

Interventions for treating chronic ankle instability (Review)

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[Intervention Review]

Interventions for treating chronic ankle instability

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ABSTRACT

Background

Chronic lateral ankle instability occurs in 10% to 20% of people after an acute ankle sprain. Initial treatment is conservative but if this fails and ligament laxity is present, surgical intervention is considered.

Objectives

To compare different treatments, conservative or surgical, for chronic lateral ankle instability.

Search methods

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register, the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, CINAHL and reference lists of articles, all to February 2010.

Selection criteria

All identified randomised and quasi-randomised controlled trials of interventions for chronic lateral ankle instability were included.

Data collection and analysis

Two review authors independently assessed risk of bias and extracted data from each study. Where appropriate, results of comparable studies were pooled.

Main results

Ten randomised controlled trials were included. Limitations in the design, conduct and reporting of these trials resulted in unclear or high risk of bias assessments relating to allocation concealment, assessor blinding, incomplete and selective outcome reporting. Only limited pooling of the data was possible.

Neuromuscular training was the basis of conservative treatment evaluated in four trials. Neuromuscular training compared with no training resulted in better ankle function scores at the end of four weeks training (Ankle Joint Functional Assessment Tool (AJFAT): mean difference (MD) 3.00, 95% CI 0.3 to 5.70; 1 trial, 19 participants; Foot and Ankle Disability Index (FADI) data: MD 8.83, 95% CI 4.46 to 13.20; 2 trials, 56 participants). The fourth trial (19 participants) found no significant difference in the functional outcome after six weeks training programme on a cyclo-ergometer with a bi-directional compared with a traditional uni-directional pedal. Longer-term follow-up data were not available for these four trials.

Four studies compared surgical procedures for chronic ankle instability. One trial (40 participants) found more nerve injuries after tenodesis than anatomical reconstruction (risk ratio (RR) 5.50, 95% CI 1.39 to 21.71). One trial (99 participants) comparing dynamic versus static tenodesis excluded 17 patients allocated dynamic tenodesis because their tendons were too thin. The same trial found that dynamic tenodesis resulted in higher numbers of people with unsatisfactory function (RR 8.62, 95% CI 1.97 to 37.77, 82 participants). One trial comparing techniques of lateral ankle ligament reconstruction (60 participants) found that operating time was shorter using the reinsertion technique than the imbrication method (MD -9.00 minutes, 95% CI -13.48 to -4.52).

Two trials (70 participants) compared functional mobilisation with immobilisation after surgery. These found early mobilisation led to earlier return to work (MD -2.00 weeks, 95% CI -3.06 to -0.94; 1 trial) and to sports (MD -3.00 weeks, 95% CI -4.49 to -1.51; 1 trial).

Authors' conclusions

Neuromuscular training alone appears effective in the short term but whether this advantage would persist on longer-term follow-up is not known. While there is insufficient evidence to support any one surgical intervention over another surgical intervention for chronic ankle instability, it is likely that there are limitations to the use of dynamic tenodesis. After surgical reconstruction, early functional rehabilitation appears to be superior to six weeks immobilisation in restoring early function.

PLAIN LANGUAGE SUMMARY

Chronic lateral ankle instability may be treated with or without surgery

Chronic ankle instability is common after an acute lateral ankle sprain. Initial treatment is conservative, either with bracing or neuromuscular training. However, if symptoms persist and the ligaments on the outside of the ankle are elongated or torn, surgery is usually considered.

This review includes 10 small and flawed trials that recruited a total of 388 people with chronic ankle instability. Limitations in the design, conduct and reporting of these trials meant that it was difficult to be certain that their results were valid.

Three trials compared neuromuscular training with no training. These found a programme of neuromuscular training appears to provide short term improvement in functional stability. One trial testing the use of a special cycle pedal found that it did not make an important difference to function. However, none of these four trials followed-up patients after the end of treatment.

Four trials compared different types of surgical intervention. There was insufficient evidence to strongly support any specific surgical procedure for treating chronic ankle instability. Two trials found that, after surgical reconstruction, early functional rehabilitation enabled patients to return to work and sports quicker than six weeks immobilisation.

BACKGROUND

Description of the condition

Damage to the lateral ankle ligaments by forced inversion of the ankle joint (outward snapping of the ankle relative to the foot) is one of the most common lower limb injuries. In most people, only the anterior talo-fibular ligament (ATFL, the front ligament on the outside ankle) is affected but in a minority this is combined with a rupture of the calcaneo-fibular ligament (CFL, the middle ankle ligament on the outside ankle) (Brostrom 1966).

Although surgical treatment for acute injuries of the lateral ankle ligaments probably gives slightly better functional results than conservative treatment, it is unclear whether this compensates for a higher risk of complications, higher costs and required operation time (Kerkhoffs 2007; Pijnenburg 2000).

Conservative treatment leads to full functional recovery in most people (Kerkhoffs 2007). However, up to 20% continue to suffer from lateral ankle instability, characterised by recurrent ankle sprains or a feeling of apprehension in the ankle (giving way). If this persists for longer than six months, the terms 'chronic (lateral) ankle instability' (CAI) is used (Karlsson 1996).

Prior to the 1960s, it was assumed that chronic ankle instability was mechanical in origin, resulting from structural laxity of the injured ankle ligaments. This 'mechanical instability' (MI) can be assessed by physical and radiological examination, using the anterior drawer test and the ankle inversion test (Karlsson 1996). However, it is now clear that chronic ankle instability may occur with or without increased ligament laxity (Bozkurt 2006). Nor does increased ligament laxity always result in symptomatic instability. These observations have led to the concept that functional instability (FI) resulting from a neuromuscular deficit is implicated along with mechanical instability in people with symptoms of chronic ankle instability (Halasi 2005; Hertel 2002; Hubbard 2007).

Description of the intervention

Initial treatment of chronic ankle instability may therefore consist of neuromuscular training of the ankle. Several training programmes have been developed. This may be supplemented by external ankle support, e.g. tape or a brace (Richie 2001). If, after a programme of rehabilitation, symptoms persist and increased ligament laxity is present, surgical treatment is usually considered (Karlsson 1996).

Surgical procedures fall into two main categories. In "anatomic" reconstructions (Brostrom 1966), the previously ruptured ligaments are tightened by overlapping (imbrication) or by re-attaching one end of the ligament into the bone (reinsertion). In 'non-anatomic' reconstructions, the structural laxity is corrected using other tissues, normally tendon (tenodesis) (Chrisman 1969; Evans 1953). Retrospective comparative studies seem to suggest that anatomic reconstructions show superior results in the long term (Krips 2002).

How the intervention might work

The aim of neuromuscular rehabilitation is to optimise lower limb postural control and restore active stability by training (Loudon 2008). The aim of surgical reconstruction is the reduction of increased ligament laxity. Tape and braces may provide some external mechanical support for an unstable ankle, but it has also been suggested that the beneficial effect is explained by enhancement of proprioception (awareness of position, movement and balance) through skin pressure (Baier 1998).

Why it is important to do this review

The effectiveness of neuromuscular training needs to be formally evaluated. Also, it remains unclear whether and in what circumstances surgery is effective in management of chronic instability, with or without a component of neuromuscular rehabilitation), and which treatment programme provides the best balance of benefits and adverse effects. In this circumstance, a regularly updated review of evidence is important.

OBJECTIVES

To assess the effects of any treatment, conservative or surgical, compared with any other treatment or no treatment, for chronic lateral ankle instability in skeletally mature people.

METHODS

Criteria for considering studies for this review

Types of studies

Any 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 alteration) controlled trial comparing any conservative or surgical treatments for chronic lateral ankle instability with any other or no treatment was considered for inclusion.

Types of participants

Skeletally mature individuals with chronic lateral ankle instability. Chronic lateral ankle instability was defined as symptoms of ankle instability, recurrent sprains or giving way, persisting for more than six months (Karlsson 1996).

Trials dealing exclusively with children or people with congenital deformities or degenerative conditions were excluded. A trial with a mixed population of adults and children would have been included if the adult population was reported separately.

Trials dealing exclusively with the prevention of ankle sprains in healthy individuals were excluded. This is the subject of another Cochrane review (Handoll 2001). A trial dealing with prevention of ankle sprains in a mixed population of healthy individuals and people suffering from chronic ankle instability would have been included if data from participants with chronic ankle instability were reported separately.

Trials evaluating the treatment of acute injury to the lateral ankle ligaments were also excluded; their effectiveness is addressed in three separate Cochrane reviews (Kerkhoffs 2007; Kerkhoffs 2002a; Kerkhoffs 2002b).

Types of interventions

Any type of treatment for chronic lateral ankle instability was considered: any form of non-operative treatment, e.g. neuromuscular training programmes or ankle joint support (orthotic braces, tape, etc); any surgical procedure to reinforce and/or shorten the lateral ankle ligaments; and any form of post-surgical rehabilitation.

Types of outcome measures

Details about outcome measures are given in Table 1. In the table, outcome measures are divided in the categories 'patient derived', 'physical examination' and 'additional'.

Primary outcomes

1. Functional outcome

2. Subjective stability

Secondary outcomes

- 1. Recurrent injury
- 2. Use of external support
- 3. Pain
- 4. Swelling
- 5. Time to return to work/sports
- 6. Patient satisfaction
- 7. Mechanical laxity (manual)
- 8. Range of motion (ROM)
- 9. Swelling
- 10. Muscle atrophy or objective muscle weakness
- 11. Mechanical laxity (radiological)
- 12. Complications of surgical interventions
- 13. Re-operation

Search methods for identification of studies

Electronic searches

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (to February 2010), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2010, Issue 1), MEDLINE (1950 to February Week 2 2010), EMBASE (1980 to 2010 Week 06) and CINAHL (1937 to February 2010). No language restrictions were applied.

In MEDLINE (OVID) the subject-specific strategy was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity-maximizing version (Lefebvre 2009) and modified for use in other databases (*see* Appendix 1).

Searching other resources

We searched reference lists of articles and contacted researchers in the field to identify further studies or additional data.

Data collection and analysis

Selection of studies

From the title, abstract or descriptors, two review authors (JdV and IS) independently reviewed literature searches to identify potentially relevant trials for full review. From the full text articles, trials which met the selection criteria were included. All randomised trials of interventions for chronic ankle instability, as defined above, were included. Disagreement was resolved by a consensus procedure, followed, if required, by scrutiny from a third review author (LB).

Data extraction and management

Two review authors (JdV and RK) extracted the data independently using a data-extraction form. If necessary, trialists were contacted in order to complete the data or provide further information on methodology. Disagreement was resolved by a consensus procedure, followed, if necessary, by scrutiny from a third review author (LB).

Assessment of risk of bias in included studies

Two review authors (JdV and IS) assessed the risk of bias in the included studies, according to Higgins 2008. Disagreement was resolved by a consensus procedure, followed, if required, by scrutiny from a third review author (LB). The domains assessed were 'Adequate sequence generation?', 'Allocation concealment?', 'Blinding?', 'Incomplete outcome data addressed?', 'Free of selective reporting?' and ' Free of other bias?'. An interpretation of the overall risk of bias per study and the risk of bias for the three comparisons was assessed according to Schünemann 2008.

Measures of treatment effect

For each study, risk ratios and 95% confidence intervals were calculated for dichotomous outcomes and mean differences and 95% confidence intervals for continuous outcomes. Where possible, ordinal data were handled as dichotomous data where there were a small number of categories (e.g. < 5) or as continuous data where there were a larger number of categories.

Unit of analysis issues

We were aware of potential unit of analysis issues in the two studies that included a few people who were treated for chronic instability of both ankles. We planned to use the data from the ankle with the worst results for such patients but this was not possible in the included trials; nor was sensitivity analysis to explore the effects of including unadjusted data.

Dealing with missing data

We contacted trial authors to request missing data. Where possible we performed intention-to-treat analyses to include all people randomised. However, where drop-outs were identified, the actual denominators of participants contributing data at the relevant outcome assessment were used. We were alert to the potential mislabelling or non identification of standard errors and standard deviations. Unless missing standard deviations could be derived from confidence intervals or standard errors, we did not assume values in order to present these in the analyses.

Assessment of heterogeneity

Heterogeneity between comparable trials was tested using a standard Chi² test, with additional consideration of the I² statistic.

Data synthesis

Where appropriate, the results of trials were pooled using both fixed-effect and random-effects models. We planned to present results for the fixed-effect model unless there was statistically significant heterogeneity (P < 0.10); in which case the results for the random-effects model would have been presented.

Subgroup analysis and investigation of heterogeneity

Proposed subgroup analyses for future updates are by activity level (athletes versus sedentary lifestyle).

Sensitivity analysis

We planned exploratory sensitivity analysis to examine the effects of excluding trials with a high risk of bias, and also the impact of missing dichotomous data on trial results.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification.

Results of the search

A total of 81 potentially eligible trials were identified. Studies were excluded because they were not randomised or controlled (31), had no clinical outcome measures (18), evaluated acute or sub-acute ankle injury (7), were retrospective (3) or for other reasons (10). Detailed reasons for exclusion can be found in the Characteristics of excluded studies. Two studies are awaiting assessment for inclusion (Helton 2008; Romero-Cruz 2004).

Included studies

Ten studies were included for analysis (Clark 2005; Hale 2007; Hennrikus 1996; Høiness 2003; Karlsson 1995; Karlsson 1997; Karlsson 1999; Larsen 1990; McKeon 2008b Rosenbaum 1999). All studies were published in English and peer reviewed medical journals between 1990 and 2008. They were all identified in MEDLINE, EMBASE or CINAHL. All studies evaluated people with chronic lateral ankle instability, although in three studies a pre-treatment duration of symptoms of more than six months was not explicitly mentioned (Larsen 1990; McKeon 2008b; Rosenbaum 1999). Since other inclusion criteria were met and according to the patient description a sufficient duration of complaints could be assumed, these studies were not excluded.

A total of 388 participants was randomised, of whom 333 were analysed at final follow-up. Mean or median age ranged from 19.5 to 29.7 years. The youngest recorded patient was 17 years and the oldest 49 years. In most studies both males and females were included, with a male participation rate varying from 39% to 100%. Two studies evaluated men only (Clark 2005; Rosenbaum 1999).

The 10 included studies were divided into three groups: four studies evaluated conservative treatment in the form of different neuromuscular training programmes for chronic (functional) ankle instability (four studies); studies comparing different forms of surgical interventions for chronic ankle instability (four studies); and studies comparing different rehabilitation programmes after a surgical intervention for chronic ankle instability (two studies). This division is used in all following sections.

Studies comparing different programmes of neuromuscular training for chronic ankle instability

All four studies in this category were designed as pre-test/ posttest randomised trials without a follow-up period. In three of the four studies, a four-week neuromuscular training programme was compared with no training (Clark 2005; Hale 2007; McKeon 2008b). The programmes consisted of 8 to 12 supervised training sessions of 20 to 30 minutes in four weeks, comprising multiple (balance) exercises. In Hale 2007, participants also had to train at home in the last two weeks. Group size varied from nine to 16 people with chronic ankle instability. In the fourth study, training with an experimental bi-directional pedal on a cyclo-ergometer (n

= 10) was compared to training with a standard uni-directional pedal (n = 9) during a six-week training programme (Høiness 2003). All four studies combined functional scores as outcome measure with physiologic outcome measures. Clark 2005 used the Ankle Joint Functional Assessment Tool (AJFAT) questionnaire, Hale 2007 and McKeon 2008b the Foot and Ankle Disability Index (FADI) and the FADI Sport, and Høiness 2003 assessed functional outcome with a modified Karlsson ankle score.

Studies comparing different surgical procedures for chronic ankle instability

None of the four studies evaluated exactly the same comparison, although two studies compared an anatomical reconstruction with a tenodesis (Hennrikus 1996; Rosenbaum 1999). Hennrikus 1996 compared the outcome after a modified Broström anatomical reconstruction of the lateral ankle ligaments with the Chrisman-Snook tenodesis in 40 people. The main outcome measure was the Sefton ankle score. Rosenbaum 1999 compared a modified Evans tenodesis with an anatomical reconstruction in 20 males. The main outcome measures were range of motion and mechanical stability. Karlsson 1997 compared two different anatomic reconstructions in 60 people. In one group, the lateral ligaments were shortened by reinsertion onto the distal fibula and reinforced by a periosteal flap. In the other group, the ligaments were imbricated (shortening of the ligament itself) and the reconstruction was reinforced by the inferior extensor retinaculum. The main outcome measure was the Karlsson ankle score. Larsen 1990 compared a dynamic tenodesis (26 people) with a static (Winfield) tenodesis (56 people). In the static tenodesis, an anatomic reconstruction according to the authors, the full-thickness distal end of the peroneus was used to reconstruct both the anterior talofibular ligament and the calcaneofibular ligament. In the dynamic variant, the distal brevis tendon was split longitudinally and the anterior half was used for dynamic repair. The main outcome measure for Larsen 1990 was a self-designed clinical ankle score.

Studies comparing different rehabilitation programmes after surgery for chronic ankle instability

Both studies, (conducted by Karlsson et al (Karlsson 1995; Karlsson 1999)) evaluating rehabilitation after surgery for chronic ankle instability, compared early mobilisation and range of motion training in a brace with six weeks of plaster immobilisation. Karlsson 1995 compared the outcome after six weeks of immobilisation by plaster cast with early range of motion training in a walking boot after an anatomical reconstruction of the lateral ankle ligaments in 40 people. The walking boot is a prefabricated brace that allows only for a preset plantar- and dorsiflexion range of motion. Participants in this group started with two weeks of immobilisation after which range of motion was gradually extended. After six weeks, both groups started with the same supervised rehabilitation programme. Main outcome measures were the Karlsson ankle score, range of motion and return to work and sports. Karlsson 1999 compared six weeks of immobilisation with controlled range of motion in an Air-Cast ankle brace after an anatomic reconstruction in 30 patients. During the first two weeks only free plantar and dorsiflexion was allowed in the brace group. Then two weeks of controlled range of motion was conducted. In weeks five and six, this was combined with co-ordination and strength training. After six weeks, both groups underwent the same rehabilitation programme again. The main outcome measure was the Karlsson ankle score.

Further details about the individual studies can be found in the Characteristics of included studies.

Risk of bias in included studies

Risk of bias assessment for the included studies is shown for each study in Characteristics of included studies, and summarised in Figure 1 and Figure 2. All studies were judged at high risk of bias for at least one domain, mostly concerning blinding and selective reporting.

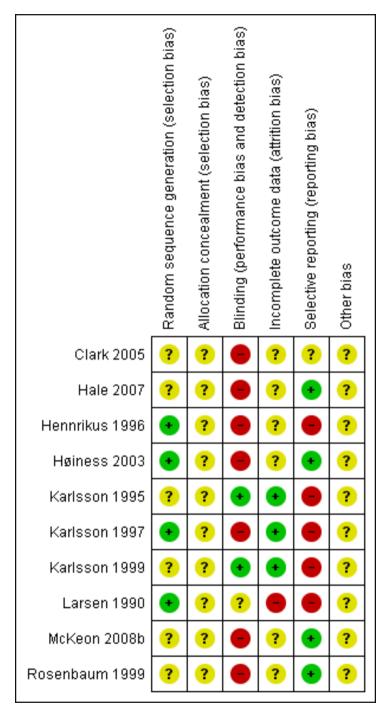
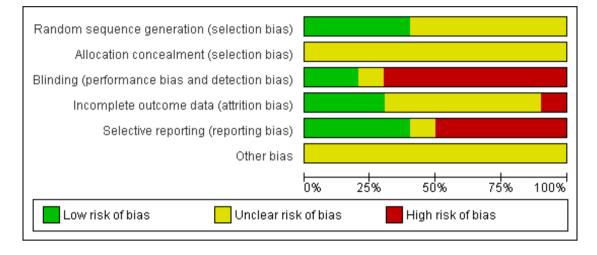


Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

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



Allocation

No study had a low risk of selection bias. In one study (Larsen 1990) the randomisation procedure was clearly described, and incomplete details were provided in three others (Hennrikus 1996; Høiness 2003; Karlsson 1997). However, adequate random sequence generation combined with adequate allocation concealment could not be confirmed in any of the studies. Conversely, no study had clearly inadequate sequence generation or allocation concealment (*see* the Characteristics of included studies for allocation concealment judgements).

Larsen 1990 clearly did not follow the intention-to-treat principle. Comparability of the groups was good and well described in seven studies (Clark 2005; Hale 2007; Høiness 2003; Karlsson 1995; Karlsson 1997; Karlsson 1999; Rosenbaum 1999). In McKeon 2008b comparability was well described and showed a small difference in age between the groups. In two studies (Hennrikus 1996; Larsen 1990), comparability was not mentioned.

Blinding

In two studies (Karlsson 1995; Karlsson 1999), it was well described that assessors were blinded; none of the other studies mentioned who performed the outcome assessment.

Incomplete outcome data

In three studies there were no participants lost to follow-up and it was clear that all participants were included in the analyses (Karlsson 1997; Karlsson 1999; Rosenbaum 1999). Three other studies described how many, and in most cases why, participants were lost to follow-up (Hale 2007; Høiness 2003; Karlsson 1995). In three more studies, it was unclear if there were participants lost to follow-up (Clark 2005; Hennrikus 1996; McKeon 2008b). In Larsen 1990, prior to surgery, participants were randomised to one of the two treatment groups (static or dynamic tenodesis), but during the operation, some of the participants in the 'dynamic' group were excluded because the procedure was not feasible. These participants underwent a static repair and were not included in the analyses.

Selective reporting

Five studies reported clearly specified outcome measures (Clark 2005; Hale 2007; Høiness 2003; McKeon 2008b; Rosenbaum 1999). The other five studies (Hennrikus 1996; Karlsson 1995; Karlsson 1997; Karlsson 1999; Larsen 1990) mentioned some outcome measures in the methods section, but reported additional outcome measures which had not been pre-specified.

Other potential sources of bias

Generally reflecting lack of information to make judgements, all studies were assessed as 'unclear' in this domain.

Effects of interventions

Studies comparing different conservative treatment (primarily neuromuscular training) for chronic ankle instability

Three (Clark 2005; Hale 2007; McKeon 2008b) of the four studies in this category compared a neuromuscular training programme with no training. In addition to several physiological outcome measures, all three trials used a foot and ankle functional score to evaluate outcome at the end of treatment. The data, estimated from a graph, for the Ankle Joint Functional Assessment Tool (AJ-FAT) in Clark 2005 showed that the training group (10 participants) had a better result than the control group (9 participants) (mean difference (MD) 3.00, 95% CI 0.3 to 5.70; see Analysis 1.1). Pooling of Foot and Ankle Disability Index (FADI) data from Hale 2007 (change scores) and McKeon 2008b (final values scores) also showed significantly higher and better scores in the neuromuscular rehabilitation groups (29 versus 27 participants; MD (fixed) 8.83, 95% CI 4.46 to 13.20; see Analysis 1.1). The same applied for the sport domain of the FADI tool (FADI Sport: MD (fixed) 11.59, 95% CI 6.48 to 16.69).

Høiness 2003 reported no significant difference in baseline or at the end of training in function measured using a modified Karlsson score (0: worst to 85: best) between the group (10 participants) using bi-directional pedal compared with the group (9 participants) using a standard uni-directional pedal during a sixweek training programme on a cycle-ergometer. The mean baseline Karlsson scores were: 71.8 versus 63.2; the scores at the end of the programme were: 76.9 versus 66.3.

Studies comparing different surgical procedures for chronic ankle instability

Non-anatomic versus anatomic reconstruction

Both Hennrikus 1996, who compared the Chrisman-Snook (CS) procedure with a modified Brostrom (B) anatomic reconstruction, and Rosenbaum 1999, who compared a tenodesis (Modified Evans procedure) with an anatomic reconstruction, reported generally good results for both operations. There was no statistically significant differences between the two operations in subjective instability (3/28 versus 1/30; RR 2.49, 95% CI 0.39 to 15.83) or pain at follow-up (4/30 versus 2/30; RR 2.00, 95% CI 0.41 to 9.86: see Analysis 2.1). Hennrikus 1996 found a statistically significantly higher rate of nerve damage in the Chrisman-Snook group (11/20 versus 2/20; RR 5.50, 95% CI 1.39 to 21.71; see Analysis 2.2). Of the 18 participants available for clinical examination in Hennrikus 1996, one person in each group had radiographic instability (*see* Analysis 2.3). Rosenbaum 1999 found a significantly greater reduction of the radiographic talar tilt at follow-up for the

non-anatomic reconstruction group (MD 5.30 degrees, 95% CI 0.89 to 9.71; see Analysis 2.4). The difference in anterior drawer test was not statistically significant (MD 0.70 mm, 95% CI -1.88 to 3.28).

Anatomic (reinsertion) versus anatomic (imbrication) reconstruction

In a study evaluating two different anatomic reconstructions, Karlsson 1997 found here were no statistically significant differences between the two groups in the numbers of participants with an unsatisfactory functional outcome (3/30 versus 5/30; *see* Analysis 3.1) or in the Tegner scores (*see* Analysis 3.2). Similar findings of non-significant differences between the two groups applied to subjective instability (2 in each group), pain at follow-up (1/30 versus 4/30; *see* Analysis 3.3), complications (*see* Analysis 3.4), and radiographic stability (*see* Analysis 3.5). However, a statistically significant shorter operating time for the reinsertion technique was found (MD -9.00 minutes, 95% CI -13.48 to -4.52; see Analysis 3.6).

Dynamic with static tenodesis

Larsen 1990 compared dynamic with static tenodesis. Though 99 patients were randomised into the study, 17 out of the 43 patients allocated dynamic tenodesis were excluded because of too thin tendons. Larsen 1990 found that the dynamic tenodesis was associated with more frequent complaints of functional limitation (8/ 26 versus 2/56; RR 8.62, 95% CI 1.97 to 37.77; *see* Analysis 4.1) and subsequent 'distortion trauma' (6/26 versus 1/56; RR 12.92, 95% CI 1.64 to 101.93; *see* Analysis 4.2). There were no statistically significant differences between the two groups in numbers of participants with other complications, swelling or having a reintervention (*see* Analysis 4.3). There was no difference between the two operations in the time to return to work (*see* Analysis 4.3). Larsen 1990 reported that dynamic tenodesis was associated with greater hindfoot inversion (*see* Analysis 4.4).

Studies comparing different rehabilitation programmes after surgery for chronic ankle instability

Pooled data from the two trials (Karlsson 1995; Karlsson 1999) comparing early mobilisation in a brace versus immobilisation after surgery showed fewer participants of the early mobilisation group had an unsatisfactory outcome (fair or poor Karlsson score) at two-year follow-up (2/35 versus 7/35; RR 0.29; 95% CI 0.06 to 1.28; *see* Analysis 5.1). Of the five participants with an unsatisfactory outcome in Karlsson 1995, one participant in each group had subjective instability. The other three participants in the immobilisation group had unsatisfactory results due to stiffness and pain. Of the four participants with unsatisfactory results in Karlsson 1999, one was because of instability, two were because of pain and

the fourth because of pain and instability. Karlsson 1999 reported no significant difference in the final Tegner scores (*see* Analysis 5.2). Fewer participants in the early mobilisation group compared with the immobilisation group in both trials failed to return to their former athletic activity (2/35 versus 4/35; RR 0.50, 95% CI 0.10 to 2.55; *see* Analysis 5.3). None of the above differences were statistically significant.

Time to return to work (MD -2.00 weeks, 95% CI -3.06 to -0.94) and time to return to sport (MD -3.00 weeks, 95% CI -4.49 to -1.51) were both statistically significantly shorter in the early mobilisation group of Karlsson 1995 (see Analysis 5.4). Karlsson 1999 found only the difference for the time to return to sport was statistically significant (see Analysis 5.5).

In Karlsson 1995, range of motion (dorsiflexion and plantarflexion) after six weeks was reported to be statistically significantly better in the early mobilisation (functionally treated) group (*see* Analysis 5.6). While range of motion continued to be better in the early mobilisation group at final follow-up, the differences between the two groups were smaller and not statistically significant. Neither trial found statistically significant differences between the two groups in radiologically assessed stability (*see* Analysis 5.7). There were no significant differences between treatment groups in the two named postoperative complications of superficial wound infection or sensory disturbance (*see* Analysis 5.8).

DISCUSSION

Summary of main results

The 10 included studies fell in three clearly distinct groups comprising four studies comparing different neuromuscular interventions for chronic ankle instability, four studies comparing different surgical techniques for chronic ankle instability, and two studies comparing different rehabilitation programmes after surgery. There were only limited opportunities for pooling of data, and few statistically significant differences in functional outcomes between groups.

Data from three studies (Clark 2005; Hale 2007; McKeon 2008b) showed a better outcome for neuromuscular training compared with no training at the end of treatment.

One trial (Høiness 2003) found that training on a bicycle with a bi-directional pedal did not significantly improve ankle function compared with training on a bicycle with a standard uni-directional pedal at the end of treatment.

Two small randomised studies have compared non-anatomic versus anatomic reconstruction, each with a different non-anatomic surgical reconstruction. Pooled data for participants with instability or pain at follow-up did not show significant differences between the two operations. In Hennrikus 1996, nerve injury was more frequent after non-anatomic reconstruction. In Rosenbaum 1999, radiological measurement of ankle laxity showed that anatomic repair provided better correction of talar tilt.

One study (Karlsson 1997), comparing two anatomic reconstruction techniques, found no difference in any clinical outcome at follow-up but operation time was significantly shorter in the reinsertion group.

One study (Larsen 1990) comparing dynamic versus static tenodesis reported two outcomes favouring static tenodesis - fewer participants reported poor function, or had radiological instability.

Pooling of data from two studies (Karlsson 1995; Karlsson 1999) comparing plaster immobilisation with early mobilisation and range of motion training in a brace found earlier return to work in the early mobilisation group; this may have reflected the significantly higher range of motion in the same groups at six weeks. Differences between the two groups at long-term follow-up in range of motion and functional outcome were, however, not statistically significant.

Overall completeness and applicability of evidence

None of the included studies have compared surgery alone versus functional rehabilitation alone, or surgery and functional rehabilitation versus functional rehabilitation alone. No randomised studies evaluating orthotics were identified.

The search and selection of studies led to the inclusion of 10 trials, and the discovery of two others that await further assessment.

In respect of external validity, the included studies are somewhat heterogeneous. In all studies interventions were described adequately, but only two studies used standardised protocols (Hennrikus 1996; Karlsson 1997). Inclusion criteria were adequately described in all studies. In five studies, the exclusion criteria were clearly described as well (Clark 2005; Hale 2007; Hennrikus 1996; Høiness 2003; McKeon 2008b). The other studies did not describe exclusion criteria or only mentioned a few criteria that did not exclude all conditions that could influence outcome.

Care programmes other than the investigated treatment were comparable or not applicable (pre-test/post-test design) in all studies. Only four studies (Karlsson 1995; Karlsson 1997; Karlsson 1999; Larsen 1990) reported active follow-up of more than one year. Rosenbaum 1999 did not evaluate functional outcome.

The four small studies evaluating the effectiveness of neuromuscular training in chronic ankle instability (Clark 2005; Hale 2007; Høiness 2003; McKeon 2008b) reported mainly physiological outcome measures, which were outside the scope of this review. However, they did report the results of validated patient-derived functional scores which, in three studies, demonstrated short-term effectiveness. It is not known whether this advantage persists on longer-term follow-up, nor is the clinical significance of the beneficial effect clear.

Quality of the evidence

Although it is generally assumed that both surgical reconstruction, and non-operative functional rehabilitation have a beneficial effect on symptomatic chronic ankle instability, this impression is not based on high level clinical evidence. Although the first CONSORT statement was published in 1996, it is unlikely to have influenced the conduct or reporting of any of the six studies of surgical procedures or of rehabilitation after surgery published before 2000. Limitations in the design, conduct and reporting of the trials resulted in judgements of unclear or high risk of selection bias, detection bias, attrition bias and reporting bias in one or more trials.

A high risk of detection bias resulted in the GRADE assessment of "moderate" for the four studies (Clark 2005; Hale 2007; Høiness 2003; McKeon 2008b) evaluating neuromuscular training. However, the lack of post-treatment follow-up is a major failing in all four studies.

High risk of bias from various defects such as lack of blinding, selective reporting, incomplete outcome data together with problems with external validity resulted in a GRADE assessment of "poor" for all the four studies (Hennrikus 1996; Karlsson 1997; Larsen 1990; Rosenbaum 1999) comparing different surgical procedures.

A high risk of bias resulting for reporting bias led to a GRADE assessment of "moderate" for the two studies comparing early mobilisation versus immobilisation after surgery.

Potential biases in the review process

Although we feel that our search strategy was comprehensive and our methods of study selection were thorough, publication bias, study identification bias and study selection bias can never completely be excluded.

Agreements and disagreements with other studies or reviews

Four systematic reviews evaluating conservative treatment options for chronic ankle instability have been published (Loudon 2008; McKeon 2008a; van der Wees 2006; Webster 2010). Three of these (Loudon 2008; McKeon 2008a; Webster 2010) included non-randomised trials as well, and two reviews (McKeon 2008a; van der Wees 2006) also evaluated prevention after an acute ankle injury. In accordance with the current review, although partially based on lower levels of evidence, in three of the studies (Loudon 2008; van der Wees 2006; Webster 2010) it was concluded that conservative measures, mainly neuromuscular training, are effective as treatment for chronic ankle instability. Only McKeon 2008a did not find a positive effect of neuromuscular training. However, this was not in accordance with a study by the same author the same year (McKeon 2008b). Two other studies that were included in the current review (Clark 2005; Hale 2007) and also showed a positive effect of training, were not evaluated in McKeon 2008a. No systematic reviews evaluating surgical treatment for chronic lateral ankle instability were identified.

AUTHORS' CONCLUSIONS

Implications for practice

In view of the small size of the study populations, the moderate to high risk of bias of the studies, and clinical heterogeneity, this review does not provide strong evidence on which to base practice. Neuromuscular training appears to improve ankle function in the short term but it is unclear whether this advantage is clinically relevant and there is no evidence available on longer term outcome. There is insufficient evidence to support any one surgical intervention over another surgical intervention for chronic ankle instability. However, the practical limitations of dynamic tenodesis in terms of tendon thickness impose some restrictions on the use of this technique. In order to reduce the time to return to work and sports, rehabilitation after surgery for chronic ankle instability should be functional, with early mobilisation of the ankle joint, rather than six weeks of immobilisation.

Implications for research

There is a need for sufficiently powered, high quality and wellreported randomised controlled trials (Moher 2001) evaluating the treatment of chronic ankle instability, including an analysis of cost effectiveness. For all trials, including those evaluating neuromuscular training programmes, a sufficient follow-up period is important. There is a need for trials evaluating the effectiveness of orthotic devices for the treatment of chronic ankle instability.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Clark 2005

Methods	Location: Department of Exercise and Sport sity, Cheshire, UK Design: Randomised trial Method of randomisation: not mentioned Assessor blinding: not mentioned Study period: not mentioned Follow-up: immediate post-treatment meas Intention-to-treat: no patients lost to follow	urement only, at 4 weeks
Participants	 19 male participants with functional ankle i 29.7 (SD 4.9) years Inclusion criteria: a) weak ankle with at least 3 ankle sprains in b) negative anterior draw test; c) normal biomechanics; d) informed consent. Exclusion criteria: no history of cardiac or relation to the second secon	
Interventions	 a) Experimental group: 4-week wobble board training. After training, exercise programme was initially practised under guidance of physiotherapist. Exercise programme performed 3 x 10 minute sessions per week b) Control group: no training Assigned: 10 / 9 Analysed: 10 / 9 (no mention of losses) 	
Outcomes	 Ankle Joint Functional Assessment Tool questionnaire, a 12-item self-report functional score (0 to 48: best result) EMG: Time to muscle activation of the anterior tibial and long peroneal muscle on sudden inversion on a trap door 	
Notes	Request sent to V.M. Clark and A.M. Burden by email for raw data of the AJFAT There was baseline comparability in the two groups in age, weight, height, and number of sprains in the last 2 years	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Sequence generation not mentioned

Interventions for treating chronic ankle instability (Review)

Allocation concealment (selection bias)

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Unclear risk

Randomisation method not mentioned

Clark 2005 (Continued)

Blinding (performance bias and detection bias) All outcomes	High risk	Observer blinding not mentioned, but not possible for patient-reported outcomes
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Probably no patients lost to follow-up but not mentioned; incomplete data not men- tioned
Selective reporting (reporting bias)	Unclear risk	Most data are reported incompletely
Other bias	Unclear risk	There was insufficient information to judge the risk from other sources of bias

Hale 2007

Methods	Location: Pennsylvania State University, PA, USA Design: Randomised trial Method of randomisation: not mentioned Assessor blinding: not mentioned Study period: not mentioned Follow-up: immediate post-treatment measurement only, at 4 weeks Intention-to-treat: 4 participants did not complete the study, not analysed
Participants	 29 participants with chronic ankle instability, 19 females and 10 males, mean age 21.5 (SD 3.3) years Inclusion criteria for people with chronic ankle instability: a) history of at least 1 unilateral ankle sprain with pain and/or limping for greater than 1 day; b) chronic ankle weakness, pain, or instability attributed to the initial injury; c) self reported giving way of the involved ankle in the last 6 months Exclusion criteria: a) bilateral ankle instability; b) history of ankle fractures; c) ankle injury within 3 months prior to participation; d) history of anterior cruciate ligament injury; e) history of balance disorders; f) current participation in supervised physical rehabilitation. Loss to follow-up: 4 participants (3 in the experimental group: ankle sprain, foot fracture, death in the family; and 1 in the control group: time constraints)
Interventions	 a) Experimental group: 4-weeks rehabilitation programme: supervised and at home: range of motion, strengthening, neuromuscular control, functional tasks a) Control group: no training Assigned: 16 / 13 Analysed: 13 / 12 (patients dropped out or lost to follow-up not analysed)

Hale 2007 (Continued)

Outcomes	 Foot and Ankle Disability Index (FADI), a 26-item self-report functional score Foot and Ankle Disability Index - Sport (FADI-Sport), an 8-item self-report function sport score Postural sway: Centre of pressure excursion velocities (COPV) measured during single leg stance on a force plate (AMTI, inc, Watertown, MA, USA): affected / non-affected, eyes open / eyes closed, 3 x 15 sec per condition Star Excursion Balance Test (SEBT): single leg stance, reach distances of the contralat- eral leg in 8 directions
Notes	Email sent to S Hale for raw data There was baseline comparability in the two groups in age and sex

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Sequence generation not mentioned
Allocation concealment (selection bias)	Unclear risk	Randomisation method not mentioned
Blinding (performance bias and detection bias) All outcomes	High risk	Observer blinding not mentioned, but not possible for patient-reported outcomes
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Patients lost to follow-up mentioned. No correction in analysis possible. No differ- ence reported in baseline measurements be- tween patients lost to follow-up and pa- tients that completed the study
Selective reporting (reporting bias)	Low risk	All data for outcome measures as men- tioned in the methods section seem to be fully reported
Other bias	Unclear risk	There was insufficient information to judge the risk from other sources of bias

Methods	Location: Department of Orthopaedic Surgery and Clinical Investigation, Naval Hos- pital, San Diego, California, USA Design: Randomised trial Method of randomisation: numbered envelopes containing randomly allocated assign- ments Assessor blinding: Not mentioned Study period: July 1989 to August 1992 Follow-up: Not fixed, mean 29 months, range 6 to 49 months Loss to follow-up: No, 2 patients lost to follow-up for the final evaluation, not analysed
Participants	 40 participants, 42 ankles, 4 females and 36 males, mean age 26 years (range 19 to 37); 39 were active-duty military personnel and 1 military 'dependent'. All were recreational athletes Inclusion criteria: a) skeletal maturity; b) history of significant ankle injury followed by episodes of giving way for at least 6 months; c) positive manual anterior drawer test on physical examination; d) pre-operative physical therapy programme showing no improvement; e) informed consent Exclusion criteria: a) generalized ligamentous laxity disorder; b) radiographic arthritis or tarsal coalition; c) previous ankle surgery Loss to follow-up: 2, both in Chrisman-Snook group
Interventions	Two methods of ankle ligament reconstruction: a) Chrisman-Snook procedure b) Modified-Brostrom procedure Assigned: 20 (all males) / 20 (female 4, male 16) Analysed: short term outcomes: 20 / 20, long-term outcomes: 18 / 20 (interview), 9 / 9 (physical examination and radiographs)
Outcomes	 Sefton score: Excellent: full activity, including strenuous exercise, no giving way or feeling of apprehension; Good: occasional aching of the ankle but only after strenuous exercise, no giving way or feeling of apprehension; Fair: residual instability and remaining apprehension but less instability and apprehension as compared with the ankle condition before surgery; Poor: recurrent ankle instability and giving way unchanged or worse in normal activities with episodes of pain and swelling Manual stability: Anterior drawer sign and talar tilt Radiographic stability: ATT and TT Post-operative complications: wound infection, nerve damage Residual instability Subjective limited function Re-operation Return to work

Notes

Hennrikus 1996 (Continued)

Risk of bias

10.5% 0] 0.005		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Numbered envelopes containing randomly allocated assignments
Allocation concealment (selection bias)	Unclear risk	Envelopes used, no mentioned of further concealment protection
Blinding (performance bias and detection bias) All outcomes	High risk	No blinding mentioned, but not possible for patient-reported outcomes
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Patients lost to final follow-up mentioned (2, both Chrisman-Snook), no mention of how lost data were addressed
Selective reporting (reporting bias)	High risk	Not all outcome measures mentioned in the results selection are described in the methods section
Other bias	Unclear risk	There was insufficient information to judge the risk from other sources of bias

Høiness 2003

Methods	Location: Ullevaal University Hospital, Oslo, Norway Design: Randomised trial Method of randomisation: closed mixed envelopes Assessor blinding: not blinded Study period: not mentioned Follow-up: immediate post-treatment measurement, at 6 weeks Intention-to-treat: no, 1 participant lost to follow-up was not analysed
Participants	 20 individuals, with data for 19 individuals, 11 females and 8 males, mean age 25.3 (SD 4.1, range 20 to 33) years Inclusion criteria: a) history of major ankle sprain; b) unilateral recurrent ankle sprains for at least 6 months; c) manual and radiographic mechanical instability of the affected leg; d) informed consent. Exclusion criteria: a) no concomitant ankle fracture; b) other lower limb injuries; c) foot deformity; d) chronic pain in foot or ankle unrelated to sprains; e) recently undergone rehabilitation programme or physiotherapeutic therapy;

Høiness 2003 (Continued)

	f) any general disease, including neurological. Loss to follow-up: 1 participant sustained a severe ankle sprain and could not complete the study
Interventions	All participants: 6 week training programme, 3 times a week, 45 minutes a day, on a cyclo- ergometer (Lifecycle 9500 HRT, Life Fitness, IL, USA), with individualised training intensity based on pre-test measurements, normal (sports) activity was allowed, unusual sports activity was discouraged a) Experimental group: training with bi-directional bicycle pedal b) Control group: training with unidirectional bicycle pedal Assigned: 10/9 (Radiographs were not taken in the case of one female in the experimental group due to pregnancy; 1 female was excluded because of an injury during testing - allocation not mentioned.) Analysed: 10/9
Outcomes	 Modified Karlsson functional ankle score: 0 to 85 points Figure of eight running: time and VAS for pain was registered for both ankles Postural sway: single leg stance on a rapidly tilting platform (Chatecx Balance System) with increasing speed, highest speed before loosing balance was registered Eversion peak torque: highest torque in the range of motion at any angle for two angular velocities, 60 and 180 degrees/sec
Notes	There was baseline comparability in the two groups in age, weight, height and BMI (body mass index)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Mixed envelopes used
Allocation concealment (selection bias)	Unclear risk	Envelopes used, no mentioned of further concealment protection
Blinding (performance bias and detection bias) All outcomes	High risk	Observers not blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Just one patient lost to follow-up; and data for figure-of-eight running lost for 1 patient as described in the caption of a table
Selective reporting (reporting bias)	Low risk	Outcome measures the same in methods and results sections
Other bias	Unclear risk	There was insufficient information to judge the risk from other sources of bias

Methods	Location: University of Goteborg, Goteborg, Sweden Design: Randomised assessor-blinded clinical trial Method of randomisation: Not mentioned Assessor blinding: Yes Study period: 12 weeks rehabilitation after ankle ligament reconstruction Follow-up: minimum 2 years Intention-to-treat: Not mentioned, complete follow-up
Participants	 40 participants, 18 females and 22 males, mean age 24 (range 17 to 35) years; all were active in sports activities Inclusion criteria: a) standard anatomical reconstruction of the lateral ankle ligaments for chronic lateral ankle instability (symptoms > 6 months); b) pre-operative rehabilitation programme without success. Exclusion criteria: a) osteoarthrosis or other forms of cartilage damage in ankle or foot Loss to follow-up: no patients lost
Interventions	Post-operative rehabilitation a) Early range of motion group, in a Walker-Boot low-leg brace applied to ankle. Im- mobilised for 2 weeks, followed by 2 weeks with 10 degrees dorsiflexion to 20 degrees plantarflexion allowed, followed by 2 weeks of 20 degrees dorsiflexion to 40 degrees plantarflexion allowed, combined with a supervised training programme from week 3 to 6; instructions for active range of motion for 15 minutes four times a day as the brace allowed b) Immobilisation group: the ankle was immobilised in a plaster cast for 6 weeks and allowed to bear full weight Both groups underwent the same supervised rehabilitation programme from week 6 to 12, consisting of range of motion and proprioceptive training, patients were allowed to return to sports activity when they regained normal range of motion and full functional stability Assigned: 20/20 Analysed: 20/20
Outcomes	 Karlsson functional ankle score: A 100 point scale with 8 items about ankle and general functioning Range of motion: Dorsiflexion and plantarflexion preoperative, at 6 weeks and at 12 weeks Subjective pain, stiffness and instability Mechanical instability, radiographic Mean time for sick leave Sports activity level Complications
Notes	
Risk of bias	

Bias Authors' judgement Support for judgement

Karlsson 1995 (Continued)

Random sequence generation (selection bias)	Unclear risk	Method of sequence generation not men- tioned
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment not mentioned
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome observers were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No patients lost to follow-up and probably no data lost
Selective reporting (reporting bias)	High risk	Addional outcome measure used but not described in the method section
Other bias	Unclear risk	There was insufficient information to judge the risk from other sources of bias
Karlsson 1997		
Methods	Location: Ostra Hospital, Goteborg, Sweden Design: Randomised trial Method of randomisation: Closed envelopes Assessor blinding: Not mentioned Study period: 1989 to 1992 Follow-up: Mean 3.2 years, range 2 to 5 years in both groups Intention-to-treat: Not mentioned, complete follow-up	
Participants	 60 participants, 18 females and 42 males, mean age 24 (range 17 to 36) years Inclusion criteria: a) chronic ankle instability for more than 6 months; b) pre-operative supervised rehabilitation programme without success; c) radiographic mechanical instability (difference compared to the contralateral side: ATT ≥ 3 mm, TT ≥ 3 degrees) Exclusion criteria: Not mentioned. Loss to follow-up: No patients lost, 2 patients (1 of each group) refused radiographic assessment at follow-up 	
Interventions	 a) Anatomic reconstruction of the anterolateral ankle ligaments with removal of a small bone block of the anterolateral side of the tip of the fibula, reinsertion of the ligaments and periosteal flap reinforcement b) Anatomic reconstruction of the anterolateral ankle ligaments by imbrication and with inferior extensor retinaculum reinforcement Both groups underwent the same post-operative rehabilitation programme: 6 weeks of immobilisation with a below-the-knee walking cast with full weight bearing followed by a standardised rehabilitation programme with ROM exercise from week 6 and isometric peroneal strengthening from 8 weeks, return to sports activity was allowed after 10 to 	

Karlsson 1997 (Continued)

	12 weeks provided that peroneal strength and proprioception were normal Assigned: 30/30 Analysed: 30/30 (2 patients, 1 in each group, did not participate in radiographic assess- ment at follow-up)
Outcomes	 Karlsson functional ankle score: A 100 point scale with 8 items about ankle and general functioning Mechanical instability, radiographic Surgical complications Reoperation
	•

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Closed envelopes used
Allocation concealment (selection bias)	Unclear risk	Envelopes used, no mentioned of further concealment protection
Blinding (performance bias and detection bias) All outcomes	High risk	Observer blinding not mentioned, but not possible for patient-reported outcomes
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 patients, 1 in each group, did not partic- ipate in radiographic assessment at follow- up, no correction possible
Selective reporting (reporting bias)	High risk	Addional outcome measure used but not described in the method section
Other bias	Unclear risk	There was insufficient information to judge the risk from other sources of bias

Karlsson 1999

Methods

Location: Sahlgrens University Hospital/Ostra, Goteborg, Sweden Design: Randomised trial Method of randomisation: Not mentioned Assessor blinding: Yes Study period: 1993 to 1995 Follow-up: at least 2 years Intention-to-treat: Not mentioned, possibly no loss to follow-up

Interventions for treating chronic ankle instability (Review)

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Karlsson 1999 (Continued)

Participants	 30 participants, 12 females and 18 males, median age 27 (range 18 to 36) years Inclusion criteria: a) anatomical reconstruction for chronic functional and mechanical lateral ankle instability; b) pre-operative supervised rehabilitation programme without success Exclusion criteria: a) degenerative changes of the ankle joint. Lost to follow-up: No patients lost
Interventions	 a) Early mobilisation: Post-operative immobilisation of the ankle for 7-10 days with a below the knee cast, followed by mobilisation Air-Cast ankle brace up to 6 weeks post-operatively combined with controlled range of motion training from week 3 and coordination and strength training from week 5 b) Post-operative immobilisation of the ankle for 6 weeks with a below the knee cast Both groups underwent the same rehabilitation programme from week 7 to 12, consisting of proprioceptive and strength training Assigned: 15/15
Outcomes	 Strength: Isokinetic concentric and eccentric plantar and dorsiflexion peak torque at an angular velocity of 60 degrees/second Mechanical stability: Radiographic assessment of both ATT and TT Karlsson functional ankle score: A 100 point scale with 8 items about ankle and general functioning
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation not men- tioned
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment not mentioned
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome observers were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No patients lost to follow-up, probably no data lost
Selective reporting (reporting bias)	High risk	Addional outcome measure used but not described in the method section

Karlsson 1999 (Continued)

Other bias	Unclear risk	There was insufficient information to judge the risk from other sources of bias	
Larsen 1990			
Methods	Design: Randomised trial Method of randomisation: Pati the treatment by use of Geigy's Assessor blinding: Radiographi Study period: 1980 to 1985 Follow-up: mean 25 months, n Intention-to-treat: No, 17 pati	Method of randomisation: Patients chose a sealed envelope containing a slip designating the treatment by use of Geigy's random numbers Assessor blinding: Radiographic evaluation at follow-up was blinded	
Participants	were excluded during operatio 36 females and 46 males, age r Inclusion criteria: a) recurrent giving way of one b) conservative treatment (tape c) manual and radiographic me d) skeletally mature. Exclusion criteria: a) exclusion during operation o brevis tendon was too thin for	 a) recurrent giving way of one or both ankles; b) conservative treatment (tape, heel wedge, training) had failed; c) manual and radiographic mechanical ankle instability; d) skeletally mature. Exclusion criteria: a) exclusion during operation of patients allocated for dynamic repair when the peroneus brevis tendon was too thin for splitting Loss to follow-up: of the 82 participants included for analysis, none were lost to follow- 	
Interventions	for a dynamic repair b) Static repair: Windfield pro is used to make an 'anatomic' Both groups underwent the sam the knee plaster cast, followed Assigned: 99 participants (108 ankles)	 b) Static repair: Windfield procedure: whole thickness of distal peroneus brevis tendon is used to make an 'anatomic' reconstruction of both the ATFL and CFL Both groups underwent the same postoperative rehabilitation programme: 6 weeks below the knee plaster cast, followed by a progressive training programme Assigned: 99 participants (108 ankles): 43 participants (48 ankles) / 56 participants (60 ankles) Analysed: 82 participants (89 ankles): 26 participants (29 ankles) / 56 participants (60 	
Outcomes	 4 points maximum) was used f 2. Functional balance: Ability 3. Mechanical stability, radiogr 4. Ankle swelling 5. Recurrent instability 6. Duration of sick leave 	5. Recurrent instability	

Larsen 1990 (Continued)

	8. Postoperative complications	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients chose a sealed envelope containing a slip designating the treatment by use of Geigy's random numbers
Allocation concealment (selection bias)	Unclear risk	Sealed envelopes used
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Radiographs assessors blinded, no blinding mentioned for other outcome observers
Incomplete outcome data (attrition bias) All outcomes	High risk	Patients after randomisation excluded and not analysed
Selective reporting (reporting bias)	High risk	A second publication with other outcome measures of the same study population has been published
Other bias	Unclear risk	There was insufficient information to judge the risk from other sources of bias

McKeon 2008b

Methods	Location: University of Kentucky, Lexington, KY, USA; University of Charlottesville, VA, USA Design: Randomised trial Method of randomisation: 'Concealed', prepared by an independent investigator Assessor blinding: Not mentioned Study period: not mentioned Follow-up: immediate post-treatment measurement, at 4 weeks Intention-to-treat: No mention of patients lost to follow-up or change of group
Participants	 31 physically active subjects with chronic ankle instability, 19 females and 12 males, mean age 20.9 (SD 3.3) years Inclusion criteria: a) more than one ankle sprain and residual symptoms, including giving way as quantified by more than four positive answers on the 'Ankle Instability Instrument' or score of 90% or less on the 'Foot and Ankle Disability Index' (FADI) and 'Foot and Ankle Disability Index Sport' (FADI Sport) Exclusion criteria: a) history of lower extremity injury;

McKeon 2008b (Continued)

	 b) ankle sprain within 6 weeks prior to inclusion; c) history of lower extremity surgery; d) balance disorders; e) neuropathies; f) diabetes; g) any condition affecting balance. Loss to follow-up: Not mentioned in this study. In McKeon 2009a the same 31 subjects were analysed regarding gait parameters. In that study, one participant in the intervention group was reported to have discontinued the training because of a sustained injury
Interventions	 a) Experimental group: 4-week progressive balance-training programme; 12 supervised sessions of 20 minutes consisting of: single-limb hops stabilization, hop to stabilization and reach, unanticipated hop to stabilization, single-limb stance activities with eyes open and closed b) Control group: no training Assigned: 16 / 15 Analysed: 16 / 15 (?)
Outcomes	 Foot and Ankle Disability Index (FADI), a 26-item self-report functional score Foot and Ankle Disability Index - Sport (FADI-Sport), an 8-item self-report function sport score Postural sway: Time To Boundary (TTB) of the Centre of Pressure (COP) measured during single leg stance on a force plate (AMTI, inc, Watertown, MA, USA): eyes open / eyes closed, mean of 3 x 10 sec per condition Star Excursion Balance Test (SEBT): single leg stance, reach distances of the contralat- eral leg in 3 directions, mean of 3 trials per direction
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of sequence generation not men- tioned
Allocation concealment (selection bias)	Unclear risk	Randomisation was 'concealed and pre- pared by an independent investigator', no detailed explanation
Blinding (performance bias and detection bias) All outcomes	High risk	Blinding not mentioned, but not possible for patient-reported outcomes
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Lost data not mentioned
Selective reporting (reporting bias)	Low risk	Outcome measures the same in methods and results sections

McKeon 2008b (Continued)

Other bias	Unclear risk	There was insufficient information to judge the risk from other sources of bias
Rosenbaum 1999		
Methods	Location: Westfalische Wilhelms-Universitat Munster, Munster, Germany Design: Randomised trial Method of randomisation: Not mentioned Assessor blinding: Not mentioned Study period: Not mentioned Follow-up: Mean 10 (range 6 to 14) months Loss to follow-up: Not mentioned, complete follow-up	
Participants	20 participants, all male, mean age 25 years, military personnel Inclusion criteria: a) chronic ankle instability: recurrent inversion injuries with pain; b) radiographic mechanical instability: TT > 10 degrees, ATT > 10 mm Exclusion criteria: Not mentioned Loss to follow-up: Not mentioned	
Interventions	 a) Evans group: Modified Evans tenodesis, according to Zwipp et al, was used for reconstruction of the anterolateral ankle ligaments b) Periost group: Anatomic reconstruction of the anterolateral ankle ligaments with reinforcement with a periosteal flap Both groups underwent the same post-operative rehabilitation programme: 2 weeks immobilisation with a plaster cast without weightbearing, followed by 2 weeks mobilisation with a brace (Aircast) with full weight bearing Assigned: 10/10 Analysed: 10/10 	
Outcomes	 Range of motion: Manually tested Mechanical stability, radiographic Dynamic pedobarography: Maximal pressure, gait line, ground reaction force and total impulse was measured with a capacitive pressure platform (EMED-SF2 System, Novel GmbH, Munich, Germany) 	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation described as stratified but no further details provided
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not mentioned

Rosenbaum 1999 (Continued)

Blinding (performance bias and detection bias) All outcomes	High risk	Blinding not mentioned
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Lost data not mentioned
Selective reporting (reporting bias)	Low risk	Outcome measures the same in methods and results sections
Other bias	Unclear risk	There was insufficient information to judge the risk from other sources of bias

ATFL: anterior talo-fibular ligament ATT: anterior talar translation CFL: calcaneo-fibular ligament TT: talar tilt

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion				
Angirasa 2008	Patients not randomised				
Baier 1998	Patients not randomised				
Beazell 2009	No clinical outcome measures				
Bernier 1998	No clinical outcome measures				
Blackburn 2000	Healthy subjects				
Camara 2009	Retrospective				
Carvalho 1997	Study about different methods of arthrodesis, patients with chronic ankle instability not separately analysed				
Chen 1990	Study about acute ankle sprains				
Chun 2002	Patients not randomised, review				
Collins 2004	Study about (sub)acute ankle sprains				
Colonna 1991	Patients not randomised				

(Continued)

Coughlan 2009	No clinical outcome measures
Delahunt 2009	Patients not randomised
Denegar 2002	Patients not randomised, review
Docherty 1998	No clinical outcome measures
Eils 2001	Patients not randomised
Eils 2002	Patients not randomised
Ekstrand 1983	Prevention study, patients with chronic ankle instability not separately analysed
Freeman 1965a	Patients not randomised
Freeman 1965b	Study about acute ankle sprains
Gribble 2009	No clinical outcome measures
Gross 1997	Patients not randomised
Halasi 2005	Healthy participants
Hale 2006	Patients not randomised
Halim 2009	Patients not randomised
Hals 2000	Patients not randomised
Han 2009	No clinical outcome measures
Hartsell 1997	Patients not randomised
Hess 2001	No clinical outcome measures
Hopper 2009	No clinical outcome measures
Jerosch 1996	Patients not randomised
Jerosch 1997	Patients not randomised
Kakihana 2005	Patients not randomised
Kaminski 2003	No clinical outcome measures
Kidgell 2007	No clinical outcome measures
Knop 1999	Study about second ruptures, not chronic ankle instability

(Continued)

Kohne 2007	No clinical outcome measures
Larsen 1991	No clinical outcome measure Included patients were part of the population studied in Larsen 1990, a randomised trial included in the review
Lee 2008	Patients not randomised
Lewis 2006	Patients not randomised
Mabit 1998	Patients not randomised
Matsusaka 2001	No clinical outcome measures
McBride 2006	Patients not randomised
Michell 2006	No clinical outcome measures
NATA 2009	Patients not randomised / diagnostic studies
Oostendorp 1987	Study about acute ankle sprains
Paterson 2000	Patients not randomised
Pellow 2001	Study about acute ankle sprains
Powers 2004	No clinical outcome measures
Refshauge 2009a	Patients not randomised
Refshauge 2009b	No clinical outcome measures
Richie 2007	Review
Rosenbaum 1997	Retrospective study
Ross 2007	No clinical outcome measures
Rozzi 1999	Patients not randomised
Sawkins 2007	Patients not randomised
Schmidt 2004	Cadaver study
Sitler 1994	Study about acute ankle sprains
Surve 1994	Prevention study, patients with chronic ankle instability not separately analysed
Thacker 1999	Patients not randomised, review

(Continued)

Vaes 1985	Patients not randomised
Vaes 1998	Patients not randomised
Vaes 2005	Lecture
Vainionpaa 1979	Retrospective study
Vicenzino 2006	Patients not randomised
Volpini 2006	Patients not randomised
Wester 1996	Study about acute ankle sprains
Wyon 2006	No clinical outcome measures
Zhao 2005	Study about chronic ankle pain

Characteristics of studies awaiting assessment [ordered by study ID]

Helton 2008

Methods	Location: Department of Physical Therapy, Shenandoah University, Winchester, VA, USA Design: Randomised (?) trial Method of randomisation: not mentioned Assessor blinding: not mentioned Study period: not mentioned Follow-up: immediate post-treatment measurement, at 4 weeks Intention-to-treat: no patients lost to follow-up mentioned
Participants	26 participants, 20 females and 6 males Inclusion criteria: uni- or bilateral ankle instability Exclusion criteria: not mentioned Loss to follow-up: not mentioned
Interventions	a) Experimental group: 4 weeks-neuromuscular control (NMC) training of the unaffected leg b) Control group: no training Assigned: 13 / 13 Analysed: 13 / 13 (?)
Outcomes	 Foot and Ankle Disability Index (FADI), a 26-item self-report functional score Foot and Ankle Disability Index - Sport (FADI-Sport), an 8-item self-report function sport score Star Excursion Balance Test (SEBT, simplified): single leg stance, reach distances of the contralateral leg in 4 directions Balance Error Scoring System (BESS): number of errors during bipedal, single leg and tandem stance on a firm and foam surface during 20 seconds per condition (120 seconds total)

Helton 2008 (Continued)

Notes	Abstract only, insufficient data for adequate analysis. Email sent to S Hale (corresponding author) for additional
	information

Romero-Cruz 2004

Methods	Location: Orthopedic service of the Central Military Hospital, Mexico Design: Randomised trial Method of randomisation: not mentioned Assessor blinding: not mentioned Study period: Not mentioned Follow-up: 6 months to 2 years Intention-to-treat: no mention of patients switching groups or loss to follow-up
Participants	39 participants, 17 females and 22 males Inclusion criteria: clinical and radiological chronic ankle instability Exclusion criteria: not mentioned Loss to follow-up: not mentioned
Interventions	a) Surgical correction, use Chrisman-Snook method b) 10 sessions of neuromuscular training Assigned: 20 / 19 Analysed: 20 / 19 (?)
Outcomes	 AOFAS Radiological measure ligament laxity Complications
Notes	Probably eligible, to be analysed for the next update

DATA AND ANALYSES

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Functional outcome scores at end of training (higher = better)	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 AJFAT (Ankle Joint Functional Assessment Tool)	1	19	Mean Difference (IV, Fixed, 95% CI)	3.0 [0.30, 5.70]
1.2 FADI (Foot and Ankle Disability Index)	2	56	Mean Difference (IV, Fixed, 95% CI)	8.83 [4.46, 13.20]
1.3 FADI Sport	2	56	Mean Difference (IV, Fixed, 95% CI)	11.59 [6.48, 16.69]

Comparison 1. Conservative treatment: Neuromuscular training versus control

Comparison 2. Surgery: Non anatomic versus anatomic reconstruction

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective instability and pain	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Subjective instability	2	58	Risk Ratio (M-H, Fixed, 95% CI)	2.49 [0.39, 15.83]
1.2 Pain	2	60	Risk Ratio (M-H, Fixed, 95% CI)	2.0 [0.41, 9.86]
2 Complications and revisions	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 Wound complications	1		Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \ [0.0, \ 0.0]$
2.2 Nerve damage	1		Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \ [0.0, \ 0.0]$
2.3 Stiffness	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.4 Reoperations	1		Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \ [0.0, \ 0.0]$
3 Radiographic instability	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4 Reduction in measures of radiographic ligament laxity	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 Anterior drawer (mm)	1		Mean Difference (IV, Fixed, 95% CI)	$0.0 \; [0.0, 0.0]$
4.2 Talar tilt (degrees)	1		Mean Difference (IV, Fixed, 95% CI)	$0.0 \; [0.0, 0.0]$

Comparison 3. Surgery: Anatomic (reinsertion) versus anatomic (imbrication)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Unsatisfactory functional score at 2 years	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2 Tegner score (0: worst to 10: best)			Other data	No numeric data
3 Subjective instability and pain 3.1 Subjective instability	1 1		Risk Ratio (M-H, Fixed, 95% CI) Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected 0.0 [0.0, 0.0]

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3.2 Chronic pain	1	Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \; [0.0, 0.0]$
3.3 Non-return to prior	1	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
athletic activity			
4 Complications	1	Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4.1 Wound complications	1	Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \ [0.0, 0.0]$
4.2 Nerve damage	1	Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \ [0.0, 0.0]$
5 Radiographic stability at follow-		Other data	No numeric data
up			
6 Operating time (minutes)	1	Mean Difference (IV, Fixed, 95% CI)	Subtotals only
6 Operating time (minutes)	1	Mean Difference (IV, Fixed, 95% CI)	Subtotals only

Comparison 4. Surgery: Dynamic tenodesis versus static tenodesis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Unsatisfactory function at 25	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
months				
2 Complications and revisions	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 'Distortion trauma'	1		Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \ [0.0, 0.0]$
2.2 Nerve damage	1		Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \; [0.0, 0.0]$
2.3 Deep venous thrombosis	1		Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \; [0.0, 0.0]$
2.4 Swelling	1		Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \ [0.0, 0.0]$
2.5 Reintervention	1		Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \; [0.0, 0.0]$
2.6 Revision	1		Risk Ratio (M-H, Fixed, 95% CI)	$0.0 \; [0.0, 0.0]$
3 Return to work (weeks)			Other data	No numeric data
4 Hindfoot inversion			Other data	No numeric data

Comparison 5. Post-operative rehabilitation: Early mobilisation in a brace versus plaster immobilisation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Karlsson score - unsatisfactory function	2	70	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.06, 1.28]
2 Tegner score (0: worst to 10: best)			Other data	No numeric data
3 Non-return to prior athletic activity	2	70	Risk Ratio (M-H, Fixed, 95% CI)	0.5 [0.10, 2.55]
4 Return to previous activity level (weeks)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 Time to return to work	1		Mean Difference (IV, Fixed, 95% CI)	$0.0 \ [0.0, 0.0]$
4.2 Time to return to sport	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Return to previous activity (weeks)			Other data	No numeric data
6 Range of motion			Other data	No numeric data
7 Radiographic stability at follow- up			Other data	No numeric data

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8 Postoperative complications	2	Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
8.1 Superficial wound infection	2	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8.2 Sensory disturbance on lateral aspect of foot	1	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

ADDITIONAL TABLES

Table 1. Outcome measures

Patient derived	Physical examination	Additional
Patient derived1. Subjective instability (primary outcome measure) a) Feeling of apprehension: yes/no2. Recurrent injury a) Yes/no b) Number of sprains per week3. Use of external support a) Yes/no b) No/ during exercise/ constant4. Pain a) Yes/no b) Visual analogue scale c) Numeric rating scale5. Swelling a) Yes/no6. Time to return to work/sports a) Weeks	 Physical examination 1. Mechanical laxity a) Yes/ no 2. Limited range of motion a) Compared to healthy side: yes/no b) Compared to pre-treatment range of motion: increased/decreased 3. Swelling a) Yes/no 4. Muscle atrophy or weakness a) Compared to healthy side: yes/no b) Medical Research Council Scale for grading muscle power 	 Functional outcome (Ankle) scoring systems (primary outcome measure) Mechanical laxity
7. Patient satisfactiona) Visual analogue scaleb) Numeric rating scale		

WHAT'S NEW

Last assessed as up-to-date: 12 May 2010.

Date	Event	Description
21 June 2011	New citation required and conclusions have changed	The main change to the conclusions reflects the inclusion of three trials testing neuromuscular training
21 June 2011	New search has been performed	 For this update, the following changes were made: 1. The search was updated to February 2010. 2. Three new studies were identified and included (Clark 2005; Hale 2007; McKeon 2008b). All three studies assessed the use of neuromuscular training. 3. Risk of bias was assessed. 4. The conclusions were revised.

HISTORY

Protocol first published: Issue 2, 2003 Review first published: Issue 4, 2006

Date	Event	Description
24 July 2008	Amended	Converted to new review format

CONTRIBUTIONS OF AUTHORS

JS de Vries designed, co-ordinated and collected data for the review. IN Sierevelt assisted with the study selection and quality assessment. Rover Krips assisted with data extraction and analysis. L Blankevoort was involved as the third reviewer to solve disagreement when necessary. CN van Dijk provided general advice and assisted with writing of the review.

DECLARATIONS OF INTEREST

One author (JdV) received support for his PhD (of which this review forms a part) from DePuy Mitek. No other conflict of interest declared.

SOURCES OF SUPPORT

Internal sources

• Orthopaedic Department, Academic Medical Centre, Amsterdam, Netherlands.

External sources

• Mitek Depuy, PO Box 188, 3800 AD Amersfoort, Netherlands.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

For the update, published in Issue 8, 2011, we assessed the risk of bias rather than methodological quality.

INDEX TERMS

Medical Subject Headings (MeSH)

*Ankle Joint [surgery]; Chronic Disease; Early Ambulation; Exercise Therapy [methods]; Joint Instability [etiology; surgery; *therapy]; Randomized Controlled Trials as Topic; Sprains and Strains [complications]

MeSH check words

Humans