Custom-made foot orthoses for the treatment of foot pain (Review)

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[Intervention Review]

Custom-made foot orthoses for the treatment of foot pain

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ABSTRACT

Background

Custom foot orthoses are commonly recommended for the treatment of foot pain.

Objectives

To evaluate the effectiveness of custom foot orthoses for different types of foot pain.

Search strategy

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2007, Issue 2), MEDLINE (from January 1966), EMBASE (from January 1980), CINAHL (from January 1982) and the Physiotherapy Evidence Database (PEDro) (to June 2007). We also contacted authors of included trials and known researchers in the field and checked the reference lists of included trials to identify trials. No language or publication restrictions were applied.

Selection criteria

Randomised controlled trials and controlled clinical trials evaluating custom-made foot orthoses for any type of foot pain. Outcomes included quantifiable levels of foot pain, function, disability, health-related quality of life, participant satisfaction, adverse effects and compliance.

Data collection and analysis

Two authors independently selected trials, rated methodological quality and cross checked data extraction. Data were analysed separately for different diagnoses of foot pain and follow-up time points.

Main results

Eleven trials involving 1332 participants were included: five trials evaluated custom-made foot orthoses for plantar fasciitis (691 participants); three for foot pain in rheumatoid arthritis (231 participants); and one each for foot pain in pes cavus (154 participants), hallux valgus (209 participants) and juvenile idiopathic arthritis (JIA) (47 participants). Comparisons to custom-made foot orthoses included sham orthoses; no intervention; standardised interventions given to all participants; non-custom (prefabricated) foot orthoses; combined manipulation, mobilisation or stretching; night splints; and surgery. Follow up ranged from one week to three years. Custom-made foot orthoses were effective for painful pes cavus (NNTB:5), rearfoot pain in rheumatoid arthritis (NNTB:4), foot pain in JIA

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(NNTB:3) and painful hallux valgus (NNTB:6); however, surgery was even more effective for hallux valgus and non-custom foot orthoses appeared just as effective for JIA but the analysis may have lacked sufficient power to detect a difference in effect. It is unclear if custom-made foot orthoses were effective for plantar fasciitis or metatarsophalangeal joint pain in rheumatoid arthritis. Custom-made foot orthoses were a safe intervention in all studies.

Authors' conclusions

There is limited evidence on which to base clinical decisions regarding the prescription of custom-made foot orthoses for the treatment of foot pain. Currently, there is gold level evidence for painful pes cavus and silver level evidence for foot pain in JIA, rheumatoid arthritis, plantar fasciitis and hallux valgus.

PLAIN LANGUAGE SUMMARY

Custom-made foot orthoses for the treatment of foot pain

This summary of a Cochrane review presents what we know from research about the effect of custom-made foot orthoses for the treatment of foot pain;

The review shows that in adults who have had painful pes cavus (high arch), for more than one month custom foot orthoses:

Decreases foot pain after 3 months compared with fake foot orthoses.

The review shows that for people at least 5 years of age and diagnosed with juvenile idiopathic arthritis (JIA), custom foot orthoses:

Reduce foot pain after 3 months compared with supportive shoes, but do not reduce foot pain after 3 months compared with using prefabricated neoprene shoe inserts.

The review shows that in adults with rheumatoid arthritis (RA), custom foot orthoses:

Reduce rearfoot pain after 3 months, compared with doing nothing, but do not reduce foot pain after 3 years, compared with using fake foot orthoses.

May not reduce pain in the metatarsophalangeal joint (where the big toe meets the foot) after 6 weeks or 3 months any more than wearing supportive shoes or using soft non-custom foot orthoses.

The review shows that for people diagnosed with plantar fasciitis (heel pain), custom foot orthoses:

May not reduce foot pain after 3 or 12 months any more than using fake foot orthoses

May not reduce foot pain after 6 weeks or 3 months any more than using night splints to hold your feet in a stretched position while you sleep. However, using custom foot orthoses and night splints together may reduce foot pain.

May not reduce foot pain after 2-3 months or 1 year any more than non-custom foot orthoses

May not reduce foot pain after 6-8 weeks when used along with a program of stretching exercises or night splints.

May not reduce foot pain after 2 weeks any more than a combined treatment of manipulation, mobilisation and stretching.

This review shows that for people younger than 60 years of age with painful hallux vagus (a condition where the base of the big toe bulges out sideways, away from the foot) custom-made foot orthoses:

Reduce foot pain after 6 months compared to no treatment, but may not reduce foot pain after 6 or 12 months compared to surgery.

Safety of custom foot orthoses

We often do not have precise information about side effects and complications. This is particularly true for rare but serious side effects. Reported adverse effects included additional foot pain, ankle instability and skin irritation.

What are custom foot orthoses and what is foot pain?

This review focuses only on custom ('custom-made') foot orthoses, which are defined in this review as contoured, removable in-shoe devices that are moulded or milled from an impression of the foot (for example a plaster cast, three-dimensional laser scan) and fabricated according to practitioner-prescribed specifications.

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Foot pain may be experienced following an injury; long-term overuse; infection; or systemic disease involving any tissue of the foot, including bones, joints, ligaments, muscles, tendons, nerves, skin, and nails. Foot pain can be generalised or more specifically diagnosed according to location (for example heel pain), structure (for example tendon or ligament damage) or condition (for example osteoarthritis).

Best estimate of what happens to people with foot pain caused by a high arch who use custom foot orthoses compared to a fake foot orthoses:

After 3 months, a custom-made foot orthoses improves foot pain by 11 more points on a scale of 0 to 100 (possibly as many as 19 points or as few as 3 points).

Best estimate of what happens to people with RA who have foot pain and who use custom foot orthoses compared to wearing supportive shoes or doing nothing:

After 3 months, custom-made foot orthoses improve foot pain by 14 more points on a scale of 0 to 100 (possibly as many as 23 points or as few as 5 points).

After 2 and a half years, custom-made foot orthoses improve foot pain.

Best estimate of what happens to children with JIA who have foot pain and who use custom foot orthoses compared to wearing supportive shoes:

After 3 months, custom-made foot orthoses improve foot pain by 19 more points on a scale of 0 to 100 (possibly as many as 36 points or as few as 3 points).

Best estimate of what happens to people with a painful bunion with hallux valgus who use custom foot orthoses:

After 6 months, custom-made foot orthoses improve foot pain by 9 more points on a scale of 0 to 100 (possibly as many as 17 points or as few as 1 point) compared to doing nothing.

After 6 months, surgery improved foot pain by 10 more points on a scale of 0 to 100 (possibly as many as 18 or as few as 2 points) compared to the custom foot orthoses.

After 12 months, surgery improved foot pain by 17 more points on a scale of 0 to 100 (possibly as many as 25 or as few as 9 points) compared to the custom foot orthoses.

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BACKGROUND

Description of the condition

Foot pain is an unpleasant sensory and emotional experience associated with perceived damage to any tissue below the ankle (IASP 1994). It may be experienced following direct injury; long-term musculoskeletal overload (for example overuse); infection or systemic disease involving any tissue of the foot, including bones, joints, ligaments, muscles, tendons, apophyses, retinacula, fascia, bursae, nerves, skin, nails and vascular structures. Foot pain can be generalised or more specifically diagnosed according to location (for example heel pain), structure (for example tendon or ligament damage) or condition (for example osteoarthritis).

While large, population-based studies of general foot pain prevalence are lacking, more narrowly focused studies have reported foot pain prevalence at 24% for women and 20% for men aged 18 to 80 years (Garrow 2004), 42% for people over 65 years of age (Badlissi 2005) and 14% for adolescents (Spahn 2004). Foot pain classified as disabling has been reported by 36% of people aged 70 to 95 years (Menz 2006) and by 10% of people aged 18 to 80 years (Garrow 2004).

Foot pain has been linked to limitations in activities of daily living, disability and deterioration of physical and mental aspects of health-related quality of life (Benvenuti 1995; Leveille 1998; Menz 2001). Foot pain is more likely to be experienced by people suffering from knee, hip, back or hand and wrist pain or a chronic disease (Garrow 2004; Leveille 1998; Menz 2006). Concerning the treatment of foot pain, in a cross-sectional, community-based randomly selected sample of 3417 people, only 36% of persons with disabling foot pain reported receiving foot-related treatment from a healthcare professional (for example a podiatrist, general practitioner or physiotherapist) in the preceding six months (Garrow 2004).

Description of the intervention

A wide variety of interventions is available for treating the different types of foot pain, including mechanical interventions, physical therapy, drug therapy and surgery. People with foot pain may be offered just one of these options or several of them in combination. In-shoe foot orthoses are one form of mechanical therapy that is widely prescribed as a conservative treatment for some types of foot pain, particularly for problems occurring during walking and running (Landorf 2000). There are many types of foot orthoses available for the treatment of foot pain, ranging from generic 'off-the-shelf' heel pads and contoured prefabricated inner soles to custom-made foot orthoses of varying styles, construction materials, additions and modifications (Landorf 2004). Consistent terminology is not always used for these different types, which has caused confusion (Landorf 2004).

This review focuses only on custom (custom-made) foot orthoses, which are defined in this review as contoured, removable in-shoe devices that are moulded or milled from an impression of the foot (for example a plaster cast or three-dimensional laser scan) and fabricated according to practitioner-prescribed specifications. There is no international or interdisciplinary consensus for the definition of customised foot orthoses. Readers are advised to check carefully whether the foot orthoses they consider 'custom-made' fall within the definition used in this review.

How the intervention might work

It is not well understood how custom-made foot orthoses might affect foot pain. There are a number of theoretical explanations, including resisting or facilitating motion (Nigg 1998; Novick 1990; Stacoff 2000); plantar pressure reduction and redistribution (Cornwall 1997; Novick 1993; Redmond 2000); altered muscle activity (Nawoczenski 1999; Tomaro 1993) and enhanced proprioception (position sense) (Nawoczenski 2004). Scientific evaluation of these theories has posed many challenges for researchers (Landorf 2000) and overwhelming support for one particular theoretical model is lacking (Razeghi 2000). It is likely, however, that orthoses have different mechanisms for different types of foot pain.

Why it is important to do this review

A broad but largely uncoordinated body of research that is relevant to the treatment of different types of foot pain with custom-made foot orthoses is accumulating. Inconsistencies in trial methodology, trial quality, orthoses-related terminology and orthosis fabrication have made understanding and assimilating the available evidence particularly challenging for interested groups, including healthcare providers, users and policy decision makers. A systematic review of the effect of custom-made foot orthoses for the treatment of different types of foot pain would assist in this assimilation process and provide a basis for an ongoing appraisal of the custom-made foot orthoses literature.

Custom-made foot orthoses have been evaluated in, or might be evaluated in future updates of, Cochrane systematic reviews on the relative effectiveness of various interventions for specific musculoskeletal conditions (Ashford 2005; Brouwer 2005; Burns 2006a; Crawford 2003; D'hondt 2002; Egan 2001; Ferrari 2004; Rome 2005; Rome 2007; Sackley 2007; Spencer 2000; Thomson 2004). This review provides an overall evaluation of the effectiveness of custom-made foot orthoses with a specific focus on treating different types of foot pain.

OBJECTIVES

To evaluate the effectiveness of custom-made foot orthoses for the treatment of different types of foot pain.

METHODS

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Criteria for considering studies for this review

Types of studies

All randomised controlled trials and controlled clinical trials (as defined by Higgins 2006) of custom-made foot orthoses for the treatment of any type of foot pain.

Types of participants

Participants of any age who reported foot pain of any type, aetiology and duration. Analyses were conducted separately for different diagnoses of foot pain.

Types of interventions

All trials investigated custom-made foot orthoses, which were defined in this review as contoured, in-shoe devices that were moulded or milled from an impression of the foot (for example a plaster cast or three-dimensional laser scan) and fabricated according to practitioner-prescribed specifications. All comparative interventions and non-interventions evaluated in trials investigating the effectiveness of custom-made foot orthoses for the treatment of foot pain were included.

Types of outcome measures

Primary outcome

The level of a quantifiable measure of foot pain, or the change in the level of pain, after intervention. Any similarly defined outcome measure used to evaluate foot pain was to be considered. Trials investigating the effectiveness of custom-made foot orthoses for the prevention of foot pain or deformity were not included.

Secondary outcomes

(1) Disability or functional ability, or both
(2) Health-related quality of life
(3) Participant satisfaction with the intervention
(4) Adverse events
(5) Compliance

Search methods for identification of studies

Electronic searches

The following databases were searched up to June 2007:
(1) MEDLINE (from 1966) (Table 1);
(2) CINAHL (from 1982) (Table 2);
(3) EMBASE (from 1980) (Table 3);
(4) Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2007, Issue 2) (Table 4); and
(5) Physiotherapy Evidence Database (PEDro) (Table 5).

Table 1. MEDLINE search strategy

Ovid MEDLINE
1. exp foot/
2. exp Foot Joints/
3. exp Foot Injuries/
4. exp Foot Bones/
5. exp Heel/
6. (foot or feet or heel$).tw.
7. or/1-6
8. exp Pain/
9. pain$.tw.
10. 8 or 9
11. 7 and 10
12. exp Fasciitis, Plantar/
13. plantar fasciitis.tw.
14. exp Sesamoid Bones/
15. sesamoiditis.tw.
16. exp Metatarsalgia/
17. exp Osteoarthritis/
18. osteoarthrit$.tw.
19. exp Tendinopathy/
20. (tendinitis or tendonitis).tw.
21. exp Fractures, Stress/

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Table 1. MEDLINE search strategy (*Continued*)

22. or/17-21
23. 7 and 22
24. or/11-16,23
25. exp Orthotic Devices/
26. (orthos$ or orthotic$).tw.
27. (shoe adj device$).tw.
28. in-shoe.tw.
29. (heel adj pad$).tw.
30. in-sole$.tw.
31. insole$.tw.
32. innersole$.tw.
33. ((orthopedic or orthopaedic) adj shoe$).tw.
34. or/25-33
35. 24 and 34
36. clinical trial.pt.
37. randomized.ab.
38. placebo.ab.
39. dt.fs.
40. clinical trials/
41. randomly.ab.
42. trial.ti.
43. groups.ab.
44. or/36-43
45. animals/
46. humans/
47. 45 and 46
48. 45 not 47
49. 44 not 48
50. 35 and 49

Table 2. CINAHL search strategy

CINAHL
1. exp FOOT/
2. exp Foot Injuries/
3. exp Foot Bones/
4. exp Foot Diseases/
5. exp HEEL/
6. (foot or feet or heel$).tw.
7. or/1-6

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Table 2. CINAHL search strategy (*Continued*)

8. exp PAIN/
9. pain$.tw.
10. 8 or 9
11. 7 and 10
12. exp PLANTAR FASCIITIS/
13. plantar fasciitis.tw.
14. exp Sesamoid Bones/
15. sesamoiditis.tw.
16. Metatarsalgia.tw.
17. exp OSTEOARTHRITIS/
18. osteoarthrit$.tw.
19. exp Tendinitis/
20. (tendinitis or tendonitis).tw.
21. exp Fractures, Stress/
22. or/17-21
23. 11 and 22
24. or/12-16,23
25. exp Orthoses/
26. (orthos$ or orthotic$).tw.
27. (shoe adj device$).tw.
28. in-shoe.tw.
29. (heel adj pad$).tw.
30. in-sole$.tw.
31. insole$.tw.
32. innersole$.tw.
33. ((orthopedic or orthopaedic) adj shoe$).tw.
34. or/25-33
35. 24 and 34

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Table 3. EMBASE search strategy

EMBASE
1. exp FOOT/
2. exp Foot Injury/
3. exp HEEL/
4. (foot or feet or heel$).tw.
5. or/1-4
6. exp PAIN/
7. pain$.tw.
8. 6 or 7
9. 5 and 8
10. exp PLANTAR FASCIITIS/
11. plantar fasciitis.tw.
12. exp Sesamoid Bone/
13. sesamoiditis.tw.
14. exp METATARSALGIA/
15. exp OSTEOARTHRITIS/
16. osteoarthrit$.tw.
17. exp Tendinitis/
18. (tendinitis or tendonitis).tw.
19. exp Stress Fracture/
20. or/15-19
21. 5 and 20
22. or/10-14,21
23. exp Orthotics/
24. (orthos$ or orthotic$).tw.
25. (shoe adj device$).tw.
26. in-shoe.tw.
27. (heel adj pad$).tw.
28. in-sole$.tw.
29. insole$.tw.

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Table 3. EMBASE search strategy (*Continued*)

30. innersole$.tw.
31. ((orthopedic or orthopaedic) adj shoe$).tw.
32. or/23-31
33. 22 and 32

Table 4. Cochrane Central Register of Controlled Trials search strategy

Search strategy
#1MeSH descriptor Foot explode all trees
#2MeSH descriptor Foot Joints explode all trees
#3MeSH descriptor Foot Injuries explode all trees
#4MeSH descriptor Foot Bones explode all trees
#5MeSH descriptor Heel explode all trees
#6(foot or feet or heel*):ti,ab
#7(#1 OR #2 OR #3 OR #4 OR #5 OR #6)
#8MeSH descriptor Pain explode all trees
#9pain*:ti,ab
#10(#8 OR #9)
#11(#7 AND #10)
#12MeSH descriptor Fasciitis, Plantar explode all trees
#13“plantar fasciitis”:ti,ab
#14MeSH descriptor Sesamoid Bones explode all trees
#15 sesamoiditis:ti,ab
#16MeSH descriptor Metatarsalgia explode all trees
#17MeSH descriptor Osteoarthritis explode all trees
#18osteoarthrit*:ti,ab
#19MeSH descriptor Tendinopathy explode all trees
#20(tendinitis or tendonitis):ti,ab
#21MeSH descriptor Fractures, Stress explode all trees
#22(#17 OR #18 OR #19 OR #20 OR #21)

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Table 4. Cochrane Central Register of Controlled Trials search strategy (*Continued*)

#23(#7 AND #22)
#24(#11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #23)
#25MeSH descriptor Orthotic Devices explode all trees
#26(orthos* or orthotic*):ti,ab
#27shoe next device*:ti,ab
#28in-shoe:ti,ab
#29heel next pad*:ti,ab
#30in-sole*:ti,ab
#31insole*:ti,ab
#32innersole*:ti,ab
#33((orthopedic or orthopaedic) next shoe*):ti,ab
#34(#25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33)
#35(#24 AND #34)

Table 5. PEDro search strategy

PEDro
Using drop-down menus:
Therapy = Orthoses, tapering, splinting
Problem = Pain
Body Part = Foot or ankle
Method = Clinical trial

The search strategies used for each of these databases are displayed under Additional Tables 01 to 05. There were no language restrictions applied.

Other sources

The reference lists of all included trials were checked recursively for other potentially relevant trials. The first authors of included trials and known researchers in the field were contacted via e-mail to assist in identifying unpublished and published trials.

Data collection and analysis

Study selection

Two review authors (FH and JB) independently assessed titles and abstracts (where available) of all trials identified by the search. Full-text copies of potentially relevant trials were then assessed independently for inclusion by the same two review authors (FH and JB) using predetermined inclusion criteria. Disagreements were

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resolved by discussion between authors or, when necessary, arbitration by a third author (JR).

Methodological quality assessment

The methodological quality of included trials was rated independently by two review authors (FH and JR) using the following criteria as described in the Cochrane Handbook of Systematic Reviews of Interventions (Higgins 2006):

(1) randomisation;
(2) concealment of allocation;
(3) blinding of intervention provider;
(4) blinding of participants;
(5) blinding of outcomes assessment;
(6) handling of withdrawals and losses (analysis by intention to treat);
(7) completeness of follow up.

Within this review, there were two essential criteria for intention-to-treat (ITT) analyses as defined by the Cochrane Handbook of Systematic Reviews of Interventions (Higgins 2006):

(1) trial participants were analysed in the groups to which they were randomised regardless of which (or how much) treatment they received; and
(2) all participants were included in analyses regardless of whether their outcomes were actually collected.

When only the first of the two criteria was fulfilled, this was termed available case analysis. When trials based analyses only on those participants for whom outcomes were measured and who complied with their allocated treatment, this was termed per protocol analysis (also known as treatment received analysis) (Higgins 2006).

Each criterion, excluding allocation concealment, was assigned a yes, no or unclear classification. Allocation concealment was classified as: adequate (A), unclear (B), inadequate (C), not used (D) in accordance with definitions provided by the Cochrane Musculoskeletal Group (Maxwell 2006) (see Table 6).

Table 6. Allocation concealment criteria

Level	Criteria
(A) Adequate	Centralised (e.g., allocation by a central office unaware of participant characteristics) or pharmacy-controlled randomisation. Pre-numbered or coded identical containers, which are administered serially to participants. On-site computer system combined with allocations kept in a locked unreadable computer file that can be accessed only after the characteristics of an enrolled participant have been entered. Sequentially numbered, sealed, opaque envelopes.

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Table 6. Allocation concealment criteria (*Continued*)

(B) Unclear	When no concealment approach is reported (e.g., merely stating that a list or table was used, only specifying that sealed envelopes were used, or reporting an apparently adequate concealment scheme in combination with other information that leads the reviewer to be suspicious).
(C) Inadequate	Includes alternation; the use of case record numbers, dates of birth or day of the week, and any procedure that is entirely transparent before allocation, such as an open list of random numbers.
(D) Not used	Clearly stated that allocation concealment was not used.

Quality criteria for individual trials were summarised using a three-category rank corresponding to overall risk of bias (Higgins 2006), classified as:

(1) low, all individual quality criteria met;

(2) moderate, one or more criteria partially met;

(3) high, one or more criteria not met.

Data extraction

One review author (FH) extracted data from included trials using separate, standardised, pilot-tested forms. Two other authors (JR and VdT) independently cross checked extracted data. Study authors were contacted via e-mail and requested to provide missing information or clarification of unclear data, as required. Each author who replied to the initial e-mail was later sent the complete data extraction form for their paper and encouraged to elaborate on clinically relevant information that was not included in the published paper, for example description of interventions. All additions made to the data extraction forms by the authors were italicised and clear notes made that the information presented was obtained through personal communication with the study author. Any disagreement in data extraction was resolved by discussion between review authors (FH, JR and VdT).

Analysis

Measures of treatment effect

Where possible, continuous data were extracted and analysed using weighted mean differences (WMD) and 95% confidence intervals (CI). When different measurement scales were used within a single analysis, standardised mean differences (SMD) were estimated. Changes from baseline (mean change scores) were used as the primary outcome. Where change scores with appropriate measures of variability were not available, follow-up scores adjusted for the baseline score on the outcome of interest were to be used, if available. When neither change scores nor baseline-adjusted scores were available with appropriate measures of variability, plain follow-up (final value) scores were used. Change scores, baseline-adjusted scores and plain follow-up scores were combined in the same analysis using WMD when equivalent outcome measures were used (Higgins 2006). Results for dichotomous data were reported as relative risks (RR) with 95% CI.

Crossover trials

Crossover trials were included, however, only data from the first phase of interventions were included in analyses (Higgins 2006) as the effectiveness of wash-out periods for custom-made foot orthoses is unknown.

Dealing with missing data

Where available, data were extracted from intention-to-treat analyses. If the original researchers did not perform intention-to-treat analyses but sufficient raw data were available to do so, intention-to-treat analysis was to be conducted before entering data into Review Manager to limit attrition bias.

Assessment of heterogeneity

Three review authors (FH, JB and JR) assessed clinical heterogeneity across trials. When trials were deemed sufficiently clinically homogenous in terms of participants, interventions and outcomes they were combined in meta-analysis. Inter-trial statistical heterogeneity was quantified using I^2 (Higgins 2006). Trials in the meta-analysis were considered to have low statistical heterogeneity if I^2 was equal to or less than 25% (Higgins 2003), in which case a fixed-effect model was used. If I^2 was greater than 25%, and the heterogeneity could not be readily explained, a random-effects model was used to incorporate inter-trial heterogeneity (Higgins 2006).

Data synthesis

The Cochrane statistical package, Review Manager 4.2 (Review Manager 2003), was used for statistical analyses. Data were entered into Review Manager by one review author (FH) and checked by a second author (JR) using the double data entry facility.

Primary analysis

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Results were analysed separately for different diagnoses of foot pain. Since the assumption of steady rates of change could not be reasonably justified, trials with differing follow-up periods were not combined (Higgins 2006).

Subgroup analysis

Subgroup analyses according to participant age (< 18 years versus ≥ 18 years) were planned but were not performed due to lack of data.

Sensitivity analyses

Sensitivity analyses were performed by including only trials of high methodological quality (low to moderate risk of bias). Where all trials had a high risk of bias, sensitivity analyses were performed by excluding trials not concealing allocation or blinding the participants to the intervention group. If one or more outliers were found to contribute to heterogeneity, and a reason for the outlying result was apparent, analyses were performed both with and without outlying trials as a component of the sensitivity analyses (Higgins 2006).

Grading the strength of evidence

The strength of evidence was graded as platinum, gold, silver or bronze using criteria described in the Cochrane Musculoskeletal Group (CMSG) module scope and in Evidence-based Rheumatology (Tugwell 2004) (see Table 7).

Table 7. Grading the strength of evidence

Level	Criteria
Platinum	Awarded if at least two individual controlled trials within the analysis had: 1. sample sizes of at least 50 per group. If they did not detect a statistically significant difference, they were adequately powered for a 20% relative difference in the relevant outcome; 2. blinding of participants and assessors of outcomes; 3. handling of withdrawals: >80% follow up (imputations based on methods such as last observation carried forward (LOCF) acceptable); and 4. concealment of allocation.
Gold	Awarded if at least one randomised clinical trial met all the following criteria for the major outcome as reported: 1. sample sizes of at least 50 per group. Note: If they did not detect a statistically significant difference, they were adequately powered for a 20% relative difference in the relevant outcome; 2. blinding of participants and outcome assessors; 3. handling of withdrawals: >80% follow up (imputations based on methods such as last observation carried forward (LOCF) acceptable); and 4. concealment of allocation.

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Table 7. Grading the strength of evidence (*Continued*)

Silver	Awarded if the above criteria were not met but the analysis included evidence from at least one study of non-randomised cohorts who did or did not receive therapy, or evidence from at least one high quality case-control study. A randomised trial with a 'head to head' comparison of interventions was considered silver ranking unless a reference was provided to a comparison of one of the interventions to placebo showing at least a 20% relative difference.
Bronze	Awarded if the above criteria were not met but included at least one high quality case series without controls (including simple before and after trials in which participants act as their own control) or if the conclusion is derived from expert opinion based on clinical experience without reference to any of the foregoing.

Clinical relevance tables

Clinical relevance tables were constructed to improve the readability of the review (Additional Tables 09 to 25). These were constructed for the primary outcome (pain) and for adverse effects as per CMSG guidelines. For dichotomous data, the weighted absolute risk difference was calculated using the risk difference (RD) statistic in RevMan; RR - 1 calculated the weighted relative per cent change (Cates 2004). Becasue all comparisons using dichotomous data found no statistically significant differences between groups, the number needed to treat to benefit (NNTB) and the number needed to treat to harm (NNTH) could not be calculated, as planned.

For continuous outcomes, weighted absolute change was calculated from the WMD statistic in RevMan when outcomes within each analysis were measured on the same scale. For outcomes pooled on different scales, the weighted absolute change was calculated by multiplying the SMD by the baseline SD in the control group. Relative per cent change from baseline was calculated by dividing the absolute benefit by the baseline mean of the control group. For outcomes where a statistically significant difference had been detected, NNTB was calculated using the MID for each outcome and the Wells calculator software available at the Cochrane Musculoskeletal Group's editorial office.

NNTB or NNTH was calculated for each statistically significant estimate of effect for any outcome. Where possible for continuous outcomes, NNT was calculated using:

(1) the minimal important differences (MID) calculated by Landorf and Radford (Landorf 2007) for the Foot Health Status Questionnaire, Foot Function Index and 100 mm visual analogue pain scale; and

(2) the Wells calculator software available at the Cochrane Musculoskeletal Group's editorial office, based on the theory of Norman et al (Norman 2001) for determining NNTB based on achieving a MID on a continuous outcome.

MID calculations by Landorf and Radford (Landorf 2007) were based on data from two trials evaluating the effectiveness of foot orthoses and low-Dye taping for plantar fasciitis. These estimates are currently the most carefully prepared estimates of MID for foot-related research. MID for types of foot pain other than plantar fasciitis and for interventions other than foot orthoses and low-Dye taping might differ from those used for this review. MID for the 36-Item Short-Form Health Survey (physical functioning and vitality domains) were based on estimates by three expert panels of physicians for Chronic Obstructive Pulmonary Disease, Asthma and Heart Disease (Wyrwich 2005).

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Details of individual trials are presented in the 'Characteristics of included studies' table.

Selection of studies

Electronic searches retrieved a total of 389 citations. Of these, 27 were identified as potentially relevant. Personal communication with authors of included trials and known researchers in the field yielded an additional eight potentially relevant trials. Recursive searching of reference lists of included trials did not retrieve any additional potentially relevant trials. In total, 35 potentially relevant trials were identified.

Excluded studies

Twenty-four potentially relevant trials were excluded upon reading the full-text versions. Reasons for exclusion were: eight were not randomised or controlled clinical trials (as defined by Higgins 2006) (Chao 1996; Doxey 1985; Magalhaes 2006; Poon 1997; Sobel 1999; Stell 1998; Torkki 2003; Turlik 1999); nine did not evaluate custom-made foot orthoses as defined in this review (Hodge 1999; Kilmartin 1994; Kusumoto 2007; Larsen 2002; Meijad 2004; Orteza 1992; Rome 2004; Russell 1999; Saygi 2005); three did not evaluate pain specific to the foot (Grau 2003; Saggini 1996; Wenger 1989); three did not report current foot pain as an inclusion criteria (Postema 1998; Wenger 1989; Whitford 2007); and one did not evaluate custom-made foot orthoses in such a way that their effect could be isolated (Lynch 1998). Details

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of individual trials are presented in the table 'Characteristics of excluded studies'.

Included studies

Eleven of the potentially relevant trials fulfilled all criteria for inclusion in the review (Burns 2006; Chalmers 2000; Conrad 1996; Dimou 2004; Landorf 2006; Martin 2001; Pfeffer 1999; Powell 2005; Roos 2006; Torkki 2001; Woodburn 2002). Electronic searching identified all of these trials. Details of individual trials are presented in the table 'Characteristics of included trials'.

Of the 11 trials included, 10 were parallel-designed randomised controlled trials and one was a crossover randomised controlled trial (Chalmers 2000). The duration of follow up ranged from two months to three years. All trials were published in the English language in peer-reviewed journals between 1996 and 2006.

Participants

A total of 1332 participants were included in the 11 trials. The number of participants recruited in each study ranged from 20 to 255. Of the 10 trials for which adequate details were reported, 889 (72.5%) were female and 337 (27.5%) were male. Conrad 1996 did not report gender. Of the 10 trials reporting mean age of participants, mean age within treatment groups ranged from 12.7 to 63 years. Conrad 1996 did not report mean age of participants. One trial included primarily children (Powell 2005) and seven explicitly excluded children.

Type of foot pain

Custom-made foot orthoses were evaluated for the treatment of foot pain in: plantar fasciitis (Dimou 2004; Landorf 2006; Martin 2001; Pfeffer 1999; Roos 2006); rheumatoid arthritis (Chalmers 2000; Conrad 1996; Woodburn 2002); juvenile idiopathic arthritis (Powell 2005); pes cavus (Burns 2006); and hallux valgus (Torkki 2001).

Comparisons

There were 12 comparisons made to custom-made foot orthoses. These included sham orthoses, no intervention or an intervention provided to all groups; manipulation, mobilisation and stretching; night splints; surgery for hallux valgus; and seven types of non-customised foot orthoses. Seven trials compared more than two intervention arms (Chalmers 2000; Landorf 2006; Martin 2001; Pfeffer 1999; Powell 2005; Roos 2006; Torkki 2001). Details of individual interventions are presented in the 'Characteristics of included studies' table.

Setting

Of those trials reporting trial setting, three were set in hospitals (Chalmers 2000; Powell 2005; Torkki 2001), three in university clinics (Burns 2006; Dimou 2004; Landorf 2006) and three in other health centres or clinics (Chalmers 2000; Conrad 1996; Pfeffer 1999). Four reported using multiple centres (Chalmers 2000; Conrad 1996; Pfeffer 1999; Torkki 2001).

Source of participants

Of those trials reporting recruitment source, three reported recruiting only from centres associated with the research (Conrad 1996; Torkki 2001; Woodburn 2002), two only through referrals from other healthcare providers (Chalmers 2000; Roos 2006) and two combined advertisements in local media with either recruitment from associated centres (Landorf 2006) or referrals from healthcare providers (Burns 2006).

Method of orthoses customisation

All included trials reported fabricating custom-made foot orthoses from impressions of the feet: 10 trials reported taking plaster casts and one (Martin 2001) reported scanning the plantar surface of the foot with a three-dimensional laser scanner. Seven trials reported impressions taken from a neutral foot position (Burns 2006; Dimou 2004; Landorf 2006; Martin 2001; Pfeffer 1999; Powell 2005; Woodburn 2002). Five of the 11 trials did not report the experience of the practitioner performing foot impression. Three trials reported that casts were taken by experienced practitioners (Burns 2006; Landorf 2006; Torkki 2001) and one trial each reported that casts were taken by a podiatrist (Conrad 1996) and that practitioners reviewed an instructional video on casting technique (Pfeffer 1999).

Orthoses prescription

Three trials reported the custom-made foot orthoses prescription process: one used a standardised, previously developed and pilot-tested prescription (Burns 2006); one based orthosis selection on devices most commonly prescribed by surveyed podiatrists (Landorf 2006) and one evaluated participants using the orthoses manufacturer's prescription form (Powell 2005).

Orthoses construction materials

All trials described the shell material used for custom-made foot orthoses construction. Four used polypropylene (Burns 2006; Landorf 2006; Pfeffer 1999; Torkki 2001); two used ethyl vinyl acetate (EVA) (Dimou 2004; Landorf 2006); and one trial each used subortholen (Chalmers 2000), rohadur (Conrad 1996), polydur (Martin 2001), metal particle-reinforced polyolefin (Powell 2005) and carbon graphite composite (Woodburn 2002). Five of the 11 trials reported incorporating a rear foot heelpost to the shells of the orthoses (Burns 2006; Chalmers 2000; Landorf 2006; Martin 2001; Powell 2005).

Orthoses manufacturing

Six trials reported using commercial laboratories to manufacture the custom-made foot orthoses (Burns 2006; Conrad 1996; Landorf 2006; Martin 2001; Pfeffer 1999; Torkki 2001) and two trials reported orthoses fabrication by a practitioner involved in the research: one by a participating occupational therapist with at least two years experience in arthritis care and according to clinical protocols (Chalmers 2000) and one by the principal researcher from the Department of Orthopaedics, Lund University Hospital (Roos 2006). Three trials did not report details of the orthoses manufacturing process (Dimou 2004; Powell 2005; Woodburn 2002).

Additional instructions

Two trials reported providing footwear advice (Burns 2006; Conrad 1996) and one trial each reported providing: identical

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written instructions specified for the randomised treatment protocol (Pfeffer 1999); instruction on caring for the orthoses (Conrad 1996); and education on a progressive wearing schedule (Burns 2006). Two trials explicitly stated that routine treatment was continued throughout the duration of the trial (Burns 2006; Conrad 1996) while one other trial disallowed any other treatment for foot pain throughout the trial (Landorf 2006). One trial permitted normal daily walking aids (Woodburn 2002) and one trial reported encouraging participants not to change their regular footwear or activity for the duration of the trial (Pfeffer 1999). It is unclear for the remaining trials whether these issues were unaddressed or unreported.

Outcomes

Foot pain was an outcome in all 11 trials. Outcome measures of pain included: the pain scale of the Foot Function Index (Conrad 1996; Pfeffer 1999; Powell 2005; Woodburn 2002); 100 mm visual analogue scale (Chalmers 2000; Martin 2001; Torkki 2001); the pain domain of the Foot Health Status Questionnaire (Burns 2006; Landorf 2006); the pain scale of the Foot & Ankle Outcome Score (Roos 2006); and the Numeric Pain Rating Scale 101 (Dimou 2004).

Function was an outcome in seven trials. Outcome measures of function included: the activity limitation scale of the Foot Function Index (Conrad 1996; Powell 2005; Woodburn 2002); the function domain of the Foot Health Status Questionnaire (Burns 2006; Landorf 2006); the sport and recreation subscale of the Foot and Ankle Outcome Score (Roos 2006); and the walking component of the Toronto Activities of Daily Living Measure (Chalmers 2000).

Disability (functional ability) was an outcome in four trials. Outcome measures of disability included: the disability scale of the Foot Function Index (Powell 2005; Woodburn 2002); the activities of daily living subscale of the Foot and Ankle Outcome Score (Roos 2006); and the 100 mm 'ability to work' visual analogue scale (Torkki 2001).

Health-related quality of life was an outcome in three trials. Outcome measures of health-related quality of life included: the four domains of the 36-Item Short-Form Health Survey (physical functioning, general health, vitality and social functioning) (Burns 2006); the quality of life subscale of Foot & Ankle Outcome Score (Roos 2006); and the Health-Related Quality of Life Index (Torkki 2001).

Participant satisfaction with intervention was an outcome in one trial (Torkki 2001), measured using 100 mm 'satisfaction' visual analogue scales (0 = totally unsatisfied and 100 = totally satisfied).

Adverse effects were reported by six trials. Three trials reported the number and nature of adverse effects per group (Burns 2006; Roos 2006; Woodburn 2002), two trials reported only the total number of all adverse effects in each group (Conrad 1996; Dimou 2004) and one trial reported only the number of adverse effects in just one group (surgical group) (Torkki 2001).

Compliance was reported by eight trials. Compliance reports were based on: log book records of use and daily wear time in two trials (Chalmers 2000; Roos 2006); participant-reported retrospective use of the intervention in a specified period before the follow-up session in four trials (Burns 2006; Conrad 1996; Torkki 2001; Woodburn 2002); participant-reported breaks of protocol in one trial (Landorf 2006); and unclear methods in one trial (Dimou 2004). Compliance data in Chalmers (2000) could not be isolated to the first phase of intervention so were not included in the analyses.

Risk of bias in included studies

Details of methodological quality are reported in Additional Table 8: Methodological quality of included studies.

Randomisation

All participants in all trials were randomly allocated to treatment groups. Allocation sequence was generated using computers (Burns 2006; Landorf 2006), random number table (Torkki 2001), a lottery method (Dimou 2004), balanced blocks of four (Woodburn 2002) and undisclosed methods (Chalmers 2000; Conrad 1996; Martin 2001; Pfeffer 1999; Powell 2005; Roos 2006).

Table 8. Methodological quality of included studies

Study ID	Random allocation	Concealed allocation	Blind therapist	Blind participants	Blind outcome assess	Withdrawals and loss	Follow-up	Risk of bias
Burns 2006	Y	A	N	Y	Y	Intention to treat	Y	High

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Table 8. Methodological quality of included studies (*Continued*)

Chalmers 2000	Y	B	N	N	Y	Available case	Y	High
Conrad 1996	Y	B	N	Y	Y	Available case	Y	High
Dimou 2006	Y	B	N	N	Y	Intention to treat	Y	High
Landorf 2006	Y	A	N	Y	Y	Available case	Y	High
Martin 2001	Y	B	N	N	N	Per protocol	N	High
Pfeffer 1999	Y	B	N	N	N	Available case	N	High
Powell 2005	Y	A	N	N	N	Available case	Y	High
Roos 2006	Y	B	N	N	N	Available case	Y	High
Torkki 2001	Y	B	N	N	N	Intention to treat	Y	High
Woodburn 2002	Y	A	N	N	N	Available case	N	High

Concealment of allocation

Concealment of allocation was adequate in three of the included trials (Burns 2006; Landorf 2006; Woodburn 2002). For all other trials, concealment of allocation was unclear from published reports.

Blinding of intervention provider

No included trial blinded the intervention provider. Intervention provider blinding is particularly difficult, if not impossible, to achieve with mechanical therapies such as custom-made foot orthoses. To the review authors' knowledge, blinding of intervention provider has never been reported in any foot orthoses research.

Blinding of participants

Three trials blinded the participants to the intervention(s) provided (Burns 2006; Conrad 1996; Landorf 2006). In these three trials, participant blinding was achieved by comparing custom-made foot orthoses to sham foot orthoses. Sham foot orthoses are developed to have minimal physical effect yet to appear similar enough to the custom-made foot orthoses that participants are unable to determine which treatment they have been provided with.

Blinding of outcomes assessment

Five trials blinded the outcome assessors (Burns 2006; Chalmers 2000; Conrad 1996; Dimou 2004; Landorf 2006).

Handling of withdrawals and losses

Three trials based analyses on principles of intention to treat (Burns 2006; Dimou 2004; Torkki 2001), seven used available case analysis (Chalmers 2000; Conrad 1996; Landorf 2006; Pfeffer 1999; Powell 2005; Roos 2006; Woodburn 2002) and one used per protocol analysis (Martin 2001), as defined in 'Methodological quality assessment'.

Completeness of follow up

Nine trials obtained measures for at least one key outcome from more than 85% of the participants initially allocated to groups (Burns 2006; Chalmers 2000; Conrad 1996; Dimou 2004; Landorf 2006; Powell 2005; Roos 2006; Torkki 2001; Woodburn 2002).

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Follow up was achieved for 81% in Pfeffer et al (Pfeffer 1999) and 76% in Martin et al (Martin 2001).

Summary ranking of overall risk of bias

All 11 trials received a high summary ranking for overall risk of bias. In three trials (Burns 2006; Conrad 1996; Landorf 2006) this ranking was only given due to the lack of intervention provider blinding. To the review authors' knowledge, this has never been achieved in any foot orthoses research. Without including intervention provider blinding in the summary ranking of overall risk of bias, Burns et al (Burns 2006) was at low risk of bias and Conrad et al (Conrad 1996) and Landorf et al (Landorf 2006) were at moderate risk of bias. Summary ranking remained the same for all other trials.

Effects of interventions

In total, 482 participants were allocated to a group receiving custom-made foot orthoses and 850 were allocated to a group receiving another intervention or no intervention. Details of all interventions are provided in the table 'Characteristics of included studies'.

Eight of the 11 published trials presented summary statistics appropriate for use in meta-analysis. Of the remaining three trials: Pfeffer et al (Pfeffer 1999) presented 95% CI from which SD were calculated (Higgins 2002); Dimou et al (Dimou 2004) presented group mean scores in a graph (from which the means were measured) and provided exact inter-group P values (from which SDs were calculated) (Higgins 2002); and Martin et al (Martin 2001) presented only mean change scores for follow up (no SD). Martin et al (Martin 2001) did not respond to requests for SDs of mean change scores. As a result, plain follow-up mean scores were calculated from the change and baseline mean scores provided and the SD estimated by carrying forward the SD of baseline scores.

Authors of three trials responded to requests for additional data for use in meta-analyses: Woodburn et al (Woodburn 2002) provided plain scores for all primary outcomes at three months and change scores for pain outcomes at three months (requested due to baseline differences); Chalmers et al (Chalmers 2000) supplied data isolated to the first phase of intervention for six and 12-weeks follow up; and Roos et al (Roos 2006) supplied mean change scores and SDs for all Foot and Ankle Outcome Score subscales at six weeks (to allow pooling with other change scores using SMD analysis).

Where possible, analyses were performed using a 0 (worst) to 100 (best) scale. To achieve this, if outcomes were reported on 0 (best) to 100 (worst) scales, group mean scores were multiplied by -1. A second review author (JR) checked all conversions. All estimates of effect using the WMD method applied 0 to 100-point scales unless otherwise indicated.

Details of all custom-made foot orthoses and comparison interventions are provided in the table 'Characteristics of included studies'. Comparisons are ordered by foot pain type, beginning with the strongest level of evidence (pes cavus, Comparison 01) followed by juvenile idiopathic arthritis (Comparisons 02, 03), rheumatoid arthritis (Comparisons 04, 05, 06), plantar fasciitis (Comparisons 07, 08, 09, 10) then hallux valgus (Comparisons 12, 13).

Comparison 01: custom-made foot orthoses versus sham orthoses for painful pes cavus

Custom-made foot orthoses were compared with sham orthoses for painful pes cavus in one trial (Burns 2006), including 154 people assessed at three months.

Foot pain

Difference in foot pain between groups was statistically significant: in favour of custom-made foot orthoses after 3 months with a WMD of 10.90 points (95% CI 3.21 to 18.59; NNT 5, 95% CI 3 to 16) (Table 9).

Function

The difference in function between groups was statistically significant: in favour of custom-made foot orthoses after 3 months with a WMD of 11.00 (95% CI 3.35 to 18.65; NNT 5, 95% CI 3 to 15).

Health-related quality of life

Differences in health-related quality of life between groups was statistically significant: in favour of custom-made foot orthoses after 3 months for the Medical Outcomes Short Form-36 domains of physical functioning (WMD 9.50, 95% CI 4.07 to 14.93); NNT 4, 95% CI 3 to 9) and vitality (WMD 5.50, 95% CI 0.26 to 10.74; NNT 7, 95% CI 4 to 221); but were not statistically significant for the domains of general health (WMD 0.5, 95% CI -5.70 to 6.70) or social functioning (WMD 2.50, 95% CI -3.28 to 8.28).

Adverse effects

Any difference in total numbers of reported adverse effects between groups was not statistically significant after 3 months (9% versus 15%; RR 0.61, 95% CI 0.26 to 1.48). Reported adverse effects included additional foot pain, ankle instability and skin irritation (Table 10).

Compliance

Differences in the proportion of participants between the custom-made and sham orthoses groups who reported not using the assigned intervention for most of their shoe wearing time were not statistically significant after 3 months (20% versus 21%; RR 0.98, 95% CI: 0.52 to 1.83).

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Table 9. Clinical relevance table for comparison 01 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
3 months (Burns 2006)	Change scores from the Pain domain of FHSQ	154 (1)	46.7	11%(3.1, 18.4)	23.3%(6.7, 39.8)	5(3 to 16)	Yes	Gold

Table 10. Clinical relevance table for comparison 01 (dichotomous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control event rate	Wt absolute RD	Wt Rel % change	NNT(H)	Stat sig	Quality of evidence
3 months (Burns 2006)	Total number of reported adverse effects	154 (1)	15.19%	-0.1%(-0.2, 0.0)	-39.0%(-74.0, 48.0)	n/a	No	Gold

Comparison 02: custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis

Custom-made foot orthoses were compared with a standardised intervention of supportive shoes provided to all groups in one trial (Powell 2005) including 33 children assessed at three months.

Foot pain

The difference in foot pain between groups was statistically significant after 3 months: in favour of custom-made foot orthoses (WMD 19.19, 95% CI 2.88 to 35.50; NNT 3, 95% CI: 2 to 23) (Table 11).

Function

Difference in function between groups was statistically significant after 3 months: in favour of custom-made foot orthoses (WMD 19.38, 95% CI 3.22 to 35.54; NNT 3, 95% CI: 2 to 19).

Disability

Difference in disability between groups was statistically significant after 3 months: in favour of custom-made foot orthoses (WMD 18.55, 95% CI 2.68 to 34.42; NNT 3, 95% CI 2 to 22).

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Table 11. Clinical relevance table for comparison 02 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
3 months (Powell 2005)	Change scores from the Pain scale of FFI	28 (1)	47.4	19.0% (2.8 to 35.1)	40.5% (6.1 to 74.9)	3 (2 to 23)	Yes	Silver

Comparison 03: custom-made foot orthoses versus non-custom foot orthoses for foot pain in juvenile idiopathic arthritis

Custom-made foot orthoses were compared with non-custom foot orthoses (prefabricated neoprene shoe inserts, Spenco Medical Corporation) for juvenile idiopathic arthritis in one trial (Powell 2005) including 30 participants assessed at three months.

Foot pain

The difference in foot pain between groups was not statistically significant after 3 months (WMD 12.11, 95% CI -4.73 to 28.95) (Table 12).

Function

The difference in function between groups was not statistically significant after 3 months (WMD 11.42, 95% CI -1.07 to 23.91).

Disability

The difference in disability between groups was not statistically significant at 3 months (WMD 14.38, 95% CI -1.46 to 30.22).

Table 12. Clinical relevance table for comparison 03 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
3 months (Powell 2005)	Plain scores of the Pain subscale of the FFI	27 (1)	47.4	12.0%(-4.7 to 28.66)	25.5%(-10.0 to 61.1)	n/a	No	Silver

Comparison 04: custom-made foot orthoses versus no intervention or standardised intervention for foot pain in rheumatoid arthritis

Custom-made foot orthoses were compared with no intervention or a standard intervention provided to all groups for foot pain in rheumatoid arthritis in two trials, at time points ranging from six weeks to 30 months: Chalmers 2000 in 16 people with metatarsophalangeal (MTP) joint pain and Woodburn 2002 in 101 people with rear foot pain. Comparisons with custom-made foot orthoses included a standard intervention of supportive shoes (Chalmers 2000) and no intervention (Woodburn 2002).

Foot pain

Foot pain was assessed after six weeks by one trial (Chalmers 2000).

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The difference in foot pain between groups after 6 weeks was not statistically significant (WMD 8.40, 95% CI -19.92 to 36.72). Foot pain was assessed after three months by both trials. When data were pooled, the difference between groups was not statistically significant (SMD 0.44, 95% CI -0.10 to 0.98), expressed in units of standard deviations. Since both trials had high risk of bias and neither blinded participants to the intervention, sensitivity analysis was performed by including only the trial that concealed allocation (Woodburn 2002). When sensitivity analysis was performed, the difference between groups was statistically significant: in favour of custom-made foot orthoses (SMD 0.59, 95% CI 0.19 to 1.00) equivalent to a WMD of 13.80 (95% CI 4.68 to 22.92; NNT 4 (95% CI 2 to 11), indicating that the result of the meta-analysis is not robust. Further research is needed to investigate the clear effect of custom-made foot orthoses on foot pain in rheumatoid arthritis after three months. Woodburn 2002 also assessed foot pain as a summary of change over 30 months. The difference between groups was statistically significant: in favour of custom-made foot orthoses (WMD 307.80, 95% CI 67.37 to 548.23; no interpretable scale range) (Table 13).

Function

Foot pain-related function was assessed after six weeks by one trial (Chalmers 2000). The difference between groups was not statistically significant (WMD 0.25, 95% CI -0.52 to 1.02). Function was assessed after three months by both trials. When data was pooled, the difference between groups was not statistically significant (SMD 0.08, 95% CI -0.29 to 0.45). Since both trials had a high risk of bias and neither blinded participants to the intervention, sensitivity analysis was performed by including only the trial that concealed allocation (Woodburn 2002). When sensitivity analysis was performed, the difference between groups remained not statistically significant (SMD 0.10, 95% CI -0.30 to 0.50) indicating that the result of meta-analysis is robust. Woodburn 2002 also assessed function as a summary of change over 30 months. The difference between groups was not statistically significant (WMD 81.40, 95% CI -86.33 to 249.13; no interpretable scale range).

Disability

Disability was assessed by one trial (Woodburn 2002). Differences between groups were not statistically significant after 3 months (WMD 0.60, 95% CI -9.34 to 10.54) but were statistically significant for scores summarising changes over 30 months (WMD 309.10, 95% CI 61.15 to 557.05; no interpretable scale range).

Compliance

Compliance was assessed as a summary of change over 30 months by one trial (Woodburn 2002). The difference between groups was not statistically significant (96% versus 94%; RR 1.02, 95% CI 0.93 to 1.12).

Table 13. Clinical relevance table for comparison 04 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
6 weeks (Chalmers 2000)	Plain scores from a 100 mm visual analogue scale	16 (1)	45.3	8.3% (-19.7, 36.4)	18.5% (-44.0, 81.1)	n/a	No	Silver
3 months (Pooled)	Change scores from the Pain scale of FFI	56 (2)	40.8	10.6% (-2.41 to 21.0)	26.2% (6.0 to 58.3)	n/a	No	Silver
Summary of change over 30 months (Woodburn 2002)	Pain scale of FFI; no interpretable scale range for sum-	98 (1)	40.8	No interpretable scale range	Summary data without scale range	Not calculable	Yes	Silver

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Table 13. Clinical relevance table for comparison 04 (continuous data) (*Continued*)

	mary statistic							

Comparison 05: custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Custom-made foot orthoses were compared with sham orthoses for the treatment of foot pain in rheumatoid arthritis in one trial (Conrad 1996) including 102 people assessed at 36 months.

Foot pain

The difference in foot pain between groups was not statistically significant after 36 months (WMD 0.90, 95% CI -10.97 to 12.77) (Table 14).

Function

The difference in function between groups was not statistically significant after 36 months (WMD -1.60, 95% CI -10.40 to 7.20).

Disability

Disability was assessed by Conrad 1996, who reported no statistically significant difference between groups at 36 months (WMD 4.20, 95% CI -7.63 to 16.03).

Adverse effects

No participant in either group reported adverse effects of the interventions (Table 15).

Compliance

The difference in the proportion of participants in the custom-made and sham orthoses groups who reported not wearing their orthoses during the previous 30 days was not statistically significant after 36 months (31% versus 31%; RR 1.00, 95% CI: 0.54 to 1.84).

Table 14. Clinical relevance table for comparison 05 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
36 months (Conrad 1996)	Plain scores from the Pain scale of the FFI	88 (1)	Not reported	0.9%(-10.9, 12.6)	Not calculable	n/a	No	Silver

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Table 15. Clinical relevance table for comparison 05 (dichotomous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control event rate	Wt absolute RD	Wt Rel % change	NNT(H)	Stat sig	Quality of evidence
36 months (Conrad 1996)	Total number of reported adverse effects	88 (1)	0	0.00 (-0.0, 0.0)	Not calculable	n/a	No	Silver

Comparison 06: custom-made foot orthoses versus non-custom foot orthoses for foot pain in rheumatoid arthritis

Custom-made foot orthoses were compared with non-custom foot orthoses for rheumatoid arthritis in one trial (Chalmers 2000) including 16 people reporting MTP joint pain in rheumatoid arthritis, assessed at six weeks and three months. Non-custom foot orthoses were soft plastazote orthoses.

Foot pain

The difference in foot pain between groups was not statistically significant after 6 weeks (WMD 5.80, 95% CI -14.74 to 26.34) or 3 months (WMD -13.30, 95% CI -32.13 to 5.53) (Table 16 and Table 17).

Function

The difference in function between groups was not statistically significant after 6 weeks (WMD 0.63, 95% CI -0.25 to 1.51) or 3 months (WMD 0.62, 95% CI: -0.54 to 1.78).

Table 16. Clinical relevance table for comparison 06 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
2 to 3 months	Change scores the Pain domain of FHSQ	165 (2)	45.1(20.6)	-2.3%(-8.6, 4.0)	-5.0%(-19.2, 8.7)	n/a	No	Silver
Not eligible for pooling: Over-the-counter arch supports 3 months	Plain scores from a 100 mm VAS	133 (1)	58.0	3.0%(-4.6, 10.6)	5.2%(-8.0, 18.4)	n/a	No	Silver

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Table 16. Clinical relevance table for comparison 06 (continuous data) (*Continued*)

(Martin 2001)								
Not eligible for pooling: Rubber heel cup after 2 months (Pfeffer 1999)	Change scores from the Pain scale of FFI	77 (1)	55.8	-8.6%(-22.1, 4.9)	-15.6%(-40.0, 8.8)	n/a	No	Silver
Not eligible for pooling: Silicone heel pad after 2 months (Pfeffer 1999)	Change scores from the Pain scale of FFI	76 (1)	55.8	3.9%(-15.8, 8.1)	-7.0%(-22.6, 14.6)	n/a	No	Silver
Prefabricated Formthotic after 12 months (Landorf 2006)	Change scores of the Pain domain of FHSQ	88 (1)	45.1	-6.9%(-17.0, 3.2)	-15.5%(-38.1, 7.1)	n/a	No	Silver

Table 17. Clinical relevance table for comparison 06 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
6 weeks (Chalmers 2000)	Change scores from the Pain subscale of the Foot & Ankle Outcome Score	16 (1)	45.3	5.7%(-32.5, 58.2)	12.8%(-32.5, 58.2)	n/a	No	Silver
3 months (Chalmers 2000)	Change scores from the Pain subscale of the Foot &	16 (1)	45.3	-13.2%(-31.8, 5.5)	-29.4%(-70.93, 12.2)	n/a	No	Silver

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Table 17. Clinical relevance table for comparison 06 (continuous data) (*Continued*)

	Ankle Outcome Score							

Comparison 07: custom-made foot orthoses versus standardised intervention for plantar fasciitis

Custom-made foot orthoses were compared with no intervention or a standard intervention provided to all groups for plantar fasciitis in two trials at time points ranging from six weeks to three months: Pfeffer 1999 in 88 people and Roos 2006 in 31 people. Standard interventions included Achilles' tendon and plantar fascia stretching (Pfeffer 1999) and night splints (Roos 2006).

Foot pain

Foot pain was assessed at six to eight weeks by both trials. When data were pooled, the difference in foot pain between groups was not statistically significant (SMD 0.05, 95% C: -0.35 to 0.46; expressed in units of SD). Sensitivity analysis could not be performed because: (1) both trials were at high risk of bias; (2) neither study concealed allocation; and (3) neither study blinded participants to the intervention. Therefore, the robustness of this not statistically significant result is unknown. Foot pain was assessed at three months by one trial (Roos 2006). The difference in foot pain between groups at 3 months was not statistically significant (WMD 6.00, 95% CI -6.75 to 18.75) (Table 18).

Function

Any limitation in function associated with foot pain was assessed by one trial (Roos 2006). The difference in function between groups was not statistically significant after 6 weeks (WMD -2.24, 95% CI -24.60 to 20.12) or 3 months (WMD -4.00, 95% CI -24.09 to 16.09).

Disability

Disability was assessed by one trial (Roos 2006). The difference in disability between groups was not statistically significant after 6 weeks (WMD -2.05, 95% CI -17.28 to 13.18) or 3 months (WMD 8.00, 95% CI -4.75 to 20.75).

Health-related quality of life

Health-related quality of life was assessed by one trial (Roos 2006). The difference in health-related quality of life between groups was not statistically significant after 6 weeks (WMD 3.69, 95% CI -13.98 to 21.36) or 3 months (WMD 8.00, 95% CI -9.76 to 25.76).

Adverse effects

Adverse effects were reported in the different groups by one trial (Roos 2006). The difference in total numbers of participant-reported adverse effects was not statistically significant at 1 week (40% versus 60%; RR 0.67, 95% CI 0.32 to 1.40) or 3 months (36% versus 36%; RR 1.02, 95% CI 0.36 to 2.91). Adverse effects included pressure, pain and sleep disturbance (Table 19).

Table 18. Clinical relevance table for comparison 07 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
6 to 8 weeks (pooled)	FFI, Pain	96 (2)	55.8	1.1% (-7.4, 9.8)	1.9% (-13.4, 17.6)	n/a	No	Silver
3 months (Roos 2006)	Foot & Ankle Outcome Score, Pain	25 (1)	53	5.9% (-6.7, 18.6)	11.3% (-12.7, 35.4)	n/a	No	Silver

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Table 19. Clinical relevance table for comparison 07 (dichotomous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control event rate	Wt absolute RD	Wt Rel % change	NNT(H)	Stat sig	Quality of evidence
1 week (Roos 2006)	Total numbers of reported adverse effects	30 (1)	60.0%	-0.2 (-0.6, 0.2)	-33.0% (-68.0, 40.0)	n/a	No	Silver
3 months (Roos 2006)	Total numbers of reported adverse effects	25 (1)	35.7%	0.01 (-0.4, 0.4)	2.0% (-64.0, 191.0)	n/a	No	Silver

Comparison 08: custom-made foot orthoses versus sham orthoses for plantar fasciitis

Custom-made foot orthoses were compared with sham orthoses for plantar fasciitis in one trial (Landorf 2006) including 92 people assessed at three and 12 months.

Foot pain

The difference in foot pain between groups was not statistically significant after 3 months (WMD 5.10, 95% CI -5.19 to 15.39) or 12 months (WMD -2.50, 95% CI -12.55 to 7.55) (Table 20).

Function

Differences in foot pain-related function between groups were statistically significant: after 3 months (WMD 10.40, 95% CI 2.43 to 18.37; NNT 4, 95% CI 2 to 19) and 12 months (WMD 10.40, 95% CI 0.22 to 20.58; NNT 5, 95% CI 3 to > 215), both favouring custom-made foot orthoses over sham orthoses for plantar fasciitis.

Compliance

The difference in the proportion of participants in the custom-made and sham orthoses groups who self reported breaking protocol (for example taken anti-inflammatory drugs, received a corticosteroid injection, used a night stretch splint or used alternative orthoses) was not statistically significant after 3 months (4% versus 9%; RR 0.49, 95% CI 0.09 to 2.53) or 12 months (18% versus 28%; RR 0.64, 95% CI 0.29 to 1.40). Differences remained not statistically significant when including only those participants who reported using alternative foot orthoses: at 3 months (0% versus 4.5%; RR 0.20, 95% CI: 0.01 to 3.96) and 12 months (2% versus 16%; RR 0.14, 95% CI 0.02 to 1.06).

Comparison 09: custom-made foot orthoses versus non-custom foot orthoses for plantar fasciitis

Custom-made foot orthoses were compared with non-custom foot orthoses for plantar fasciitis in three trials assessed at time points ranging from two to 12 months: Landorf 2006 in 90 people; Martin 2001 in 170 people; and Pfeffer 1999 in 190 people. Non-custom foot orthoses included: prefabricated off-the-shelf orthoses (Formthotics, Foot Science International, Christchurch, New Zealand) (Landorf 2006); over-the-counter arch supports (Foot Soldiers, Professional Footcare International, Valencia, California) (Martin 2001); felt inserts (Hapad, Bethel Park, PA) (Pfeffer 1999); rubber heel cups (Tuli International Comfort Products, San Marcos, CA) (Pfeffer 1999); and silicone heel pads (Bauerfeind, Kennesaw, GA) (Pfeffer 1999).

Foot pain

Foot pain was assessed at two to three months in three trials (Landorf 2006, Martin 2001 and Pfeffer 1999). Due to the combination of change and plain scores for different measurement scales, data from all three trials could not be pooled in the same meta-analysis. Meta-analysis could be conducted by dropping Martin 2001 from the analysis or by estimating the SD of pain scores for Pfeffer 1999. Since the SD for Martin 2001 are imprecise estimations, Martin 2001 was dropped from the analysis. SMD was, therefore, used to pool results from two trials (Pfeffer 1999; Landorf 2006). Pfeffer 1999 compared custom-made foot orthoses to three different types of non-custom foot orthoses. Since only one group could be combined in this pooled estimate, the non-custom foot orthoses most similar to those used by Landorf 2006 was selected for pooling (the felt insert). When groups were pooled, the difference between the custom-made foot orthoses and the other orthoses groups was not statistically significant (SMD -0.11, 95% CI -0.42 to 0.19). Since all trials were at high risk of bias, sensitivity analysis was performed by only including trials that concealed allocation or blinded participants to the intervention group (Landorf 2006). When sensitivity analysis was performed, the difference between groups remained not statistically significant (SMD -0.21, 95% CI -0.63 to 0.20); equivalent to the WMD of -5.90 (95% CI -17.25 to 5.45), indicating that the result of the meta-analysis is ro-

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bust. For the other types of non-custom foot orthoses evaluated by Pfeffer 1999 and Martin 2001, the difference in foot pain between groups was not statistically significant at 2 months for rubber heel cups (WMD -8.70, 95% CI: - 22.32 to 4.92) or silicone heel pads (WMD -3.90 points, 95% CI: -15.94 to 8.14), or at 3 months for over-the-counter arch supports (WMD 3.00 points, 95% CI -4.66 to 10.66). Foot pain was assessed at 12 months in one trial (Landorf 2006). The difference in foot pain between groups was not statistically significant (WMD -7.00 points, 95% CI -17.20 to 3.20).

Function

Function was assessed by one trial (Landorf 2006). The difference in function between groups was not statistically significant after 3 months (WMD -3.80 points, 95% CI -13.42 to 5.82) or 12 months (WMD -3.40 points, (95% CI -13.44 to 6.64).

Compliance

Compliance was assessed in one trial (Landorf 2006). The difference in the proportion of participants in the custom-made and sham orthoses groups who self reported breaking protocol (for example taken anti-inflammatory drugs, received a corticosteroid injection, used a night stretch splint or used alternative orthoses) was not statistically significant after 3 months (4% versus 9%; RR 0.65, 95% CI 0.11 to 3.71) or 12 months (18% versus 26%; RR 0.69, 95% CI 0.31 to 1.56). Differences remained not statistically significant when including only those participants who reported not using alternative foot orthoses: after 3 months (0% versus 0%; RR not estimable) and 12 months (2% versus 4.7%; RR 0.48, 95% CI 0.04 to 5.08).

Table 20. Clinical relevance table for comparison 08 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
3 months (Landorf 2006)	Change scores from the Pain domain of the FHSQ	89 (1)	45.1	5%(-5.1, 15.2)	11.3%(-11.5, 34.1)	n/a	No	Silver
12 months (Landorf 2006)	Change scores from the Pain domain of the FHSQ	88 (1)	45.1	-2.0%(-12.4, 7.5)	-5.5%(-27.8, 16.7)	n/a	No	Silver

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Comparison 10: custom-made foot orthoses versus manipulation, mobilisation and stretching for plantar fasciitis

Custom-made foot orthoses were compared with a combined treatment of manipulation, mobilisation and stretching for plantar fasciitis in one trial (Dimou 2004) including 20 people assessed at two weeks, one month and two months.

Foot pain

The difference in foot pain between groups was statistically significant: in favour of manipulation, mobilisation and stretching after 2 weeks (WMD -23.30, 95% CI: -42.67 to -3.93; NNT 2, 95% CI 2 to 30) but was not statistically significant after 1 month (WMD -11.10, 95% CI -28.81 to 6.61) or 2 months (WMD -6.10, 95% CI -21.35 to 9.15) (Table 21).

Adverse effects

No participant in either group reported any adverse effect.

Compliance

Dimou 2004 reported that compliance was "very good". The method used to measure compliance to produce this result was unclear.

Table 21. Clinical relevance table for comparison 10 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
2 weeks (Dimou 2006)	Plain scores from the Pain Scale Form: Worst of the Numeric Pain Rating Scale 101.	20 (1)	53.7	-23.1% (-42.3, -3.9)	-43.4% (-79.5, -7.3)	2 (2 to 30)	Yes	Silver
1 month (Dimou 2006)	Plain scores from the Pain Scale Form: Worst of the Numeric Pain Rating Scale 101.	20 (1)	53.7	-11.0% (-28.5, 6.5)	-20.7% (-53.7, 12.3)	n/a	No	Silver

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Table 21. Clinical relevance table for comparison 10 (continuous data) (*Continued*)

2 months (Dimou 2006)	Plain scores from the Pain Scale Form: Worst of the Numeric Pain Rating Scale 101.	20 (1)	53.7	-6.0% (-21.1, 9.1)	-11.4% (-39.8, 17.0)	n/a	No	Silver

Comparison 11: custom-made foot orthoses versus night splint for plantar fasciitis

Custom-made foot orthoses were compared with night splints for plantar fasciitis in one trial (Roos 2006) including 29 participants assessed at six weeks and three months. Details of the interventions are provided in the table 'Characteristics of included studies'.

Foot pain

The difference in foot pain between groups was not statistically significant after 6 weeks (WMD -0.89, 95% CI -14.51 to 12.73) or 3 months (WMD 6.00, 95% CI -12.72 to 24.72) (Table 22).

Function

The difference in function between groups was not statistically significant after 6 weeks (WMD -15.01, 95% CI -34.78 to 4.76) or 3 months (WMD -1.00, 95% CI -24.38 to 22.38).

Disability

The difference in disability between groups was not statistically significant after 6 weeks (WMD 1.05, 95% CI -14.64 to 16.74) or 3 months (WMD 1.00, 95% CI -16.54 to 18.54).

Health-related quality of life

The difference in health-related quality of life between groups was not statistically significant at 6 weeks (WMD -5.99, 95% CI -23.69 to 11.71) or 3 months (WMD 9.00, 95% CI -11.35 to 29.35).

Adverse effects

The difference in participant-reported adverse effects between the orthoses and night splint groups was not statistically significant at 6 weeks (23% versus 60%; RR 0.38, 95% CI 0.13 to 1.13) or 3 months (11% versus 36%; RR 0.31, 95% CI 0.04 to 2.25). Adverse effects included pressure-related pain and tiredness of the foot in the orthoses group and pressure, pain and sleep disturbance in the night splint group (Table 23).

Compliance

The difference in compliance between orthoses and night splint groups was not statistically significant at 3 months (RR 1.17, 95% CI 0.76 to 1.79).

Table 22. Clinical relevance table for comparison 11 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
6 weeks (Roos 2006)	Change scores from the Pain subscale of the Foot and Ankle Outcome score.	25 (1)	53	0.9% (-14.4, 12.6)	1.7% (-27.4, 24.0)	n/a	No	Silver

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Table 22. Clinical relevance table for comparison 11 (continuous data) (*Continued*)

3 months (Roos 2006)	Plain scores from the Pain subscale of the Foot and Ankle Outcome score.	23 (1)	53	5.9% (-12.6, 24.5)	11.3% (-24.0, 46.6)	n/a	No	Silver

Table 23. Clinical relevance table for comparison 11 (dichotomous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control event rate	Wt absolute RD	Wt Rel % change	NNT(H)	Stat sig	Quality of evidence
1 week (Roos 2006)	Adverse effects	28 (1)	60%	-0.4 (-0.7, -0.0)	-62.0% (-87.0, 13.0)	n/a	No	Silver
3 months (Roos 2006)	Adverse effects	23 (1)	35.7%	-0.3 (-0.6, 0.1)	-69.0% (-96.0, 125.0)	n/a	No	Silver

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Comparison 12: custom-made foot orthoses versus no intervention for painful bunion with hallux valgus

Custom-made foot orthoses were compared with no intervention for painful hallux valgus in one trial (Torkki 2001) including 138 people assessed at six and 12 months.

Foot pain

Differences in foot pain between groups were statistically significant after 6 months (WMD 9.00, 95% CI 1.16 to 16.84; NNT 6, 95% CI 3 to 52) but not after 12 months (WMD 0.00, 95% CI -8.19 to 8.19) (Table 24).

Disability

Differences in foot pain between groups were not statistically significant after 6 months (WMD 4.00, 95% CI -4.86 to 12.86) or 12 months (WMD -2.00, 95% CI -10.51 to 6.51).

Health-related quality of life

Differences in health-related quality of life between groups were not statistically significant after 6 months (WMD 1.50, 95% CI -0.97 to 3.97) or 12 months (WMD 0.50, 95% CI -1.90 to 2.90).

Participant satisfaction with intervention

Differences in foot pain between groups were statistically significant after 6 months (WMD 25.00, 95% CI 14.52 to 35.48; NNT not calculable due to unknown MID) but not after 12 months (WMD 9.00, 95% CI -1.67 to 19.67).

Compliance

The difference in compliance between groups was not statistically significant after 12 months (97% versus 94%; RR 1.03, 95% CI 0.96 to 1.11).

Table 24. Clinical relevance table for comparison 12 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
6 months (Torkki 2001)	Plain scores from 100 mm VAS	138 (1)	45	8.9%(1.2, 16.7)	20.0%(2.6, 37.4)	6(3 to 52)	Yes	Silver
12 months (Torkki 2001)	Plain scores from 100 mm VAS	138 (1)	45	0.0%(-8.1, 8.1)	0%	n/a	No	Silver

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Comparison 13: custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Custom-made foot orthoses were compared with surgery for painful bunion with hallux valgus in one trial (Torkki 2001) including 140 people assessed at six and 12 months.

Foot pain

The difference in foot pain between groups was statistically significant: in favour of surgery at 6 months (WMD -10.00, 95% CI -17.79 to -2.21; NNT 5, 95% CI 3 to 33) and 12 months (WMD -17.00, 95% CI -24.62 to -9.38; NNT 3, 95% CI 2 to 5) (Table 25).

Disability

The difference in disability between groups was not statistically significant at 6 months (WMD -1.00, 95% CI -9.12 to 7.12) but was statistically significant in favour of surgery at 12 months (WMD -8.00, 95% CI -15.56 to -0.44; NNT not calculable due to unknown MID).

Health-related quality of life

The difference in health-related quality of life between groups was not statistically significant at 6 months (WMD 0.00, 95% CI -2.29 to 2.29) or 12 months (WMD -0.20 points, 95% CI -2.39 to 1.99).

Participant satisfaction with intervention

Differences in participant satisfaction with the intervention was not statistically significant between groups at 6 months (WMD -8.00, 95% CI -17.65 to 1.65) but was statistically significant in favour of surgery at 12 months (WMD -10.00, 95% CI -18.95 to -1.05; NNT not calculable due to unknown MID).

Adverse effects

Differences in adverse effects between groups could not be calculated as adverse effects were only reported for the surgery group.

Compliance

The difference in the proportion of participants in the custom-made foot orthoses group who reported retrospective use of orthoses at least six days per week to the proportion of participants in the surgery group who received surgery was not statistically significant at 6 months (96% versus 93%; RR 1.01, 95% CI 0.93 to 1.11) or 12 months (97% versus 93%; RR 1.04, 95% CI 0.97 to 1.13).

Table 25. Clinical relevance table for comparison 13 (continuous data)

Type of foot pain	Outcome (scale)	# pts (# trials)	Control baseline m*	Wt absolute change	Relative % change*	NNT(B)	Stat sig	Quality of evidence
6 months (Torkki 2001)	Plain scores from a 100 mm VAS	140 (1)	45	-9.9% (-17.6, -2.2)	-22.2% (-39.5, -4.9)	5(3 to 33)	Yes	Silver
12 months (Torkki 2001)	Plain scores from a 100 mm VAS	140 (1)	45	-16.8% (-24.4, -9.3)	-37.8% (-54.7, -20.8)	3(2 to 5)	Yes	Silver

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DISCUSSION

Strength of evidence

Since the different types of foot pain were analysed separately, an overall conclusion regarding the effectiveness of custom-made foot orthoses for the treatment of foot pain cannot be drawn and all results cannot be classified into a single 'level of evidence'. The levels of evidence for the primary outcome (pain) and the most commonly reported secondary outcome (function) are presented below, beginning with the strongest evidence (summarised further in Table 26).

Table 26. Summary table of level of evidence and number needed to treat the benefit (NNTB)

Foot pain type	Platinum	Gold	Silver	Bronze	NNTB
Painful pes cavus		*			5
Foot pain in juveinlile idiopathic arthritis			*		3
Foot pain in rheumatoid arthritis			*		4
Plantar fasciitis			*		-
Painful bunion with hallux valgus			*		6

Painful pes cavus

There is gold level evidence that custom-made foot orthoses are more effective than sham orthoses for reducing foot pain and improving function after three months in people aged 18 years or older with bilateral pes cavus and musculoskeletal foot pain of more than one month duration.

Juvenile idiopathic arthritis

There is silver level evidence that for people at least five years of age and diagnosed with juvenile idiopathic arthritis, custom-made foot orthoses are:

- more effective than a standardised intervention of supportive shoes for reducing foot pain and improving function, after three months;
- not more effective than prefabricated neoprene shoe inserts for reducing foot pain or improving function, after three months.

Rheumatoid arthritis

There is silver level evidence that for people diagnosed with rheumatoid arthritis, custom-made foot orthoses are:

- more effective than no intervention for reducing rearfoot pain but not for improving function, after three months and as a summary of change over 30 months;

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- not more effective than sham orthoses for reducing foot pain or improving function, after 36 months;
- not more effective than a standard intervention of supportive shoes for reducing metatarsophalangeal (MTP) joint pain or improving function, after six weeks or three months;
- not more effective than soft plastazote non-custom foot orthoses for reducing MTP joint pain or improving function, after six weeks or three months.

Plantar fasciitis

There is silver level evidence that for people diagnosed with plantar fasciitis, custom-made foot orthoses:

- are more effective than sham orthoses for improving function, but not for reducing foot pain, after three and 12 months;
- are not more effective than night splints but do increase the effectiveness of a standard intervention of night splints for reducing foot pain or improving function, after six weeks or three months;
- are not more effective than non-custom foot orthoses for reducing foot pain or improving function, after two to three months or 12 months;
- do not increase the effectiveness of a standard intervention of Achilles' tendon and plantar fascia stretching or night splints for reducing foot pain, after six to eight weeks;
- are less effective than a combined treatment of manipulation/mobilisation/stretching for reducing foot pain after two weeks, but not after one or two months.

Painful hallux valgus

There is silver level evidence that for people aged less than 60 years with a painful bunion, mild to moderate hallux valgus and no limitation of the first MTP joint range of motion, custom-made foot orthoses are less effective than surgery for reducing foot pain after six or 12 months of wear but are more effective than no intervention for reducing foot pain after six months but not after 12 months of wear.

Effect of custom-made foot orthoses over time

From the available evidence, it does not appear that there is a linear time-effect relationship between the use of custom-made foot orthoses and pain reduction; that is, custom-made foot orthoses do not seem to reduce foot pain incrementally over time. In contrast, the difference between groups tended to decrease over time. This could be due to the natural history of pain resolving over time or a relative reduction in effectiveness of custom-made foot orthoses over time, from: (1) reduced mechanical or a psychophysiological effect of the custom-made foot orthoses, or both; or (2) a continued increasing effect of comparison interventions.

Clinical applicability

The findings of research can only be safely applied to clinical practice when there is reasonable similarity between clinical practice and the research protocol; in this case between the types of foot pain, participants and custom foot orthoses evaluated within included trials. Due to the marked variation among included trials, all analyses within this review contain data from only one, two or three trials. The vast majority of analyses contain data from only one trial. The applicability of results from these analyses is the same as those of the primary trials. For analyses where data from two or three trials were pooled, the applicability extends across the characteristics of all trials pooled. Information to guide applicability of these comparisons is available in the table 'Characteristics of included studies'.

Limitations of included trials

All included trials have methodological limitations that, according to the grading system used in this review, expose trial findings to a high risk of bias. The only criterion unmet by all trials was intervention provider blinding, which is inherently difficult in orthotic therapy as: (1) it is standard clinical practice for the practitioner to check the fit of the orthoses to the feet; and (2) practitioners are typically able to differentiate between custom-made and sham orthoses. As a result, there exists the risk in all trials that intervention providers may have intentionally or unintentionally influenced participants with their preconceived expectations of intervention effectiveness. Unless a feasible method is devised to achieve intervention provider blinding while maintaining high standards of clinical care, this risk will remain as a potential source of bias in all future randomised trials evaluating custom-made foot orthoses.

Trials with more participants tended to detect statistically significant differences in favour of custom-made foot orthoses over no intervention, standardised intervention or sham orthoses for reducing pain, while trials with fewer participants did not. This might be due to type II errors within the statistical analyses of data from small samples; that is, failure to detect true differences in effects between interventions (Keech 2007). For all future research, minimum sample size should be calculated a priori to ensure analyses are adequately powered to detect a clinically important difference in effectiveness between the interventions evaluated.

Limitations of available evidence

The evidence base of custom-made foot orthoses for the treatment of foot pain is incomplete. Many clinically important aspects of custom-made foot orthotic therapy have not been evaluated in

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randomised or controlled clinical trials. The following list identifies just some of the evidence gaps in the current body of literature.

- Effectiveness of custom-made foot orthoses for the treatment of foot pain other than in plantar fasciitis, rheumatoid and juvenile idiopathic arthritis, painful pes cavus and painful hallux valgus. For example, in osteoarthritis, diabetes, tendinopathies (particularly tibialis posterior dysfunction), stress fractures, compression neuropathies (e.g. interdigital neuroma), sesamoiditis, metatarsalgia or painful plantar callosities (hyperkeratosis).
- Effectiveness of custom-made foot orthoses for the treatment of foot pain in children other than for juvenile idiopathic arthritis.
- Effectiveness of custom-made foot orthoses for the treatment of foot pain experienced during moderate to heavy physical activity, e.g. within sporting or military populations.
- The difference in effectiveness between the many styles, modifications, construction materials or prescription rationales of custom-made foot orthoses for the treatment of foot pain.
- Whether improvements can be maintained or additional clinical benefits achieved by using custom-made foot orthoses for a period longer than 36 months.

Limitations of the review

Defining custom foot orthoses

There is no international or interdisciplinary consensus for defining custom-made foot orthoses. As a result, the definition used in this review might be different to that used by some other healthcare providers. Where this is the case, readers are advised to refer to the table 'Characteristics of excluded studies' to determine if they consider the foot orthoses excluded from this review as being custom made.

Scope of the review

This review does not evaluate the effectiveness of custom-made foot orthoses for the treatment of any pain other than foot pain, nor does it evaluate the effectiveness of custom-made foot orthoses for the prevention of foot pain. This review also does not evaluate the cost effectiveness of custom-made foot orthoses for the treatment of foot pain, however, as this review has a broad international perspective, international differences in healthcare practices and economic conditions limit the usefulness of financial comparisons (Higgins 2002). Readers are, therefore, encouraged to seek information regarding the local costs of the interventions evaluated in this review and to use this information in making decisions about the use of custom-made foot orthoses for the treatment of foot pain.

Readers are also reminded that some of the evidence presented in this review may overlap with other Cochrane systematic reviews evaluating the relative effectiveness of various interventions for specific musculoskeletal conditions (Ashford 2005; Brouwer 2005; Burns 2006a; Crawford 2003; D'hondt 2002; Egan 2001; Ferrari 2004; Rome 2005; Rome 2007; Sackley 2007; Spencer 2000; Thomson 2004).

Locating relevant trials

All trials in this review have been published in English-language journals and were initially identified through electronic searching. While efforts were made to identify unpublished trials and trials published in non-English language journals, none were eligible for inclusion. Given that only about 60% of randomised or controlled clinical trials presented as summaries or abstracts at professional gatherings are subsequently published in peer-reviewed journals (Scherer 2003), there is a risk that trials eligible for inclusion were not identified, which threatens the internal validity of this review. However, we are reasonably confident that all relevant trials were identified because:

(1) randomised or controlled trials evaluating custom-made foot orthoses are rare and are, therefore, typically well publicised and subsequently published;

(2) some non-English language and unpublished papers were identified for potential inclusion but were excluded due to failing to meet all inclusion criteria; and

(3) no first author of included trials or known researchers in the field were able to identify additional relevant trials.

Exclusion bias

Authors of included trials were not contacted to obtain information on excluded participants. Analyses within this review are, therefore, only based on principles of intention to treat where primary study researchers had done so. Therefore, there is a risk of exclusion bias influencing the available case analyses presented in this review (see Table 8: Methodological quality of included studies).

AUTHORS' CONCLUSIONS

Implications for practice

Considering the range of diagnoses for which custom-made foot orthoses are prescribed and the many types of custom-made foot orthoses available, very few have been adequately evaluated in randomised or controlled clinical trials. As such, there is limited evidence on which to base clinical decisions for the use of custom-

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made foot orthoses for the treatment of foot pain. Nonetheless, evidence for clinical practice is accumulating (summary in Additional table 26). Currently, there is gold level evidence for painful pes cavus and silver level evidence for foot pain in juvenile idiopathic arthritis (JIA), rheumatoid arthritis, plantar fasciitis and hallux valgus. Custom-made foot orthoses were effective for painful pes cavus (NNTB: 5), rear foot pain in rheumatoid arthritis (NNTB: 4), foot pain in JIA (NNTB: 3) and painful hallux valgus (NNTB: 6); however, surgery was even more effective for hallux valgus and non-custom foot orthoses appeared just as effective for JIA but the analysis may have lacked sufficient power to detect a difference in effect. It is unclear if custom-made foot orthoses were effective for plantar fasciitis or metatarsophalangeal joint pain in rheumatoid arthritis. Overall, custom-made foot orthoses were a safe intervention for foot pain. Clinical applicability of all these results will depend on the healthcare context, including: timely access to interventions; monetary cost of interventions; time commitment required for therapy; and strength of evidence for (and safety of) alternative interventions.

Implications for research

To develop a strong evidence base for the treatment of foot pain, the effectiveness of custom foot orthoses requires further evaluation in well designed and clearly reported randomised controlled trials. Recommendations to improve the quantity and quality of evaluating custom foot orthoses for the treatment of foot pain include: investigating other types of foot pain; recruiting more children; assessing efficacy in athletes; experimenting with different orthotic styles, adjunctive therapy and standardised footwear (as in the military and industrial setting); developing an effective and safe protocol for intervention blinding; and measuring long term outcomes. For all future research, minimum sample size should be calculated *a priori* to ensure analyses are adequately powered to detect clinically important differences in effects between interventions evaluated.

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* *Indicates the major publication for the study*

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CHARACTERISTICS OF STUDIES

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

Burns 2006

Methods	RCT. Two-arm parallel-group design. Type of foot pain: Plantar fasciitis.
Participants	Community sample of participants recruited in Sydney, Australia by referral from healthcare providers and advertisements in local media. Inclusion criteria: Men and women 18 years or older who had musculoskeletal foot pain for more than 1 month and bilateral cavus feet of any aetiology. Cavus foot defined by a Foot Posture Index score of -2 or less. Exclusion criteria: Pregnancy; recent foot trauma; current use of ankle-foot orthoses; lack of willingness to return for follow up. Nr = 154. Na = 154. PARTICIPANT CHARACTERISTICS Custom-made foot orthoses group Age, mean (SD): 49.8 (14.3) Sex, % females: 52 % Pain duration, mean yrs (SD): 7.3 (9.4) BMI, mean (SD): 28.1 (6.1) Sham orthoses group Age, mean (SD): 49.5 (14.4) Sex, % females: 61 % Pain duration, mean yrs (SD): 8.9 (11.4) BMI, mean (SD): 27.4 (6.0) Pes cavus aetiology was classified as congenital (130 patients had idiopathic and 1 had residual clubfoot), neuromuscular (16 had Charcot-Marie-Tooth disease, 4 had poliomyelitis, and 1 had polyneuropathy), or traumatic (2 had osseous malunion). Foot pain was bilateral in 68% of the cases, and common diagnoses included metatarsalgia, plantar heel pain, and mid-foot osteoarthritis.
Interventions	Treatment group: Custom-made foot orthoses moulded from neutral-suspension plaster casts. Casts scanned using a 3-dimensional laser scanner. Orthoses fabricated from 3 mm polypropylene using computer-aided design and computer-aided manufacturing milling machine to a standardised prescription that had been developed and pilot tested. Cast/scan modifications: Balance metatarsals 1-5; 20% medial arch expansion; 0° corrected calcaneal position; 0° intrinsic forefoot. Shell shape: Length proximal to metatarsal heads; standard (1-5) forefoot width; 6 mm lateral heel expansion; 12 mm heel cup height. Shell material: 3 mm polypropylene. Shell posting: Lateral half extrinsic heel post. Cast/scan modifications: 0° motion; 0 mm elevation; 0 mm heel lift. Top cover: Full-length 3 mm Poron Medical urethane (Rogers Corp, Woodstock, Connecticut) and Kashmeer. Control group: Sham insoles made from flat, non-supportive, 3 mm latex foam covered with Kashmeer. Casts were made of both feet using the same technique as for the treatment group. However, the casts were not used to fabricate the intervention. Written instructions for a progressive wearing schedule and footwear advice were provided. Participants with their own orthoses and insoles shoe inserts etc. were not allowed to use them at any time during the study. Routine treatment, such as medication, physical therapy, and massage, were continued as usual.

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Burns 2006 (*Continued*)

Outcomes	Pain: Foot Health Status Questionnaire (pain domain). Function: Foot Health Status Questionnaire (function domain). Health related quality of life: 36-Item Short-Form Health Survey; physical functioning, general health, vitality, and social functioning domains. Compliance: Self-reported use of assigned intervention for most of shoe wearing time. Adverse effects: Number and nature of adverse effects per group.
Notes	

Risk of bias

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

Chalmers 2000

Methods	RCT. Crossover trial. Each participant was randomised to a sequence of 3 × 12 week phases, separated by 2 week washouts. Type of foot pain: Metatarsal phalangeal joint painful synovitis in participants with rheumatoid arthritis.
Participants	Recruited from occupational therapy referrals.Screened by rheumatologist and occupational therapist. Inclusion criteria: Diagnosis of rheumatoid arthritis using American College of Rheumatology criteria; over 18 years of age; minimum of 2 subluxed metatarsal phalangeal joints bilaterally; metatarsal phalangeal joint pain as most significant foot problem; participants using foot orthoses or shoe adaptations were required to stop their use and participate in a 2 week wash-out. Exclusion criteria: Midtarsal pain with passive motion and on weight bearing; prior foot surgery (except hallux valgus correction); unstable medication regimen; impaired mental status; poor English comprehension; concurrent foot treatment (except scheduled regular podiatric skin and nail care). Nr = 28. Na = 24. Participant characteristics: Of those participants who completed the study: 21 women with a mean (SD) age of 60 (10) years; 3 men with a mean (SD) age of 63 (2) years; mean (SD) body weight 154 (46) lb.; average (SD) duration of rheumatoid arthritis 15 (9) years; mean of 7 metatarsal phalangeal joints with synovitis and 8 with subluxations.
Interventions	Supportive shoes: Extra-depth shoes with high, firm heel counter, heel height of 1.5 to 2.0 cm, instep lacing, a wide and deep toe box, and a thick, composite sole, made by P.W. Minor or Drew Co. Supportive shoes worn with soft orthoses: Soft orthoses formed by participant standing on preheated ¼ inch, low-density, full-foot length plastazote. Medium density, ¼ inch plastazote lifts added to underside. Supportive shoes worn with custom foot orthoses: Semi-rigid orthoses made from 3 mm subortholen, from casts taken in a non-weightbearing position. Distal end of the subortholen followed the metatarsal heads line and ended just proximal to them. Underlying forefoot and hindfoot nickleplast posts were attached. A full-length leather liner, cushioned under the forefoot with 1/8 inch PPT foam, was added. Adjustments to orthoses were completed within 2 weeks.

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Chalmers 2000 (*Continued*)

Outcomes	Pain: 100 mm visual analogue scale, anchored by 'no pain' and 'pain as bad as it can be'. Function: Toronto Activities of Daily Living Measure (walking). Compliance: Daily logs of intervention use and wear time.
Notes	

Risk of bias

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

Conrad 1996

Methods	RCT. Two-arm parallel-group design. Type of foot pain: Foot pain and disability in rheumatoid arthritis
Participants	Recruited from the arthritic clinics of Hines, Chicago and North Chicago. Inclusion criteria: Between 18 and 75 years of age; foot pain; fulfilled American Rheumatism Association (ARA) criteria for classic or definite rheumatoid arthritis (RA) and were in an ARA functional class I or II; radiological changes of stage I or stage II in 1or both feet; active disease defined as having 6 or more painful joints or being tender on motion and/or 3 or more swollen joints with 45 minutes or longer of joint stiffness in the morning or a Westergreen sedimentation rate of 28 mm or more per hour; flexible functional discrepancies in their feet, measured as calcaneal valgus stance positions that could be controlled by a functional foot orthosis; and a minimum range of motion in feet and ankles making ambulation possible. In general, participants were chosen on the basis of their likelihood of benefiting from orthoses. Exclusion criteria: Severe clinical foot deformity such as hallux valgus, rigid hammer digit syndrome, plantar displacement of metatarsal bones, hallux rigidus, surgical fusion of the hallux, rigidity or deformity of the midfoot or hindfoot, including ankle joints; comorbid conditions that could cause apropulsive gait; previous foot surgery; inability to write and provide responses on the questionnaire; inability to follow instructions; inability to comply with study protocols. Nr = 102, Na = 88. Participant characteristics: 63 had classic RA, 39 had definite RA, with 76 in stage I and 26 in stage II anatomical radiological stage.No sig. Differences were found at $p<0.05$ between groups in age.15 were receiving NSAIDs only; 62 were receiving NSAIDs and prednisone; 35 were receiving NSAIDs and prednisone and disease modifying anti-rheumatic drugs.
Interventions	All participants were measured for foot orthoses and had plaster moulds made of their feet. Custom-made foot orthoses: fabricated from Rohadur and posted at rear and forefoot. Placebo orthoses: Thin naugahyde shoe inserts designed to fit each participant's feet. No posting or inclined planes All participants were instructed to wear comfortable dress shoes with boxed toes or gym shoes and were instructed on how to care for their foot orthoses. Participants continued receiving customary treatment regimen for their arthritis at the clinics, which included medications, joint injections, physical therapy, hospitalisation or surgical treatment.

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Conrad 1996 (*Continued*)

Outcomes	Pain: Pain scale of the Foot Function Index. Function: Activity Limitation scale of Foot Function Index. Compliance: Self-reported estimated time of wearing orthoses during the week prior to each visit. Adverse effects: Total number of all adverse effects in each group.
Notes	

Risk of bias

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

Dimou 2004

Methods	RCT. Two-arm parallel-group design. Type of foot pain: Plantar fasciitis
Participants	Inclusion criteria: More than 18 and less than 60 years of age; compliance with researchers' instructions; diagnosis of plantar fasciitis, made if: plantar heel pain present for more than 7 weeks; 'first-step pain' when rising from bed or after prolonged sitting; heel pain relieved after a few steps; pain on palpation of the medial calcaneal tubercle; positive plantar fasciitis test (palpation of the anterior medial tubercle and along the arch distally as the big toe with foot and ankle dorsiflexed to tighten the fascia); pain that deteriorates toward the end of the day; heel pain relieved by rest. Exclusion criteria: Pregnancy; calcaneal bursitis; tenosynovitis; fat pad syndrome; tarsal tunnel syndrome; calcaneal fracture; connective tissue / autoimmune disorders; 'etc.' Nr = 20, Na = 20. PARTICIPANT CHARACTERISTICS Custom foot orthoses group Age, mean years (range): 40.6 (23-58) Sex, % female: 30% Pain duration, mean months (range): 21.2 (2-96) Manipulation, mobilisation and stretching group Age, mean years (range): 44.0 (27-59) Sex, % female: 40% Pain duration, mean months (range): 22.4 (2.5-60)
Interventions	Custom-made foot orthoses: From non-weight bearing subtalar and mid-tarsal neutral casts. An outer layer of high-density ethyl vinyl acetate (EVA), and an inner layer of low-density EVA. These were supplied to the participants 1 week after initial consultation and remained fitted in their shoes for the whole 8-week period. The participants were carefully advised as to how they should slowly 'break in', or accommodate to, the orthoses (i.e., 2 hours the first 2 days, 3 hours the next 2 days etc.). Manipulation and mobilisation of foot with stretching: Chiropractic adjustments of all foot and ankle subluxations (joint hypomobility or fixation) twice a week for 4 weeks and at 1-month follow up. Various foot and ankle adjustments were delivered. The 'mortice separation', subtalar adjustment and forefoot figure-8 mobilisation were used most frequently. Participants were prescribed Achilles' tendon stretching

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Dimou 2004 (*Continued*)

	exercises, both with the knee straight and flexed. These were to be held statically with a comfortable sense of stretch for 20 seconds and performed 10 times each, morning, afternoon, and evening, on a daily basis for the whole 8 weeks.
Outcomes	Pain: Foot & Ankle Outcome Score (pain domain). Compliance: Unclear measure. Adverse effects: Total number of all adverse effects in each group.
Notes	

Risk of bias

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

Landorf 2006

Methods	RCT. Three-arm parallel-group design. Type of foot pain: Plantar fasciitis.
Participants	Inclusion criteria: Diagnosis of plantar fasciitis; symptoms for at least 4 weeks. Exclusion criteria: History of major orthopaedic or medical condition (e.g. inflammatory arthritis or diabetes) that may have influenced the condition. Nr = 136, Na at 3 months = 133, Na at 12 months = 131 PARTICIPANT CHARACTERISTICS Custom-made foot orthoses group Age, mean years (SD): 49.2 (12.0) Women, No. (%): 34 (74) BMI, mean (SD): 30.3 (6.1) Symptom duration, median months (range): 12 (2-360) Sham orthoses group Age, mean years (SD): 48.5 (9.6) Women, No. (%): 30 (67) BMI, mean (SD): 29.6 (4.9) Symptom duration, median months (range): 12 (1-240) Non custom foot orthoses group Age, mean years (SD): 47.3 (11.6) Women, No. (%): 25 (57) BMI, mean (SD): 32.9 (6.1) Symptom duration, median months (range): 11 (2-360)

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Landorf 2006 (*Continued*)

Interventions	Neutral suspension plaster casts taken of each participant's feet. An appointment was made for 2 to 3 weeks later to issue the orthoses. Customised orthoses: Fabricated using principles described by Hice. Plaster cast posted to neutral calcaneal stance position. Semirigid 4.5mm polypropylene heated and vacuum moulded over cast. Firm 400kg/m3 heel post applied inferior to heel. Inferior heel ground to 1-2mm thickness and parallel to forefoot (i.e. 0 degrees). Sham orthoses: Fabricated by moulding 6 mm, soft (120 kg/m3) ethyl vinyl acetate foam over an unmodified cast of the foot. Inferior heel ground to 1-2mm thickness and parallel to forefoot (i.e. 0 degrees). Non-custom made orthoses: A three-quarter-length (retail mould) Formthotic (Foot Science International, Christchurch, New Zealand) dispensed using the manufacturer's instructions. Made from a firm-density polyethylene foam sufficiently thick to fill the arch area and prevent orthosis flattening. No other treatments (e.g. anti-inflammatory drugs or corticosteroid injections) were allowed during the 12 months that the participants were in the trial.
Outcomes	Pain: Foot Health Status Questionnaire (pain domain). Function: Foot Health Status Questionnaire (pain domain). Compliance: Proportion of participants who self-reported breaking protocol (e.g. taken anti-inflammatory drugs, received a corticosteroid injection, used a night stretch splint or used alternative orthoses).
Notes	

Risk of bias

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

Martin 2001

Methods	RCT. Three-arm parallel-group design. Type of foot pain: Plantar fasciitis
Participants	Inclusion criteria: Plantar heel tenderness; history of pain in arising in the morning or after rest (first-step pain); no history of trauma to the heel within the previous 3 months. Exclusion criteria: Other types of heel pain consistent with other diagnoses such as bursitis, tendinitis, or neurologic pain; self-treatment or professional treatment within 1 month of being evaluated in the podiatry clinic, including rigid over-the-counter (OTC) arch supports, injections, and non-steroidal anti-inflammatory drugs. Nr = 255, Na = 220 PARTICIPANT CHARACTERISTICS Custom-made foot orthoses group Age, mean yrs (SD): 47 (13) Sex, % female: 72 BMI, mean (SD): 32.0 (7.3) Duration of symptoms, median (wks): 20

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Martin 2001 (*Continued*)

	Non custom orthoses group Age, mean yrs (SD): 48 (11) Sex, % female: 76 BMI, mean (SD): 31.9 (6.6) Duration of symptoms, median (wks): 16
Interventions	Custom made orthoses (plus taping): At the initial visit, each participant was placed in the supine position while the foot was held with the subtalar joint neutral and the midtarsal joint fully pronated. The plantar contour of the foot underwent scanning by a laser beam and the resultant image was transmitted to a computer. The information was processed in a prescription format and sent to Bergmann Orthotic Laboratory in Northfield, Illinois. All orthoses were made of rigid 5 mm Polydur (Atlas International, Sacramento, California) plastic material. The orthoses were intrinsically balanced in forefoot-to-rearfoot neutral bisection. They were posted using a non-compressible composition cork material. The orthoses were intrinsically balanced with 4° of rearfoot varus and with intrinsic forefoot posting. No top covers were used. The foot was taped using a low-Dye technique for approximately 2 weeks, after which the orthoses were dispensed. Non custom made orthoses (plus taping): Made of a rigid plastic (Foot Soldiers, Professional Footcare Internationa, Valencia, California). The foot was taped using a low-Dye technique for 2 weeks, after which the arch supports were dispensed. Posterior tension night splint group: Did not receive pre intervention taping, therefore excluded from analyses (unable to isolate effect of custom foot orthoses).
Outcomes	Pain: 100 mm visual analogue scale.
Notes	If the plantar fasciitis was bilateral, only the more symptomatic foot was entered into the study.

Risk of bias

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

Pfeffer 1999

Methods	RCT. Five-arm parallel-group design. Type of foot pain: Proximal plantar fasciitis (heel pain syndrome)
Participants	15 orthopaedic foot and ankle centres participated in the study. All participants were examined by an orthopaedic surgeon who specialised in foot and ankle disorders. Inclusion criteria: Isolated pain over the medial calcaneal tuberosity, consistent with proximal plantar fasciitis; maximal tenderness over the medial calcaneal tuberosity at the insertion of the plantar fascia; 16 years of age and older [not clear if an inclusion criteria]. Exclusion criteria: Systemic disease; sciatica; local nerve entrapment (1st branch of lateral plantar nerve or posterior tibial nerve); previous treatment for the condition. Nr = 236, Na = 190.

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Pfeffer 1999 (*Continued*)

	PARTICIPANT CHARACTERISTICS Stretching group Median age, yrs (range): 47 (25-81) Sex, % female: 71.8% BMI, median (range): 28.0 (21.6-50.5) Custom foot orthoses (plus stretching) group Median age, yrs (range): 48.5 (23-69) Sex, % female: 67.7% BMI, median (range): 29.3(21.5-46.6) Silicone heel pad (plus stretching) group Median age, yrs (range): 49.5 (30-75) Sex, % female: 59.5% BMI, median (range): 28.0(20.0-43.6) Felt insert (plus stretching) group Median age, yrs (range): 48 (26-76) Sex, % female: 69.1% BMI, median (range): 28.1(18.3-48.9) Rubber heel cup (plus stretching) group Median age, yrs (range): 44 (27-69) Sex, % female: 69.8% BMI, median (range): 27.1(20.4-50.2)
Interventions	Stretching: Achilles' and plantar fascia stretching for approximately 10 min, twice a day. Stretching exercises demonstrated with diagrams and a written explanation. Custom foot orthoses (plus stretching): Made from a negative cast of each participant's foot, taken while the subtalar joint was in a neutral position. Orthoses were made in a uniform manner at Prolab (San Fransisco, CA). Either 1/4 inch or 3/16 inch polypropylene was used for each neutral orthosis, with the thickness determined by the weight of the participant. The time from casting to dispensing each orthotic was 10 to 12 days. The baseline questionnaire was not filled out until the participant received the orthotic device. Non-custom foot orthoses (plus stretching): Silicone heel pad (Bauerfeind, Kennesaw, GA). Non-custom foot orthoses (plus stretching): Felt insert (Hapad, Bethel Park, PA). Non-custom foot orthoses (plus stretching): Rubber heel cup (Tuli International Comfort Products, San Marcos, CA). All participants given identical written instructions specific to randomised treatment protocol. No other treatment modalities were used in this study, including anti-inflammatory agents. Participants were encouraged not to change their regular shoe wear or activity level.
Outcomes	Pain: Foot Function Index (pain scale).
Notes	

Risk of bias

Item	Authors' judgement	Description

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Pfeffer 1999 (*Continued*)

Allocation concealment?	Unclear	B - Unclear

Powell 2005

Methods	RCT. Three-arm parallel-group design. Type of foot pain: Juvenile idiopathic arthritis (JIA)
Participants	Recruited from three paediatric rheumatology clinics at three Southern California children's hospitals. Inclusion criteria: Assessed by paediatric rheumatologist to ensure diagnosis of juvenile idiopathic arthritis according to the International League of Associations for Rheumatology (ILAR) criteria; persistent pain in the joints of the lower extremity (ankle, subtalar, hindfoot, and/or metatarsal joints); at least 5 years of age; presence of active disease of the ankle, subtalar, hindfoot, and/or metatarsal joints as determined by the tender and swollen foot joint count; history of persistent foot/ankle pain for more than 1 month but less than 2 years; no foot osseous anomaly noted during the physical evaluation; no history of foot/ankle surgery; stable medication(s) for 1 month prior to entry and during the course of the study; no joint injections for at least 6 month prior to entry and during the course of the study; no previous use of shoe inserts or foot orthoses; ability to walk 50 feet without assistive devices. Exclusion criteria: Not reported. Nr = 47, Na = 40 PARTICIPANT CHARACTERISTICS Supportive shoe group Age, mean yrs (SD): 13.77 (4.55) Sex, % female: 69% Custom-made foot orthoses (plus supportive shoes) group Age, mean yrs (SD): 12.14 (3.32) Sex, % female: 87% Non-custom foot orthoses (plus supportive shoes) group Age, mean yrs (SD): 12.17 (3.04) Sex, % female: 67% Types of JIA: enthesiitis related arthropathy = 11, polyarthritis = 21, oligoarthritis = 6, systemic arthritis = 2.
Interventions	New supportive athletic shoes with a medial longitudinal arch support and shock absorbing soles (cross-training type shoes). All children educated by a physical therapist about the recommended supportive athletic shoes to be worn during the study. Custom foot orthoses (plus new supportive athletic shoes): Orthoses made of metal particle-reinforced polyolefin with shock absorbing functional posts, made from non-weight-bearing casting in a subtalar neutral position. Non custom foot orthoses (plus new supportive athletic shoes): Inserts made of 1/8 inch flat neoprene (Spenco Medical Corporation).
Outcomes	Pain: Foot Function Index (pain scale). Function: Foot Function Index (activity Limitation scale). Disability: Foot Function Index (disability scale).

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Powell 2005 (*Continued*)

Notes		
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Roos 2006

Methods	RCT. Three-arm parallel-group design. After 12 weeks participants were allowed to crossover to another treatment group. Type of foot pain: Plantar fasciitis
Participants	Inclusion criteria: Between 20 and 60 years of age; seeking treatment for plantar fasciitis; activity level before current symptoms at least equivalent to heavy household work, heavy yard work, or walking on even ground; at least moderate pain when performing physical activities; duration of symptoms more than 4 weeks. Exclusion criteria: Diagnosis other than plantar fasciitis. Nr = 44, Na at 6, 12, and 26 weeks = 24, Na at 52 weeks = 38. PARTICIPANT CHARACTERISTICS Gender: 79% female Age, mean (range): 46 (22 to 63) years Symptom duration before treatment, median (range): 4.2 (1-240) months
Interventions	Custom-made foot orthoses: Non-weightbearing plaster cast was taken with the participant lying prone and the subtalar and midtarsal joints placed in neutral alignment. The alignment was achieved by manipulation manually. No wedges or posts were used during casting. The cast was total contact with the longitudinal arch. Bilateral foot orthoses were fabricated for all participants. Orthoses were made of ethyl-vinyl-acetate material of 55 shore A density and were fitted into each participant's shoes. Daily use of orthoses was recommended. Night splint: An anterior night splint was used to hold the foot in 90° of dorsiflexion. Maintaining a foot position of neutral plantigrade, a 3.2 mm thickness of Omega Plus (North Coast Medical, USA) a low temperature thermoplastic material, was draped directly onto the anterior lower leg and foot of each participant. Each template of material was 70 mm wide and of length equal to the measure from the tibial tuberosity to the metatarsal heads. Reinforcement was applied at the anterior ankle crease before heating. Skin protection was provided by a stockinette. Once cooled, a liner of 3 mm low-density polyethylene was added, along with 4 Velcro straps for securing the night splint. These were placed immediately inferior to the tibial tuberosity at the proximal malleoli, at the level of the midtarsal joints and across the metatarsal heads. Each participant was directed on proper application of the splint and on its nighttime use only. Recommended 7 nights per week. Foot orthosis and night splint:

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Roos 2006 (*Continued*)

Outcomes	Pain: Foot & Ankle Outcome Score (pain scale). Function: Foot and Ankle Outcome Score (sport and recreation scale). Disability: Foot and Ankle Outcome Score (Activities of Daily Living scale). Health-related quality of life: Foot & Ankle Outcome Score (quality of life scale). Compliance: Participant daily logs of intervention use, returned by mail at 6 weeks and 3 months. Compliance considered 'good' if at least 75% of recommended wear time was reported (i.e. used at least five days per week). Adverse effects: Number and nature of adverse effects per group.
Notes	

Risk of bias

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

Torkki 2001

Methods	RCT. Three-arm parallel-group design. Type of foot pain: Painful hallux valgus
Participants	Patients of 4 hospitals of the Uusimaa Health District Area, referred by general practitioners for orthopaedic evaluation because of hallux valgus. Inclusion criteria: Adult less than 60 years of age; mild or moderate hallux valgus deformation; painful bunion with the hallux valgus angle (angle between the first metatarsal bone and the proximal phalanx) 35° or less and the intermetatarsal angle (angle between the 1st and 2nd metatarsal bones) 15° or less. All angles measured by the same investigator using the centre-of-head method. Exclusion criteria: Any foot that had previously undergone bunion surgery, had hallux rigidus, or had hallux limitus; rheumatoid arthritis; use of foot orthoses; pregnancy; age older than 60 years. Nr = 209, Na = 209. PARTICIPANT CHARACTERISTICS Custom foot orthoses group Age, mean (SD), years: 49 (10) Women, %: 89 BMI, mean (SD): 23.9 (13.0) Surgery group Age, mean (SD), years: 48 (10) Women, %: 93 BMI, mean (SD): 24.0 (14.0) Watchful waiting group Age, mean (SD), years: 47 (9) Women, %: 96 BMI, mean (SD): 24.2 (15.0)

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Torkki 2001 (*Continued*)

Interventions	Custom-made foot orthoses: Negative casts with individual prescriptions written according to foot deformity were sent to ProLab (South San Fransisco, California). ProLab fabricated the polypropylene functional foot orthoses for both feet and sent the orthoses and usage instructions to the participant within 8 weeks. Surgery: Chevron procedure. Most procedures performed by 1 of 3 experienced orthopaedic surgeons. Watchful waiting: Participants were asked to avoid surgical and foot orthotic therapy during the follow-up period. Foot orthosis group did not receive orthoses for up to 2 months after randomisation and surgery group did not receive surgery on the day of randomisation. All participants were asked to contact the independent observer if their foot pain had so worsened that they required surgery before the end of follow up.
Outcomes	Pain: 100 mm visual analogue scale. Disability: 100 mm 'ability to work' visual analogue scale. Health-related quality of life: Health-Related Quality of Life Index. Satisfaction: 100 mm 'satisfaction' visual analogue scales (0= totally unsatisfied and 100=totally satisfied). Compliance: Proportion of participants in the: (1) custom foot orthoses group who reported retrospective use of orthoses at least six days per week; (2) no intervention group who did not use foot orthoses or have surgery; (3) surgery group who received surgery. Adverse effects number of adverse effects in just the surgery group.
Notes	If bilateral deformity, outcome measures were recorded separately for each foot. The foot with lower AOFAS (worse signs and symptoms) was included in data analysis.

Risk of bias

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

Woodburn 2002

Methods	RCT. Two-arm parallel-group design. Type of foot pain: Painful correctable valgus deformity in the rearfoot in rheumatoid arthritis.
Participants	Enrolled from hospital outpatient clinics. Inclusion criteria: Participants with rheumatoid arthritis, satisfying the 1987 American College of Rheumatology revised criteria for rheumatoid arthritis; history of bilateral, subtalar and/or ankle and/or talonavicular pain and valgus heel deformity; normal ranges of motion at the ankle, subtalar and midtarsal joints; passive range of motion testing revealing valgus heel deformity was correctable with =10° of subtalar inversion past neutral. Exclusion criteria: Concomitant musculoskeletal disease; central or peripheral nervous system disease; endocrine disorders, especially diabetes mellitus; history of orthopaedic foot surgery; current use of foot orthoses; inappropriate footwear. Nr = 101, Na = 98.

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Woodburn 2002 (*Continued*)

	PARTICIPANT CHARACTERISTICS Custom-made foot orthoses group Age, mean (SD), years: 54.0 (11.8) Sex, % female: 68% Disease duration, median (IQR), yrs: 3 (1,7) No intervention group Age, mean (SD), years: 53.1 (11.1) Sex, % female: 65% Disease duration, median (IQR), yrs: 3 (2,6)
Interventions	Custom-made foot orthoses: Designed and manufactured to a standardised protocol from impression casts taken of the feet using subtalar neutral suspension technique. Orthoses were constructed of Super-Lyte carbon graphite composite with deep heel cup and contoured medial arch. The inbuilt correction was customised for each participant according to the degree of valgus heel deformity present using intrinsic posting in the rearfoot and maximum forefoot balancing techniques. All devices were covered with 1.6mm cushioning material (PPT) extended to the toe sulcus region. No intervention group: Were not prescribed foot orthoses at baseline. Over 30 months these participants were permitted orthoses if prescribed at any subsequent outpatient medical consultation. Normal daily walking aids were permitted.
Outcomes	Pain: Foot Function Index (pain scale). Function: Foot Function Index (activity limitation scale). Disability: Foot Function Index (disability scale). Compliance: Compared the proportion of participants allocated to the custom-made foot orthoses group who reported wearing the orthoses during the week prior to each follow-up (averaged across study) with the proportion of participants allocated to the no-intervention group who were not referred from outpatient clinics for foot orthoses. The mean reported wear time of orthoses was 6.3 (SD 3.5) hours per day, 6.1 (SD 1.9) days per week. Adverse effects: Number and nature of adverse effects per group.
Notes	

Risk of bias

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

RCT = Randomised Controlled Trial
Nr = Number randomised
Na = Number included in analysis

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

Budiman-Mak 1995	Foot pain data not reported. Pain data presented in Conrad, K., Budiman-Mak, E., Roach, K., Hedeker, D. (1996). "Impacts of foot orthoses on pain and disability in rheumatoid arthritics". Journal of Clinical Epidemiology 49(1):1-7.
Chao 1996	Not a randomised controlled trial or controlled clinical trial.
Doxey 1985	Not a randomised controlled trial or controlled clinical trial.
Grau 2003	Pain not specific to foot: Achilles' tendon problems.
Hodge 1999	Not custom-made foot orthoses: ethyl vinyl acetate formed directly to the foot and trimmed to fit.
Kilmartin 1994	Not custom-made foot orthoses: cobra orthoses consisting of an heel menisci and arch filler made from 7 mm thick, hard, compressed felt, adhered to the under-surface of a fibreboard insole. Not made from an impression of the foot.
Kusumoto 2007	Not custom-made foot orthoses: Sorbothane (polyurethane) pads of prepared shapes and sizes combined to make insole to conform to walking characteristics and shoes of individual participants. Not made from an impression of the foot.
Larsen 2002	No initial foot pain: investigated the prevention of problems in the back and lower extremity. Not custom-made foot orthoses: Formthotic (Foot Science International, Christchurch, New Zealand)
Lynch 1998	Unable to isolate the effect of custom-made foot orthoses due to the unknown carry over effect of the low-dye taping provided to only the custom-made orthoses group.
Magalhaes 2006	Not a randomised controlled trial or controlled clinical trial.
Meijad 2004	Not custom-made foot orthoses: palliative orthoses, made of semiflexible, 10 mm thick Podofaam XE 1000. Performed on standing patients, printing the plantar projections.
Orteza 1992	Not custom-made foot orthoses: Aquaplast orthoses formed directly to the foot. Not made from an impression of the foot. Pain not specific to foot.
Poon 1997	Not randomised controlled trial or controlled clinical trial.
Postema 1998	No initial foot pain: pain or history of pain at the metatarsal region. No subgroup analysis for those presenting with pain at baseline. No use of validated pain measure.
Rome 2004	Not custom-made foot orthoses: prefabricated orthoses, manufactured by Talar Made Orthotics Ltd, Chesterfield, England.

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(*Continued*)

Russell 1999	Not custom-made foot orthoses: Aquaplast orthoses formed directly to the foot. Not made from an impression of the foot.
Saggini 1996	Pain not specific to foot: diffuse pain and hyperalgesia in the peroneus longus muscle.
Saygi 2005	Not custom-made foot orthoses: metatarsal pads.
Sobel 1999	Not a randomised controlled trial or controlled clinical trial.
Stell 1998	Not a randomised controlled trial or controlled clinical trial.
Torkki 2003	Not randomised controlled trial. Patient preference: surgery offered to participants in the nonsurgical treatment arms.
Turlik 1999	Not a randomised controlled trial. Patient preference: participants offered adjunctive non-steroidal anti-inflammatory drugs (NSAIDS), local steroid injection or ultrasound therapy. Uneven use of NSAIDS between groups (18 in heel pad group vs 5 in custom-made foot orthoses group). Not considered in analyses
Wenger 1989	No initial foot pain and no foot specific pain outcome measure.
Whitford 2007	No initial foot pain. Note: subgroup data for participants reporting foot pain at baseline may be made available for future review updates.

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

Burns (n.d.)

Trial name or title	The effect of custom-made foot orthoses for foot pain in people with diabetes and peripheral arterial disease: A randomised controlled trial.
Methods	
Participants	People over the age of 18 year, with diabetes, foot pain and peripheral arterial disease. Target sample size: 60 people. Key exclusion criteria: wheelchair-bound; foot infection; current foot ulceration; amputation; pregnancy; recent foot trauma; current usage of prescribed foot orthoses; unwilling to wear supplied footwear, or lack of willingness to return for follow up.
Interventions	Custom-made foot orthoses plus footwear versus sham foot orthoses plus footwear.
Outcomes	Primary: Foot pain. Secondary: plantar pressure, health related quality of life, functional ability, foot comfort, and activity levels.
Starting date	10th of July 2007

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Burns (n.d.) (*Continued*)

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Notes	Australian New Zealand Clinical Trials Registry number 12607000300471

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DATA AND ANALYSES

Comparison 1. Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Function	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 Health-related quality of life	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 SF-36 Physical functioning domain at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.2 SF-36 General health domain at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.3 SF-36 Vitality domain at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.4 SF-36 Social functioning domain at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 Adverse effects	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4.1 Total adverse effects at 3 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.2 Additional foot pain at 3 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.3 Ankle instability at 3 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.4 Skin irritation at 3 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5 Compliance	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.1 3 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 2. Custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Function	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 Disability	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable

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Comparison 3. Custom-made foot orthoses versus non custom foot orthoses for foot pain in juvenile idiopathic arthritis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Prefabricated off-the-shelf shoe insert at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Function	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 Prefabricated off-the-shelf shoe insert at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 Disability	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 Prefabricated off-the-shelf shoe insert at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable

Comparison 4. Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 6 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 Summary of change over 30 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Foot pain 3 months	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 3 months	2	113	Std. Mean Difference (IV, Random, 95% CI)	0.44 [-0.10, 0.98]
2.2 Sensitivity analysis	1	98	Std. Mean Difference (IV, Random, 95% CI)	0.59 [0.19, 1.00]
3 Function	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 6 weeks (1 to 9 scale)	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.2 30 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 Function 3 months	2		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 3 months	2	113	Std. Mean Difference (IV, Fixed, 95% CI)	0.08 [-0.29, 0.45]
4.2 Sensitivity analysis	1	98	Std. Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.30, 0.50]
5 Disability	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
5.1 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
5.2 30 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
6 Compliance	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
6.1 Over 30 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

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Comparison 5. Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 36 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Function	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 36 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 Disability	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 36 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 Adverse effects	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4.1 36 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5 Compliance	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.1 36 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 6. Custom-made foot orthoses versus non custom foot orthoses for foot pain in rheumatoid arthritis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Soft plastazote orthoses 6 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 Soft plastazote orthoses at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Function	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 Soft plastazote at 6 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 Soft plastazote at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable

Comparison 7. Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain 6-8 weeks	2		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 6-8 weeks	2	96	Std. Mean Difference (IV, Fixed, 95% CI)	0.05 [-0.35, 0.46]
2 Foot pain 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 Function	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 6 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.2 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 Disability	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 6 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.2 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
5 Health-related quality of life	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

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5.1 6 weeks	1	Mean Difference (IV, Fixed, 95% CI)	Not estimable
5.2 3 months	1	Mean Difference (IV, Fixed, 95% CI)	Not estimable
6 Adverse effects	1	Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
6.1 1 week	1	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.2 3 months	1	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 8. Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Function	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 Compliance	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
3.1 3 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.2 3 months (using alternative foot orthoses)	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.3 12 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.4 12 months (using alternative foot orthoses)	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 9. Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain 2-3 months	2		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 2-3 months	2	165	Std. Mean Difference (IV, Fixed, 95% CI)	-0.11 [-0.42, 0.19]
1.2 Sensitivity analysis 2-3 months	1	89	Std. Mean Difference (IV, Fixed, 95% CI)	-0.21 [-0.63, 0.20]
2 Foot pain	3		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 Rubber heel cup at 2 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 Silicone heel pad at 2 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.3 Over-the-counter arch support at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.4 Prefabricated Formthotic at 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 Function	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 Prefabricated Formthotic at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable

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3.2 Prefabricated Formthotic at 12 months	1	Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 Compliance	1	Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4.1 Prefabricated Formthotic at 3 months	1	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.2 Prefabricated Formthotic at 3 months (using alternative foot orthoses)	1	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.3 Prefabricated Formthotic at 12 months	1	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.4 Prefabricated Formthotic at 12 months (using alternative foot orthoses)	1	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 10. Custom-made foot orthoses versus manipulation, mobilisation and stretching for plantar fasciitis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 2 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 1 month	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.3 2 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Adverse effects	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 2 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 11. Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 6 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Function	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 6 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 Disability	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 6 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.2 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 Health-related quality of life	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 6 weeks	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.2 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
5 Adverse effects	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.1 1 week	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.2 3 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6 Compliance	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

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6.1 3 months	1	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 12. Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Disability	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 Health-related quality of life	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.2 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 Participant satisfaction with treatment	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.2 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
5 Compliance	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.1 12 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 13. Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Foot pain	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 Disability	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 Health-related quality of life	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.2 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 Participant satisfaction with treatment	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.2 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
5 Compliance	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.1 6 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.2 12 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

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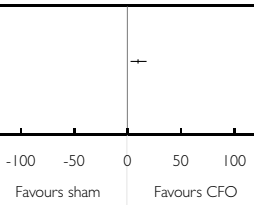
Analysis 1.1. Comparison 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Burns 2006	75	31.2 (25.8)	79	20.3 (22.7)		10.90 [3.21, 18.59]

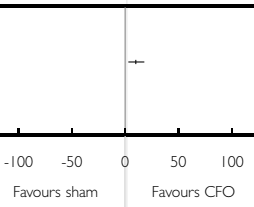


Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Burns 2006	75	31.2 (25.8)	79	20.3 (22.7)		10.90 [3.21, 18.59]



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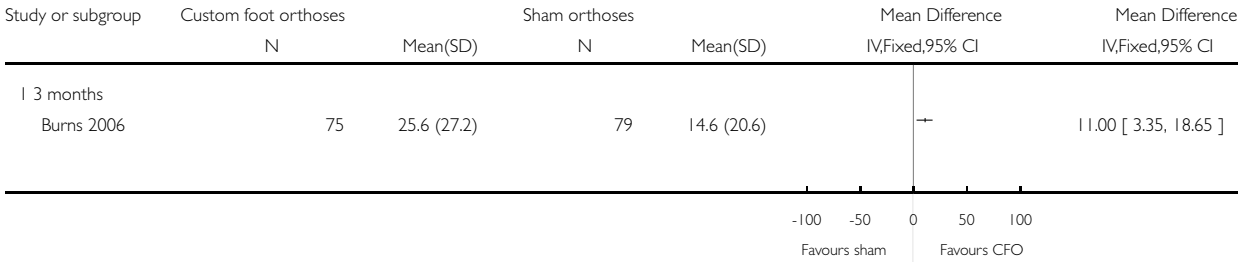
Analysis 1.2. Comparison 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet, Outcome 2 Function.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

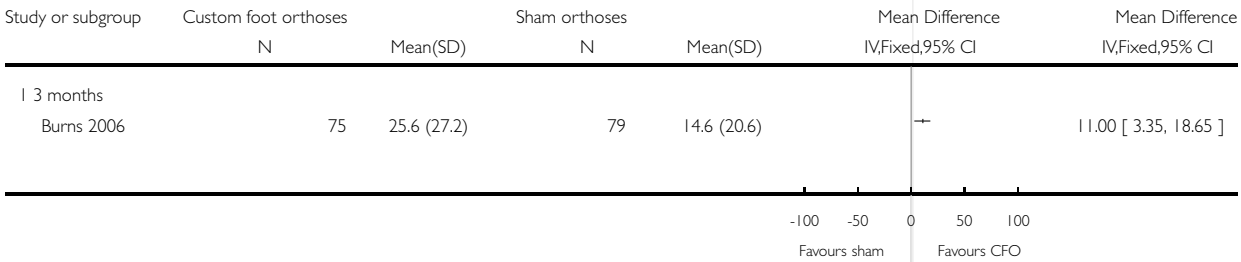
Outcome: 2 Function



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 2 Function



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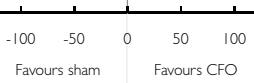
Analysis 1.3. Comparison 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet, Outcome 3 Health-related quality of life.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 SF-36 Physical functioning domain at 3 months						
Burns 2006	75	12.1 (19.3)	79	2.6 (14.6)		9.50 [4.07, 14.93]
2 SF-36 General health domain at 3 months						
Burns 2006	75	3.5 (18.4)	79	3 (20.8)		0.50 [-5.70, 6.70]
3 SF-36 Vitality domain at 3 months						
Burns 2006	75	8.5 (17.8)	79	3 (15.2)		5.50 [0.26, 10.74]
4 SF-36 Social functioning domain at 3 months						
Burns 2006	75	8.7 (20.1)	79	6.2 (16.2)		2.50 [-3.28, 8.28]

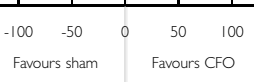


Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 SF-36 Physical functioning domain at 3 months						
Burns 2006	75	12.1 (19.3)	79	2.6 (14.6)		9.50 [4.07, 14.93]



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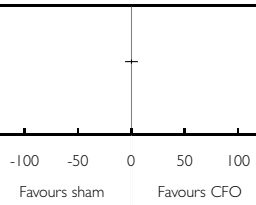
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 SF-36 General health domain at 3 months						
Burns 2006	75	3.5 (18.4)	79	3 (20.8)		0.50 [-5.70, 6.70]

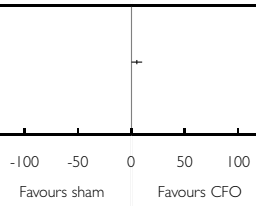


Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
3 SF-36 Vitality domain at 3 months						
Burns 2006	75	8.5 (17.8)	79	3 (15.2)		5.50 [0.26, 10.74]



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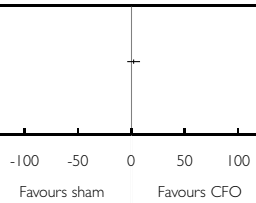
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
4 SF-36 Social functioning domain at 3 months						
Burns 2006	75	8.7 (20.1)	79	6.2 (16.2)		2.50 [-3.28, 8.28]



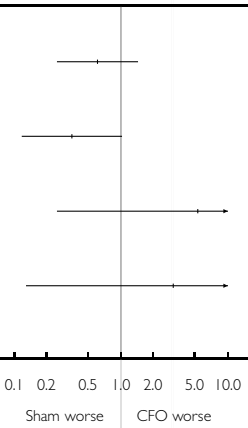
Analysis 1.4. Comparison 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet, Outcome 4 Adverse effects.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 4 Adverse effects

Study or subgroup	Custom foot orthoses n/N	Sham orthoses n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 Total adverse effects at 3 months				
Burns 2006	7/75	12/79		0.61 [0.26, 1.48]
2 Additional foot pain at 3 months				
Burns 2006	4/75	12/79		0.35 [0.12, 1.04]
3 Ankle instability at 3 months				
Burns 2006	2/75	0/79		5.26 [0.26, 107.86]
4 Skin irritation at 3 months				
Burns 2006	1/75	0/79		3.16 [0.13, 76.33]



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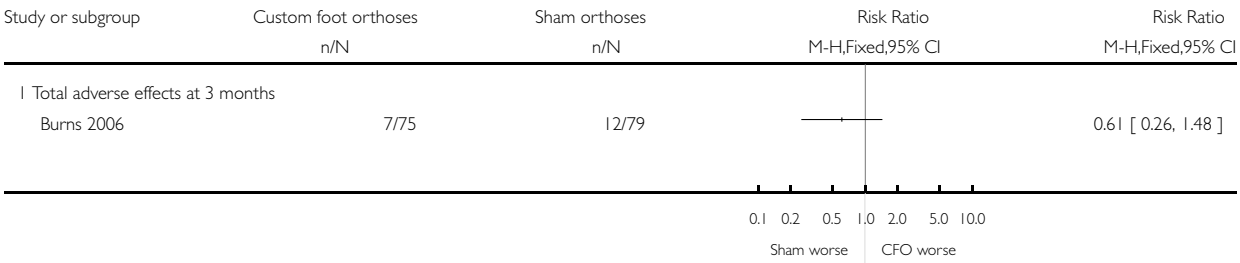
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

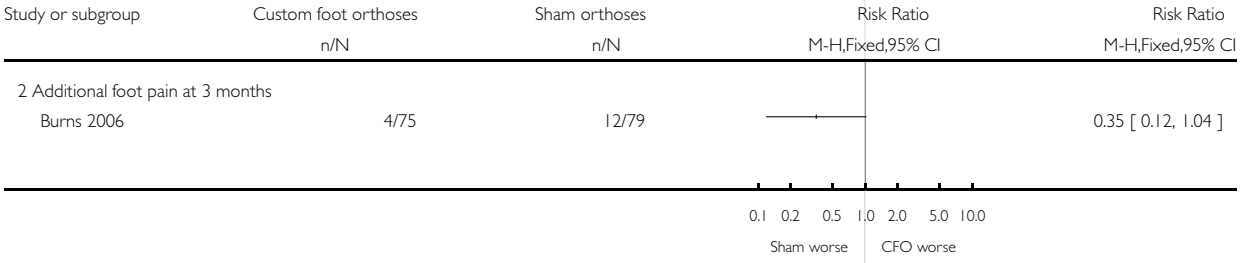
Outcome: 4 Adverse effects



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 4 Adverse effects



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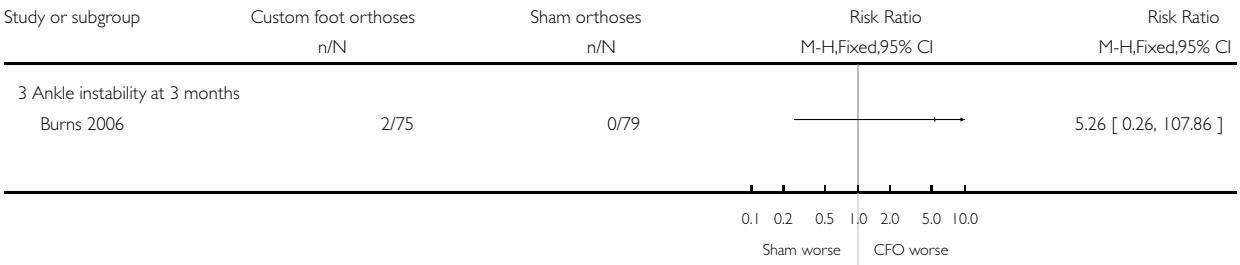
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

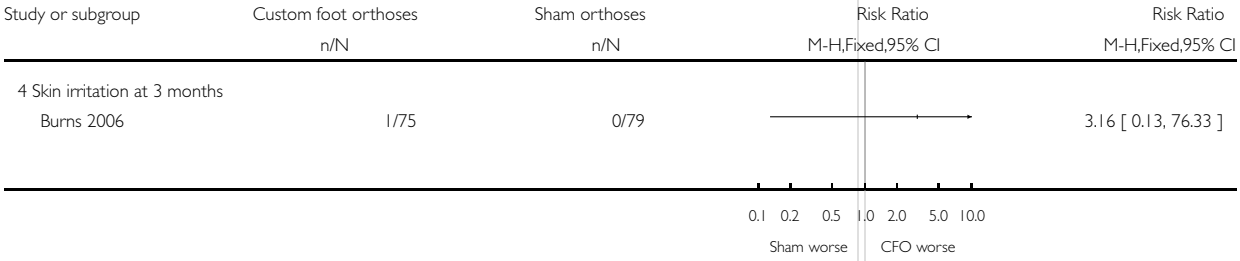
Outcome: 4 Adverse effects



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 4 Adverse effects



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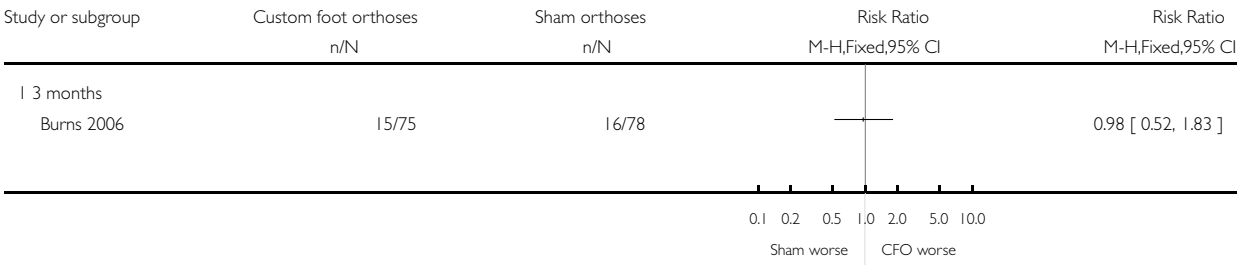
Analysis 1.5. Comparison 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet, Outcome 5 Compliance.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

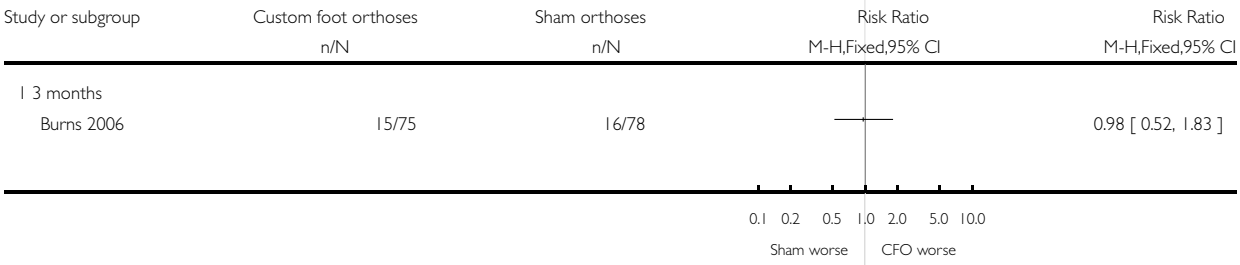
Outcome: 5 Compliance



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 1 Custom-made foot orthoses versus sham orthoses for painful cavus feet

Outcome: 5 Compliance



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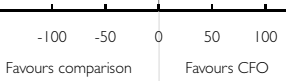
Analysis 2.1. Comparison 2 Custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 2 Custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Powell 2005	15	-18.35 (17.05)	13	-37.54 (25.47)		19.19 [2.88, 35.50]



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 2 Custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Powell 2005	15	-18.35 (17.05)	13	-37.54 (25.47)		19.19 [2.88, 35.50]

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Analysis 2.2. Comparison 2 Custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis, Outcome 2 Function.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 2 Custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis

Outcome: 2 Function

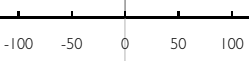
Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Powell 2005	15	-8.54 (11.06)	13	-27.92 (27.89)		19.38 [3.22, 35.54]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 2 Custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis

Outcome: 2 Function

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Powell 2005	15	-8.54 (11.06)	13	-27.92 (27.89)		19.38 [3.22, 35.54]



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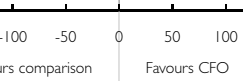
Analysis 2.3. Comparison 2 Custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis, Outcome 3 Disability.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 2 Custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis

Outcome: 3 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Powell 2005	15	-15.6 (13.51)	13	-34.15 (26.35)		18.55 [2.68, 34.42]



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 2 Custom-made foot orthoses versus standardised intervention for foot pain in juvenile idiopathic arthritis

Outcome: 3 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Powell 2005	15	-15.6 (13.51)	13	-34.15 (26.35)		18.55 [2.68, 34.42]

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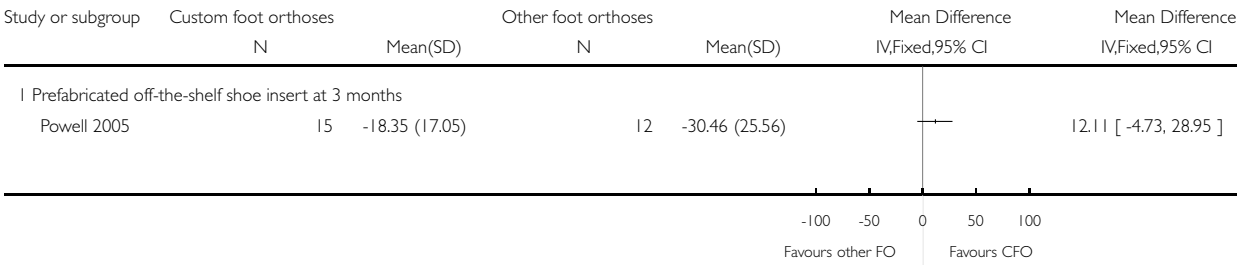
Analysis 3.1. Comparison 3 Custom-made foot orthoses versus non custom foot orthoses for foot pain in juvenile idiopathic arthritis, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 3 Custom-made foot orthoses versus non custom foot orthoses for foot pain in juvenile idiopathic arthritis

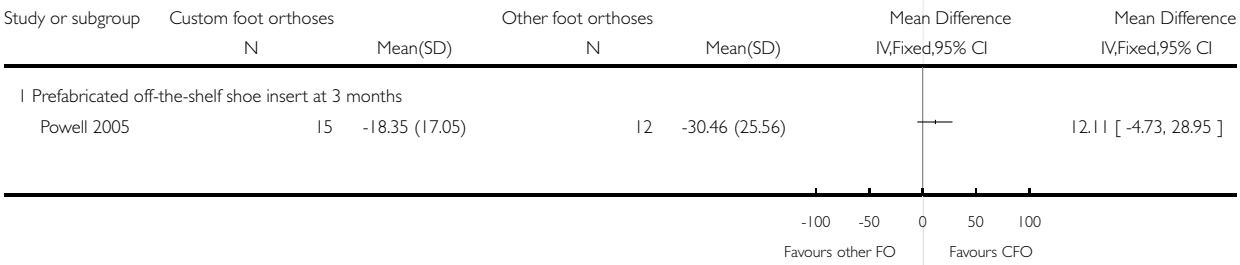
Outcome: 1 Foot pain



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 3 Custom-made foot orthoses versus non custom foot orthoses for foot pain in juvenile idiopathic arthritis

Outcome: 1 Foot pain



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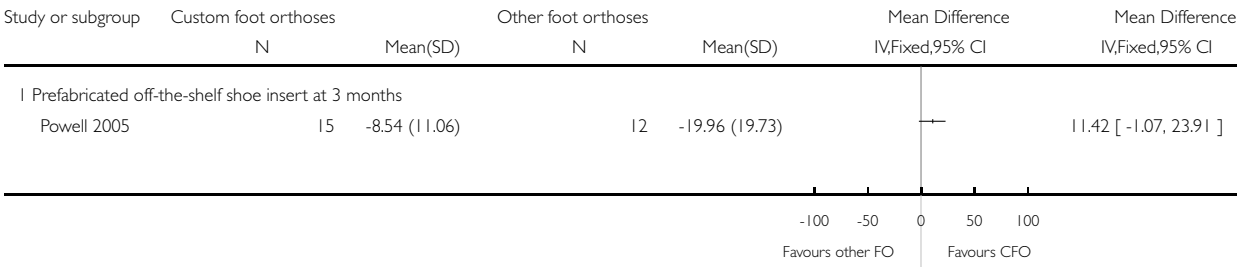
Analysis 3.2. Comparison 3 Custom-made foot orthoses versus non custom foot orthoses for foot pain in juvenile idiopathic arthritis, Outcome 2 Function.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 3 Custom-made foot orthoses versus non custom foot orthoses for foot pain in juvenile idiopathic arthritis

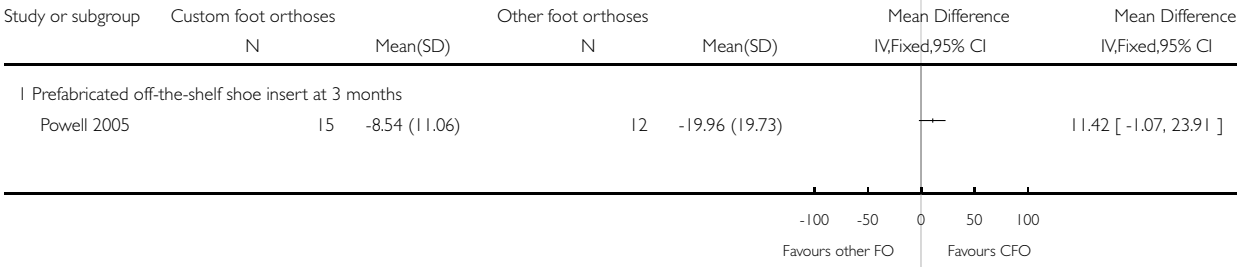
Outcome: 2 Function



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 3 Custom-made foot orthoses versus non custom foot orthoses for foot pain in juvenile idiopathic arthritis

Outcome: 2 Function



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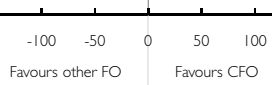
Analysis 3.3. Comparison 3 Custom-made foot orthoses versus non custom foot orthoses for foot pain in juvenile idiopathic arthritis, Outcome 3 Disability.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 3 Custom-made foot orthoses versus non custom foot orthoses for foot pain in juvenile idiopathic arthritis

Outcome: 3 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Prefabricated off-the-shelf shoe insert at 3 months						
Powell 2005	15	-15.6 (13.51)	12	-29.98 (25.26)		14.38 [-1.46, 30.22]



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 3 Custom-made foot orthoses versus non custom foot orthoses for foot pain in juvenile idiopathic arthritis

Outcome: 3 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Prefabricated off-the-shelf shoe insert at 3 months						
Powell 2005	15	-15.6 (13.51)	12	-29.98 (25.26)		14.38 [-1.46, 30.22]

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Analysis 4.1. Comparison 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Chalmers 2000	8	-36.6 (21.6)	8	-45 (34.7)		8.40 [-19.92, 36.72]
2 Summary of change over 30 months						
Woodburn 2002	50	333.4 (632.8)	48	25.6 (581.3)		307.80 [67.37, 548.23]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Chalmers 2000	8	-36.6 (21.6)	8	-45 (34.7)		8.40 [-19.92, 36.72]

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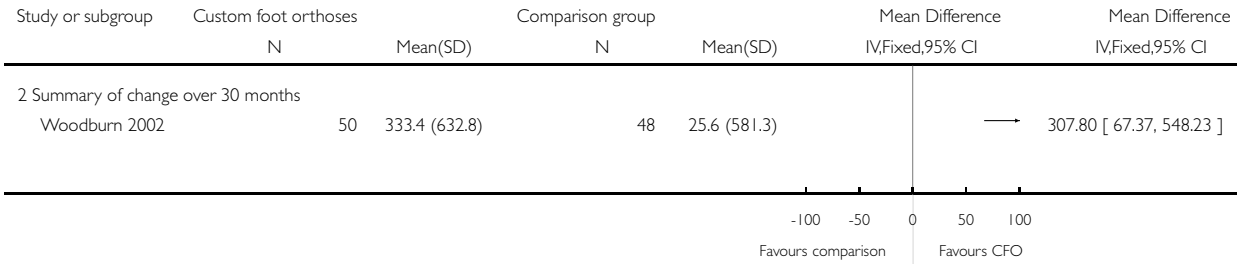
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 1 Foot pain

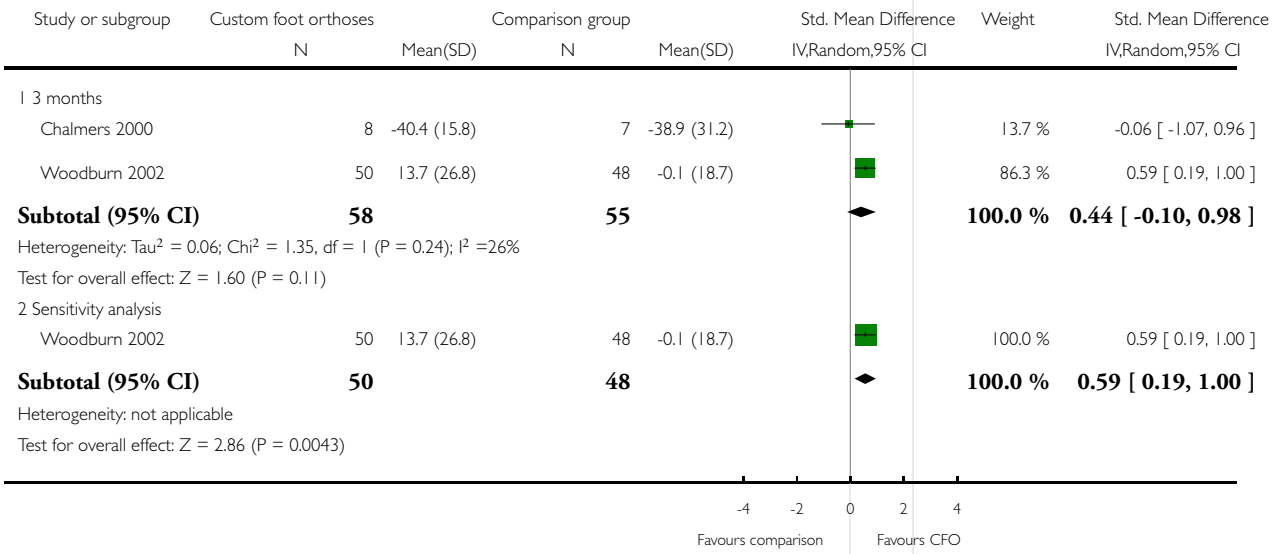


Analysis 4.2. Comparison 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis, Outcome 2 Foot pain 3 months.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 2 Foot pain 3 months



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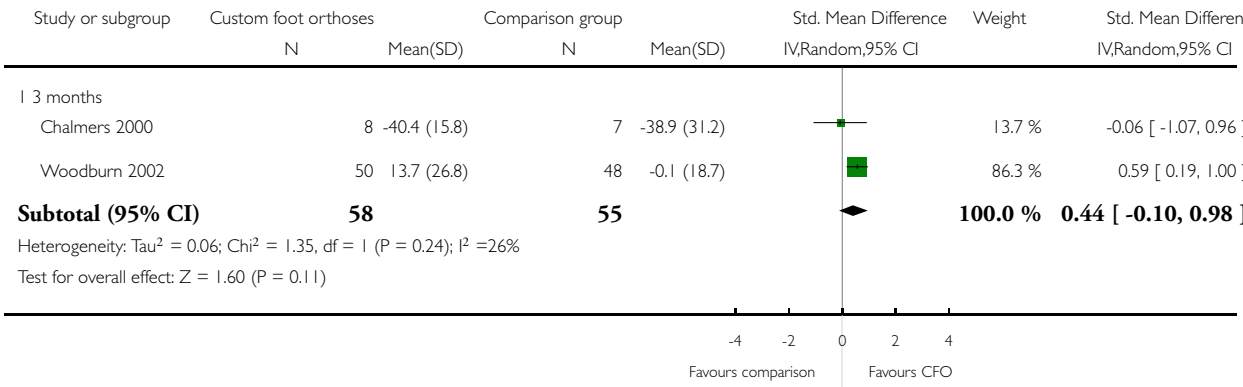
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

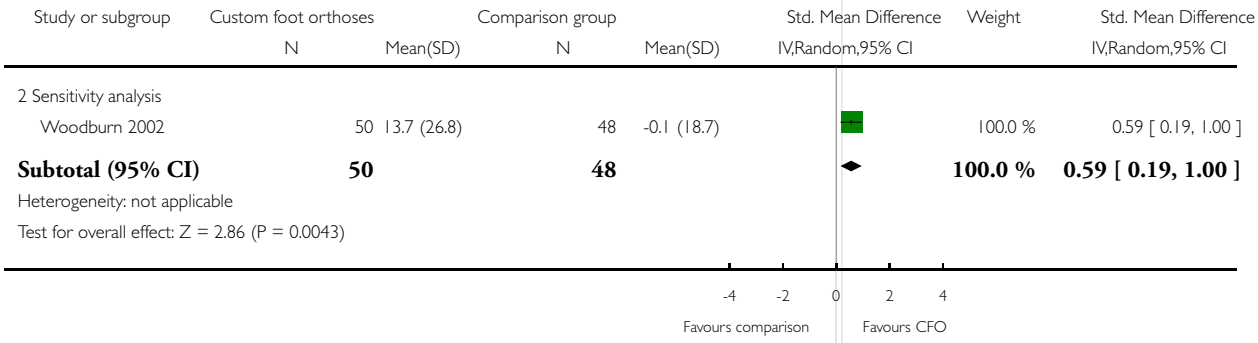
Outcome: 2 Foot pain 3 months



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 2 Foot pain 3 months



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Analysis 4.3. Comparison 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis, Outcome 3 Function.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 3 Function

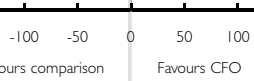
Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks (1 to 9 scale)						
Chalmers 2000	8	7.38 (0.52)	8	7.13 (0.99)		0.25 [-0.52, 1.02]
2 30 months						
Woodburn 2002	50	63.9 (416.1)	48	-17.5 (430.5)		81.40 [-86.33, 249.13]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 3 Function

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks (1 to 9 scale)						
Chalmers 2000	8	7.38 (0.52)	8	7.13 (0.99)		0.25 [-0.52, 1.02]



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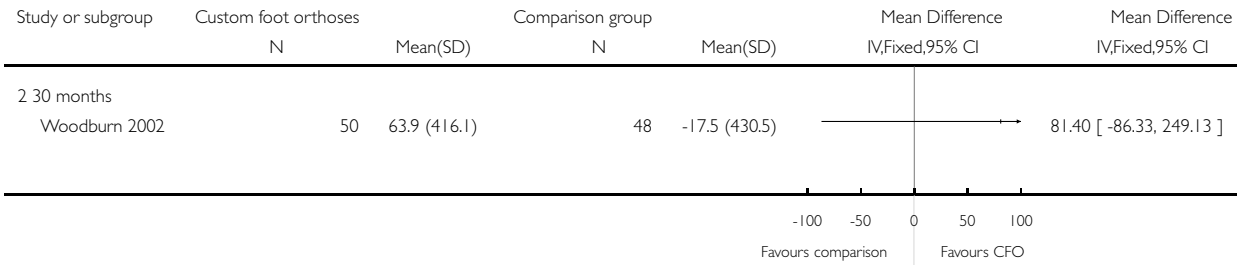
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 3 Function

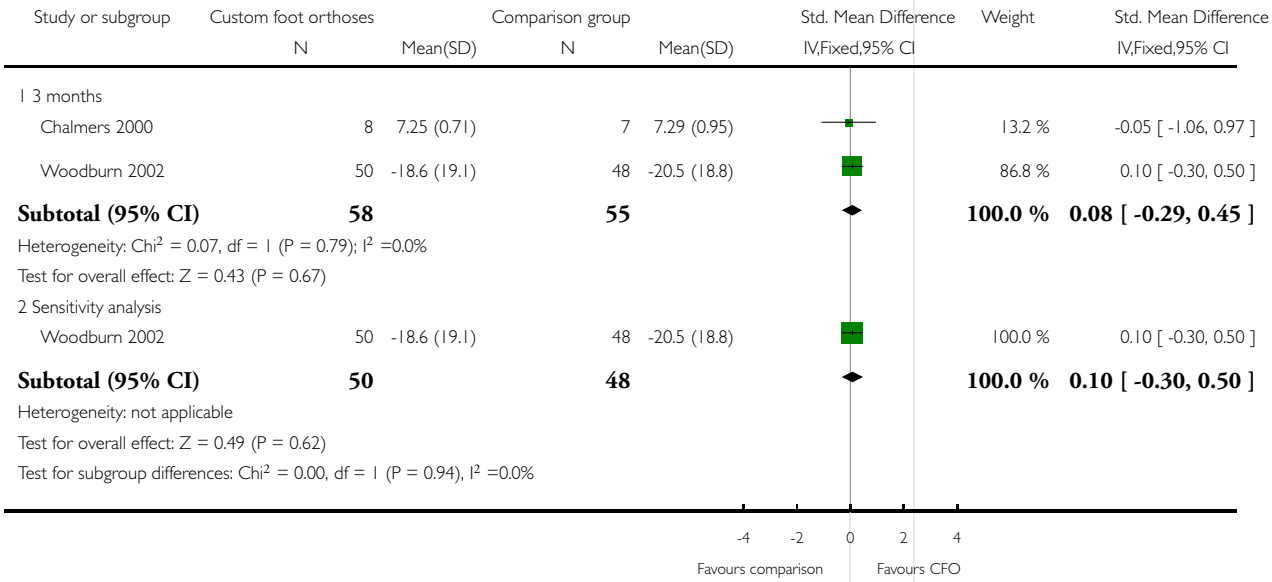


Analysis 4.4. Comparison 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis, Outcome 4 Function 3 months.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 4 Function 3 months



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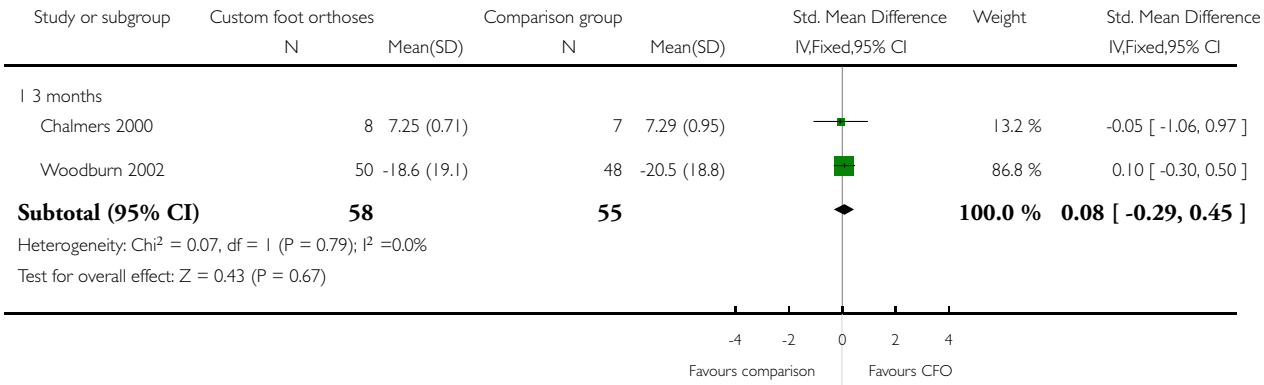
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

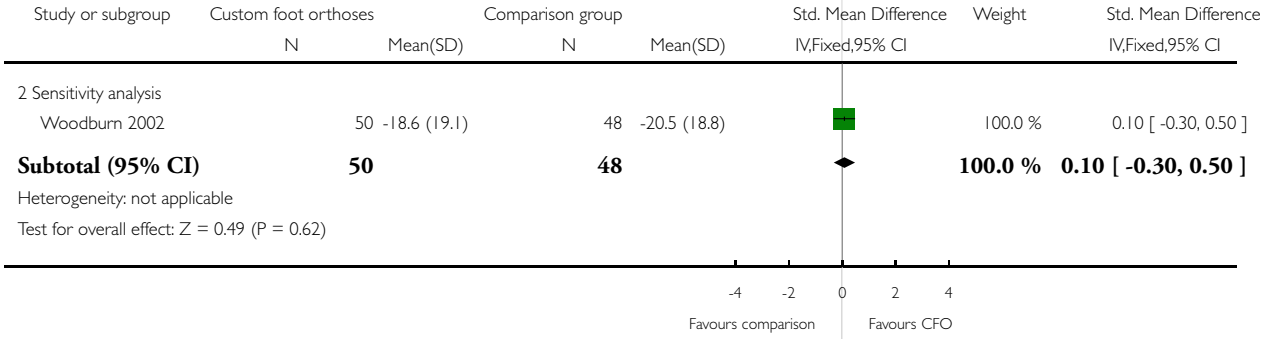
Outcome: 4 Function 3 months



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 4 Function 3 months



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Analysis 4.5. Comparison 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis, Outcome 5 Disability.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 5 Disability

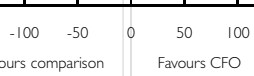
Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Woodburn 2002	50	-38.6 (26.4)	48	-39.2 (23.8)		0.60 [-9.34, 10.54]
2 30 months						
Woodburn 2002	50	334.1 (634)	48	25 (618.3)		309.10 [61.15, 557.05]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 5 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Woodburn 2002	50	-38.6 (26.4)	48	-39.2 (23.8)		0.60 [-9.34, 10.54]



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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 5 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 30 months						
Woodburn 2002	50	334.1 (634)	48	25 (618.3)		309.10 [61.15, 557.05]

Analysis 4.6. Comparison 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis, Outcome 6 Compliance.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 6 Compliance

Study or subgroup	Custom foot orthoses n/N	Comparison group n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 Over 30 months				
Woodburn 2002	48/50	45/48		1.02 [0.93, 1.12]

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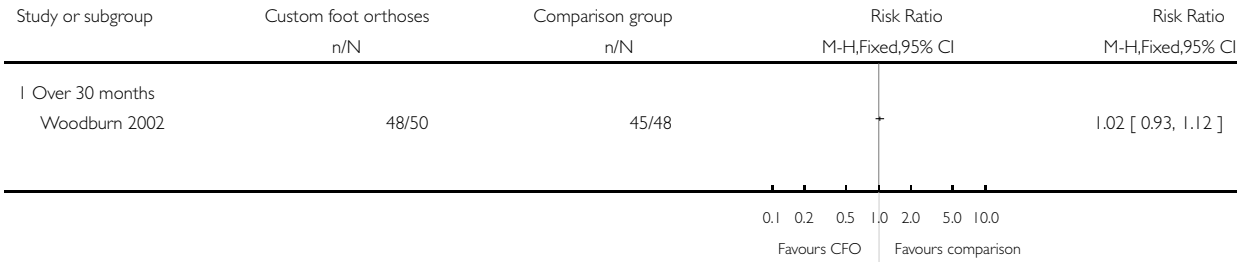
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 4 Custom-made foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis

Outcome: 6 Compliance

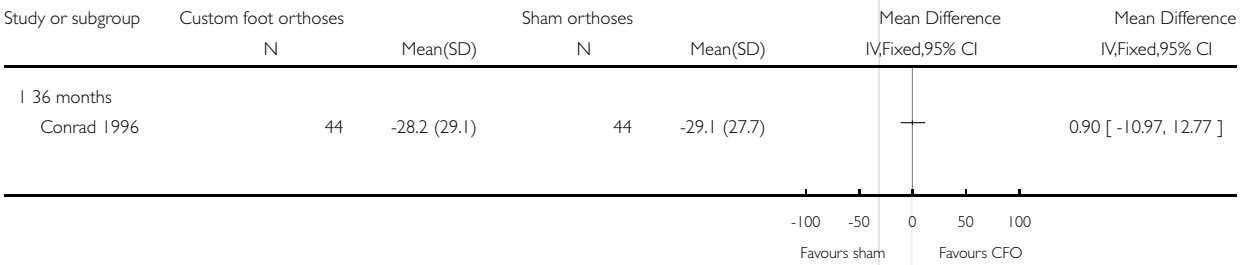


Analysis 5.1. Comparison 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome: 1 Foot pain



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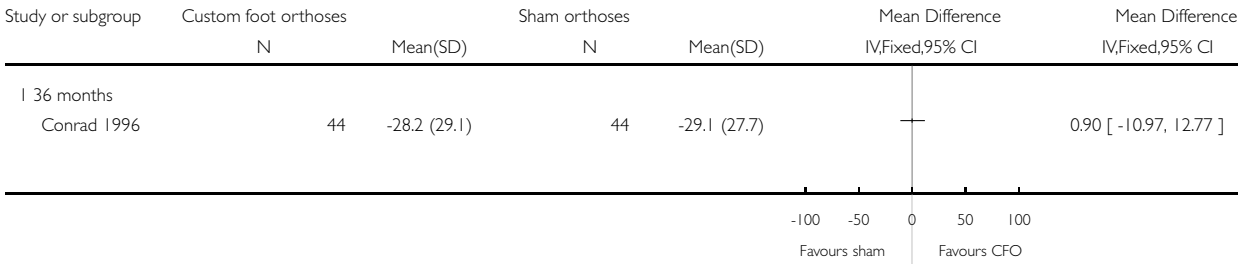
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome: 1 Foot pain

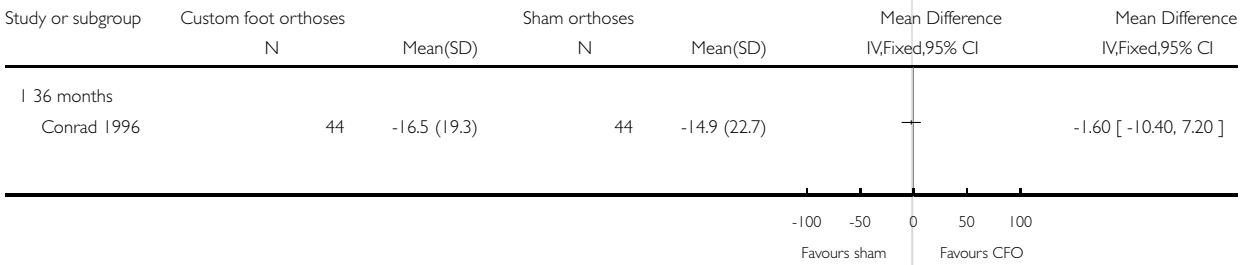


Analysis 5.2. Comparison 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis, Outcome 2 Function.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome: 2 Function



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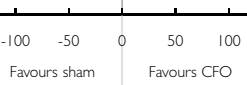
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome: 2 Function

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 36 months						
Conrad 1996	44	-16.5 (19.3)	44	-14.9 (22.7)		-1.60 [-10.40, 7.20]



Analysis 5.3. Comparison 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis, Outcome 3 Disability.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome: 3 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 36 months						
Conrad 1996	44	-34.1 (28.6)	44	-38.3 (28)		4.20 [-7.63, 16.03]

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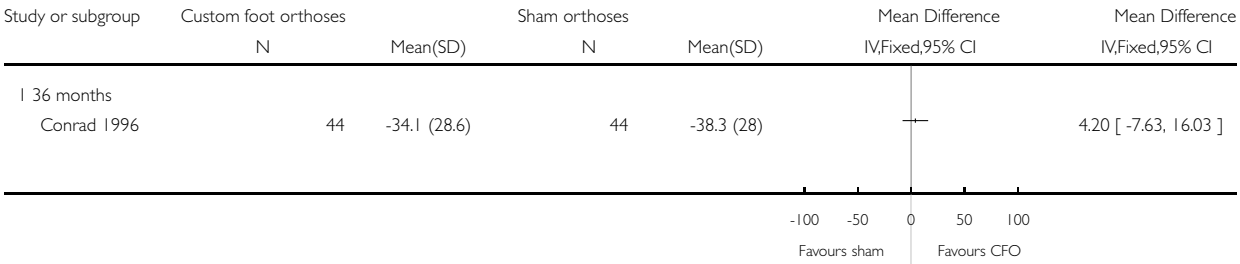
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome: 3 Disability

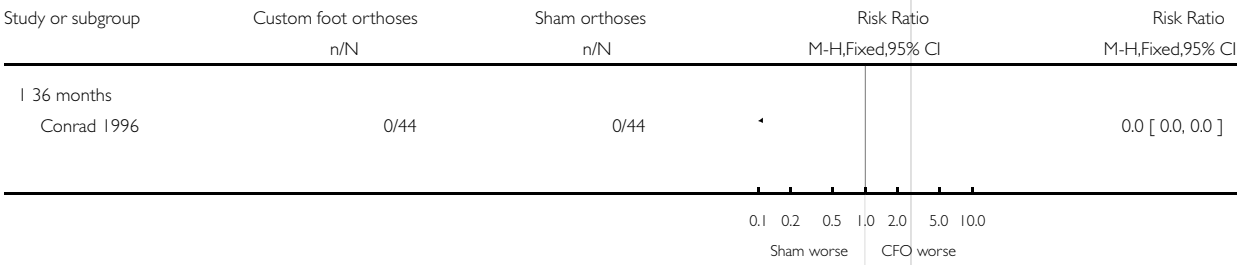


Analysis 5.4. Comparison 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis, Outcome 4 Adverse effects.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome: 4 Adverse effects



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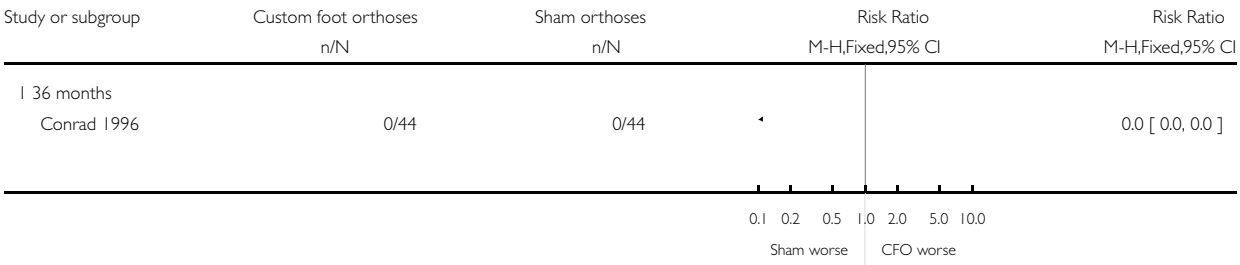
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome: 4 Adverse effects

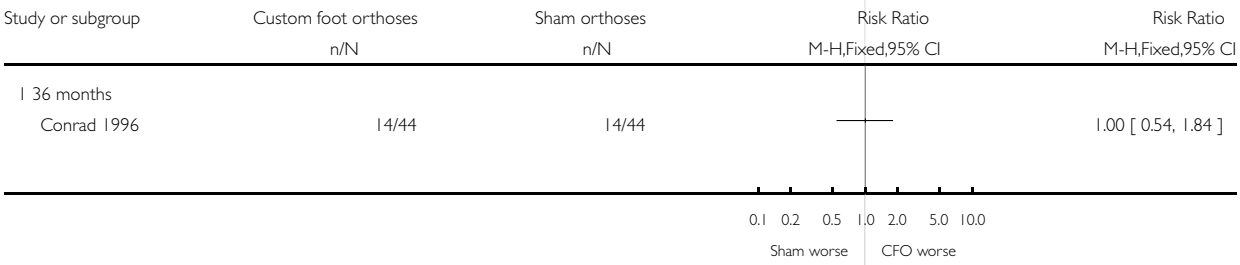


Analysis 5.5. Comparison 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis, Outcome 5 Compliance.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome: 5 Compliance



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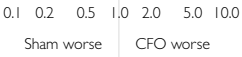
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 5 Custom-made foot orthoses versus sham orthoses for foot pain in rheumatoid arthritis

Outcome: 5 Compliance

Study or subgroup	Custom foot orthoses n/N	Sham orthoses n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 36 months				
Conrad 1996	14/44	14/44		1.00 [0.54, 1.84]



Analysis 6.1. Comparison 6 Custom-made foot orthoses versus non custom foot orthoses for foot pain in rheumatoid arthritis, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 6 Custom-made foot orthoses versus non custom foot orthoses for foot pain in rheumatoid arthritis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Soft plastazote orthoses 6 weeks						
Chalmers 2000	8	-36.6 (21.6)	8	-42.4 (20.3)		5.80 [-14.74, 26.34]
2 Soft plastazote orthoses at 3 months						
Chalmers 2000	8	-40.4 (15.8)	8	-27.1 (22.1)		-13.30 [-32.13, 5.53]

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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 6 Custom-made foot orthoses versus non custom foot orthoses for foot pain in rheumatoid arthritis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Soft plastazote orthoses 6 weeks						
Chalmers 2000	8	-36.6 (21.6)	8	-42.4 (20.3)		5.80 [-14.74, 26.34]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 6 Custom-made foot orthoses versus non custom foot orthoses for foot pain in rheumatoid arthritis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 Soft plastazote orthoses at 3 months						
Chalmers 2000	8	-40.4 (15.8)	8	-27.1 (22.1)		-13.30 [-32.13, 5.53]

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Analysis 6.2. Comparison 6 Custom-made foot orthoses versus non custom foot orthoses for foot pain in rheumatoid arthritis, Outcome 2 Function.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 6 Custom-made foot orthoses versus non custom foot orthoses for foot pain in rheumatoid arthritis

Outcome: 2 Function

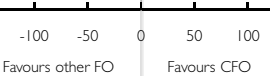
Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Soft plastazote at 6 weeks						
Chalmers 2000	8	7.38 (0.52)	8	6.75 (1.16)		0.63 [-0.25, 1.51]
2 Soft plastazote at 3 months						
Chalmers 2000	8	7.25 (0.71)	8	6.63 (1.51)		0.62 [-0.54, 1.78]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 6 Custom-made foot orthoses versus non custom foot orthoses for foot pain in rheumatoid arthritis

Outcome: 2 Function

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Soft plastazote at 6 weeks						
Chalmers 2000	8	7.38 (0.52)	8	6.75 (1.16)		0.63 [-0.25, 1.51]



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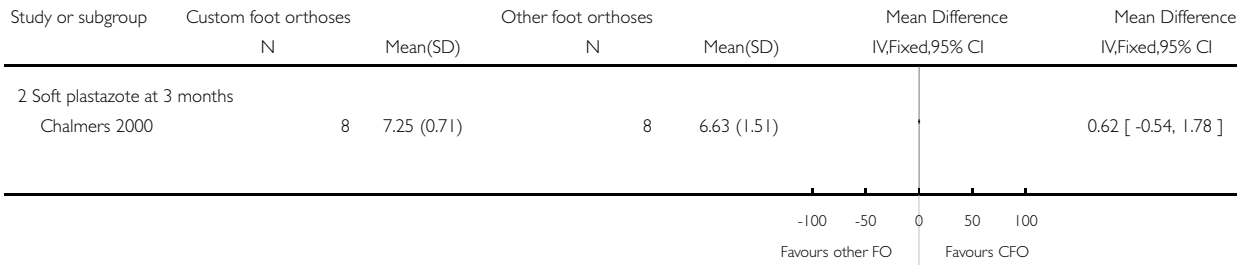
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 6 Custom-made foot orthoses versus non custom foot orthoses for foot pain in rheumatoid arthritis

Outcome: 2 Function

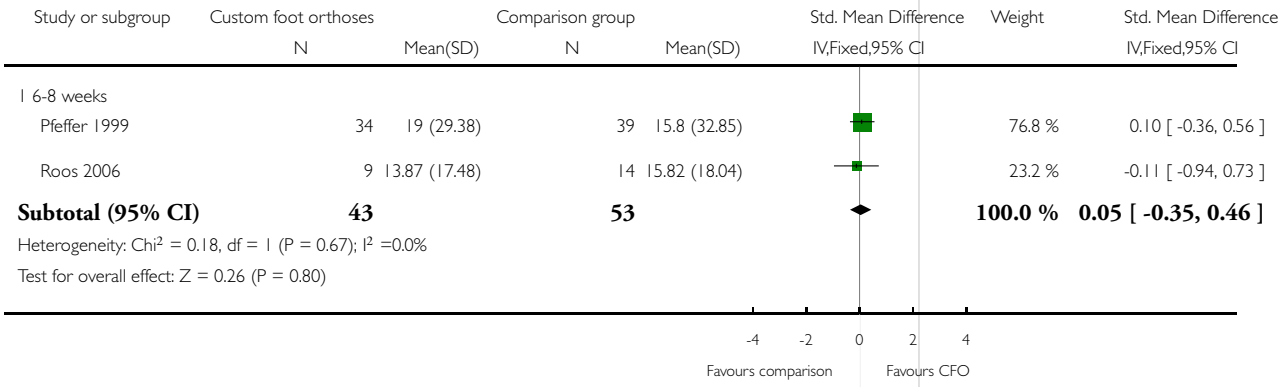


Analysis 7.1. Comparison 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis, Outcome 1 Foot pain 6-8 weeks.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 1 Foot pain 6-8 weeks



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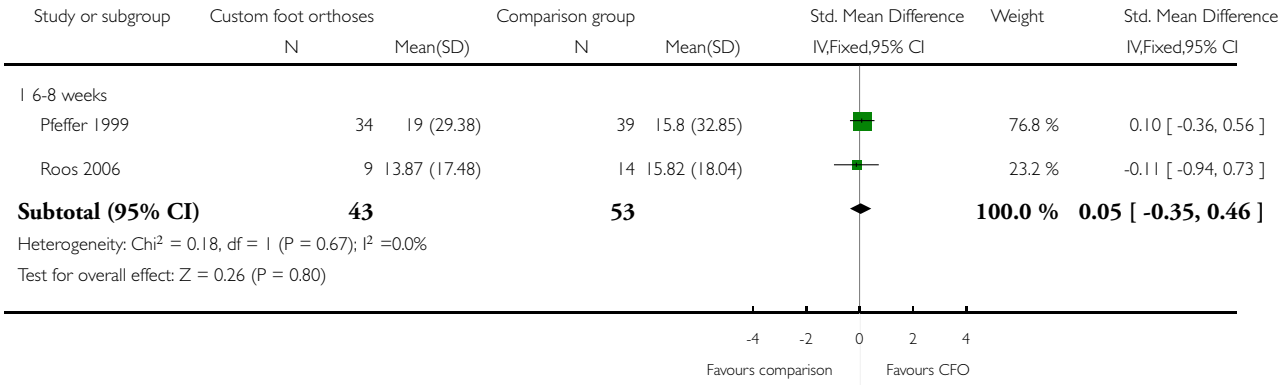
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 1 Foot pain 6-8 weeks

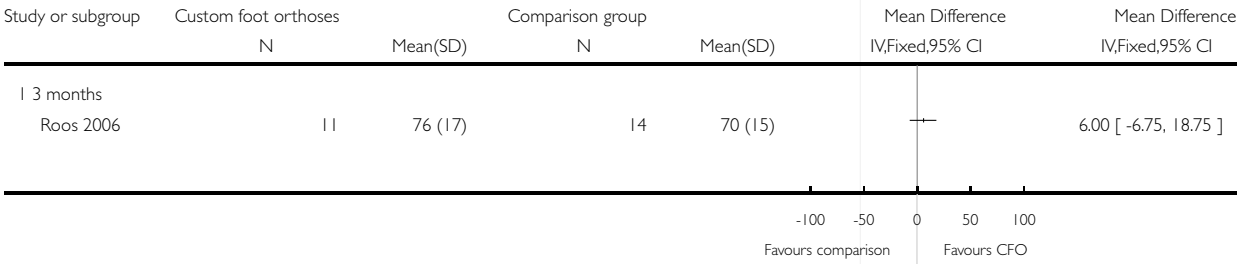


Analysis 7.2. Comparison 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis, Outcome 2 Foot pain 3 months.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 2 Foot pain 3 months



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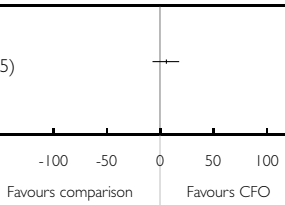
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 2 Foot pain 3 months

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Roos 2006	11	76 (17)	14	70 (15)		6.00 [-6.75, 18.75]



Analysis 7.3. Comparison 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis, Outcome 3 Function.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 3 Function

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Roos 2006	9	18.98 (23.21)	14	21.22 (31.38)		-2.24 [-24.60, 20.12]
2 3 months						
Roos 2006	11	59 (29)	14	63 (20)		-4.00 [-24.09, 16.09]

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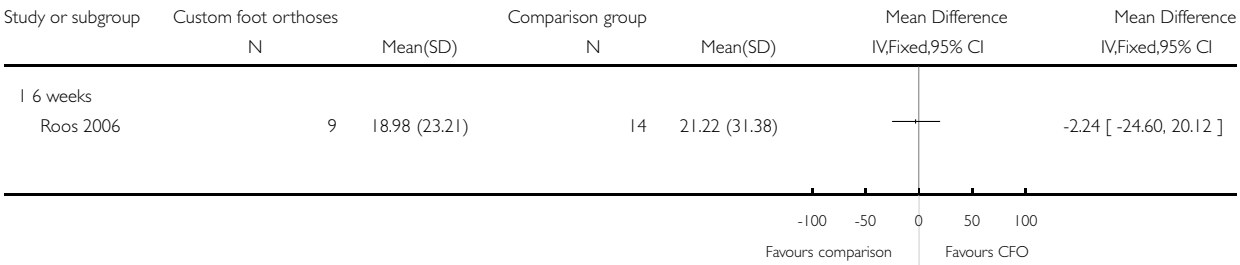
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

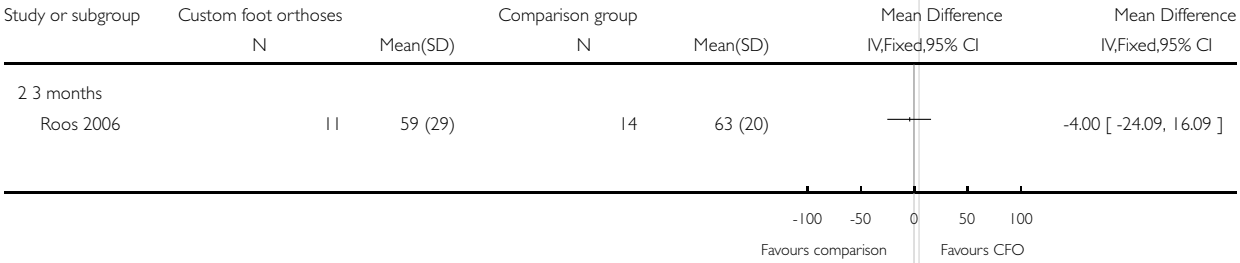
Outcome: 3 Function



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 3 Function



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Analysis 7.4. Comparison 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis, Outcome 4 Disability.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 4 Disability

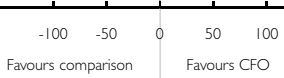
Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Roos 2006	9	10.11 (16.75)	14	12.16 (20.21)		-2.05 [-17.28, 13.18]
2 3 months						
Roos 2006	11	83 (17)	14	75 (15)		8.00 [-4.75, 20.75]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 4 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Roos 2006	9	10.11 (16.75)	14	12.16 (20.21)		-2.05 [-17.28, 13.18]



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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 4 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 3 months						
Roos 2006	11	83 (17)	14	75 (15)		8.00 [-4.75, 20.75]

Analysis 7.5. Comparison 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis, Outcome 5 Health-related quality of life.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 5 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Roos 2006	9	13.66 (19.57)	14	9.97 (23.29)		3.69 [-13.98, 21.36]
2 3 months						
Roos 2006	11	54 (26)	14	46 (17)		8.00 [-9.76, 25.76]

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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 5 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Roos 2006	9	13.66 (19.57)	14	9.97 (23.29)		3.69 [-13.98, 21.36]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 5 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 3 months						
Roos 2006	11	54 (26)	14	46 (17)		8.00 [-9.76, 25.76]

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Analysis 7.6. Comparison 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis, Outcome 6 Adverse effects.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 6 Adverse effects

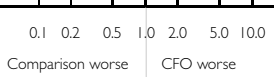
Study or subgroup	Custom foot orthoses n/N	Comparison group n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 1 week				
Roos 2006	6/15	9/15		0.67 [0.32, 1.40]
2 3 months				
Roos 2006	4/11	5/14		1.02 [0.36, 2.91]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 6 Adverse effects

Study or subgroup	Custom foot orthoses n/N	Comparison group n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 1 week				
Roos 2006	6/15	9/15		0.67 [0.32, 1.40]



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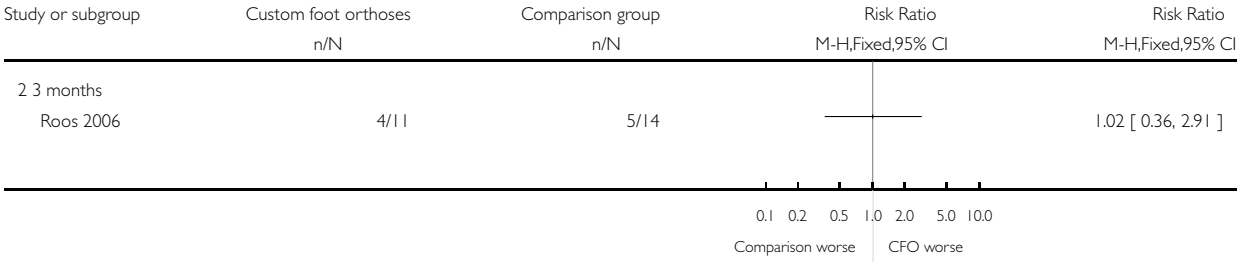
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 7 Custom-made foot orthoses versus standardised intervention for plantar fasciitis

Outcome: 6 Adverse effects

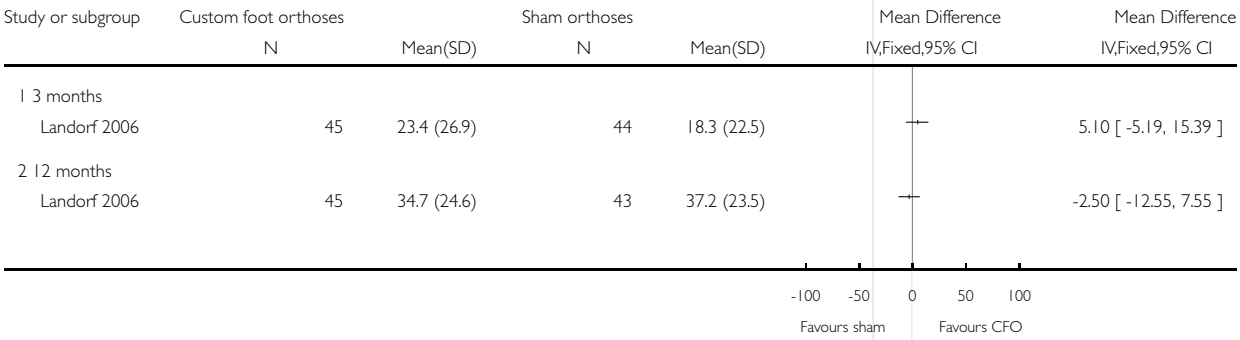


Analysis 8.1. Comparison 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome: 1 Foot pain



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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Landorf 2006	45	23.4 (26.9)	44	18.3 (22.5)		5.10 [-5.19, 15.39]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 12 months						
Landorf 2006	45	34.7 (24.6)	43	37.2 (23.5)		-2.50 [-12.55, 7.55]

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Analysis 8.2. Comparison 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis, Outcome 2 Function.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome: 2 Function

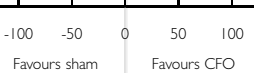
Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Landorf 2006	45	21.9 (21.9)	44	11.5 (16.1)		10.40 [2.43, 18.37]
2 12 months						
Landorf 2006	45	30 (22.5)	43	19.6 (26)		10.40 [0.22, 20.58]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome: 2 Function

Study or subgroup	Custom foot orthoses N	Mean(SD)	Sham orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 3 months						
Landorf 2006	45	21.9 (21.9)	44	11.5 (16.1)		10.40 [2.43, 18.37]



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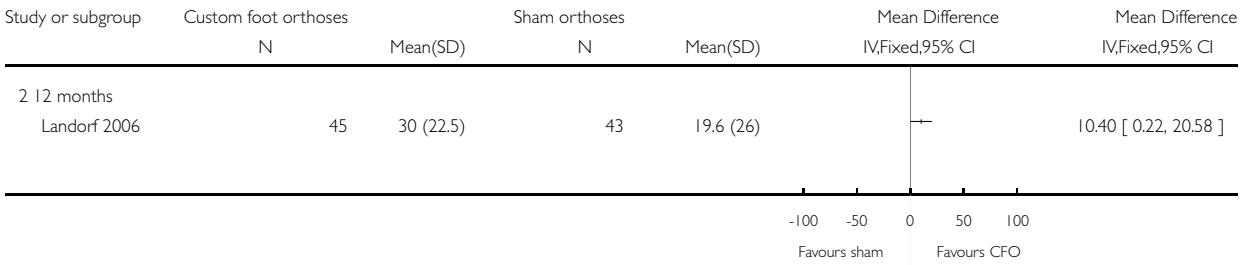
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome: 2 Function

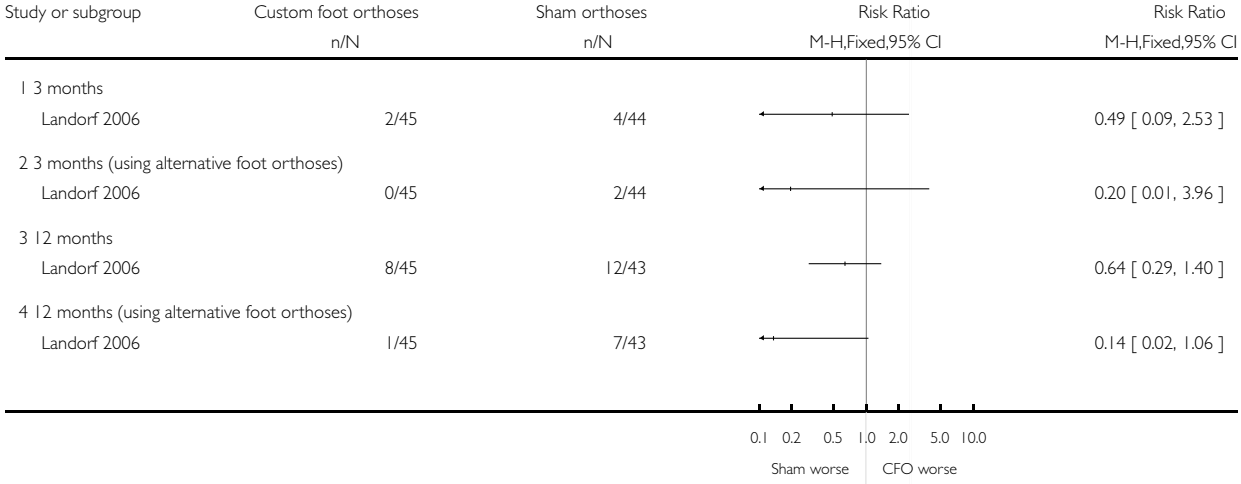


Analysis 8.3. Comparison 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis, Outcome 3 Compliance.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome: 3 Compliance



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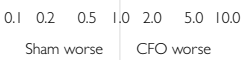
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome: 3 Compliance

Study or subgroup	Custom foot orthoses n/N	Sham orthoses n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 3 months				
Landorf 2006	2/45	4/44		0.49 [0.09, 2.53]

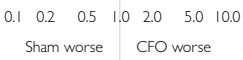


Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome: 3 Compliance

Study or subgroup	Custom foot orthoses n/N	Sham orthoses n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
2 3 months (using alternative foot orthoses)				
Landorf 2006	0/45	2/44		0.20 [0.01, 3.96]



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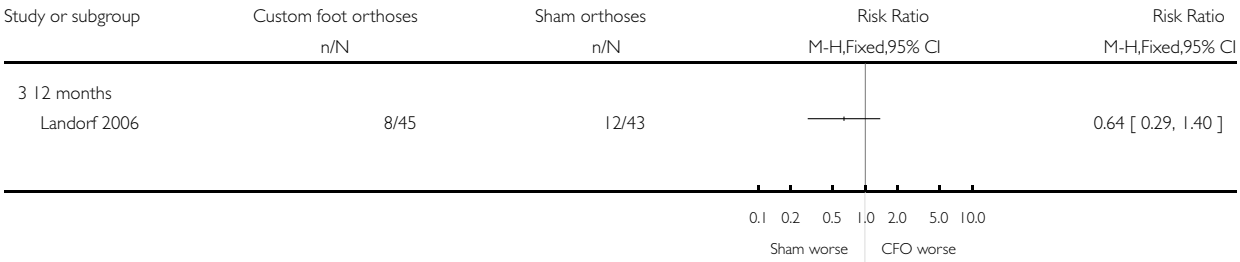
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

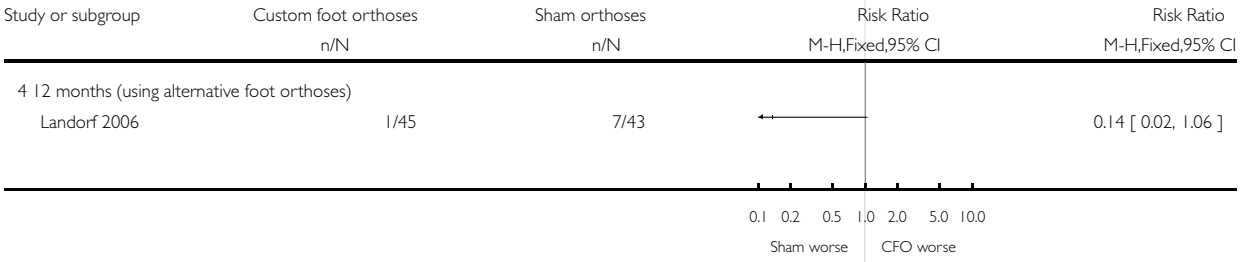
Outcome: 3 Compliance



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 8 Custom-made foot orthoses versus sham orthoses for painful plantar fasciitis

Outcome: 3 Compliance



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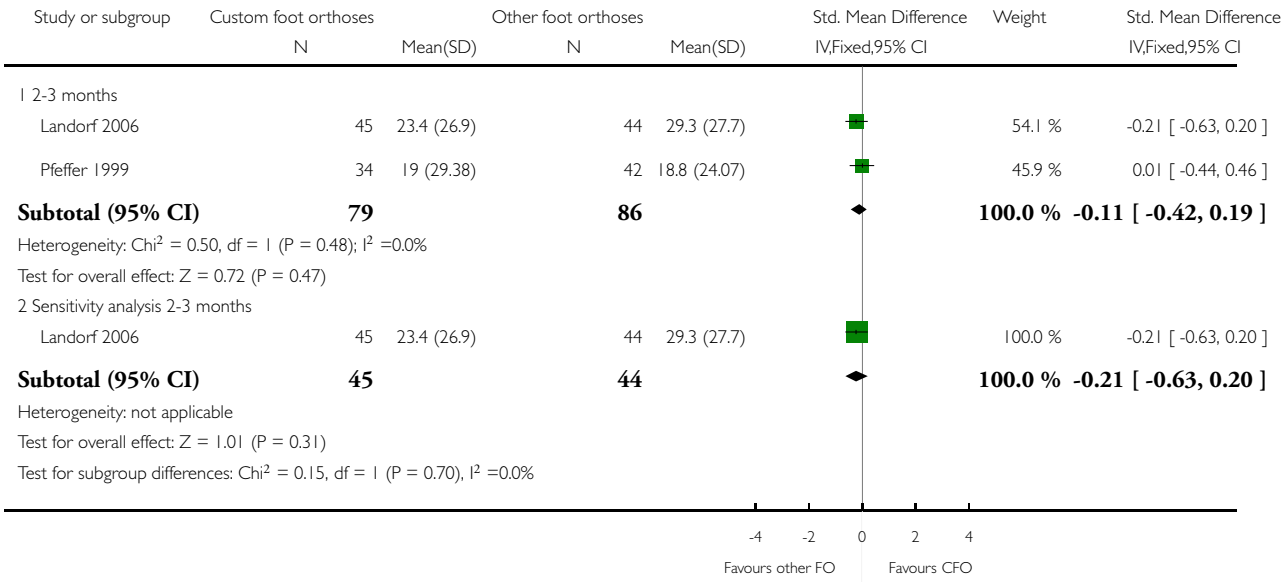
Analysis 9.1. Comparison 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis, Outcome 1 Foot pain 2-3 months.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

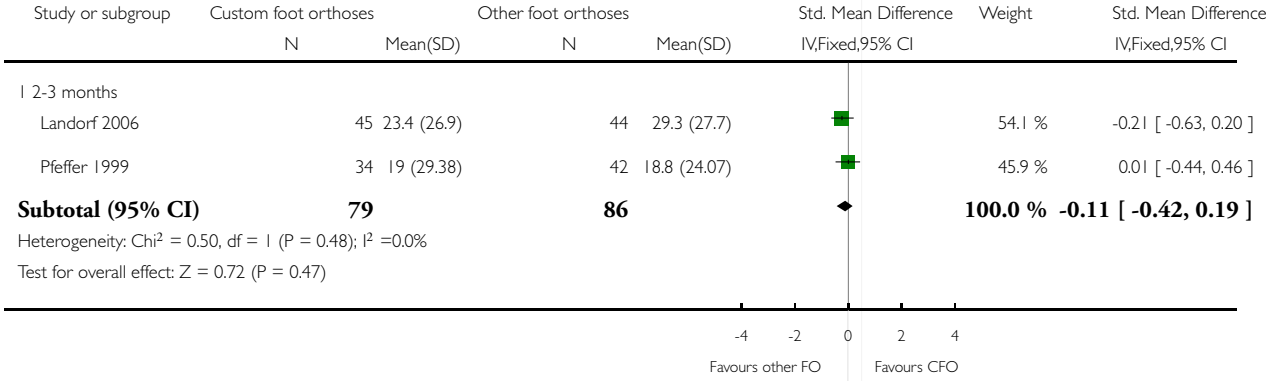
Outcome: 1 Foot pain 2-3 months



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 1 Foot pain 2-3 months



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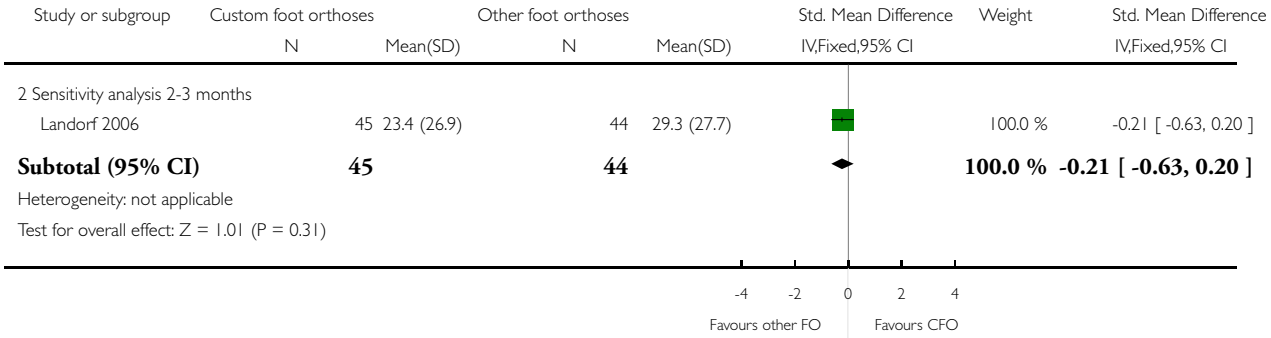
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 1 Foot pain 2-3 months

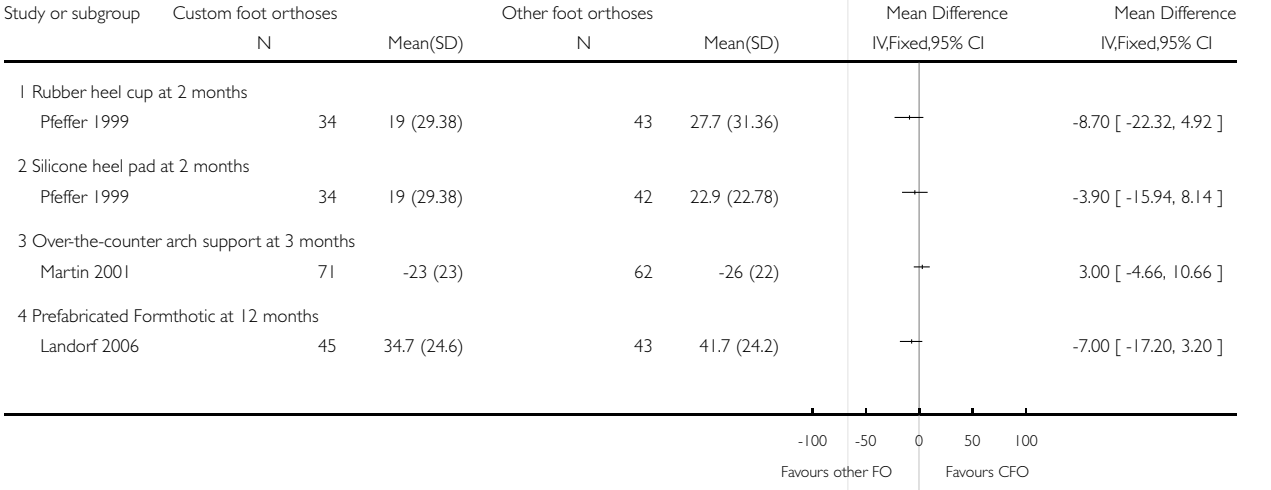


Analysis 9.2. Comparison 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis, Outcome 2 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 2 Foot pain



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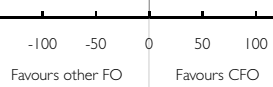
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 2 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Rubber heel cup at 2 months						
Pfeffer 1999	34	19 (29.38)	43	27.7 (31.36)		-8.70 [-22.32, 4.92]

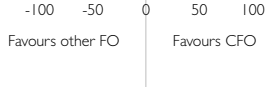


Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 2 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 Silicone heel pad at 2 months						
Pfeffer 1999	34	19 (29.38)	42	22.9 (22.78)		-3.90 [-15.94, 8.14]



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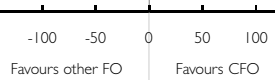
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 2 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
3 Over-the-counter arch support at 3 months						
Martin 2001	71	-23 (23)	62	-26 (22)		3.00 [-4.66, 10.66]



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 2 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
4 Prefabricated Formthotic at 12 months						
Landorf 2006	45	34.7 (24.6)	43	41.7 (24.2)		-7.00 [-17.20, 3.20]

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Analysis 9.3. Comparison 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis, Outcome 3 Function.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 3 Function

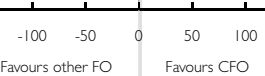
Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Prefabricated Formthotic at 3 months						
Landorf 2006	45	21.9 (21.9)	44	25.7 (24.3)		-3.80 [-13.42, 5.82]
2 Prefabricated Formthotic at 12 months						
Landorf 2006	45	30 (22.5)	43	33.4 (25.4)		-3.40 [-13.44, 6.64]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 3 Function

Study or subgroup	Custom foot orthoses N	Mean(SD)	Other foot orthoses N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Prefabricated Formthotic at 3 months						
Landorf 2006	45	21.9 (21.9)	44	25.7 (24.3)		-3.80 [-13.42, 5.82]



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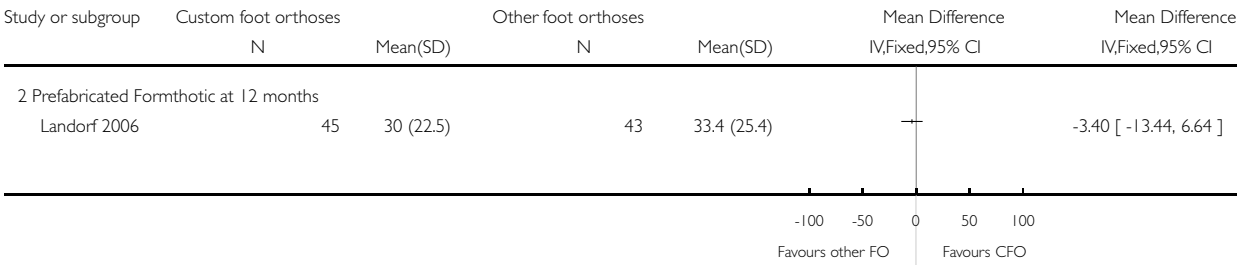
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 3 Function

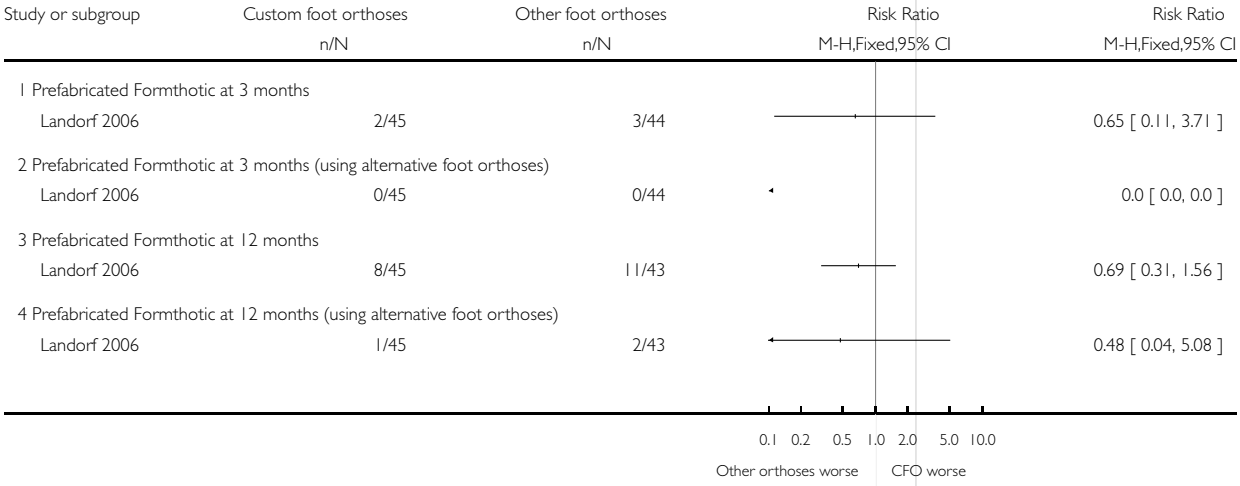


Analysis 9.4. Comparison 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis, Outcome 4 Compliance.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 4 Compliance



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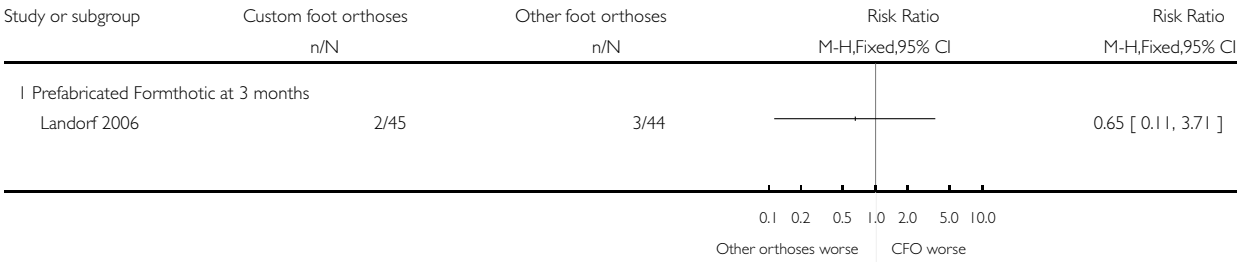
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

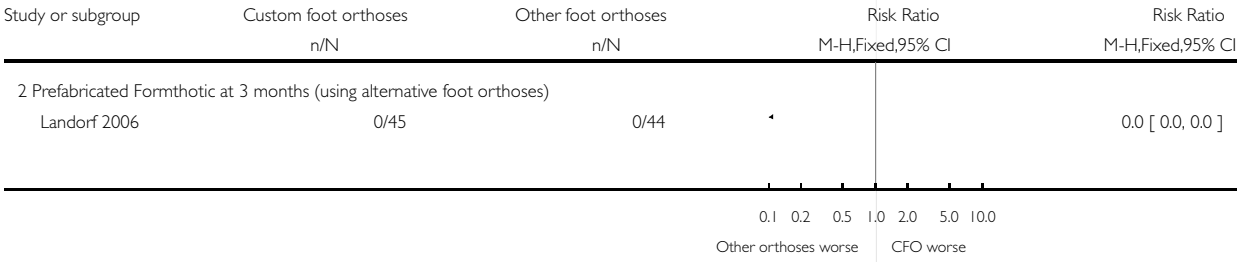
Outcome: 4 Compliance



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 4 Compliance



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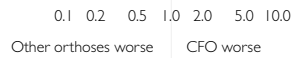
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 4 Compliance

Study or subgroup	Custom foot orthoses n/N	Other foot orthoses n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
3 Prefabricated Formthotic at 12 months				
Landorf 2006	8/45	11/43		0.69 [0.31, 1.56]

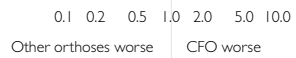


Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 9 Custom-made foot orthoses versus non custom foot orthoses for plantar fasciitis

Outcome: 4 Compliance

Study or subgroup	Custom foot orthoses n/N	Other foot orthoses n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
4 Prefabricated Formthotic at 12 months (using alternative foot orthoses)				
Landorf 2006	1/45	2/43		0.48 [0.04, 5.08]



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Analysis 10.1. Comparison 10 Custom-made foot orthoses versus manipulation, mobilisation and stretching for plantar fasciitis, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 10 Custom-made foot orthoses versus manipulation, mobilisation and stretching for plantar fasciitis

Outcome: 1 Foot pain

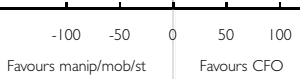
Study or subgroup	Custom foot orthoses N	Mean(SD)	Manip/mob/stretch N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 2 weeks						
Dimou 2004	10	-44.6 (22.1)	10	-21.3 (22.1)		-23.30 [-42.67, -3.93]
2 1 month						
Dimou 2004	10	-34.4 (20.2)	10	-23.3 (20.2)		-11.10 [-28.81, 6.61]
3 2 months						
Dimou 2004	10	-30.4 (17.4)	10	-24.3 (17.4)		-6.10 [-21.35, 9.15]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 10 Custom-made foot orthoses versus manipulation, mobilisation and stretching for plantar fasciitis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Manip/mob/stretch N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 2 weeks						
Dimou 2004	10	-44.6 (22.1)	10	-21.3 (22.1)		-23.30 [-42.67, -3.93]



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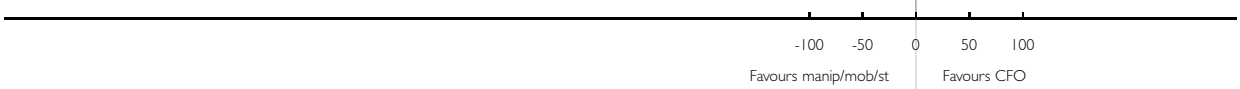
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 10 Custom-made foot orthoses versus manipulation, mobilisation and stretching for plantar fasciitis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Manip/mob/stretch N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 1 month						
Dimou 2004	10	-34.4 (20.2)	10	-23.3 (20.2)		-11.10 [-28.81, 6.61]



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 10 Custom-made foot orthoses versus manipulation, mobilisation and stretching for plantar fasciitis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Manip/mob/stretch N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
3 2 months						
Dimou 2004	10	-30.4 (17.4)	10	-24.3 (17.4)		-6.10 [-21.35, 9.15]

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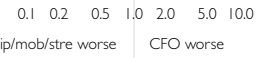
Analysis 10.2. Comparison 10 Custom-made foot orthoses versus manipulation, mobilisation and stretching for plantar fasciitis, Outcome 2 Adverse effects.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 10 Custom-made foot orthoses versus manipulation, mobilisation and stretching for plantar fasciitis

Outcome: 2 Adverse effects

Study or subgroup	Custom foot orthoses n/N	Manip/mob/stretch n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 2 months				
Dimou 2004	0/10	0/10		0.0 [0.0, 0.0]

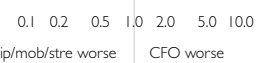


Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 10 Custom-made foot orthoses versus manipulation, mobilisation and stretching for plantar fasciitis

Outcome: 2 Adverse effects

Study or subgroup	Custom foot orthoses n/N	Manip/mob/stretch n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 2 months				
Dimou 2004	0/10	0/10		0.0 [0.0, 0.0]



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Analysis 11.1. Comparison 11 Custom-made foot orthoses versus night splint for plantar fasciitis, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 1 Foot pain

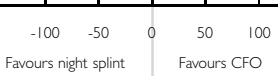
Study or subgroup	Custom foot orthoses N	Mean(SD)	Night splint N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Roos 2006	11	14.93 (16.6)	14	15.82 (18.04)		-0.89 [-14.51, 12.73]
2 3 months						
Roos 2006	9	76 (26)	14	70 (15)		6.00 [-12.72, 24.72]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Night splint N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Roos 2006	11	14.93 (16.6)	14	15.82 (18.04)		-0.89 [-14.51, 12.73]



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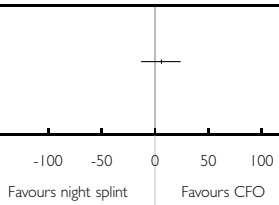
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Night splint N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 3 months						
Roos 2006	9	76 (26)	14	70 (15)		6.00 [-12.72, 24.72]



Analysis 11.2. Comparison 11 Custom-made foot orthoses versus night splint for plantar fasciitis, Outcome 2 Function.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 2 Function

Study or subgroup	Custom foot orthoses N	Mean(SD)	Night splint N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Roos 2006	11	6.21 (18.6)	14	21.22 (31.38)		-15.01 [-34.78, 4.76]
2 3 months						
Roos 2006	9	62 (32)	14	63 (20)		-1.00 [-24.38, 22.38]

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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 2 Function

Study or subgroup	Custom foot orthoses N	Mean(SD)	Night splint N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Roos 2006	11	6.21 (18.6)	14	21.22 (31.38)		-15.01 [-34.78, 4.76]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 2 Function

Study or subgroup	Custom foot orthoses N	Mean(SD)	Night splint N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 3 months						
Roos 2006	9	62 (32)	14	63 (20)		-1.00 [-24.38, 22.38]

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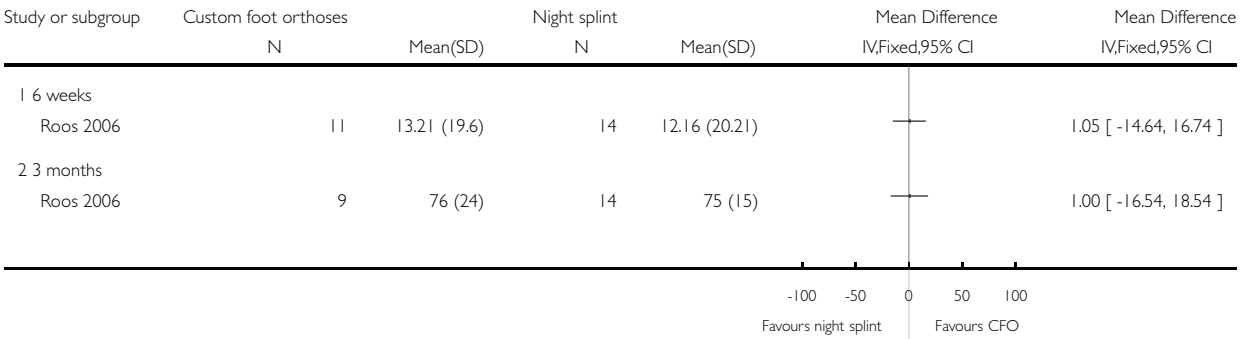
Analysis 11.3. Comparison 11 Custom-made foot orthoses versus night splint for plantar fasciitis, Outcome 3 Disability.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

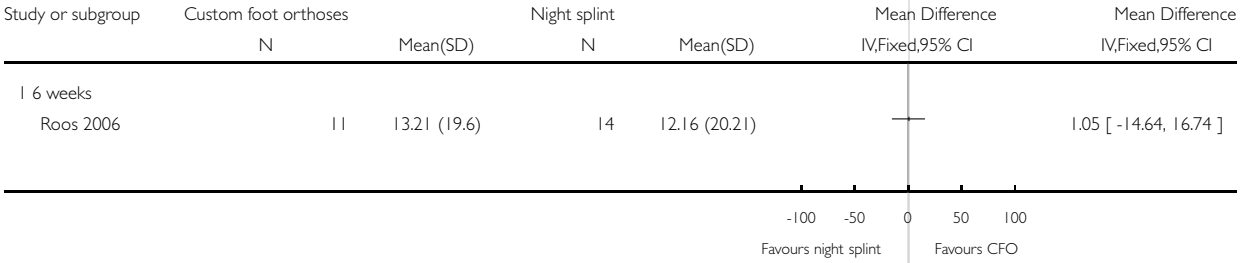
Outcome: 3 Disability



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 3 Disability



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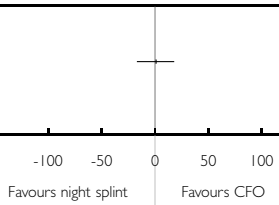
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 3 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Night splint N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 3 months						
Roos 2006	9	76 (24)	14	75 (15)		1.00 [-16.54, 18.54]



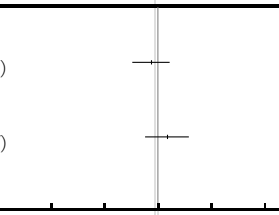
Analysis 11.4. Comparison 11 Custom-made foot orthoses versus night splint for plantar fasciitis, Outcome 4 Health-related quality of life.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 4 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Night splint N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 weeks						
Roos 2006	11	3.98 (21.7)	14	9.97 (23.29)		-5.99 [-23.69, 11.71]
2 3 months						
Roos 2006	9	55 (28)	14	46 (17)		9.00 [-11.35, 29.35]



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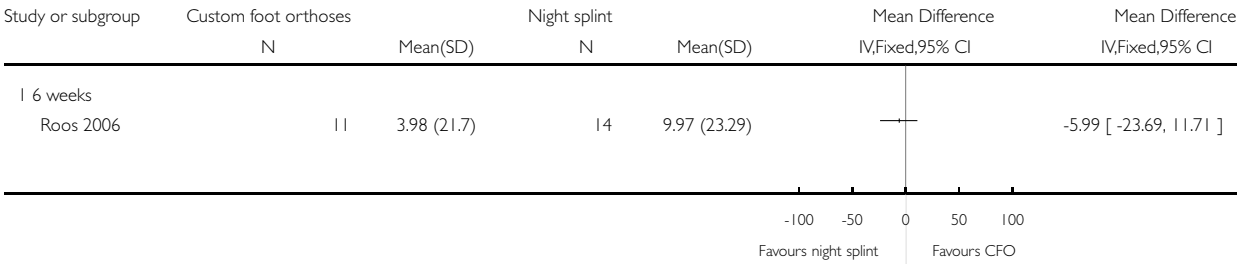
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

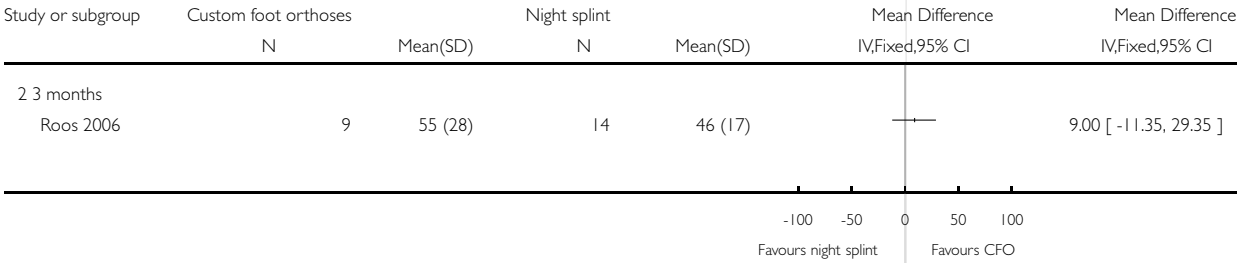
Outcome: 4 Health-related quality of life



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 4 Health-related quality of life



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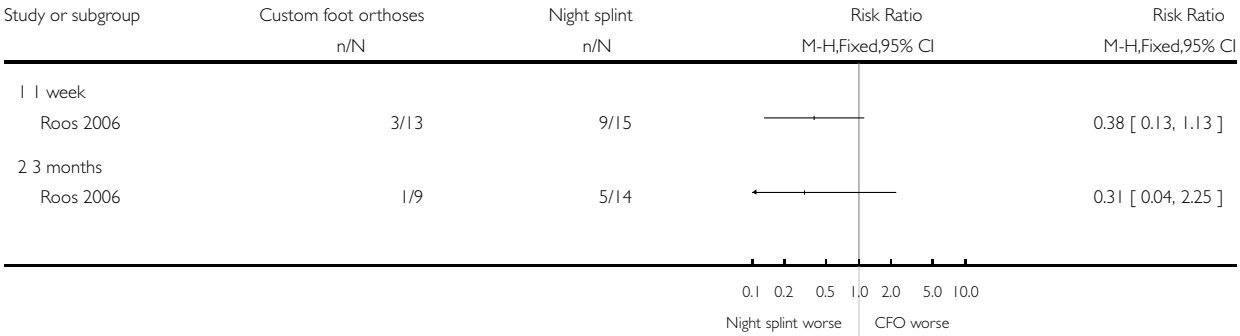
Analysis 11.5. Comparison 11 Custom-made foot orthoses versus night splint for plantar fasciitis, Outcome 5 Adverse effects.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

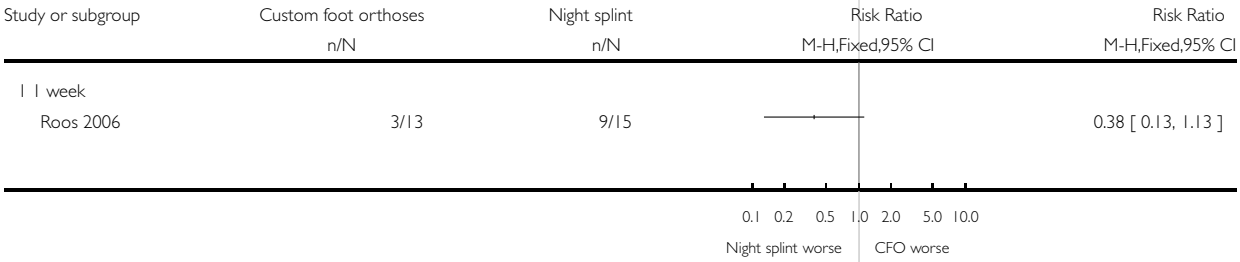
Outcome: 5 Adverse effects



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 5 Adverse effects



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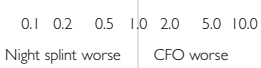
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 5 Adverse effects

Study or subgroup	Custom foot orthoses n/N	Night splint n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
2 3 months				
Roos 2006	1/9	5/14		0.31 [0.04, 2.25]



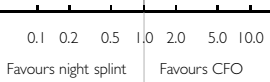
Analysis 11.6. Comparison 11 Custom-made foot orthoses versus night splint for plantar fasciitis, Outcome 6 Compliance.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 6 Compliance

Study or subgroup	Custom foot orthoses n/N	Night splint n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 3 months				
Roos 2006	14/20	15/25		1.17 [0.76, 1.79]



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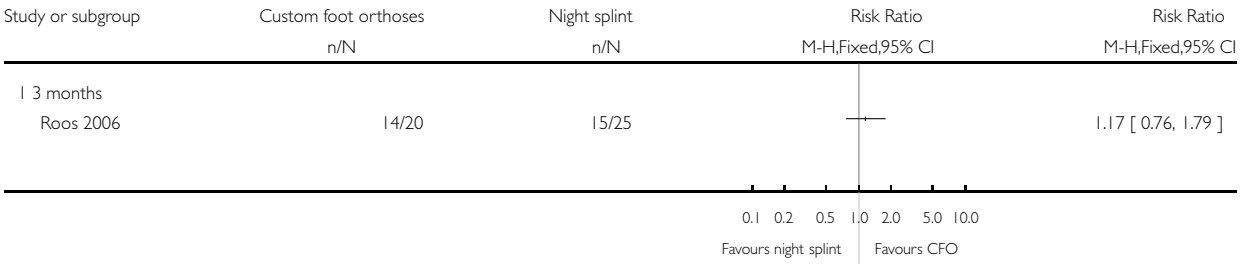
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 11 Custom-made foot orthoses versus night splint for plantar fasciitis

Outcome: 6 Compliance

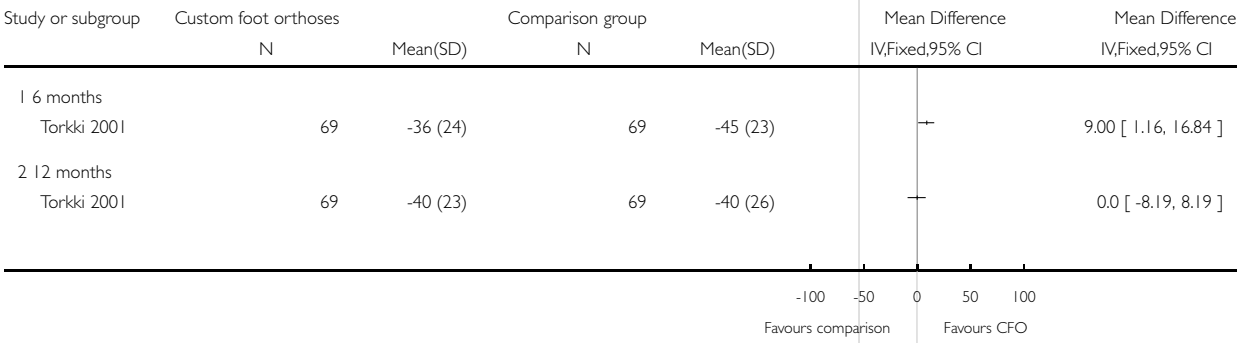


Analysis 12.1. Comparison 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 1 Foot pain



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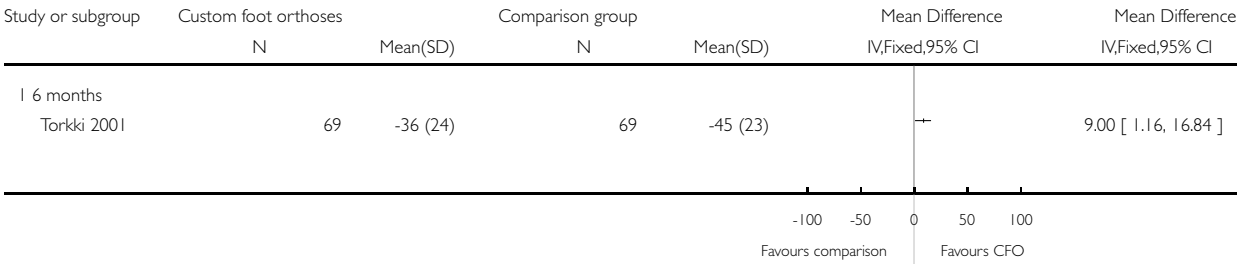
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

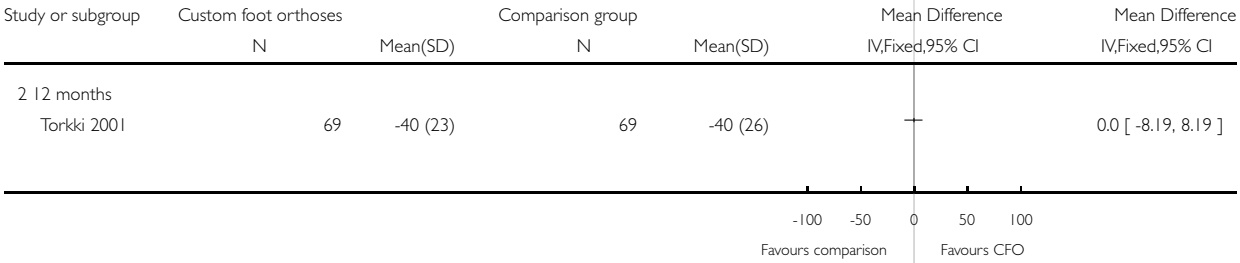
Outcome: 1 Foot pain



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 1 Foot pain



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Analysis 12.2. Comparison 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus, Outcome 2 Disability.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 2 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	84 (25)	69	80 (28)		4.00 [-4.86, 12.86]
2 12 months						
Torkki 2001	69	81 (26)	69	83 (25)		-2.00 [-10.51, 6.51]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 2 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	84 (25)	69	80 (28)		4.00 [-4.86, 12.86]

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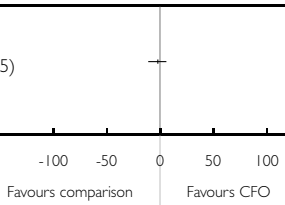
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 2 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 12 months						
Torkki 2001	69	81 (26)	69	83 (25)		-2.00 [-10.51, 6.51]



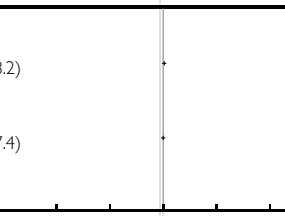
Analysis 12.3. Comparison 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus, Outcome 3 Health-related quality of life.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	92 (6.5)	69	90.5 (8.2)		1.50 [-0.97, 3.97]
2 12 months						
Torkki 2001	69	92.7 (7)	69	92.2 (7.4)		0.50 [-1.90, 2.90]



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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	92 (6.5)	69	90.5 (8.2)		1.50 [-0.97, 3.97]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 12 months						
Torkki 2001	69	92.7 (7)	69	92.2 (7.4)		0.50 [-1.90, 2.90]

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Analysis 12.4. Comparison 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus, Outcome 4 Participant satisfaction with treatment.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 4 Participant satisfaction with treatment

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	66 (26)	69	41 (36)		25.00 [14.52, 35.48]
2 12 months						
Torkki 2001	69	70 (26)	69	61 (37)		9.00 [-1.67, 19.67]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 4 Participant satisfaction with treatment

Study or subgroup	Custom foot orthoses N	Mean(SD)	Comparison group N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	66 (26)	69	41 (36)		25.00 [14.52, 35.48]

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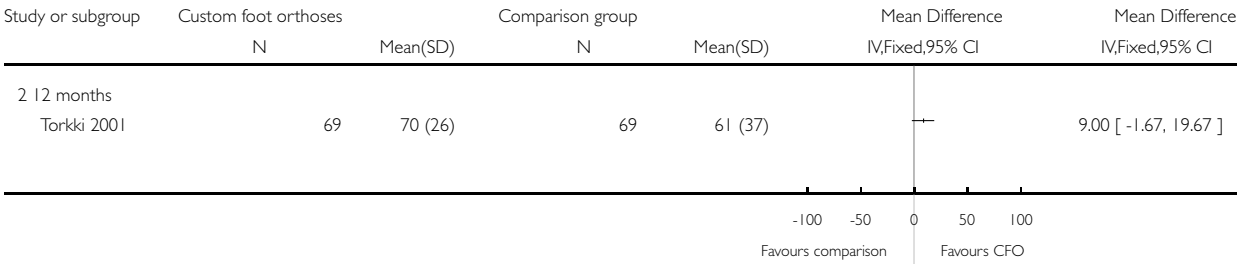
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 4 Participant satisfaction with treatment

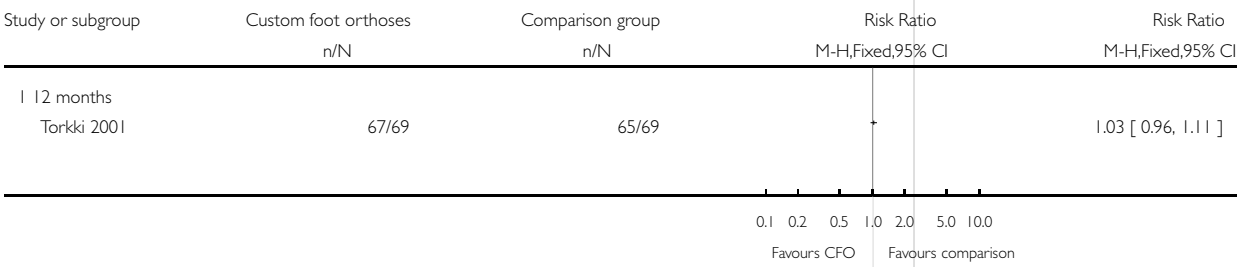


Analysis 12.5. Comparison 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus, Outcome 5 Compliance.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 5 Compliance



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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 12 Custom-made foot orthoses versus no intervention for painful bunion with halgus valgus

Outcome: 5 Compliance

Study or subgroup	Custom foot orthoses n/N	Comparison group n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 12 months				
Torkki 2001	67/69	65/69		1.03 [0.96, 1.11]

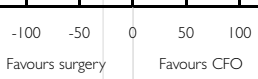
Analysis 13.1. Comparison 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus, Outcome 1 Foot pain.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	-36 (24)	71	-26 (23)		-10.00 [-17.79, -2.21]
2 12 months						
Torkki 2001	69	-40 (23)	71	-23 (23)		-17.00 [-24.62, -9.38]



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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	-36 (24)	71	-26 (23)		-10.00 [-17.79, -2.21]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 1 Foot pain

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 12 months						
Torkki 2001	69	-40 (23)	71	-23 (23)		-17.00 [-24.62, -9.38]

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Analysis 13.2. Comparison 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus, Outcome 2 Disability.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 2 Disability

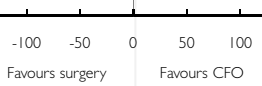
Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	84 (25)	71	85 (24)		-1.00 [-9.12, 7.12]
2 12 months						
Torkki 2001	69	81 (26)	71	89 (19)		-8.00 [-15.56, -0.44]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 2 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	84 (25)	71	85 (24)		-1.00 [-9.12, 7.12]



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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 2 Disability

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 12 months						
Torkki 2001	69	81 (26)	71	89 (19)		-8.00 [-15.56, -0.44]

Analysis 13.3. Comparison 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus, Outcome 3 Health-related quality of life.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	92 (6.5)	71	92 (7.3)		0.0 [-2.29, 2.29]
2 12 months						
Torkki 2001	69	92.7 (7)	71	92.9 (6.2)		-0.20 [-2.39, 1.99]

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Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	92 (6.5)	71	92 (7.3)		0.0 [-2.29, 2.29]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 3 Health-related quality of life

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 12 months						
Torkki 2001	69	92.7 (7)	71	92.9 (6.2)		-0.20 [-2.39, 1.99]

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Analysis 13.4. Comparison 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus, Outcome 4 Participant satisfaction with treatment.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 4 Participant satisfaction with treatment

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	66 (26)	71	74 (32)		-8.00 [-17.65, 1.65]
2 12 months						
Torkki 2001	69	70 (26)	71	80 (28)		-10.00 [-18.95, -1.05]

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 4 Participant satisfaction with treatment

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 6 months						
Torkki 2001	69	66 (26)	71	74 (32)		-8.00 [-17.65, 1.65]

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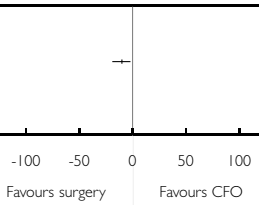
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 4 Participant satisfaction with treatment

Study or subgroup	Custom foot orthoses N	Mean(SD)	Surgery N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 12 months						
Torkki 2001	69	70 (26)	71	80 (28)		-10.00 [-18.95, -1.05]



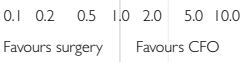
Analysis 13.5. Comparison 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus, Outcome 5 Compliance.

Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 5 Compliance

Study or subgroup	Custom foot orthoses n/N	Surgery n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 6 months				
Torkki 2001	65/69	66/71		1.01 [0.93, 1.11]
2 12 months				
Torkki 2001	67/69	66/71		1.04 [0.97, 1.13]



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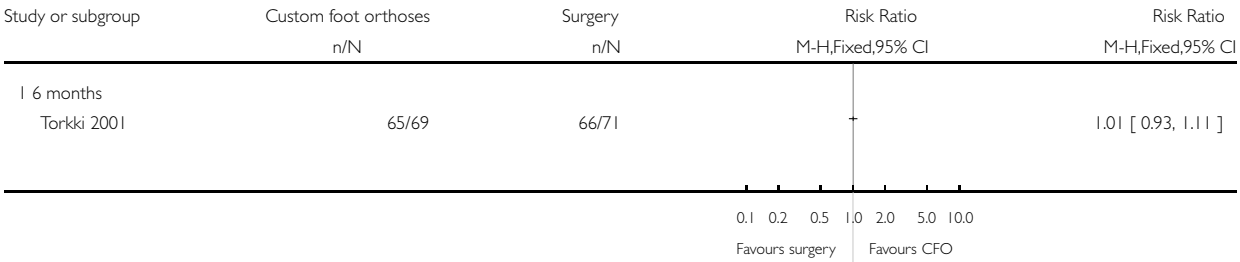
Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

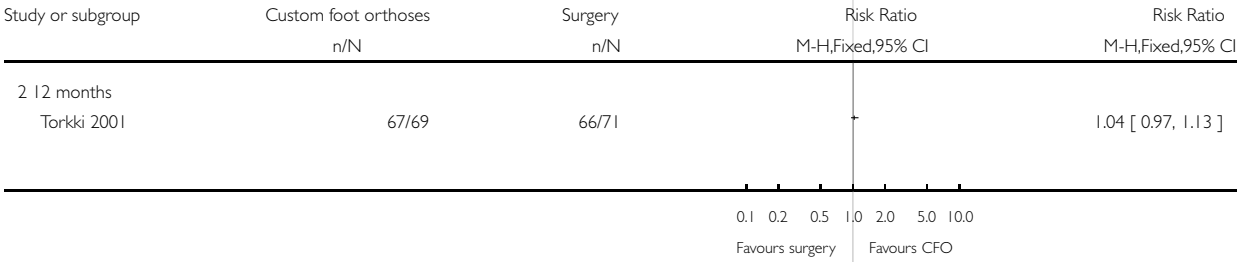
Outcome: 5 Compliance



Review: Custom-made foot orthoses for the treatment of foot pain

Comparison: 13 Custom-made foot orthoses versus surgery for painful bunion with hallux valgus

Outcome: 5 Compliance



WHAT'S NEW

Last assessed as up-to-date: 10 May 2008.

12 May 2008	Amended	CMSG ID A006-R
16 April 2008	Amended	Converted to new review format.

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HISTORY

Protocol first published: Issue 4, 2007

Review first published: Issue 3, 2008

CONTRIBUTIONS OF AUTHORS

FH was responsible for selecting trials; assessing trial quality; extracting, converting, entering and analysing data; interpreting results; and writing the review. JB was responsible for conceiving the review; selecting trials; and providing comments on the draft review. JR was responsible for assessing trial quality; checking data extraction; checking the conversion of data; performing double data entry; and providing comments on the draft review. VdT was responsible for checking data extraction and providing comments on the draft review.

DECLARATIONS OF INTEREST

J Burns (JB) was principal investigator of an included trial (Burns 2006).

SOURCES OF SUPPORT

Internal sources

- Podiatry program, School of Biomedical and Health Sciences, University of Western Sydney, Australia.

External sources

- National Health and Medical Research Council (NHMRC), Australia.

INDEX TERMS

Medical Subject Headings (MeSH)

Arthritis [therapy]; Equipment Design; Foot Deformities [complications]; Foot Diseases [* therapy]; *Orthotic Devices; Pain [*therapy]; Randomized Controlled Trials as Topic; Shoes

MeSH check words

Humans

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