CADTH

CADTH RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

Custom-Made Foot Orthoses versus Prefabricated foot Orthoses: A Review of Clinical Effectiveness and Cost-Effectiveness

Service Line:	Rapid Response Service
Version:	1.0
Publication Date:	September 23, 2019
Report Length:	16 Pages

CADTH

Authors: Khai Tran, Carolyn Spry

Cite As: Custom-Made Foot Orthoses versus Prefabricated Foot Orthoses: A Review of Clinical Effectiveness and Cost-Effectiveness. Ottawa: CADTH; 2019 Sep. (CADTH rapid response report: summary with critical appraisal).

ISSN: 1922-8147 (online)

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to Requests@CADTH.ca

Abbreviations

AEs	Adverse events
BMI	Body mass index
AMSTAR	Assessing the Methodological Quality of Systematic Reviews
CI	Confidence interval
FFI	Foot Functional Index
FHSQ	Foot Health Status Questionnaire
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
HTA	Health technology assessment
ITT	Intention-to-treat
IU	International unit
IVH	Intraventricular hemorrhage
JBI	Joanna Briggs Institute
MA	Meta-analysis
MFPDQ	The Manchester Foot Pain Disability Questionnaire
MD	Mean difference
NA	Not applicable
NR	Not reported
OR	Odds ratio
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomized controlled trial
ROB	Risk of Bias
RR	Risk ratio
SIGN	The Scottish Intercollegiate Guidelines Network
SFMPQ	The Short Form McGill Pain Questionnaire
SMD	Standardized mean difference
SR	Systematic review
VAS	Visual Analogue Scale

Context and Policy Issues

Foot orthoses (commonly referred as “orthotics”) are devices made to insert into the shoes to provide cushioning and off-loading of foot structures.[1] They are either prefabricated or custom-made.[2] Custom-made foot orthoses are contoured devices made from a plaster cast or three-dimensional laser scan of the foot.[3] Prefabricated foot orthoses (also referred as “over-the-counter” or “non-prescription”) are mass-produced based on foot sizes.[4]

Foot orthoses are used in adjunct to standard medical care of patients with foot and lower limb problems including pronated foot,[5] plantar heel pain,[6] rheumatoid arthritis,[7] juvenile idiopathic arthritis,[8] risk of diabetic plantar ulceration,[9] or hallux valgus (bunions).[10] They are intended to alter the function of the joints of the foot and lower limb during weight bearing activities including standing, walking or running, to reduce pain and improve the function of the foot and quality of life.[11] Global demand of foot orthoses has dramatically increased over the past years and the market is estimated to reach $US 3.5 billion by 2020.[12]

Although custom-made foot orthoses are generally considered the gold standard, the underlined mechanism is not well understood.[11] Several studies found that custom-made orthoses were more effective than prefabricated orthoses for objective outcome measures through biomechanical assessments including dynamic balance,[13] and pressure relief and load redistribution across plantar regions.[4,14,15] However, a previous systematic review[16] found no evidence that custom-made orthoses were more effective than prefabricated orthoses in the treatment of different types of foot pain. As custom-made orthoses are relatively more expensive than prefabricated orthoses,[17] their clinical effectiveness and cost-effectiveness need to be evaluated.

The aim of this report is to review the comparative clinical and cost effectiveness of custom-made foot orthoses versus prefabricated foot orthoses for patients requiring a foot orthotics.

Research Question

1. What is the clinical effectiveness of custom-made foot orthoses for patients requiring a foot orthosis?
2. What is the cost-effectiveness of custom-made foot orthoses for patients requiring a foot orthosis?

Key Findings

This review included two systematic reviews, one randomized controlled trial and one prospective cohort study. No cost-effectiveness studies of custom-made foot orthoses were identified.

The evidence showed no difference between custom-made and prefabricated foot orthoses for pain reduction or functional improvement after short-term (6 weeks), medium-term (12 weeks) and long-term (12 months) treatment in adult patients with plantar heel pain. There was also no difference between interventions for short-term self-reported recovery and patient satisfaction. Evidence on comfort was mixed.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including PubMed, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were custom-made foot orthoses. No filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2014 and August 20, 2019.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed

for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients of all ages requiring a foot orthosis
Intervention	Custom-made foot orthoses (also referred as custom-made orthotics, including custom modified orthoses and orthoses manufactured specifically for the patient)
Comparator	Pre-fabricated foot orthoses (off-the-shelf orthoses)
Outcomes	Q1: Clinical effectiveness (e.g., patient quality of life, falls, adverse events) Q2: Cost-effectiveness
Study Designs	Health technology assessments (HTAs), systematic reviews (SRs), meta-analyses (MAs), randomized controlled trials (RCTs), non-randomized studies, and economic evaluations

Exclusion Criteria

Studies were excluded if they did not meet the selection criteria in Table 1 and if they were published prior to 2014. Primary studies were excluded if they had been included in the identified SRs.

Critical Appraisal of Individual Studies

The AMSTAR-2 checklist was used to assess the quality of SRs.[18] The critical appraisal checklists of the Joanna Briggs Institute were used to assess the quality of the included RCTs[19] and non-randomized studies.[20] Summary scores were not calculated for the included studies; rather, a review of the methodological qualities and limitations were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 301 citations were identified in the literature search. Following screening of titles and abstracts, 282 citations were excluded and 19 potentially relevant reports from the electronic search were retrieved for full-text review. No potentially relevant publications were retrieved from the grey literature search. Of the 19 potentially relevant articles, 15 publications were excluded for various reasons, while four publications including two SRs, one RCT, and one non-randomized study met the inclusion criteria and were included in this report. No economic evaluations were identified. Appendix 1 presents the PRISMA flowchart[21] of the study selection.

Summary of Study Characteristics

The characteristics of the identified SRs (Table 2),[22,23] RCT[24] and non-randomized study[25] (Table 3) are presented in Appendix 2.

Study Design

Two SRs[22,23] were identified that investigated the effects of foot orthoses for pain and function in adults with plantar heel pain. Both SRs searched for RCTs using multiple databases with search dates from inception to 2017. One SR[23] assessed the risk of bias of

the included four relevant RCTs using the Cochrane Risk of Bias tool, while the other SR[22] assessed the risk of bias of the included five relevant RCTs using criteria recommended by the Cochrane Back Review Group.[26]

One additional single-blinded parallel RCT[24] and one prospective cohort study[25] were identified. In the RCT,[24] blinding was applied to the assessor only. Both studies were carried out in a single centre.

Country of Origin

The SRs were conducted by the authors from the Netherland[22] and Australia.[23] The additionally identified RCT and cohort study were conducted by authors from China[24] and the UK,[25] respectively.

Population

In both SRs,[22,23] participants were adult patients with acute or chronic plantar heel pain. The mean age ranged from 44 to 49 years. The proportion of females was higher than males, ranging from 63% to 76%. Participants in the additionally identified RCT[24] and cohort study[25] were also adult patients with a clinical diagnosis of plantar heel pain. In the RCT,[24] the mean age of participants was 41.4 years and 50% were female. In the cohort study,[25] the mean age of participants was 48 years and 61% were female.

Interventions and Comparators

Both SRs[22,23] included studies comparing foot orthoses with any comparator. Only the findings of customized foot orthoses compared with prefabricated foot orthoses were presented in this review. The identified RCT[24] compared customized 3-D printed foot orthoses with prefabricated foot orthoses, while the cohort study[25] compared casted foot orthoses with prefabricated foot orthoses.

Treatment duration of the RCTs cited in the SRs[22,23] varied from two weeks to 12 months. In both the additionally identified RCT[24] and cohort study,[25] treatment duration was eight weeks.

Outcomes

The outcomes evaluated in the SRs[22,23] were improvement in pain and function. The cited RCTs included in the SRs[22,23] measured pain using the Visual Analogue Scale (VAS), the Short Form McGill Pain Questionnaire (SFMPQ), or the Foot Health Status Questionnaire (FHSQ) subscale. Function was measured using Foot Functional Index (FFI) total, or FHSQ. One SR[22] included self-reported recovery using the Likert scale as an outcome. The RCT[24] measured comfort scores using VAS, while the cohort study[25] evaluated foot pain/disability using the Manchester foot Pain Disability Questionnaire (MFPDQ) and participant satisfaction using VAS as clinical outcomes.

Summary of Critical Appraisal

The quality assessments of the identified SRs (Table 4),[22,23] RCT (

Table 5),[24] and cohort study (Table 6)[25] are presented in Appendix 3.

Both SRs[22,23] provided appropriate research questions, explanations for selection of the study designs for the inclusion in the review, and used comprehensive literature search strategies. In both SRs, study selection and data extraction were performed in duplicate,

the authors provided a description of included studies' characteristics, used satisfactory techniques for assessing the risk of bias of the included studies, used appropriate methods for statistical combination of the results, and incorporated of the risk of bias in individual studies when interpreting or discussing of the results. The authors of both SRs provided explanation and discussion of any heterogeneity observed in the results, and a declaration of conflict of interest. One SR[22] had an *a priori* published protocol, while the other[23] did not. Both SRs[22,23] did not provide lists of excluded studies, did not report on the sources of funding for the included studies, and did not assess the potential impact of risk of bias in individual studies on the results of the meta-analysis. Investigation of publication bias was not applicable in both SRs[22,23] due to the few numbers of included studies.

The identified RCT[24] reported an appropriate method for randomization and allocation concealment. The patient characteristics between treatment groups were similar at baseline. The outcome assessor, but not the participants or the therapist, was blinded to treatment assignment. Both treatment groups were treated identically other than the intervention of interest, and all participants completed the follow up. The outcomes were measured in the same way for treatment groups using reliable methods. The comparison of the results was conducted using appropriate statistical analysis.

The cohort study[25] provided appropriate research questions and objectives, and included a control group. The participants in treatment groups received similar treatment and care other than the exposure or intervention of interest, and the outcomes of participants were measured in the same and reliable way. The results were analyzed using appropriate statistical analysis. Demographics of participants in both treatment groups were not reported.

Summary of Findings

The main findings and conclusions of the SRs (Table 7),[22,23] and RCT[24] and cohort study[25] (Table 8) are presented in Appendix 4.

What is the clinical effectiveness of custom-made foot orthoses for patients requiring a foot orthosis?

Pain

Both SRs[22,23] found no significant difference in short-term (0 to 6 weeks), medium-term (7 to 12 weeks) and long-term (12 months) pain between custom-made and prefabricated orthoses in patients with plantar heel pain.

The identified prospective cohort study[25] compared casted foot orthoses with prefabricated foot orthoses in patients with plantar heel pain. The study reported foot pain and disability as a clinical outcome, and found that both types of foot orthoses were effective for the treatment of plantar heel pain, and there was no significant difference between groups at 8 weeks.

Function

Both SRs[22,23] found no significant difference in function between custom-made and prefabricated orthoses after 7 to 12 weeks of treatment.

Other outcomes

One RCT cited in the SR[22] found a significant effect of self-reported recovery at short-term (8 weeks), which was in favoured of prefabricated orthoses.

The identified RCT[24] compared customized 3-D printed foot orthoses with prefabricated foot orthoses in patients with plantar fasciitis. The study reported comfort scores after 8 weeks of treatment, and found a significant effect in favor of the customized 3-D foot orthoses.

The identified prospective cohort study[25] found no difference between groups in mean scores measuring patient satisfaction including ease of use, comfort, hygiene and satisfaction. No adverse effects were identified in both groups during treatment.[25]

What is the cost-effectiveness of custom-made foot orthoses for patients requiring a foot orthosis?

No comparative cost-effectiveness studies of custom-made foot orthoses versus prefabricated foot orthoses were identified; therefore, no summary can be provided.

Limitations

The medical condition in studies cited in the SRs[22,23] and additional identified studies[24,25] was limited to foot plantar heel pain only, therefore the findings could not be generalizable to other clinical conditions. A broad definition of plantar heel pain was used by the SRs[22,23] and the cohort study[25] suggesting that there were heterogeneity of included participants with different subcategories of plantar heel pain. It is not possible for participants and physicians to be blinded to the intervention, therefore there was a risk of performance bias or detection bias. One SR[23] used the GRADE approach for outcome level assessment, and found that the quality of evidence ranged from very low to low quality, therefore the findings should be interpreted with cautions.

Conclusions and Implications for Decision or Policy Making

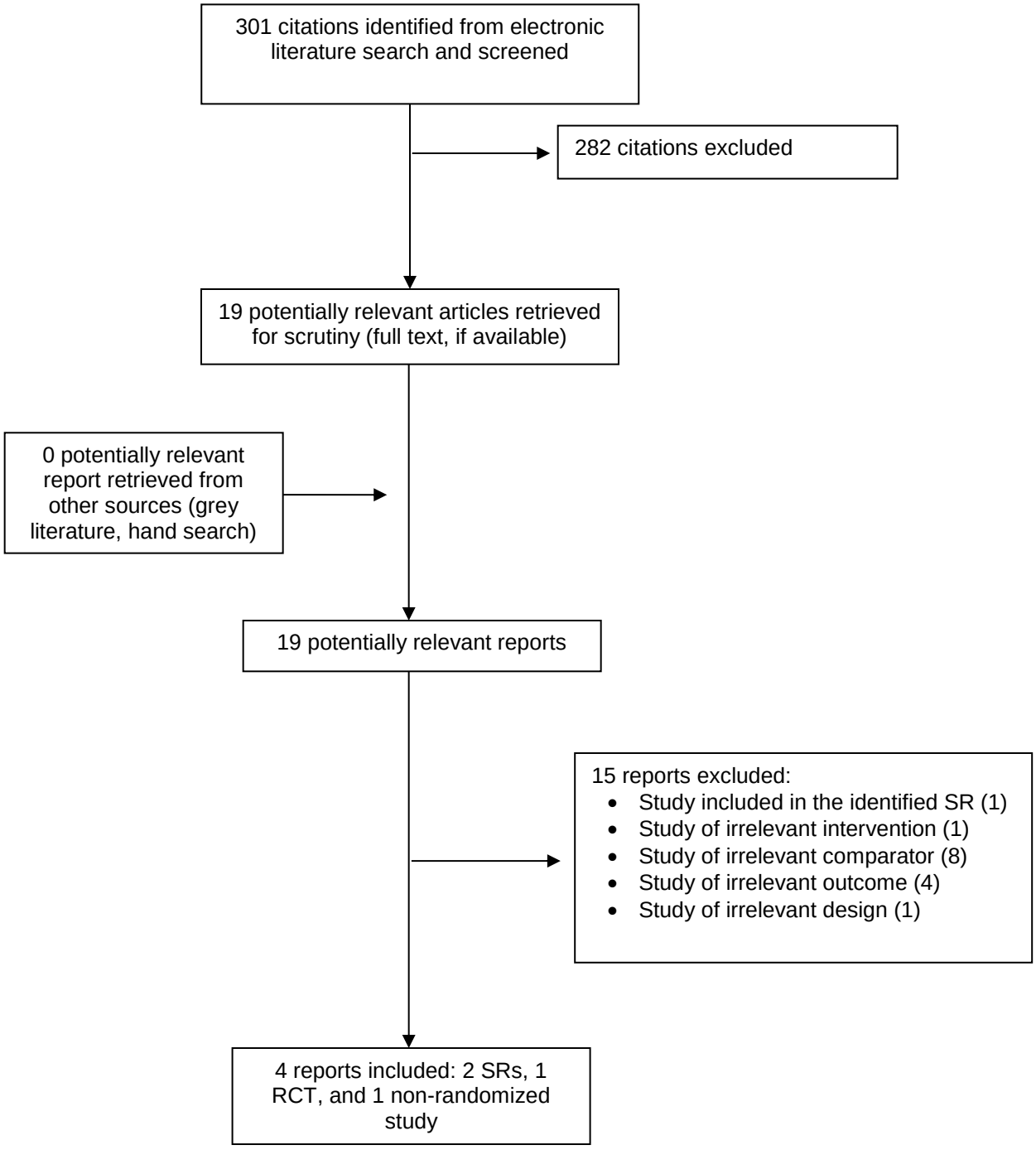
This review included two SRs[22,23] and two additionally identified primary studies (one RCT[24] and one prospective cohort study[25]) for the comparison between custom-made and prefabricated foot orthoses in adult patients with plantar heel pain. Studies on the clinical effectiveness of foot orthoses in pediatric and older adult populations, as well as cost-effectiveness studies of custom-made foot orthoses were not identified.

There was no difference between custom-made and prefabricated foot orthoses for pain reduction or functional improvement after short-term (6 weeks), medium-term (12 weeks) and long-term (12 months) treatment in adult patients with plantar heel pain from very low-quality evidence to low-quality evidence. There was also no difference between interventions for short-term self-reported recovery and patient satisfaction. Evidence on comfort was mixed. The overall methodological quality of the included studies in this review was strong. More studies are needed to determine the comparative clinical effectiveness custom-made foot orthoses versus prefabricated foot orthoses in different populations with different foot disorders. Cost-effectiveness studies of custom-made foot orthoses are also warranted.

References

1. Custom foot orthotics. 2019; https://www.pedorthic.ca/orthotics/. Accessed 2019 Aug 20.
2. Prefabricated vs. prescription foot orthotics. 2014; https://www.spine-health.com/wellness/ergonomics/prefabricated-vs-prescription-foot-orthotics. Accessed 2019 Aug 20.
3. Landorf K, Keenan AM, Rushworth RL. Foot orthosis prescription habits of Australian and New Zealand podiatric physicians. *J Am Podiatr Med Assoc.* 2001;91(4):174-183.
4. Redmond AC, Landorf KB, Keenan AM. Contoured, prefabricated foot orthoses demonstrate comparable mechanical properties to contoured, customised foot orthoses: a plantar pressure study. *J Foot Ankle Res.* 2009;2:20.
5. Gijon-Nogueron G, Palomo-Toucedo I, Gil-Tinoco A, Ortega-Avila AB, Munuera-Martinez PV. Effect produced on ground reaction forces by a prefabricated, weight-bearing and non-weight-bearing foot orthosis in the treatment of pronated foot: Pilot study. *Medicine (Baltimore).* 2018;97(22):e10960.
6. Wrobel JS, Fleischer AE, Crews RT, Jarrett B, Najafi B. A randomized controlled trial of custom foot orthoses for the treatment of plantar heel pain. *J Am Podiatr Med Assoc.* 2015;105(4):281-294.
7. Tenten-Diepenmaat M, Dekker J, Heymans MW, Roorda LD, Vliet Vlieland TPM, van der Leeden M. Systematic review on the comparative effectiveness of foot orthoses in patients with rheumatoid arthritis. *J Foot Ankle Res.* 2019;12:32.
8. Coda A, Fowlie PW, Davidson JE, Walsh J, Carline T, Santos D. Foot orthoses in children with juvenile idiopathic arthritis: a randomised controlled trial. *Arch Dis Child.* 2014;99(7):649-651.
9. Parker DJ, Nuttall GH, Bray N, Hugill T, Martinez-Santos A, Edwards RT, et al. A randomised controlled trial and cost-consequence analysis of traditional and digital foot orthoses supply chains in a National Health Service setting: application to feet at risk of diabetic plantar ulceration. *J Foot Ankle Res.* 2019;12:2.
10. Nakagawa R, Yamaguchi S, Kimura S, Sadamasu A, Yamamoto Y, Muramatsu Y, et al. Efficacy of foot orthoses as nonoperative treatment for hallux valgus: A 2-year follow-up study. *J Orthop Sci.* 2019;24(3):526-531.
11. Landorf KB, Keenan AM. Efficacy of foot orthoses. What does the literature tell us? *J Am Podiatr Med Assoc.* 2000;90(3):149-158.
12. Industry Arc. Foot orthotic insoles market to reach 3.5 USD billion by 2020. PR Newswire Association; 2016: https://www.prnewswire.com/news-releases/foot-orthotic-insoles-market-to-reach-35-usd-billion-by-2020-570502031.html. Accessed 2019 Aug 20.
13. Abbasi F, Bahramizadeh M, Hadadi M. Comparison of the effect of foot orthoses on Star Excursion Balance Test performance in patients with chronic ankle instability. *Prosthet Orthot Int.* 2019;43(1):6-11.
14. Caravaggi P, Giangrande A, Lullini G, Padula G, Berti L, Leardini A. In shoe pressure measurements during different motor tasks while wearing safety shoes: The effect of custom made insoles vs. prefabricated and off-the-shelf. *Gait Posture.* 2016;50:232-238.
15. Bus SA, Ulbrecht JS, Cavanagh PR. Pressure relief and load redistribution by custom-made insoles in diabetic patients with neuropathy and foot deformity. *Clin Biomech (Bristol, Avon).* 2004;19(6):629-638.
16. Hawke F, Burns J, Radford JA, du Toit V. Custom-made foot orthoses for the treatment of foot pain. *Cochrane Database Syst Rev.* 2008(3):Cd006801.
17. The cost of custom orthotics - are they worth the high price? 2017; https://treadlabs.com/blogs/insoles-reach-your-stride/the-cost-of-custom-orthotics. Accessed 2019 Aug 20.
18. Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ.* 2017;358:j4008. http://www.bmj.com/content/bmj/358/bmj.j4008.full.pdf. Accessed 2019 Aug 20.
19. The JBI checklist for randomized controlled trials. Adelaide (AUS): Joanna Briggs Institute; 2017: https://joannabriggs.org/sites/default/files/2019-05/JBI_RCTs_Appraisal_tool2017_0.pdf. Accessed 2019 Aug 20.
20. The JBI checklist for quasi-experimental studies. Adelaide (AUS): Joanna Briggs Institute; 2017: https://joannabriggs.org/sites/default/files/2019-05/JBI_Quasi-Experimental_Appraisal_Tool2017_0.pdf. Accessed 2019 Aug 20.
21. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol.* 2009;62(10):e1-e34.
22. Rasenberg N, Riel H, Rathleff MS, Bierma-Zeinstra SMA, van Middelkoop M. Efficacy of foot orthoses for the treatment of plantar heel pain: a systematic review and meta-analysis. *Br J Sports Med.* 2018;52(16):1040-1046.
23. Whittaker GA, Munteanu SE, Menz HB, Tan JM, Rabusin CL, Landorf KB. Foot orthoses for plantar heel pain: a systematic review and meta-analysis. *Br J Sports Med.* 2018;52(5):322-328.
24. Xu R, Wang Z, Ma T, Ren Z, Jin H. Effect of 3D printing individualized ankle-foot orthosis on plantar biomechanics and pain in patients with plantar fasciitis: A randomized controlled trial. *Med Sci Monit.* 2019;25:1392-1400.
25. Ring K, Otter S. Clinical efficacy and cost-effectiveness of bespoke and prefabricated foot orthoses for plantar heel pain: a prospective cohort study. *Musculoskeletal care.* 2014;12(1):1-10.
26. Furlan AD, Pennick V, Bombardier C, van Tulder M. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. *Spine.* 2009;34(18):1929-1941.

Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Studies

Table 2: Characteristics of Included Systematic Reviews

First Author, Publication Year, Country, Funding	Objectives, Types and Numbers of Primary Studies Included, Quality Assessment Tool, Databases and Search Date	Patient Characteristics	Types of Comparisons, Treatment Setting, Duration of Treatment	Outcomes
Rasenberg et al., 2018[22] The Netherlands Funding: None	Objective: To investigate the effects of different orthoses on pain, function and self-reported recovery in patients with plantar heel pain Total 20 RCTs; 5 RCTs (n = 449) comparing custom-made versus prefabricated orthoses Quality assessment tool: Cochrane Back Review Group Databases: MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Web of Science, CINAHL Search date: Since inception to January 2017	Adult patients with clinical diagnosis of plantar heel pain Mean age: 44 to 49 years % Female: 63 to 75 Duration of pain: < 1 year	Customized (n = 226) Prefabricated (n = 223) Setting: Clinics for podiatric care Treatment duration: 2 weeks to 12 months	– Pain (VAS, SFMPQ, FFI subscale, FHSQ subscale) – Function (FFI total, FHSQ) – Self-reported recovery (Likert)
Whittaker et al., 2018[23] Australia Funding : Public	Objective: To investigate the effectiveness of foot orthoses for pain and function in adults with plantar heel pain Total 19 RCTs; 4 RCTs (n = 413) comparing custom-made versus prefabricated orthoses Quality assessment tool: Cochrane Risk of Bias Outcome level assessment: GRADE approach Databases: Medline, CINAHL, SPORTDiscus, EMBASE, Cochrane Library Search date: Since inception to 14 July 2016. Search was updated on 26 June 2017	Adult patients with clinical diagnosis of plantar heel pain Mean age: 47.3 to 49.6 years % Female: 63 to 76 Duration of pain: NR	Customized (n = 214) Prefabricated (n = 199) Setting: Clinics for podiatric care Treatment duration: 2 weeks to 12 months	– Pain (VAS, FFI subscale, FHSQ subscale) – Function (FFI total, FHSQ)

FFI = Foot Functional Index; FHSQ = Foot Health Status Questionnaire; GRADE = Grading Recommendations Assessment, Development and Evaluation; NR = not reported; SFMPQ = the Short Form McGill Pain Questionnaire; VAS = Visual Analogue Scale

Table 3: Characteristics of Included Primary Studies

First Author, Publication Year, Country, Funding	Study Design and Analysis	Patient Characteristics	Interventions	Comparators	Outcomes
Xu et al., 2019[24] China Funding: NR	Single-blinded, parallel RCT Single-centre ITT analysis: NR Sample size calculation: No Statistical analysis: Appropriate	Adult patients with bilateral plantar fasciitis Mean age: 41.4 years (range: 31 to 60) Mean BMI: 26.1 kg/m^2 (range: 15.9 to 28.3) % Female: 50	Customized 3-D printed foot orthosis (n = 30) Treatment duration: 8 weeks	Prefabricated foot orthosis (n = 30) Treatment duration: 8 weeks	Comfort (VAS)
Ring and Otter 2014[25] UK Funding: NR	Prospective cohort study Single-centre Sample size calculation: Yes Statistical analysis: Appropriate ITT analysis: No	Adult patients with clinical diagnosis of plantar heel pain Mean age: 48 years (range: 27 to 63) Mean BMI: 26.2 kg/m^2 (range: 22 to 28.75) % Female: 61	Casted foot orthosis (n = 35) Treatment duration: 8 weeks	Prefabricated foot orthosis (n = 34) Treatment duration: 8 weeks	Foot pain and disability (MFPDQ) – Functional limitation – Pain intensity – Personal appearance Participation satisfaction Adverse effects

BMI = body mass index; ITT = intention-to-treat; MFPDQ = the Manchester Foot Pain Disability Questionnaire; NR = not reported; VAS = Visual analogue Scale

Appendix 3: Quality Assessment of Included Studies

Table 4: Quality Assessment of Systematic Reviews

AMSTAR 2 Checklist[18]	Rasenberg et al., 2018[22]	Whittaker et al., 2018[23]
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	Yes
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	No
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	Yes
4. Did the review authors use a comprehensive literature search strategy?	Yes	Yes
5. Did the review authors perform study selection in duplicate?	Yes	Yes
6. Did the review authors perform data extraction in duplicate?	Yes	Yes
7. Did the review authors provide a list of excluded studies and justify the exclusions?	No	No
8. Did the review authors describe the included studies in adequate detail?	Yes	Yes
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Yes
10. Did the review authors report on the sources of funding for the studies included in the review?	No	No
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	Yes
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	No	No
13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	Yes	Yes
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes	Yes
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	NA	NA
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes	Yes

AMSTAR = Assessing the Methodological Quality of Systematic Reviews; NA = not applicable; PICO = Population, Intervention, Comparator, and Outcome

Table 5: Quality Assessment of Randomized Controlled Trials

JBI Critical Appraisal Checklist for RCT[19]	Xu et al., 2019[24]
1. Was true randomization used for assignment of participants to treatment groups?	Yes
2. Was allocation to treatment groups concealed?	Yes
3. Were treatment groups similar at the baseline?	Yes

JBI Critical Appraisal Checklist for RCT[19]	Xu et al., 2019[24]
4. Were participants blind to treatment assignment?	No
5. Were those delivering treatment blind to treatment assignment?	No
6. Were outcomes assessors blind to treatment assignment?	Yes
7. Were treatment groups treated identically other than the intervention of interest?	Yes
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	Yes
9. Were participants analyzed in the groups to which they were randomized?	Yes
10. Were outcomes measured in the same way for treatment groups?	Yes
11. Were outcomes measured in a reliable way?	Yes
12. Was appropriate statistical analysis used?	Yes
13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	Yes

JBI = Joanna Briggs Institute; RCT = randomized controlled trial

Table 6: Quality Assessment of Non-Randomized Studies

JBI Critical Appraisal Checklist for Non-Randomized Studies[20]	Ring and Otter, 2014[25]
1. Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	Yes
2. Were the participants included in any comparisons similar?	NR
3. Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	Yes
4. Was there a control group?	Yes
5. Were there multiple measurements of the outcome both pre and post the intervention/exposure?	Yes
6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	Yes
7. Were the outcomes of participants included in any comparisons measured in the same way?	Yes
8. Were outcomes measured in a reliable way?	Yes
9. Was appropriate statistical analysis used?	Yes

NR = not reported

Appendix 4: Main Study Findings and Author's Conclusions

Table 7: Summary of Findings of Systematic Reviews

Main Study Findings	Author's Conclusions
Rasenberg et al., 2018[22]	
Prefabricated Foot Orthoses versus Customized Foot Orthoses ***Pain*** – Short-term (8 to 12 weeks; 5 RCTs [1 moderate ROB, 1 high ROB], n = 449; 3 low ROB,) SMD (95% CI) = 0.03 (-0.15 to 0.22); I^2 = 0%; *P* = 0.73 – Long-term (12 months; 1 RCT [low ROB], n = 88) MD (95% CI) = 2.30 (-5.60 to 10.10) ***Function*** – Short-term (8 to 12 weeks; 2 RCTs [low ROB], n = 194) SMD (95% CI) = -0.17 (-0.45 to 0.12); I^2 = 0%; *P* = 0.25 – Long-term (12 months; 1 RCT [low ROB], n = 88) MD (95% CI) = 1.20 (-6.10 to 8.50) ***Self-reported recovery*** – Short-term (8 weeks; 1 RCT [moderate ROB], n = 76) OR (95% CI) = 2.03 (1.35 to 3.06)	*"There was no difference in improvement in pain or function between prefabricated, custom-made and sham orthoses in the treatment of patients with plantar heel pain."*[22] p. 7
Whittaker et al., 2018[23]	
Customized Foot Orthoses versus Prefabricated Foot Orthoses ***Pain*** – Short-term (0 to 6 weeks; 2 RCTs, n = 190) SMD (95% CI) = -0.04 (-0.33 to 0.24); I^2 = 0%; *P* = 0.76 Quality of evidence[a]: Very low – Medium-term (7 to 12 weeks; 4 RCTs, n = 413) SMD (95% CI) = -0.07 (-0.26 to 0.12); I^2 = 0%; *P* = 0.48 Quality of evidence[a]: Low – Long-term (52 weeks; 1 RCT, n = 90) MD (95% CI) = 0.04 (-0.38 to 0.45); *P* = 0.87 Quality of evidence: Very low ***Function*** – Medium-term (7 to 12 weeks; 2 RCTs, n = 121) SMD (95% CI) = -0.06 (-0.39 to 0.27); I^2 = 0%; *P* = 0.71 Quality of evidence[a]: Low	*"This review found no difference between customized and prefabricated foot orthoses for pain or function from very-low quality evidence to low quality evidence. As such, health practitioners may considered using prefabricated foot orthoses that are appropriately contoured to the foot rather than customized foot orthoses, as they may be less expensive."*[23] p. 7

CI = confidence interval; GRADE = Grading Recommendations Assessment, Development and Evaluation; MD = mean difference; OR = odds ratio; RCT = randomized controlled trial; ROB = risk of bias; RR = risk ratio; SMD = standardized mean difference

[a] Quality of evidence was assessed by the authors using GRADE

Table 8: Summary of Findings of Included Primary Studies

Main Study Findings	Author's Conclusions
Xu et al., 2019[24]	
Customized 3-D Printed Foot Orthoses versus Prefabricated Foot Orthoses ***Comfort score***[a] – At week 0: 7.34 ± 3.43 versus 8.72 ± 3.93; *P* > 0.05 – At week 8: 3.12 ± 0.51 versus 5.25 ± 1.22; *P* < 0.05	*"This study supports the efficiency of customized 3D printing foot orthosis for reducing damage associated with plantar lesions an improving comfort in patients with plantar fasciitis compared with prefabricated foot orthosis."*[24] p. 1392
Ring and Otter, 2014[25]	
Casted Foot Orthoses versus Prefabricated Foot Orthoses ***Foot pain and disability (MFPDQ score)*** – At baseline: 20.5 ± 8.85 versus 20.4 ± 6.8; *P* = 0.462 – At week 8: 2.2 ± 3.9 versus 3.2 ± 5.66; *P* = 0.839 ***Participant satisfaction (mean scores)*** – Ease of use: 7.3 versus 7.9 – Comfort: 7.4 versus 7.6 – Hygiene: 7.4 versus 7.8 – Satisfaction: 8.1 versus 8.3 ***Adverse effects*:** Not identified	*"For most patients with plantar heel pain, prefabricated semi-rigid insoles such as Powerstep™ devices used in the present trial provide short-term benefit equivalent to that of bespoke, casted foot orthoses, but at considerably reduced costs."*[25] p. 1

[a]10-cm VAS score: 0 indicates no discomfort and 10 indicated the highest level of discomfort

MFPDQ = = the Manchester Foot Pain Disability Questionnaire; VAS = Visual analogue Scale