A Critical Review of the Literature on Foot Orthoses

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Many reports have been published on the value of foot orthoses in treating a variety of biomechanical problems. This article reports on the application of rules developed in the 1980s to assess the scientific rigor, and hence the clinical applicability, of these publications. (J Am Podiatr Med Assoc 90(7): 339-341, 2000)

The use of foot orthoses has been extensively described for the treatment of many biomechanical problems. These interventions can be grouped according to their goals, with some studies belonging to more than one group: 1) prevention or correction of a deformity; 2) promotion of a sound base of support; 3) facilitation of training in standing or walking; and 4) improvement in the efficiency of walking.1

This article reports on the use of an established method to judge the scientific rigor of some of these studies to ascertain whether their stated aim was significantly supported by the research findings.

It is often difficult to judge the scientific merit of recommendations made in these studies. Recommendations are affected by many factors, such as the biomechanical problem of the patient, the subject groupings, use of controls, the general methodology applied, or time limitations. However, each publication comments on clinical management, and it would therefore be useful to know how generally applicable the results are.

Method

In 1986, Sackett2 published a useful method for clinicians and researchers to use in judging the conclusions from the scientific and medical literature on the management of patients. Although his report was based on the assessment of antithrombotic agents, the rules he developed have a wider, more general application. Sackett’s “levels of evidence” provide guidelines for the assessment of the scientific merit of published articles. These take into account such factors as the type of randomization used, the likelihood of false-positive and false-negative results, whether controls were included, and the number of subjects and their groupings. Sackett’s levels of evidence are as follows:

1) Randomized trial with low rate of false-positive and low rate of false-negative errors.
2) Randomized trial with high rate of false-positive and high rate of false-negative errors.
3) Nonrandomized concurrent cohort comparisons between contemporaneous patients—for example, controlled single-subject, pre-post, or matched case-control series.
4) Nonrandomized historical cohort comparisons—for example, nonexperimental studies, such as comparative and correlational descriptive and case studies.
5) Case series without controls—that is, case reports.

There is no doubt that a large number of articles and textbooks report on the value of orthotic management of the foot. What is not clear is how valid their findings may be for general application. For the purposes of this article, only literature in which the foot and shoe are treated as a basic functional unit was examined. This is because it is usual for footwear to be used for everyday walking and thus for orthoses to function together with footwear.

A review of the orthotic literature made it clear that the publications could be realistically grouped into only three grades according to the general clinical value of their results. Grade A was assigned to publications supported by a level 1 randomized trial; grade B to publications supported by a level 2 randomized trial; and grade C to levels 3 to 5. Thus grade A publications carry a strong recommendation...
for clinical practice. Grade B publications provide some support for clinical practice, and grade C publications can be regarded as providing only clinical inference for the aim, rather than sound scientific data. A grade B or C does not mean that the reported aim or approach has no clinical or scientific value. It implies that the study has reduced scientific rigor and that the clinical value may be either limited or yet to be proven. Grade C reports, by their very nature, carry a high risk of error, and so their results must be interpreted cautiously.

Results

A total of 40 references were studied for this review. The perhaps surprising finding was that only one achieved better than a C grade. All of the others fell under Sackett’s levels 3 to 5. In fact, many of the reports were so anecdotal that they failed even to reach Sackett’s level 5.

The only publication to rate higher than C was the one by Kilmartin et al. This article reports on a controlled prospective trial of a foot orthosis for juvenile hallux valgus. It clearly fulfills the criteria for Sackett’s level 2, but fails to reach level 1 because of the inherent errors associated with the methods used. This is not a specific criticism of this article, but a recognition that the assessment and casting techniques are felt by many to be flawed.

Conclusion

The findings of this report are not atypical in the medical field. The very nature of the patients and their problems can make the carrying out of a level 1 study impossible or ethically unacceptable. This may also apply to a level 2 study. Given this result, what is perhaps surprising is how quickly and energetically the findings of publications that are of a fairly low scientific level are accepted as fact and clinical practice is changed. This statement should not be taken as a criticism of clinicians and scientists working in this particular area. For example, a result similar to that reported here was found following a meeting in Durham, North Carolina, in 1994 on the lower-limb orthotic management of cerebral palsy. In that study, 82 articles and abstracts and 7 textbook chapters were investigated; only one paper achieved a grade B; all of the rest were grade C, with many of these found to be below Sackett’s level 5. In fact, at the Durham meeting, it was mentioned that clinical practice in other areas, such as physiotherapy, was based on similarly scientifically flawed publications.

Does this mean that all that we do is wrong? The answer is clearly no. What these kinds of reviews cannot do is acknowledge the contribution of clinical experience, which does have its merits. This does not mean that all practices carried out from personal clinical experience are sound; reports have appeared from time to time that demonstrate the deficiencies of such an approach. However, the value of treatments of all kinds does have to be demonstrated by scientifically sound research—what is often called “evidence-based practice.” What this review has done is show that to date the literature is rather weak and that everyone must be aware of this and do their part to rectify this situation.

Clearly, many more reports exist on this topic, but previous experience suggests that they will tend to follow the trend already identified and show a relatively low level of scientific rigor and thus limited direct clinical applicability. Anecdotal reports and other less scientific publications should not be dismissed as of no value; they still have a role to play in bringing new techniques to the notice of other practitioners, who can then try them out.

It would be very difficult to actually carry out a study to Sackett’s level 1 or 2 because of the multivariate nature of the whole area of orthotic management. While not every publication has to be at Sackett’s level 1 or 2 to be of value, this should remain the goal for all who study the topic of orthotic management.

References


