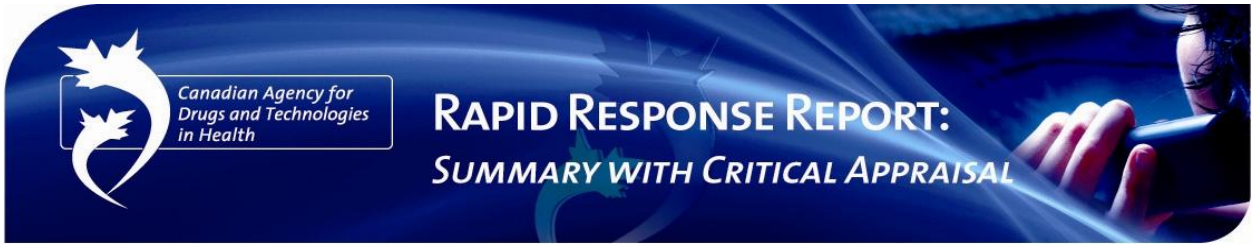

TITLE: Custom Foot Orthotics for Adults with Foot Conditions: A Review of the Clinical and Cost Effectiveness

DATE: 21 June 2012

CONTEXT AND POLICY ISSUES

Foot orthotics represent a mechanical treatment modality commonly employed in the conservative management of several primary foot conditions.[1] However, orthotics are increasingly being employed more broadly (e.g., above the ankle) in the treatment and prevention of various overuse injuries, particularly of athletic origin,[2-11] and as an adjunct treatment in some systemic medical conditions.[1,12-14]

Although foot orthotics have been categorized as either custom-made or pre-fabricated,[1,2] no universally accepted definition for custom foot orthotic exists.[1,2,14] Moreover, considerable uncertainty remains around the mechanism through which orthotics exert their putative beneficial effects.[1,7] Further complicating the definition of custom foot orthotic is the wide variability of construction materials,[1,2] differences in design,[1] and potential mechanical additions or modifications[1] that may distinguish one custom orthotic from another. In addition to these device-related issues, some foot conditions, such as plantar fasciitis,[15] may be self-limiting.

The purpose of this review is to examine the clinical and cost-effectiveness of custom foot orthotics for adults with foot conditions.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of custom foot orthotics for adults with foot conditions?

2. What is the cost effectiveness of custom foot orthotics for adults with foot conditions?

KEY MESSAGE

There is some evidence to support the use of custom foot orthotics (CFOs) in pes cavus or high-arched foot (pain, function, and quality of life), plantar fasciitis (function), or painful bunion with hallux valgus (pain); mixed evidence in rheumatoid arthritis (pain); and one trial found no improvement in pain function or quality of life in patients with diabetic peripheral arterial disease.

Important research gaps remain in establishing universally accepted descriptions and definitions of CFOs. No economic reviews of CFOs were identified in the literature search.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2012, Issue 5), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, and economic studies. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2007 and May 24, 2012.

Selection Criteria and Methods

One reviewer screened the titles and abstracts from the list of identified citations. Potentially relevant articles were retrieved and reviewed for final selection. Articles reporting on custom foot orthotics for adults with foot conditions were selected for inclusion, according to the criteria listed in Table 1.

Table 1: Selection Criteria

Population	Adult patients with foot conditions
Intervention	Custom foot orthotics
Comparator	• Regular shoes without orthotics • No comparator
Outcomes	• Pain relief • Improved ambulation • Prevention of other foot conditions • Improved quality of life
Study Designs	• Health technology assessments, systematic reviews and meta-analyses • Randomized controlled trials • Non-randomized studies • Economic evaluations

Exclusion Criteria

Studies were excluded if they: involved pre-fabricated (i.e., non-custom) foot orthotics, ankle-foot-or lateral wedge orthotics, orthopedic shoes, actuated orthotics, or textured insoles; consisted of multi-interventions or co-interventions, where the effect of the custom orthotic could not be isolated; were laboratory (i.e., biomechanic or biodynamic) experiments or primary prevention studies (i.e., no diagnosed foot problem); involved above-foot athletic overuse

injuries (e.g., patellofemoral pain syndrome). To be included, systematic reviews had to have review content updated to 2007.

Critical Appraisal of Individual Studies

Critical appraisal of the methodological quality of individual studies was performed using the Downs and Black instrument[16] for randomized and non-randomized studies while the methodological quality of systematic reviews was assessed using the AMSTAR instrument.[17]

An annotated critical appraisal of the strengths and limitations of the individual included studies is provided in Appendix 3.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search yielded 619 citations. After screening titles and abstracts, 584 articles were excluded and 35 potentially relevant reports were selected for full-text review. No relevant citations were identified in the grey literature. Of these 35 articles, 30 did not meet the inclusion criteria and were excluded, leaving a total of five relevant reports,[1,2,13,14,18] three[1,2,13] of which were systematic reviews. The two other studies included one randomized controlled trial[14] and one prospective cohort study.[18] No economic evaluations were identified.

The study selection process is outlined in Appendix 1.

Summary of Study Characteristics

Characteristics of the included studies are summarized below and detailed in Appendix 2.

Country of origin

Of the five included studies, two[1,14] were from Australia, and one each was from New Zealand,[2] the UK,[13] and the USA.[18] No studies from Canada were identified.

Population

All of the included studies investigated adult populations. The systematic review by Hawke et al.[1] investigated several etiologies under the broad term of 'foot pain', including pes cavus (high-arched foot), rheumatoid arthritis, plantar fasciitis, and painful bunion with hallux valgus. Plantar fasciitis was examined in the systematic review of prevention and treatment of injuries by Hume et al.[2] while Hennessy et al.[13] reviewed rheumatoid arthritis. The single-blind, randomized controlled trial (RCT) by Burns et al.[14] studied adults with diabetes and peripheral arterial disease recruited from the community while the prospective cohort study by Drake et al.[18] investigated plantar fasciitis in a community sample of predominantly female participants.

Intervention

The three systematic reviews[1,2,13] looked at different types of orthotics, including the intervention of interest, custom-made orthotics. Since there is no universally accepted definition for custom foot orthotic (CFO),[2,14] Hawke et al.[1] defined it operationally 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." However, no operational definitions for CFO were provided in the other two systematic reviews.[2,13]

In the RCT by Burns et al.,[14] the CFO intervention was "moulded from neutral-suspension plaster casts of the feet"; detailed information was also provided on the composition of the CFO material. By comparison, trained investigators completed a plaster mould cast of each participant's feet and then fabricated a low-cost, temporary CFO designed to be worn for only a short duration in the prospective cohort study by Drake et al.[18]

Comparators

In the systematic review by Hawke et al.,[1] any comparative intervention or non-intervention was deemed eligible for examination while comparators were not pre-specified in the other two systematic reviews.[2,13]

Sham insoles made from removable shoe insoles were used as the comparator in the RCT by Burns et al.[14] while no comparator was used in the before-and-after cohort study by Drake et al.[18]

Outcomes

Foot pain or change in level of foot pain was the primary outcome in the systematic review by Hawke et al.;[1] secondary outcomes included disability or functional ability and health-related quality of life, as well as participant satisfaction, adverse events, and compliance. In the review by Hume et al.,[2] outcomes of interest were loosely described as comprising patient pain and comfort, and prevention of injury. Hennessy et al.[13] did not pre-specify any particular outcomes of interest, but did define six upon identification of the included studies: pain, foot function, walking speed, forefoot plantar pressure, gait parameters, and hallux abductovalgus (HAV) angle progression.

Primary outcomes of interest in the RCT by Burns et al.[14] were foot pain and function while secondary outcomes included toe-brachial index, average daily steps, disability, patient perceived comfort, health-related quality of life, adherence, and adverse events. Various surveys were employed by Drake et al.[18] to assess the following outcomes of interest: first-step heel pain, activities of daily living and sports, and perceived change in overall improvement.

Summary of Critical Appraisal

Of the three systematic reviews,[1,2,13] the Cochrane review by Hawke et al.[1] was the most comprehensive and well-executed based on the AMSTAR[17] measurement tool for appraising the methodological quality systematic reviews. It was an a priori-designed systematic review that included both duplicate study selection and data extraction, a comprehensive literature review without language or publication restriction, and documentation of both included and excluded studies with a scientific quality assessment of the included studies. The review by Hume et al.[2] was found to have several limitations in methodological quality including a lack of reporting of the scientific quality of the included trials; the absence of a listing of excluded trials; and a restriction to published journal articles in the English language. Similarly, the review by Hennessy et al.[13] was found to have several limitations in methodological quality including a

lack of clarity with respect to whether or to what extent unpublished trials were pursued; a lack of description of the study selection and data extraction process; the absence of a listing of excluded trials; and no information provided on declarations of interest or financial support. In addition, neither the review by Hume et al.[2] nor Hennessy et al.[13] provided operational definitions for 'custom foot orthotic'. Finally, none of the systematic reviews[1,2,13] reported an assessment of the risk of publication bias.

In the RCT by Burns et al.,[14] the design was a single-blind (patients only) where investigators remained unblinded to study treatments. No information was provided as to whether the enrolled patients were representative of the larger population from which they were recruited. Adherence to treatment, as assessed by self-report, was shown to be only 70% in the CFO group compared with 79% in the sham orthotic (control) group, which may have affected the study's power; no information is provided about potential differences in characteristics between those who adhered versus those who did not adhere.

In the prospective cohort trial of a temporary CFO by Drake et al.,[18] the study is limited by its non-randomized, observational design in that bias may be present owing to a lack of control of potential confounders. The study's convenience sample was also small (n=15), mostly female (~87%) and short in duration (12 weeks). The external generalizability of the study may be limited by the in-house fabrication of the CFO, the temporary (2 weeks) wear time, the biomechanical positioning method used to obtain a mould-casting for the orthotic, and the lower-cost materials used to construct the temporary CFO. There is also no report of whether adherence was assessed, nor whether orthotic weaning-off activities or times differed among participants.

A more detailed review of the strengths and limitations of the individual included studies is described in Appendix 3.

Summary of Findings

What is the clinical effectiveness of custom foot orthotics for adults with foot conditions?

Pes cavus (high-arched foot)

For pes cavus or high-arched foot, Hawke et al.[1] identified one trial comparing CFO to sham orthoses and found that after 3 months, CFOs were favoured over sham orthotics on the outcomes of foot pain [weighted mean difference (WMD) = 10.90, 95% CI: 3.21 to 18.59; number needed to treat (NNT) 5, 95% confidence interval (CI): 3 to 16] and function [WMD = 11.00, 95% CI: 3.35 to 18.65; NNT 5, 95% CI: 3 to 15]; likewise, CFOs were favoured over sham orthotics in the health-related quality of life (HRQOL) 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 not of general health or social functioning.

Rheumatoid arthritis

For rheumatoid arthritis, Hawke et al.[1] identified two trials, one of which compared CFO with no intervention and the other with sham orthoses. Hennessy et al.[13] identified two additional trials, one of which compared CFO with no orthoses and the other with unshaped material.

In Hawke et al.,[1] the trial of CFO versus no intervention favoured CFO in foot pain [WMD = 307.80, 95% CI: 67.37 to 548.23], but showed no difference between groups in function; HRQOL was not reported. The trial of CFO versus sham orthoses revealed no difference between groups in either foot pain or function; HRQOL was not reported.

In Hennessy et al.,[13] the trial of CFO versus no orthoses favoured CFO in foot pain [standard mean difference (SMD) = 1.60; 95% CI: 0.79 to 2.41]; function and HRQOL were not reported. The trial of CFO versus unshaped material reported no difference between groups in foot pain; function and HRQOL were not reported.

Plantar fasciitis

For plantar fasciitis, Hawke et al.[1] identified one trial which compared CFO with sham orthoses. Hume et al.[2] identified one additional non-comparative, before-and-after CFO study. Drake et al.[18] conducted a non-comparative, prospective cohort CFO study.

In Hawke et al.,[1] the trial of CFO versus sham orthoses showed no difference between groups in foot pain while CFOs were favoured in foot function at both 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]; HRQOL was not reported.

In Hume et al.,[2] the non-comparative before-and-after CFO study showed an association with reduced foot pain and improved foot function post-CFO; HRQOL was not reported.

In the non-comparative, prospective cohort CFO study by Drake et al.,[18] a temporary CFO was associated with a reduction in pain and improved activities of daily living and sports after 12 weeks.

Painful bunion with hallux valgus

For painful bunion with hallux valgus, Hawke et al.[1] identified one trial which compared CFO with no intervention. In this trial, CFOs were favoured at 6 months [WMD = 9.00, 95% CI: 1.16 to 16.84; NNT 6, 95% CI: 3 to 52], but not at 12 months for foot pain. There was no difference between groups at 6 or 12 months for HRQOL. Foot function was not reported.

Diabetic peripheral arterial disease

For diabetic peripheral arterial disease, Burns et al.[14] conducted a single-blind (patients blinded) RCT of CFO compared with sham orthotics. At the end of 8 weeks, there was no difference between groups in foot pain, function, or HRQOL.

None of the included studies reported outcomes on the prevention other foot conditions.

Findings from the individual studies are presented in greater detail in Appendix 4.

What is the cost effectiveness of custom foot orthotics for adults with foot conditions?

No economic evaluations were identified from the literature review.

Limitations

None of the included studies was conducted in Canada. It is therefore uncertain whether, or to what extent, subtle, but important differences may exist in the approach Canadian clinicians might take in treating the variously identified foot problems compared with that taken by clinicians in the countries whose research is profiled in this report.

There were few relevant studies identified within the three systematic reviews, and the studies identified had a limited number of participants (range: 15 to 154), much like the sample sizes from the included RCT (n=61) and prospective cohort (n=15) studies. Many of the studies summarized in the systematic reviews used comparators other than placebo or no intervention, or included co-interventions.

There is no universally accepted definition for custom foot orthotic coupled with considerable uncertainty around the mechanism through which orthotics may exert their putative beneficial effects. There is also wide variability in the type of materials used to construct foot orthotics. Moreover, some foot conditions, such as plantar fasciitis, may be self-limiting.

No economic reviews were identified from the literature search.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Of the foot conditions examined, custom foot orthotics (CFOs) would appear effective in reducing pain and improving function along with some aspects of quality of life in pes cavus (high-arched foot). The evidence, however, was mixed for rheumatoid arthritis, where CFOs relieved pain in two studies compared with no orthoses or no intervention, but was not different from placebo comparator in the other two studies; this suggests a possible placebo effect in the first two studies. Some evidence was found in support of CFOs for pain reduction in in painful bunion with hallux valgus for up to 6 months; however, this benefit was lost at 12 months. In plantar fasciitis, CFOs would appear effective for improving function, but evidence for improvement in foot pain was lacking. No evidence was found to support the use of CFOs in diabetic peripheral arterial disease.

Although a large database exists in orthotics research, there remain important research gaps around basic issues of device definition and description, which complicate and confound comparisons between studies. Prevention of complications (i.e., other foot conditions) was not among the outcomes investigated. No economic reviews were identified from the literature search.

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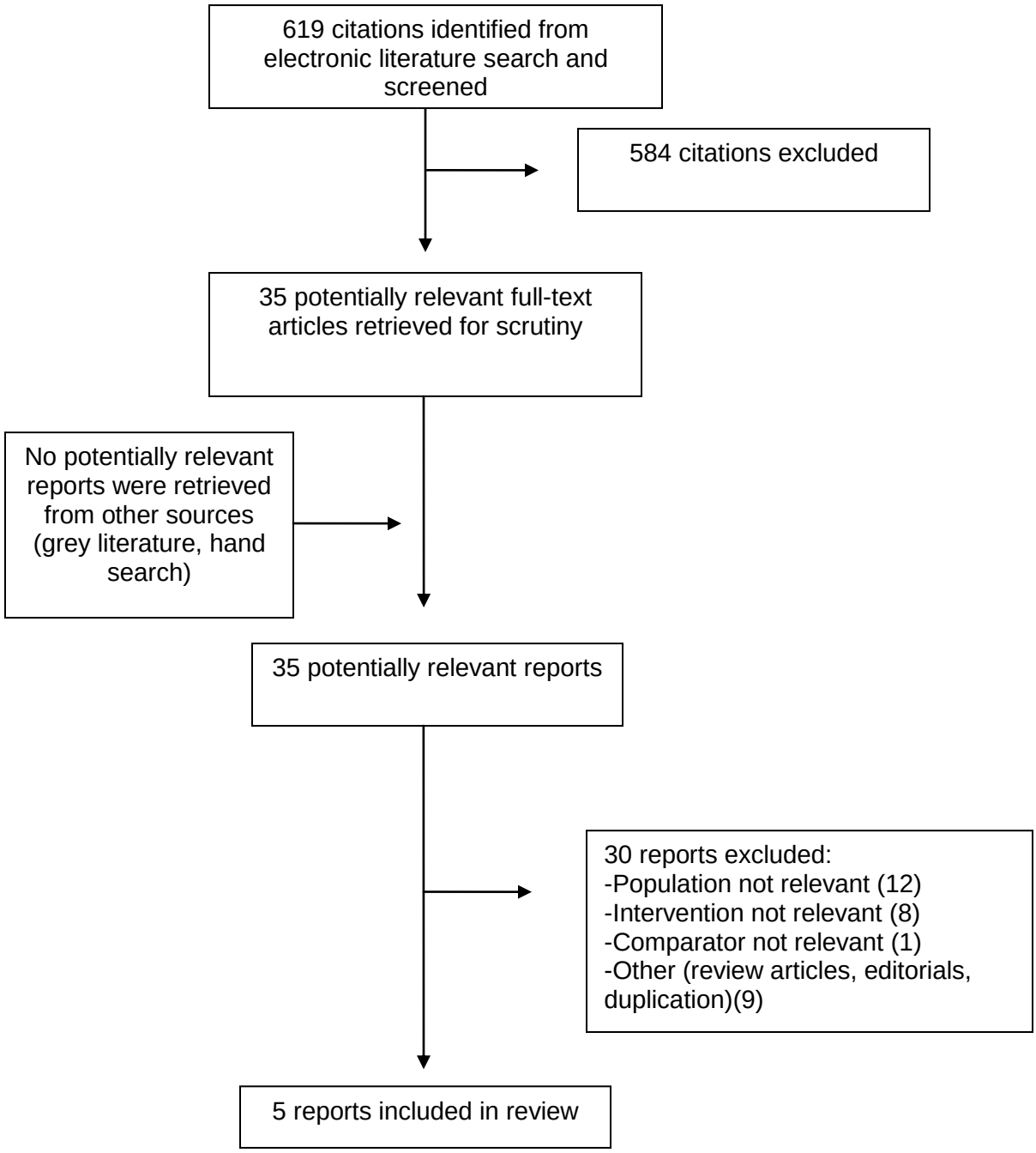
Appendix 1: Selection of Included Studies



Appendix 2: Summary of Study Characteristics

First Author, Publication Year, Country	Study Design	Population	Intervention	Comparator	Outcomes
Foot pain					
Hawke, 2008,[1] Australia	Systematic review	Participants of any age who reported foot pain of any type, etiology and duration.	Custom-made foot orthoses (contoured in-shoe devices that were moulded or milled from an impression of the foot and fabricated according to practitioner-prescribed specifications)	Any comparative intervention or non-intervention evaluated in trials investigating the effectiveness of custom-made foot orthoses for the treatment of foot pain.	Primary: -level of a quantifiable measure of foot pain, or the change in level of pain, after intervention. Secondary: -disability or functional ability, or both -HRQOL -participant satisfaction -compliance
Plantar fasciitis					
Hume, 2008,[2] New Zealand	Systematic review	Subjects diagnoses with: -Plantar fasciitis -Tibial stress fracture -Patellofemoral pain syndrome	Customized (contoured, removable, in-shoe device moulded or milled from impressions of the feet, whether by plaster cast or 3D laser scan and fabricated according to practitioner-prescribed specifications) or prefabricated rigid, semi-rigid, or soft orthoses.	Not specified *a priori* for the systematic review; however, the one relevant study within this systematic review, before-and-after study design	-treatment of injuries or deformities of the leg and foot in terms of patient pain and discomfort -prevention of lower limb injury in terms of reduced incidence of injury.
Drake, 2011,[18] USA	Prospective cohort study	Volunteers who had heel pain and first-	Temporary custom foot orthotics	No comparator group	At baseline: -2 subscales of the Foot and

First Author, Publication Year, Country	Study Design	Population	Intervention	Comparator	Outcomes
		step pain in the morning for which they had not received treatment in the previous 12 weeks.	followed by a stretching program.		Ankle Mobility Measure (FAAM) [activities of daily living (FAAM-A) and the sports sub-scale (FAAM-S)] -a baseline numeric pain rating scale (NPRS) to assess first-step heel pain At 2, 4, and 12 weeks: -Global Rating of Change to measure perceived change in overall improvement
Diabetic peripheral arterial disease					
Burns, 2009,[14] Australia	Randomized controlled trial	A community sample of adults with diabetes mellitus, peripheral arterial disease, and weight-bearing musculoskeletal foot pain of at least 6 months.	Custom-made foot orthoses moulded from neutral suspension plaster casts of the feet.	Sham insoles – casts were made of both feet but insoles were made from removable shoe innersoles covered with the same material as the treatment group.	Primary: foot pain and function measured using the Foot Health Status Questionnaire (FHSQ) Secondary: toe-brachial index -average daily steps -disability -patient-perceived comfort -HRQOL -adherence -adverse events
Rheumatoid arthritis					
Hennessy, 2012,[13] UK	Systematic review	Adult patients with rheumatoid arthritis.	All types of orthoses for the foot and ankle.	Not specified *a priori* for the systematic review; however, in the two relevant studies within this systematic review,	No particular outcomes were pre-specified, rather “all of the outcome measures [from the studies] were selected for further analysis”(p.312) However, six outcomes of interest

First Author, Publication Year, Country	Study Design	Population	Intervention	Comparator	Outcomes
				one trial used 'no orthoses' while the other used 'unshaped material' as the comparator.	were later identified from the included studies: -foot pain -foot function -walking speed -forefoot plantar pressure -gait parameters -hallux abductovalgus angle progression

HRQOL = Health-related quality of life

Appendix 3: Summary of Critical Appraisal

First Author, Publication Year, Country	Strengths	Limitations
Foot pain		
Hawke, 2008,[1] Australia	*Systematic review* • Well described, *a priori* design with comparators pre-specified • Duplicate study selection; independent verification of extracted data by two separate authors • Comprehensive literature search performed with no language restriction; attempts made to identify unpublished trials by contacting authors of included trials and known researchers in the field • Characteristics of both included and excluded studies reported • Scientific quality of included studies was assessed and reported • Results analyzed separately by foot pain etiology; heterogeneity across trials was assessed using I^2 statistic; studies only pooled if sufficient clinical homogeneity • Quality of evidence for 'pain' and 'function' outcomes were reported in the conclusions for each foot pain etiology studied • Declarations of interest and sources of financial support both reported • Operational definition of custom orthotic provided • Multiple foot conditions examined	• Assessment of the risk of publication bias not reported
Plantar fasciitis		
Hume, 2008,[2] New Zealand	*Systematic review* • Comprehensive literature search performed, including two independent searches to minimize risk of unintentional omissions of publications • Included studies could be randomized controlled trials, controlled or uncontrolled clinical studies; systematic	• Pre-specified comparators not reported • Only English language journal publications were considered in literature search • Initial study selection performed by single reviewer • A list of excluded studies was not provided, nor was

First Author, Publication Year, Country	Strengths	Limitations
	reviews were also eligible for inclusion • Characteristics of included studies provided • Declarations of interest and sources of financial support both reported	there any indication of the absolute number of studies initially identified and subsequently excluded • Critical appraisal of the scientific quality of included studies not reported • Review did not include a pooling or meta-analysis of data • Assessment of the risk of publication bias not reported • No operational definition of custom orthotic provided
Drake, 2011,[18] USA	*Prospective cohort study* • Study objective, inclusion/exclusion criteria, intervention, and outcomes clearly described • Characteristics of study patients reported • Adverse effects reported (none) • All participants completed the study protocol; no drop-outs	• Convenience sample used; small sample size (n=15), mostly female (~87%); short study duration (12 weeks) • Unblinded, uncontrolled design • No baseline measurement performed for the Global Rating of Change instrument; risk of underestimation of perceived change • Unclear whether there were inter-participant differences in orthotic weaning-off activities or times • Unclear whether or how adherence to wearing the orthotic was assessed • Although orthotic was custom-fabricated (plaster cast of foot) for each participant, the orthotic was designed as a temporary device to be worn for only 2 weeks, which may not be representative of the usual length of orthotic treatment of plantar fasciitis • Positioning of orthotic differed from usual positioning of temporary orthotics (i.e., non-weight-bearing position, foot in plantar flexion and inversion versus neutral subtalar joint positioning)
Diabetic peripheral arterial disease		
Burns, 2009,[14] Australia	*Randomized controlled trial* • Study objective, inclusion/exclusion criteria, intervention, and outcomes clearly described • Power calculation performed *a priori* to estimate sample	• Single blind only (patients) • No information provided as to whether the study patients were representative of the population from

First Author, Publication Year, Country	Strengths	Limitations
	size needed • Randomization allocation was concealed from both patients and research staff; randomization code was computer-generated off-site • Characteristics of study patients reported • Published, validated instrument used for assessing primary outcomes (foot pain and function) • Results reported with p values and 95% confidence intervals • Adverse effects reported • 95% of participants completed study protocol (power calculation based on 5% drop-out rate)	which they were recruited • Self-reported adherence was only 70% for custom orthotic (intervention) compared with 79% for sham orthotic (control); no information is provided about potential differences in characteristics between those who adhered versus those who did not adhere
Rheumatoid arthritis		
Hennessy, 2012,[13] UK	*Systematic review* • Comprehensive database literature search performed with no language restriction • Characteristics of included studies reported • Scientific quality of included studies was assessed and reported • Heterogeneity across trials was assessed using I^2 statistic; random effects modeling employed on pooled results • Quality of evidence for outcomes reported in the conclusions	• Pre-specified comparators and particular outcomes of interest not reported • Unclear whether, or to what extent, unpublished trials were sought • Study selection and data extraction process not described • Characteristics of excluded studies not reported • Declarations of interest and sources of financial support not reported • Assessment of the risk of publication bias not reported • No operational definition of custom orthotic provided

Appendix 4: Summary of Findings

First Author, Publication Year, Country, Study Design	Main Study Findings	Authors' conclusions
Foot pain		
Hawke, 2008,[1] Australia Systematic Review	Pes Cavus (high-arched foot) CFO vs sham orthoses (one trial; n=154) *Foot pain:* favoured CFO [WMD = 10.90, 95% CI: 3.21 to 18.59; NNT 5, 95% CI: 3 to 16] *Function :* favoured CFO [WMD = 11.00, 95% CI: 3.35 to 18.65; NNT 5, 95% CI: 3 to 15] *HRQOL:* favoured CFO for 'physical functioning' and 'vitality'; no difference between groups for 'general health' and 'social functioning' MO-SF-36[a] (physical functioning) [WMD = 9.50, 95% CI: 4.07 to 14.93; NNT 4, 95% CI: 3 to 9] MO-SF-36[a] (vitality) [WMD = 5.50, 95% CI: 0.26 to 10.74; NNT 7; 95% CI: 4 to 221] MO-SF-36[a] (general health) [WMD = 0.5, 95% CI: -5.70 to 6.70] MO-SF-36[a] (social functioning) [WMD = 2.50, 95% CI: -3.28 to 8.28] *Prevention of other foot conditions – not reported* [a]MO-SF-36 =Medical Outcomes Short Form-36	"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." (p.14)
	Rheumatoid arthritis • CFO vs no intervention in rear foot pain (one trial; n=101) *Foot pain:* favoured CFO [WMD = 307.80, 95% CI: 67.37 to 548.23] *Function:* no difference between groups [WMD = 81.40, 95% CI: -86.33 to 249.13]	"There is silver level evidence that for people diagnosed with rheumatoid arthritis, custom-made foot orthoses are: • more effective than no intervention for reducing rear foot pain but not for improving function, after three months and as a summary of change over

First Author, Publication Year, Country, Study Design	Main Study Findings	Authors' conclusions
	HRQOL not reported *Prevention of other foot conditions – not reported* • CFO vs sham orthoses (one trial; n=102) *Foot pain:* no difference between groups [WMD = 0.90, 95% CI: -10.97 to 12.77] *Function:* no difference between groups [WMD = -1.60, 95% CI: -10.40 to 7.20] *HRQOL not reported* *Prevention of other foot conditions – not reported*	30 months; • not more effective than sham orthoses for reducing foot pain or improving function, after 36 months;" (p.14)
	Plantar fasciitis CFO versus sham orthoses (one trial; n=92) *Foot pain:* no difference between groups 3 months [WMD = 5.10, 95% CI: -5.19 to 15.39] 12 months [WMD = -2.50, 95% CI: -12.55 to 7.55] *Function:* favoured CFO 3 months [WMD = 10.40, 95% CI: 2.43 to 18.37; NNT 4, 95% CI: 2 to 19] 12 months [WMD = 10.40, 95% CI: 0.22 to 20.58; NNT 5, 95% CI: 3 to > 215] *HRQOL not reported* *Prevention of other foot conditions – not reported*	"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." (p.14)
	Painful bunion with hallux valgus CFO versus no intervention (one trial; n=138) *Foot pain:* favoured CFO at 6 months; no difference between groups at 12	"There is silver level evidence that for people aged less than 60 years with a painful bunion, mild to moderate hallux valgus

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	months 6 months [WMD = 9.00, 95% CI: 1.16 to 16.84; NNT 6, 95% CI: 3 to 52] 12 months [WMD = 0.00, 95% CI: -8.19 to 8.19] *HRQOL*: no difference between groups 6 months [WMD = 1.50, 95% CI: -0.97 to 3.97] 12 months [WMD = 0.50, 95% CI: -1.90 to 2.90] *Function not reported* *Prevention of other foot conditions – not reported*	and no limitation of the first MTP [metatarsalphalangeal] joint range of motion, custom-made foot orthoses... are more effective than no intervention for reducing foot pain after six months but not after 12 months of wear." (p.14)
Plantar fasciitis		
Hume, 2008,[2] New Zealand Systematic Review	CFO, no comparator; pre/post design, 100-m timed walk (one trial; n=15) *Foot pain:* 10-cm visual analog scale ratings lower post-FO Pre-FO: 3.0 ± 1.7 Post-FO (12-17 days): 0.7 ± 0.7 *Function*: Foot Function Index score lower post-FO Raw data not reported. Post-FO (12-17 days): Maximum pain and maximum disability pain subscale scores were reduced by 66% and 75%, respectively. *HRQOL not reported* *Prevention of other foot conditions – not reported*	"... there is some evidence that FOs can effectively treat pain associated with plantar fasciitis." (p.775)
Drake, 2011,[18] USA Prospective cohort	CFO followed by stretching (n=15), no comparator group (before-after design) *Descriptive Data for Primary Outcome Measures* Initial 2 week 4 week 12 week	"Overall, findings suggest that wearing a TCFO for 2 weeks, followed by a stretching program, decreases overall pain and increases foot and ankle function in participants with

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	NPRS[a]	5.5 ± 2.5 (2-10)	2.5 ± 2.1 (0-7)	2.2 ± 2.4 (0-7)	2.7 ± 2.5 (0-9)	plantar fasciitis." (p.225-6)
	FAAM-A,[b] %	66.3 ± 17.0 (41.2-95.2)	85.1 ± 13.4 (55.9-100.0)	83.2 ± 15.1 (55.9-100.00)	85.3 ± 14.5 (60.00-100.0)	
	FAAM-S,[c] %	45.6 ± 24.6 (0.1-81.3)	70.2 ± 22.6 (28.1-100.0)	73.7 ± 26.0 (25.0-100.0)	77.1 ± 15.7 (53.0-100.0)	
	GRC[d]	---	4.4 ± 1.8 (-1, +7)	4.5 ± 1.9 (-1, +7)	4.2 ± 2.3 (-1, +7)	
	-values are mean ± SD (range)					
	Change Scores for Primary Outcome Measures					
		2 week	4 week	12 week		
	NPRS[a] (0-10)	-3.1 (-4,4, -1.7)	-3.3 (-4.6, -2.0)	-2.8 (-4.6, -1.0)		
	FAAM-A,[b] %	18.8 (10.1, 27.5)	16.9 (7.8, 25.9)	19.0 (10.1, 27.9)		
	FAAM-S,[c] %	24.6 (14.6, 34.6)	28.1 (15.9, 40.1)	31.5 (14.9, 48.1)		
	-average 95% CI					
	Prevention of other foot conditions – not reported					
	[a]NPRS = Numeric Pain Rating Scale; [b]FAAM-A = Foot and Ankle Ability Measure (activity); [c]FAAM-S = Foot and Ankle Ability Measure (sports); [d]GRC = Global Rating of Change					
Diabetic peripheral arterial disease						
Burns, 2009,[14] Australia	CFO (n=30) vs sham orthoses (n=31)					"At 8 weeks, foot pain and foot function scores improved with

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Randomized Controlled Trial	*Foot pain:* no difference between groups at 8 weeks [-2.0; 95% CI: -10.3 to 14.4; P=0.746] *Function:* no difference between groups at 8 weeks [1.9; 95% CI: -14.0 to 10.2; P=0.756] *Quality of Life:* no difference between groups 8 weeks Physical function [-4.5; 95% CI: -12.4 to 3.4; P=0.257] Physical role [-1.6; 95% CI: -18.3 to 15.1; P=0.847] Bodily pain [-5.3; 95% CI: -16.2 to 5.5; P=0.332] General health [1.3; 95% CI: -8.1 to 5.5; P=0.700] Vitality [-4.2; 95% CI: -11.3 to 3.0; P=0.249] Social function [-6.3; 95% CI: -16.8 to 4.2; P=0.232] Emotional role [-8.9; 95% CI: -28.4 to 10.6; P=0.366] Mental health [0.0; 95% CI: -7.4 to 7.4; P=0.997] *Prevention of other foot conditions – not reported*	both custom orthotics and the sham, but there were no significant differences between groups. Both interventions were safe with few adverse events." (p.897)
Rheumatoid arthritis		
Hennessy, 2012,[13] UK Systematic Review	• CFO versus no orthoses (1 trial; n=32) *Pain:* favoured CFO [SMD = 1.60; 95% CI: 0.79 to 2.41] • CFO versus unshaped material (1 trial; n=40) *Pain:* no difference between groups [SMD = 0.49; 95% CI: -0.14 to 1.12] *Function not reported* *HRQOL not reported*	"Weak levels of evidence were found for custom foot orthotics reducing pain... Inconclusive evidence was present for foot function..." (p.316)

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	Prevention of other foot conditions – not reported No quantitative data provided on the outcomes of interest for the observational studies.	

CFO = custom foot orthoses; CI = Confidence interval; HRQOL = Health-related quality of life; NNT = number needed to treat; PFO = pre-fabricated orthoses; SD = standard deviation; SMD = standard mean difference; WMD = weighted mean difference