

# Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults (Review)

Kerkhoffs GMMJ, Handoll HHG, de Bie R, Rowe BH, Struijs PAA



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Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults (Review)  
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[Intervention Review]

# Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Gino MMJ Kerkhoffs<sup>1</sup>, Helen HG Handoll<sup>2</sup>, Rob de Bie<sup>3</sup>, Brian H Rowe<sup>4</sup>, Peter AA Struijs<sup>5</sup>

<sup>1</sup>Department of Orthopaedic Surgery, Orthopaedic Research Center Amsterdam, Amsterdam, Netherlands. <sup>2</sup>Centre for Rehabilitation Sciences (CRS), Research Institute for Health Sciences and Social Care, University of Teesside, Middlesborough, UK. <sup>3</sup>Department of Epidemiology, Maastricht University, Maastricht, Netherlands. <sup>4</sup>Department of Emergency Medicine, University of Alberta, Edmonton, Canada. <sup>5</sup>Department of Orthopaedic Surgery, Academic Medical Center, Amsterdam, Netherlands

Contact address: Gino MMJ Kerkhoffs, Department of Orthopaedic Surgery, Orthopaedic Research Center Amsterdam, Academic Medical Centre, Meibergdreef 9, Amsterdam, 1105 AZ, Netherlands. [g.m.kerkhoffs@amc.uva.nl](mailto:g.m.kerkhoffs@amc.uva.nl). [gino.kerkhoffs@kssg.ch](mailto:gino.kerkhoffs@kssg.ch).

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## ABSTRACT

### Background

Ankle sprains are one of the most commonly treated musculoskeletal injuries. The three main treatment modalities for acute lateral ankle ligament injuries are immobilisation with plaster cast or splint, 'functional treatment' comprising early mobilisation and use of an external support (e.g. ankle brace), and surgical repair or reconstruction.

### Objectives

We aimed to compare surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults.

### Search methods

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (January 2006), the Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2005, Issue 4), MEDLINE (1966 to December 2005), EMBASE, CINAHL and reference lists of articles, and contacted researchers in the field. This review is considered updated to January 2006.

### Selection criteria

Randomised or quasi-randomised controlled trials comparing surgical with conservative interventions for treating ankle sprains in adults.

### Data collection and analysis

At least two authors independently assessed methodological quality and extracted data. Where appropriate, results of comparable studies were pooled. We performed sensitivity analyses to explore the robustness of the findings.

## Main results

Twenty trials were included. These involved a total of 2562 mostly young active adult males. All trials had methodological weaknesses. Specifically, concealment of allocation was confirmed in only one trial. Data for pooling individual outcomes were only available for a maximum of 12 trials and under 60% of participants.

The findings of statistically significant differences in favour of the surgical treatment group for the four primary outcomes (non-return to pre-injury level of sports; ankle sprain recurrence; long-term pain; subjective or functional instability) when using the fixed-effect model were not robust when using the random-effects model, nor on the removal of one low quality (quasi-randomised) trial that had more extreme results. A corresponding drop in the  $I^2$  statistics showed the remaining trials to be more homogeneous.

The functional implications of the statistically significantly higher incidence of objective instability in conservatively treated trial participants are uncertain. There was some limited evidence for longer recovery times, and higher incidences of ankle stiffness, impaired ankle mobility and complications in the surgical treatment group.

## Authors' conclusions

There is insufficient evidence available from randomised controlled trials to determine the relative effectiveness of surgical and conservative treatment for acute injuries of the lateral ligament complex of the ankle. High quality randomised controlled trials of primary surgical repair versus the best available conservative treatment for well-defined injuries are required.

## PLAIN LANGUAGE SUMMARY

### Surgery versus conservative treatment for acute ankle sprains in adults

Ankle sprain is one of the commonest musculoskeletal injuries in active people. It generally involves damage to the lateral or outer ligaments, which connect bones together on the outside of the ankle joint. Treatment is usually either immobilisation of the leg in a plaster cast, or 'functional treatment' where the ankle is kept in use while protected by an external support. After treatment, however, some people still have a weak and sometimes painful ankle. This review aimed to find out if primary surgical repair of the torn ligament(s) gives a better result than either of these two non-surgical or conservative treatments.

Twenty trials were included. These involved a total of 2562 mostly young active adult males. All trials had methodological flaws that could have affected their results. Data for pooling individual outcomes were only available for a maximum of 12 trials. Additionally, there was one low quality and potentially biased trial with very positive results in favour of surgery. When this trial was excluded, the findings of better results for surgery in terms of return to sports, re-injury, persistent pain and ankle instability as judged by the patient were no longer statistically significant. Thus, the trend to a better result from surgery remains unproven. Ankle stability, as judged by the clinician using standard tests, was better after surgery than with conservative treatment. Conversely, there was some limited evidence for longer recovery times, and higher incidences of ankle stiffness, impaired ankle mobility and complications in the surgical treatment group.

We concluded that there was not enough evidence from randomised controlled trials to say whether surgery gives a better result than conservative treatment for acute ankle sprain in adults.

## BACKGROUND

Inversion injuries, primarily sprains, of the ankle are one of the most commonly treated musculoskeletal injuries. In the UK, approximately one person in every 10,000 is treated for an ankle injury each day (Kannus 1991). In people with a sedentary lifestyle such injuries may be less disruptive; however, in athletes and those

whose work is more demanding physically, such injuries may have an important life-long effect. Some sports (e.g. basketball, soccer and volleyball) have a very high incidence of ankle injuries. Overall, ankle sprains make up about 10% to 15% of sports-related injuries (MacAuley 1999).

The most common mechanism of injury is internal rotation (inversion) of the plantarflexed foot (toes on ground and heel up). Injury occurs to the anterior talo-fibular ligament first, followed to a varying degree by injury to the calcaneofibular ligament. The posterior talofibular ligament is usually uninjured unless there is a frank dislocation of the ankle. Together, these lateral ligaments, which connect bones together on the outside of the ankle joint, form the lateral ligament complex.

Traditionally, lateral ligament injuries are graded I to III. Grade I (mild) represents a stretch, II (moderate) represents a partial tear, and III (severe) represents a complete tear (Kannus 1991). Practically, this gradation may be considered as purely theoretical, because it has no therapeutic or prognostic consequences (De Bie 2002). Most injuries resolve; however, some people may suffer from chronic functional instability of the ankle joint. Persistent ligament laxity can present as both subjective (giving way) and objective instability (anterior drawer-talar tilt) and lead to chronic functional instability of the ankle joint. When the duration of functional instability of the ankle joint exceeds six months it is considered chronic and a ligament reconstruction may be considered (De Vries 2006).

The diagnosis of this injury is made following a delayed physical examination four to seven days after trauma (Klenerman 1998; Van Dijk 1996) and by exclusion of a fracture. The Ottawa Ankle Rule is a decision rule increasingly used to save unnecessary X-ray investigation (Stiell 1994). A variety of treatments for acute lateral ankle ligament injuries without fracture are used, with the three main modalities being:

- Immobilisation with plaster cast or splint;
- Functional treatment; this is an early mobilisation programme and involves the use of an external support;
- Operative treatment.

Kannus and Renstrom (Kannus 1991) in their narrative review of Grade III ankle injuries compared operation, cast, or early controlled mobilisation and identified 12 clinical trials in the English literature. In a comprehensive narrative review of treatment modalities for soft tissue injuries of the ankle (Ogilvie-Harris 1995), 58 RCTs were identified of which 18 compared pharmacological interventions, 12 surgical repair, 12 active mobilisation, three cryotherapy, five diathermy, and a further eight compared other modalities including three studies of ultrasound. A more recent systematic review (Pijnenburg 2000) summarised the results of 27 RCTs, comparing operation, cast, functional treatment and minimal treatment. The authors concluded that primary operative repair led to better results; however, they also questioned whether it should be the treatment of choice given the risk of surgical complications and increased costs. Pijnenburg 2000 based results on three outcomes: time lost from work, residual pain and giving-

way. Their assessment of trial quality was based on three criteria: the method of randomisation, assessor blinding and intention-to-treat analysis. The current review is restricted to trials which compare surgery with conservative interventions for acute ankle sprains, includes other clinically important outcomes and considers other aspects of trial methodology.

Three other Cochrane reviews on the treatment of ankle sprains are now available. Two (Kerkhoffs 2002a; Kerkhoffs 2002b) compare conservative interventions involving immobilisation and functional treatment strategies respectively, and one (Van der Windt 1999) evaluates the use of ultrasound.

## OBJECTIVES

The objective of this review is to examine the evidence from randomised and quasi-randomised controlled clinical trials comparing surgery versus conservative (non-operative) treatments for the management of acute injuries of the lateral ligament complex of the ankle. The main focus is on skeletally mature individuals up to middle age. The relative effects of the two treatments are considered primarily in terms of the return to pre-injury level of activity; re-injury or recurrence; persistent pain; and subjective instability.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomised or quasi-randomised (methods of allocating participants to a treatment which are not strictly random; e.g. date of birth, hospital record number or alternation) controlled trials comparing interventions, specified below, for the treatment of acute injuries to the lateral ligament complex of the ankle.

#### Types of participants

Adults with an acute injury of the lateral ligament complex of the ankle. Trials dealing exclusively with children (where growth plate injuries predominate) or participants with congenital deformities or degenerative conditions were excluded. Studies involving a mixed population of adults and children were eligible provided the proportion of children was clearly small (< 10%).

Trials focusing on the treatment of chronic instability or post-surgical treatment were excluded. Patients with chronic instability have symptoms of pain, swelling, recurrent sprains and instability for longer than six months (Karlsson 1997). If studies included participants with chronic ankle sprains or other ankle injuries such

as fractures, then results from these studies were included in the review provided such injuries were under 10% of the entire study population.

### Types of interventions

Surgical intervention could be either ligament repair or reconstruction followed by conservative modalities. The main conservative modalities involved either immobilisation, such as in a plaster cast, or functional treatment involving mobilisation and use of external ankle supports such as functional braces. Only trials comparing surgical with conservative treatment were included.

### Types of outcome measures

A variety of outcomes were collected.

#### Primary outcomes

The primary outcome measures were:

- return to pre-injury level of activity (sports or work);
- re-injury or recurrence;
- persistent pain (long-term);
- subjective instability (e.g. 'giving way').

#### Secondary outcomes

Secondary outcomes were:

- objective instability (e.g. talar tilt, anterior drawer measures);
- swelling;
- stiffness;
- ankle mobility (range of motion);
- muscle atrophy;
- complications (e.g. sensory deficit, infection, allergic reaction, skin problems, osteoarthritis);
- satisfaction.

In addition, note was taken of reports of service utilisation or resource use, for instance length of hospital stay and outpatient attendance.

### Search methods for identification of studies

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (to January 2006), the Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2005, Issue 4), MEDLINE (1966 to December 2005), EMBASE (1980 to January 2006), CINAHL (1982 to December 2005), CURRENT CONTENTS (1993 to 1999), BIOSIS (to 1999) and reference lists of articles. We also contacted researchers in the field.

The search strategy for *The Cochrane Library* (2005, Issue 4) is shown in [Appendix 1](#). The current and previous MEDLINE strategies are shown in [Appendix 2](#). The revised subject specific search for the current MEDLINE search strategy was combined with all three levels of the highly sensitive search strategy for randomised controlled trials ([Higgins 2005](#)); only the first two levels were used in the previous search (1966 to May 2000). [Appendix 3](#) displays the current search strategies for CINAHL and EMBASE.

No language restriction was applied and translations to English were obtained where necessary. This review is considered updated to January 2006.

### Data collection and analysis

#### Selecting trials for inclusion

At least two authors independently assessed all identified trials for inclusion using the above criteria. Disagreement was resolved by discussion, with arbitration by a third author where differences remained.

#### Assessment of methodological quality

At least two authors independently assessed methodological quality via a piloted, subject-specific modification of the generic evaluation tool used by the Cochrane Bone, Joint and Muscle Trauma Group. Titles of journals, names of authors or supporting institutions were not masked at any stage ([Verhagen 1998](#)). The 11 aspects of internal validity and external validity assessed are shown in [Table 1](#). From the first update of the review, the scores of individual items were no longer summed. Disagreement was resolved by discussion, followed if necessary by scrutiny from another author. Studies were also ranked by quality of allocation concealment (Cochrane score A, B or C).

#### Data collection

At least two authors independently extracted data using a piloted data extraction form. Disagreement was resolved as above. If necessary, we contacted trialists in order to complete the data extraction form and for further information on methodology.

#### Data synthesis

For each study, relative risks (RRs) and 95% confidence intervals (CIs) were calculated for dichotomous outcomes, and mean differences and 95% CIs for continuous outcomes. Where possible, the results of comparable groups of trials were pooled using both the fixed-effect and random-effects models. Heterogeneity between comparable trials was tested using the  $\chi^2$  and  $I^2$  tests ([Higgins 2003](#)). Sensitivity analyses were conducted to assess the effects of excluding the results of one outlier trial and trials where allocation was clearly not concealed. To test whether subgroups, split by the type of treatment (functional versus plaster cast) in the conservative treatment group, were statistically significantly different from one another, we tested the interaction using the technique described by [Altman 2003](#).

## RESULTS

### Description of studies

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

Updating the search from December 2001 to January 2006 resulted in the identification of three potentially relevant additional studies, all of which were included ([Kolind-Sorensen 1975](#); [Pijnenburg 2003](#); [Specchiulli 2001](#)). Of the four trials previously awaiting assessment, three were excluded ([Knop 1999](#); [Otto 1997](#); [Zoltan 1977](#)). A report and thesis in German remains in 'Studies awaiting assessment' due to delays in securing and translating the manuscript ([Grasmueck 1997](#)). Finally, several abstracts and reports were also located for already included trials.

Of 32 potentially eligible studies, 20 were included in this review. Of the remainder, 11 are excluded for reasons given in the 'Characteristics of excluded studies' table and one is in 'Studies awaiting assessment' pending the review selection procedure. Most of the 20 included studies were fully reported in medical journals. The report of one trial ([Delfosse 1994](#)) is only available as an abstract. The trials were initially identified in the following ways: Cochrane Bone, Joint and Muscle Trauma Group (2 trials); MEDLINE (7); bibliography checking (7 trials); and handsearching (4).

The publication dates of the trials span 38 years; [Clark 1965](#) and [Freeman 1965](#) being the earliest. The trials were conducted in one of the following 10 countries: Austria (1 trial), Belgium (1), Canada (1), Denmark (4), Finland (2), Germany (4), Italy (1), Netherlands (3), Norway (1), and the UK (2). Translations were obtained for two trials in Danish ([Kolind-Sorensen 1975](#); [Petersen 1985](#)), one in Finnish ([Hietaniemi 1997](#)) and two in German ([Eggert 1986](#); [Klein 1988](#)); a translation of one of three reports in German of [Zwipp 1986](#) was also obtained.

The 20 included studies involved a total of 2562 mostly young active adult males. Where data were provided, the percentage of males ranged from 55% to 100%. Where provided, median or mean ages of trial populations ranged between 23 and 27 years. The youngest recorded participant was nine years old in [Zwipp 1986](#) and the oldest was 55 years in [Povacz 1998](#). Lower age limits were set by nine trials ([Delfosse 1994](#): 16 years; [Eggert 1986](#): 12 years; [Evans 1984](#): 16 years; [Hietaniemi 1997](#): 18 years; [Klein 1988](#): 16 years; [Korkala 1987](#): 15 years; [Niedermann 1981](#): 12 years; [Petersen 1985](#): 15 years; [Pijnenburg 2003](#): 18 years). However, the youngest participant in [Pijnenburg 2003](#) was 17 years. Though not easily quantifiable, only a small proportion of children were included in any trial; three trials specified that the epiphysis should be closed ([Niedermann 1981](#); [Povacz 1998](#); [Specchiulli 2001](#)). Upper age limits were set by 11 trials ([Delfosse 1994](#): 35 years; [Evans 1984](#): 35 years; [Hietaniemi 1997](#): 30 years; [Klein 1988](#): 40 years; [Korkala 1987](#): 50 years; [Moller-Larsen 1988](#): 50 years; [Niedermann 1981](#): 50 years; [Petersen 1985](#): 50 years;

[Pijnenburg 2003](#): 45 years; [Povacz 1998](#): 40 years; [Specchiulli 2001](#): 40 years).

Injuries were generally reported to be acute or recent; some trials provided more tightly defined inclusion criteria ([Hietaniemi 1997](#) and [Pijnenburg 2003](#): within 2 days; [Klein 1988](#), [Povacz 1998](#) and [Specchiulli 2001](#): within 24 hours). Diagnostic confirmation, using arthrography, stress radiographs and other objective measures of ligament rupture, was indicated in all but one study ([Clark 1965](#)); however, it is likely they were used in this trial as well.

Fourteen trials, with two treatment groups, compared surgical with conservative treatment: [Clark 1965](#); [Delfosse 1994](#); [Evans 1984](#); [Gronmark 1980](#); [Hietaniemi 1997](#); [Kolind-Sorensen 1975](#); [Klein 1988](#); [Niedermann 1981](#); [Petersen 1985](#); [Pijnenburg 2003](#); [Povacz 1998](#); [Prins 1978](#); [Sommer 1987](#); and [Specchiulli 2001](#). Five trials compared three treatments. In four of these trials ([Freeman 1965](#); [Korkala 1987](#); [Moller-Larsen 1988](#); [Van Moppes 1982](#)) there was one surgical group, and in the other trial ([Eggert 1986](#)) there were two treatment groups involving surgery. There were two surgical treatment groups and two conservative treatment groups in the remaining trial ([Zwipp 1986](#)).

Where detailed, operative treatment involved surgical repair where the ruptured ends of the ligament were sutured together. No anatomic reconstruction was performed. Treatment following surgery was either identical or essentially the same as that provided to conservatively treated participants in one or more comparisons in 16 trials. Exceptions were four trials ([Hietaniemi 1997](#); [Povacz 1998](#); [Sommer 1987](#); [Specchiulli 2001](#)) where surgery was followed by cast immobilisation while conservatively treated participants were given functional treatment. Conservative treatment was not defined in one trial ([Clark 1965](#)), in which it was assumed to involve immobilisation for a similar length of time to the surgical treatment group.

Secondary to the overall surgery versus conservative treatment comparison are the following four comparisons based on the conservative treatment interventions applied to surgical and non-surgical groups:

**(1) Surgery + cast immobilisation versus cast immobilisation**  
This comparison was examined in 14 trials ([Clark 1965](#); [Delfosse 1994](#); [Evans 1984](#); [Freeman 1965](#); [Gronmark 1980](#); [Klein 1988](#); [Kolind-Sorensen 1975](#); [Korkala 1987](#); [Moller-Larsen 1988](#); [Niedermann 1981](#); [Petersen 1985](#); [Prins 1978](#); [Van Moppes 1982](#); [Zwipp 1986](#)).

**(2) Surgery + cast immobilisation versus functional treatment**  
This comparison was examined in 12 trials ([Eggert 1986](#); [Freeman 1965](#); [Hietaniemi 1997](#); [Korkala 1987](#); [Moller-Larsen 1988](#); [Niedermann 1981](#); [Petersen 1985](#); [Prins 1978](#); [Sommer 1987](#); [Specchiulli 2001](#); [Van Moppes 1982](#); [Zwipp 1986](#)).

**(3) Surgery + functional treatment versus functional treatment**  
This comparison was examined in three trials ([Eggert 1986](#); [Pijnenburg 2003](#); [Zwipp 1986](#)).

**(4) Surgery + functional treatment versus cast immobilisation**



This comparison was examined in only one trial (Zwipp 1986). Further details of the individual trials are presented in the 'Characteristics of included studies' table.

### Risk of bias in included studies

All trials had methodological weaknesses as shown by the low scores for many of the individual items of methodological quality; see table below. In particular, concealment of allocation (item A) was confirmed in only one trial (Povacz 1998). Thirteen trials provided inadequate or no details of their method of randomisation; we were unable to judge whether allocation was concealed for these. Allocation was not concealed in six trials (Eggert 1986; Kolind-Sorensen 1975; Pijnenburg 2003; Prins 1978; Specchiulli 2001; Zwipp 1986). However, while allocation was not concealed, participants of Specchiulli 2001 were not informed of the "treatment model" (i.e. study) prior to their treatment. Intention-to-treat analysis (item B) was hard to confirm. Most trials failed to achieve the top score (2 points) for this item, for reasons such as post-randomisation exclusions, failure to provide the numbers entered into the trial based on treatment allocation, and lack of account of losses. Blinding of patients and care providers (items E and F) is unlikely in these comparisons and none was claimed. Blinding of outcome assessors (item C) should be possible in some circumstances; however, this was not reported in these trials with the exception of blinded assessment of radiographs for long-term degenerative changes in Pijnenburg 2003. Independent assessment was reported in three trials (Evans 1984; Povacz 1998; Zwipp 1986) but this is not rated in our methodological quality scoring system.

Baseline characteristics and their comparability (item D) were usually inadequately detailed; the failure to provide characteristics for all patients entered into the trial rather than those in the analyses was a common reason for a lower score. Most trials did not provide sufficient information to confirm the comparability of care programmes (item G). Some details of the intended trial populations (item H) were given in all trials except Clark 1965 and Kolind-Sorensen 1975. Whilst the outcome measures used were generally well defined (item I), outcome measurement (item J) was usually rated lower. For instance, follow ups were not always conducted at regular follow-up times (e.g. Gronmark 1980). Results at one year and above for all patients were reported in 13 trials (item K).

### Table of the results of the quality assessment (see Table 1 for description of items A to K)

A	B	C	D	E	F	G	H	I	J	K	Trial ID
1	2	0	0	0	0	0	0	2	1	0	Clark 1965
1	0	0	1	0	0	1	1	2	1	1	Delfosse 1994
0	0	0	1	0	0	0	2	2	1	1	Eggert 1986
1	0	0	2	0	1	2	2	1	2		Evans 1984
1	1	0	1	0	0	2	2	1	2		Freeman 1965
1	2	0	0	0	2	1	2	0	1		Gronmark 1980

1	1	0	1	0	0	0	2	2	0	2	Hietaniemi 1997
1	0	0	1	0	0	1	2	2	2	1	Klein 1988
0	0	0	0	0	0	0	1	1	0		Kolind-Sorensen 1975
1	1	0	0	0	1	2	2	1	2		Korkala 1987
1	0	0	0	0	1	2	2	1	2		Moller-Larsen 1988
1	0	0	0	0	0	2	2	1	2		Niedermann 1981
1	0	0	0	0	1	2	2	1	2		Petersen 1985
0	0	0	0	0	1	2	2	2	2		Pijnenburg 2003
2	1	0	1	0	0	1	2	2	2	2	Povacz 1998
0	1	0	0	0	0	2	2	2	1		Prins 1978
1	0	0	0	0	1	2	1	1	2		Sommer 1987
0	2	0	2	0	0	2	2	0	2		Specchiulli 2001
1	0	0	0	0	1	1	2	2	2		Van Moppes 1982
0	0	0	1	0	0	1	2	1	2		Zwipp 1986

### Effects of interventions

The primary comparison in this review is of any surgical intervention versus any conservative intervention. Secondary analyses comprising analyses subgrouped by the type of conservative intervention, either cast immobilisation or functional treatment, for primary outcome measures and two secondary outcomes are presented. Insufficient data precluded further subgroup analyses by intervention type, such as surgery followed by functional treatment versus either functional treatment alone or cast immobilisation alone. Some sensitivity analyses are also presented to explore the effects of excluding the results of trials, including quasi-randomised trials, where allocation was not concealed (Eggert 1986; Kolind-Sorensen 1975; Pijnenburg 2003; Prins 1978; Specchiulli 2001; Zwipp 1986) and of variations in the definitions of outcome measures. In the first version of the review, we realised that the results of Prins 1978 were more extreme and often differed from the other trials. Coincidentally, it was the only trial whose quasi-randomised method of treatment allocation had been confirmed. While all three of the newly included trials are quasi-randomised, we have continued to examine the effect of the exclusion of Prins 1978 from the analyses where its results still appear to be at variance to the other trials.

Unless specified otherwise, fixed-effect analyses are presented in the following.

### Surgical versus conservative treatment

#### Primary outcomes

The variety of measures used to show longer-term recovery to pre-injury activity levels in the included trials are displayed in the analyses (see Analysis 01.01). Pooled data failed to demonstrate a statistically significant return in surgically treated patients (non-return: RR 0.85, 95% CI 0.65 to 1.11); however, these results were highly heterogeneous ( $I^2 = 65.6\%$ ) and dominated (see "Weight %" column in figure) by one quasi-randomised study (Prins 1978). Excluding the results from Prins 1978 considerably reduces the statistical heterogeneity ( $I^2 = 15.3\%$ ) as well as reversing the direc-

tion of the effect (non-return: RR 1.10, 95% CI 0.81 to 1.49; *see* Analysis 01.02). Pooled data from five trials (*see* Analysis 01.01) showed that significantly more surgically treated people returned to their pre-injury sports level (non-return: RR 0.57, 95% CI 0.39 to 0.83). Again this analysis was strongly influenced by the results from Prins 1978; the removal of this trial results in a non-significant result (RR 0.79, 95% CI 0.49 to 1.27; *see* Analysis 01.02). Analysis 01.03 shows non-return to pre-injury sports level split by definition, either non-return to any sports or reduction of sports activity, with and without Prins 1978. This again demonstrates the effect of inclusion of the data from Prins 1978; reduction in sports activity was defined in terms of sports involving running for this trial.

The majority of the 15 trials reporting on the time to resumption of normal activities (usually defined as work), reported a longer time of return for surgically treated patients; only Prins 1978 reported a shorter time. There were no data available for pooling for this outcome.

There was a statistically significant difference decrease in the numbers of people with recurrent ankle sprain in the surgical group compared with the conservative treatment group (recurrence: RR 0.80, 95% CI 0.65 to 0.98; *see* Analysis 01.04). The result is no longer statistically significant (RR 0.85, 95% CI 0.69 to 1.04) upon the removal of Prins 1978 (*see* Analysis 01.05); again, the statistical heterogeneity is considerably reduced ( $I^2$  decreased from 22.7% to 3.4%). Nonetheless, there remains a tendency towards there being less recurrent ankle sprain in the surgery group: based on the 95% confidence interval, there could be as much as a 31% reduction in risk for those in the surgery group and up to a 4% increase in risk.

The definition of pain was often vague, and varied among trials. Analysis 01.06 shows the pooled data for long term findings of pain split into three analyses: pain at rest; pain on weight-bearing or during activity, or unspecified or overall pain; and tenderness. The statistically significant difference in favour of the surgery groups in the numbers of patients with pain of the second category (activity pain: RR 0.67, 95% CI 0.54 to 0.82) is not evident when the random-effects model is used (*see* Analysis 01.07: RR 0.70, 95% CI 0.45 to 1.11). The latter result is more appropriate given the significant heterogeneity between the trials ( $I^2 = 69.5%$ ). Upon removal of the trials with unconcealed allocation (Eggert 1986; Klein 1988; Pijnenburg 2003; Prins 1978), heterogeneity is substantially reduced ( $I^2 = 46.6%$ ) and there is no statistically significant difference between the two groups (*see* Analysis 01.08). Using the fixed-effect model to pool results from 12 trials, people in the surgical groups demonstrated less frequent subjective or functional instability (RR 0.69, 95% CI 0.57 to 0.83). The pooled result, however, was highly heterogeneous ( $I^2 = 74.8%$ ) and the results of the random-effects model (*see* Analysis 01.10) are not statistically significant (instability: RR 0.75, 95% CI 0.48 to 1.17). Similarly, no statistically significant difference was iden-

tified between the two groups, as well as some reduction in heterogeneity, following removal of Prins 1978; *see* Analysis 01.11.

### Secondary outcomes

Objective instability, as defined by a positive talar tilt on stress radiographs (*see* Analysis 01.12: RR 0.38, 95% CI 0.24 to 0.60) or positive anterior drawer sign (RR 0.54, 95% CI 0.43 to 0.67), was significantly less common in the surgical treatment group. The removal of trials with no concealment of allocation produced a similar result; the wider 95% confidence intervals reflecting the inclusion of fewer trials (*see* Analysis 01.13). Despite the variability in the threshold values among trials, these pooled results were statistically homogeneous. Where reported, the mean or median values for talar tilt or anterior draw were more similar (*see* Analysis 01.14); equivalent results for the two treatment methods were reported for talar tilt by three other studies (Klein 1988; Moller-Larsen 1988; Povacz 1998), and for anterior draw in one study (Klein 1988).

Pooled results from 12 trials showed no statistically significant difference between the two treatment groups in the number of people with longer-term swelling, either intermittent or constant (swelling: RR 0.84, 95% CI 0.64 to 1.10; *see* Analysis 01.15). The significant heterogeneity ( $I^2 = 47.1%$ ) was reduced ( $I^2 = 22.2%$ ) and the relative risk moved towards 1 (RR 0.97) following the removal of Prins 1978 (*see* Analysis 01.16).

Using the fixed-effect model to pool results from three trials, significantly more surgically treated patients complained of ankle stiffness (*see* Analysis 01.17: RR 2.24, 95% CI 1.41 to 3.55). While the results of the random-effects model (*see* Analysis 01.18: RR 2.17, 95% CI 0.99 to 4.77) do not achieve statistical significance, these limited data still indicate a tendency for more stiffness in the ankle surgery group.

Likewise, pooled results of seven trials showed significantly more surgically treated people with impaired ankle mobility using the fixed-effect model (*see* Analysis 01.19; reduced range of motion: RR 1.95, 95% CI 1.16 to 3.28) but not using the random-effects model (*see* Analysis 01.20: RR 1.80, 95% CI 0.95 to 3.42). Two trials found no participants with muscle atrophy at one year or above; the only trial (Niedermann 1981) detecting muscle atrophy at one year found no difference between the two groups (*see* Analysis 01.21). Specchiulli 2001 similarly found no statistically significant difference between the two groups in the mean side-to-side difference in calf circumference (mean difference 1.20 cm, 95% CI -1.06 to 3.46 cm).

Aside from deep vein thrombosis, which occurred in a few cases in both groups (RR 2.89, 95% CI 0.81 to 10.33), all recorded complications (scar tenderness, sensory loss or disturbance, infection and one case of Sudeck's atrophy) were in surgically treated patients (*see* Analysis 01.22). No arthrosis was recorded by Hietaniemi 1997. There was no statistically significant differences between the two groups in the numbers of people with an increase in radiographically-rated signs of arthrosis in Pijnenburg 2003 at a median

of eight-years follow up (see Analysis 01.22).

Similar numbers of participants of both groups from seven trials considered that they had a poor result (see Analysis 01.23: RR 0.77, 95% CI 0.36 to 1.65).

### **Surgical versus conservative treatment: sub-group analysis by conservative method (plaster cast immobilisation or functional treatment)**

Subgroup analysis by the method of conservative treatment was performed for the primary outcomes and two secondary outcomes. Only data from surgical treatment groups where surgery was followed by cast immobilisation are presented. Thus data from the surgery followed by functional treatment groups of [Eggert 1986](#) and [Zwipp 1986](#) are not included in the following; nor are those for all the participants of [Pijnenburg 2003](#). No analysis showed a statistically significant difference in the results of the two subgroups. In several analyses the removal of [Prins 1978](#) increased the agreement between the results of the two subgroups. (Supplementary analyses showing the effect of removing [Prins 1978](#) are presented for the primary outcomes only.)

Five trials presented data for the numbers of patients returning to their pre-injury sports level (see Analysis 02.01). A test of interaction shows no statistically significant difference between the results of the two subgroups ( $P = 0.21$ ). The dominant effect of [Prins 1978](#) is notable; the results of the two subgroups were very similar (test for interaction:  $P = 0.977$ ) after its exclusion (see Analysis 02.02). A similar finding applies to recurrence or re-injury, where the agreement between the two subgroups increases on the exclusion of [Prins 1978](#) (see Analyses 02.03 and 02.04); neither tests for interaction gave statistically significant results ( $P = 0.174$ ;  $P = 0.476$ ).

The random-effects model was used to pool the results for the remaining outcomes given the significant heterogeneity in at least one of the subgroups of each analysis. A test of interaction shows no statistically significant difference between the results of the two subgroups for pain or tenderness (see Analysis 02.05;  $P = 0.312$ ;  $P = 0.24$ ). On removal of [Prins 1978](#) (see Analysis 02.06), the agreement between the two subgroups increased for pain and remained about the same for tenderness (test for interaction:  $P = 0.715$ ;  $P = 0.187$ ). As shown by inspection of the analyses 02.07 and 02.08, the agreement between the two subgroups is also increased on the removal of [Prins 1978](#) for the outcome of subjective instability (test for interaction:  $P = 0.57$ ;  $P = 0.978$ ). There is no statistically significant difference between the results for the two treatment subgroups for either of the two measures of objective instability (see Analysis 02.09; test for interaction:  $P = 0.51$ ;  $P = 0.957$ ), or swelling (see Analysis 02.10; test for interaction:  $P = 0.272$ ).

## **DISCUSSION**

This systematic review presents a comprehensive examination of all randomised controlled clinical trials comparing surgery with

conservative treatment for acute lateral ankle ligament injuries. The pooled data from these trials fail to demonstrate a clearly superior treatment approach. While there is some evidence indicating that surgery may provide benefit over conservative treatment in some less important secondary outcomes, the heterogeneity in the results for primary outcomes underlines the need for a very cautious interpretation of the available evidence.

Although our search for trials was both comprehensive, systematic, recently updated and we also attempted to contact corresponding authors, the possibility of publication and study identification biases remains ([Dickersin 1994](#)). In the first version of our review, we referred to two studies ([Grasmueck 1997](#); [Otto 1997](#)) involving 260 patients, published as conference proceedings for which data were unavailable. After our cut-off date for study inclusion, we received full reports, both in German, from a trialist ([Grasmueck 1997](#)). One of these reports is a journal article that was not indexed in either MEDLINE or EMBASE, and the other is a thesis. This trial is now awaiting assessment. We have now excluded [Otto 1997](#); provisional on the full report of this trial ever being made available. The identification of one newly included trial ([Kolind-Sorensen 1975](#)), published in a Danish journal, again shows that our previous search failed to find important evidence, again in a non-English journal. While this is probably inevitable, it does highlight the need to search for both old and new trials for updating purposes. We continue to encourage the trialists of any other trials to contact us as well as publish their results, so that future versions of this review will provide clearer evidence. There is also a possibility of study selection bias ([Mulrow 1987](#); [Oxman 1994](#)); however, at least two independent reviewers performed the selection of trials and we feel confident that the studies excluded were done so for consistent and appropriate reasons ([Dickersin 1992](#)).

There is moderate to high potential for systematic bias impinging on the validity of the evidence from the 20 included trials. The shortcomings in the trial methods, such as failure to control for selection bias through adequate concealment of allocation and lack of outcome assessment blinding, have already been described. Pooling of data for individual outcomes was hampered by inconsistent availability of data and the variation of the outcome measures. It is of particular note that, at maximum, data for under two thirds of the trials (12 out of 20) and just over half the participants (under 57%) were available for pooling (for the outcomes of recurrence, subjective instability, swelling, long-term pain). Significant heterogeneity of pooled results was a common finding and its influence on both the effect size and statistical test for an overall effect was noteworthy. While the heterogeneity could result from variations in outcome definition and other variations in study characteristics, the influence of study quality in this review was impressive. For example, one quasi-randomised trial ([Prins 1978](#)) demonstrated markedly different primary outcomes from the other studies. The results of [Prins 1978](#) are consistent with the

observation by [Schulz 1995](#) of an exaggerated treatment effect in trials in which allocation concealment was inadequate. Whilst we cannot examine in any meaningful way the effects of publication and study identification biases or the non-availability of data from many of the included trials, the results of sensitivity analyses (use of random-effects compared with the fixed-effect model; exclusion of data from trials with a known lack of allocation concealment) emphasise the lack of robustness of the available evidence.

The pooling of results from trials with different conservative modalities was examined. Most trials compared either surgical repair versus plaster cast immobilisation, or surgical repair versus functional treatment. In most cases surgical repair was followed by plaster cast immobilisation. Subgroup analyses were conducted for six outcomes according to the method of conservative treatment. Testing for interaction, we identified a statistically significant difference between the two subgroups for pain. However, the agreement in the results for two subgroups was generally enhanced (with the loss of a statistically significant result for pain) on the removal of [Prins 1978](#). There is some evidence from direct comparisons of functional treatment with immobilisation of better short-term outcomes with functional treatment; however, the evidence from better quality trials was less conclusive ([Kerkhoffs 2002a](#)).

The majority (15) of the trials in this review were clearly conducted at least 20 years ago and reflect previous practice, especially in the use of prolonged cast immobilisation. Post-surgical treatment, especially the extent of immobilisation, is also open to debate and change. Thus, there are questions regarding how much of the evidence from these trials is applicable to current practice. Current trends in practice, however, tend towards functional treatment of acute lateral ankle ligament ruptures in adults ([Ogilvie-Harris 1995](#); [Kannus 1991](#); [Pijnenburg 2000](#); [Tiling 1994](#); [Shrier 1995](#)) and are consistent with the results from this review. The patient populations, comprising younger and active adults, are generally representative as well as conforming to the main focus of our review: individuals from late adolescence to middle age.

In our data synthesis, preliminary investigations appear to favour surgical intervention in terms of return to previous sporting activity, recurrence, pain, functional and objective instability, and swelling. Sensitivity analyses, however, reveal the susceptibility of these findings to changes and specifically in the exclusion of data from one quasi-randomised trial ([Prins 1978](#)). In the absence of significant heterogeneity between studies, the enhanced objective stability after surgical treatment may be a valid finding; however, its clinical relevance is unclear. There was also some evidence of stiffness and restrictions in ankle mobility after surgery. As an invasive intervention, the risk of complications associated with surgery always needs to be considered, as well as the additional resources required. There was some evidence of additional complications associated with surgery and that, in many trials, surgically treated patients took longer to return to work. This review addressed the question of whether primary surgical repair for an

acute injury is appropriate. It did not examine the effectiveness of secondary surgery, such as reconstruction, following treatment failure or chronic symptoms; this issue is now under review ([De Vries 2006](#)).

## AUTHORS' CONCLUSIONS

### Implications for practice

There is insufficient evidence available from randomised controlled trials to determine the relative effectiveness of surgical and conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults. Treatment decisions must be made on an individual basis, carefully weighing the relative benefits and risks of each option. Given the risk of operative complications and the higher costs (including those of hospital admission) associated with surgery, the best available option for most patients would be conservative treatment for acute injuries and close follow up to identify patients who may remain symptomatic.

### Implications for research

There is an urgent need for sufficiently powered, high quality and appropriately reported ([Moher 2001](#)) randomised trials of surgical repair versus the best available conservative treatment for well-defined injuries. The findings of systematic reviews examining conservative interventions should help to inform the selection of the conservative treatment. Since there is evidence that the traditional grading of lateral ligament injuries does not predict outcome ([De Bie 2002](#)), there is need for research to identify the characteristics of those injuries that are likely to have a poorer outcome and may be considered as candidates for more intensive or surgical treatment. Two other reviews examining a) the effectiveness, timing and type of secondary surgery and b) post-operative treatment are recommended and may assist the choice of surgical intervention and subsequent treatment. The former topic is now addressed in a recently completed Cochrane review on interventions for chronic ankle instability ([De Vries 2006](#)).

Attention should be given to outcome assessment in future trials. Future research should focus on obtaining sufficiently long-term follow-up (ideally two years or more) on all patients using a systematic and prospective approach. In addition, while blinding of interventions is not possible, concealed allocation and blinded outcome measurement would improve the quality and validity of future results. The use of well-defined and validated functional outcome measures, including patient-derived quality of life measures, is preferable. Finally, the recording of all relevant cost outcomes would be useful.

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\* Indicates the major publication for the study



## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

#### Clark 1965

Methods	Randomisation method: not stated Assessor blinding: not mentioned Loss to follow up: none Intention to treat: likely	
Participants	Canadian Forces Hospital, Kingston, Ontario, Canada. 24 people with lateral ligament tears; all young males? Exclusion criteria: not stated.	
Interventions	Period of study: Mar 1963 to Feb 1964. 1. Operative: ligament repair using sutures, suture removal at 14 days, then non weight bearing cast for 14 days, walking cast 14 days, then intensive physiotherapy. 2. Conservative: plaster immobilisation (period not defined but may have been until asymptomatic, then application of bandage until oedema disappeared, intensive physiotherapy). Assigned: 12/12 Analysed: 12/12	
Outcomes	Length of follow up: not stated 1. Time to return to full military duty 2. Subjective instability 3. Objective instability (clinical examination) 4. Pain 5. Swelling 6. Limited movement 7. Complications 8. Days in hospital	
Notes	Conservative treatment not described but the report of a retrospective study gives details of conservative treatment schedule applied in previous year	
<b><i>Risk of bias</i></b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Delfosse 1994**

Methods	Randomisation method: not stated Assessor blinding: not mentioned Loss to follow up: 19 at 8 months Intention to treat: problems - baseline figures for treatment groups not given
Participants	Brussels, Belgium. 76 participants, of age between 16 and 35 years. All with a first acute inversion injury of the ankle causing a rupture of the fibular collateral ligaments. Drawer sign > 6.5 mm. Exclusion criteria: very severe sprains (talar tilt < 25 degrees)
Interventions	Period of study: around 1994. 1. Operative: surgical repair and 6 weeks below-knee plaster cast. 2. Conservative: 6 weeks below-knee plaster cast. Assigned: ?/? (76 in all) Analysed at 8 months: 28/29
Outcomes	Length of follow up: 8 months. 1. Return to pre-injury level of activity in sport 2. Return to work 3. Objective instability (talar tilt) 4. Mean ankle displacement 5. Complications 6. Subjective assessment of results
Notes	Abstract report only

**Risk of bias**

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

**Eggert 1986**

Methods	Randomisation method: open method Assessor blinding: not mentioned Loss to follow up: 8 at first follow up, 18 at second follow up Intention to treat: problems - baseline figures for initial 145 participants not given; also exclusions: 21 (11;9;1) for non-compliance or intra-operative diagnosis of cartilage lesion or bone tears
Participants	Allgemeines Krankenhaus Bergedorf, Hamburg, Germany. 145 or 144 participants? Of 124 allocated participants - mean age 23 years; 70 male, 54 female. Exclusion criteria: <12 years of age; bone and cartilage tears; talar tilt/anterior draw under 15 kp stress <8 deg/8 mm
Interventions	Period of study: 1983 to 1984. 1. Operative: suture of the ligament with a walking cast for 6 weeks. 2. Operative: suture of the ligament with a Spring shoe and wearing a splint cast during the night for 6

**Eggert 1986** (Continued)

	<p>weeks. (Spring shoe = high-leg sport shoe with angular support edge for preventing bending and supination; secure fastening of laces to limit flexion.)</p> <p>3. Conservative: a Spring shoe, and wearing a splint cast during the night for 6 weeks.</p> <p>Assigned: ?/?/? (36/38/50)</p> <p>Analysed at 68 days: 30/33/37 (100 in all)</p> <p>Analysed at 458 days: 35/33/42 (110)</p>	
Outcomes	<p>Length of follow up: mean 458 days; also mean 68 days.</p> <ol style="list-style-type: none"> <li>1. Return to work</li> <li>2. Return to sport</li> <li>3. Proneness to sprain</li> <li>4. Objective instability (talar tilt drawer)</li> <li>5. Pain</li> <li>6. Swelling</li> <li>7. Gait pattern disturbance</li> <li>8. Ankle joint mobility</li> <li>9. Muscular atrophy</li> <li>10. Patient assessment</li> <li>11. Sensitivity disturbance</li> </ol>	
Notes	<p>Trial report in German translated by MOD, UK.</p> <p>Figures in text and tables do not tally. Text states overall number of patients = 144 but 21 exclusions shown thus overall number could 145.</p> <p>Also problems over loss to follow up and numbers analysed.</p>	
<b><i>Risk of bias</i></b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	No	C - Inadequate

**Evans 1984**

Methods	<p>Randomisation method: not stated</p> <p>Assessor blinding: no, at 3 months. Independent assessment at 2 years</p> <p>Loss to follow up: 8 (7 not traced, 1 death) at 2 years</p> <p>Intention to treat: problems - treatment allocation for losses not known</p>	
Participants	<p>Robert-Jones &amp; Agnes Hunt Orthopaedic Hospital, Oswestry, and the North Staffordshire Royal Infirmary, Stoke-on-Trent, UK.</p> <p>100 people with isolated ATF with or without a CF ligament rupture, aged between 16 to 35 years; mean 25 years; 75 male, 25 female.</p> <p>Exclusion criteria: fractures (but small avulsions at tip of lateral malleolus included)</p>	
Interventions	<p>Period of study: around 1984.</p> <ol style="list-style-type: none"> <li>1. Operative: primary suture of lateral ligaments, maximum delay for repair 4 days, then 3 weeks immobilisation in below-knee plaster cast with weight-bearing permitted, then elasticated support, physiotherapy.</li> <li>2. Conservative: immobilisation in cast for 3 weeks, with weight bearing, elasticated support, physiother-</li> </ol>	

Evans 1984 (Continued)

	<p>apy. Assigned: 50/50 Analysed at 3 months: 50/50 Analysed at 2 years: ?/? (92 in all)</p>	
Outcomes	<p>Length of follow up: 2 years; also review at 3 months</p> <ol style="list-style-type: none"> <li>1. Time to return to physical work</li> <li>2. Recurrent sprains</li> <li>3. Subjective instability (giving way)</li> <li>4. Objective instability (talar tilt &gt;5 degrees; anterior draw)</li> <li>5. Pain ('aching')</li> <li>6. Swelling</li> <li>7. Loss of movement</li> <li>8. Subtalar inversion</li> <li>9. Complications: including thrombosis, sensory loss, tender scar and Sudeck's atrophy</li> </ol>	
Notes		
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

Freeman 1965

Methods	<p>Randomisation method: not stated Assessor blinding: not mentioned Loss to follow up: 5 participants (6 injuries) at clinical (asymptomatic) follow up; 1 participant (1 injury) at 1 year follow up. Intention to treat: possible</p>	
Participants	<p>Middlesex Hospital, London, UK. 45 people with 46 partial/ or complete ruptures of lateral ligament. Diagnosed by stress radiograph when &gt;6 degrees difference between talar tilt of injured compared with uninjured ankle. 42 young men, 1 woman, 2 children. Exclusion criteria: not stated (2 participants found to have transchondral fracture of supero-lateral corner of the dome of the talus)</p>	
Interventions	<p>Period of study: around 1965.</p> <ol style="list-style-type: none"> <li>1. Operative: suture repair followed by immobilisation for unstated time, then physiotherapy to restore mobility and power.</li> <li>2. Conservative: immobilisation for 6 weeks in cast, then physiotherapy.</li> <li>3. Conservative: mobilisation: physiotherapy with strapping.</li> </ol> <p>Assigned: 16/18/12 (number of injuries) Analysed: 14/14/12 (followed clinically until asymptomatic) Analysed at 1 year: 16/17/12 (by postal questionnaire)</p>	

**Freeman 1965** (Continued)

Outcomes	Length of follow up: 1 year 1. Duration of disability - time until symptom free 2. Subjective (functional) instability with pain and with/without swelling 3. Objective instability (degrees talar tilt) 4. Pain 5. Swelling 6. Loss of movement	
Notes		
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Gronmark 1980**

Methods	Randomisation method: not stated Assessor blinding: not mentioned Loss to follow up: none Intention to treat: possible (All 95 participants were reviewed)	
Participants	Telemark Central Hospital, Skien, Norway. 95 participants; mean age 26 years (range 14-53 years); 67 men and 28 women. All with rupture of the lateral ligaments of the ankle. 43% of injuries were sports related. Exclusion criteria: not stated.	
Interventions	Period of study: before 1980. Average observation time 17 months (4-34 months). 1. Operative: primary suture and plaster cast for 6 weeks. 2. Conservative: plaster cast for 6 weeks. 3. Conservative: strapping, treated in physiotherapy department. Assigned: 32/33/30 Analysed at 4 to 34 months: 32/33/30	
Outcomes	Length of follow up: mean 17 months (4 to 34 months). 85 patients were reviewed clinically and radiographically, and 10 were reviewed by postal enquiry. 1. Length of rehabilitation 2. Residual symptoms 3. Complications 4. Length of hospital stay	
Notes		
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>

**Gronmark 1980** (Continued)

Allocation concealment?	Unclear	B - Unclear
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**Hietaniemi 1997**

Methods	Randomisation method: using lots Assessor blinding: not mentioned Loss to follow up: 9 at mean 4 years Intention to treat: problems - baseline not presented, only 23 followed up at 3 months
Participants	Helsinki, Finland. 52 military conscripts with acute (<2 days old) first-time severe ankle ligament injuries (grade III ruptures) diagnosed using stress radiography; age 18 to 30 years (actual: 18-26 years). Clinically unstable ankle and radiological talar tilt >6 degrees, and ADS >5 mm compared with opposite ankle. Of 43: all male, mean age 20 years. Participants had either ATF rupture or ATF and CF ruptures. Exclusion criteria: patient expressed preference for specific treatment. Other injuries
Interventions	Period of study: before 1993. 1. Operative: suture repair of ligament and plaster cast for 6 weeks. 2. Conservative: functional, light-weight orthotic device (Air-Stirrup (Air-Cast) ankle brace) for 6 weeks; allowing immediate dorsi- and plantar flexion but restricting inversion and eversion of ankle. After immobilisation period, patient initiated rehabilitation until walking was normal. Assigned: 26/26 Analysed at 3 months: 23 in all Analysed at mean 4 years: 23/20
Outcomes	Length of follow up: mean 4 years; also 3 months. 1. Subjective evaluation 2. Clinical result 3. Objective instability (talar tilt/anterior talar dislocation) 4. Complications: arthritic changes (none)
Notes	Translation from Finnish provided by H Arola.

**Risk of bias**

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

**Klein 1988**

Methods	Randomisation method: pre-determined random cards Assessor blinding: not mentioned Loss to follow up: 4 (from operative group) Intention to treat: problems - no details of the 4 lost from operative group	
Participants	University Hospital of Mannheim, Cologne, Germany. 60 people with recent ruptures of lateral ligament seen on stress radiography compared with normal side. At least one of: anterior talar dislocation >7 mm; talar tilt >7 degrees; >5 mm or >5 degrees difference between injured and normal ankle. Aged between 16 and 40 years. Of 56: mean age 24 years, 31 male, 25 female. Exclusion criteria: multiple injuries, fracture, previous supination injury, intolerance of anaesthetic, >24 hours between injury and care, blood circulation difficulties, generalised infection, collagenosis, open injuries, "Marcumar therapy"	
Interventions	Period of study: Sept 1984 to Feb 1986. 1. Operative: suture under general/ spinal anaesthetic, heparin-calcium given, stitches removed day 10, below-knee cast for 6 weeks, tape for 3-4 days, no physiotherapy. 2. Conservative: cast immobilisation: below-knee for 10 days, then walking cast for 6 weeks, tape 3-4 days, no physiotherapy. Assigned: 30/30 Analysed at 6 months: 26/30	
Outcomes	Length of follow up: 6 months (by clinical examination, validated questionnaire, and evaluation with a 120 point scoring scale). 1. Return to sporting activity 2. Time to return to work 3. Recurrent sprain 4. Subjective instability, plus load capacity 5. Objective instability (talar tilt / anterior talar dislocation) 6. Pain 7. Swelling 8. Ankle mobility 9. Complications (including scar sensitivity, infection)	
Notes	Two year follow-up indicated but no results reported. Translation of main report from German provided by MOD, UK.	
<b><i>Risk of bias</i></b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Kolind-Sorensen 1975**

Methods	Randomisation method: by date of birth Assessor blinding: not mentioned Loss to follow up: 13 Intention to treat: problems - treatment allocation for losses not known
Participants	Arhus Community Hospital, Denmark. 124 patients with lateral ligament tears diagnosed clinically and stress radiography (angle not measured). 77 of 111 participants were under 25 years, of which 34 had had a sports injury. Exclusion criteria: not stated.
Interventions	Period of study: June 1973 to Aug 1974. 1. Operative: ligament and capsule repair using sutures, then 5 weeks of plaster cast immobilisation. 2. Conservative: 5 weeks of plaster cast immobilisation. Assigned: ?? Analysed at 3 months: 52/59
Outcomes	Length of follow up: 3 months (4 to 5 months post injury) 1. Overall result (free of symptoms) 2. Subjective instability (looseness and tendency to twist ankle) 3. Objective instability (clinical and radiological examination) 4. Pain (when ankle loaded) 5. Reduced movement 6. Complications (dysaesthesia next to operation scar)
Notes	Translation from Danish provided by Pia Elgaard.

***Risk of bias***

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

**Korkala 1987**

Methods	Randomisation method: not stated Assessor blinding: not mentioned Loss to follow up: 33 at 2 years Intention to treat: potential problems, no baseline details and uneven loss to follow up (16;3;14)
Participants	University Central Hospital, Department of Orthopaedics and Traumatology, Helsinki, Finland. 150 severe tears of lateral ligament as seen on stress radiographs; age 15-50 years. At least one of: ADS >6 mm; >3 mm difference between injured and normal ankle; talar tilt >15 degrees; >10 degrees difference between injured and normal ankle. Exclusion criteria: serious medical conditions, psychiatric illness, alcoholism, previous sprain, athletes, non consent
Interventions	Period of study: before 1987. 1. Operative: suture, immobilisation in below-knee cast for 4 weeks, full weight bearing after 1 week. 2. Conservative: below-knee cast immobilisation for 4 weeks, full weight bearing after 1 week.



**Korkala 1987** (Continued)

	3. Conservative: functional: semi-elastic bandage for 1 week, then elastic bandage for 1-3 weeks, full weight bearing immediately. Assigned: 50/50/50 Analysed at 2 years: 34/47/36	
Outcomes	Length of follow up: 2 years. 1. Reduced sporting activity 2. Recurrent sprain 3. Subjective instability (fear of giving way) 4. Objective instability (anterior drawer sign/ talar-tilt) 5. Tenderness (pain) 6. Complications	
Notes	At 2 years: 99 patients attended & an additional 18 sent questionnaires	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Moller-Larsen 1988**

Methods	Randomisation method: not stated Assessor blinding: not mentioned Loss to follow up: 25 failed to attend 1 year follow up Intention to treat: problems - baseline figures for groups not given	
Participants	Arhus Municipal Hospital, Denmark. 200 patients with arthrographically verified acute lateral ligament rupture (ATF with or without CF) with or without avulsion. Of 175, median ages 23-25 years (range 15-47 years), 108 male, 67 female. Exclusion criteria: >50 years, fractures, other ligament injury, refusals (68), open epiphyses	
Interventions	Period of study: Nov 1983 to Aug 1985. 1. Operative: suture under general/ epidural anaesthetic, below-knee cast for 10 days with no weight bearing, removed sutures at 10 days, then below-knee cast for 5 weeks, with weight bearing. 2. Conservative: leg elevation for 5 days, then immobilisation in below-knee cast for 5 weeks and weight bearing. 3. Conservative: leg elevation for 5 days, then inelastic tape strapping (not intended to immobilise) for 5 weeks and weight bearing. Assigned: ?/?/? Analysed at 1 year: 55/55/65	
Outcomes	Length of follow up: 1 year (use of questionnaire). 1. Return to sports 2. Return to work (time to) 3. Restored to pre-injury state 4. Subjective instability: on walking, running, on rough/even ground	

**Moller-Larsen 1988** (Continued)

	5. Objective instability: talar tilt 6. Swelling during activity 7. Stiffness during activity 8. Asymptomatic ankles 9. Symptoms on activity 10. Patient assessment of treatment	
Notes	Results spilt by ligament rupture: ATF or ATF & CF.	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Niedermann 1981**

Methods	Randomisation method: not stated Assessor blinding: not mentioned Loss to follow up: 27 of 102 in operative group (26%), 45 of 107 in cast group (42%) Intention to treat: problems - no details of losses; uneven losses (27;45)
Participants	Department of Orthopaedic Surgery and Radiology Alborg Hospital, Denmark. 209 people with acute rupture confirmed by arthrography. Of 444 people during trial period, age range 12-50 years; 59% male, 41% female Exclusion criteria: open epiphyseal lines, >50 years, fractures, no rupture, arthrography within 24 hours of rupture
Interventions	Period of study: Oct 1977 to Aug 1978. 1. Operative: suture then below-knee plaster cast for 5 weeks without weight bearing. 2. Conservative: below-knee plaster cast immobilisation for 5 weeks without weight bearing. Assigned: 102/107 Analysed at 1 year: 75/62
Outcomes	Length of follow up: 1 year. 1. Return to pre-injury level of activity in sports 2. Recurrence (tendency to sprain) 3. Objective instability: lateral instability 4. Pain & tenderness 5. Swelling 6. Stiffness 7. Mobility (subtalar and talocrural) 8. Muscular atrophy: calf 9. Assessment of overall clinical result 10. Patients' subjective assessment of ankle 11. Complications 12. Complaints in work, walking, running, in sports, on rough/even ground

**Niedermann 1981** (Continued)

Notes	Results spilt by ligament rupture: ATF or ATF & CF. 20% had symptomatic ankle before injury.	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Petersen 1985**

Methods	Randomisation method: by drawing of envelopes Assessor blinding: not mentioned Loss to follow up: reported to be 26 at one year. However, it is not clear if exclusions: 6 (or 8) who did not satisfy age criterion or who did not wish to take part were post-randomisation. Intention to treat: problems - baseline figures for groups not given; contradictory account of losses	
Participants	Haderslev Hospital, Haderslev, Denmark. 84 or 85 or 91 or 93 people, aged between 15 and 50 years with acute (trauma < 24 hours old) arthrographically verified rupture of the ATF with or without CF rupture following supination trauma. Male or female. Exclusion criteria: fresh or old osseous damage in the ankle, ankle fractures	
Interventions	Period of study: May 1979 to June 1981. 1. Operative: suture of ruptured ligament followed by below-knee walking-cast immobilisation for 5 weeks. 2. Conservative: walking-cast immobilisation for 5 weeks. Assigned: ?/? (41/43) or (46/45) Analysed at 12 months: 29/30	
Outcomes	Length of follow up: 12 months; also 3 and 6 months. 1. Recovery of normal walking and mobility 2. Re-injury or recurrence 3. Objective instability (talar tilt) 4. Pain and ligament tenderness 5. Swelling 6. Stiffness 7. Complications	
Notes	Uncertainty concerning numbers of patients allocated and lost to follow up. Figures in text do not tally. Munk et al (Munk B, Holm-Christensen K, Lind T. Long-term outcome after ruptured lateral ankle ligaments. Acta Orthopaedica Scandinavica 1995;66:452-4) provides long-term follow up for this trial, but combines data from this trial and a subsequent one Translation from Danish provided by MOD, UK.	
<b>Risk of bias</b>		

**Petersen 1985** (Continued)

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

**Pijnenburg 2003**

Methods	<p>Randomisation method: by week of presentation (even and odd)</p> <p>Assessor blinding: of final X-rays only</p> <p>Loss to follow up: 71 of which 53 (or 52) were lost to follow up at 8 years and 18 (or 19) did not receive treatment as allocated</p> <p>Intention to treat: problems - exclusion of protocol violations and small discrepancies in reported numbers</p>
Participants	<p>Academic Medical Centre, Amsterdam, The Netherlands.</p> <p>388 participants presenting within 48 hours with a painful ankle caused by an indirect supination injury. Disruption of at least one of the fibular collateral ligaments shown by blinded physical examination or arthrography. Informed consent. Age 18 to 45 (actual 17 to 45 years). Of 370, 258 male, 112 female.</p> <p>Exclusion criteria: pre-existing instability of affected ankle, fracture, residence too distant for follow up</p>
Interventions	<p>Period of study: Mar 1988 to Mar 1991.</p> <p>1. Operative: (in orthopaedic department) suture of ruptured ligament(s) followed by 5 days with non weight bearing below-knee cast, then 6 weeks of either taping or elastic bandaging. Standardised rehabilitation programme.</p> <p>2. Conservative: (in general surgery department) functional treatment: 5 days with non weight bearing below-knee cast, then 6 weeks of either taping or elastic bandaging. Standardised rehabilitation programme.</p> <p>Assigned 185/203</p> <p>Analysed at 6 years 159/158</p>
Outcomes	<p>Length of follow up: median 8 years (range 6 to 11 years); also 2, 6 weeks and 3 and 6 months.</p> <ol style="list-style-type: none"> <li>1. Return to sports (no split by treatment)</li> <li>2. Return to work (time)</li> <li>3. Activity level (Tegner score)</li> <li>4. Recurrent sprain.</li> <li>5. Persistent pain (history; on palpation)</li> <li>6. Subjective instability ('Giving way')</li> <li>7. Objective instability (Anterior drawer test)</li> <li>8. Swelling (history; on examination)</li> <li>9. Tenderness</li> <li>10. Overall ankle function: Povacz and Good scores</li> <li>11. Complications</li> <li>12. Patient satisfaction</li> <li>13. Radiographic signs of arthrosis</li> </ol>
Notes	Very poor method of randomisation acknowledged by trialists.

***Risk of bias***

Item	Authors' judgement	Description
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**Pijnenburg 2003** (Continued)

Allocation concealment?	No	C - Inadequate
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**Povacz 1998**

Methods	Randomisation method: computer-generated randomisation cards, blinded Assessor blinding: no, but independent examiners at final follow up Loss to follow up: 21 (8 unknown address, 13 refusals - none had subsequent operation) Intention to treat: likely
Participants	General Hospital Salzburg and General Hospital Wels, Austria. 167 people aged <40 years with acute (<24 hours from injury) lateral ligaments injuries of the ankle, verified on stress X-ray. Informed consent, closed growth-plates. Of 126: mean 23 years, range 16-39 years, 94 male, 52 female. Sport related injuries: 67%. Exclusion criteria: history of instability or injury of the ankle, multiple injuries
Interventions	Period of study: Jan to Aug 1991. 1. Operative: suture repair with 6 weeks below-knee walking cast. Then, instructions for proprioceptive muscle training and isometric exercises. 2. Conservative: RICE for 3-7 days (until swelling subsided), followed by 6 weeks ankle brace (Aircast) treatment and exercises: ROM, proprioceptive and isometric exercises. Assigned: 79/88 Analysed at mean 27 months: 73/73
Outcomes	Length of follow up: mean 27 months (range 24-31 months). Overall scoring system used. 1. Return to work 2. Sports participation 3. Overall patient rating 4. Recurrent sprains 5. Pain 6. Subjective instability 7. Objective instability (anterior drawer test, talar tilt) 8. Swelling 9. ROM 10. Atrophy of muscles 11. Complications 12. Compliance 13. Patient satisfaction

Notes

**Risk of bias**

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

**Prins 1978**

Methods	Randomisation method: odd / even admission numbers (quasi-randomised) Assessor blinding: not mentioned Loss to follow up: none Intention to treat: possible (All 104 participants were reviewed)
Participants	Catharina Hospital, Eindhoven, The Netherlands. 104 people enrolled with arthrographically proven grade III lateral ligament injuries; ATF and CF ruptures suggested. Mean age 24 years; range 11 to 55 years. 76 male, 28 female. Sports: 83 (80%) Exclusion criteria: not stated?
Interventions	Period of study: Oct 1975 to Jan 1977. 1. Operative: suture repair, 3 weeks below-knee plaster cast, 2 weeks Unna boot. 2. Conservative: 6 weeks below-knee plaster cast All advised to use elastic bandage during day after cast removal. Assigned: 45/59 Analysed at 6 months: 45/59
Outcomes	Length of follow up: 6 months. 1. Resumption of normal activities 2. Return to sports 3. Recurrent injury 4. Pain (on weightbearing, tenderness) 5. Subjective instability 6. Objective instability (talar tilt and ADS) 7. Swelling 8. Discomfort when walking 9. Movement limitation 10. Complications
Notes	The 2 cases of transient paraesthesiae (sensory loss) and 3 cases of superficial wound infection were reported out of a group of 69 or 70 patients treated surgically, 45 of who were in this comparison

***Risk of bias***

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

**Sommer 1987**

Methods	Randomisation method: not stated Assessor blinding: not mentioned Loss to follow up: 17 Intention to treat: problems - baseline figures for groups not given
Participants	Department of Orthopaedic Surgery, University of Heidelberg, Germany. 80 people, aged between 18 and 45 years with recent ruptures of the fibular ligament. Of 63: mean age 27 years, 4/1 male and female ratio. Exclusion criteria: bone or cartilage injury, previous injuries, chronic instability, and competitive sports

**Sommer 1987** (Continued)

	people, non consent	
Interventions	<p>Period of study: 1986.</p> <p>1. Operative: repair, below-knee plaster for 3 weeks, then bandage for up to 5 weeks.</p> <p>2. Conservative: functional treatment by circumferential elastic strapping for 2 weeks, then bandage for a further 6 weeks.</p> <p>Both groups: weightbearing as soon as possible, crutches for 2 weeks. No physiotherapy</p> <p>Assigned: ?/? (80 in all)</p> <p>Analysed at 1 year: 36/27</p>	
Outcomes	<p>Length of follow up: 1 year; also 6 weeks. Outcomes:</p> <p>1. Recurrence</p> <p>2. Objective instability (talar tilt)</p> <p>3. Ankle mobility</p> <p>4. "Active muscular stabilisation"</p>	
Notes	Trialists stated their intention to follow up for up to 5 years	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

**Specchiulli 2001**

Methods	<p>Randomisation method: by date of birth (participants were blinded to inclusion in study beforehand)</p> <p>Assessor blinding: not mentioned</p> <p>Loss to follow up: probably none (not stated)</p> <p>Intention to treat: likely</p>	
Participants	<p>University Hospital, Bari, Italy.</p> <p>100 people, skeletally mature (closed epiphyseal growth plates), with acute (within 24 hours of presentation) grade III injuries of the lateral ankle ligaments, diagnosed clinically and arthrographically. Consent. Aged &lt; 40 years. Mean age 25 years, 2/1 male and female ratio.</p> <p>Exclusion criteria: previous history of ankle instability.</p>	
Interventions	<p>Period of study: Jan 1995 to June 1996.</p> <p>1. Operative: repair with sutures then non weight bearing below-knee cast for 5 weeks</p> <p>2. Conservative: adhesive ankle taping for 40 days, changed every 10 days.</p> <p>Both groups had same rehabilitation programme under guidance of physiotherapist.</p> <p>Assigned: 50/50</p> <p>Analysed between 24 to 31 months: 50/50</p>	
Outcomes	<p>Length of follow up: average 27 months (range 24-31 months).</p> <p>1. Return to sport (time and level of sport)</p> <p>2. Subjective instability (residual disturbance: giving way, recurrent sprains, apprehension)</p> <p>3. Objective instability (anterior drawer test; signs of mechanical instability)</p>	

Specchiulli 2001 (Continued)

	4. Ankle mobility (loss of motion and range of movement) 5. Swelling 6. Overall ankle function and pain score (Ankle-Hindfoot scale: Kitaoka) 7. Calf atrophy	
Notes	Quasi-randomised controlled trial without patient consent.	
<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	No	C - Inadequate

Van Moppes 1982

Methods	Randomisation method: not stated Assessor blinding: not mentioned Loss to follow up: none (follow up was incomplete in 3 participants) Intention to treat: possible but for the 3 above participants
Participants	St. Annadel Hospital, University of Limburg, The Netherlands. 150 people, selected 5 to 6 days after trauma. All with arthrographically proven lateral ligament lesions. 60% sports-related injuries. Exclusion criteria: not stated.
Interventions	Period of study: Mar 1979 to May 1980. 1. Operative: surgical repair within one day of admission, plaster splint and bedrest 3-4 days, then after 1 week: 5 weeks below-knee walking cast, followed by tubular bandage and physiotherapy. 2. Conservative: below-knee walking cast up to 6 weeks followed by tubular bandage and physiotherapy. 3. Conservative: 'Couman's bandage', new every 2 weeks, for 6 weeks. Immediate mobilisation, after a short exercise program. No further physiotherapy after bandage removal. Assigned: 50/50/50 Analysed at 1 year: 50/50/50
Outcomes	Length of follow up: 1 year; also 9, 12 and 24 weeks. 1. Resumption of daily work activities and other activities of daily living 2. Resumption of sports activities 3. Re-injury or recurrence 4. Subjective instability 5. Objective instability (talar tilt, anterior draw) 6. Pain (on weight-bearing/at rest/tenderness) 7. Ankle swelling 8. Muscle atrophy 9. Ankle mobility 10. Abnormal walking pattern 11. Complications
Notes	Coumans bandage was applied by the originator of the specially constructed bandage



Van Moppes 1982 (Continued)

<b>Risk of bias</b>		
<b>Item</b>	<b>Authors' judgement</b>	<b>Description</b>
Allocation concealment?	Unclear	B - Unclear

Zwipp 1986

Methods	<p>Randomisation method: use of consecutively marked documentation sheets; study charts drawn at random.</p> <p>Participants could select treatment after allocation</p> <p>Assessor blinding: not mentioned; some independent assessment</p> <p>Loss to follow up: 41 at 2 years</p> <p>Intention to treat: no, problems; participant withdrawal after allocation; text (50 each group) in several papers differs from tables (52;50;48;50); 64% lost at 1 year in one paper but 84% in 2 other papers, exclusion if other damage (see next column) found during operation</p>
Participants	<p>University Hospital of Hannover, Germany.</p> <p>200 recent ankle ligament ruptures (arthrography in 189 /227 cases); of 227 originally eligible: 136 male, 91 female; mean age 23.6 years, range 9-51 years. Most involved in sports.</p> <p>Exclusion criteria: history of supination trauma, additional cartilage lesion or second stage rupture evident during operation</p>
Interventions	<p>Period of study: Apr 1985 to July 1986</p> <ol style="list-style-type: none"> <li>Operative + immobilisation: suture repair, 1-2 days hospital stay, heparin, below-knee plaster applied 5-8 days, removed after 5 weeks.</li> <li>Operative + functional: suture repair, 1-2 days hospital stay, heparin, home produced orthotic brace / splint applied 5-10 days for 5 weeks (worn overnight).</li> <li>Conservative + immobilisation: below-knee plaster applied 3-5 days, removed after 5 weeks.</li> <li>Conservative + functional: home produced orthotic brace / splint applied 3-5 days for 5 weeks (worn overnight).</li> </ol> <p>All groups had 6 sessions of physiotherapy afterwards.</p> <p>Assigned: 52/50/48/50</p> <p>Analysed at 3 months: 46/44/45/50</p> <p>Analysed at 1 year: 32/30/31/35 (=128 but 168 in 2 papers)</p> <p>Analysed at 2 years: ?/?/?/? (159 in all)</p>
Outcomes	<p>Length of follow up: 2 years; also 3 and 12 months.</p> <ol style="list-style-type: none"> <li>Work incapacity time</li> <li>Overall functional grade</li> <li>Limitation in sports</li> <li>Subjective instability (fear of giving way; gait stability)</li> <li>Objective instability (anterior drawer sign/ talar-tilt)</li> <li>Joint mobility (pronation, supination etc)</li> <li>Complications</li> </ol>
Notes	<p>5 full reports of trial; 3 in German and 2 in English. Translation of one German paper provided by MOD, UK</p>

**Zwipp 1986** (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

c. = around / about

ADS = anterior draw sign

ATF = anterior talofibular ligament

CF = calcaneofibular ligament

MOD: Ministry of Defence

RICE = rest, immobilisation, chill, elevation

ROM = range of motion / movement

**Characteristics of excluded studies** [ordered by study ID]

Study	Reason for exclusion
Brostrom 1966	Mixed population of non-randomised surgical treatment patients and randomised patients. Separate data quasi-randomised comparison of surgical versus plaster cast versus ankle strapping were not available
Hennrikus 1996	Randomised comparison of two surgical techniques for chronic ankle stability (6 months or more from original injury)
Kaikkonen 1996	Quasi-randomised trial seriously compromised by post-randomisation exclusion and secondary matching of trial participants
Karlsson 1997a	Randomised comparison of two anatomic reconstructions for chronic lateral instability of the ankle joint (duration of instability 6 months or more)
Knop 1999	Randomised comparison of surgical repair versus no surgery for recurrent ankle ligament ruptures. Not in the scope of the review
Larsen 1990	Randomised comparison of two surgical techniques for chronic ankle stability (5 months or more from original injury)
Otto 1997	Randomised comparison of operative (ligament repair) versus functional conservative treatment in 160 people. We have been unsuccessful in our attempts to get more information on this trial, which is only available as an abstract reporting insufficient details for inclusion
Pace 1990	Not a randomised trial.
Stadelmayer 1992	Not a randomised trial: treatment selection by patients.

*(Continued)*

Van der Ent 1994	Not a randomised trial.
Zoltan 1977	Not in the scope of the review. The intervention group of this quasi-randomised trial was given ankle joint aspiration and local injection of xylocaine

## DATA AND ANALYSES

### Comparison 1. Surgical versus Conservative treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Non-return to pre-injury level of activity	9	941	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.65, 1.11]
1.1 Non-return to pre-injury state - unspecified	1	175	Risk Ratio (M-H, Fixed, 95% CI)	1.69 [1.10, 2.59]
1.2 Non-return to sport or reduction in sporting activity	5	526	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.39, 0.83]
1.3 Non-return to work	1	31	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 Reduction in walking distance	1	59	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.12, 3.83]
1.5 Impaired ability to jump	1	150	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.35, 3.72]
2 Non-return to pre-injury level of activity - Prins 1978	8	858	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.81, 1.49]
2.1 Non-return to pre-injury state - unspecified	1	175	Risk Ratio (M-H, Fixed, 95% CI)	1.69 [1.10, 2.59]
2.2 Non-return to sport or reduction in sporting activity	4	443	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.49, 1.27]
2.3 Non-return to work	1	31	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.4 Reduction in walking distance	1	59	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.12, 3.83]
2.5 Impaired ability to jump	1	150	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.35, 3.72]
3 Non-return to sport or reduction in sports: by definition	5		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 Non-return to sports	4	409	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.35, 1.35]
3.2 Reduction in sports activity	5	526	Risk Ratio (M-H, Fixed, 95% CI)	0.53 [0.33, 0.86]
3.3 Non-return to sports - Prins 1978	3	326	Risk Ratio (M-H, Fixed, 95% CI)	0.62 [0.25, 1.58]
3.4 Reduction in sports activity - Prins 1978	4	443	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.49, 1.53]
4 Recurrence or reinjury	12	1393	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.65, 0.98]
5 Recurrence or reinjury - Prins 1978	11	1289	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.69, 1.04]
6 Long term pain or tenderness	14		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
6.1 At rest	3	230	Risk Ratio (M-H, Fixed, 95% CI)	0.34 [0.07, 1.58]
6.2 On weight-bearing/ on activity/ not defined/ not separated	12	1430	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.54, 0.82]
6.3 On palpation (tenderness)	6	866	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.70, 1.13]
7 Long term pain or tenderness (random-effects model)	14		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
7.1 At rest	3	230	Risk Ratio (M-H, Random, 95% CI)	0.34 [0.08, 1.57]

7.2 On weight-bearing/ on activity/ not defined/ not separated	12	1430	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.45, 1.11]
7.3 On palpation (tenderness)	6	866	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.65, 1.23]
8 Long term pain or tenderness - trials with no concealment of allocation	10		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
8.1 At rest	3	230	Risk Ratio (M-H, Fixed, 95% CI)	0.34 [0.07, 1.58]
8.2 On weight-bearing/ on activity/ not defined/ not separated	9	790	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.70, 1.16]
8.3 On palpation (tenderness)	4	445	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.52, 1.25]
9 Subjective or functional instability	12	1445	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.57, 0.83]
10 Subjective or functional instability (random-effects model)	12	1445	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.48, 1.17]
11 Subjective or functional instability - Prins 1978	11	1341	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.61, 1.29]
12 Objective instability (talar tilt or anterior draw)	12		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
12.1 Positive talar tilt	8	781	Risk Ratio (M-H, Fixed, 95% CI)	0.38 [0.24, 0.60]
12.2 Positive anterior draw	6	913	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.43, 0.67]
13 Objective instability (talar tilt or anterior draw) - trials with no concealment of allocation	6		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
13.1 Positive talar tilt	4	332	Risk Ratio (M-H, Fixed, 95% CI)	0.36 [0.18, 0.72]
13.2 Positive anterior draw	3	392	Risk Ratio (M-H, Fixed, 95% CI)	0.55 [0.30, 1.00]
14 Objective instability (severity)	4		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
14.1 Severity of tilt (degrees)	4	216	Mean Difference (IV, Fixed, 95% CI)	-0.63 [-1.28, 0.02]
14.2 Severity of anterior draw (mm)	2	100	Mean Difference (IV, Fixed, 95% CI)	0.17 [-0.77, 1.12]
15 Swelling	12	1423	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.64, 1.10]
16 Swelling - Prins 1978	11	1319	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.74, 1.28]
17 Stiffness	3	423	Risk Ratio (M-H, Fixed, 95% CI)	2.24 [1.41, 3.55]
18 Stiffness (random-effects model)	3	423	Risk Ratio (M-H, Random, 95% CI)	2.17 [0.99, 4.77]
19 Ankle mobility: reduced range of motion (ROM)	7	746	Risk Ratio (M-H, Fixed, 95% CI)	1.95 [1.16, 3.28]
20 Ankle mobility: reduced range of motion (ROM) (random-effects model)	7	746	Risk Ratio (M-H, Random, 95% CI)	1.80 [0.95, 3.42]
21 Muscle atrophy	3	397	Risk Ratio (M-H, Fixed, 95% CI)	0.73 [0.40, 1.34]
22 Complications	14		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
22.1 DVT	5	571	Risk Ratio (M-H, Fixed, 95% CI)	2.89 [0.81, 10.33]
22.2 Tenderness of scar	6	700	Risk Ratio (M-H, Fixed, 95% CI)	8.80 [2.62, 29.49]
22.3 Sensory loss	5	607	Risk Ratio (M-H, Fixed, 95% CI)	10.58 [2.47, 45.26]
22.4 Dysaesthesia near operative scar	1	111	Risk Ratio (M-H, Fixed, 95% CI)	7.92 [0.42, 149.91]
22.5 Infection or wound necrosis	8	1136	Risk Ratio (M-H, Fixed, 95% CI)	5.61 [1.27, 24.89]
22.6 Sudeck's atrophy	1	100	Risk Ratio (M-H, Fixed, 95% CI)	3.0 [0.13, 71.92]

22.7 Arthrosis	2	360	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.81, 1.29]
23 Poor (much worse) result according to patients	7	979	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.36, 1.65]

## Comparison 2. Surgical versus Conservative treatment: by conservative method

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Non-return to sport or reduction in sporting activity	5		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Plaster cast	3	267	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.31, 0.76]
1.2 Functional treatment	3	293	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.43, 1.39]
2 Non-return to sport or reduction in sporting activity - Prins 1978	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Plaster cast	2	184	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.39, 1.50]
2.2 Functional treatment	3	293	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.43, 1.39]
3 Recurrence or reinjury	10		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 Plaster cast	8	639	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.63, 1.18]
3.2 Functional treatment	5	421	Risk Ratio (M-H, Fixed, 95% CI)	1.21 [0.83, 1.77]
4 Recurrence or reinjury - Prins 1978	9		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 Plaster cast	7	535	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.73, 1.39]
4.2 Functional treatment	5	421	Risk Ratio (M-H, Fixed, 95% CI)	1.21 [0.83, 1.77]
5 Pain or tenderness	12		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.1 Plaster cast: pain on weight-bearing or activity or not defined	9	765	Risk Ratio (M-H, Random, 95% CI)	0.59 [0.31, 1.14]
5.2 Functional treatment: pain on weight-bearing or activity or not defined	5	413	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.47, 2.05]
5.3 Plaster cast: tenderness	5	468	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.42, 1.39]
5.4 Functional treatment: tenderness	2	157	Risk Ratio (M-H, Random, 95% CI)	0.39 [0.15, 1.03]
6 Pain or tenderness - Prins 1978	11		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
6.1 Plaster cast: pain on weight-bearing or activity or not defined	8	661	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.51, 1.36]
6.2 Functional treatment: pain on weight-bearing or activity or not defined	5	413	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.47, 2.05]
6.3 Plaster cast: tenderness	4	364	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.45, 1.62]
6.4 Functional treatment: tenderness	2	157	Risk Ratio (M-H, Random, 95% CI)	0.39 [0.15, 1.03]
7 Subjective or functional instability	11		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
7.1 Plaster cast	9	719	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.39, 1.27]
7.2 Functional treatment	6	564	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.48, 1.71]

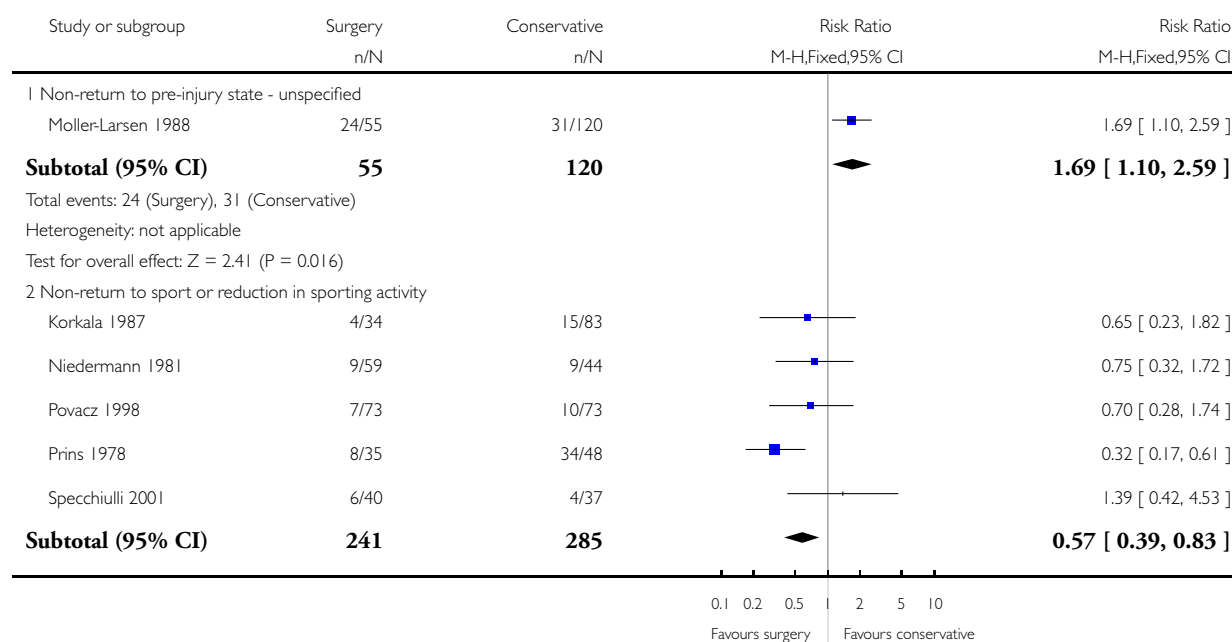
8 Subjective or functional instability - Prins 1978	10		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
8.1 Plaster cast	8	615	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.57, 1.44]
8.2 Functional treatment	6	564	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.48, 1.71]
9 Objective instability (talar tilt or anterior draw)	11		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
9.1 Plaster cast: positive talar tilt	7	568	Risk Ratio (M-H, Random, 95% CI)	0.35 [0.20, 0.60]
9.2 Functional treatment: positive talar tilt	4	222	Risk Ratio (M-H, Random, 95% CI)	0.57 [0.15, 2.20]
9.3 Plaster cast: positive anterior draw	3	270	Risk Ratio (M-H, Random, 95% CI)	0.53 [0.35, 0.82]
9.4 Functional treatment: positive anterior draw	4	402	Risk Ratio (M-H, Random, 95% CI)	0.54 [0.32, 0.93]
10 Swelling	11		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
10.1 Plaster cast	9	723	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.38, 1.18]
10.2 Functional treatment	5	469	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.62, 1.66]

### Analysis 1.1. Comparison 1 Surgical versus Conservative treatment, Outcome 1 Non-return to pre-injury level of activity.

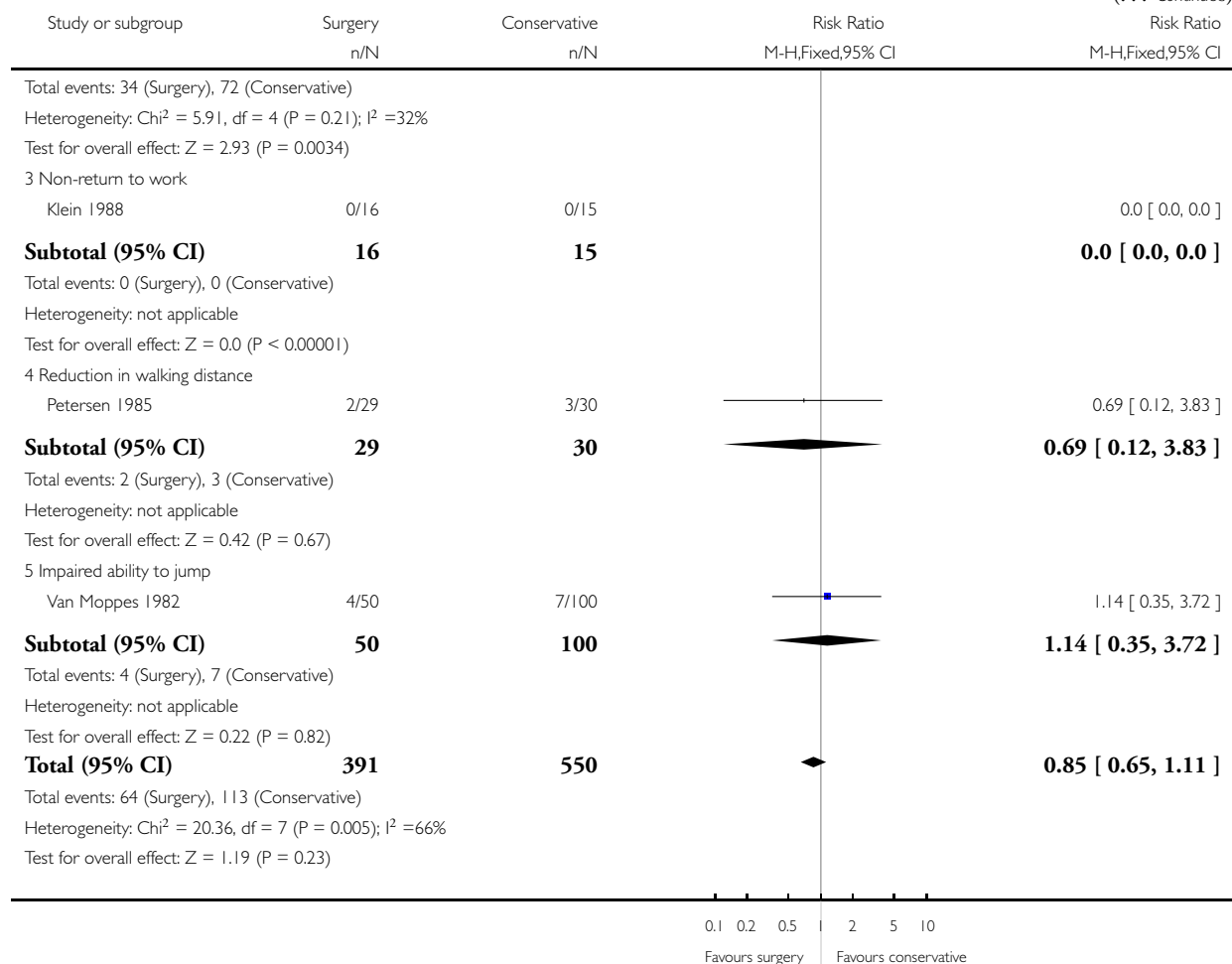
Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 1 Non-return to pre-injury level of activity



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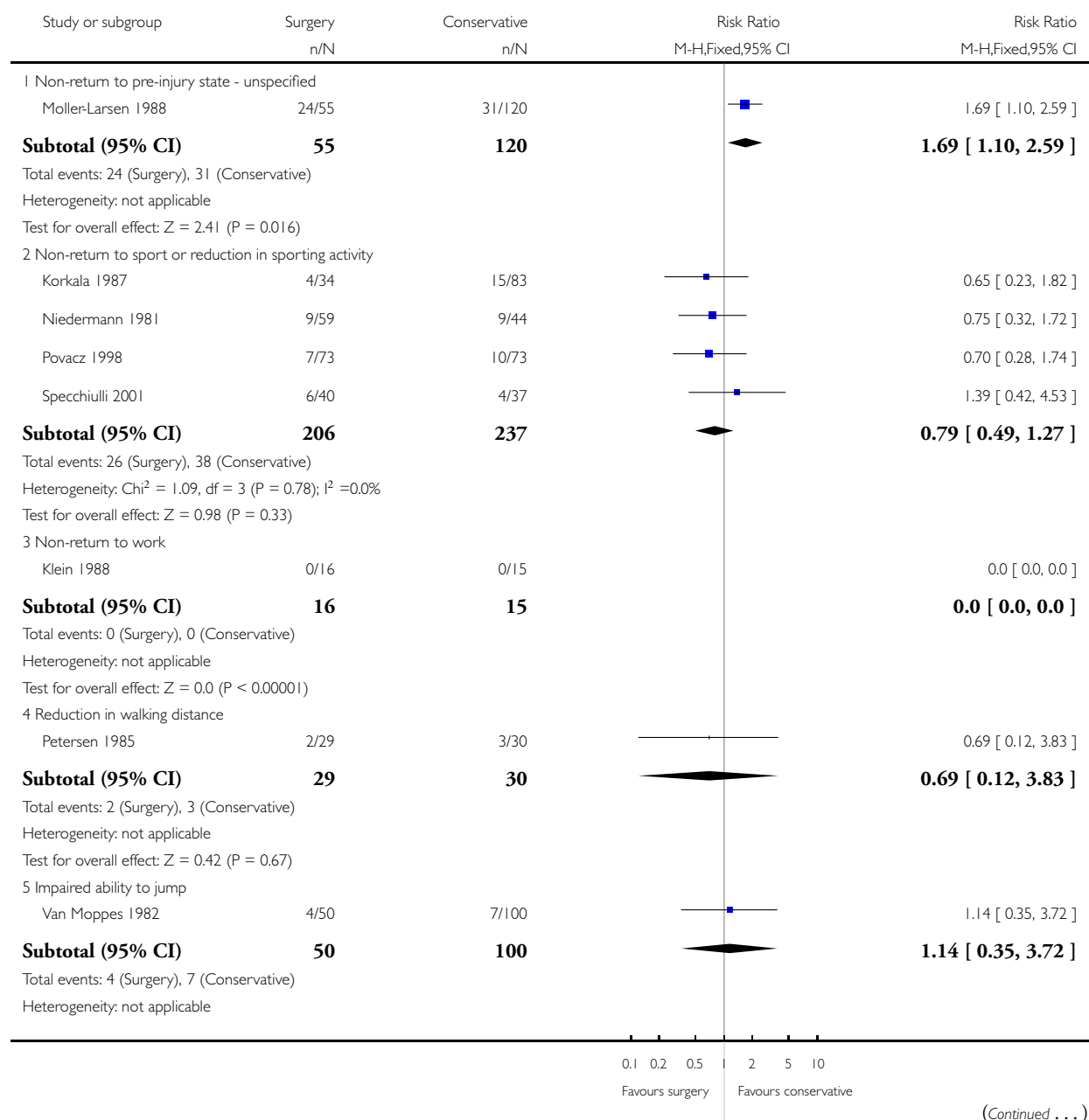


## Analysis 1.2. Comparison 1 Surgical versus Conservative treatment, Outcome 2 Non-return to pre-injury level of activity - Prins 1978.

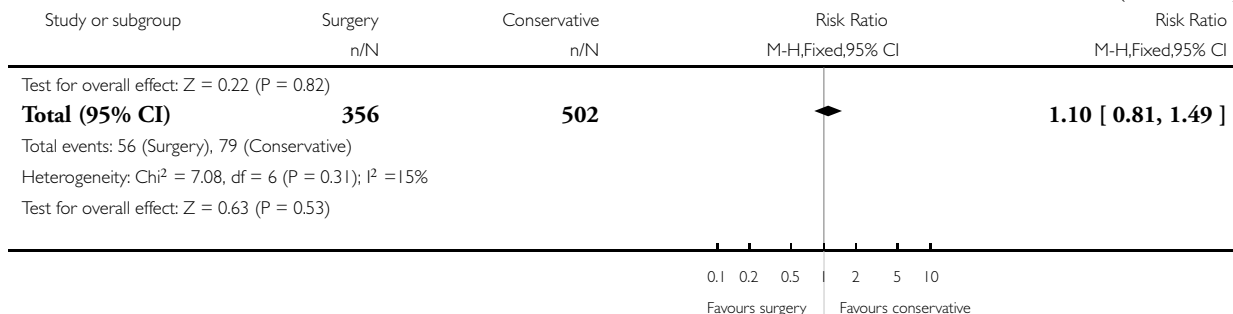
Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 2 Non-return to pre-injury level of activity - Prins 1978



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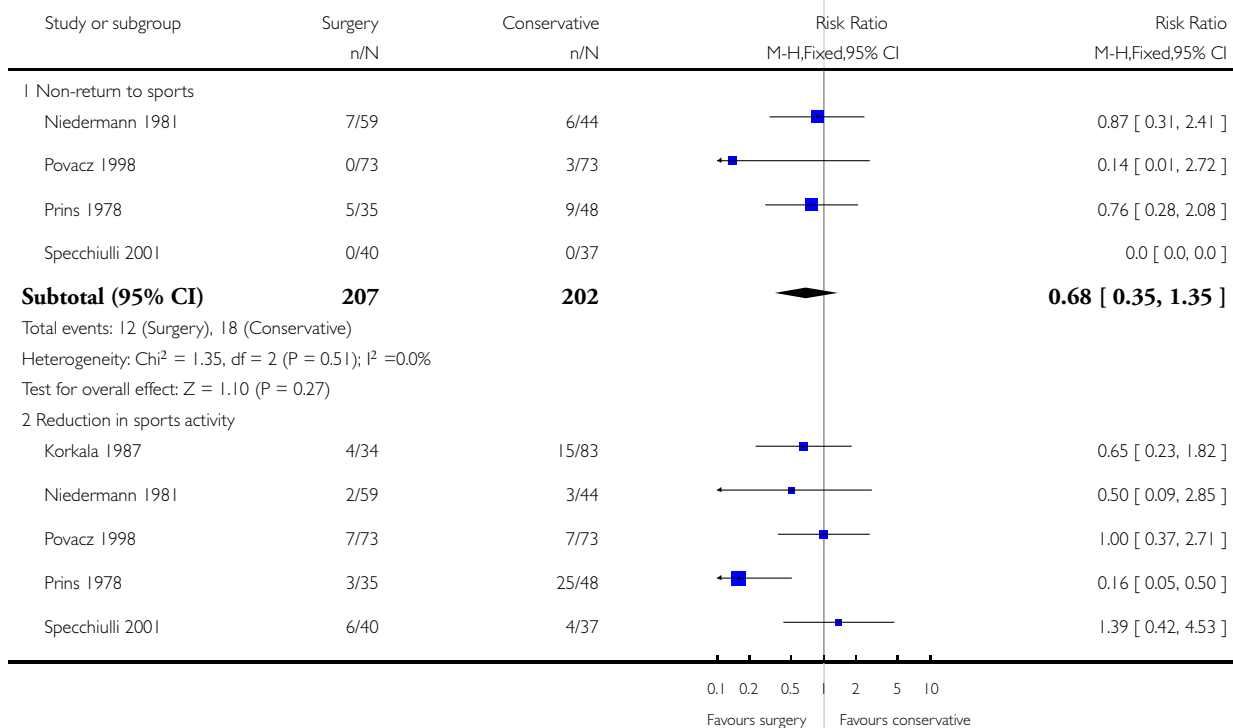


### Analysis 1.3. Comparison 1 Surgical versus Conservative treatment, Outcome 3 Non-return to sport or reduction in sports: by definition.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

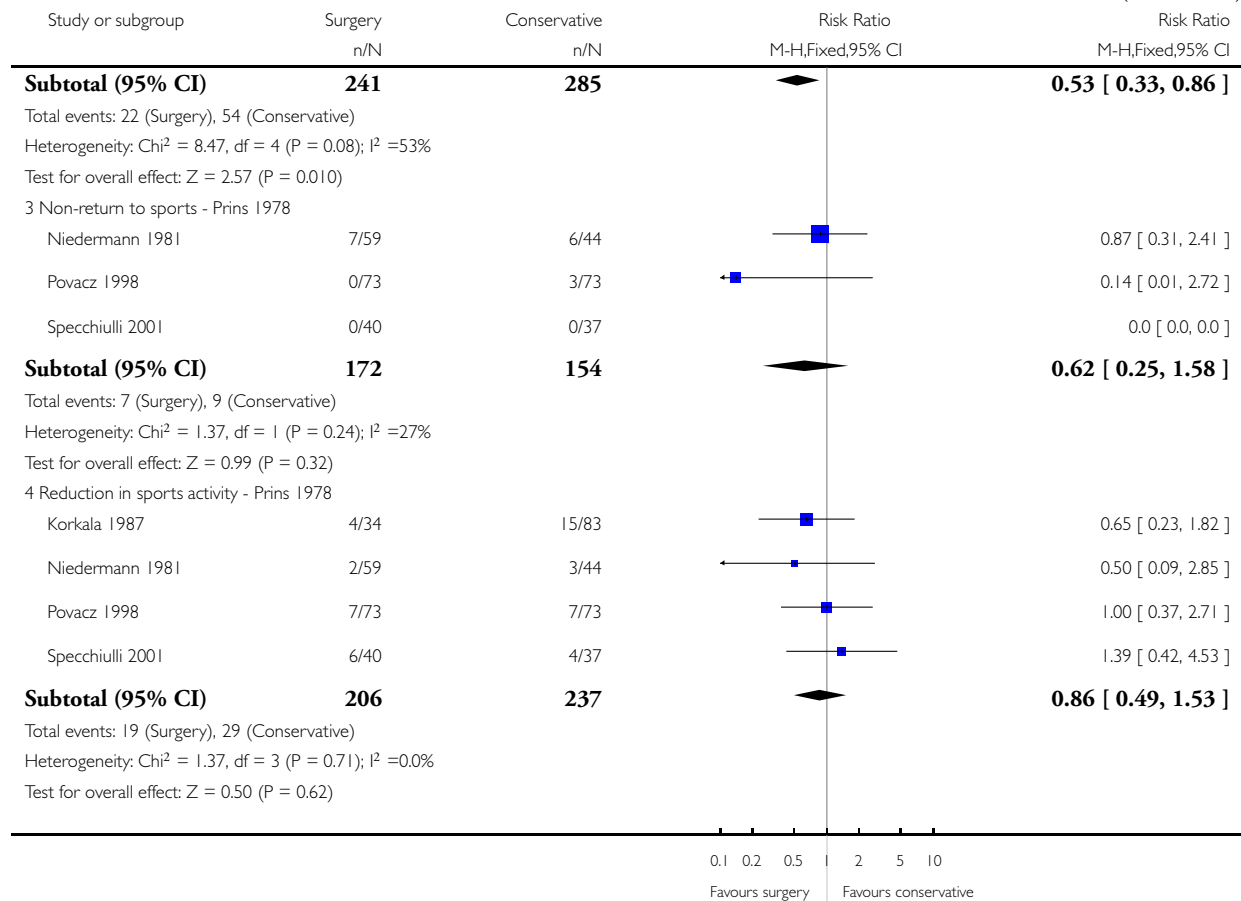
Comparison: 1 Surgical versus Conservative treatment

Outcome: 3 Non-return to sport or reduction in sports: by definition



(Continued ...)

(... Continued)

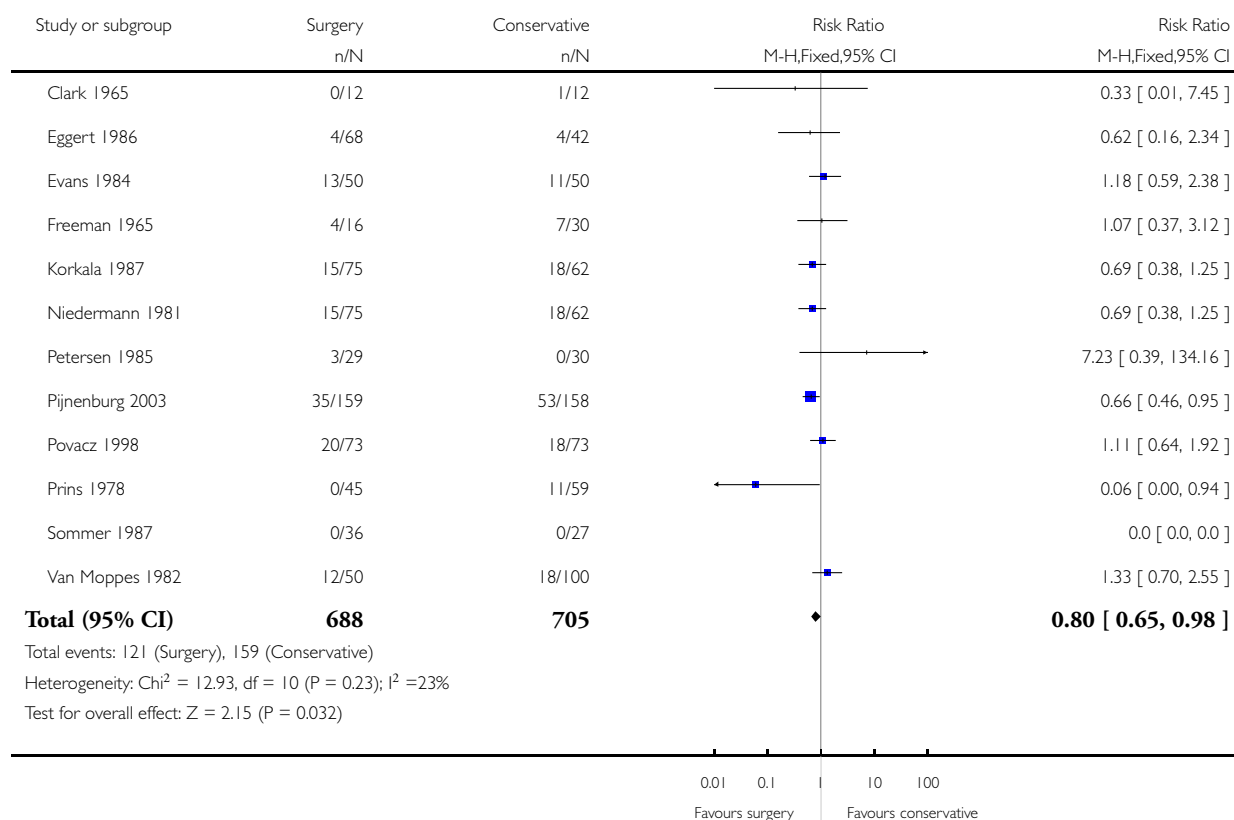


### Analysis 1.4. Comparison 1 Surgical versus Conservative treatment, Outcome 4 Recurrence or reinjury.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 4 Recurrence or reinjury

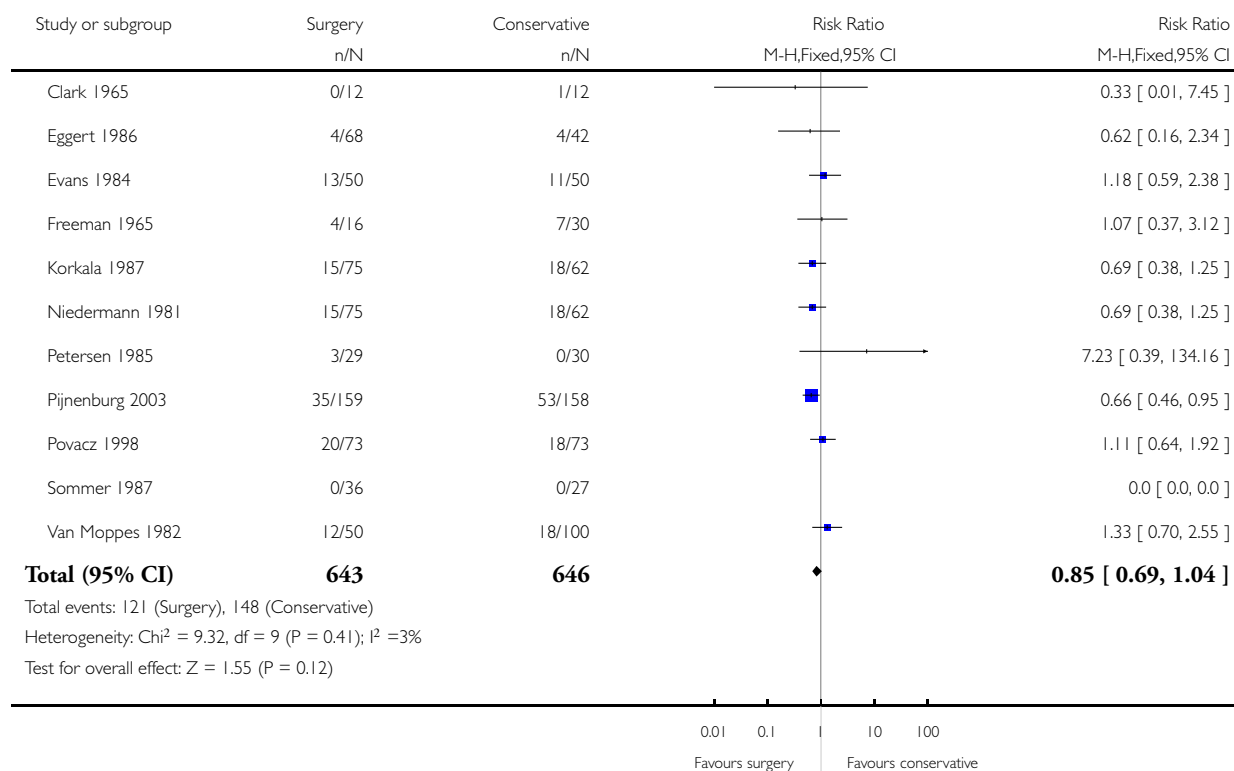


### Analysis 1.5. Comparison 1 Surgical versus Conservative treatment, Outcome 5 Recurrence or reinjury - Prins 1978.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 5 Recurrence or reinjury - Prins 1978

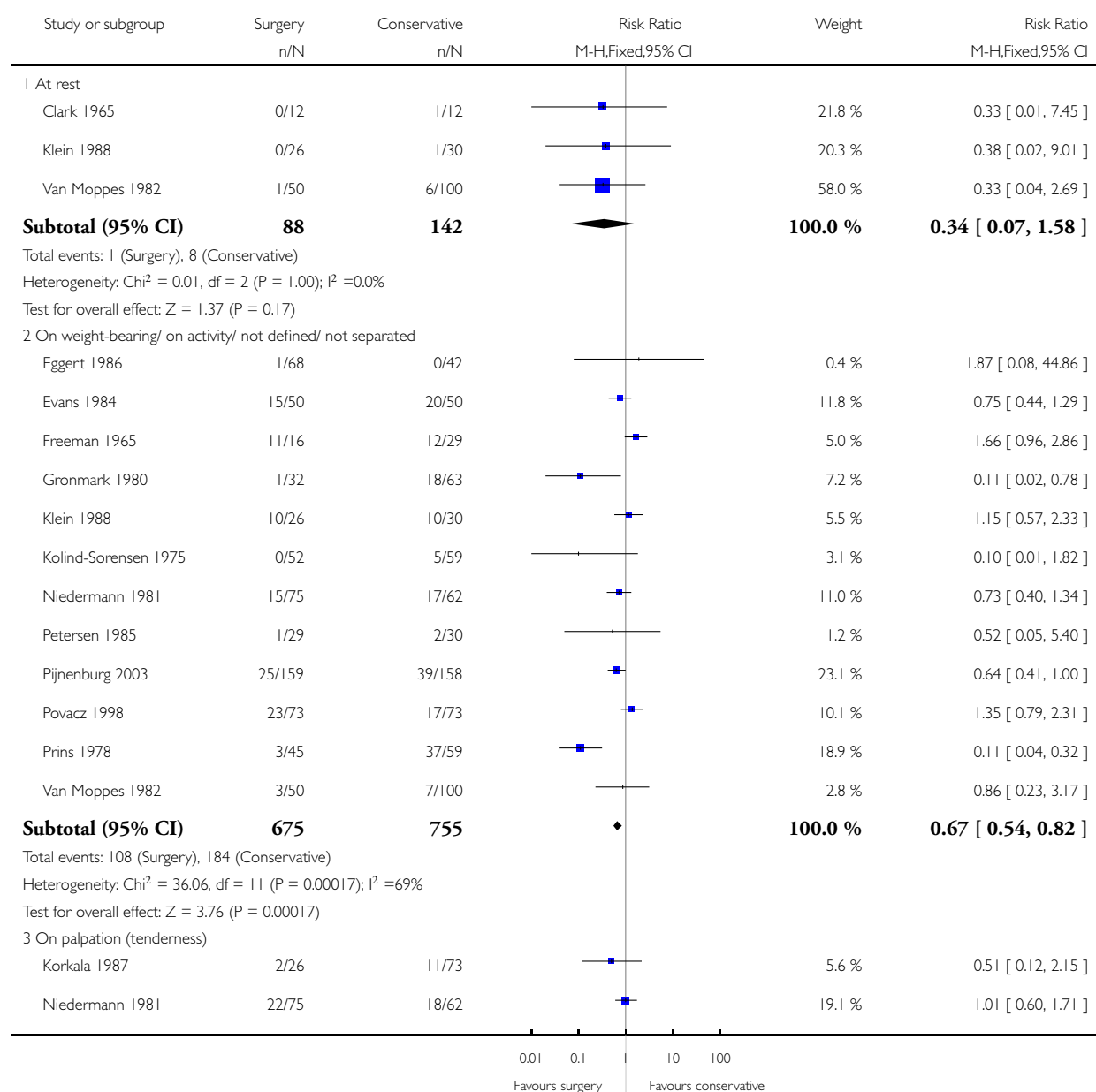


### Analysis 1.6. Comparison 1 Surgical versus Conservative treatment, Outcome 6 Long term pain or tenderness.

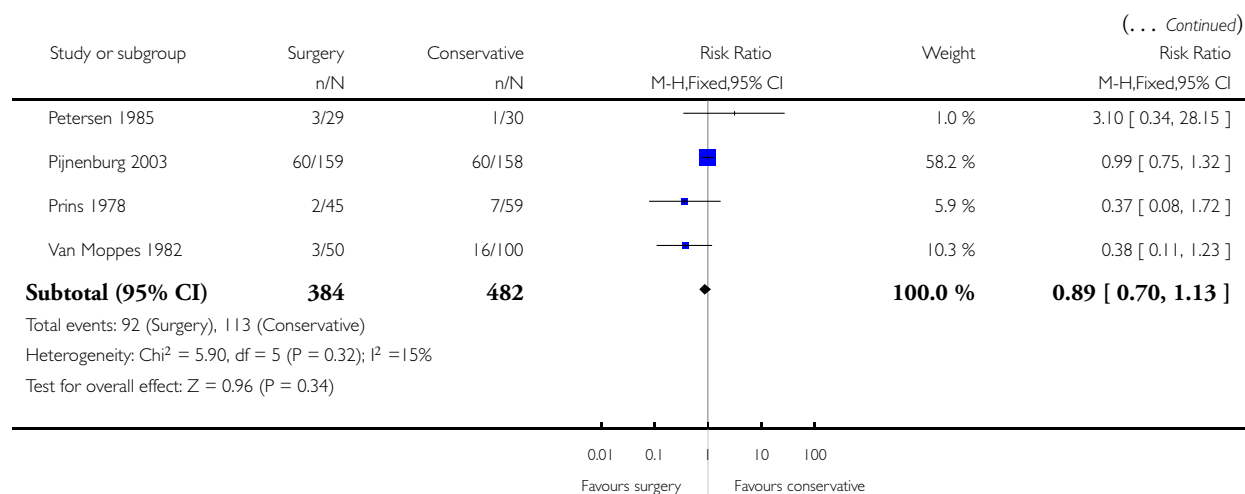
Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 6 Long term pain or tenderness



(Continued ...)

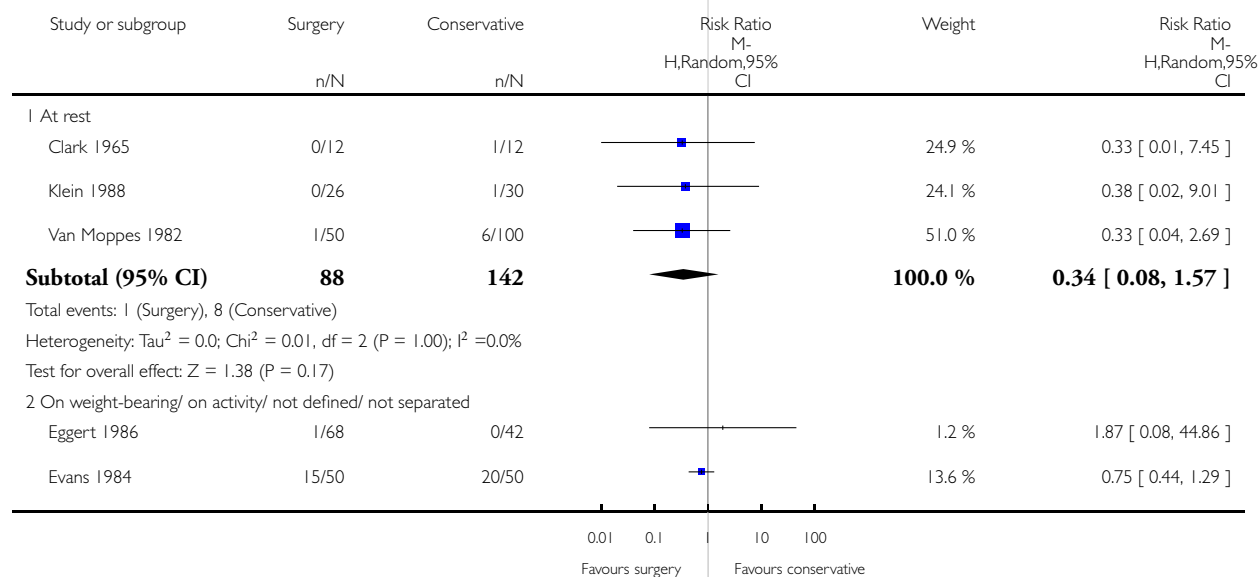


### Analysis 1.7. Comparison 1 Surgical versus Conservative treatment, Outcome 7 Long term pain or tenderness (random-effects model).

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

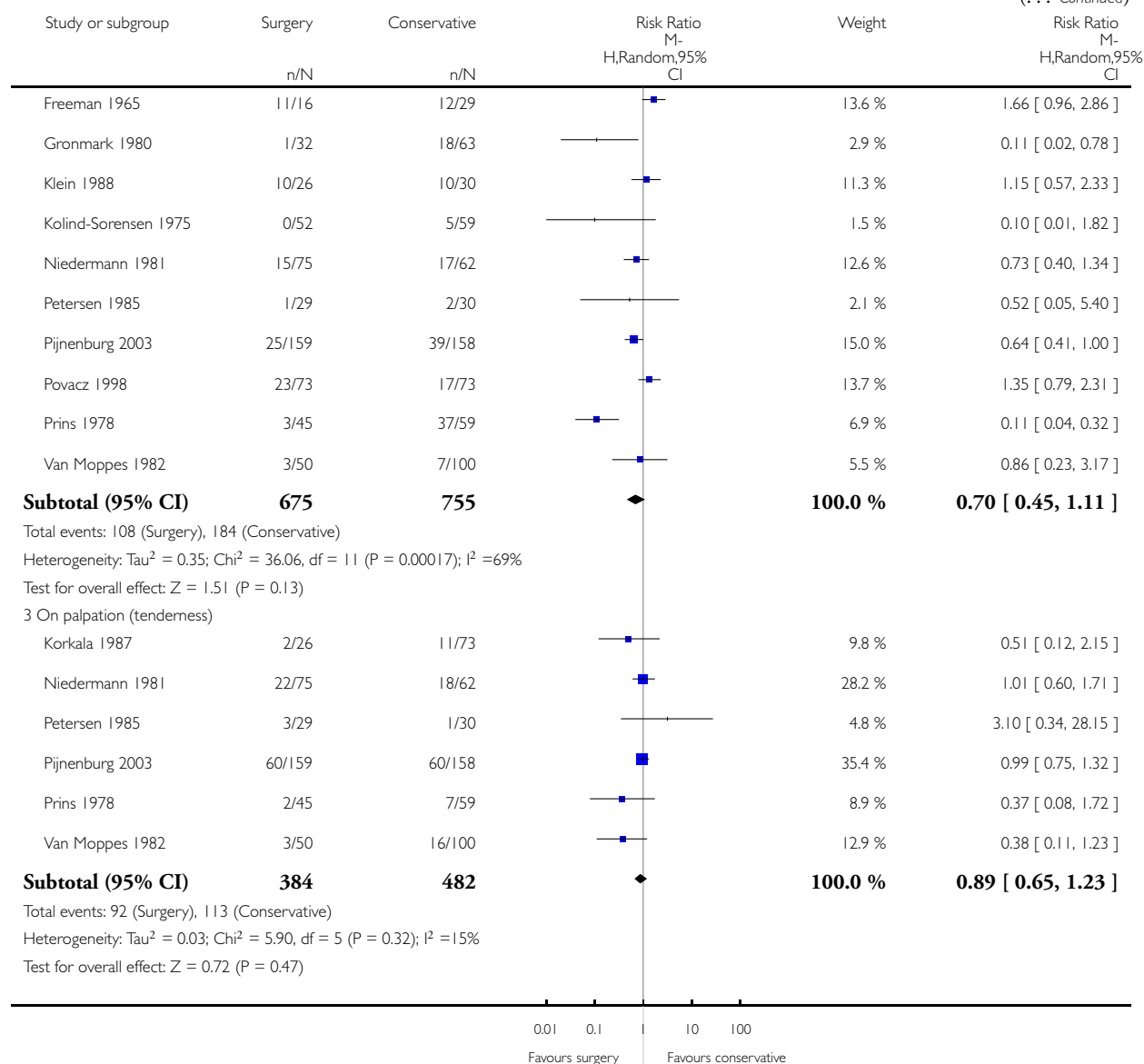
Comparison: 1 Surgical versus Conservative treatment

Outcome: 7 Long term pain or tenderness (random-effects model)



(Continued . . .)

(... Continued)



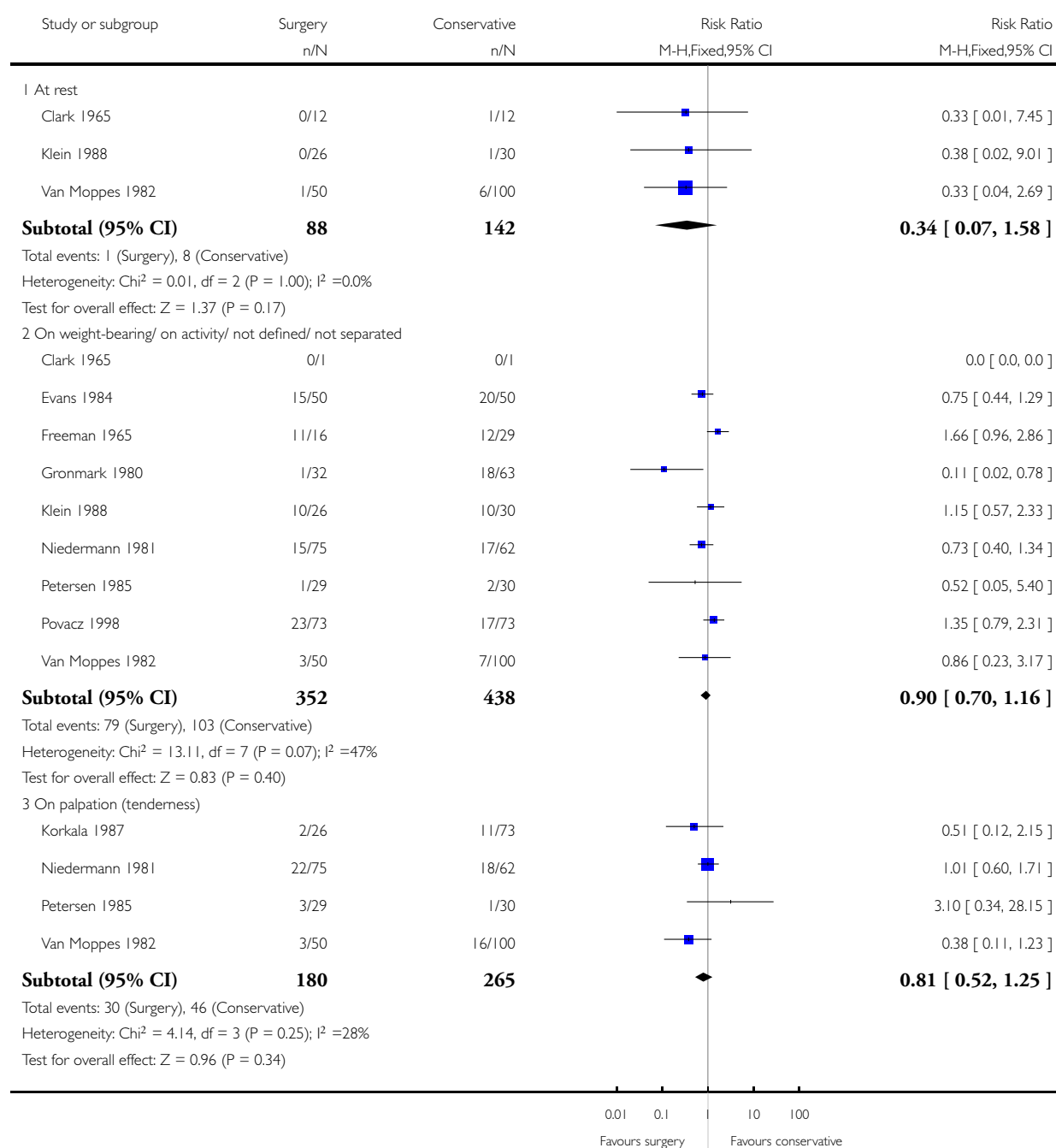


### Analysis 1.8. Comparison 1 Surgical versus Conservative treatment, Outcome 8 Long term pain or tenderness - trials with no concealment of allocation.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 8 Long term pain or tenderness - trials with no concealment of allocation

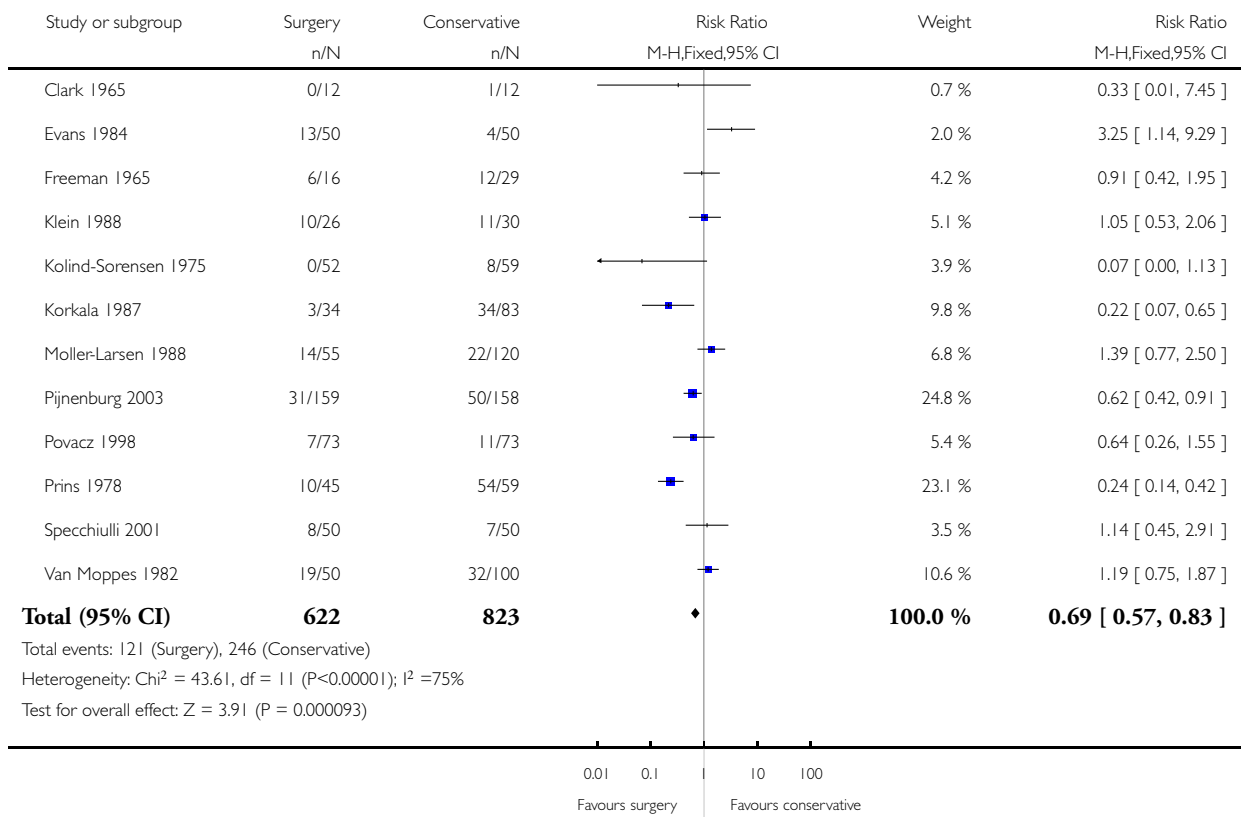


### Analysis 1.9. Comparison 1 Surgical versus Conservative treatment, Outcome 9 Subjective or functional instability.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 9 Subjective or functional instability

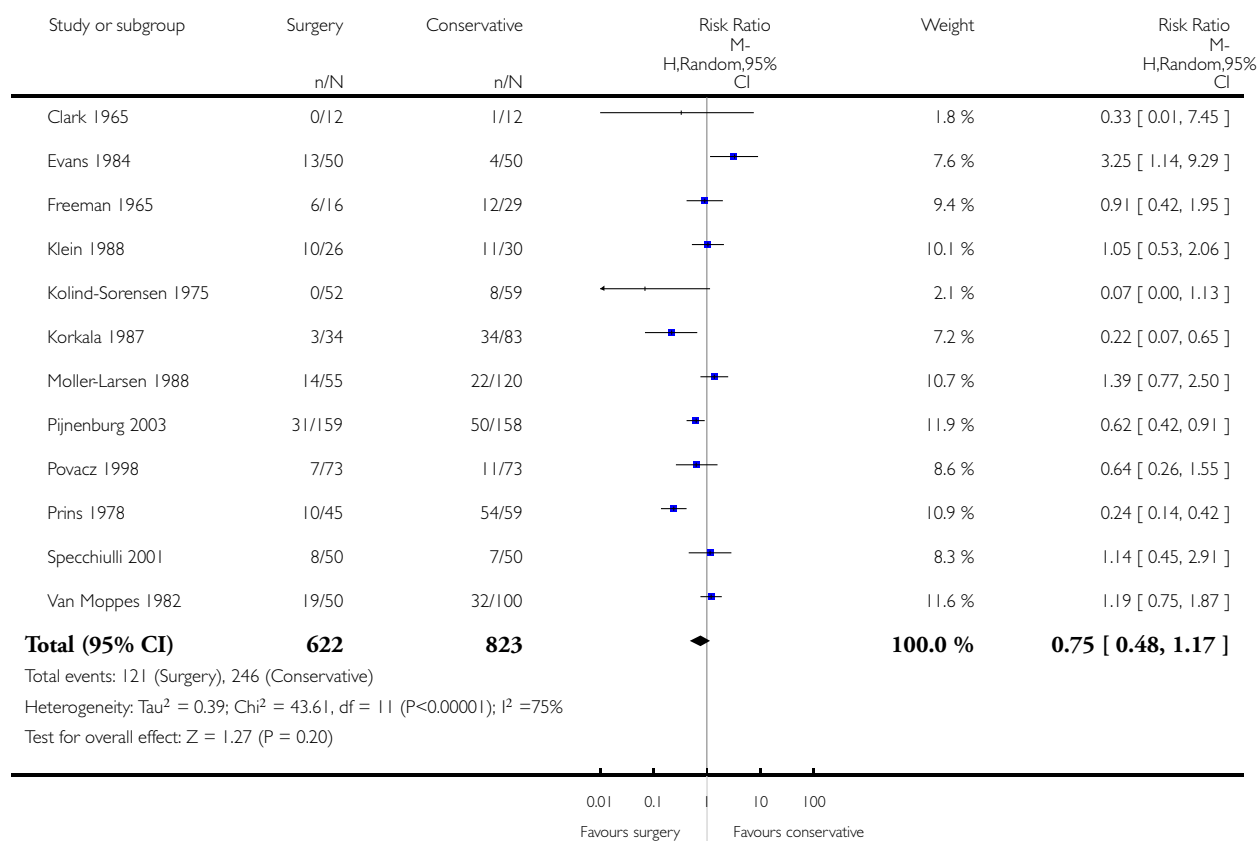


### Analysis 1.10. Comparison 1 Surgical versus Conservative treatment, Outcome 10 Subjective or functional instability (random-effects model).

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 10 Subjective or functional instability (random-effects model)

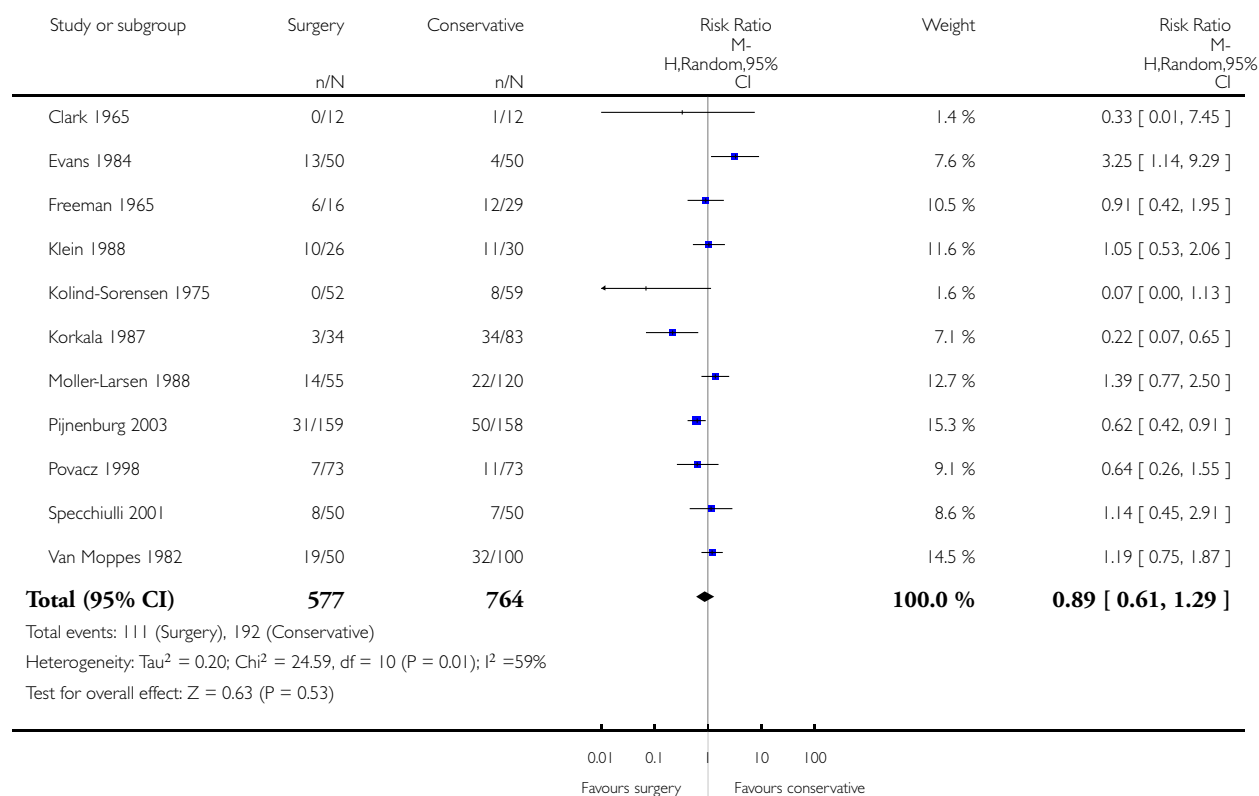


### Analysis 1.11. Comparison 1 Surgical versus Conservative treatment, Outcome 11 Subjective or functional instability - Prins 1978.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 11 Subjective or functional instability - Prins 1978

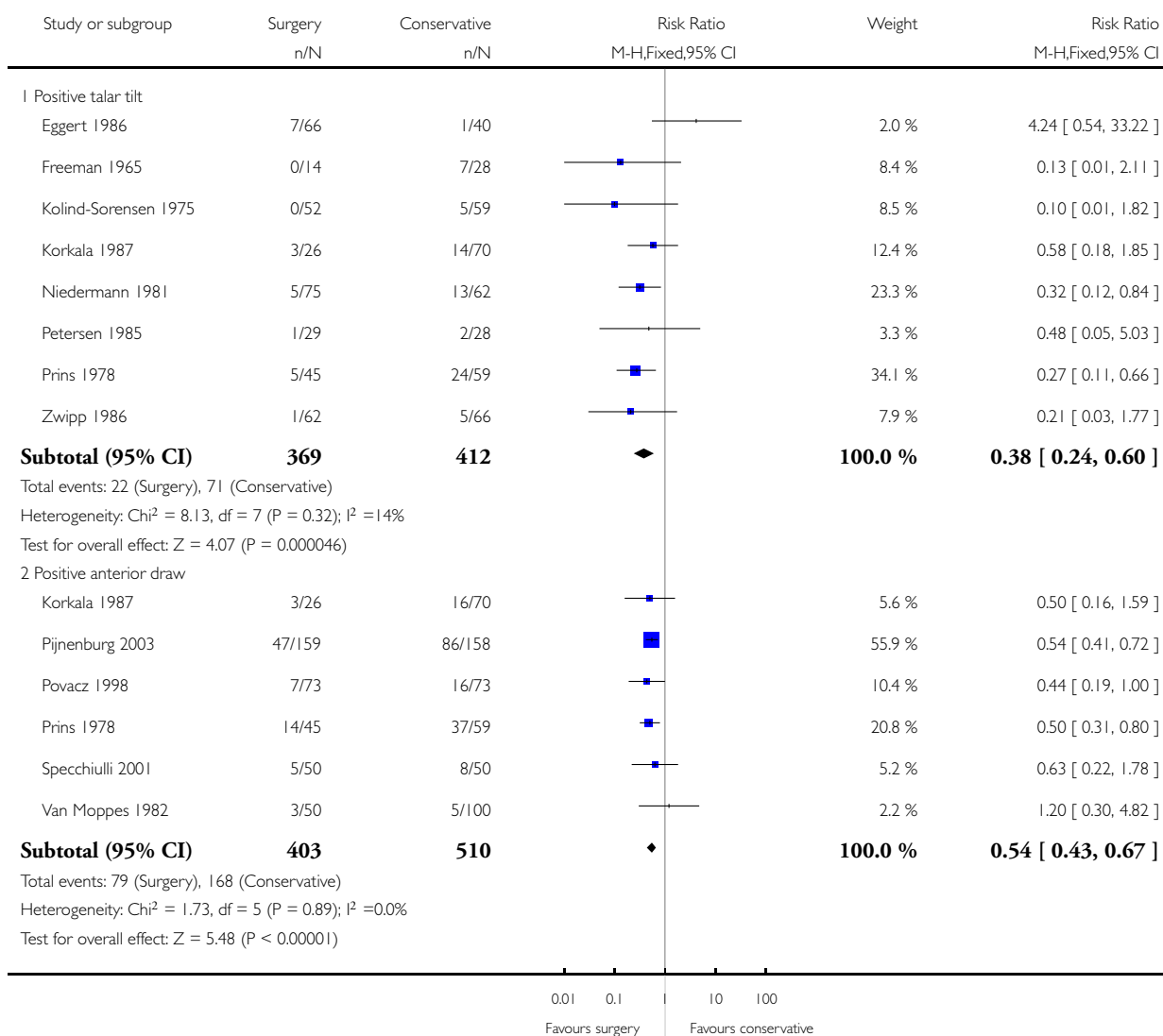


### Analysis 1.12. Comparison 1 Surgical versus Conservative treatment, Outcome 12 Objective instability (talar tilt or anterior draw).

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 12 Objective instability (talar tilt or anterior draw)

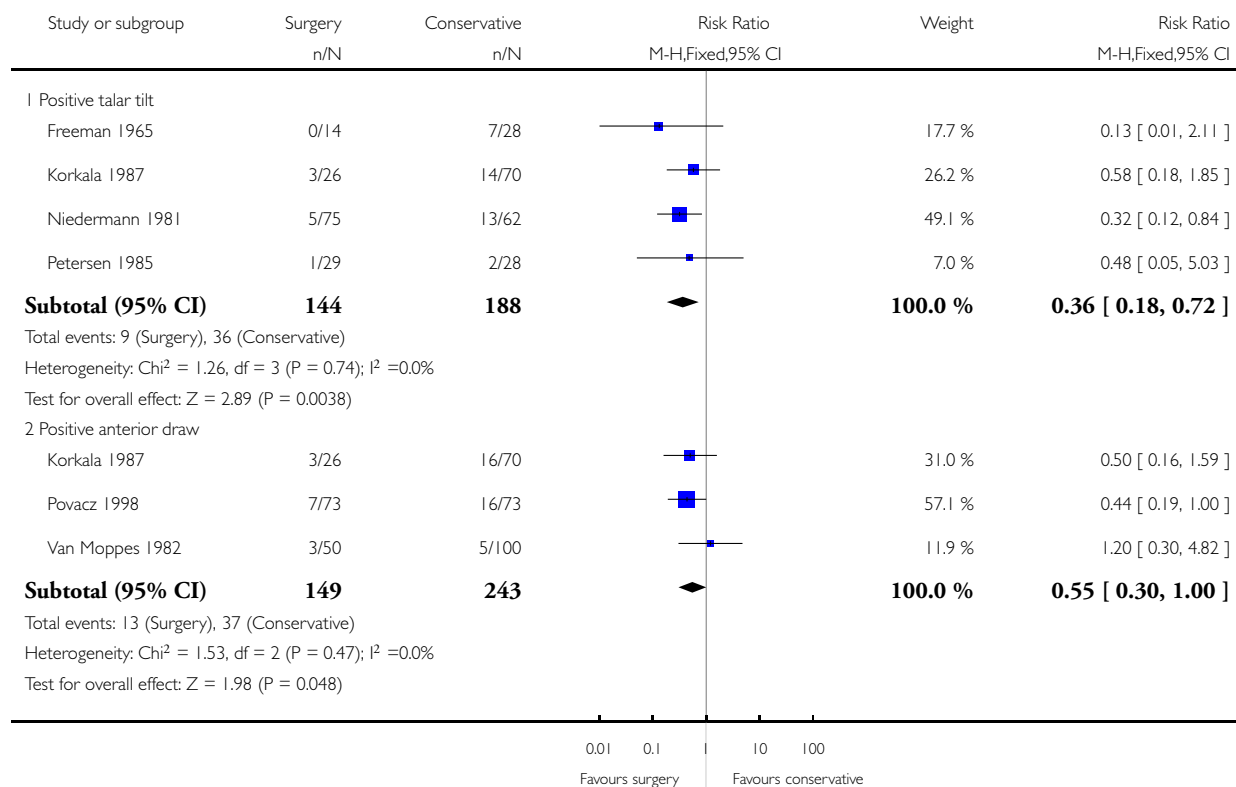


**Analysis 1.13. Comparison 1 Surgical versus Conservative treatment, Outcome 13 Objective instability (talar tilt or anterior draw) - trials with no concealment of allocation.**

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 13 Objective instability (talar tilt or anterior draw) - trials with no concealment of allocation

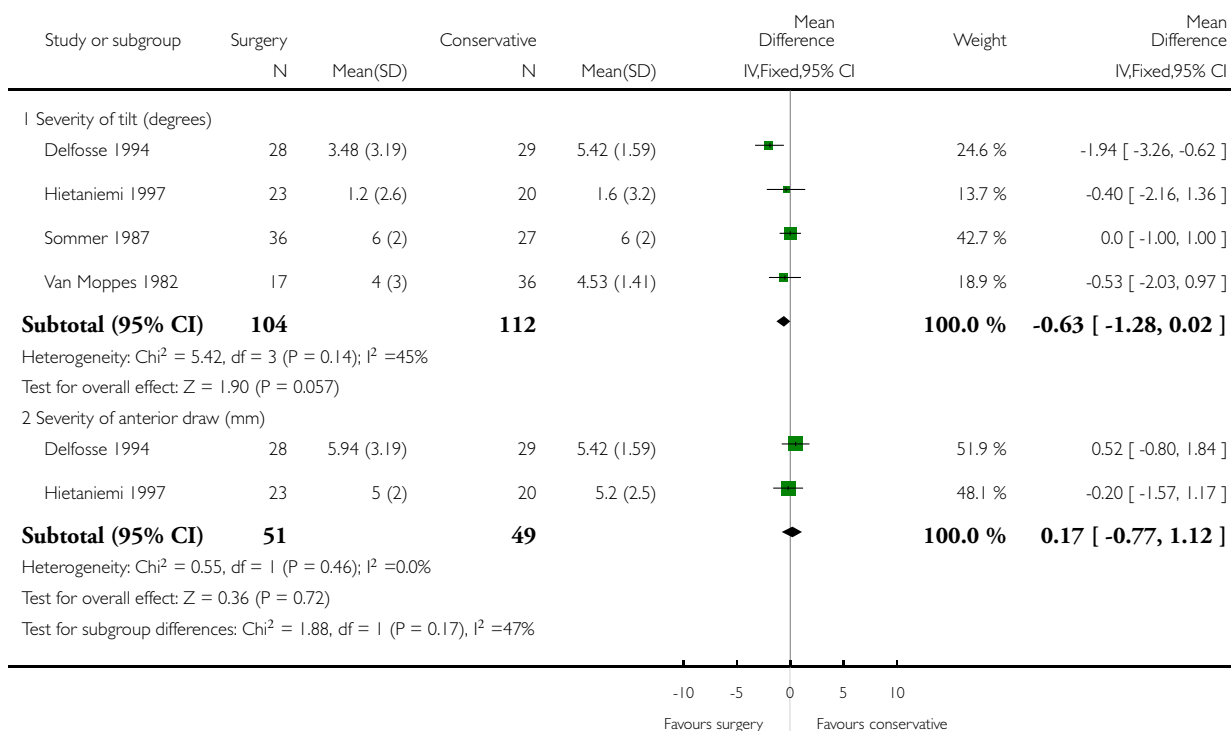


### Analysis 1.14. Comparison 1 Surgical versus Conservative treatment, Outcome 14 Objective instability (severity).

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 14 Objective instability (severity)

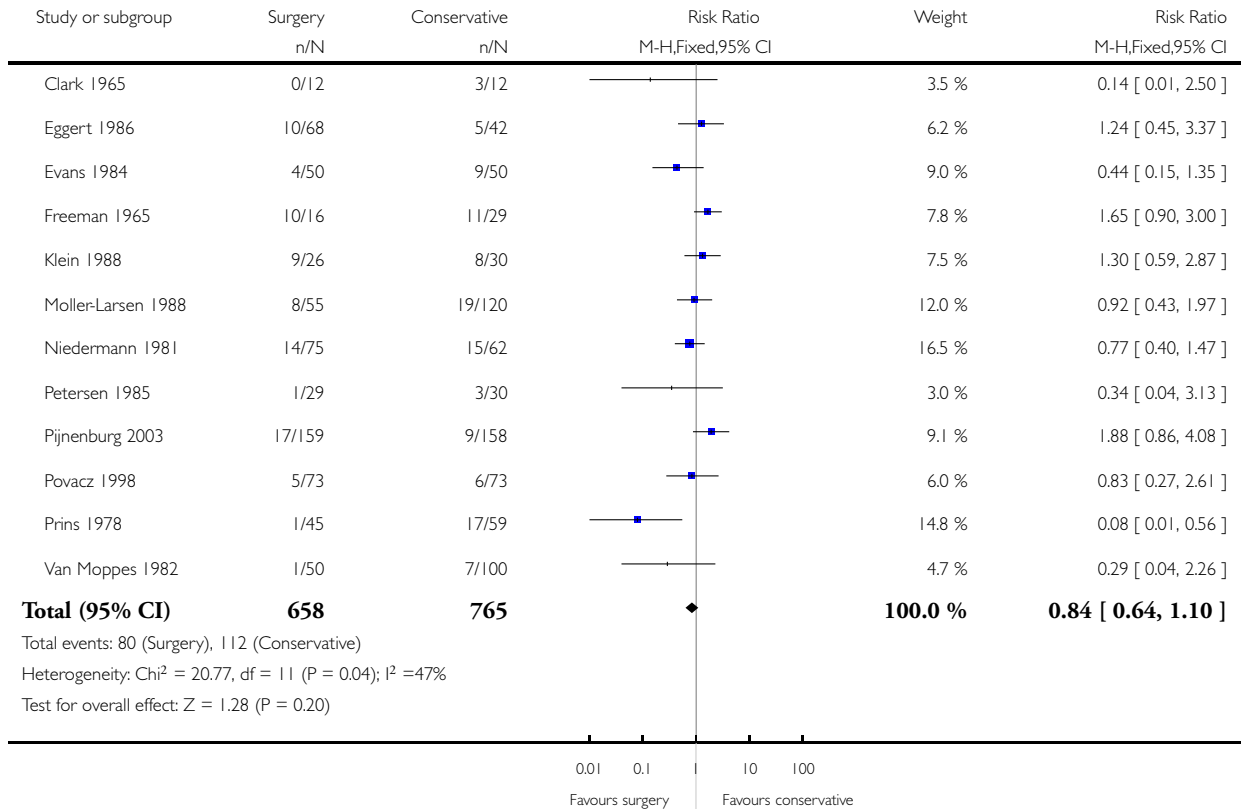


### Analysis 1.15. Comparison 1 Surgical versus Conservative treatment, Outcome 15 Swelling.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 15 Swelling



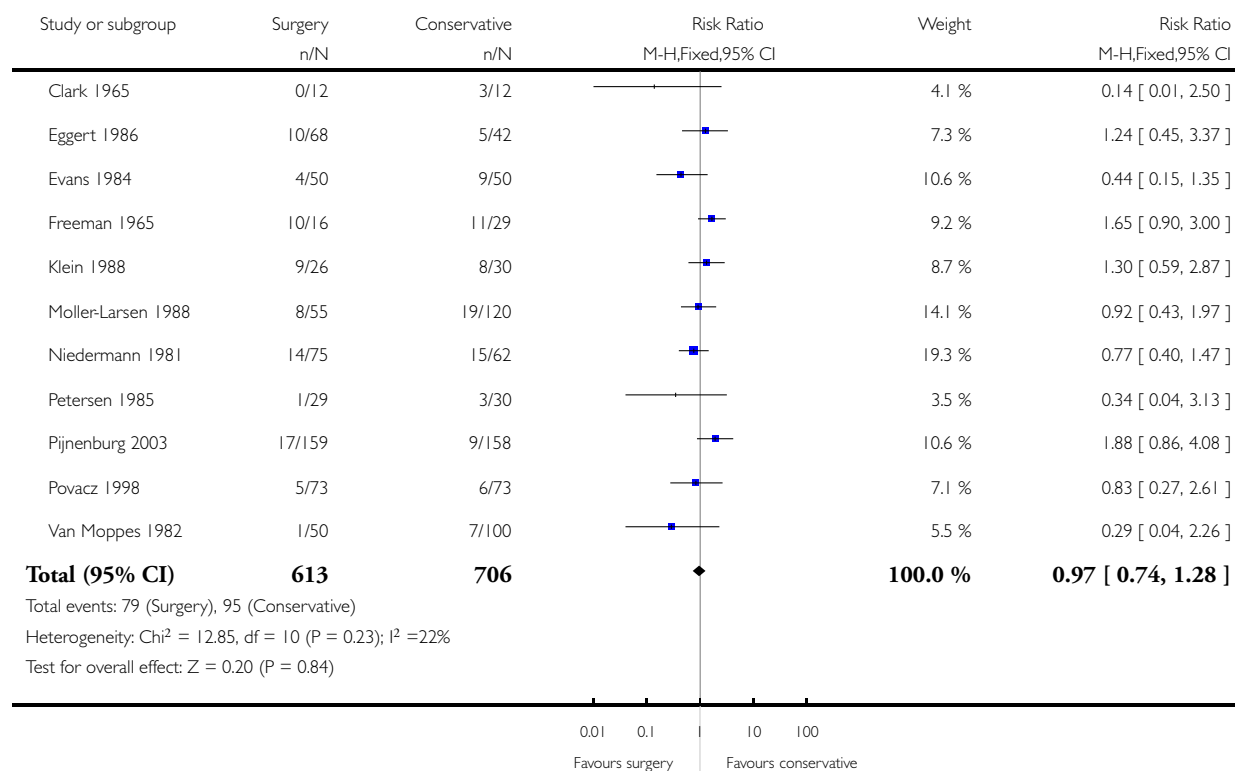


### Analysis 1.16. Comparison 1 Surgical versus Conservative treatment, Outcome 16 Swelling - Prins 1978.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 16 Swelling - Prins 1978

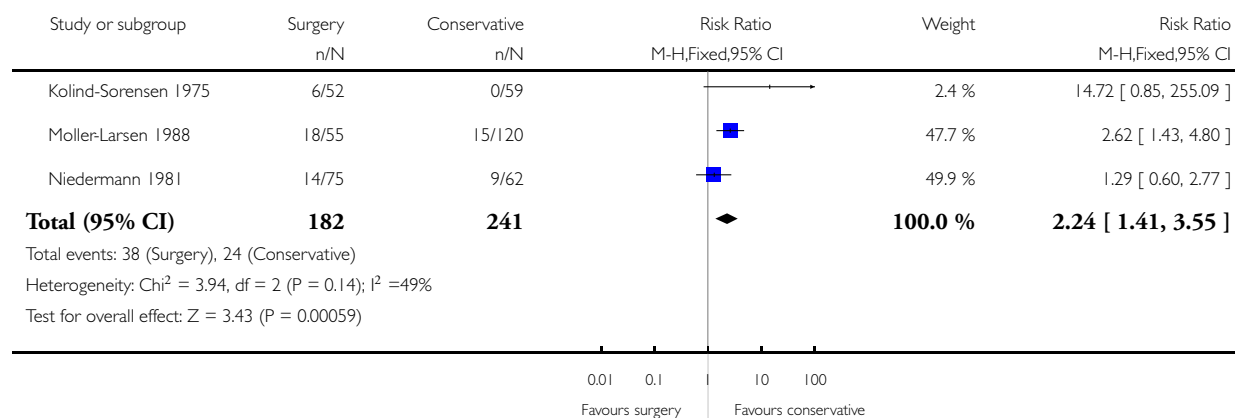


### Analysis 1.17. Comparison 1 Surgical versus Conservative treatment, Outcome 17 Stiffness.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 17 Stiffness

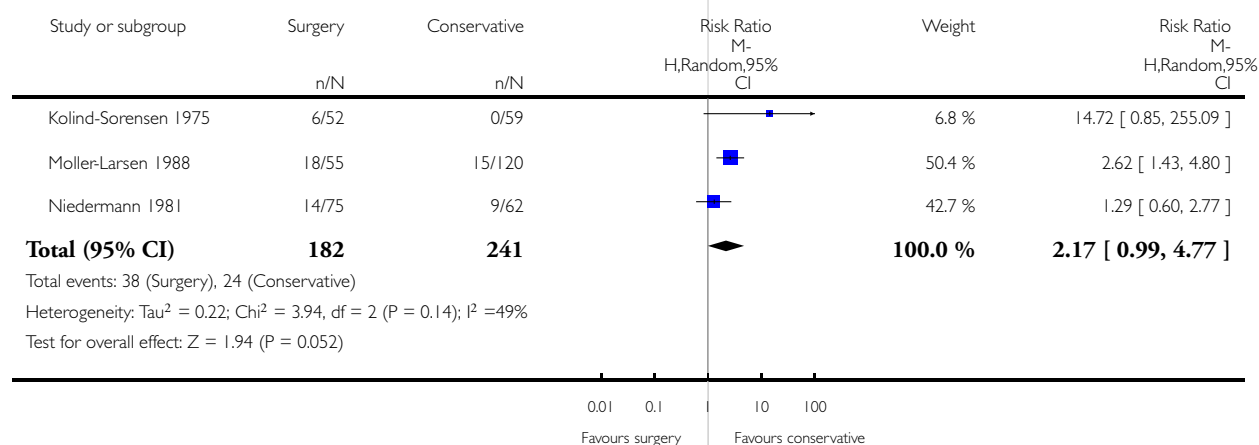


### Analysis 1.18. Comparison 1 Surgical versus Conservative treatment, Outcome 18 Stiffness (random-effects model).

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 18 Stiffness (random-effects model)

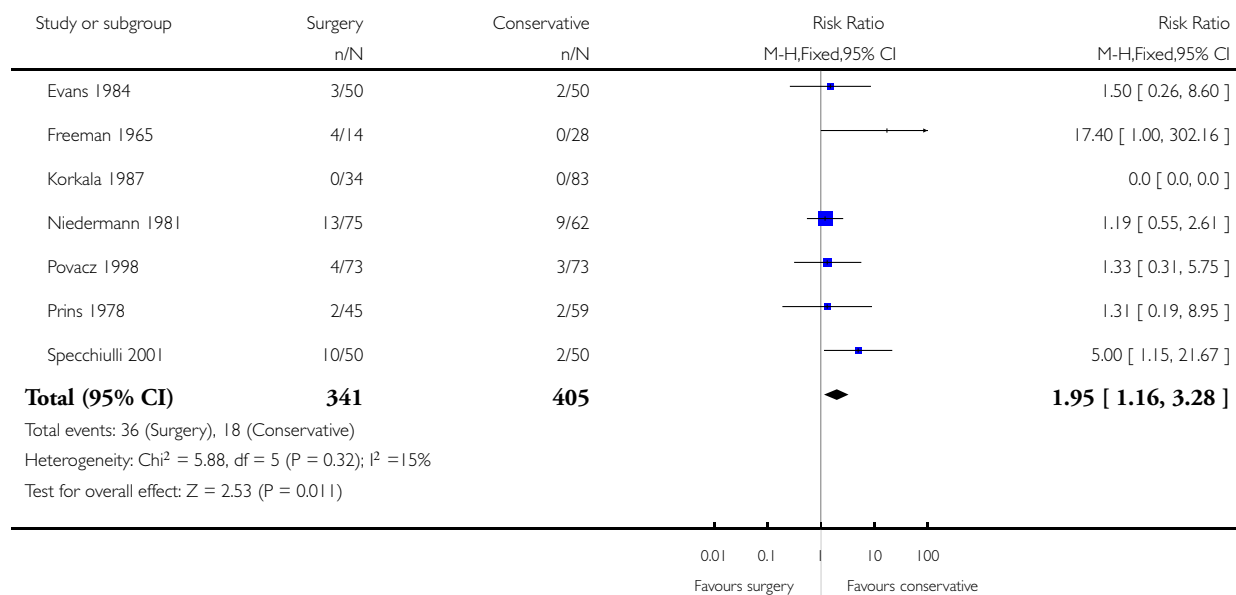


**Analysis 1.19. Comparison 1 Surgical versus Conservative treatment, Outcome 19 Ankle mobility: reduced range of motion (ROM).**

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 19 Ankle mobility: reduced range of motion (ROM)

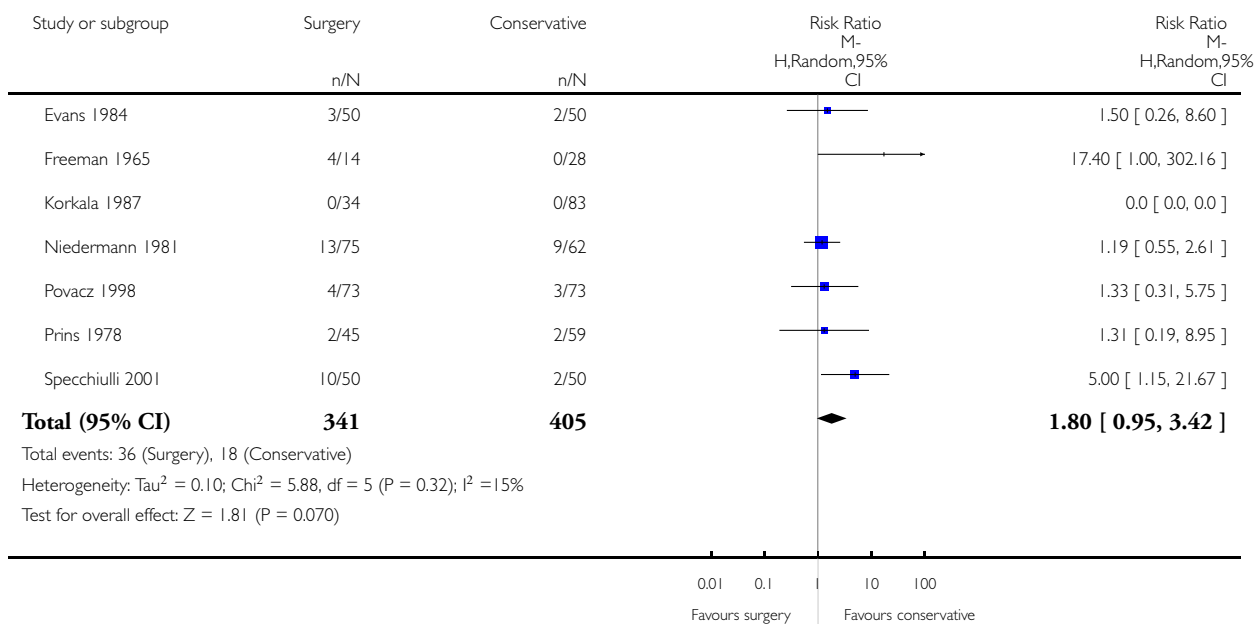


**Analysis 1.20. Comparison 1 Surgical versus Conservative treatment, Outcome 20 Ankle mobility: reduced range of motion (ROM) (random-effects model).**

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 20 Ankle mobility: reduced range of motion (ROM) (random-effects model)

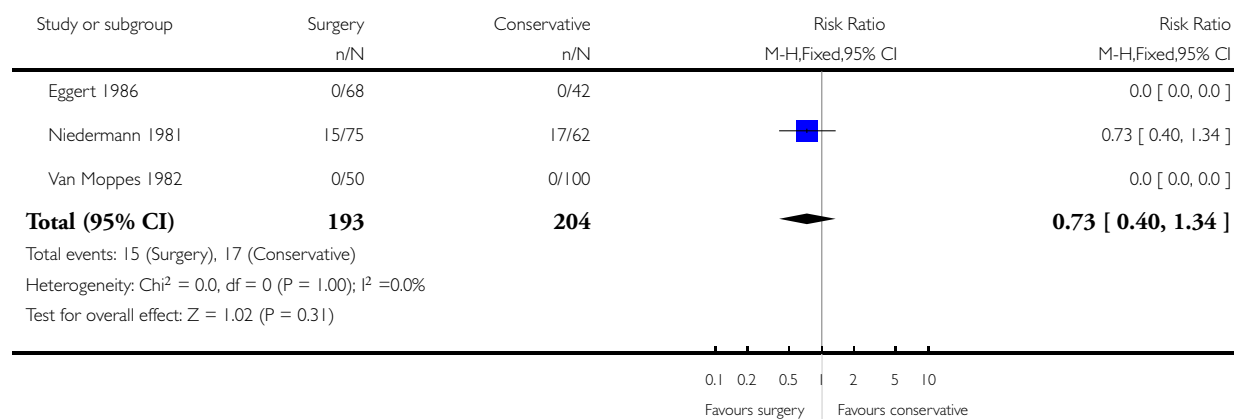


### Analysis 1.21. Comparison 1 Surgical versus Conservative treatment, Outcome 21 Muscle atrophy.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 21 Muscle atrophy

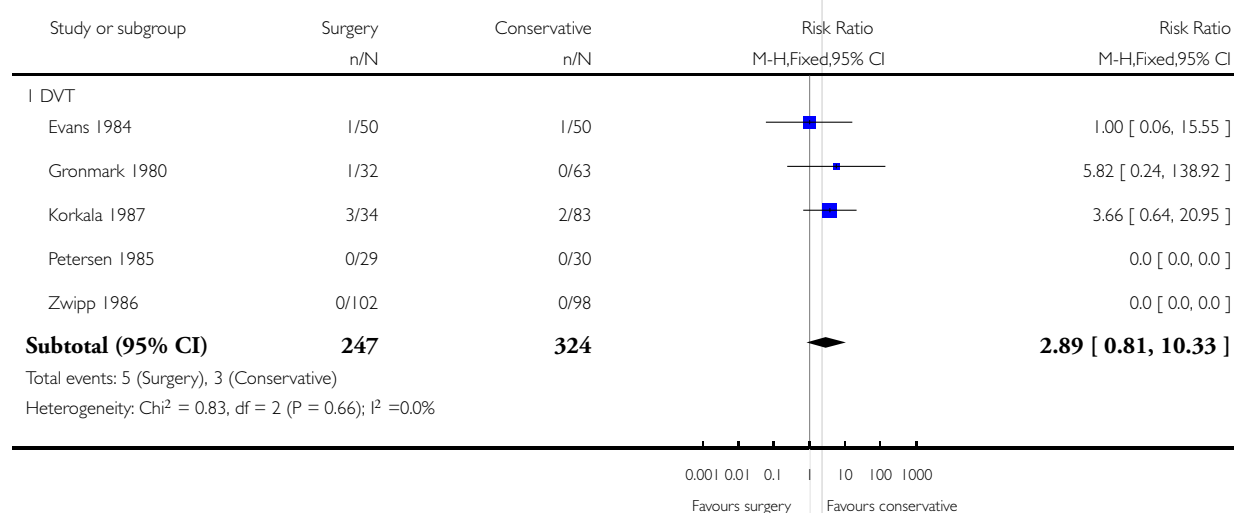


### Analysis 1.22. Comparison 1 Surgical versus Conservative treatment, Outcome 22 Complications.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

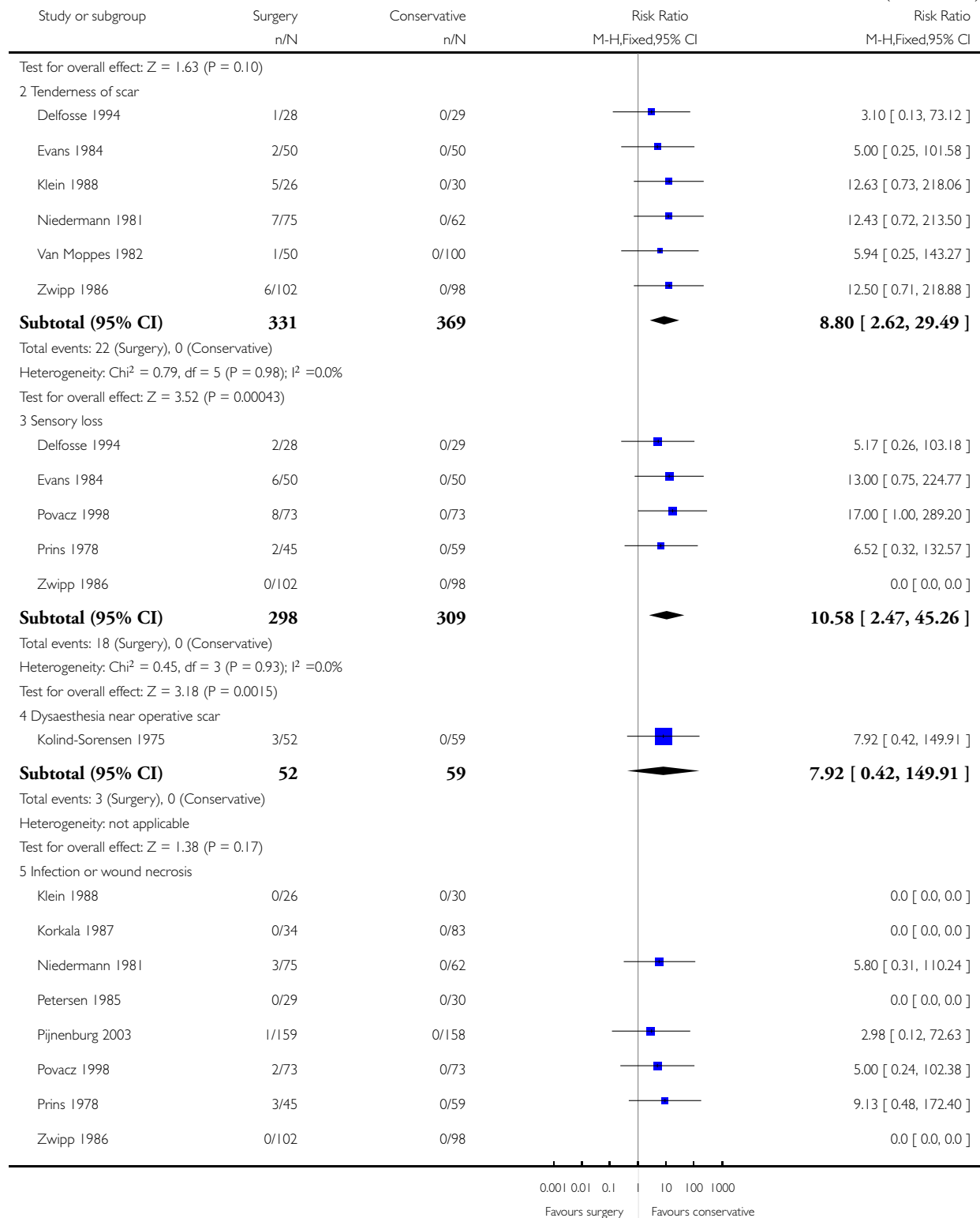
Comparison: 1 Surgical versus Conservative treatment

Outcome: 22 Complications



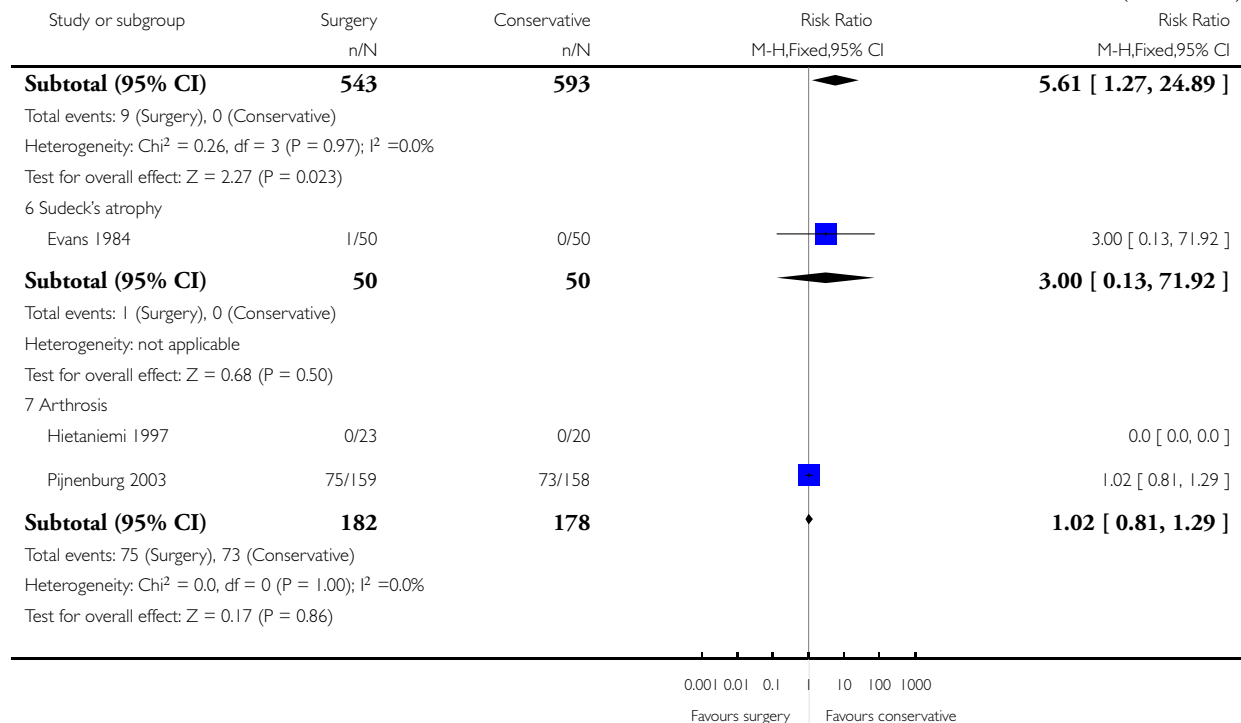
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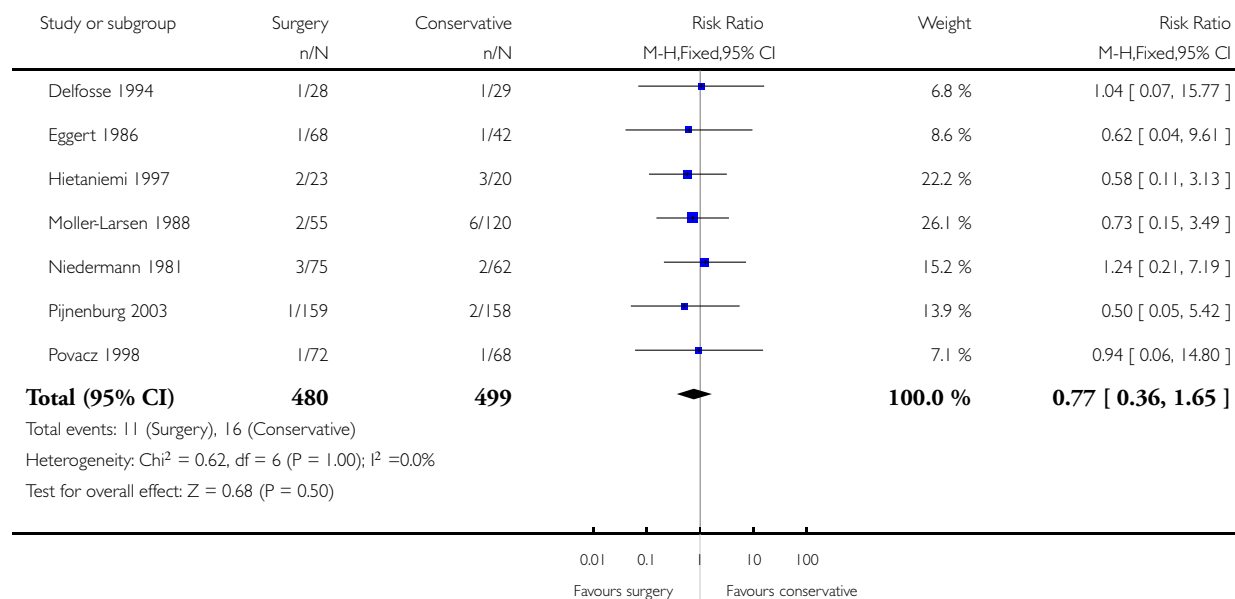


### Analysis 1.23. Comparison 1 Surgical versus Conservative treatment, Outcome 23 Poor (much worse) result according to patients.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 1 Surgical versus Conservative treatment

Outcome: 23 Poor (much worse) result according to patients



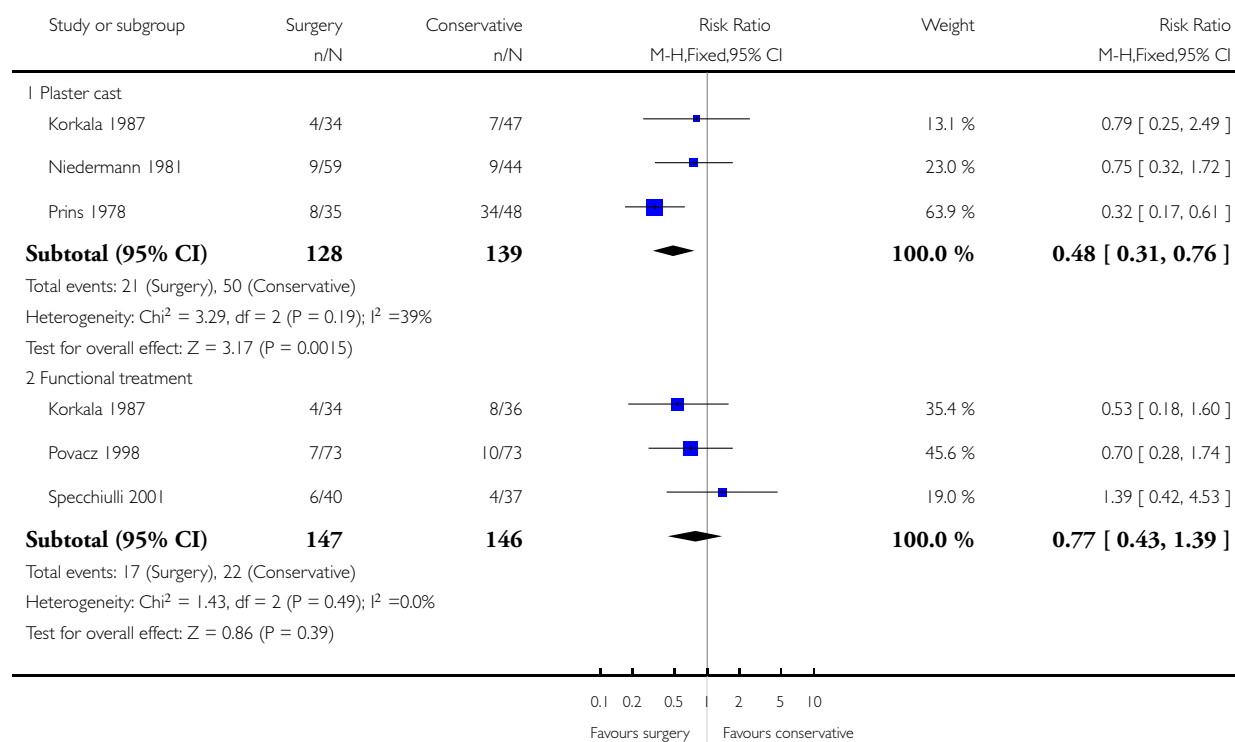


## Analysis 2.1. Comparison 2 Surgical versus Conservative treatment: by conservative method, Outcome 1 Non-return to sport or reduction in sporting activity.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 2 Surgical versus Conservative treatment: by conservative method

Outcome: 1 Non-return to sport or reduction in sporting activity

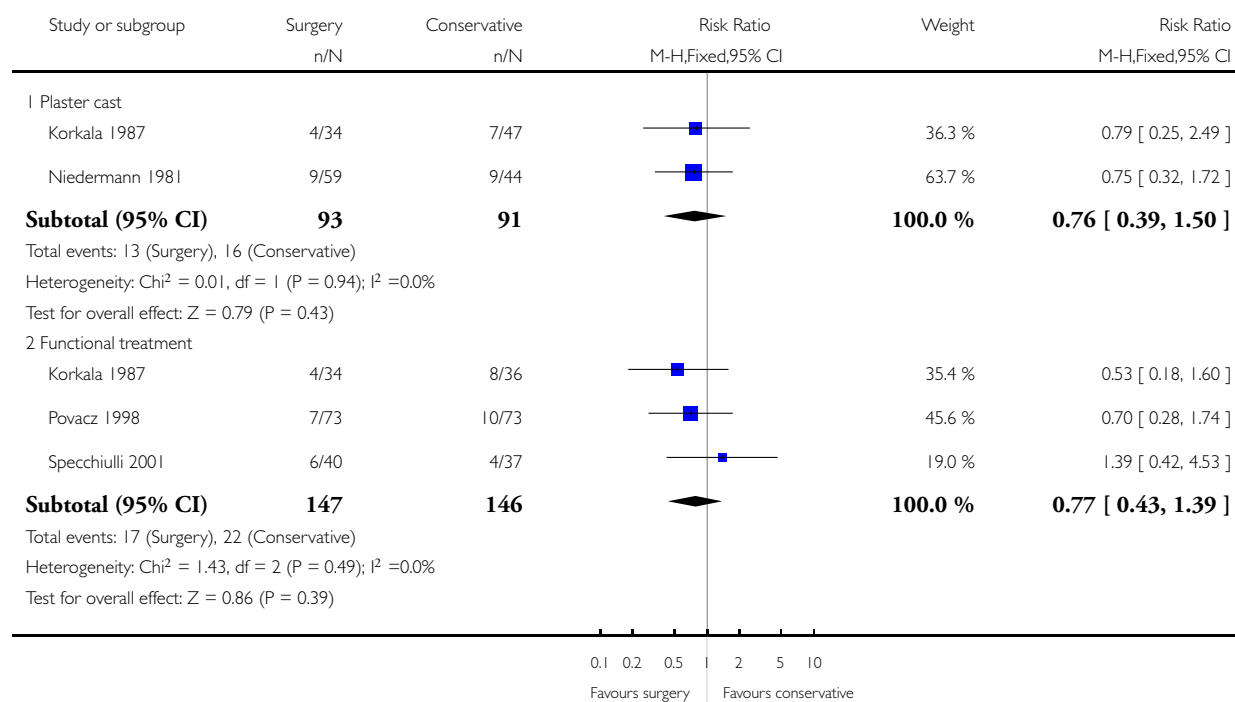


## Analysis 2.2. Comparison 2 Surgical versus Conservative treatment: by conservative method, Outcome 2 Non-return to sport or reduction in sporting activity - Prins 1978.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 2 Surgical versus Conservative treatment: by conservative method

Outcome: 2 Non-return to sport or reduction in sporting activity - Prins 1978

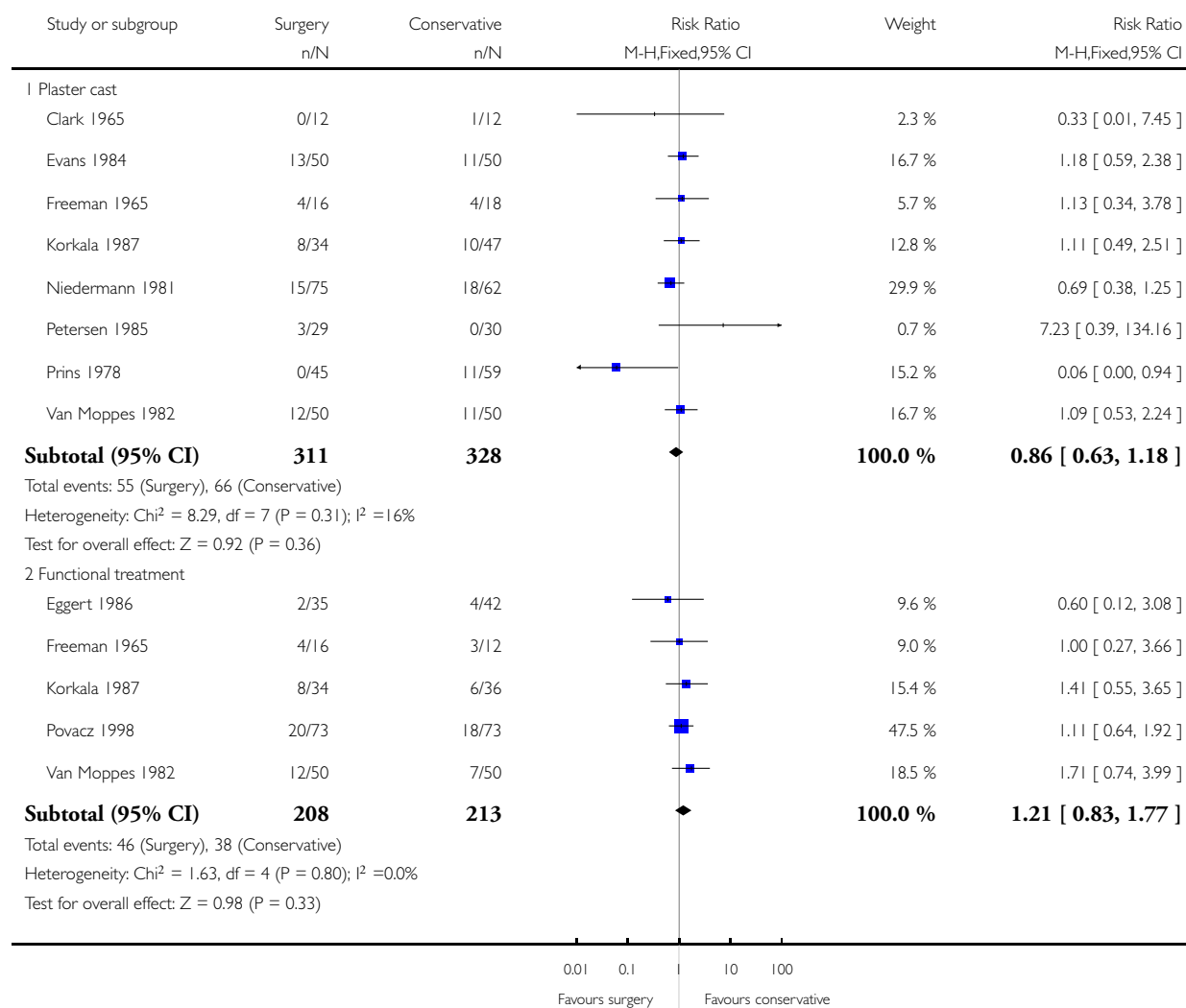


### Analysis 2.3. Comparison 2 Surgical versus Conservative treatment: by conservative method, Outcome 3 Recurrence or reinjury.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 2 Surgical versus Conservative treatment: by conservative method

Outcome: 3 Recurrence or reinjury

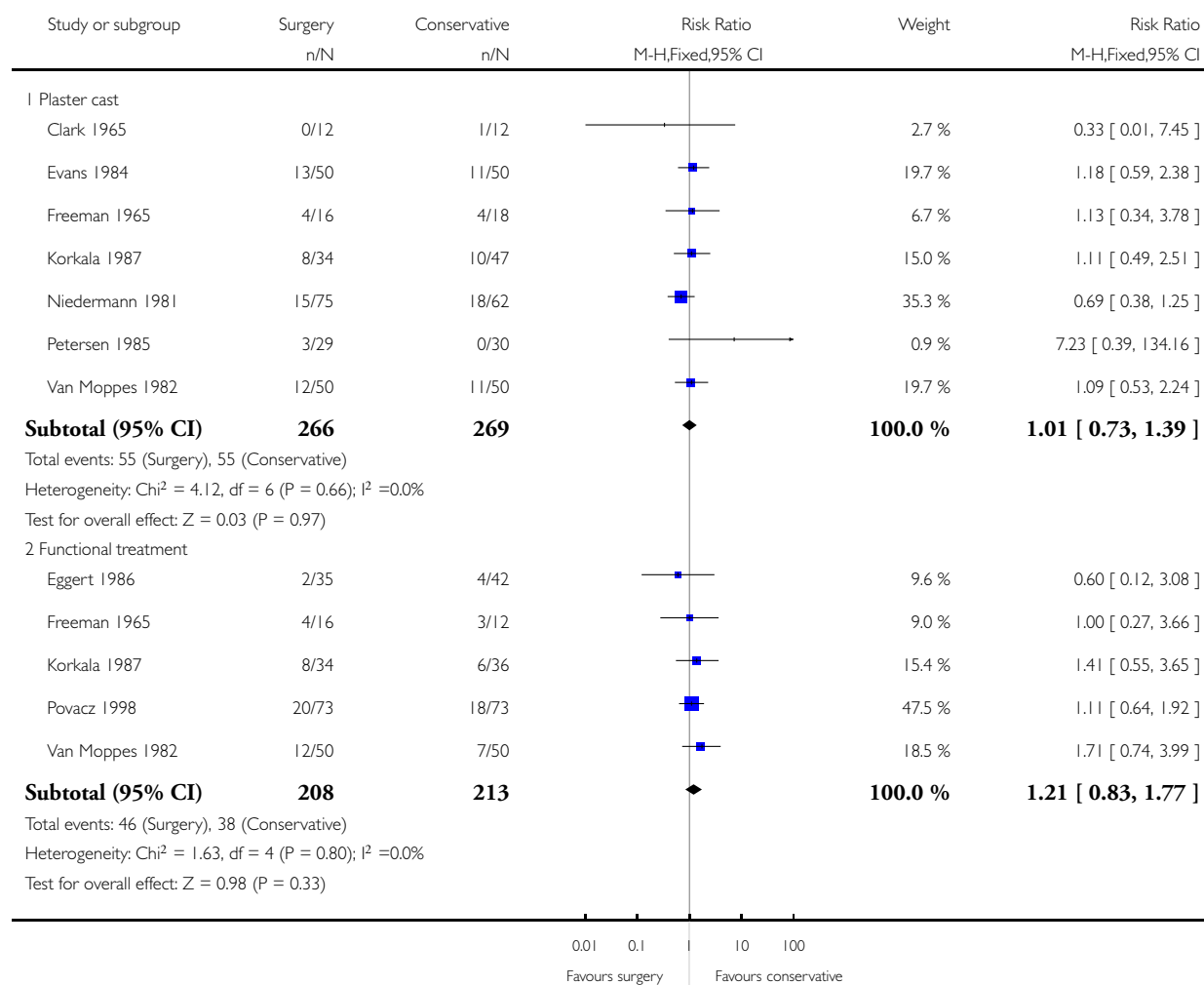


### Analysis 2.4. Comparison 2 Surgical versus Conservative treatment: by conservative method, Outcome 4 Recurrence or reinjury - Prins 1978.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 2 Surgical versus Conservative treatment: by conservative method

Outcome: 4 Recurrence or reinjury - Prins 1978

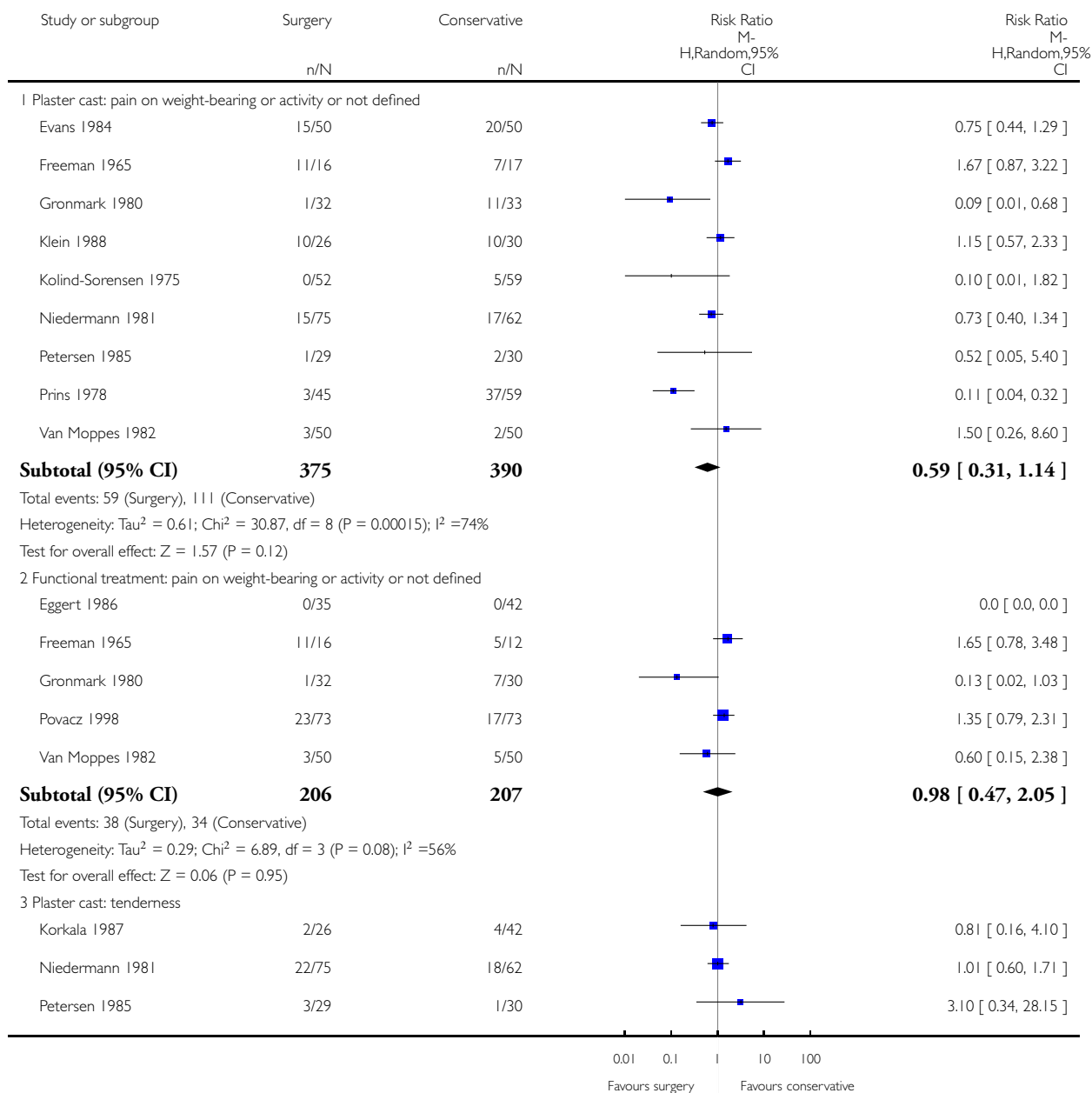


## Analysis 2.5. Comparison 2 Surgical versus Conservative treatment: by conservative method, Outcome 5 Pain or tenderness.

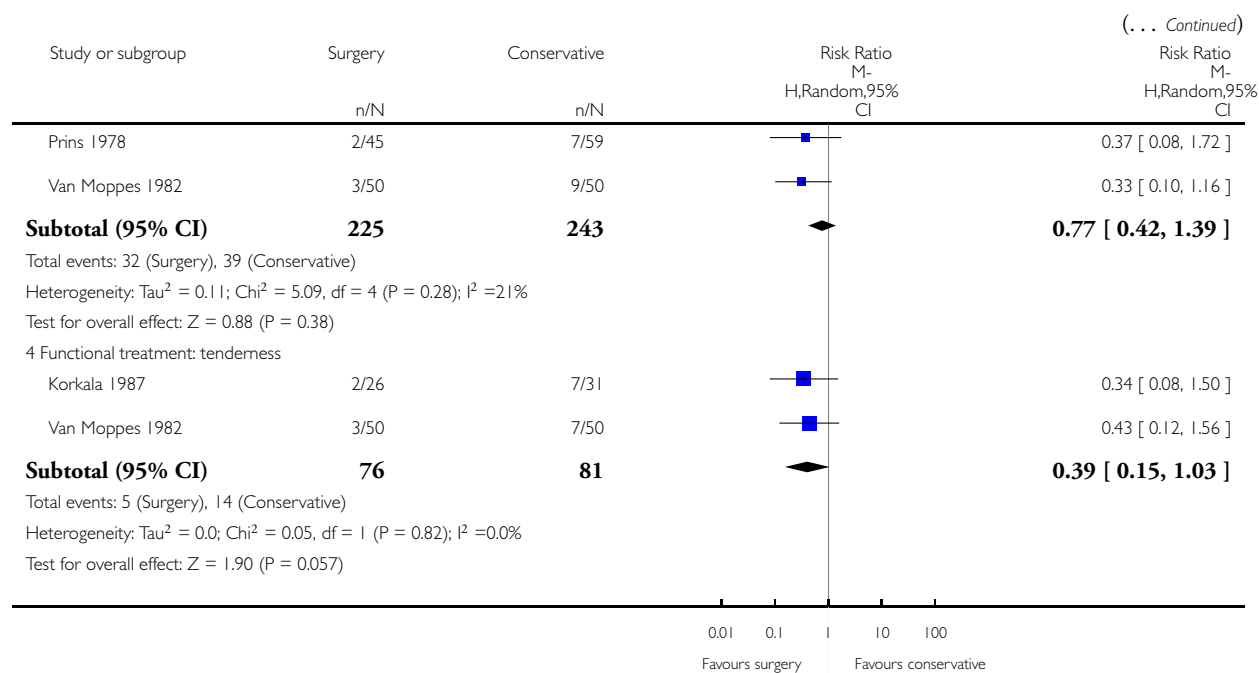
Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 2 Surgical versus Conservative treatment: by conservative method

Outcome: 5 Pain or tenderness



(Continued ...)

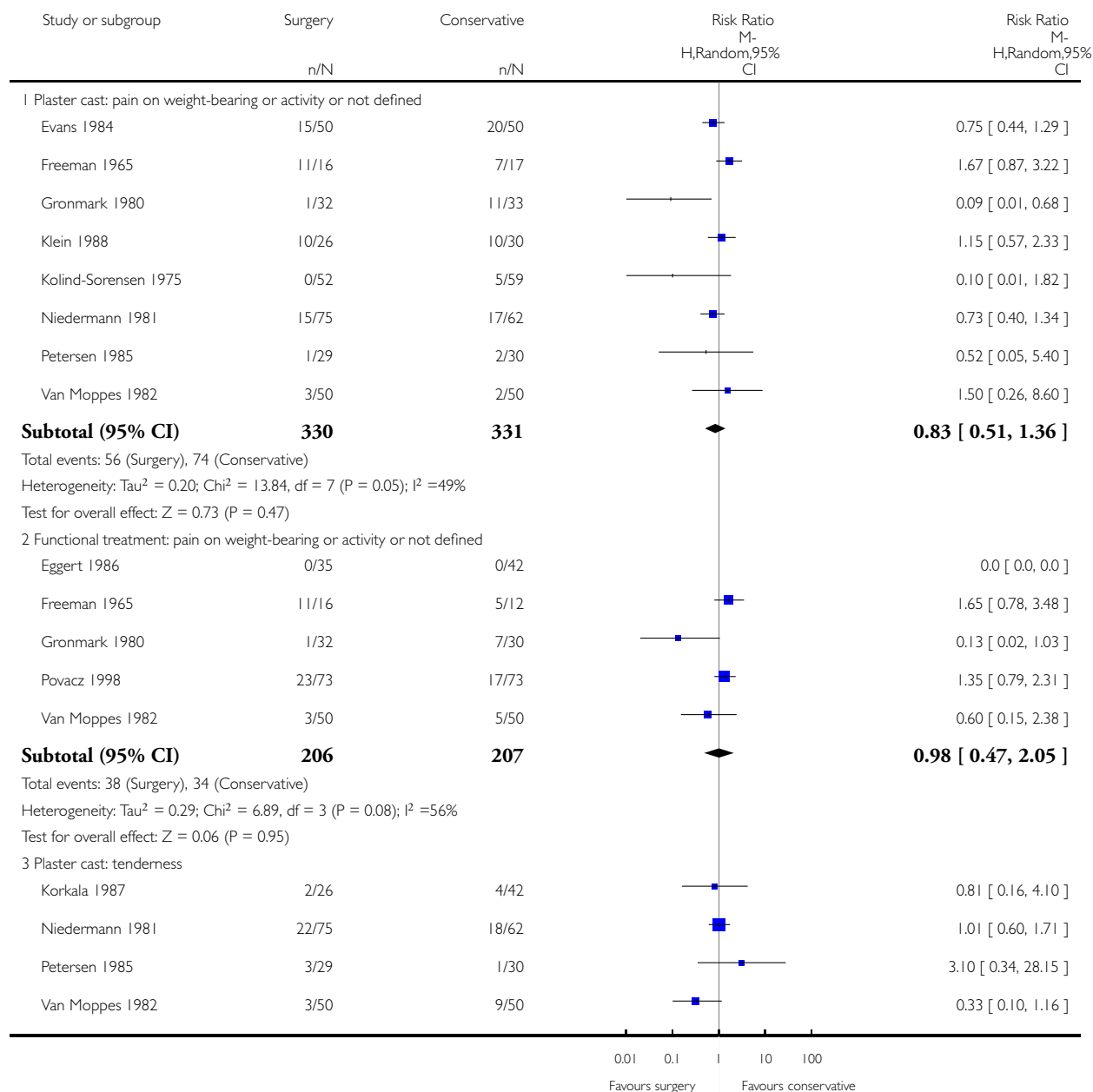


## Analysis 2.6. Comparison 2 Surgical versus Conservative treatment: by conservative method, Outcome 6 Pain or tenderness - Prins 1978.

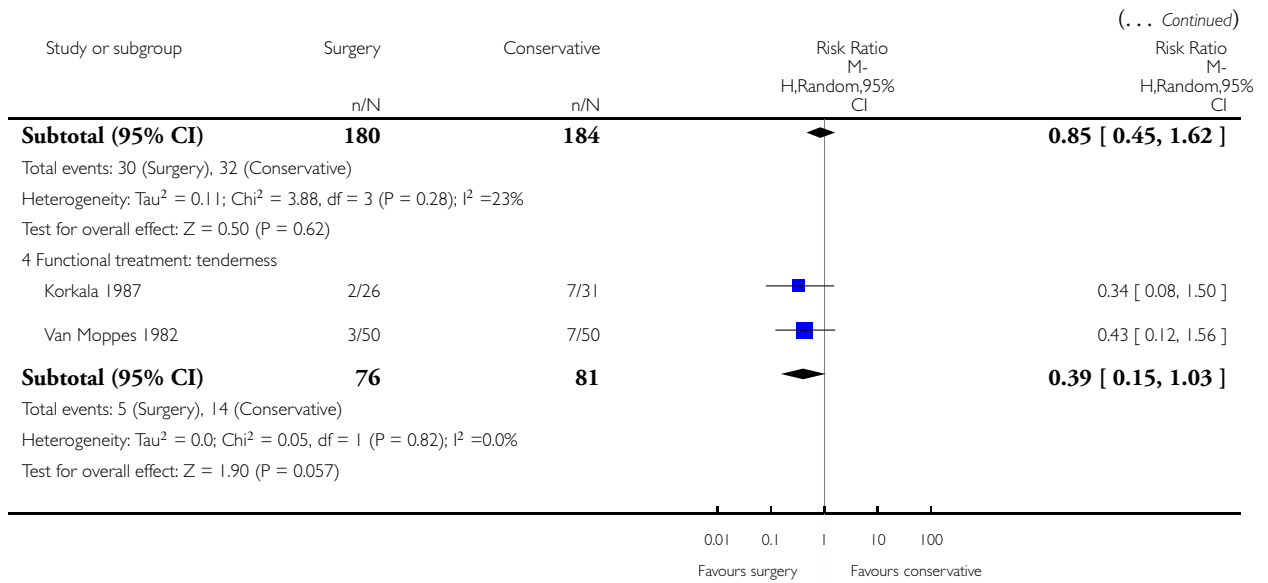
Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 2 Surgical versus Conservative treatment: by conservative method

Outcome: 6 Pain or tenderness - Prins 1978



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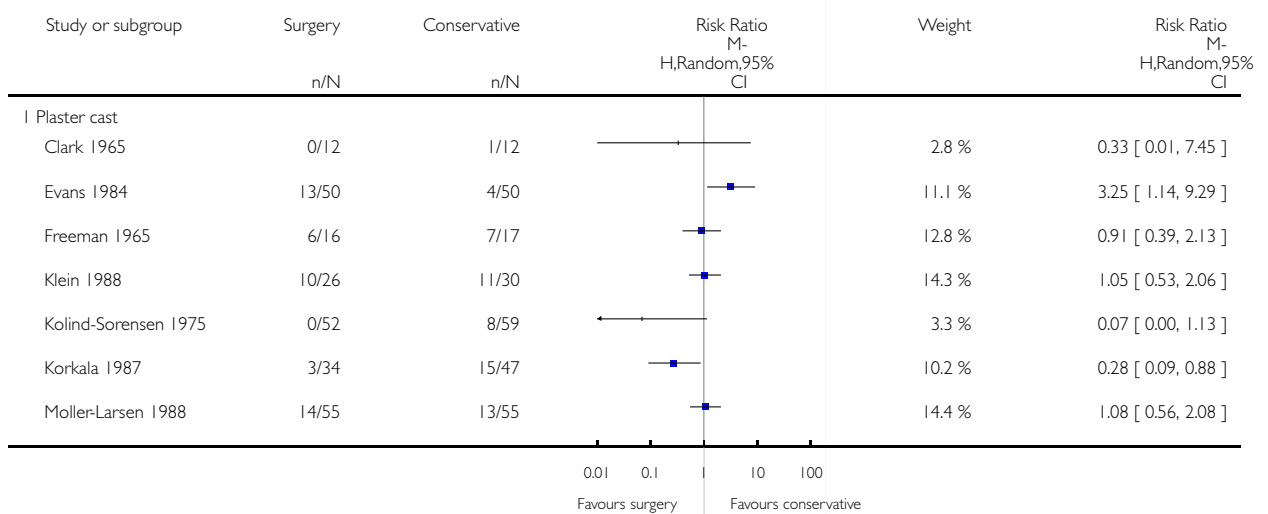


### Analysis 2.7. Comparison 2 Surgical versus Conservative treatment: by conservative method, Outcome 7 Subjective or functional instability.

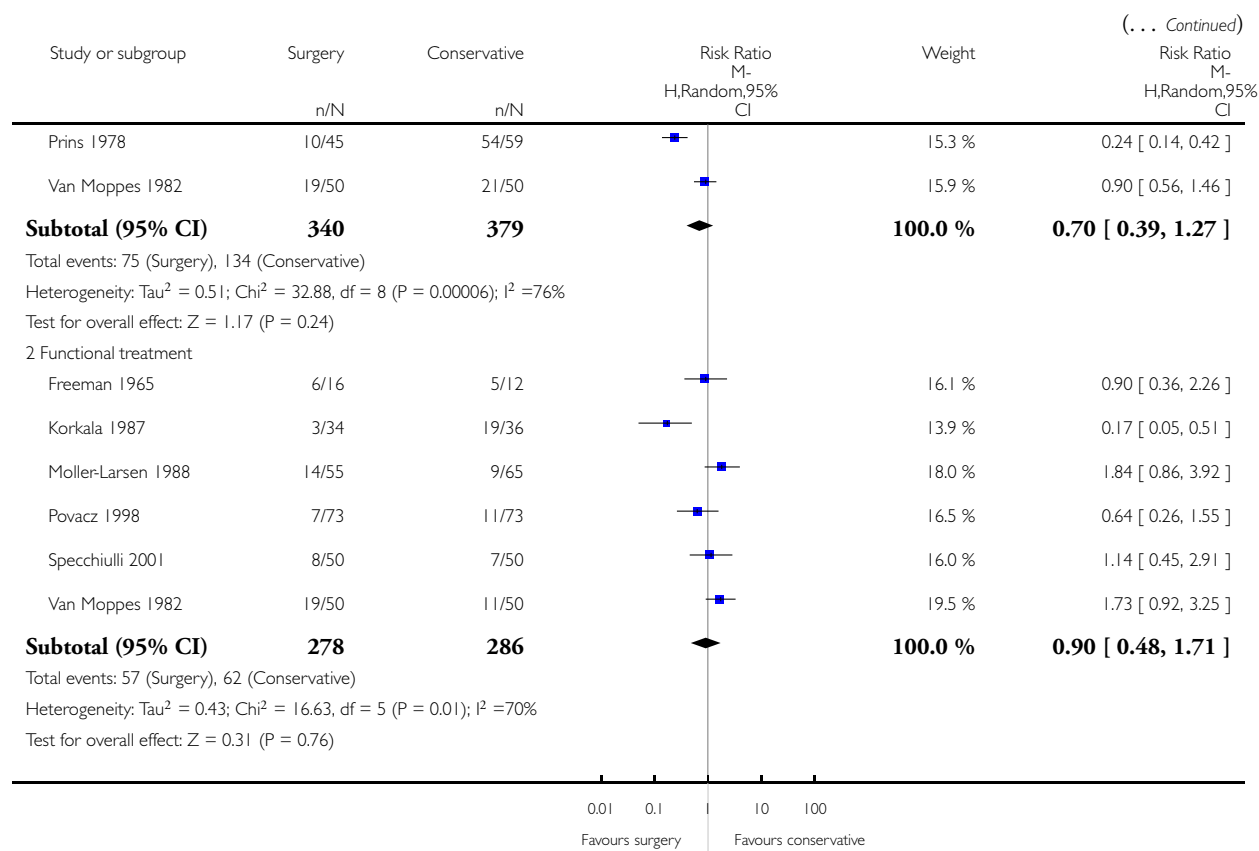
Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 2 Surgical versus Conservative treatment: by conservative method

Outcome: 7 Subjective or functional instability





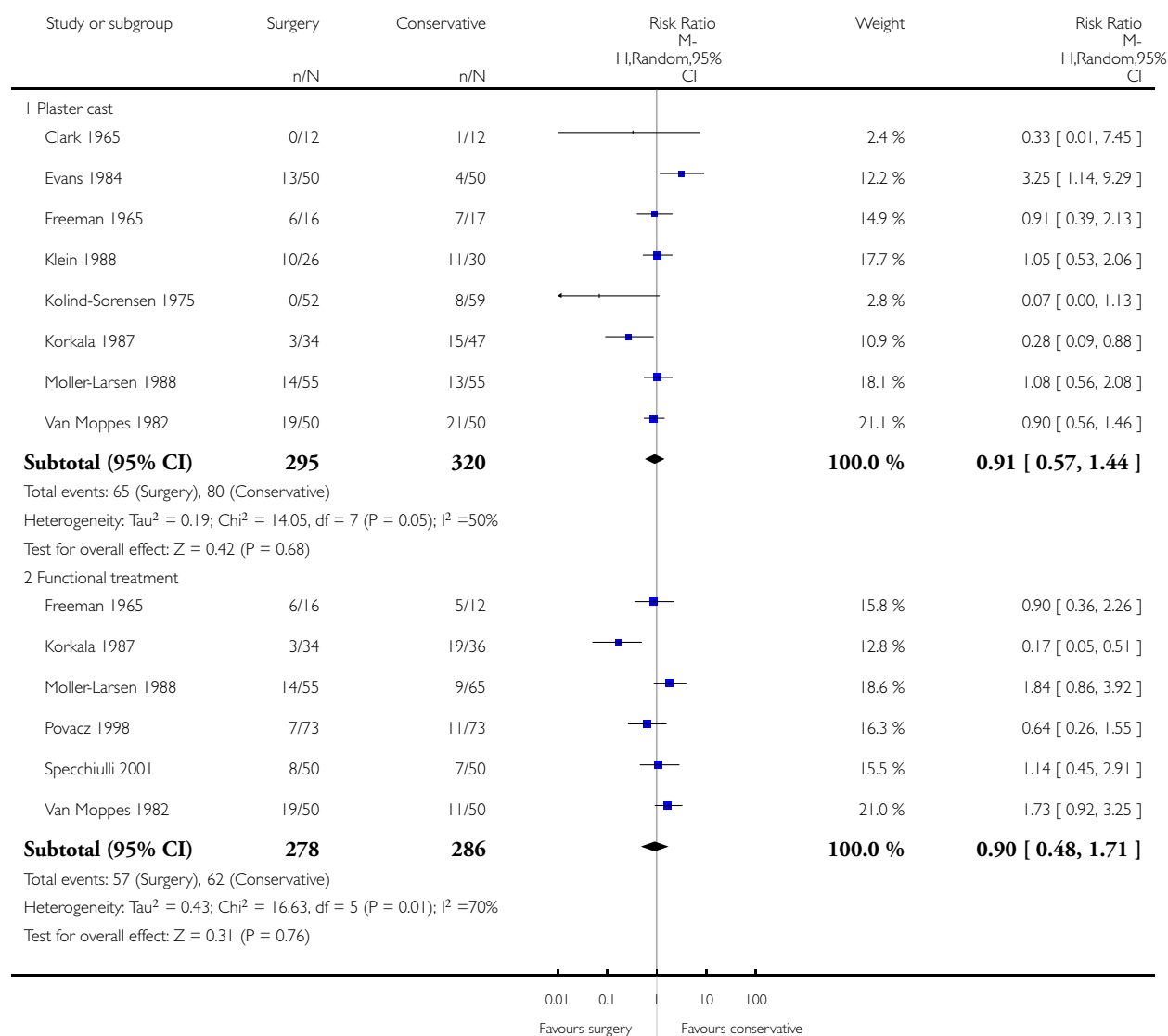


## Analysis 2.8. Comparison 2 Surgical versus Conservative treatment: by conservative method, Outcome 8 Subjective or functional instability - Prins 1978.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 2 Surgical versus Conservative treatment: by conservative method

Outcome: 8 Subjective or functional instability - Prins 1978

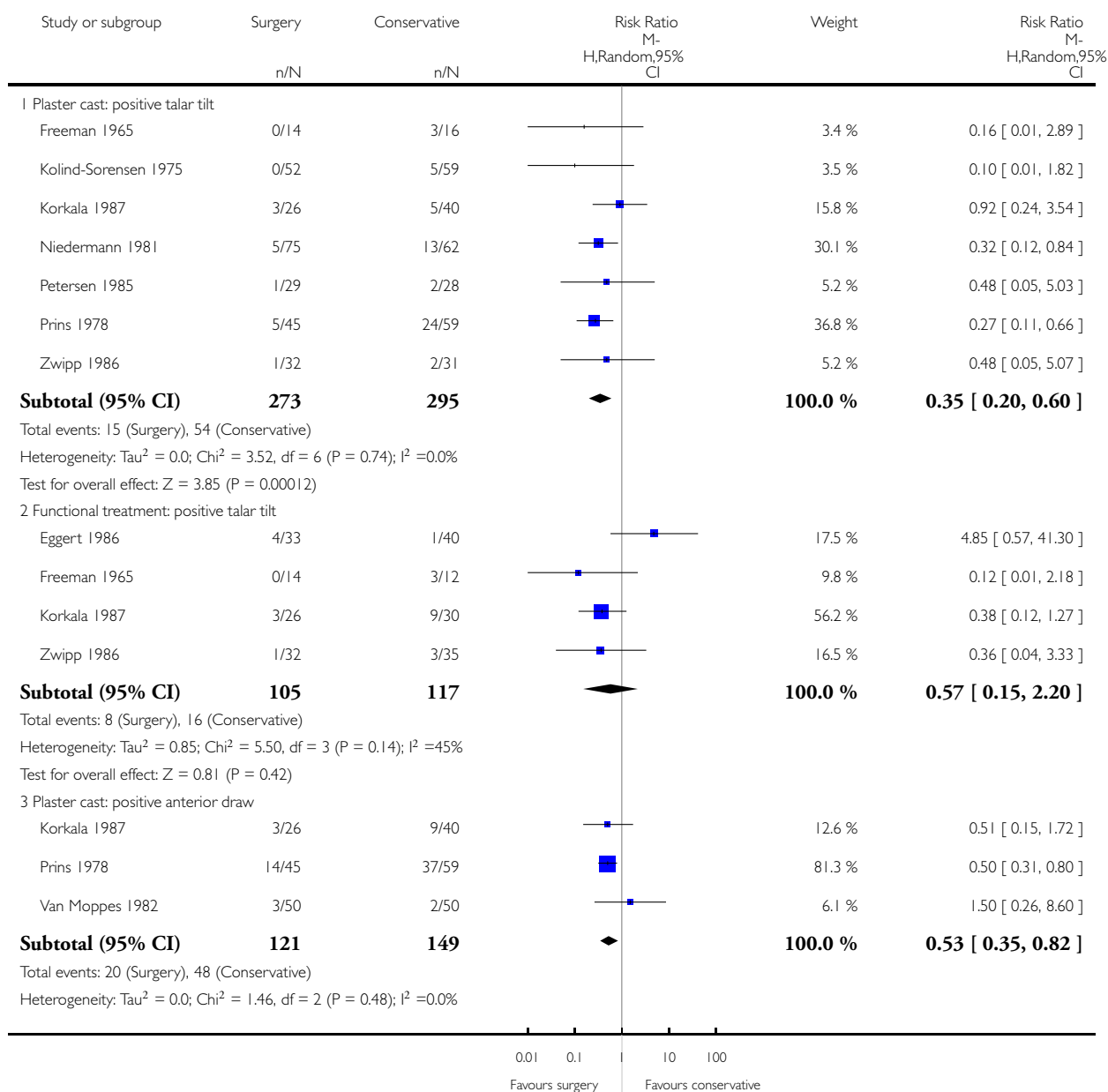


## Analysis 2.9. Comparison 2 Surgical versus Conservative treatment: by conservative method, Outcome 9 Objective instability (talar tilt or anterior draw).

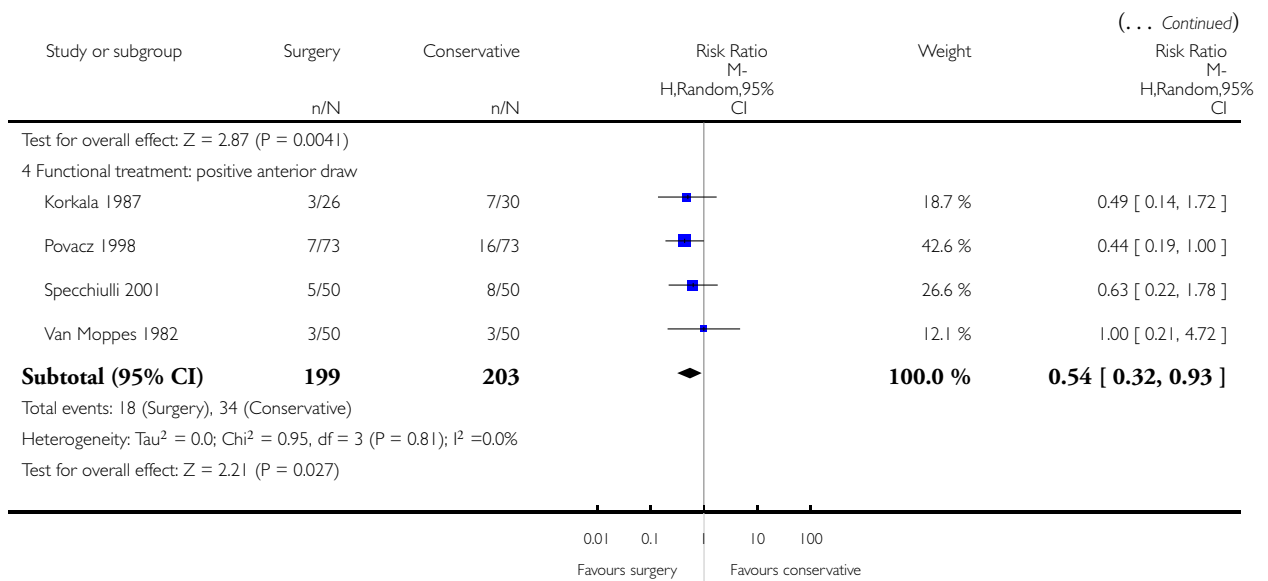
Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

Comparison: 2 Surgical versus Conservative treatment: by conservative method

Outcome: 9 Objective instability (talar tilt or anterior draw)



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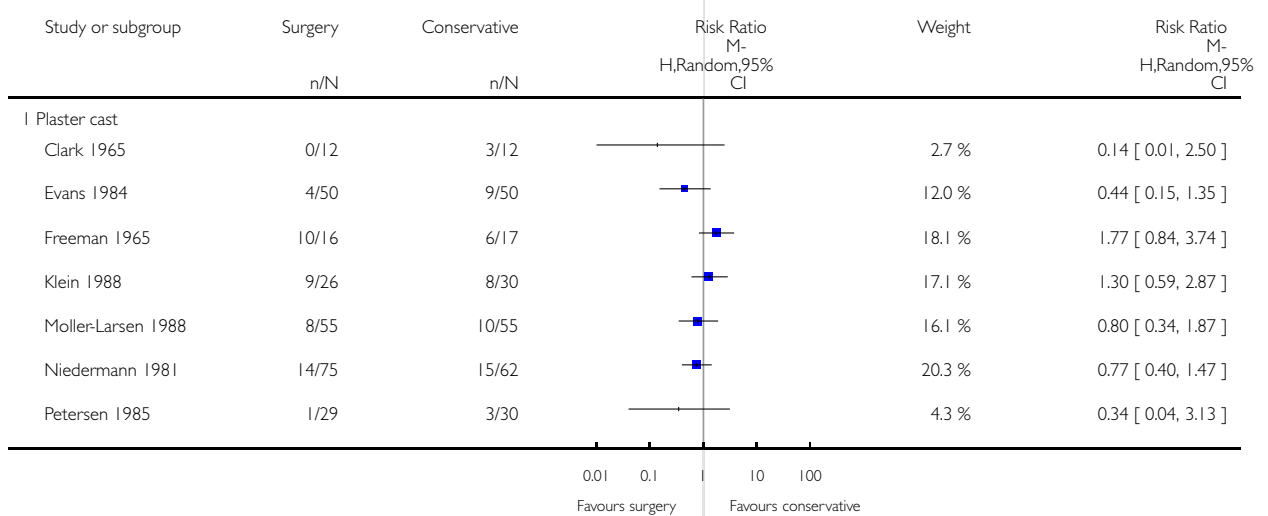


### Analysis 2.10. Comparison 2 Surgical versus Conservative treatment: by conservative method, Outcome 10 Swelling.

Review: Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults

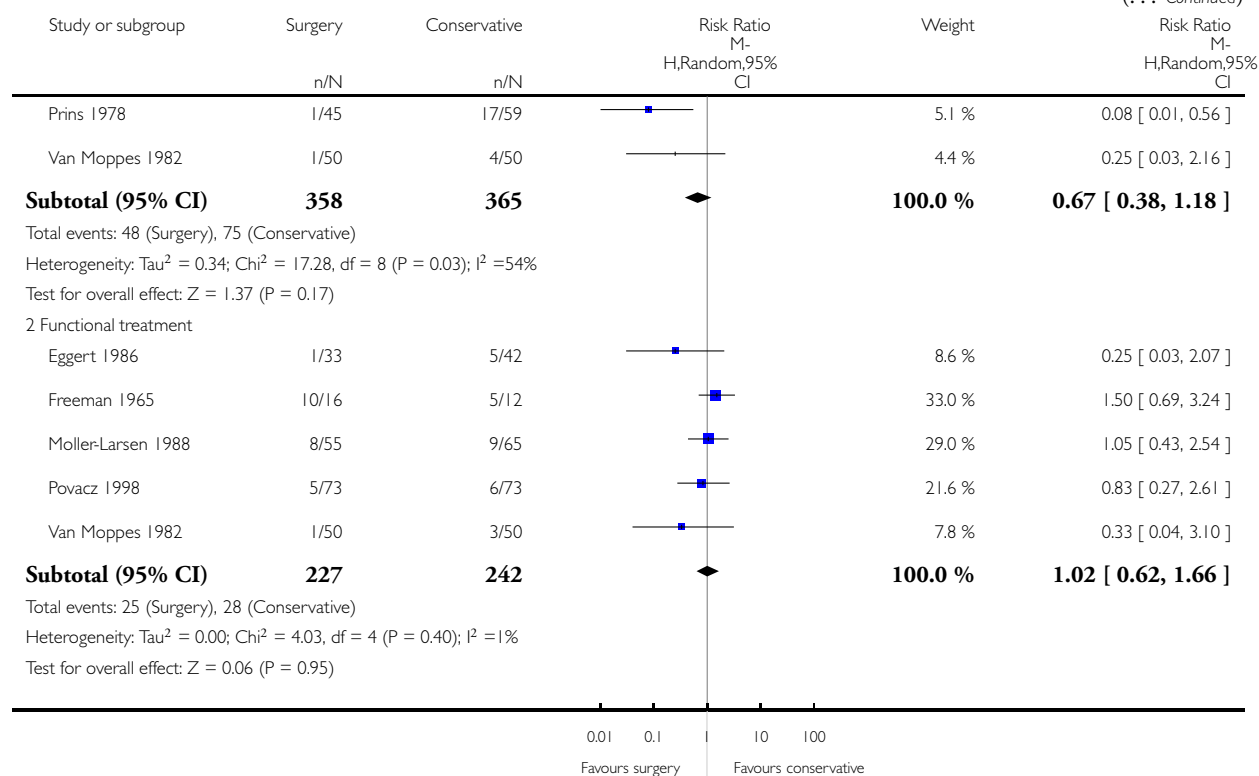
Comparison: 2 Surgical versus Conservative treatment: by conservative method

Outcome: 10 Swelling



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## ADDITIONAL TABLES

**Table 1. Methodological quality assessment criteria**

Criteria	Scores
A. Was the assigned treatment adequately concealed prior to allocation?	2 = method did not allow disclosure of assignment. 1 = small but possible chance of disclosure of assignment or unclear. 0 = quasi-randomised or open list or tables.
B. Were the outcomes of participants who withdrew described and included in the analysis (intention to treat)?	2 = withdrawals well described and accounted for in analysis. 1 = withdrawals described and analysis not possible. 0 = not mentioned, inadequately mentioned, or obvious differences and no adjustment
C. Were the outcome assessors blinded to treatment status?	2 = effective action taken to blind assessors. 1 = small or moderate chance of unblinding of assessors. 0 = not mentioned or not possible.

**Table 1. Methodological quality assessment criteria** (Continued)

D. Were the treatment and control group comparable at entry?	2 = good comparability of groups, or confounding adjusted for in analysis. 1 = confounding small; mentioned but not adjusted for. 0 = large potential for confounding, or not discussed.
E. Were the participants blind to assignment status after allocation?	2 = effective action taken to blind participants. 1 = small or moderate chance of unblinding of participants. 0 = not possible, or not mentioned (unless double-blind), or possible but not done
F. Were the treatment providers blind to assignment status?	2 = effective action taken to blind treatment providers. 1 = small or moderate chance of unblinding of treatment providers. 0 = not possible, or not mentioned (unless double-blind), or possible but not done
G. Were care programmes, other than the trial options, identical?	2 = care programmes clearly identical. 1 = clear but trivial differences. 0 = not mentioned or clear and important differences in care programmes
H. Were the inclusion and exclusion criteria clearly defined?	2 = clearly defined. 1 = inadequately defined. 0 = not defined.
I. Were the outcome measures used clearly defined?	2 = clearly defined. 1 = inadequately defined. 0 = not defined.
J. Was follow-up active (pre-defined/scheduled follow-up times) and appropriate?	2 = optimal, active and appropriate. 1 = adequate, appropriate but mode of follow-up either passive or not defined. 0 = not defined, not adequate.
K. Was duration of surveillance clinically appropriate?	2 = optimal (one year or above). 1 = adequate (six months up to one year) 0 = not defined, not adequate (under six months).

## APPENDICES

### Appendix 1. Search strategy for *The Cochrane Library* (Wiley Interscience)

Strategy
#1 MeSH descriptor Lateral Ligament, Ankle explode all trees in MeSH products
#2 ligament* near ankle* in Record Title or ligament* near ankle* in Abstract in all products
#3 (#1 OR #2)
#4 MeSH descriptor Sprains and Strains, this term only in MeSH products
#5 MeSH descriptor Ankle Injuries explode all trees in MeSH products
#6 sprain* or strain* or injur* or rupture* or tear* or torn in Record Title or sprain* or strain* or injur* or rupture* or tear* or torn in Abstract in all products
#7 (#4 OR #5 OR #6)
#8 (#3 AND #7)

### Appendix 2. Search strategies for MEDLINE (OVID WEB)

Search: 1999 onwards	Old search (to 2000)
<ol style="list-style-type: none"> <li>1. Lateral Ligament, Ankle/</li> <li>2. (ligament\$ adj6 ankle\$).tw.</li> <li>3. or/1-2</li> <li>4. "Sprains and Strains"/</li> <li>5. Ankle Injuries/</li> <li>6. (sprain\$ or strain\$ or injur\$ or rupture\$ or tear\$ or torn).tw.</li> <li>7. or/4-6</li> <li>8. and/3,7</li> <li>9. randomized controlled trial.pt.</li> <li>10. controlled clinical trial.pt.</li> <li>11. Randomized Controlled Trials/</li> <li>12. Random Allocation/</li> <li>13. Double Blind Method/</li> <li>14. Single Blind Method/</li> <li>15. or/9-14</li> <li>16. Animals/ not Humans/</li> <li>17. 15 not 16</li> <li>18. clinical trial.pt.</li> <li>19. exp Clinical Trials/</li> <li>20. (clinic\$ adj25 trial\$).tw.</li> <li>21. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).tw.</li> <li>22. Placebos/</li> <li>23. placebo\$.tw.</li> <li>24. random\$.tw.</li> <li>25. Research Design/</li> </ol>	<p>This subject specific search was combined with the first two levels of the sensitive search strategy for randomised controlled trials from 1966 to May 2000.</p> <ol style="list-style-type: none"> <li>1. Ankle Injuries/</li> <li>2. Ligaments, Articular/</li> <li>3. "Sprains and Strains"/</li> <li>4. or/1-3</li> <li>5. ankle\$.tw.</li> <li>6. ligament\$.tw.</li> <li>7. and/5-6</li> <li>8. (sprain\$ or strain\$ or injur\$ or rupture\$ or tear\$ or torn).tw.</li> <li>9. and/7-8</li> <li>10. and/4,9</li> <li>11. Lateral Ligament, Ankle/</li> <li>12. or/10-11</li> </ol>

(Continued)

26. or/18-25	
27. 26 not 16	
28. 27 not 17	
29. Comparative Study/	
30. exp Evaluation Studies/	
31. Follow Up Studies/	
32. Prospective Studies/	
33. (control\$ or prospectiv\$ or volunteer\$).tw.	
34. or/29-33	
35. 34 not 16	
36. 35 not (17 or 28)	
37. or/17,28,36	
38. and/8,37	

### Appendix 3. Search strategies for CINAHL (OVID WEB) and EMBASE (OVID WEB)

CINAHL: 1982 onwards	EMBASE: 1988 onwards
1. Lateral Ligament, Ankle/	1. Ankle Lateral Ligament/
2. (ligament\$ adj6 ankle\$).tw.	2. (ligament\$ adj5 ankle\$).tw.
3. or/1-2	3. or/1-2
4. (sprain\$ or strain\$ or injur\$ or rupture\$ or tear\$ or torn).tw.	4. Ankle Sprain/ or Ankle Injury/ or Ligament Injury/ or Ligament Rupture/
5. "Sprains and Strains"/	5. (sprain\$ or strain\$ or injur\$ or rupture\$ or tear\$ or torn).tw.
6. Ankle Injuries/	6. or/4-5
7. or/4-6	7. and/3,6
8. and/3,7	8. exp Randomized Controlled trial/
9. exp Clinical Trials/	9. exp Double Blind Procedure/
10. exp Evaluation Research/	10. exp Single Blind Procedure/
11. exp Comparative Studies/	11. exp Crossover Procedure/
12. exp Crossover Design/	12. Controlled Study/
13. clinical trial.pt.	13. or/8-12
14. or/9-13	14. ((clinical or controlled or comparative or placebo or prospective or randomi#ed) adj3 (trial or study)).tw.
15. ((clinical or controlled or comparative or placebo or prospective or randomi#ed) adj3 (trial or study)).tw.	15. (random\$ adj7 (allocat\$ or allot\$ or assign\$ or basis\$ or divid\$ or order\$)).tw.
16. (random\$ adj7 (allocat\$ or allot\$ or assign\$ or basis\$ or divid\$ or order\$)).tw.	16. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj7 (blind\$ or mask\$)).tw.
17. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj7 (blind\$ or mask\$)).tw.	17. (cross?over\$ or (cross adj1 over\$)).tw.
18. (cross?over\$ or (cross adj1 over\$)).tw.	18. ((allocat\$ or allot\$ or assign\$ or divid\$) adj3 (condition\$ or experiment\$ or intervention\$ or treatment\$ or therap\$ or control\$ or group\$)).tw.
19. ((allocat\$ or allot\$ or assign\$ or divid\$) adj3 (condition\$ or experiment\$ or intervention\$ or treatment\$ or therap\$ or control\$ or group\$)).tw.	19. or/14-18
20. or/15-19	20. or/13,19
21. or/14,20	21. limit 20 to human
22. and/8,21	22. and/7,21



## WHAT'S NEW

Last assessed as up-to-date: 9 April 2006.

Date	Event	Description
30 November 2009	Amended	Contact details updated.

## HISTORY

Protocol first published: Issue 1, 1997

Review first published: Issue 3, 2002

Date	Event	Description
8 July 2008	Amended	Converted to new review format.
6 February 2007	New search has been performed	For this first update (Issue 2, 2007) of the review, the main changes were: (1) Search updated to January 2006. (2) Inclusion of three newly identified studies (Kolind-Sorensen 1975; Pijnenburg 2003; Specchiulli 2001). (3) Exclusion of three trials previously awaiting assessment (Knop 1999; Otto 1997; Zoltan 1977). A report and thesis in German were belatedly obtained for Grasmueck 1997, which remains in 'Studies awaiting assessment'. (4) Several abstracts and reports were also located for already included trials; their inclusion resulted in no important changes. (5) Modifications to methods (e.g. consideration of I-squared statistics) and structure and style in keeping with the updated Handbook and Style Guidelines. (6) There were no changes to the conclusions.

## CONTRIBUTIONS OF AUTHORS

This review was initiated by Paul Parker and others, including three review group authors (Rob de Bie, Helen Handoll and Brian Rowe) (please see acknowledgements), and some preliminary work done. Helen Handoll (HH) took over a caretaker role until the lead was taken by Gino Kerkhoffs (GK) and the scope of the review refined. Although some of the preliminary work from the above project was taken forward to this review, all the results were checked and the analyses restructured to conform to the revised protocol and availability of results from the more recently identified trials. Initial trial location was performed by HH and Kathryn Quinn, and subsequently by HH, GK and Lesley Gillespie. Study selection was by at least two review authors, and always GK and HH. All authors participated in quality assessment and data extraction of the included trials. Compilation of the comparisons, structuring of the review, data entry into RevMan, and composition of the first drafts and rewrites of the text were shared by HH and GK. Rob de Bie, Brian Rowe and Peter Struijs advised on the analysis and content and provided critical feedback on the work at various stages. Similar arrangements applied to the update. Gino Kerkhoffs and Helen Handoll are guarantors of the review.

## DECLARATIONS OF INTEREST

None known; the review authors were not involved in any of the primary studies.

## SOURCES OF SUPPORT

### Internal sources

- Department of Emergency Medicine, University of Alberta, Edmonton, Alberta, Canada.
- Orthopaedic Research Center, Department of Orthopaedic Surgery, University of Amsterdam, Amsterdam, Netherlands.
- University of Teesside, Middlesbrough, UK.

### External sources

- Canadian Institutes of Health Research (CIHR), Ottawa, Canada.

## NOTES

To better represent the scope of this review, the title was changed from that in the protocol: “Surgical interventions for treating acute injuries of the lateral ligament complex of the ankle in adults”.

## INDEX TERMS

### Medical Subject Headings (MeSH)

Acute Disease; Early Ambulation; Immobilization; Lateral Ligament, Ankle [\*injuries; surgery]; Randomized Controlled Trials as Topic; Rupture [surgery; therapy]; Sprains and Strains [surgery; \*therapy]; Treatment Outcome

### MeSH check words

Humans