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CADTH RAPID RESPONSE REPORT: SUMMARY OF ABSTRACTS

Orthotics Material for Patients Requiring Foot Orthotics: Clinical Effectiveness and Cost Effectiveness

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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.

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Research Questions

1. What is the clinical effectiveness of one orthotics material versus another orthotic material for patients requiring a foot orthotic?
2. What is the cost-effectiveness of one orthotics material versus another orthotic material for patients requiring a foot orthotic?

Key Findings

Two systematic reviews (one with a meta-analysis), one randomized controlled trial, and one non-randomized study were identified regarding the clinical effectiveness of orthotic materials for patients requiring a foot orthotic. No relevant health technology assessments or economic evaluations were identified.

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 foot orthoses and materials/equipment design. No methodological filters were used 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 July 31, 2019. 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	Patients of all ages requiring a foot orthotic
Intervention	One orthotic material (e.g., carbon fibre, leather, plastic, rubber or combination of material)
Comparator	Other orthotic material (e.g., carbon fibre, leather, plastic, rubber or combination of material)
Outcomes	Q1: Clinical effectiveness (e.g., patient quality of life, falls, adverse events) Q2: Cost-effectiveness
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized control trials, non-randomized studies, economic evaluations.

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 economic evaluations.

Two systematic reviews[1,2] (one with a meta-analysis),[1] one randomized controlled trial,[3] and one non-randomized study[4] were identified regarding the clinical effectiveness of orthotic materials for patients requiring a foot orthotic. No relevant health technology assessments or economic evaluations were identified.

Additional references of potential interest are provided in the appendix.

Overall Summary of Findings

Two systematic reviews[1,2] (one with a meta-analysis),[1] one randomized controlled trial,[3] and one non-randomized study[4] were identified regarding the clinical effectiveness of orthotic materials for patients requiring a foot orthotic.

The authors of one systematic review with a meta-analysis[1] summarized the comparative effectiveness of foot orthotics and suggested that there was a medium effect for reduction of forefoot plantar pressure for soft foot orthotics when compared to semi-rigid foot orthotics. The authors concluded that soft materials may lead to more forefoot plantar pressure reduction compared to semi-rigid materials.[1] The authors of another systematic review reported that altering the softness and texture of material had no effect on postural sway.[2] The primary outcome was number of falls, but there were no reported results for this outcome.[2] The authors of the systematic review concluded that material properties do not affect static balance or gait.[2]

The authors of one randomized controlled trial,[3] which focused on pediatrics, compared the clinical outcomes of serial casting with Bebax (leather) orthotics. The authors found that there was a cost savings with Bebax compared to serial casting, but there was no significant difference in clinical results, including in symptoms of heel valgus.[3]

The authors of one non-randomized study investigated functionally optimized foot orthotics (manufactured using selective laser sintering or fused deposition modelling) compared with standard foot orthotics.[4] The authors found that the functionally optimized foot orthotics provided equivalent or better patient experience compared with standard foot orthotics.[4] The authors reported no adverse reactions.[4]

References Summarized

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

1. 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. PubMed: PM31210785

2. Paton J, Hatton AL, Rome K, Kent B. Effects of foot and ankle devices on balance, gait and falls in adults with sensory perception loss: a systematic review. *JBI Database System Rev Implement Rep*. 2016 Dec;14(12):127-162. PubMed: PM28009675

Randomized Controlled Trials

Pediatrics

3. Herzenberg JE, Burghardt RD. Resistant metatarsus adductus: prospective randomized trial of casting versus orthosis. *J Orthop Sci*. 2014 Mar;19(2):250-256. PubMed: PM24248551

Non-Randomized Studies

4. Gibson KS, Woodburn J, Porter D, Telfer S. Functionally optimized orthoses for early rheumatoid arthritis foot disease: a study of mechanisms and patient experience. *Arthritis Care Res*. 2014 Oct;66(10):1456-1464. PubMed: PM23836484

Economic Evaluations

No literature identified.

Appendix — Further Information

Systematic Reviews

Alternative Comparator

5. Tenten-Diepenmaat M, van der Leeden M, Vliet Vlieland TPM, Roorda LD, Dekker J. The effectiveness of therapeutic shoes in patients with rheumatoid arthritis: a systematic review and meta-analysis. *Rheumatol Int.* 2018 May;38(5):749-762. PubMed: PM29556705

Pediatrics

6. Aboutorabi A, Arazpour M, Ahmadi Bani M, Saeedi H, Head JS. Efficacy of ankle foot orthoses types on walking in children with cerebral palsy: a systematic review. *Ann Phys Rehabil Med*. 2017 Nov;60(6):393-402. PubMed: PM28713039

Alternative Outcome

7. Eddison N, Mulholland M, Chockalingam N. Do research papers provide enough information on design and material used in ankle foot orthoses for children with cerebral palsy? A systematic review. *J Child Orthop*. 2017 Aug 1;11(4):263-271. PubMed: PM28904631

Alternative Population

8. McDaid C, Fayter D, Booth A, et al. Systematic review of the evidence on orthotic devices for the management of knee instability related to neuromuscular and central nervous system disorders. *BMJ Open*. 2017 Sep 5;7(9):e015927. PubMed: PM28877943

Mechanical Evaluations and Simulation Testing

9. Lo WT, Yick KL, Ng SP, Yip J. New methods for evaluating physical and thermal comfort properties of orthotic materials used in insoles for patients with diabetes. *J Rehabil Res Dev*. 2014;51(2):311-324. PubMed: PM24933729

10. Zou D, He T, Dailey M, et al. Experimental and computational analysis of composite ankle-foot orthosis. *J Rehabil Res Dev*. 2014;51(10):1525-1536. PubMed: PM25856154