

# Randomised controlled trial of the use of three dressing preparations in the management of chronic ulceration of the foot in diabetes

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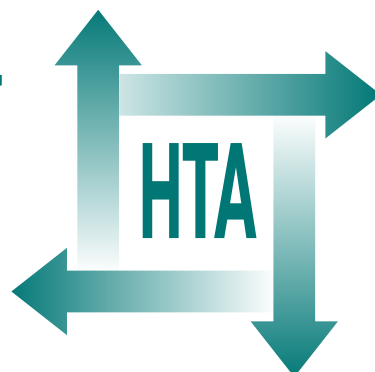


## Executive summary

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## Executive summary

### Aims

This study had five stated aims:

1. To test whether a modern dressing product is more clinically effective than traditional dressings in the treatment of diabetes-related foot ulcers.
2. To investigate changes in condition of foot ulcers associated with each dressing and recurrence during the study period.
3. To determine the relative cost-effectiveness of the three dressings.
4. To assess patients' health-related quality of life, physical and social functioning, and pain associated with each of the dressings.
5. To investigate the contribution made by patient and carer in terms of involvement with self-care.

### Methods

This was a multicentre, observer-blinded, randomised controlled trial in which patients were randomised 1:1:1 to receive one of three dressing products: a simple non-adherent preparation [N-A<sup>®</sup> (Johnson & Johnson Medical, Berkshire, UK)], a widely used modern antiseptic preparation [Inadine<sup>®</sup> (Johnson & Johnson Medical, Berkshire, UK)] and a new hydrocolloid preparation of higher unit cost [Aquacel<sup>®</sup> (ConvaTec Ltd, Middlesex, UK)].

### Results

A total of 317 patients were randomised. After 88 withdrawals, 229 remained evaluable. A greater proportion of smaller (25–100 mm<sup>2</sup> ulcers healed within the specified time (48.3% versus 37.3%;  $p = 0.048$ ). There was, however, no difference between the three dressings in terms of percentage healed by 24 weeks, or in the mean time to healing, whether analysed on the basis of intention to treat (Inadine 44.4%, N-A 38.7%, Aquacel 44.7%; not significant) or per protocol (Inadine 55.2%, N-A 59.4%, Aquacel 63.0%; not significant). There was no difference in the quality of healing, as reflected

in the incidence of recurrence within 12 weeks. Likewise, there was no difference in the incidence of adverse events, although a greater proportion of those randomised to the non-adherent dressings were withdrawn from the study (34.9% versus 29.1% Aquacel and 19.4% Inadine;  $p = 0.038$ ). The only statistically significant difference found in the health economic analysis was the cost associated with the provision of dressings (mean cost per patient: N-A £14.85, Inadine £17.48, Aquacel £43.60). The higher cost of Aquacel was not offset by the fewer dressings required. There was no difference in measures of either generic or condition-specific measures of quality of life. However, there was a significant difference in the change in pain associated with dressing changes between the first and second visits, with least pain reported by those receiving non-adherent dressings ( $p = 0.012$ ). There was no difference in the costs of professional time, and this may relate to the number of dressing changes undertaken by non-professionals. Fifty-one per cent of all participants had at least one dressing change undertaken by themselves or a non-professional carer, although this ranged from 22% to 82% between the different centres.

### Discussion

The higher rate of withdrawal of patients randomised to receive non-adherent dressings was unexplained but may relate to the involvement in dressing changes of other professional staff – some of whom may have had their own preconceptions about the most suitable dressing for the wound in question. Such preconceptions could have triggered withdrawal of patient consent, or a protocol violation. Despite this we failed to observe any trend towards a difference in the effectiveness, safety or quality of life measures associated with the use of these three products, whether the results were analysed by intention to treat or *per protocol*. We also found no evidence that any particular dressing may be more effective in any one type of wound – for instance, an antiseptic product in ulcers which are covered with greater degrees of surface slough. On the other hand we observed a significant difference in product costs, and this has

implications for the choice of dressings in routine clinical practice. Many newer dressing products are also marketed on the basis that they need to be changed less often, with the associated implications for reduced costs of professional time. We observed, however, that almost 70% of all dressings were undertaken by non-professionals and there was no difference in professional time between the three groups.

## Conclusions

As there was no difference in effectiveness, there is no reason why the least costly of the three dressings could not be used more widely across the UK National Health Service, thus generating potentially substantial savings.

## Implications/ recommendations for practice

All dressing products should have their clinical effectiveness proven before they are widely adopted in clinical practice. Proof of effectiveness would usually require randomised trials using hard, clinically relevant, outcomes in well characterised populations. Any of the products used in this study could be adopted as the comparator for such trials. The wide difference observed between centres in the percentage of dressing changes undertaken on one or more occasions by non-professional staff may indicate that professionals may be involved more often than is necessary in some cases, and this may also have implications for routine care. The option to involve patients and non-professional

carers needs to be assessed more formally and could be associated with significant reductions in health-care costs.

## Recommendations for future research

1. The effectiveness of newer products currently in widespread use should be determined using a similar approach.
2. The specific effect of antiseptic products should be determined in terms of both healing and prevention of secondary infection of ulcers contaminated by lesser or greater degrees of slough.
3. The acceptability and cost-effectiveness of encouraging greater involvement of the patient and non-professional carers in routine management should be explored.
4. There is a clear need to establish a country-wide network of specialist units managing diabetic foot ulcers in order to facilitate the more ready conduct of such research.

## Trial registration

This trial is registered as ISRCTN78366977.

## Publication

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# NIHR Health Technology Assessment programme

The Health Technology Assessment (HTA) programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 01/74/03. The contractual start date was in June 2003. The draft report began editorial review in October 2007 and was accepted for publication in January 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

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