

Therapeutic Footwear in Diabetes

The good, the bad, and the ugly?

In recent years, it has generally been accepted by the diabetes community that “good” footwear prevents foot ulceration. Indeed, it is virtually an axiom of diabetes care that a patient with a history of foot ulcer is a footwear patient for life (1). Similarly, most health care professionals believe that “bad” footwear is a major cause of ulceration in diabetes and that in the past, the fact that most therapeutic footwear was perceived as “ugly” resulted in poor compliance when such footwear was prescribed (2). Where is the evidence to support these beliefs? The last two points are easier dealt with than the first.

There are studies that support the belief that bad or inappropriate footwear causes ulceration. Apelqvist et al. (3) identified shoes as the precipitating cause in the majority of toe ulcers and a significant minority of lesions elsewhere on the foot. In another European study (4), footwear was implicated as being contributory to 21% of all ulcers in a large series.

As we identified in an editorial (5) on the same subject 3 years ago, compliance with regular wearing of the footwear is a major problem. In our U.K. center, when provided with therapeutic footwear free of charge, only 22% of patients admitted that they regularly wore the shoes (2). Similar problems have been reported in the U.S. (6).

It is unclear whether a patient’s perception of such footwear as being “ugly” or cosmetically unattractive is a major contributory factor to this nonadherence behavior. Another factor may be the patient’s belief that the home environment is safe; in a study using continuous activity monitoring, Armstrong et al. (7) reported that “high-risk” patients were much less likely to wear their prescribed footwear when at home than when outside. As such patients are more active when in the home (7), this nonadherence may well be important in the causation of ulcers. The same authors (8) recently confirmed that even patients with active foot ulcers do

not regularly wear removable cast walkers when advised to do so.

In the current issue of *Diabetes Care*, Maciejewski et al. (9) attempt to answer the first point in a structured literature review; that is, can therapeutic footwear prevent the occurrence of ulceration? As no studies have assessed footwear in the primary prevention of ulcers (1), Maciejewski et al. review those reports on the prevention of ulcer recurrence. They identified nine studies from a Medline search and determined that in six of them, footwear was a primary intervention, and in three, it was part of a multifactorial intervention. Each study was rated according to the study design and internal consistency. They conclude in this review that although protective benefit was found, a number of these studies may have been influenced by design issues.

It is perhaps a little unfortunate that the only study that was assigned a study design rating of 1 was by the same authors as those who conducted the review (10). However, having reviewed all of the works, we would entirely agree that the study of Reiber et al. (10) was carefully and appropriately designed and thus warranted a level 1 rating. This study could find no benefits of therapeutic footwear over the patients’ own shoes. In an exchange of correspondence in the literature following the publication of this trial (11–13), surprise was expressed that >40% of patients with an ulcer history had normal peripheral sensation. Moreover, the definition of an ulcer as a lesion that did not heal within 30 days was also a point of discussion. In their reply, Reiber et al. (13) reported that a subset analysis of those patients with sensory loss similarly showed no benefit of therapeutic shoes.

Where does this discussion position us with regard to specialist footwear in 2004? Some years ago, Janisse (14) reviewed “the art and science of footwear design”—at that time it was more art than science. More than 10 years later, the words of Jeffcoate and Harding (15) sug-

gest that little has changed when they concluded about diabetic foot care in general that “clinical practice is based more on opinion than scientific fact.”

There can be little doubt that there is an urgent need for well-designed studies of footwear in both the primary as well as the secondary prevention of neuropathic foot ulceration. Evidence from the literature as reviewed briefly above and by Maciejewski et al. (9) in this issue remains equivocal. Surely, in the 21st century we should be moving toward computer-aided design and manufacture of footwear. In addition, as recently demonstrated (7,8), modern technology now permits the accurate assessment of compliance with footwear provision, which could potentially remove another confounding variable in such studies.

Whereas bad shoes cause ulcers and “ugly” shoes are likely to remain in the closet, a major effort is required to demonstrate that good shoes do actually benefit our high-risk patients.

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