

Evidence-Based Podiatric Medicine

Importance of Systematic Reviews in Clinical Practice

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Due to the exponential increase in the quantity and quality of podiatric medicine–related research during the past decade, podiatric physicians are inundated with an insurmountable volume of research relevant to clinical practice. Systematic reviews can refine this literature by using explicit, rigorous, and reproducible methods to identify, critically appraise, and synthesize the best evidence from all clinical trials to answer clearly defined clinical questions. The Cochrane Collaboration is an international not-for-profit organization created to improve the user-friendliness and accessibility of medical literature mainly through preparing and maintaining systematic reviews of health-care interventions. The Cochrane Library currently contains more than 50 podiatric medicine–relevant systematic reviews summarizing and synthesizing evidence from many hundreds of randomized controlled trials evaluating interventions for foot problems. Although more than 60 countries worldwide have open online access to The Cochrane Library, in the United States, only the state of Wyoming has free access to full-text reviews. In an era demanding an evidence-based approach for every clinical intervention, high-quality systematic reviews streamline podiatric medical literature by reducing the time, cost, and training necessary to establish a solid evidence base for practice. (J Am Podiatr Med Assoc 99(3): 260-266, 2009)

The motivations of podiatric physicians involved in clinical decision making are complex.¹ Guidance is conventionally drawn from a combination of clinical and personal experiences, research evidence, patient preferences, and applicable regulations.^{2,3} Since the middle of the 20th century, the expected contribution of evidence to the clinical decision-making process in professions such as podiatric medicine has increased markedly.³ This process of incorporating the conscientious, explicit, and judicious use of current best evidence in decision making has been termed *evidence-based practice*.⁴

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Developing an Evidence Base for Podiatric Medical Practice

The evidence-based movement has provoked an exponential increase in the quantity and quality of research evidence available to podiatric physicians.^{2,3} The MEDLINE database currently contains more than 16 million predominantly English-language citations.⁵ When searching by the term *foot* alone, more than 75,000 publications are retrieved. Although this figure in isolation may be intimidating, an investigation⁶ in the mid-1990s found that electronic searching of MEDLINE yielded not even half of all randomized controlled trials relevant to a topic. The current rate of publication of new biomedical research articles is approximately 5,000 per day.⁷ As a result, podiatric physicians are inundated with unmanageable amounts of information,⁸ and clinically relevant research is likely to be lost among the many articles left unnoticed and unread by any particular podiatric physician.¹ As T. S. Eliot posed in the poem “The Rock,” “Where is the knowledge we have lost in information?”^{9(p96)}

Even if a podiatric physician manages to locate a relevant article in the literature, the subsequent task of full-text retrieval, appraisal, and synthesis into the greater research body can be discouragingly time-consuming and mentally taxing.¹ Perhaps not surprisingly, there are reports of mounting conviction among health-care providers that the implementation of research findings into practice is a complex and chaotic task.² This finding is highlighted by recent research¹⁰ suggesting that podiatric physicians who prescribe custom foot orthoses rely on their undergraduate training rather than on current best evidence.

A broad research body evaluating interventions for foot problems is accumulating. At present, however, this research is largely uncoordinated and is home to a diverse range of inconsistencies spanning trial methods, trial quality, terminology, participant compliance, adjunctive therapy, outcome measures, and methodological and statistical reporting. This variation has made understanding and assimilating the available evidence particularly challenging for podiatric physicians and for health-care users (patients) and policy decision makers (eg, health insurance companies).

Systematic Reviews in Evidence-Based Practice

To encourage the development of evidence-based podiatric medical practice, the research community must address the rising despondence and provide podiatric physician-friendly avenues for the transfer of research findings from the medical literature to the clinical setting. One viable option is to conduct reviews and more robust systematic reviews of scientific articles.³ Reviews are capable of refining large volumes of literature into efficient and informative packages that may be integrated into clinical practice with less difficulty than the numerous primary research articles.^{8, 11} A classic example published in the *Journal of the American Podiatric Medical Association* (JAPMA) is by Landorf and Keenan,¹² "Efficacy of Foot Orthoses: What Does the Literature Tell Us?" Understandably, many medical literature users prefer this review format to the original publications from which the reviews were derived.¹

Reviews, however, are not impervious to the effects of bias or systematic or random errors. This became widely recognized in the late 1980s when groups of health-care professionals drew attention to the poor scientific quality of the narrative, heavily opinionated health-care review articles.¹³⁻¹⁵ Often, these types of reviews evolve from the authors' previous thoughts about a particular topic, which may lead to selective use of the available evidence. To help sup-

port a particular argument, authors may, for example, assign equal importance to the findings from poor-quality studies as to those from high-quality studies. Worse still is the blatant disregard of evidence from high-quality studies if such studies do not support the authors' argument. Dissatisfaction from such biased reviews led to emergence of the precise, thorough, and robust methods of systematic reviews.^{16, 17} Systematic reviews have since been acclaimed as the highest level of evidence supporting interventions.¹⁸

Systematic reviews adopt explicit, rigorous, and reproducible methods to identify, critically appraise, and synthesize all relevant evidence from clinical trials (typically randomized controlled trials) to answer clearly defined clinical questions.^{11, 17, 19} Systematic reviews can be used to evaluate the consistency of treatment effects of interventions, to investigate methodological differences between studies (heterogeneity), to generate new clinical questions, and to explore the generalizability of findings to clinical practice regarding variations in patients, clinical settings, and treatments.^{8, 11, 17}

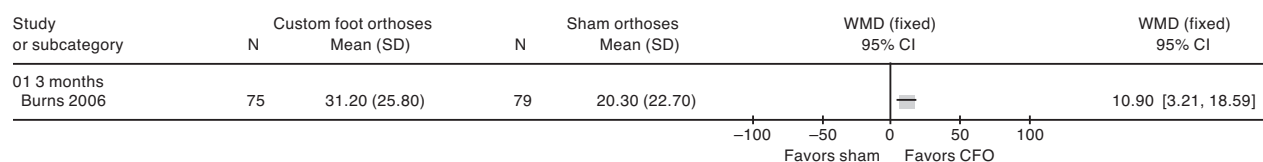
Systematic reviews may also incorporate a meta-analysis, whereby quantitative results of two or more primary studies are pooled.¹ By pooling data from appropriate trials, meta-analysis produces an overall estimate of the treatment effect that is generally more precise and more likely to detect a treatment effect if one exists (increased statistical power), mainly because of an increased total sample size of participants.^{8, 17} Results of meta-analyses are typically presented graphically in a forest plot.^{11, 20} Figure 1 presents an example of two forest plots and guidelines for interpretation. More detailed guidelines are available in the literature.^{17, 20}

Stakeholders in Evidence-Based Podiatric Medicine

Systematic reviews can help all stakeholders in the health-care system make informed decisions about podiatric medical care: 1) podiatric physicians can access efficient, contemporary, and comprehensive evidence with which to inform and monitor clinical practice; 2) patients can obtain concise information on potential treatments and associated risks; 3) health policy makers may use results of systematic reviews when writing practice guidelines, clinical decision analyses, economic evaluations, and legislations^{1, 3, 8}; and 4) researchers can use systematic reviews to form, refine, and justify hypotheses, estimate sample size, and guide methods when planning future clinical trials.¹ An often-quoted metaphor describes the systematic review as "a tower of statistical power that al-

A

Comparison 01 Custom foot orthoses versus sham orthoses for painful cavus feet
Outcome: 01 Foot pain



B

Comparison 04 Custom foot orthoses versus no intervention or standard intervention for foot pain in rheumatoid arthritis
Outcome: 02 Foot pain 3 months

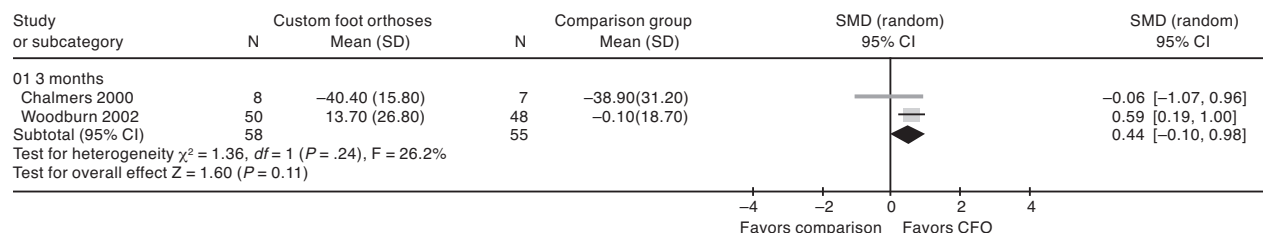


Figure 1. A, Forest plot of single-trial data.^{21, 22} B, Forest plot with meta-analysis of multiple-trial data.^{21, 23, 24} N indicates the number of participants per group included in the analysis; Mean (SD), each group's mean score (change or follow-up) and its standard deviation; and WMD (weighted mean difference) or SMD (standardized mean difference), the difference (treatment effect) between the mean scores of groups in the analysis. In A, the difference in mean foot pain improvement between people using custom (CFO) and sham foot orthoses was 10.9 points on a 101-point scale and was statistically significant. The shaded box is centered over the point estimate of effect (the WMD). When data from two or more trials are combined (B), the size of the shaded box indicates the weight (influence) of the data in meta-analysis. Trials with larger samples or more precise data are given more weight. The horizontal line running through the shaded box indicates the upper and lower limits of the 95% confidence interval (CI). Wider intervals indicate lower precision in the estimate of treatment effect. If the line crosses the vertical line of no effect, the effect is not statistically significant. The black diamond (B) indicates the result of the meta-analysis, when data from two or more trials are pooled. The diamond is centered over the pooled point estimate, and its horizontal tips represent the 95% confidence interval (CI). If any part of the diamond crosses the vertical line of no effect, the effect is not statistically significant. To further understand the language of Cochrane systematic reviews, a glossary of terms is available at <http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/glossary.pdf>.

lows researchers to rise above the body of evidence, survey the landscape and map out future direction.”^{25(p461)} We believe that this also applies to podiatric physicians in clinical practice, where systematic reviews can expose the best evidence from the entire field of relevant research. This source of evidence can be kept fresh by systematic updates of the review to ensure that the most recent research is included.

Limitations and Misperceptions

Although Cochrane systematic reviews provide high-level evidence that can inform practice and policy, they are not impervious to some limitations and misperceptions. One common misperception is that a lack of evidence indicates that an intervention is not effective. This is not the case. Altman and Bland²⁶ elo-

quently coined the phrase *absence of evidence is not evidence of absence* in response to this issue. A clear example is found in the recent systematic review “Custom-made Foot Orthoses for the Treatment of Foot Pain.”²¹ This review summarized and synthesized evidence from all randomized controlled trials that evaluated the effectiveness of custom foot orthoses for the treatment of any type of foot pain. To date, however, only five conditions causing foot pain have been assessed in randomized controlled trials: plantar fasciitis, pes cavus, hallux valgus, rheumatoid arthritis, and juvenile idiopathic arthritis. For all other types of foot pain, no evidence from randomized controlled trials is available. This does not indicate that custom foot orthoses are not effective for all other types of foot pain. In such cases, evidence-based medicine recommends that the best available evi-

dence be used to inform clinical practice. This may mean, then, that findings from less robust studies (ie, lower-level evidence, such as case studies or case series) need to be used when better-quality evidence (such as randomized controlled trials) is not available.

A second limitation concerns the process of determining the relevance of a review to individual patients.²⁷ Systematic reviews should report details of the types of participants in the trials included in the review. Participant characteristics will often be included in a table, and it is up to the reader to assess this detail and to decide whether the types of participants, or indeed the interventions used, are sufficiently similar to translate the findings to individual patients.

Developing Systematic Reviews

Systematic reviews have a great potential to strengthen the link between best research evidence and clinical practice.¹ However, the task of extracting the research evidence encoded in the millions of existing clinical studies and incorporating the best of these into systematic review literature is enormous.³ The undertaking has been likened, in scope and importance, to the Human Genome Project.²⁸

The Cochrane Collaboration

The Cochrane Collaboration was established in 1993 as an international not-for-profit organization aiming to help people make well-informed decisions about health care mainly by preparing, maintaining, and promoting the accessibility of systematic reviews of the effects of health-care interventions.^{1, 29, 30} The Cochrane Library (<http://www.thecochranelibrary.com>) was the first large-scale product of The Cochrane Collaboration.^{1, 30} The Cochrane Library consists of a quarterly updated online collection of multidisciplinary medicine databases. Issue 1 of the 2009 Cochrane Database of Systematic Reviews contains more than 5,500 systematic reviews of health-care interventions.³¹ More than 50 of these reviews are directly relevant to podiatric medicine (Table 1).

Many countries and regions have provisions for residents to freely access The Cochrane Library online, including Australia; New Zealand; the United Kingdom; Ireland; Norway; Sweden; Finland; Poland; India; Latin America and the Caribbean; the Canadian provinces of New Brunswick, Saskatchewan, and Nova Scotia; the Canadian Northwest Territories, Nunavut, and Yukon; and all 53 World Bank-listed low-income countries.⁸⁵ In the United States, only the state of Wyoming currently has free access to full-text reviews in The Cochrane Library. For those accessing

The Cochrane Library from regions without free access to full-text reviews, review abstracts are freely accessible, but full-text versions currently cost \$29.95. In the future, podiatric medicine journals such as JAPMA may also publish important duplicates of Cochrane systematic reviews, since The Cochrane Collaboration permits republication provided it does not interfere with publication of the original review by The Cochrane Collaboration. The Cochrane Library is also available on a personal digital assistant from Skyscape Inc (Marlborough, Massachusetts).⁸⁶

Conclusions

To develop and implement effective and efficient treatment of foot and ankle problems, evidence-based podiatric medicine requires the conscientious, explicit, and judicious use of current best research evidence in clinical decision making. At present, the insurmountable quantity and varying quality of discrete research reports limit the ability of podiatric physicians, patients, policy makers, and researchers to make full use of the available evidence. High-quality systematic reviews present an opportunity to streamline the foot- and ankle-related literature, reducing the time, cost, training, and skills necessary to establish a solid evidence base for clinical practice.

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Table 1. Titles of Cochrane Systematic Reviews of Foot and Ankle Interventions by Group

Back group

- Insoles for prevention and treatment of back pain.³²

Bone, joint, and muscle trauma group

- Different functional treatment strategies for acute lateral ankle ligament injuries in adults.³³
- Immobilisation and functional treatment for acute lateral ankle ligament injuries in adults.³⁴
- Interventions for preventing and treating stress fractures and stress reactions of bone of the lower limbs in young adults.³⁵
- Interventions for preventing ankle ligament injuries.³⁶
- Interventions for preventing lower limb soft-tissue injuries in runners.³⁷
- Interventions for treating acute and chronic Achilles tendinitis.³⁸
- Interventions for treating calcaneal fractures.³⁹
- Interventions for treating chronic ankle instability.⁴⁰
- Interventions for treating hallux valgus (abductovalgus) and bunions.⁴¹
- Interventions for treating plantar heel pain.⁴²
- Orthotic devices for treating patellofemoral pain syndrome.⁴³
- Pharmacotherapy for patellofemoral pain syndrome.⁴⁴
- Prescription of prosthetic ankle-foot mechanisms after lower limb amputation.⁴⁵
- Stretching to prevent or reduce muscle soreness after exercise.⁴⁶
- Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults.⁴⁷
- Interventions for treating acute Achilles tendon ruptures.⁴⁸
- Ultrasound for acute ankle sprains.⁴⁹

Breast cancer group

- Physical therapies for reducing and controlling lymphoedema of the limbs.⁵⁰

Musculoskeletal group

- Braces and orthoses for treating osteoarthritis of the knee.⁵¹
- Custom-made foot orthoses for the treatment of foot pain.²¹
- Interventions for pes planus.⁵²
- Low level laser therapy (Classes I, II and III) for treating rheumatoid arthritis.⁵³
- Non-surgical interventions for paediatric pes planus.⁵⁴
- Thermotherapy for treating rheumatoid arthritis.⁵⁵

Neuromuscular disease group

- Interventions for increasing ankle range of motion in patients with neuromuscular disease.⁵⁶
- Interventions for the prevention and treatment of pes cavus.⁵⁷
- Interventions for the treatment of Morton's neuroma.⁵⁸
- Rehabilitation interventions for foot drop in neuromuscular disease.⁵⁹

Peripheral vascular diseases group

- Compression stockings for preventing deep vein thrombosis in airline passengers.⁶⁰
- Supervised exercise therapy versus non-supervised exercise therapy for intermittent claudication.⁶¹
- Treatment for superficial thrombophlebitis of the leg.⁶²
- Vitamin E for intermittent claudication.⁶³

Pregnancy and childbirth

- Interventions for leg cramps in pregnancy.⁶⁴

Skin group

- Interventions for chronic palmoplantar pustulosis.⁶⁵
- Oral treatments for fungal infections of the skin of the foot.⁶⁶
- Oral treatments for toenail onychomycosis.⁶⁷
- Surgical treatments for ingrowing toenails.⁶⁸
- Topical treatments for cutaneous warts.⁶⁹
- Topical treatments for fungal infections of the skin and nails of the foot.⁷⁰

Wounds group

- Antibiotics and antiseptics for venous leg ulcers.⁷¹
- Compression for preventing recurrence of venous ulcers.⁷²
- Compression for venous leg ulcers.⁷³
- Debridement of diabetic foot ulcers.⁷⁴
- Dressings and topical agents for arterial leg ulcers.⁷⁵
- Silver based wound dressings and topical agents for treating diabetic foot ulcers.⁷⁶
- Hyperbaric oxygen therapy for chronic wounds.⁷⁷
- Laser therapy for venous leg ulcers.⁷⁸
- Oral zinc for arterial and venous leg ulcers.⁷⁹
- Patient education for preventing diabetic foot ulceration.⁸⁰
- Pressure relieving interventions for preventing and treating diabetic foot ulcers.⁸¹
- Therapeutic ultrasound for venous leg ulcers.⁸²
- Topical agents or dressings for pain in venous leg ulcers.⁸³
- Topical silver for treating infected wounds.⁸⁴

Note: To access a review, simply type the review title into the search field at <http://www.thecochranelibrary.com>.

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