TITLE: Prefabricated and Custom Made Foot Orthotics: A Review of the Clinical and Cost-Effectiveness

DATE: 27 May 2010

CONTEXT AND POLICY ISSUES:

Foot Orthotics are in-shoe devices designed to optimize lower limb function. They are used in the prevention or treatment of injury, pain, or disability. Custom made foot orthotics are molded or milled from an impression of a patient's foot to match the plantar surface. Prefabricated (off-the-shelf) orthotic devices are generically shaped but may allow some individual customization by heat molding or add-on posts. The time and resources to fit and manufacture a custom made orthotic is greater than for prefabricated devices. This report will review the clinical and cost-effectiveness of the two types of devices in order to help inform policy options.

RESEARCH QUESTIONS:

1. What is the clinical effectiveness of prefabricated foot orthotics and custom made foot orthotics?
2. What is the cost-effectiveness of prefabricated foot orthotics and custom made foot orthotics?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, CINAHL, The Cochrane Library (Issue 4, 2010), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between Jan 1, 2005 and Apr 29, 2010. No filters were applied to limit the retrieval by study type.

Studies that assessed biomechanical measures, or that were laboratory based, were excluded.
SUMMARY OF FINDINGS:

The search identified four systematic reviews that included orthotic devices.\textsuperscript{1-4} Two relevant RCTs\textsuperscript{5,6} identified in the search were discussed in the systematic reviews\textsuperscript{2,3} and therefore have not been summarized in this report. Two additional RCTs were found and are reviewed (Appendix 1).\textsuperscript{7,8}

Two additional systematic reviews of potential interest are listed in Appendix 2. These reviews included RCTs that evaluated custom made orthotics but did not include prefabricated orthotics as a comparator.

No health technology assessments, controlled clinical trials, or economic studies were identified in the search. Since there were a number of systematic reviews and RCTs identified in the search we did not include any observational studies in this report.

Systematic reviews and meta-analyses

A Cochrane review published in 2008 evaluated custom-made orthotics used for the treatment of foot pain (Appendix 1 Table 1).\textsuperscript{2} The report included 11 RCTs of pediatric and adult patients with different health conditions. Comparators included prefabricated orthotics, sham insoles, no intervention, supportive shoes, stretching, splints, or surgery. Custom orthotics were compared to pre-fabricated shoe inserts or orthotics in patients with juvenile idiopathic arthritis (1 study), rheumatoid arthritis (1 study), or plantar fasciitis (3 studies). These studies enrolled 16 to 190 patients and all were classified by the review authors as having a high risk of bias. None of the studies found a statistically significant difference between groups in the change in foot pain, or improvement in function after 6 weeks to 12 months of follow up. The review authors concluded that based on lower quality evidence, custom made orthotics are not more effective than prefabricated foot inserts in reducing pain or improving function in patients with arthritis or plantar fasciitis.\textsuperscript{2}

A second systematic review was found that assessed multiple interventions for the treatment of plantar heel pain and fasciitis (Appendix 1 Table 2).\textsuperscript{3} The report included 15 systematic reviews or RCTs on orthotics, other shoe inserts, taping, corticosteroid injections, extracorporeal shock wave therapy, local anesthetics, splints, stretching, surgery, or ultrasound therapy. They identified one RCT comparing custom made orthotics to prefabricated orthotics or placebo shoe inserts. This study\textsuperscript{8} was also included in the Cochrane review\textsuperscript{2} and found no difference between groups on pain or function after three months or 12 months. The authors concluded that prefabricated and custom orthotics were equally effective in reducing plantar heel pain and improving function based on this moderate quality evidence.\textsuperscript{3}

A systematic review conducted by Aaltonen et al. (2007)\textsuperscript{4} evaluated interventions used to prevent sports injuries (Appendix 1 Table 3). The authors identified 32 RCTs, of which five RCTs compared the injury rate among military recruits using custom made insoles, prefabricated insoles, or no insoles. One of the five studies (Finestone 2004) compared custom made orthotics to prefabricated orthotics. The study enrolled 874 participants who were followed for 14 weeks. There was no difference between groups on the incidence of lower extremity injuries. The trial was rated as moderate methodological quality by the review authors. The
review authors concluded that custom-made and prefabricated insoles were equally effective in preventing lower extremity injuries among military recruits.4

A fourth systematic review (Collins et al. 2007') evaluated foot orthotics used for the prevention or treatment of lower limb overuse conditions (Appendix 1 Table 4). The report included a total of 22 RCTs comparing orthotics to control (no orthotic), prefabricated orthotics, or other types of interventions. Of these studies, four RCTs were relevant to this report, and all have been discussed in the summaries of the previous systematic reviews.2,4 This systematic review included information on orthotic related adverse effects reported in eight of the studies. Four RCTs reported that discomfort was the main reason for discontinuing use of orthotics. In one trial, 21% of participants stopped use in the first 14 days due to discomfort. Other adverse effects reported were arch or metatarsal pain, shin splints, and slipping of orthotics in boots. The review authors concluded that there was no difference between custom and prefabricated orthotics for the prevention or treatment of lower limb overuse injuries, in the studies available to date.1

Randomized controlled trials

The RCT by Baldassin et al. 20097 compared custom-made to prefabricated foam orthotics in 142 adults with uncomplicated plantar fasciitis. To maintain blinding, patients in the prefabricated orthotic group underwent the same initial customization procedure. Outcome assessors were also blinded to the type of orthotic the patient received. Patients were assessed after four and eight weeks for changes in pain using the Foot Function Index (FFI). The patients enrolled had a mean age of 47 years, 75% were female, and most had a sedentary lifestyle. Seventy four per cent of patients completed the eight-week study. Both study groups reported reductions in pain over time. After eight weeks, the change from baseline in the FFI pain score was -23 points (SD 26) in the prefabricated orthotic group, and -29 (SD 32) in the customized orthotic group. There were no statistically significant differences between groups on the pain scores. The prefabricated group had higher pain scores than the custom orthotics group at four and eight weeks [mean difference 4 points (95% CI -4 to 12) on FFI], which was below the minimum clinically important difference of 13 points. The use of co-interventions, such as ice, or anti-inflammatory drugs, was similar in each group. The authors concluded that prefabricated and customized foot orthotics had similar effectiveness in the treatment of plantar fasciitis.7

The RCT by Whitford et al 20078 recruited 178 children with flexible excess foot pronation. Patients were allocated to one of three interventions: customized foot orthotic; prefabricated orthotic; or no treatment. Patients were assessed by a podiatrist (blinded to the treatment group) for pain, motor skills (speed, balance, coordination, and strength), exercise efficiency, and self perception after three and 12 months. The average age was 10 years and 53% of children were male. Ninety per cent of children completed the 12 month study. Pain was reported among 18.6% and 20.3% of patients at baseline in the prefabricated and custom-made orthotic groups, respectively. After 12 months, 25.9% and 32.7% of children in these groups reported pain. The authors reported there were no statistically significant differences between the prefabricated or custom orthotic group, compared to the control group, on any of the outcomes assessed. They did not report results comparing prefabricated to custom orthotics. In an analysis combining all three groups, statistically significant changes were found over time in all but three self perception measures. However, the authors reported that these changes were small and were
not of clinical importance. The authors concluded there was no evidence to justify the use of orthotics in children with flexible excessive foot pronation.\(^8\)

**Limitations**

The overall quantity and quality of evidence comparing custom made to prefabricated orthotics was limited. The systematic review authors expressed methodological concerns regarding selection of patients and allocation concealment, blinding, intention to treat analysis, small sample size, dropouts, and limited reporting of adverse effects. Blinding is difficult to achieve in studies such as these, and given the subjective nature of the outcome measures, the potential for bias in the outcomes reported should be considered. The Cochrane review rated all studies evaluating prefabricated orthotics as having a high risk of bias. No economic evaluations were identified.

**CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:**

The RCTs summarized in this review did not detect statistically significant differences between custom and prefabricated orthotics used in the prevention of injuries (1 RCT), or management of pain or disability related to juvenile idiopathic arthritis (1 RCT), rheumatoid arthritis (1 RCT), or plantar fasciitis (4 RCTs). There is evidence to suggest that custom or prefabricated orthotics are not necessary in children with excessive foot pronation. Most of the studies had methodological limitations that could potentially bias the findings.

No evidence was found on the cost-effectiveness and therefore conclusions about the cost-effectiveness of custom made and prefabricated foot orthotics cannot be made.

Overall, the evidence appears to suggest that custom foot orthotics and prefabricated orthotics have similar effectiveness. The limited quality of the evidence identified, as well as the lack of economic studies, may be a consideration for decision-making about custom made foot orthotics or prefabricated (off-the-shelf) foot orthotics.

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REFERENCES:


APPENDIX 1: Summary of Systematic Reviews

Table 1. Systematic Review by Hawke et al. 2008

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<tr>
<th>Title</th>
<th>Custom-made orthoses for the treatment of foot pain</th>
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| Methods | Search: multiple databases until June 2007; hand-search of reference lists; any language  
Population: patients with foot pain  
Intervention: custom made foot orthotics  
Comparator: any comparator  
Outcomes: foot pain, function, disability, HRQL, satisfaction, adverse effects, compliance  
Study designs: RCTs, CCTs  
Selection/extraction: two independent researchers |
| Included Studies | 11 RCTs included (n=1,332, range 20 to 255) |
| Results | Juvenile idiopathic arthritis (1 RCT, n=30, 3 month follow up)  
- no statistically significant differences between groups in foot pain, function, or disability scores.  
Rheumatoid arthritis (1 RCT, n=16, 3 month follow up)  
- no statistically significant differences between groups in foot pain or function at 6 weeks or 3 months.  
Plantar fasciitis (3 RCTs, n=450, 2 to 12 month follow up)  
- no statistically significant differences between groups were detected in foot pain after 2 to 12 months.  
- Function and compliance were reported in 1 RCT. No statistically significant differences were detected between groups at 3 or 12 months. |
| Authors’ Conclusions | Based on lower quality evidence, custom-made orthoses are not more effective than pre-fabricated foot inserts for reducing foot pain or improving function in patients with rheumatoid arthritis or plantar fasciitis. |
| Limitations | Studies in all patient groups were rated as lower quality evidence with a high risk of bias. It is difficult to blind participants to the type of orthotic. |

CCT=controlled clinical trial; HRQL=health related quality of life; RCT=randomized controlled trial
Table 2. Systematic review by Landorf and Menz 2008³

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<th>Title</th>
<th>Plantar heel pain and fasciitis</th>
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| Methods | Search: multiple databases until June 2007; grey literature search and hand-search of reference lists; any language  
Population: patients with plantar fasciitis or heel pain  
Interventions: any treatment or comparator  
Study designs: systematic reviews, RCTs with 20 or more participants; 80% follow up. Excluded open label studies unless blinding was not possible.  
Outcomes: clinical outcomes, adverse effects  
Selection/extraction: librarian verified by lead author |
| Included Studies | 15 systematic reviews or RCTs |
| Results | Custom orthotics compared to prefabricated orthotics (1 RCT [Landorff 2006⁶ n=135]  
- No statistically significant differences between groups in pain or function at 3 or 12 months |
| Authors’ Conclusions | Custom made orthotics are as effective as prefabricated orthotics at reducing pain and improving function in patients with plantar heel pain based on moderate quality evidence. |
| Limitations | Limited description of systematic review methods. Quantity and quality of studies limited. |

RCT=randomized controlled trial
Table 3. Systematic review by Aaltonen et al. 2007

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<th>Title</th>
<th>Prevention of Sports Injuries: Systematic Review of Randomized Controlled Trials</th>
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| Methods | Search: multiple databases until December 2005; hand-searched reference lists; English language  
Population: patients at risk for sports injuries  
Interventions: any treatment used for the prevention of sports injuries  
Study designs: RCTs  
Outcomes: injury rate or number of injured individuals  
Selection/extraction: two independent reviewers |
| Included Studies | 32 RCTs, n=24,931 |
| Results | 5 RCTs (including 6 comparisons) evaluated various types of insoles (custom or prefabricated) compared to no insoles in military recruits (n=2,446; age range 17 to 27 years).  
- Use of insoles reduced the risk or injury by 30% or more in all 6 comparisons.  
1 RCT (Finestone 2004) compared custom-made orthotics to prefabricated orthotics (n=874) after 14 weeks.  
- No differences were observed between groups on the incidence of lower extremity overuse injuries. |
| Authors’ Conclusions | Insoles were effective in reducing sports injuries. Prefabricated and custom-made insoles showed similar effectiveness in the prevention of sports injuries based on data from 1 study. |
| Limitations | Study quality scores on trials evaluating insoles ranged from 1 to 7 out of a possible 11 points based on randomization and sample comparability, blinding dropouts, outcome measures and intention to treat analysis.  
Quality score of Finestone 2004 was 4 out of 11 |

RCT=randomized controlled trial
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<th>Table 4. Systematic review by Collins et al. 2007&lt;sup&gt;1&lt;/sup&gt;</th>
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| **Methods** | Search: multiple databases until September 2005; hand-search of reference lists; any language  
Population: patients with, or at risk of, lower limb overuse conditions  
Interventions: foot orthotics  
Comparator: any comparator  
Study designs: RCTs  
Outcomes: clinical outcomes, adverse effects, costs  
Selection/extraction: two independent reviewers |
| **Included Studies** | 22 RCTs (prevention 7 studies, treatment of injuries 15 studies) |
| **Results** Custom orthotics versus prefabricated orthotics | Prevention of overuse injuries:  
- 1 RCT (Finestone 2004) showed no difference between groups (RR 1.14 [95% CI 0.9 to 1.4])  
Treatment of plantar fasciitis:  
- 3 RCTs all showed no difference between groups (pooled data from 2 RCTs: RR 0.88 [95% CI 0.4 to 1.8])  
Adverse effects reported in 8 of 22 papers:  
- 2 RCTs reported no adverse effects occurred  
- In 1 RCT the incidence of adverse effects were similar between groups  
- Discomfort was the main reason for discontinuing use or orthotics in 4 RCTs  
- Other adverse effects reported were arch or metatarsal pain, shin splints, and slipping of orthotics in boots. |
| **Authors’ Conclusions** | There is no difference between custom orthotics and prefabricated orthotics for the prevention or treatment of lower-limb overuse injuries. |
| **Limitations** | Studies were generally of lower methodological quality, with unclear definitions of what constitutes a foot orthotic. Follow up time in trials was short. |

CI=confidence interval; RCT=randomized controlled trial; RR=relative risk
APPENDIX 2: Other systematic reviews of interest
