

CADTH RAPID RESPONSE REPORT: REFERENCE LIST

Customized or Prefabricated Shoe Inserts for Chronic, Non-Cancer Pain: Clinical Effectiveness and Guidelines

Service Line: Rapid Response Service
Version: 1.0
Publication Date: January 30, 2020
Report Length: 7 Pages

Authors: Shannon Hill, Robyn Butcher

Cite As: *Customized or Prefabricated Shoe Inserts for Chronic, Non-Cancer Pain: Clinical Effectiveness and Guidelines*. Ottawa: CADTH; 2020 Jan. (CADTH rapid response report: reference list).

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

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Research Questions

1. What is the clinical effectiveness of customized foot orthotics or prefabricated shoe inserts for chronic non-cancer pain?
2. What are the evidence-based guidelines regarding customized foot orthotics or prefabricated shoe inserts for chronic non-cancer pain?

Key Findings

Six systematic reviews (four with meta-analyses), seven randomized controlled trials, and two non-randomized studies were identified regarding the clinical effectiveness of customized or prefabricated shoe inserts for chronic non-cancer pain. Two evidence-based guidelines were also identified regarding customized foot orthotics and prefabricated shoe inserts for chronic non-cancer pain.

Methods

A limited literature search was conducted by an information specialist on key resources including Ovid Medline, 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 foot orthotics and chronic pain. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2015 and January 20, 2020. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults living with chronic non-cancer pain, excluding pregnant patients
Intervention	Customized foot orthotics or prefabricated shoe inserts
Comparator	Q1: Pharmacological interventions No treatment (no orthotics) Usual care (if usual care is pharmacological interventions only) Q2: Not applicable

Outcomes	Q1: Clinical effectiveness (pain reduction, functional performance, quality of life, disability level, safety, global impression of recovery, adverse events) Q2: Guidelines
Study Designs	Health technology assessments, systematic reviews, randomized control trials, non-randomized studies, evidence-based guidelines.

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, and evidence-based guidelines.

Six systematic reviews¹⁻⁶ (four with meta-analyses),²⁻⁵ seven randomized controlled trials,⁷⁻¹³ and two non-randomized studies^{14,15} were identified regarding the clinical effectiveness of customized or prefabricated shoe inserts for chronic non-cancer pain. Two evidence-based guidelines^{16,17} were also identified regarding customized foot orthotics and prefabricated shoe inserts for chronic non-cancer pain. No relevant health technology assessments were identified.

Additional references of potential interest are provided in the appendix.

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

1. Arias-Martin I, Reina-Bueno M, Munuera-Martinez PV. Effectiveness of custom-made foot orthoses for treating forefoot pain: a systematic review. *Int Orthop*. 2018 08;42(8):1865-1875.
[PubMed: PM29423640](#)
2. Gijon-Nogueron G, Ramos-Petersen L, Ortega-Avila AB, Morales-Asencio JM, Garcia-Mayor S. Effectiveness of foot orthoses in patients with rheumatoid arthritis related to disability and pain: a systematic review and meta-analysis. *Qual Life Res*. 2018 Dec;27(12):3059-3069.
[PubMed: PM29922913](#)
3. 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 Aug;52(16):1040-1046.
[PubMed: PM29555795](#)
4. Zhang J, Wang Q, Zhang C. Ineffectiveness of lateral-wedge insoles on the improvement of pain and function for medial knee osteoarthritis: a meta-analysis of controlled randomized trials. *Arch Orthop Trauma Surg*. 2018 Oct;138(10):1453-1462.
[PubMed: PM30030612](#)

5. Conceicao CS, Gomes Neto M, Mendes SM, Sa KN, Baptista AF. Systematic review and meta-analysis of effects of foot orthoses on pain and disability in rheumatoid arthritis patients. *Disabil Rehabil.* 2015;37(14):1209-1213.
[PubMed: PM25249238](#)
6. Duivenvoorden T, Brouwer RW, van Raaij TM, Verhagen AP, Verhaar JA, Bierma-Zeinstra SM. Braces and orthoses for treating osteoarthritis of the knee. *Cochrane Database Syst Rev.* 2015 Mar 16(3):CD004020.
[PubMed: PM25773267](#)

Randomized Controlled Trials

7. Felson DT, Parkes M, Carter S, et al. The efficacy of a lateral wedge insole for painful medial knee osteoarthritis after prescreening: a randomized clinical trial. *Arthritis Rheumatol.* 2019 06;71(6):908-915.
[PubMed: PM30615299](#)
8. Whittaker GA, Munteanu SE, Menz HB, Gerrard JM, Elzarka A, Landorf KB. Effectiveness of foot orthoses versus corticosteroid injection for plantar heel pain: the SOOTHE randomized clinical trial. *J Orthop Sports Phys Ther.* 2019 Jul;49(7):491-500.
[PubMed: PM31130060](#)
9. Yurt Y, Sener G, Yakut Y. The effect of different foot orthoses on pain and health related quality of life in painful flexible flat foot: a randomized controlled trial. *Eur J Phys Rehabil Med.* 2019 Feb;55(1):95-102.
[PubMed: PM29553223](#)
10. Bonanno DR, Murley GS, Munteanu SE, Landorf KB, Menz HB. Effectiveness of foot orthoses for the prevention of lower limb overuse injuries in naval recruits: a randomised controlled trial. *Br J Sports Med.* 2018 Mar;52(5):298-302.
[PubMed: PM29056595](#)
11. Cambron JA, Dexheimer JM, Duarte M, Freels S. Shoe orthotics for the treatment of chronic low back pain: a randomized controlled trial. *Arch Phys Med Rehabil.* 2017 09;98(9):1752-1762.
[PubMed: PM28465224](#)
12. Moreira E, Jones A, Oliveira HA, Jennings F, Fernandes A, Natour J. Effectiveness of insole use in rheumatoid feet: a randomized controlled trial. *Scand J Rheumatol.* 2016 Oct;45(5):363-370.
[PubMed: PM26815734](#)
13. 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 Jul;105(4):281-294.
[PubMed: PM25941995](#)

Non-Randomized Studies

14. Kirmizi M, Simsek IE, Elvan A, Akcali O, Angin S. Investigation of the effects of flat cushioning insole on gait parameters in individuals with chronic neck pain. *Acta Bioeng.* 2019;21(2):135-141.
[PubMed: PM31741472](#)

15. Moyne-Bressand S, Dhieux C, Decherchi P, Dousset E. Effectiveness of foot biomechanical orthoses to relieve patients' knee pain: changes in neural strategy after 9 weeks of treatment. *J Foot Ankle Surg.* 2017 Nov - Dec;56(6):1194-1204.
[PubMed: PM29079236](#)

Guidelines and Recommendations

16. Achilles pain, stiffness, and muscle power deficits: midportion achilles tendinopathy revision: clinical practice guidelines linked to the international classification of functioning, disability and health from the Orthopaedic Section of the American Physical Therapy Association. *J Orthop Sports Phys Ther.* 2018;48(5):A1-A38.
<https://www.jospt.org/doi/pdfplus/10.2519/jospt.2018.0302>. Accessed 2020 Jan 20.
See: Orthoses: 2010 Recommendation, page A17
17. National Institute for Health and Care Excellence. Low back pain and sciatica in over 16s: assessment and management. (*NICE guideline NG59*) 2016;
<https://www.nice.org.uk/guidance/ng59/resources/low-back-pain-and-sciatica-in-over-16s-assessment-and-management-pdf-1837521693637>.. Accessed 2020 Jan 20
See: Orthotics 1.2.4, page 7.

Appendix — Further Information

Previous CADTH Reports

18. Custom-made foot orthoses versus prefabricated foot orthoses: a review of clinical effectiveness and cost-effectiveness. (*CADTH Rapid response: summary with critical appraisal*). Ottawa (ON): CADTH; 2019:
<https://www.cadth.ca/custom-made-foot-orthoses-versus-prefabricated-foot-orthoses-review-clinical-effectiveness-and-cost>. Accessed 2020 Jan 20.

Randomized Controlled Trials

Custom Foot Orthotics Versus Prefabricated Shoe Inserts

19. Xu R, Wang Z, Ren Z, et al. Comparative study of the effects of customized 3d printed insole and prefabricated insole on plantar pressure and comfort in patients with symptomatic flatfoot. *Med Sci Monit*. 2019 May 12;25:3510-3519.
[PubMed: PM31079137](#)

Literature Review

20. Papuga MO, Cambron J. Foot orthotics for low back pain: the state of our understanding and recommendations for future research. *Foot (Edinb)*. 2016 Mar;26:53-57.
[PubMed: PM26896703](#)