Clinical choices in wound care without trial evidence

Sirs,

I am writing in reply to a letter by AC Felix Burden (2009) regarding a recent case study (Turns, 2009), both published in *The Diabetic Foot Journal*. The case study reported my experience using a glucose oxidase dressing on a chronic diabetic foot ulcer.

The letter raised a number of issues that are of great relevance to the management of diabetic foot ulcers, including: (i) the lack of randomised control trials (RCTs) in support of wound care products in general; (ii) the small number of people with diabetes in a case series I cited; (iii) the occurrence of an adverse event in one of those case series; and (iv) the suggestion of a study design for future wound dressing trials.

RCTs usually fail to be undertaken because they are expensive to conduct, require a large participant population and a robust methodology that accounts for the many variables among people with wounds. However, with the current emphasis on evidence-based practice, the lack of RCTs assessing the efficacy of wound care products and, as a result, the lack of quality evidence for their use will eventually require the attention both of clinicians and the wound care industry.

"... with the current emphasis on evidence-based practice, the lack of RCTs assessing the efficacy of wound care products and, as a result, the lack of quality evidence for their use will eventually require the attention both of clinicians and the wound care industry."

While RCTs in wound care products are few (e.g. Schmutz et al, 2008), those focused specifically on the diabetic foot ulcers are fewer still (e.g. Jude et al, 2007). At the recent *Diabetic Foot Journal Conference and Exhibition* (London, 2009), I undertook some impromptu research. I asked all the wound care companies in attendance if they had any RCTs on their products. Two said yes, one of which was in a population with leg ulcers. It is quite obvious that the evidence available for the use of many wound care products in the diabetic foot needs raising considerably.

Despite the lack of robust data, clinicians must still make clinical decisions with regard to the products that are available, as was the situation in the case that I reported (Turns, 2009). The principles behind the glucose oxidase hydrogel dressing used were sound. A variety of wounds, including diabetic foot ulcers, were included in other case series that had tested the dressing. I made a judgement, based on the evidence available to me, to use the dressing for the management of Mr C's diabetic foot ulcer and, as a result of this course of treatment, Mr C (46 years old; type 1 diabetes) has now been ulcer-free for nearly 2 years.

One adverse event was reported in a case series using this dressing that I cited. The event was wound maceration, a common complication of diabetic foot ulceration. This event suggests that care should be exercised when using this dressing, but it is not a reason to exclude the dressing from practice.

The suggestion of a methodology for an n=1 RCT is useful and should be explored further.

I thank the author for raising these issues, especially concerning the lack of robust evidence in wound care. Perhaps this evidence vacuum warrants an editorial from *The Diabetic Foot Journal* Editors.

Yours sincerely,

Martin Turns
Lead Podiatrist in Diabetes, Brighton

Burden ACF (2009) Letter to the Editors. *The Diabetic Foot Journal* **12**: 118

Jude EB, Apelqvist J, Spraul M et al (2007) Prospective randomized controlled study of Hydrofiber dressing containing ionic silver or calcium alginate dressings in non-ischaemic diabetic foot ulcers. *Diabet Med* **24**: 280–8

Schmutz JL, Meaume S, Fays S et al (2008) Evaluation of the nano-oligosaccharide factor lipido-colloid matrix in the local management of venous leg ulcers: results of a randomised, controlled trial. *Int Wound J* **5**: 172–82

Turns M (2009) Experience using a glucose oxidase dressing on chronic diabetic foot ulcers. *The Diabetic Foot Journal* **12**: 39–43