#) (to 4 June 2010) for ongoing or recently completed trials. We then updated our search up to 6 February 2012, setting the initial date of search from 1 January 2010, for the following: the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register, the Cochrane Central Register of Controlled Trials (*The Cochrane Library*, 2012 Issue 1), MEDLINE, EMBASE (searched using the Ovid interface), CINAHL and the WHO International Clinical Trials Registry Platform and Current Controlled Trials. The MEDLINE strategy was developed in accordance with the guidelines outlined in the Cochrane Handbook for Systematic Reviews of Interventions ([Lefebvre 2009a](#)). The subject-specific search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version ([Lefebvre 2009b](#)). This strategy was adapted to the syntax and capacities of the other databases (*see Appendix 1*). There were no restrictions based on language.

Searching other resources

We looked for additional relevant trials by checking the reference lists of identified randomised trials. All authors of included trials were asked for additional information on any published, unpublished, or ongoing trials.

Data collection and analysis

Selection of studies

The titles, abstracts and descriptor terms of all downloaded material from the electronic searches were read by CD, who discarded clearly irrelevant reports. The remaining citations were then

screened independently by CD and HA to establish the need for obtaining full articles. Full articles were also obtained where there was any uncertainty about the relevance of the study. Subsequently, CD and HA independently applied the inclusion criteria. Any differences in study inclusion were resolved by discussion with a third review author (CL).

Data extraction and management

Two review authors (CD and HA) independently extracted the data using a pre-piloted data extraction form. Any disagreement was resolved by discussion, if necessary approaching a third author. Where necessary, trial authors were contacted for further information on their trials. Extracted data were stored and managed using Review Manager. If required, interim statistical calculations were performed by CD and CL.

Assessment of risk of bias in included studies

Two review authors (CD and HA) independently assessed the risk of bias of each included study. Any differences were resolved by discussion, with arbitration by a third review author (CL). We used The Cochrane Collaboration's 'Risk of bias' tool ([Higgins 2008](#)). Each study was graded for risk of bias in each of the following domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and 'other' (for instance, extreme baseline imbalance). We also assessed performance bias, specifically in terms of surgeon's experience.

Measures of treatment effect

Treatment effect was measured using risk ratios for binary data, and mean differences or, where different outcome measures were used, standardised mean differences for continuous data. Ninety-five percent confidence intervals were used throughout.

Unit of analysis issues

As expected, the unit of randomisation was the individual patient in the included trials. There were no trials with a cluster-randomised design.

Dealing with missing data

Trial investigators were contacted for additional data if necessary. Where appropriate, we performed intention-to-treat analyses to include all people randomised to the intervention groups. We investigated the effect of drop-outs and exclusions by conducting sensitivity analyses. We were also alert to the potential mislabelling or non identification of standard errors and standard deviations. In case of missing data, we investigated whether they were missing at random, in which case the missing data was to be regarded as not having an important influence on outcome, or missing not

at random. If data were deemed to be missing not at random, we stated that replacement values would not be imputed but sensitivity analyses would be considered.

Assessment of heterogeneity

We judged the appropriateness of pooling by assessing clinical diversity in terms of participants, interventions and outcomes of the included studies. Statistical heterogeneity was assessed by visual inspection of the forest plot and by using the I^2 and Chi^2 statistical tests.

Assessment of reporting biases

Had sufficient data for the primary outcomes been available, we planned to assess publication bias using funnel plots.

Data synthesis

Where judged appropriate, we planned to pool data using both the fixed-effect (DeMets 1987) and random-effects models (DerSimonian 1986). Where there was no important difference between the two results, the results from the fixed-effect model were presented. Otherwise, depending on the results of heterogeneity tests, results from both models would have been presented.

Subgroup analysis and investigation of heterogeneity

If sufficient pooled data were available, we intended to conduct subgroup analyses to compare the effects of the interventions according to the risk of bias of the trials (low risk versus unclear or high risk), type of fracture (Weber A, B and C; displaced versus non-displaced), age (under 65 years; 65 or over), comorbidity (diabetic; non-diabetic), surgical experience (resident versus surgeon), different definitions of union (clinical versus radiological), and types of surgical (plate versus other fixation) or conservative treatment (e.g. early mobilisation versus immobilisation).

Sensitivity analysis

We intended to perform sensitivity analysis of pooled data examining various aspects of trial and review methodology, including the effects of missing data, and the inclusion of trials at high risk of bias (primarily, lack of allocation concealment) and trials only reported in abstracts.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Results of the search

After performing the first search up to 4 June 2010 (see [Appendix 1](#)) and removing duplicates, 1352 titles and abstracts were reviewed. Our subsequent search (2010 to 6 February 2012) resulted in 399 reference citations after the removal of duplicates (MEDLINE (48); *The Cochrane Library* (16); EMBASE (262); CINAHL (115)). Overall, of 18 potentially eligible studies, four were included, nine were excluded and five are ongoing or yet to be published trials (as of February 2012). All contact authors of the included trials (and the contact author of [Salai 2000](#)) were approached for additional information and clarification. While we were successful in contacting the authors of [Phillips 1985](#) and [Salai 2000](#), neither was able to provide additional information.

Included studies

The four included studies ([Bauer 1985](#); [Makwana 2001](#); [Phillips 1985](#); [Rowley 1986](#)) involved a total of 292 participants. These are summarised below, with a full summary for each trial detailed in the [Characteristics of included studies](#).

Design

Three included trials ([Bauer 1985](#); [Makwana 2001](#); [Phillips 1985](#)) were randomised controlled trials and one trial ([Rowley 1986](#)) was a quasi-randomised controlled trial.

Sample sizes

The study population sizes at randomisation varied: 42 patients ([Rowley 1986](#)), 43 patients ([Makwana 2001](#)), 96 patients ([Phillips 1985](#)) and 111 patients ([Bauer 1985](#)).

Setting

All four trials were hospital based. [Bauer 1985](#) was conducted in two hospitals in Sweden. The other three were single centre trials carried out in the UK ([Makwana 2001](#); [Rowley 1986](#)) and the US ([Phillips 1985](#)). The first year of patient recruitment spanned from 1968 in [Bauer 1985](#) to 1995 in [Makwana 2001](#).

Participants

Information on gender was available for three trials: [Bauer 1985](#) (64 female, 44 male); [Makwana 2001](#) (31 female, 12 male); and [Phillips 1985](#) (54 female, 42 male). In all, participant age varied between 15 and 91 years but [Makwana 2001](#) set a lower age limit

of 55 years and thus recruited an older population than the other three trials.

Bauer 1985 included patients with a displaced type A or B malleolar fracture. Makwana 2001 included patients with a displaced ankle fracture. Phillips 1985 evaluated patients with a closed supination-external rotation grade-4 or a pronation-external rotation grade-4 ankle fracture, classified according to the modified Lauge Hansen system (Lauge Hansen 1942), for whom a satisfactory closed reduction had been achieved. Rowley 1986 included patients with a displaced ankle fracture. Closed reduction was performed in all four trials.

Interventions

Essentially, all four trials compared open reduction and internal fixation (ORIF) versus closed reduction and plaster cast immobilisation (conservative treatment).

In Bauer 1985, Makwana 2001 and Rowley 1986, surgical treatment was in accordance with AO/ASIF principles (Müller 1979). Phillips 1985 described the use of surgical techniques based on those of the Association for the Study of Internal Fixation (ASIF) (not referenced).

Bauer 1985 compared ORIF (followed by bed rest for five days, partial weight bearing from six weeks and full weight bearing at nine weeks) versus closed reduction and a plaster cast for six weeks (followed by partial weight bearing from six weeks and full weight bearing at nine weeks).

Makwana 2001 compared ORIF followed by a below-knee plaster cast for six weeks with protected weight bearing versus closed reduction followed by a below-knee plaster cast for six weeks with protected weight bearing.

In Phillips 1985, all participants had had a satisfactory closed reduction before randomisation to ORIF (followed by a below-knee plaster cast for one week; walking on crutches without weight bearing started a few days after surgery until the tenth week) versus a long-leg plaster cast for six weeks without weight-bearing and a below-knee for a further four weeks.

Rowley 1986 compared ORIF (followed by a below-knee backslab and active ankle movement for up to five days, then plaster cast for six weeks) versus closed reduction and a long-leg plaster cast for six weeks. Early weight bearing was encouraged in both groups.

The criteria for successful closed reduction were not clearly/precisely defined in Bauer 1985 and Rowley 1986. Both Makwana 2001 and Phillips 1985 used the same set of five criteria to define a satisfactory closed reduction.

Outcomes

Length of follow-up duration varied between 20 weeks (Rowley 1986) and an average of seven years (Bauer 1985). All four trials used different approaches to measuring function and clinical outcome. Bauer 1985 and Phillips 1985 used non-validated tools, whereas Makwana 2001 used the Olerud and Molander ankle score (Olerud 1984) as well as a visual analogue score to assess pain. The composite scoring scheme devised by Phillips 1985 assessed clinical and anatomical outcomes and arthritis. Rowley 1986 reported on the presence of foot deformity and foot print analysis for detecting abnormal foot angles. All four trials reported on complications and, to various extents, radiological outcomes.

Excluded studies

There were nine excluded studies. Strömsöe 1995 did not compare surgical versus conservative treatment. The other eight studies compared surgical versus conservative treatment in ankle fractures, but were excluded because they were not randomised controlled trials (see the Characteristics of excluded studies). In particular, the claim to be a randomised trial in the report of Salai 2000 was not substantiated either through contact with the trial author or by the inappropriate presentation of study results.

Ongoing studies

We identified five ongoing trials (Gray; Harris; Pakarinen; Sanders; Willett), details of which can be found in the Characteristics of ongoing studies. Three trials are multi-centre studies. Two studies will be finished in 2014 and 2016. The publication of three studies was delayed; although they were due to finish in 2010, no published results were identified by our search in February 2012.

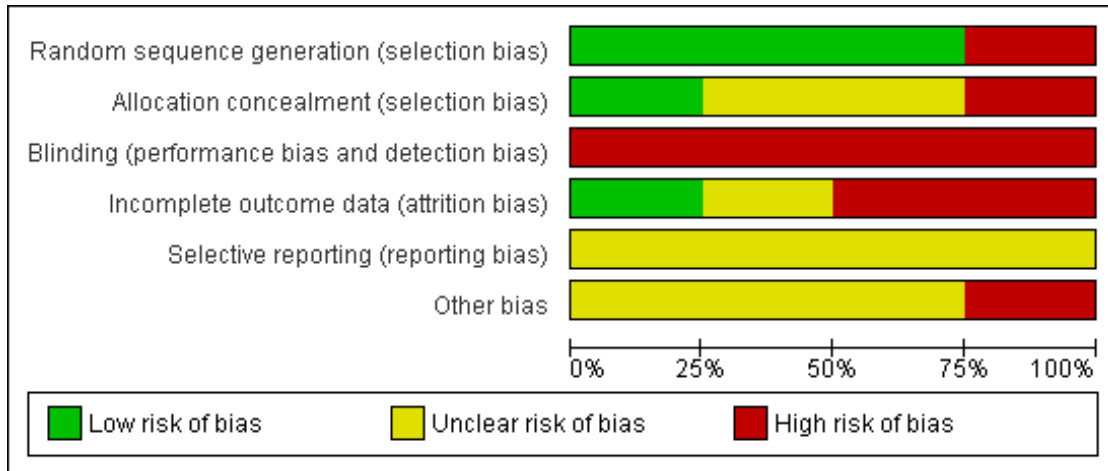
Risk of bias in included studies

See: Risk of bias in included studies; Figure 1; Figure 2.

Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bauer 1985	+	?	-	?	?	?
Makwana 2001	+	?	-	-	?	-
Phillips 1985	+	+	-	-	?	?
Rowley 1986	-	-	-	+	?	?

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Due to the high level of missing data, all authors were approached for additional information. Only one attempt was successful (Phillips 1985), but no additional information was obtained.

Allocation

Generation of the allocation sequence was considered of low risk of bias in three trials (Bauer 1985; Makwana 2001; Phillips 1985) and high risk in Rowley 1986, the allocation of which was based on the patient's record number. Allocation concealment was judged at low risk of bias in Phillips 1985, at high risk in Rowley 1986, and of unclear risk in the remaining two trials (Bauer 1985; Makwana 2001) which provided no details of this aspect.

Blinding

We acknowledge blinding can be difficult due to the nature of the intervention, but nevertheless none of the studies provided information about blinding and thus all were judged at being at high risk of both performance and detection bias.

Incomplete outcome data

The risk of attrition bias was considered high in Phillips 1985 (large (49%) loss of follow-up) and Makwana 2001 (exclusion of eight conservatively treated patients with secondary dislocation; lack of intention-to-treat analysis). Bauer 1985 was judged at unclear risk of bias: while intention-to-treat-analysis was performed and few were lost to follow-up, the effect of the exclusion of type A fractures at follow-up is unknown. In Rowley 1986, two patients were excluded from the analysis because they required secondary surgery after failed manipulation. The authors' intention was to analyse these patients separately but this was not done and

intention-to-treat analysis was not performed. However, this was unlikely to alter the findings of the trial, which was thus judged to be at low risk of attrition bias.

Selective reporting

As we did not have access to the study protocols, we judged this to be at unclear (unknown) risk of bias.

Other potential sources of bias

In Makwana 2001, the imbalance in the number of smokers (0 versus 6) between the two groups was considered to be another potential source of bias. No information was available to assess potential other sources of bias in any of the included studies.

Effects of interventions

All authors were contacted to obtain the original data, but none was forthcoming. The lack of these data prevented our plans to study the outcomes in different subgroups.

Primary outcomes

Based on the results of a non-validated questionnaire, Bauer 1985 found no difference between the two groups at seven years in the incidence of people with self-assessed significant 'troubles' from their ankle (11/43 versus 14/49; risk ratio (RR) 0.90, 95% CI 0.46 to 1.76; see Analysis 1.1). With the exception of a marginally statistically significant difference in favour of the conservative treatment group in the numbers of participants reporting swelling,

there were no statistically significant differences between the two groups in participants reporting problems of pain, restricted range of motion, unsteadiness and 'passing stiffness' (see Analysis 1.1). There were also no statistically significant differences between the two groups in walking difficulties on rough or even ground (see Analysis 1.1). Four participants, two from each group, formerly employed as heavy manual labourers, changed occupation or quit working because of their ankle fracture. Makwana 2001 found a significantly better mean Olerud score (Olerud 1984) in the surgically treated group after a mean follow-up of 27 months (mean difference (MD) 17.00, 95% CI 0.64 to 33.36; see Analysis 1.2). At 3.5 years of follow-up, Phillips 1985 found a significant difference in favour of the surgical group for a non-validated combined score (0 to 150: best outcome) that rated clinical, anatomical and arthritis outcome (MD 10.30, 95% CI 0.93 to 19.67; see Analysis 1.2); however, there was no difference between the two groups in the clinical scores (subjective + objective assessment: 100 possible points): 88.8 versus 84.3, difference reported as non significant. Makwana 2001 found no difference in pain scores at 27 months (see Analysis 1.3).

While Bauer 1985 and Phillips 1985 retained for the purposes of intention-to-treat analyses those patients who did not receive their allocated intervention or were otherwise early treatment failures (i.e. failure of closed reduction), the other two trials explicitly excluded these. There were significantly more early treatment failures in the conservative treatment group (2/116 versus 19/129; RR 0.18, 95% CI 0.06 to 0.54; see Analysis 1.4). Skin damage precluded operations for two participants allocated surgery in Bauer 1985. As shown in the rest of the analyses in Analysis 1.4, there were no significant differences between the two groups in any of the specified complications (deep infection, superficial infection, surgical wound closure problem, skin ulcer, deep vein thrombosis, complex regional pain syndrome type 1 (Stanton-Hicks 1995), need for removal of internal fixation, surgical scar tenderness). It is noteworthy that all four conservative treatment group patients with wound infections in Bauer 1985 were patients who received surgery after closed treatment had failed.

Secondary outcomes

Bauer 1985 showed no differences between the surgical and conservative groups in range of motion parameters at seven years (see Analysis 1.6). In Makwana 2001, the loss of dorsal range of motion compared with the contralateral ankle at follow-up was significantly less in the surgically treated group (9 versus 16 degrees, reported $P = 0.044$). Rowley 1986 found no statistically significant differences between the two groups regarding restriction of dorsiflexion or abnormal foot angle at 20 weeks follow-up (see Analysis 1.5). Time to independent weight bearing by all patients in Rowley 1986 was 16 weeks for the surgical group and 12 weeks for the conservative group.

At 3.5 years of follow-up, Phillips 1985 found a significant dif-

ference in favour of the surgical group in the anatomical scores (26.7 versus 22.1 (out of a maximum score of 35); reported $P < 0.05$). Pooled results for participants with radiological signs of osteoarthritis from two trials (Bauer 1985; Phillips 1985) showed no between-group differences (44/66 versus 50/75; RR 1.05, 95% CI 0.83 to 1.31; see Analysis 1.8).

In Bauer 1985, patients receiving surgical treatment left the hospital significantly later than conservatively treated patients (mean 9.5 versus 5.0 days, reported $P < 0.05$); 17 (30%) participants of the conservative treatment group were treated as outpatients. The median time of sick leave of fully employed participants was 14 weeks in both groups of Bauer 1985. In Makwana 2001, patients receiving surgery also left the hospital significantly later than the conservatively treated patients (mean 6.7 versus 2.6 days, mean difference 4.10 days, 95% CI 2.62 to 5.58; see Analysis 1.9).

DISCUSSION

Summary of main results

Four controlled trials (three randomised and one quasi-randomised) involving a total of 292 adults with displaced ankle fractures were included in this review.

Meta-analyses for functional outcome and pain were impossible due to the incompatible outcome measures used by the trials. The largest trial (Bauer 1985), following up 92 of 111 randomised participants, found no statistically significant differences between surgery and conservative treatment in the number of patients reporting symptoms and walking difficulties at seven years follow-up. One trial (Makwana 2001), reporting data for 31 of 43 randomised participants, found a significantly better mean Olerud score in the surgically treated group but no difference between the two groups in pain scores after a mean follow-up of 27 months. A third trial (Phillips 1985), reporting data for 49 of 96 randomised participants at 3.5 years follow-up, reported no difference between the two groups in a non-validated clinical score.

Early treatment failure, generally reflecting the failure of closed reduction (criteria not reported in two trials) probably or explicitly leading to surgery in patients allocated conservative treatment, was significantly higher in the conservative treatment group. Such patients were incorrectly excluded from the analyses of two trials. Otherwise, there were no significant differences between the two groups in any of the reported complications.

Bauer 1985 found no differences between the surgical and conservative groups in range of motion at seven years, whereas Makwana 2001 reported a better range of motion result for the surgically treated group. One trial (Rowley 1986) reporting data for 40 participants at 20 weeks follow-up found no statistically significant differences between the two groups regarding restriction of dorsiflexion or abnormal foot angle. Phillips 1985 found better anatom-

ical scores in the surgical group at 3.5 years of follow-up. Pooled results for participants with radiological signs of osteoarthritis from two trials showed no between-group differences.

Two trials found that patients receiving surgical treatment stayed in hospital on average four days longer than conservatively treated patients.

Overall completeness and applicability of evidence

This review contains only four trials with a total of 292 participants. However, functional outcome data were available for far fewer participants (170 patients in three trials) and, moreover, these could not be pooled.

There were important differences between the four trials, including the types of participants (e.g. [Makwana 2001](#) only recruited people over 55 years old), the surgical techniques (e.g. in [Bauer 1985](#), ligamentous injuries were sutured, whereas this was not done in [Makwana 2001](#)), conservative treatment (e.g. types and duration of plaster cast immobilisation), the post-surgical treatment regimens (type and duration of plaster cast, early weight-bearing or not, early active movements or not), and in the duration of follow-up and assessment of outcome. This variation, as well as lack of information on these trial characteristics (including the criteria for a satisfactory closed reduction), hinder the assessment of the applicability of the already limited and flawed evidence.

Duration of follow-up in [Rowley 1986](#) of just 20 weeks is clearly unsatisfactory for a full assessment of outcome but it is also noteworthy that even a follow-up of seven years as in [Bauer 1985](#) is insufficient to ascertain post-traumatic osteoarthritis. [Horisberger 2009](#) showed that the latency time to end stage osteoarthritis after an ankle fracture can be as much as 20 years.

Quality of the evidence

Overall, the quality of the evidence is very limited. We judged the risk of bias was unclear or high in the majority of categories for the four trials. [Rowley 1986](#) was quasi-randomised and thus at high risk of selection bias and all trials were at risk of bias due to lack of blinding, including of assessors. Of note is the high risk of attrition bias from incomplete outcome data in [Makwana 2001](#), which incorrectly excluded patients after randomisation, and [Phillips 1985](#), which had a large loss to follow-up. All trials were small and insufficient to confirm any lack of differences between the two groups.

Potential biases in the review process

The review was performed according to the unchanged published protocol. We tried to minimise publication bias by undertaking a

comprehensive search strategy and checking non-English language citations (a translation of a Polish and German study resulted in their exclusion). Our search also included a search for ongoing and recently completed trials. However, it is still possible that potentially relevant trials have been missed. Additionally, although unsuccessful, we tried to obtain additional data and information from the included trialists.

Agreements and disagreements with other studies or reviews

The conclusion of this review is in line with another systematic review about the surgical versus conservative treatment of ankle fractures ([Petrisor 2006](#)). [Petrisor 2006](#) also included [Salai 2000](#), which we excluded because it did not appear to be randomised (and its data were unusable). Our search also located five ongoing or unpublished trials that may be included in a future update of this review.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence to conclude whether surgical or conservative treatment produces superior long-term outcomes for ankle fractures in adults.

Implications for research

In future, adequately powered well designed and conducted, and appropriately reported clinical trials could provide more robust data. They should use validated outcome measures. Ideally, patients should be followed up for several years after randomisation and standard treatment regimens for surgical or conservative interventions should be used. Inclusion criteria and randomisation should take into account fracture type and displacement. However, before embarking on any new trials, it is important to note the existence of several ongoing studies, including a large multi-centre trial aiming to recruit over 600 patients. These trials also point to the importance of updating this review in due course.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Bauer 1985

Methods	<p>Method of randomisation: random number tables.</p> <p>Blinding: unclear.</p> <p>Loss of follow-up: 11 (7 died, 4 lost to follow-up) out of 111. However, type A fractures (n = 8) are excluded in the analysis. The study reports the follow-up results of only the type B fractures (n = 92).</p> <p>Patients' consent to randomisation: unclear.</p> <p>Number of surgeons: 10 surgeons with at least one year of experience in fracture treatment participated</p>
Participants	<p>Study locations: departments of orthopaedic surgery of the Malmö General Hospital in Malmö and the Östersund Hospital in Östersund, both in Sweden</p> <p>Study period: between 1 February 1968 and 21 June 1970.</p> <p>Study participants: 111 randomised, baseline data for 108. Follow-up in 92 patients</p> <p>Age: 44 years, range 16 to 77 years.</p> <p>Gender: 44 men and 64 women (of which 8 patients with type A fractures are excluded)</p> <p>Inclusion criteria: patients with a diagnosis of a malleolar fracture</p> <p>Exclusion criteria: pilon fractures or tibial plafond fractures, type C fractures, patients with open fractures, other concomitant injuries to the lower limb, nondisplaced fractures, patients with open growth zones and those with diseases which entail increased risk of complications</p>
Interventions	<p>Surgery: according to the AO principles (Müller 1979). Ligamentous injuries were sutured. Suction drainage as applied for 24 hours. Active movements started on the first postoperative day. The patients were kept in bed with the operated leg elevated in a splint until the fifth postoperative day. After 6 weeks, 20% weight bearing was allowed. Full weight bearing was allowed after 9 weeks</p> <p>Conservative: closed reduction was performed and a plaster cast was applied. The patients were discharged as soon as they were able to walk on crutches. Weight bearing was not allowed during the first 6 weeks in either group to prevent load-induced displacement. After 6 weeks, the cast was removed and 20% weight bearing was allowed. Full weight bearing was allowed after 12 weeks</p>
Outcomes	<p>Length of follow-up: mean 7 years, range 6 to 8 years.</p> <p>A questionnaire (not validated and only introduced in the present study) measuring ankle girth, range of motion, presence of foot deformity, ability of walking, radiological outcome (bony union, anatomical result and osteoarthritis (according to Cedell (Cedell 1967) and Magnusson (Magnusson 1944)), hospital stay, mean time of treatment, sick-leave, complications (infection, DVT, pulmonary embolism, tenderness)</p>
Notes	<p>Long-term results in this study only reported for displaced type B fractures. Early results were provided for 108 patients</p>
<i>Risk of bias</i>	

Bauer 1985 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A list of random numbers was used.
Allocation concealment (selection bias)	Unclear risk	The authors only state: "random allocation was performed with the aid of a list of random numbers".
Blinding (performance bias and detection bias) All outcomes	High risk	The authors state: "all films were evaluated by the same radiologist" and "at follow-up all patients were seen by two of the authors".
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The results at follow-up of 8 patients with type A fractures were not incorporated in the study. However baseline data were shown. After exclusion of these 8 patients, 'protocol deviants' were kept in their allocated group
Selective reporting (reporting bias)	Unclear risk	There is no study protocol available.
Other bias	Unclear risk	No information to judge this.

Makwana 2001

Methods	<p>Method of randomisation: computer-generated random numbers.</p> <p>Blinding: unclear.</p> <p>Loss of follow-up: 7 (6 unwilling to attend, 1 died) out of 43 (16%). Eight (of which only 5 were available at follow-up) conservatively treated patients with secondary dislocation were excluded and not analysed (separately)</p> <p>Patients' consent to randomisation: yes.</p> <p>Number of surgeons: unknown number of registrars, senior registrars and consultants</p>
Participants	<p>Study location: level 1 trauma centre; Leicester Royal Infirmary, United Kingdom</p> <p>Study period: between January 1995 and February 1997.</p> <p>Study participants: 43 randomised, baseline data for 43. Follow-up in 31 patients</p> <p>Age: 66 years, range 55 to 81 years.</p> <p>Gender: 12 men and 31 women at baseline. Gender distribution at follow-up is unknown</p> <p>Inclusion criteria: all patients with a displaced ankle fracture over 55 years of age requiring operative treatment</p> <p>Exclusion criteria: pre-existing ipsilateral or contralateral ankle pathology, a pathological fracture (e.g. a stress fracture), an intra-articular fracture (e.g. a pilon fracture), inability to attend follow-up or inability to follow the postoperative regimen, unsatisfactory closed reduction (according to criteria by Phillips (Phillips 1985)), blisters precluding operative treatment, pilon fractures or tibial plafond fractures</p>

Interventions	<p>Surgery: standard AO implants and techniques according to the AO/ASIF manual (Müller 1979). Additional information from correspondence (Ramasamy 2001): Nearly all the fractures of the ankle (96%) were fixed using a 1/3 semitubular plate on the lateral side, with or without lag screws. In one patient the lateral malleolus was treated by a Rush pin. AO cancellous screws were used in 82% of cases on the medial side, and this was supplemented in one by a Kirschner wire. No fixation was necessary in three medial malleoli. Postoperative regimen: a below-knee cast was retained for six weeks. The leg was elevated for 48 hours after which protected weight-bearing was allowed</p> <p>Conservative: a moulded below-knee plaster cast, with 48 hours limb elevation, after which protected weight-bearing was allowed for 6 weeks</p>	
Outcomes	<p>Length of follow-up: mean 27 months, range 15 to 42 months.</p> <p>Olerud and Molander ankle score (Olerud 1984), visual analogue score for pain, ankle girth, range of motion, inpatient stay, radiological outcome (bony union, malunion, nonunion, talar tilt and degenerative changes using the criteria of Magnusson (Magnusson 1944)), complications (wound problems, tenderness of the scar, malunion, nonunion, Complex Regional Pain Syndrome type 1 (Stanton-Hicks 1995), secondary dislocation and further surgery).</p>	
Notes	<p>It is unclear from the report whether there were 47 randomised patients (Abstract states: "Forty-seven patients ... were entered into a prospective, randomised study") or 43 (according to the flow chart and 'Patients and methods section', where randomisation occurred after assessment of a satisfactory closed reduction). We have opted for the latter</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A computer random number generator was used.
Allocation concealment (selection bias)	Unclear risk	The authors only state: " <i>patients had been randomised by computer-generated random numbers in theatre</i> ".
Blinding (performance bias and detection bias) All outcomes	High risk	The authors only state: " <i>all patients were assessed clinically and radiographically by the same observer (first author) at follow-up in order to minimise interobserver error</i> ".
Incomplete outcome data (attrition bias) All outcomes	High risk	Of the 22 patients in the ORIF group only 19 had successful manipulative reduction; the 3 patients with unsuccessful reduction were excluded, because they required surgery. Eight (of which only 5 were available at follow-up) conservatively treated patients with secondary dislocation were excluded and not analysed (separately). No

		intention-to-treat-analysis was performed
Selective reporting (reporting bias)	Unclear risk	There is no study protocol available.
Other bias	High risk	The conservative group had significantly more smokers (6 versus 0)

Phillips 1985

Methods	<p>Method of randomisation: random number tables.</p> <p>Blinding: unclear.</p> <p>Loss of follow-up: 47 (could not be located or refused to be evaluated) of 96 (49%)</p> <p>Patients' consent to randomisation: yes.</p> <p>Number of surgeons: two members of the attending orthopaedic staff in combination with a resident</p>
Participants	<p>Study location: level 1 trauma centre; University of Chicago Hospitals, Chicago, United States of America</p> <p>Study period: between June 1975 and June 1979.</p> <p>Study participants: 96 randomised, baseline characteristics for 93 (3 lost charts). Follow-up in 71 patients</p> <p>Age: 41.6 years, range 15 to 78 years.</p> <p>Gender: 42 men and 54 women.</p> <p>Inclusion criteria: patients with a diagnosis of a closed supination-external rotation grade-4 or a pronation-external rotation grade-4 ankle fracture, classified according to the modification of the Lauge Hansen system (Lauge Hansen 1942).</p> <p>Exclusion criteria: open ankle fractures, pilon or tibial plafond fractures, open epiphyses, a previous fracture, concomitant injuries, pregnant women, a medical contraindication to a specific form of treatment that would hamper randomisation</p>
Interventions	<p>There were two treatment categories relevant to this review:</p> <p>Surgery: satisfactory closed reduction and then open reduction and internal fixation by the Association for the Study of Internal Fixation (ASIF) technique. The leg was immobilised in a below-the-knee plaster cast. Walking on crutches without weight bearing started a few days after surgery until the tenth week. The cast was removed after 1 week to allow early active motion exercises. The trans-syndesmotic screw (if present) was removed after 10 weeks</p> <p>Conservative: satisfactory closed reduction followed by continued closed treatment. A toe-to-thigh cast with the knee flexed in 30 degrees was applied for 6 weeks, without weight-bearing. At the end of 6 weeks a below-the-knee walking cast was applied for an additional 4 weeks</p>
Outcomes	<p>Length of follow-up: 3.5 years, range 1.7 to 6.0 years.</p> <p>The authors devised 3 scoring systems for this study that provided clinical (maximum 100 points for pain, range of motion and function), anatomical (maximum 35 points for talocrural angle, medial clear space, integrity of tibiofibular syndesmosis, medial malleolar displacement, size of posterior malleolar fragment, lateral malleolar displacement and shortening, talar tilt, talar subluxation, aspect of anteromedial corner) and arthritis scores (maximum 15 points for non-union, synostosis, osteoporosis, irregular articular</p>

Phillips 1985 (Continued)

	<p>surface, osteophytes, periarticular cysts and joint-space narrowing). These three scores were combined to give a total score, for which a perfect result was 150 points.</p> <p>Complications (secondary operation; pressure sores; superficial skin sloughs; non-union; deep infection)</p> <p>Death (post-operative)</p>
Notes	<p>The trial also compared two methods of surgery where there was unsatisfactory closed reduction in 42 patients (open reduction and internal fixation by the ASIF technique versus open reduction and internal fixation of the medial malleolus). These groups are not included in this review</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A random numbers table was used.
Allocation concealment (selection bias)	Low risk	Sealed envelopes were used.
Blinding (performance bias and detection bias) All outcomes	High risk	No information about blinding is provided in the study.
Incomplete outcome data (attrition bias) All outcomes	High risk	In 47 patients follow-up could not be performed because patients could not be located or refused to be evaluated. In three of these patients baseline characteristics could not be provided, because of the loss of their charts
Selective reporting (reporting bias)	Unclear risk	There is no study protocol available.
Other bias	Unclear risk	No information to judge this.

Rowley 1986

Methods	<p>A quasi-randomised study using Accident and Emergency number</p> <p>Blinding: unclear.</p> <p>Loss of follow-up: 2 (excluded because of open reduction and internal fixation after failed manipulation) of 42 (5%)</p> <p>Patients' consent to randomisation: unclear.</p> <p>Number of surgeons: unclear.</p>
Participants	<p>Study location: The Royal Hallamshire Hospital, University of Sheffield, United Kingdom</p> <p>Study period: unclear.</p> <p>Study participants: 42 randomised, no baseline characteristics provided (only type of</p>

	<p>fracture). Follow-up in 40 patients Age: mean not provided, range 16 to 70 years. Gender: not provided. Inclusion criteria: patients with a diagnosis of a displaced type ankle fracture Exclusion criteria: patients with pilon or tibial plafond fracture</p>	
Interventions	<p>Surgery: Open reduction and internal fixation, using the standard AO technique (Müller 1979), fixing the fibula with compression screws and a buttress plate, and the medial malleolus with screws or tension bands according to the fragment size. No attempt was made to institute any ligamentous repair. After fixation, the limb was placed in a below-knee backslab; early active movement was started on the first day after operation and continued for five days until a reasonable range of movement was established. The ankle was then placed in a below-knee plaster for 6 weeks and early weight-bearing was encouraged. At 6 weeks, patients were mobilised out of plaster and weight bearing was encouraged as soon as possible. No formal physiotherapy was offered</p> <p>Conservative: After manipulation, the position of the fracture was subsequently maintained in a long-leg plaster for 6 weeks and early weight-bearing was encouraged. The criteria of a good reduction were defined as correction of talar shift on the anterolateral radiograph and of posterior talar subluxation on the lateral film. On both views, the fibula had to be corrected in terms of rotation and length. The medial malleolus had to have a smooth articular profile, although a small step on its medial aspect was acceptable. Further radiographs were taken at one and two weeks from injury; if there was significant loss of position the patient was re-admitted and open reduction and internal fixation was carried out. At 6 weeks, patients were mobilised out of plaster and weight bearing was encouraged as soon as possible. No formal physiotherapy was offered</p>	
Outcomes	<p>Length of follow-up: 20 weeks, no range provided. Time to normal weight-bearing. Time for dorsiflexion to return to normal. Time for foot angle to return to normal (the position of the foot during walking by means of a footprint analysis). Complications (none) Treatment failure</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	The study was quasi-randomised according to the last digit of the Accident and Emergency number
Allocation concealment (selection bias)	High risk	The authors provide no information about allocation concealment and was quasi-randomised
Blinding (performance bias and detection bias)	High risk	No information about blinding is provided in the study.

Rowley 1986 (Continued)

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Low risk	Two patients were excluded in the analysis, because they required secondary surgery after failed manipulation. The authors' intention was to analyse these patients separately, but this was not done. The effects of these two missing patients were explored in analysis 1.2 and revealed no significant impact on the results
Selective reporting (reporting bias)	Unclear risk	There is no study protocol available.
Other bias	Unclear risk	No information to judge this.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Dietrich 2002	Not a randomised controlled trial.
Dolez al 1995	Not a randomised controlled trial.
Hughes 1979	Not a randomised controlled trial. Depending on the hospital of presentation patients received only operative treatment (Kantonsspital-St. Gallen, Switzerland) or conservative and operative treatment (University Surgery Clinic, Freiburg, Germany and Kantonsspital-Liestal, Switzerland)
Richter 1994	Not a randomised controlled trial.
Salai 2000	The absence of clarification of study methods from the trial author has failed to convince us that this was a randomised trial. Even if it was randomised, the reported results from the study could not be used given that the data from 19 surgically-treated patients who "met the above criteria for randomisation" were combined with 30 other surgically-treated patients, and compared with those of "an additional 16 [who] completed treatment by closed reduction"
Strömsöe 1995	This randomised controlled trial including patients with an unstable Weber B or C ankle fracture without a medial malleolar fracture compared different surgical approaches. No patients were treated conservatively
Velkovski 1995	Not a randomised controlled trial.
Yde 1980a	Not a randomised controlled trial. Depending on the hospital of presentation, patients with supination-eversion stage II fractures received conservative treatment (Fredrikhavn Hospital, Denmark) or operative treatment (Hjørring Hospital, Denmark)

(Continued)

Yde 1980b	Not a randomised controlled trial. Depending on the hospital of presentation, patients with supination-ever- sion stage IV fractures received conservative treatment (Fredrikhavn Hospital, Denmark) or operative treatment (Hjørring Hospital, Denmark)
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Characteristics of ongoing studies [ordered by study ID]

Gray

Trial name or title	Influence of ankle skin perfusion on fracture treatment outcomes in the elderly: a randomised controlled trial comparing total contact cast with open reduction and internal fixation, the effect on cutaneous blood supply and relationship to skin complications
Methods	Randomised interventional trial
Participants	Patients aged over 60 years old with an unstable ankle fracture Estimated enrolment: 120.
Interventions	Patients will be anaesthetised and undergo either closed manipulation of the fracture and then application of a close contact cast or have a surgical open reduction and internal fixation by a contemporary method using metal plates and screws
Outcomes	Olerud and Molander score, skin complications, radiological assessment, quality of life at 6 weeks and 6 months
Starting date	May 2004
Contact information	Gray B, Kadoorie Centre for Critical Care Research, Level 3, Headley Way, Headington, Oxford, United Kingdom, OX3 9DU
Notes	Expected end date: 2010

Harris

Trial name or title	Combined randomised and observational study of type B ankle fracture treatment (CROSSBAT)
Methods	A prospective randomised multi-centre study
Participants	Patients aged between 18 and 65 years with a diagnosis of undisplaced (AO type 44-B1) distal fibula fracture Estimated enrolment: 160
Interventions	Operative versus non operative treatment
Outcomes	American Academy of Orthopaedic Surgeons (AAOS) Foot and Ankle Questionnaire and SF-12 version 2 Health Survey
Starting date	August 2010

Harris (Continued)

Contact information	Mittal R, Bsc (Med), MBB, The University of New South Wales, Australia, +61 2 9828 3947, rajatmittal.sydney@gmail.com
Notes	December 2016

Pakarinen

Trial name or title	Syndesmotic injury and fixation in supination-external (SE) ankle fractures
Methods	Randomised controlled trial
Participants	All skeletally mature patients (≥ 16 years old) with a unilateral Lauge-Hansen supination-external rotation type 4 ankle fractures treated within one week after injury at their hospital Estimated enrolment: 140
Interventions	Comparing syndesmotic transfixation to no fixation in AO/OTA Weber B-type ankle fracture
Outcomes	Olerud-Molander scoring system, RAND 36-Item Health Survey, and visual analogue scale (VAS) to measure pain and function after a minimum 1-year of follow-up
Starting date	June 2007
Contact information	Pakarinen HJ, Oulu University Hospital, Finland
Notes	Expected end date: 2010

Sanders

Trial name or title	Operative versus non operative treatment for unstable ankle fractures
Methods	A prospective randomised multi-centre study
Participants	Patients aged between 18 and 65 years with a diagnosis of unstable Weber B unilateral fibular fracture Estimated enrolment: 80
Interventions	Operative versus non operative treatment
Outcomes	Comparison of physical functioning score on SF36
Starting date	November 2001
Contact information	Sanders D, M.D., FRCSC, University of Western Ontario, Canada, 519-685-8055
Notes	Expected end date: 2010

Willett

Trial name or title	Comparison of close contact cast (CCC) technique to open surgical reduction and internal fixation (ORIF) in the treatment of unstable ankle fractures in patients over 60 years
Methods	Multi-centre pragmatic individually randomised controlled equivalence study
Participants	Patients aged over 60 years with a diagnosis of an isolated displaced unstable ankle fracture Estimated enrolment: 620
Interventions	Close contact cast versus open reduction and internal fixation
Outcomes	Olerud and Molander ankle score, Iowa ankle score, radiological measurements of fracture and ankle joint congruence, Euroqol EQ-5D and SF-12 health survey
Starting date	October 2009
Contact information	Prof. K. Willett, Kadoorie Centre John Radcliffe Hospital, OX3 9DU, University of Oxford, United Kingdom
Notes	Expected end date: 2014

DATA AND ANALYSES

Comparison 1. Surgical versus conservative treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Complaints of symptoms (pain, restricted range of ankle motion, unsteadiness, swelling) and walking difficulties at 7 years	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 Complaints of significant symptoms	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 Pain	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 Restricted range of motion	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.4 Unsteadiness	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.5 Swelling	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.6 Passing stiffness	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.7 Walking difficulties on rough ground	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.8 Walking difficulties on even ground	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Functional or combined scores	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 Olerud scores at mean 27 months (0 to 100: best score)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Combined (clinical, anatomical + arthritis: 0 to 150: best) scores at mean 3.5 years	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Pain scores (VAS: assume maximum of 100: worst) at mean of 27 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4 Adverse events	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 Early treatment failure (usually secondary operation)	4	242	Risk Ratio (M-H, Fixed, 95% CI)	0.18 [0.06, 0.54]
4.2 Deep / more serious infection	3	172	Risk Ratio (M-H, Fixed, 95% CI)	0.23 [0.01, 4.61]
4.3 Superficial infection	3	172	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.21, 4.37]
4.4 Skin ulcer(s)	2	80	Risk Ratio (M-H, Fixed, 95% CI)	0.22 [0.03, 1.93]
4.5 Deep vein thrombosis	1	92	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.13, 4.34]
4.6 Complex regional pain syndrome	1	31	Risk Ratio (M-H, Fixed, 95% CI)	3.25 [0.17, 62.40]
4.7 Wound closure problem	1	31	Risk Ratio (M-H, Fixed, 95% CI)	1.95 [0.09, 44.32]
4.8 Removal of internal fixation	1	31	Risk Ratio (M-H, Fixed, 95% CI)	4.55 [0.26, 81.03]
4.9 Surgical scar tenderness	1	31	Risk Ratio (M-H, Fixed, 95% CI)	3.25 [0.17, 62.40]
5 Functional impairment at 20 weeks	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.1 Restricted dorsiflexion	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.2 Abnormal foot angle	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

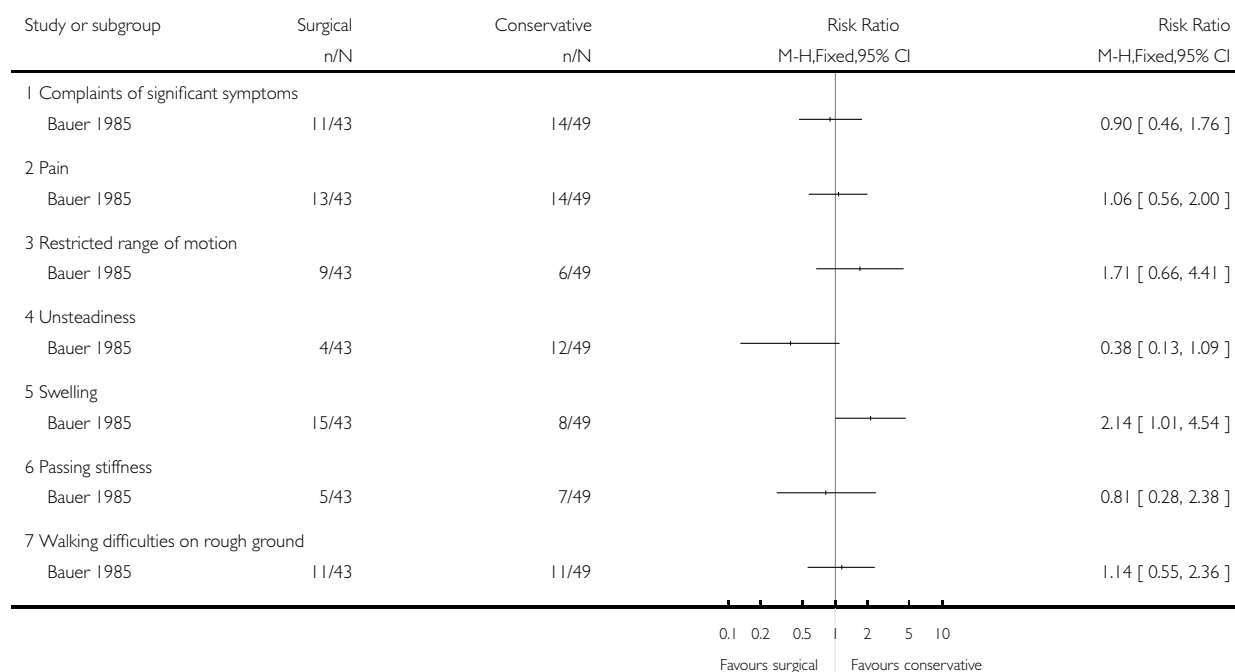
6 Differences in range of motion (injured ankle - other ankle)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
6.1 Dorso-plantar (degrees)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.2 Dorsiflexion (degrees)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.3 Pro-supination (degrees)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Radiological results: non-union and malunion	4		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
7.1 Non union	4		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.2 Malunion	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Radiological signs of osteoarthritis	2	141	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.83, 1.31]
8.1 Findings at mean of 7 years	1	92	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.84, 1.45]
8.2 Findings at mean of 3.5 years	1	49	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.64, 1.40]
9 Length of hospital stay (days)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

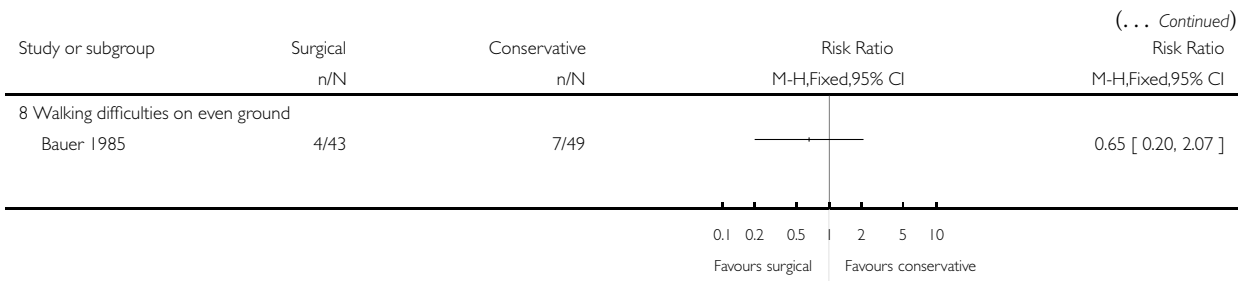
Analysis 1.1. Comparison 1 Surgical versus conservative treatment, Outcome 1 Complaints of symptoms (pain, restricted range of ankle motion, unsteadiness, swelling) and walking difficulties at 7 years.

Review: Surgical versus conservative interventions for treating ankle fractures in adults

Comparison: 1 Surgical versus conservative treatment

Outcome: 1 Complaints of symptoms (pain, restricted range of ankle motion, unsteadiness, swelling) and walking difficulties at 7 years



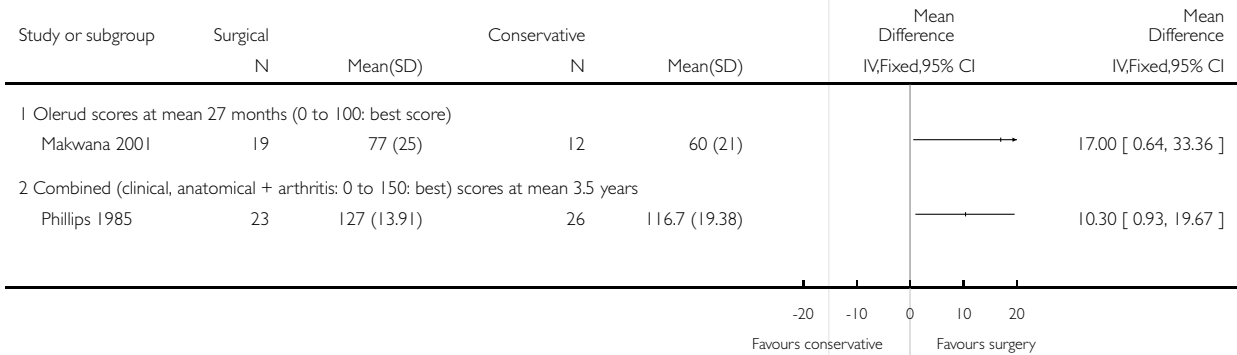


Analysis 1.2. Comparison 1 Surgical versus conservative treatment, Outcome 2 Functional or combined scores.

Review: Surgical versus conservative interventions for treating ankle fractures in adults

Comparison: 1 Surgical versus conservative treatment

Outcome: 2 Functional or combined scores

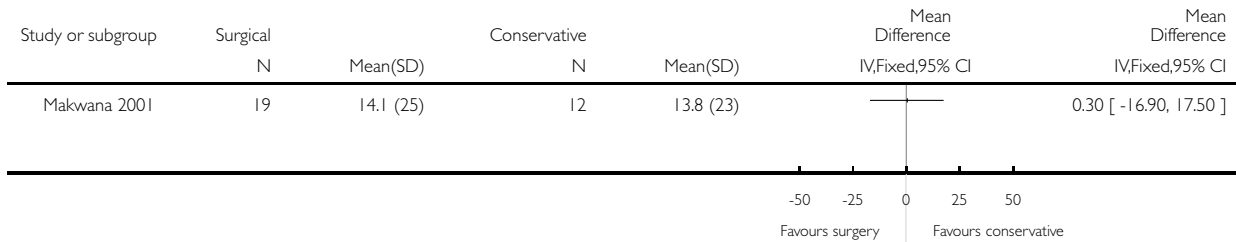


Analysis I.3. Comparison I Surgical versus conservative treatment, Outcome 3 Pain scores (VAS: assume maximum of 100: worst) at mean of 27 months.

Review: Surgical versus conservative interventions for treating ankle fractures in adults

Comparison: I Surgical versus conservative treatment

Outcome: 3 Pain scores (VAS: assume maximum of 100: worst) at mean of 27 months

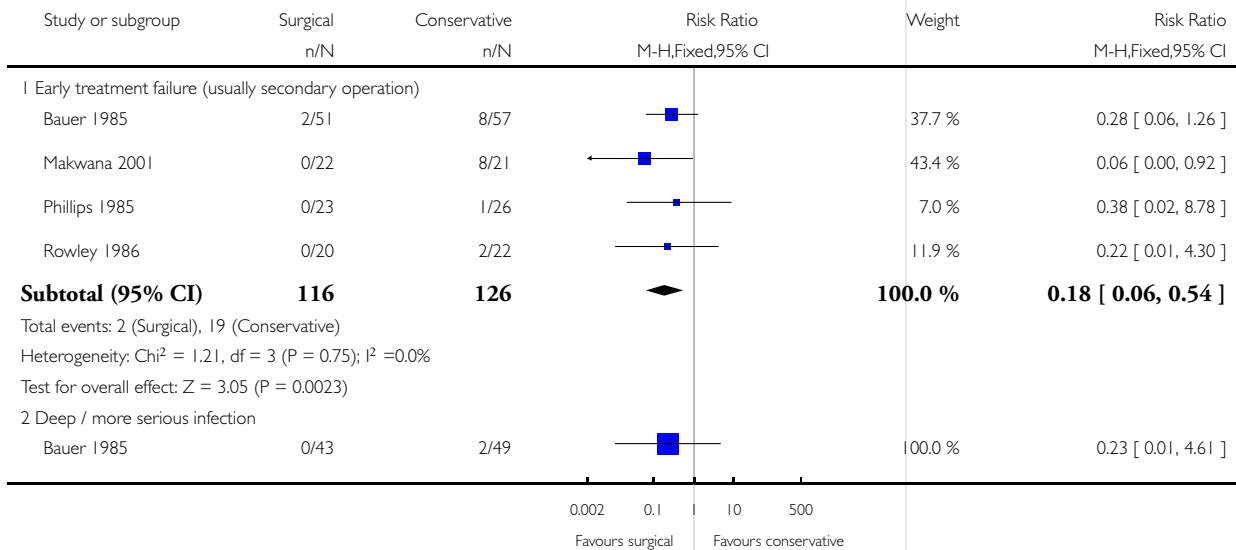


Analysis I.4. Comparison I Surgical versus conservative treatment, Outcome 4 Adverse events.

Review: Surgical versus conservative interventions for treating ankle fractures in adults

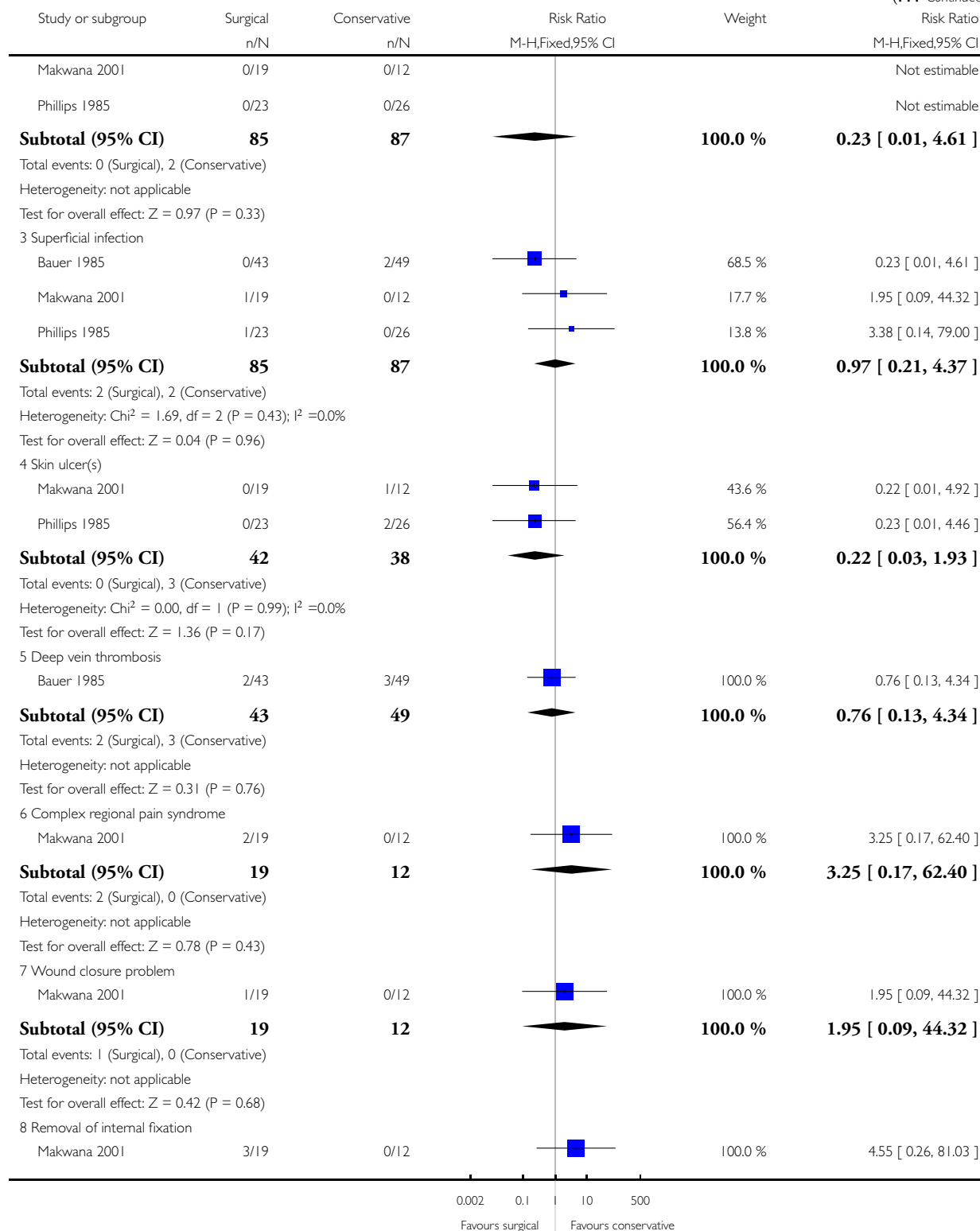
Comparison: I Surgical versus conservative treatment

Outcome: 4 Adverse events



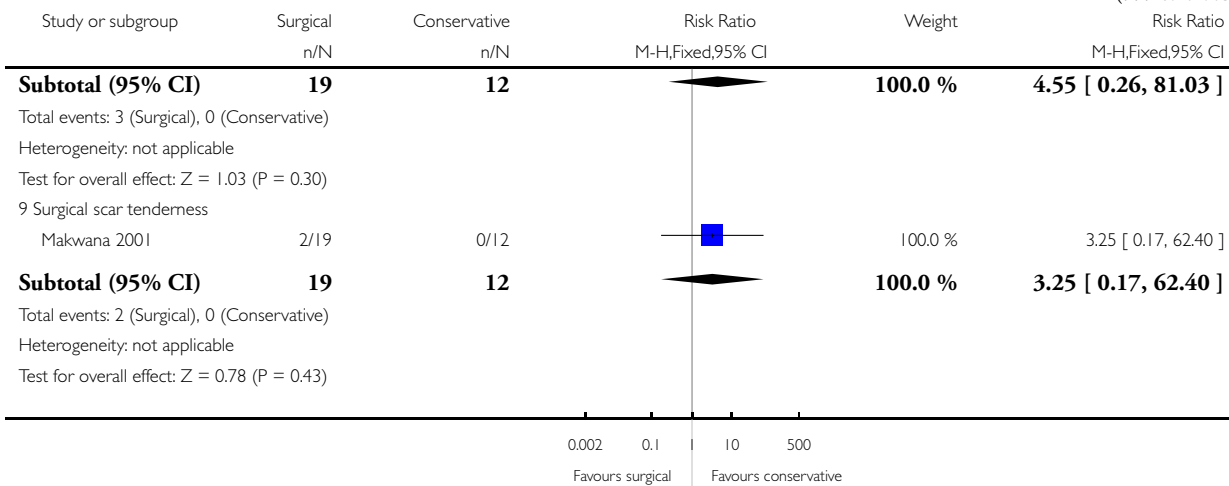
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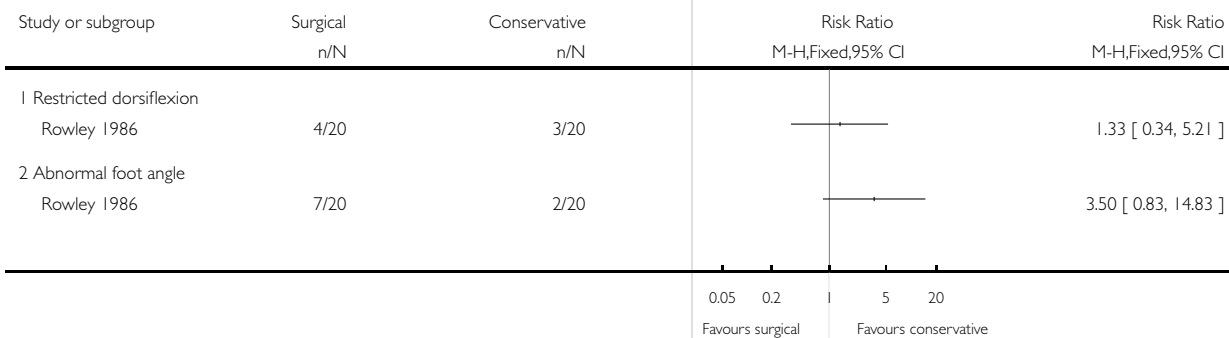


Analysis 1.5. Comparison 1 Surgical versus conservative treatment, Outcome 5 Functional impairment at 20 weeks.

Review: Surgical versus conservative interventions for treating ankle fractures in adults

Comparison: 1 Surgical versus conservative treatment

Outcome: 5 Functional impairment at 20 weeks

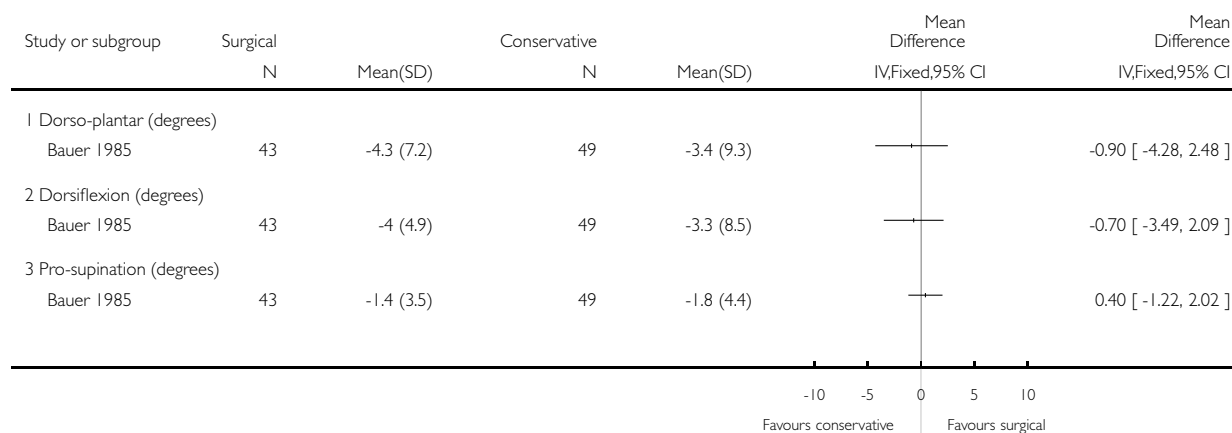


Analysis 1.6. Comparison 1 Surgical versus conservative treatment, Outcome 6 Differences in range of motion (injured ankle - other ankle).

Review: Surgical versus conservative interventions for treating ankle fractures in adults

Comparison: 1 Surgical versus conservative treatment

Outcome: 6 Differences in range of motion (injured ankle - other ankle)

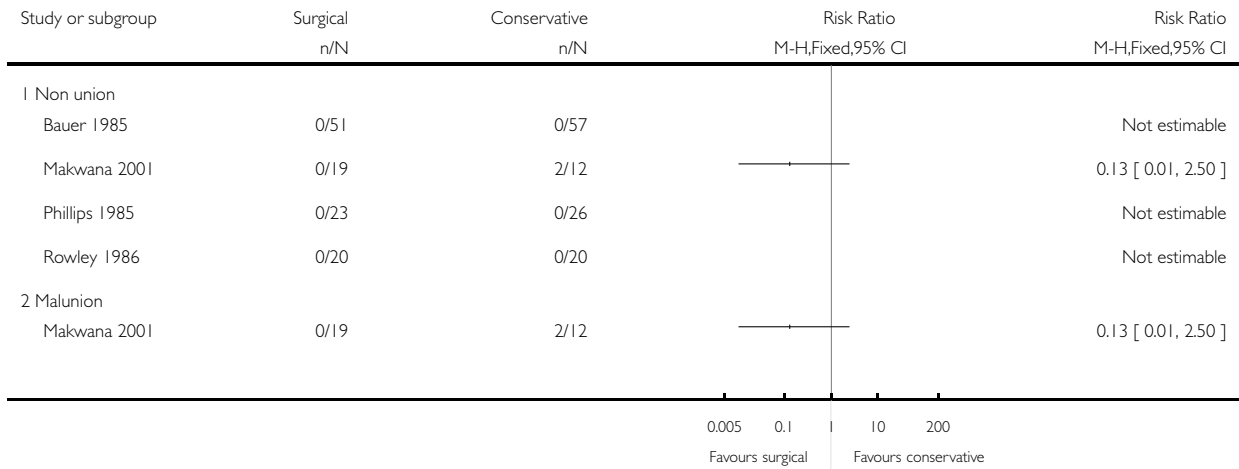


Analysis 1.7. Comparison 1 Surgical versus conservative treatment, Outcome 7 Radiological results: non-union and malunion.

Review: Surgical versus conservative interventions for treating ankle fractures in adults

Comparison: 1 Surgical versus conservative treatment

Outcome: 7 Radiological results: non-union and malunion

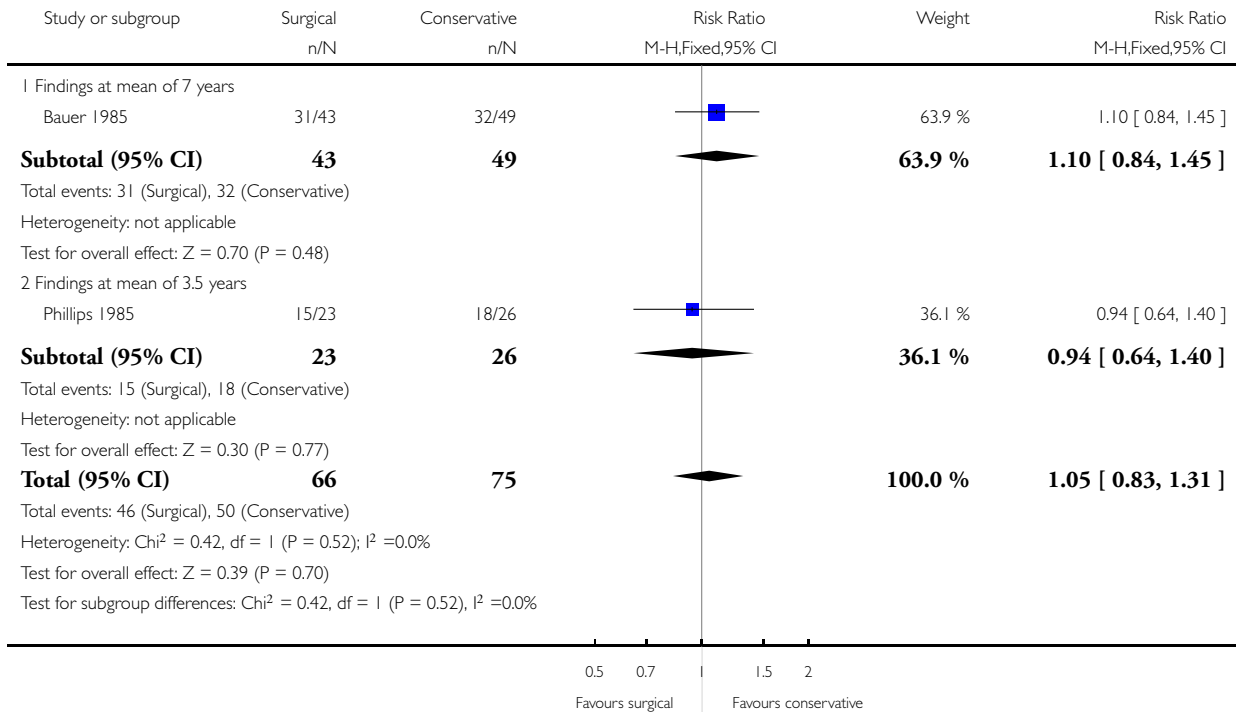


Analysis 1.8. Comparison 1 Surgical versus conservative treatment, Outcome 8 Radiological signs of osteoarthritis.

Review: Surgical versus conservative interventions for treating ankle fractures in adults

Comparison: 1 Surgical versus conservative treatment

Outcome: 8 Radiological signs of osteoarthritis



Analysis 1.9. Comparison 1 Surgical versus conservative treatment, Outcome 9 Length of hospital stay (days).

Review: Surgical versus conservative interventions for treating ankle fractures in adults

Comparison: 1 Surgical versus conservative treatment

Outcome: 9 Length of hospital stay (days)

Study or subgroup	Surgical		Conservative		Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
	N	Mean(SD)	N	Mean(SD)		
Makwana 2001	22	6.7 (3.2)	21	2.6 (1.5)		4.10 [2.62, 5.58]

APPENDICES

Appendix I. Search strategies

MEDLINE (PubMed)

#1: Ankle Injuries[MeSH] OR Ankle[MeSH] OR Ankle Joint[MeSH]

#2: Fractures, Bone[MeSH] OR Fracture Healing[MeSH] OR Fracture Fixation[MeSH]

#3: #1 AND #2

#4: (Fracture*[TW] AND (ankle[TW] OR malleol*[TW] OR unimalleo*[TW] OR bimalleo*[TW] OR trimalleo*[TW] OR potts[TW] OR weber[TW] OR (distal[TW] AND (tibia*[TW] OR fibula*[TW])))

#5: #3 OR #4

#6: Randomized Controlled Trial[PT]

#7: Controlled Clinical Trial[PT]

#8: randomized[TIAB]

#9: placebo[TIAB]

#10: Clinical Trials as Topic[MeSH: noexp]

#11: randomly[TIAB]

#12: trial[TI]

#13: #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12

#14: Animals[MeSH] NOT Humans[MeSH]

#15: #13 NOT #14

#16: #5 AND #15

The Cochrane Library (Wiley Online Library)

- #1: MeSH descriptor Ankle explode all trees
- #2: MeSH descriptor Ankle Injuries explode all trees
- #3: MeSH descriptor Ankle Joint explode all trees
- #4: (#1 OR #2 OR #3)
- #5: MeSH descriptor Fractures, Bone explode all trees
- #6: MeSH descriptor Fracture Healing explode all trees
- #7: MeSH descriptor Fracture Fixation explode all trees
- #8: (#5 OR #6 OR #7)
- #9: (#4 AND #8)
- #10: (fracture* NEAR/5 (ankle OR malleol* OR unimalleo* OR bimalleo* OR trimalleo* OR potts OR weber OR (distal AND (tibia* OR fibula*))))).ti,ab,kw
- #11: (#9 OR #10)

EMBASE

1. Elsevier (1974 to June 2010)

- #1 (('ankle'/exp OR 'ankle fracture'/exp OR 'ankle injury'/exp OR 'ankle dislocation'/exp) AND ('fracture'/exp OR 'fracture healing'/exp OR 'fracture fixation'/exp OR 'joint injury'/exp OR 'bone injury'/exp)) OR ((fracture* AND (ankle* OR malleol* OR unimalleo* OR bimalleo* OR trimalleo* OR potts OR weber OR (distal AND (tibia* OR fibula*)))) AND [<1950-2009]/py)
- #2 (('crossover procedure'/exp OR 'double blind procedure'/exp OR 'randomized controlled trial'/exp OR 'clinical trial'/exp OR 'single blind procedure'/exp OR 'placebo'/exp) OR (random* OR factorial* OR crossover* OR 'cross over' OR placebo* OR 'double blind' OR 'single blind' OR assign* OR allocate* OR volunteer*)) AND [<1950-2009]/py)) AND ('human'/exp)
- #3 #1 AND #2

2. Ovid (January 2010 to February 2012)

- 1 exp Ankle Dislocation/ or exp Ankle Injury/ or exp Ankle/ or exp Ankle Fracture/
- 2 exp Fracture Healing/ or exp Fracture/ or exp Fracture Fixation/ or exp Joint Injury/ or exp Bone Injury/
- 3 1 and 2
- 4 (ankle* or malleol* or unimalleo* or bimalleo* or potts or weber or (distal and (tibia* or fibula*))).tw.
- 5 fracture*.tw.
- 6 4 and 5
- 7 3 or 6
- 8 Randomized Controlled Trial/
- 9 Clinical Trial/
- 10 Controlled Clinical Trial/
- 11 Randomization/
- 12 Single Blind Procedure/
- 13 Double Blind Procedure/
- 14 Crossover Procedure/
- 15 Placebo/
- 16 Prospective Study/
- 17 ((clinical or controlled or comparative or placebo or prospective\$ or randomi#ed) adj3 (trial or study)).tw.
- 18 (random\$ adj7 (allot\$ or allot\$ or assign\$ or basis\$ or divid\$ or order\$)).tw.
- 19 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj7 (blind\$ or mask\$)).tw.
- 20 (cross?over\$ or (cross adj1 over\$)).tw.
- 21 ((allot\$ or allot\$ or assign\$ or divid\$) adj3 (condition\$ or experiment\$ or intervention\$ or treatment\$ or therap\$ or control\$ or group\$)).tw.
- 22 RCT.tw.
- 23 or/8-22

- 24 Case Study/ or Abstract Report/ or Letter/
 25 23 not 24
 26 7 and 25
 27 (2010\$ or 2011\$ or 2012\$).em.
 28 26 and 27
 29 limit 28 to human

CINAHL (EBSCO)

- S1: (MH "Fracture Healing") OR (MH "Fracture Fixation") OR (MH "Ankle Fractures") OR (MH "Fibula Fractures")
 S2: (MM "Ankle") OR (MH "Ankle Injuries") OR (MH "Ankle Joint")
 S3: S1 AND S2
 S4: (fracture* AND (ankle* OR malleol* OR unimalleo* OR bimalleo* OR trimalleo* OR potts OR weber OR (distal AND (tibia* OR fibula*))))
 S5: S3 OR S4
 S6: (MH "Clinical Trials")
 S7: (MH "Evaluation Research")
 S8: (MH "Comparative Studies")
 S9: (MH "Crossover Design")
 S10: PT clinical trial
 S11: S6 OR S7 OR S8 OR S9 OR S10
 S12: TX ((clinical OR controlled OR comparative OR placebo OR prospective OR randomi*ed) AND (trial OR study))
 S13: TX (random* AND (allocate* OR allot* OR assign* OR basis* OR divid* OR order*))
 S14: TX ((singl* OR doubl* OR trebl* OR tripl*) AND (blind* OR mask*))
 S15: TX (cross*over* OR (cross AND over*))
 S16: TX ((allocat* OR allot* OR assign* OR divid*) AND (condition* OR experiment* OR intervention* OR treatment* OR therap* OR control* OR group*))
 S17: S12 OR S13 OR S14 OR S15 OR S16
 S18: S11 OR S17
 S19: S5 AND S18

HISTORY

Protocol first published: Issue 4, 2010

Review first published: Issue 8, 2012

CONTRIBUTIONS OF AUTHORS

CD produced the first drafts of the protocol, search strategy and review. HA assisted with the search strategy. CL provided statistical feedback. All authors contributed to subsequent drafts of the protocol and review and approved the final versions. CD is the guarantor of the review.

DECLARATIONS OF INTEREST

None known.

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Internal sources

- Luton and Dunstable NHS Trust, London, UK.
Salary for healthcare activities and training medical students and residents
- St. Elisabeth Hospital, Tilburg, Netherlands.
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- St. Radboud University Medical Centre, Nijmegen, Netherlands.
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External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

Ankle Injuries [surgery; *therapy]; Fracture Fixation [methods]; Fractures, Bone [surgery; *therapy]; Randomized Controlled Trials as Topic; Treatment Outcome

MeSH check words

Adult; Female; Humans; Male