# Clinical*digest 6*

## **Lower limb complications**

## The things dreams are made of . . .



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ugust 2003 saw the 40th anniversary of Martin Luther King's famous Lincoln Memorial speech, popularly known as 'I have a dream'. I shared my own personal dream for the diabetes care team at the *Glasgow Diabetic Foot conference*. The articles in this

issue reflect another dream: the rapid recognition of treatment failures allowing modification of therapy, and simple but effective measures to heal ulcers and reduce the toll of amputations.

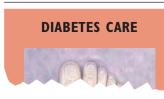
I make no excuse for restating that the core of diabetic foot care is debridement, pressure relief and infection control. After these measures are optimised and the ulcer fails to heal, vascular intervention and advanced techniques need to be brought into play. Felted foam is a long-established method of pressure relief. The article by Zimny et al is the second paper this year to highlight the effectiveness of felted foam, particularly in patients who may not always wear orthoses.

If we are sure that the basics have been addressed, then how is it possible to determine

whether an ulcer is healing adequately? Margolis et al and Sheehan et al describe the use of healing velocity as surrogates of healing and to predict healing. Measures of healing in the first 4 weeks of therapy can accurately predict final healing and 20 week healing. These markers are advocated as surrogates for the rapid evaluation of new therapies in smaller, shorter studies. More importantly, in clinical practice they could be used to identify slow-to-heal ulcers and the need to modify treatment.

Finally, a randomised study of chiropody care from Austria has shown that, once an ulcer has healed, regular chiropody follow-up reduces the incidence of recurrent ulceration. The level of training in Austria is significantly below the standard of UK podiatrists and it might be expected that UK-trained podiatrists might be able to have an even greater impact.

So, in summary, simple cheap foam offloading is effective, but if it fails to heal an ulcer this can be spotted early and alterations made to the treatment regimen. Once an ulcer has healed, regular follow-up by trained podiatrists can reduce the risk of further ulceration. More small steps towards the day when all people with diabetes will be ulcer-free.



### Surrogate markers help predict success of wound care therapy

 Readability
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 Applicability to practice
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 WOW! factor
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This study set out to determine whether surrogate markers based on changes in wound size can predict which diabetic foot ulcers will heal after 12 or 20 weeks of care.

A total of 39 918 neuropathic wounds on 20 213 people with diabetes were evaluated (using the Curative Health Services database); 7 surrogates based on changes in wound size were evaluated. Surrogates based on percentage change in area, log area ratio and log healing rate, and measured after 2, 4 or 8 weeks of care, differentiated wounds that healed from those that did not, by week 12 or 20 of care.

After 4 weeks of care, percentage change in wound area can be used to correctly discriminate 76% of the time between wounds that heal and those that do not by week 20 of care.

**5** Surrogates may help healthcare professionals predict whether a wound care therapy is likely to be successful.

**6** Surrogate markers can be used in clinical trials: shorter, smaller trials can be conducted with reasonable accuracy to determine which potential new therapies should be studied in larger, longer trials.

Margolis DJ, Gelfand JM, Hoffstad O, Berlin JA (2003) Surrogate end points for the treatment of diabetic neuropathic foot ulcers. *Diabetes Care* **26**: 1696–700

#### **DIABETIC MEDICINE**



### Felted foam proves effective for pressure relief

 Readability
 Image: V
 Image: V

 Applicability to practice
 Image: V
 Image: V

 WOW! factor
 Image: V
 Image: V

The aim of this controlled prospective randomised study was to investigate the effects of felted foam padding on wound radius reduction and healing times in neuropathic foot ulcers, compared with a standard method of plantar pressure relief.

2 Wound healing was evaluated over 10 weeks in 54 people with type 1 and type 2 diabetes and neuropathic plantar foot ulcers; 24 people were randomised to the felted foam treatment and 30 were randomised to the conventional treatment.

**3** planimetric measurement of the wound area at the start of the study and after 10 weeks or at least until wound healing.

A In the felted foam group, the initial wound area was  $102.3 \pm 45.3 \text{ mm}^2$  (mean  $\pm$  SD) and  $5.4 \pm 3.1 \text{ mm}^2$  after 10 weeks, with an average healing time of 75 days.

**5** In the conventional therapy group, the initial average wound area was  $112.5 \pm 50.8 \text{ mm}^2$ , and  $10.6 \pm 4.2 \text{ mm}^2$ after 10 weeks, with an average healing time of 85 days.

**6** The mean wound radius decreased by 0.48 mm per week in the felted foam group and by 0.39 mm per week in the conventional group.

The felted foam technique is as effective as the conventional plantar ulcer treatment for pressure relief.

Zimny S, Schatz H, Pfohl U (2003) The effects of applied felted foam on wound healing and healing times in the therapy of neuropathic diabetic foot ulcers. *Diabetic Medicine* **20**: 622–5

<sup>4</sup> If vibration perception threshold could be used to identify at-risk groups, resources could be concentrated on these individuals, thereby potentially improving health outcomes and saving resources.<sup>3</sup>

#### <sup>4</sup> Secondary preventive measures by a chiropodist may reduce recurrence of foot ulcers in diabetes.<sup>9</sup>

## DIABETES CARE

## Vibration perception threshold can identify at-risk groups

 Applicability to practice
 Image: Applicability to practice

 WOW! factor
 Image: Image: Applicability to practice

This US study aimed to estimate the predicted complications and costs associated with reduced vibration detection (RVD), using a quantitative sensory testing device.

A Markov model was constructed for a hypothetical cohort of people with diabetic peripheral neuropathy (DPN), and run over a 10-year period. Monte Carlo simulations were used to model the predicted costs and outcomes for normal and reduced VD cohorts.

**3** The average person with RVD incurs approximately five times more foot ulcer and amputation costs, yields 0.18 fewer quality-adjusted life-years and lives for 2 months less than an average person with normal vibration detection over 10 years.

4 If vibration perception threshold could be used to identify at-risk groups, resources could be concentrated on these individuals, thereby potentially improving health outcomes and saving resources.

Shearer A, Gordois A, Scuffham P, Oglesby A (2003) Predicted costs and outcomes from reduced vibration detection in people with diabetes in the UK. *Diabetes Care* **26**: 2305–10

#### **DIABETES CARE**



 Readability
 V

 Applicability to practice
 V

 WOW! factor
 V

**1** This study assessed the influence of chiropodist care on the recurrence rate of diabetic foot ulcers within 1 year.

2 Ninety-one people with diabetes (outpatients) and healed foot ulcers were randomised to a group that

#### **DIABETES CARE**



## wound healing

Applicability to practiceWOW! factor

This study sought to determine whether a human fibroblast-derived dermal substitute can promote healing of diabetic foot ulcers.

2 A total of 314 people with diabetes and a foot ulcer that had been present for at least 2 weeks took part in this randomised, controlled, multicentre study, which evaluated complete wound closure by 12 weeks.

**3**People with chronic foot ulcers of >6 weeks' duration experienced significant clinical benefit when treated with Dermagraft compared with those receiving conventional treatment.

In terms of complete wound healing by week 12, 30% of people treated with Dermagraft healed compared with 18.3% of the control group.

**5** The addition of Dermagraft to a regimen of diabetic foot ulcer treatment, including debridement, infection control and pressure offloading, resulted in significant benefit compared with a regimen without Dermagraft.

Marston WA, Hanft J, Norwood P, Pollak R (2003) The efficacy and safety of Dermagraft in improving the healing of chronic diabetic foot ulcers. *Diabetes Care* **26**: 1701–5

received monthly routine chiropodist care (47) or a control group (44).

3 Ulceration recurred in 18 of the chiropodist group and 25 of the control group over the 386 day (median) follow-up period.

4 Analysis of ulceration per foot demonstrated a significant reduction in favour of chiropodist care.

Results suggest that secondary

• preventive measures by a chiropodist may reduce recurrence of foot ulcers in diabetes.

Plank J, Haas W, Rakovac I et al (2003) Evaluation of the impact of chiropodist care in the secondary prevention of foot ulcerations in diabetic subjects. *Diabetes Care* **26**: 1691–5

#### **DIABETES CARE**



### Percentage change in ulcer area at 4 weeks predicts healing

 Readability
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 Applicability to practice
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 WOW! factor
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This prospective, randomised controlled trial examined the change in ulcer area over a 4-week period as a predictor of wound healing within 12 weeks in 203 people with diabetes and foot ulcers.

**2** Wound measurements were performed at baseline and after 4 weeks.

**3** The midpoint between the percentage area reduction from baseline at 4 weeks in people healed versus those not healed at 12 weeks was 53%.

People with a reduction in ulcer area greater than the 4-week median had a 12-week healing rate of 58%; people with a reduction in ulcer area less than the 4-week median had a healing rate of 9%.

**5** The absolute change in ulcer area at 4 weeks was greater in healers than in nonhealers.

**6** Percentage change in wound area at 4 weeks in those who healed was 82%, compared with 25% in those who failed to heal.

**7** Percentage change in foot ulcer at 4 weeks' observation is a robust predictor of healing at 12 weeks.

This tool could serve as a pivotal clinical decision point in the care of diabetic foot ulcers for early identification of people who may not respond to standard care and may need additional treatment.

Sheehan P, Jones P, Caselli A, Giurini JM, Veves A (2003) Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. *Diabetes Care* **26**(6): 1879–82