Journal of Athletic Training 2011;46(1):103–106

www.nata.org/jat

Foot Orthoses in Lower Limb Overuse Conditions: A Systematic Review and Meta-Analysis—Critical Appraisal and Commentary

Randy R. Richter, PhD, PT; Tricia M. Austin, PhD, PT, ATC; Mark F. Reinking, PhD, PT, ATC, SCS

Department of Physical Therapy and Athletic Training, Doisy College of Health Sciences, Saint Louis University, St Louis, MO

Reference/Citation: Collins N, Bisset L, McPoil T, Vicenzino B. Foot orthoses in lower limb overuse conditions: a systematic review and meta-analysis. *Foot Ankle Int.* 2007;28(3):396–412.

Clinical Question: Among patients with or at risk for musculoskeletal overuse conditions, (1) do foot orthoses provide clinically meaningful improvements, and (2) are foot orthoses cost-effective?

Data Sources: Studies published through September 28, 2005, were identified by using MEDLINE, EMBASE, CINAHL and Pre-CINAHL, Physiotherapy Evidence Database (PEDro), PubMed, SPORTDiscus, Biological Abstracts, Web of Science, Allied Health and Complementary Medicine Database, and the full Cochrane Library. The authors did not provide the search strategy used. Reference lists of included randomized controlled trials (RCTs) and identified systematic reviews were searched by hand.

Study Selection: Studies were included if (1) they were RCTs that included the use of foot orthoses (either custom or prefabricated) in 1 of the intervention groups, (2) the clinical problem was an overuse condition as defined by the American College of Foot and Ankle Orthopedics and Medicine guidelines for which foot orthoses were recommended, and (3) at least 1 clinically relevant outcome was measured for a minimum of 1 week. Limits were not placed on year of publication, status of publication, or language.

Data Extraction: The journal, authors, and author affiliations of included RCTs were masked from 2 of the reviewers who independently assessed the included RCTs for methodologic quality using a modified PEDro scale plus 3 additional items (justification of sample size, use of outcome measures with known validity and reliability, and reporting of adverse or side effects). Disagreements on methodologic quality were resolved with consensus or by a third reviewer. The effect sizes for the included RCTs were represented by relative risk (RR) for dichotomous outcomes and standardized mean difference (SMD) for continuous data. Confidence intervals (CIs) were reported for RR and SMD. Study data were extracted directly from each of the included studies. If provided, data from intention-to-treat analysis were extracted. Study authors were contacted when insufficient data were reported. A meta-analysis (random-effects model) was conducted using Review Manager (version 4.2; The Nordic Cochrane Centre, Copenhagen, Denmark).

Main Results: The search identified 3192 potentially relevant studies. Full articles were retrieved for 327 studies. Twenty-two of the 327 studies met the inclusion criteria. Because the authors of 1 study used the same methods to report on 2 populations, a total of 23 RCTs were included in the systematic review. Prevention of lower limb overuse conditions with the use of foot orthoses was reported in 8 RCTs (7 studies). The effect of foot orthoses in the treatment of lower limb overuse conditions was reported in 15 RCTs. Of the 23 RCTs, the cost-effectiveness of foot orthoses was reported in 2 and the adverse effects of foot orthoses were reported in 8. Across the prevention RCTs, data were available for analysis for a range of 47 to 417 participants with 8 to 16 weeks of follow-up. Based on 4 RCTs in which the researchers examined prevention of lower limb overuse conditions with foot orthoses versus control in military personnel, the RR was 1.49 (95% CI = 1.07, 2.08). A clinically beneficial effect size was set a priori at 1.5 or greater for the foot-orthoses group or at 0.7 or less for the comparison group. Based on 2 RCTs reported in 1 study of the use of custom versus prefabricated foot orthoses for prevention of lower limb overuse conditions, no significant difference in risk was found (RR = 1.14, 95% CI = 0.90, 1.44). In their calculating and reporting of RR, the authors do not appear to have followed convention. Across the treatment RCTs, data were available for analysis for a range of 18 to 133 participants with 8 to 52 weeks of follow-up. The authors of the treatment RCTs reported a variety of outcome measures. Two of these, patient-perceived treatment effect (PPE) and pain on the visual analog scale (VAS), were used to calculate an overall treatment effect (PPE as RR and VAS as SMD). Based on 2 RCTs examining foot orthoses versus control, no significant difference in PPE was found (RR = 1.01, 95% CI = 0.61, 1.68). Based on 2 RCTs in which custom versus prefabricated foot orthoses were examined, no significant difference in PPE was found (RR = 0.88, 95% CI = 0.42, 1.81). The VAS data reported in the text appear to contradict the VAS data reported in Figure 2 for foot orthoses versus control for the treatment of lower limb overuse conditions. Specifically, the lower limit of the CI in the text was negative (−0.28) and in Figure 2 was positive. Because of this apparent contradiction, we did not interpret these data. Authors of 2 RCTs reported cost-effectiveness, but the data could not be pooled. Adverse events were reported in 8 of the 22 studies. The most common adverse effect reported was discomfort, which was the main reason for discontinuing foot-orthoses use in 2 studies.

Conclusions: The evidence supports the use of foot orthoses to prevent a first occurrence of lower limb overuse conditions and shows no difference between custom and prefabricated foot orthoses. The evidence was insufficient to recommend foot orthoses (custom or prefabricated) for the treatment of lower limb overuse conditions.

Key Words: overuse injuries, foot orthotics

COMMENTARY

Lower limb overuse injuries commonly are seen by certified athletic trainers across sports and competitive levels. The use of foot orthoses for the prevention or treatment of these injuries is recommended in standard athletic training textbooks.[1] Underpinning the use of foot orthoses is a theoretical model that links abnormal foot motion with excessive tissue stresses in the foot, leg, knee, hip, and spine that, over time, lead to tissue breakdown and pain.[2] Limited evidence has demonstrated the effect of foot orthoses on lower limb kinetics.[3] Eickhoff et al[4] reported athletes' subjective descriptions of decreased lower limb pain with the use of foot orthoses. The authors[5] of a systematic review on the use of custom orthotics for foot pain concluded that gold-level evidence (a well-conducted randomized controlled trial [RCT] powered to find a 20% relative difference) supports the use of orthotic devices to treat painful pes cavus and that silver-level evidence (an RCT with less than 20% relative difference, a nonrandomized trial, or a well-conducted case-control study) supports their use to treat plantar fasciitis. To promote evidence-based clinical decision making, Collins et al[6] performed this systematic review of RCTs, in which they examined the efficacy of using foot orthoses to manage lower limb overuse injuries.

As noted, effect sizes were represented by 2 statistics, relative risk (RR) and standardized mean difference (SMD) and their respective confidence intervals (CIs). When studying treatments designed to reduce the number of harmful events or outcomes, authors could base the RR on the 2 different ratios of proportions.[7] First, RR could be represented as the ratio of the proportion of people in the treated group who had a harmful event or outcome to the proportion of people in the control group who had a harmful event or outcome. The RR calculated in this manner indicates the amount of risk for a harmful event or outcome still present when people receive the experimental treatment.[8] An RR less than 1.0 indicates that the treatment is reducing the risk of a harmful event or outcome.[8] Conversely, authors could report the RR as the ratio of the proportion of people in the treated group who did not have a harmful event or outcome to the proportion of people in the control group who did not have a harmful event or outcome. In this case, an RR indicates the amount of "risk" for not having a harmful event or outcome that is still present when people receive the experimental treatment. An RR greater than 1.0 indicates that the treatment is increasing the "risk" of not having a harmful event or outcome. Because Collins et al[6] reported the RR for prevention of lower limb overuse conditions with foot orthoses versus the control condition in military personnel as 1.49 and noted that their meta-analysis demonstrated a preventive effect for orthoses, it appears that they calculated RR as the proportion of people in the treated group who did not have an overuse condition to the proportion of people in the control group who did not have an overuse condition. Collins et al[6] did not provide the data for their RR calculations, making interpretation of their RR results difficult (Table). Regardless of the ratio used to calculate RR, CIs of RR that include 1.0 indicate no significant difference in risk between groups.[7]

The SMD is used when a continuous outcome is measured with different scales in multiple studies.[13] The SMD is in standardized units, making it possible to combine the results of studies in which different scales were used. The CIs of SMD that include 0 indicate no significant difference between groups.[14]

We used the AMSTAR tool (a measurement tool to assess systematic reviews)[9,10] to frame our critical appraisal and commentary of the Collins et al[6] systematic review. The Table describes our review of their systematic review using items from the AMSTAR tool and our interpretative comments.

After appraising a systematic review, the question for an athletic trainer is how to apply the study results in an evidence-based manner. Evidence-based practice requires the athletic trainer to recognize that evidence might not indicate a definitive course of action for all patients. When making a clinical decision, an athletic trainer must incorporate the evidence; his or her clinical judgment; and the patient's values, preferences, and circumstances.[8] Collins et al[6] set a clinically beneficial effect in favor of either foot-orthoses or comparison group as RR greater than 1.5 or less than 0.7. The 95% CI for RR in the prevention studies was 1.07 to 2.08. Because this CI does not include 1.0, the result is statistically significant; however, whether this result represents a clinically beneficial effect requires clinical judgment. These results point out the usefulness of considering the upper and lower limits of a CI when interpreting study results.[8] The lower limit of the CI (1.07), which was close to 1.0, suggested almost no effect. The upper limit (2.08) suggested an effect. Interpreting CIs for clinical meaningfulness requires evaluation of the risks and benefits of a preventive strategy for a lower limb overuse condition in light of the patient's values and circumstances. For example, when considering injury risk, using a prefabricated foot orthosis to prevent overuse injury in a competitive high school cross-country athlete with excessive pronation seems reasonable, whereas using it to prevent overuse injury in an adult recreational tennis player who has a normal foot and plays occasionally does not seem reasonable.

Another area requiring clinical judgment is determining if study participants are similar enough to those considered for the intervention to warrant application of the intervention. In relation to the data cited by Collins et al,[6] all of the prevention RCTs were conducted with military personnel, who might differ from the population typically seen by an athletic trainer (eg, in sex and age profiles, physical fitness level, and training demands); therefore, athletic trainers must use their clinical judgment when determining if these results apply to their patients.

When discussing the use of foot orthoses with a patient, 2 pragmatic findings from Collins et al[6] should be considered: the cost of prefabricated foot orthoses is relatively low, and the adverse effects of using foot orthoses are minor. Patients likely would value low-cost

Table. Review of Collins et al[6] Using the AMSTAR[a] Tool[9,10]

AMSTAR Item	Review[b]	Comment
1. Was an "a priori" design provided?	Can't answer	Collins et al[6] did not indicate if the study design was established before conducting the review. Determining such things as study inclusion and exclusion criteria a priori might reduce possible bias when selecting studies to include in a systematic review.
2. Was there duplicate study selection and data extraction?	Yes/can't answer	Two individuals independently extracted data related to study methods (ie, random assignment, blinding). A third reviewer resolved disagreements. The authors did not state if study selection or extraction of study results was performed by 2 independent reviewers. They also gave no indication of how disagreements on study selection or extraction of study results were resolved. When more than 1 person selects studies and extracts, study results, errors, and bias might be reduced.[8,11]
3. Was a comprehensive literature search performed?	Yes	The search strategy was developed using guidelines provided by Alderson et al.[12] The particular search terms used were not reported, making it difficult to assess and replicate the search strategy.
4. Was the status of publication (ie, grey literature) used as an inclusion criterion?	Yes	No restriction was placed on status of publication, and conference presentations were searched. Providing more information related to the conference presentations searched (ie, which conferences, what dates) and the results of this part of the search (ie, the number of abstracts from conferences retrieved and included or excluded) would help the reader determine the effect that the grey literature might have had on the results of the systematic review.
5. Was a list of studies (included and excluded) provided?	Yes/can't answer	Although a flowchart illustrating the number of included and excluded studies with the reasons for exclusion was provided, a list of excluded studies was not provided. Listing these studies with the main reason for excluding them informs the reader that they were considered.[11]
6. Were the characteristics of the included studies provided?	Yes	Although group-level data needed to calculate standardized mean difference were provided, the data needed to calculate the relative risk were not provided. Providing these data would enable the interested reader to better understand how the relative risk was calculated.
7. Was the scientific quality of the included studies assessed and documented?	Yes	Collins et al[6] used a modified Physiotherapy Evidence Database (PEDro) scale to assess the methodologic quality of the studies.
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	Yes	All trials included in the meta-analysis had random assignment; however, none of the authors of randomized controlled trials for prevention reported using blinding or allocation concealment. In the Discussion and Summary sections, Collins et al[6] noted the limitations of this body of literature when interpreting the results of the systematic review.
9. Were the methods used to combine the findings of studies appropriate?	Can't answer	The Cochran *Q* test for heterogeneity and I^2 were not reported. Without this information, it is difficult for the reader to make informed judgments when interpreting the meta-analysis results.
10. Was the likelihood of publication bias assessed?	Can't answer	Although Collins et al[6] maintained that publication bias was reduced, they did not report an assessment of publication bias.
11. Was the conflict of interest stated?	No	Authors of systematic reviews should report if they do or do not have a conflict of interest and if the authors of included randomized controlled trials did or did not report conflicts of interest. Collins et al[6] did not address either of these areas of conflict of interest.

[a] AMSTAR is a measurement tool used to assess the methodologic quality of systematic reviews. Explanatory statements for each AMSTAR item can be found in the original reports.[9,10]

[b] *Can't answer* indicates that the item was relevant but was not described by the authors.

and low-risk interventions that reduce the risk of injury. Consequently, when incorporating the evidence and patient values into the clinical decision, we suggest athletic trainers consider the potential benefits of prefabricated foot orthoses to prevent a first occurrence of lower limb overuse injury.

The use of foot orthoses for the treatment of lower limb conditions also requires clinical judgment. The evidence reported by Collins et al[6] neither supports nor refutes the use of foot orthoses for the treatment of lower limb overuse conditions. However, as they noted, this finding is based on a "generally poor research base"[6] that included studies that were highly heterogeneous in condition, age, and symptom duration of participants, thus precluding a clear conclusion supporting or refuting the use of foot orthoses for this

purpose by athletic trainers. Additional evidence to aid in the clinical judgment exists. As noted, the cost of prefabricated foot orthoses is low, and few adverse effects have been reported with the use of foot orthoses. Furthermore, athletes report decreased lower limb pain with the use of foot orthoses.[4] Although Collins et al[6] did not support or refute the use of orthoses to treat lower extremity overuse injury, we believe that, based on the low risk and potential benefits of this intervention, athletic trainers should consider the use of foot orthoses as part of the treatment of an athlete with a lower limb overuse injury.

REFERENCES

1. Starkey C, Johnson G. American Academy of Orthopaedic Surgeons. *Athletic Training and Sports Medicine.* 4th ed. Sudbury, MA: Jones and Bartlett Publishers; 2006.
2. Tiberio D. Pathomechanics of structural foot deformities. *Phys Ther*. 1988;68(12):1840–1849.
3. McMillan A, Payne C. Effect of foot orthoses on lower extremity kinetics during running: a systematic literature review. *J Foot Ankle Res*. 2008;17(1):13.
4. Eickhoff CA, Hossain SA, Slawski DP. Effect of prescribed foot orthoses on medial tibial stress syndrome in collegiate cross-country runners. *Clin Kinesiol*. 2000;54(4):76–80.
5. 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, doi: 10.1002/14651858.CD006801.pub2
6. Collins N, Bisset L, McPoil T, Vicenzino B. Foot orthoses in lower limb overuse conditions: a systematic review and meta-analysis. *Foot Ankle Int*. 2007;28(3):396–412.
7. Simon SD. Understanding the odds ratio and the relative risk. *J Androl*. 2001;22(4):533–536.
8. Guyatt G, Drummond R, Meade MO, Cook DJ, eds. *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice.* 2nd ed. New York, NY: McGraw-Hill Medical; 2008.
9. Shea BJ, Grimshaw JM, Wells GA, et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Med Res Methodol*. 2007;7:10.
10. Shea BJ, Hamel C, Wells GA, et al. AMSTAR is a reliable and valid measurement tool to assess the methodological quality of systematic reviews. *J Clin Epidemiol*. 2009;62(1):1013–1020.
11. Higgins JPT, Deeks JJ. Selecting studies and collecting data. In: Higgins JPT, Green S, eds. *Cochrane Handbook for Systematic Reviews of Interventions*. Chichester, UK: The Cochrane Collaboration and John Wiley & Sons; 2008:151–185.
12. Alderson P, Green S, Higgins JPT, eds. Cochrane reviewer's handbook 4.2. Updated December 2003. In: *The Cochrane Library.* Issue 1. Chichester, UK: John Wiley & Sons; 2004.
13. Deeks JJ, Higgins JPT, Altman DG. Analyzing data and undertaking meta-analysis. In: Higgins JPT, Green S, eds. *Cochrane Handbook for Systematic Reviews of Interventions*. Chichester, UK: The Cochrane Collaboration and John Wiley & Sons; 2008:243–296.
14. Sim J, Reid N. Statistical inference by confidence intervals: issues of interpretation and utilization. *Phys Ther*. 1999;79(2):186–195.

Address correspondence to Randy R. Richter, PhD, PT, Department of Physical Therapy and Athletic Training, Doisy College of Health Sciences, Saint Louis University, 3437 Caroline Street, St Louis, MO 63104. Address e-mail to richterrr@slu.edu.