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Debridement of diabetic foot ulcers

[Reviews]

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Cochrane Wounds Group

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Abstract

Background: Foot ulceration is thought to affect 15% of people with diabetes at some time in their lives. Debridement is widely regarded as an effective intervention to speed up ulcer healing. The most effective method is unclear.

Objectives: The aim of this review is to assess the evidence for the effectiveness of debridement as a treatment for diabetic foot ulcers.

Search strategy: We searched the Cochrane Wounds Group Specialised Register (May 2005) and the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* Issue 2, 2005). We performed hand searches of journals, and reference lists and wrote to recognised experts in the diabetic foot.

Selection criteria: Randomised controlled trials evaluating a method of debridement in the treatment of diabetic foot ulcers and measuring complete healing or rate of healing. There was no restriction on articles/trials based on language or publication status.

Data collection and analysis: Data extraction and assessment of study quality were undertaken by one author and checked by an Editor of the Wounds Group.

Main results: Five RCTs of debridement were identified; three RCTs assessed the effectiveness of a hydrogel as a debridement method, one RCT evaluated surgical debridement and one RCT evaluated larval therapy. Pooling the three hydrogel RCTs suggested that hydrogels are significantly more effective than gauze or standard care in healing diabetic foot ulcers (Relative Risk 1.84, 95% Confidence Interval (CI) 1.3 to 2.61). Surgical debridement and larval therapy showed no significant benefit in these small trials. Other debridement methods such as enzyme preparations or polysaccharide beads have not been evaluated in people with diabetes.

Authors' conclusions: There is evidence to suggest that hydrogel increases the healing rate of diabetic foot ulcers compared with gauze dressings or standard care. More research is needed to evaluate the effects of a range of widely used debridement methods and of debridement per se.

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Plain language summary

More research is needed on surgical and non-surgical methods of cleaning and removing dead tissue from sores on the feet of people with diabetes.

People with diabetes often develop foot ulcers (open sores on the feet that go through the skin), which can lead to serious complications. Cleaning and removing dead tissue from the ulcers is a common procedure also known as 'debridement'. Debridement may also include the removal of calluses which may surround or 'roof over' the ulcer and can be done in several ways, including surgery and special gels (such as hydrogels). The review found that diabetic foot ulcers heal faster when a hydrogel is used instead of gauze or standard care.

Background

Approximately 2% of the UK population is estimated to have diabetes, of whom approximately 200,000 have Type 1 diabetes and more than a million have Type 2 diabetes ([Calman 1998](#)). Foot ulceration is thought to affect 15% of people with diabetes at some time in their lives ([Spencer 2000](#)). The complications of diabetes are not limited to the foot; other complications can affect the eyes (cataracts, retinopathy or neurological disturbances), kidneys (due to sclerotic renal disorder peculiar to diabetes), vascular and neurological complications. In addition diabetes renders people more prone to pulmonary tuberculosis, Candida skin infections and other opportunistic infections ([Davies 1989](#)). People with diabetes are between 15 and 70 times more likely to undergo lower limb amputations than people without diabetes ([SIGN 1997](#)). Prevalence of amputations due to diabetes (excludes loss of toes or single metatarsals) in Scotland is 1% of people with diabetes ([SIGN 1997](#)); the total UK figure is thought to be similar ([Macleod 1991](#)). However there is some uncertainty as to the true incidence and prevalence of diabetic foot ulcers as much of the treatment is delivered within the community and outpatients departments where data collection is patchy and surveillance is limited. The cost of the amputation itself is only a small part of the total care, since most patients who have an amputation have many admissions before and after surgery with the average length of stay over 200 days ([SIGN 1997](#)).

The cost to the UK National Health Service of diabetic foot ulcers is thought to be about

[pounds]13 million per year ([King's Fund 1996](#)). However, such costings do not take into account the personal costs to the patient, e.g. a reduction in ability to work; time taken off work; altered body image; worry and threat of amputation; dressing regimens and hospital visits.

Health professionals with an interest in diabetes met in St Vincent over 10 years ago to review the problem of diabetes complications. Many standards for diabetes care were agreed at this meeting, including a 50% reduction in lower limb amputations by the year 1995 ([SVD 1990](#)).

Aetiology of Diabetic Foot Ulcers

The breakdown of the diabetic foot has traditionally been considered to be the result of peripheral vascular disease, peripheral neuropathy and infection. More recently, other contributory causes, such as psychosocial factors have been implicated ([Boulton 2000](#)).

Vascular Pathology

Disease of blood vessels is a major cause of complications in diabetes and affects all types of vessel ([Faris 1991a](#)). The Framingham study reported that more than 50% of men and women with diabetes had absent foot pulses ([Abbott 1990](#)). Peripheral vascular disease (PVD) tends to occur at a younger age in people with diabetes and is more likely to involve smaller blood vessels further away from the heart. Reports from USA, UK and Finland ([Pecoraro 1990](#); [Reiber 1999](#); [Siitonen 1993](#)) have confirmed that PVD is a major contributory factor in the pathogenesis of foot ulceration and subsequent major amputations ([Boulton 2000](#)).

Neuropathy

Impairment of nerve function is an important and frequent complication of diabetes. All types of fibres are involved so that motor, sensory and autonomic functions are affected. Patients with impaired nerve function in the foot are at risk of the complication of neuropathy whether or not they are aware of its presence. Neuropathy remains one of the major factors leading to the development of foot lesions in people with diabetes ([Le Quesne 1991](#)).

Sensory neuropathy

Damage to the nerves carrying signals from the foot renders the foot insensitive to temperature, vibration, pressure and pain and is referred to as sensory neuropathy. The loss of sensation means that small injuries often go undetected.

Motor neuropathy

Denervation of muscles has important effects on the function of the foot. The small muscles of the foot, the extensor digitorum brevis, lumbrical and interosseus muscles are commonly affected. The paralysis of these small muscles results in the metatarsophalangeal joints becoming hyper extended and the interphalangeal joints becoming flexed. The joints initially remain mobile but later degenerative changes occur and the joints become fixed ([Le Quesne 1991](#)). The consequence of

such muscle wastage is a foot shape that allows increased foot pressures (i.e. the altered loading results from neuropathy and is not a distinct complication).

Autonomic neuropathy

In recent times it has been suggested that autonomic neuropathy contributes to the pathogenesis of ulceration, neuropathic oedema and Charcot arthropathy ([Le Quesne 1991](#)). Impairment of sweating is suggested to contribute, through dehydration, to the formation of hyperkeratotic plaques and fissures in the skin. If this callus (increased glycation of keratin) is allowed to become too thick, it will press on the soft tissues underneath and cause ulceration ([Edmonds 2000a](#)). Callus is defined as a build up of keratinised skin, in reaction to persistent pressure ([Cutting 1999](#)), and will itself exert pressure.

Pathway to Ulceration

Despite the presence of predisposing factors such as peripheral vascular disease and peripheral neuropathy, an uninjured foot may not develop serious problems. However physical trauma is a potent cause of trouble e.g. a puncture wound, localised pressure, repeated mechanical trauma, heat or chemical injury ([Faris 1991b](#)). Where there is sensory impairment, a small lesion may progress because it is not recognised and the source of injury not removed. Impairment of the blood supply may result in delayed healing. Infection is an important factor responsible for increasing the amount of damaged tissue ([Faris 1991b](#)). It is the infection, which increases the amount of damaged tissue present at the initial site of the damage. An ulcer is the result of a break in the dermal barrier, with subsequent erosion of underlying subcutaneous tissue. In severe cases, the breach may be extended to muscle and bone. Lack of sensation allows the damage to progress to ulceration. The progression to ulceration can be attributed to an impaired arterial supply, neuropathy, musculo-skeletal deformities, or a combination of these factors ([Bauer 2000](#)).

Current practice

Debridement is the removal of devitalised or contaminated tissue from within or adjacent to a wound, until surrounding healthy tissue is exposed; it may also include the removal of foreign material that has become embedded in the wound ([Dorland's 1998](#)). Pressure relief is widely thought to be a crucial aid to ulcer healing although direct research evidence for this is lacking ([Spencer 2000](#)). Debridement is also widely regarded as an effective intervention to speed up ulcer healing. It is widely believed that sharp debridement of an ulcer, including the removal of callus which may surround or 'roof over' the ulcer, and of all devitalised tissue, is essential to healing. Once the foot has reached this ulcerated stage the aim is to heal the ulcer in as short a time period as possible and prevent reoccurrence. Margolis ([Margolis 1999](#)) conducted a study of the healing of diabetic, neuropathic foot ulcers in which 24% healed after 12 weeks and 31% of ulcers healed after 20 weeks of good wound care. The management of diabetic foot ulceration is multidisciplinary in its most effective form, and requires communication between primary and secondary care providers ([Young 2000](#)).

Edmonds ([Edmonds 2000b](#)) suggests six areas of diabetic control which should be addressed when treating the diabetic foot:

- * mechanical control;
- * wound control;
- * microbiological control;
- * vascular control;
- * metabolic control;
- * educational control.

Debridement

Debridement (see Table 01Methods of debridement) is recommended in the Scottish Guidelines ([SIGN 1997](#)) alongside antibiotic therapy for infection and pressure relief as a treatment for patients who have developed ulceration or gangrene with risk of amputation. The Royal College of General Practitioners Guidelines ([RCGP 2000](#)) also recommend debridement for the treatment of the ulcerated foot alongside local wound management and appropriate dressings. Neither of the guidelines recommend a specific method of debridement.

[Edmonds 2000b](#) gave the following rationale for debridement of neuropathic ulcers:

- * Debridement enables the true dimensions of the ulcer to be perceived.
- * Debridement allows drainage of exudate and removal of dead tissue, both render infection less likely.
- * Debridement enables a deep swab to be taken for culture.
- * Debridement encourages healing, by restoring a chronic wound to an acute wound.

It is the evidence to support this last statement which this review will scrutinise.

Objectives

The aim of this review was to assess the evidence for the effectiveness of debridement as a treatment for diabetic foot ulcers.

The review will aim to answer the following questions:

1. Does debridement increase diabetic foot healing?
2. If yes, then which methods are most effective, quickest, most cost effective and acceptable to the patient?

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), either published or unpublished, which measure the effectiveness of one or more methods of debridement in the treatment of diabetic foot ulcers.

Types of participants

People with Type 1 or 2 diabetes, with an active foot ulcer of neuropathic, neuroischaemic or ischaemic aetiology.

Types of intervention

Comparison of any method of debridement (i.e. the removal of necrotic tissue from the wound, by either mechanical or non-mechanical debridement) with no debridement or other debridement methods.

Types of outcome measures

Primary outcomes

1. Time to complete healing.
2. Proportion of people whose ulcers heal completely in the trial period.
- 3 The rate of reduction in wound size expressed in either absolute or relative terms.

Secondary outcomes

4. The proportion of ulcers recurring after healing.
5. Number of complications/adverse events reported.
6. Quality of life.

To be eligible for inclusion, studies had to report outcome measure 1 or 2.

Search methods for identification of studies

See: methods used in reviews.

For the original review, the Cochrane Wounds Group Specialised Register (January 2000) and the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* Issue 1, 2000) were searched for RCTs of the debridement of diabetic foot ulcers, using the following key words:

Diab*

Diabetic foot ulcer

Debrid*

Larv*

Hydrogel*

Enzym*

Wound* near healing

For this first update, the Cochrane Wounds Group Specialised Register (May 2005) and CENTRAL (*The Cochrane Library Issue 2*, 2005) were searched, using the following search strategy:

1. DIABETIC FOOT explode all trees (MeSH)
2. (diabet* near foot) or (diabet* near ulcer*)
3. (#1 or #2)
4. DEBRIDEMENT explode all trees (MeSH)
5. (debrid* or larv* or enzym* or hydrogel*)
6. (#4 or #5)
7. (#3 and #6)

Reference lists of relevant papers were scrutinised to identify additional studies and relevant conference proceedings and journals were handsearched. The search was not limited by language or publication status.

The search retrieved 39 citations, eight of which were considered potentially relevant after initial screening. After further consideration, four studies ([Armstrong 2000](#); [Gottrup 2001](#); [Piaggese 2001](#); [Saap 2002](#)) were excluded from the review. Three studies ([Capillas 2002](#); [Dolynchuk 2001](#); [Whalley 2001](#)) were available as abstracts only and letters have been sent to the authors requesting further information, the studies have been placed in 'Studies awaiting assessment'. One study ([Piaggessi 1998](#)) is an additional report of a trial included in the review and has been added as a secondary reference.

[Mulder 1994b](#), which was awaiting assessment in the original review, has now been excluded as attempts to obtain further information from the authors have failed. This study will be reassessed, should further information become available.

Methods of the review

For the original review, one author assessed the titles and abstracts of studies in terms of their relevance and design, according to the selection criteria. Full versions of articles were then

obtained if, from this initial assessment, they appeared to satisfy the inclusion criteria. Full papers were checked to identify those that fitted the inclusion criteria; any full papers which were rejected were checked by an Editor of the Cochrane Wounds Group (Andrea Nelson). For the updated review the full papers that were rejected were checked by the Assistant Review Group Co-ordinator (Wendy Milborrow). Any uncertainty was referred to the Review Group Co-ordinator (Sally Bell-Syer) for adjudication.

The following data were extracted for each review:

- * patient inclusion/exclusion criteria;
- * care setting;
- * key baseline variables by group (eg age, sex, baseline risk, baseline area of ulceration);
- * description of intervention;
- * number of patients randomised to each intervention;
- * description of co-interventions/standard care;
- * period of follow-up;
- * outcomes (time to complete healing; proportion of people whose ulcers healed completely within the trial period; rate of reduction of wound size; proportion of ulcers recurring; number of complications/adverse events; quality of life).

Each study was appraised using a standard checklist for the validity of the methods used.

Validity data extracted were:

- * allocation concealment;
- * use of intention-to-treat analysis;
- * extent of loss to follow up;
- * blinded outcome assessment.

If data were missing from reports then attempts were made to contact the authors to obtain missing information. This was only the case where the studies were published as an abstract only. Data from studies published in duplicate were included only once. Data extraction was undertaken by one author and checked by Andrea Nelson. Any disagreements were resolved by referring to the Cochrane Wounds Review Group Co-ordinator.

Clinical heterogeneity was explored by examining trial related factors that may influence outcomes such as concurrent use of antibiotic therapy, pressure relieving devices, frequency of dressing change, care setting, patient and ulcer characteristics. The chi-squared test was used to test for statistical heterogeneity, whilst I^2 was used to estimate the extent of heterogeneity.

Description of studies

Five eligible randomised control trials (RCTs) were identified. Four of the five evaluated the effectiveness of a hydrogel as a method of debridement; one trial compared the effectiveness of sodium carboxymethylcellulose (NaCMC) aqueous based-gel (hydrogel) and good wound care with good wound care alone (D'Hemecourt 1998). In this trial good wound care for all groups consisted of

initial and ongoing sharp debridement of ulcers when necessary to remove nonviable tissue, daily saline dressing changes, off loading of pressure and systematic control of infection if present. One trial compared two moist wound healing protocols: Carrasyn hydrogel wound dressing (CHWD) against wet-to-moist saline gauze (Jensen 1998). The pharmaceutical composition of CHWD was not reported in the paper. The third hydrogel trial compared an 'immunomodulating' hydrogel, containing 65% glycerin (giving it a bacteriostatic action) with dry gauze (Vandeputte 1997). One trial compared the effectiveness of larval therapy with a hydrogel (Markevich 2000). It is unclear from the papers the extent to which the pharmaceutical composition of the four hydrogels differed. The other trial compared the effectiveness of surgical with conservative non-surgical debridement (conservative treatment consisting of relief of weight-bearing and regular dressings (Piaggessi 1998). Only two trials identified neuropathy as the primary aetiology of the included wounds (Markevich 2000; Piaggessi 1998). The other three trials did not report on the primary aetiology and classified the wounds as diabetic foot ulcers.

Study Settings

The study setting was described in two studies (Jensen 1998; Piaggessi 1998) where patients were seen in the outpatients' department. Only one trial reported the source of patients as the diabetic foot clinic (Piaggessi 1998), the other four trials did not describe where participants were recruited from. The primary outcome of all five trials was complete wound closure, either the time taken to achieve complete wound closure or the proportions of wounds achieving complete wound closure were reported. Three of the trials reported healing rates as an outcome (D'Hemecourt 1998; Jensen 1998; Piaggessi 1998).

Methodological quality

Methodological quality is drawn upon in the narrative interpretation of the results. Methodological quality is described for each study in Characteristics of included studies table.

Use of clear inclusion and exclusion criteria

(See Table 02 - Inclusion and Exclusion Criteria)

The quality of reporting of inclusion and exclusion criteria was extremely variable amongst the five trials. The most detailed (D'Hemecourt 1998) outlined precise inclusion and exclusion criteria. Although (Jensen 1998) had clear inclusion criteria, no exclusion criteria were listed: in such cases where criteria were not listed, it was presumed that all people with diabetic foot ulcers were eligible for inclusion in the trial. Markevich (Markevich 2000) makes no reference to inclusion or exclusion criteria. Three trials (Markevich 2000; Piaggessi 1998; Vandeputte 1997) entered people with diabetic foot ulcers into their trials regardless of ulcer size, depth, duration or blood supply. Vandeputte (Vandeputte 1997) had a single exclusion criterion of patients receiving systemic antibiotics.

Random allocation

(See Characteristics of included studies table)

Random allocation to intervention groups remains the only method of ensuring that the groups being compared are on an equivalent footing at study outset, thus eliminating selection and confounding biases. The success of randomisation depends on two interrelated processes. The first entails generating a sequence by which participants in a trial are allocated to intervention groups. To ensure unpredictability of that allocation sequence investigators should generate it by a random process (e.g. computer generated numbers, random number tables or coin flipping) (EBN 2001). The reporting of methods of random allocation for each of the trials was poor.

Allocation concealment

This is the second process of allocation, and shields those involved in the trial from knowing upcoming assignments in advance. Without this protection, investigators have been known to change who gets the next assignment, making the comparison groups less equivalent (EBN 2001). The process of allocation concealment was not reported in any of the included trials.

Baseline comparability of treatment groups for important variables

(See Table 03 - Baseline comparability)

It is essential that the trials involving diabetic foot ulcers ensure baseline comparability of the treatment groups for initial area of ulceration. Margolis 1999 has demonstrated that baseline wound area is an important prognostic variable for foot ulcer healing. Trials involving diabetic foot ulcers (as with any other wound healing trials) often express the change in wound area as the percentage change, which takes into account the initial size of the wound, unlike the absolute change in area. (Margolis 1999) For two wounds healing at the same linear rate (as measured by diameter reduction) percentage area calculations will show a larger change for a smaller wound than a big wound. The converse is true when the absolute change in area is measured, since for any unit reduction in wound radius a bigger area reduction will occur for a larger wound (Bradley 1999). This has important consequences for the validity of trial results where there is poor comparability of wound size at baseline between the treatment groups. In large trials random allocation should ensure that the average wound size and variance in each group is similar. In a small trial random allocation is unlikely to result in an even distribution of wound sizes. In a trial where there is poor comparability between groups for wound size at baseline, and the outcome is based on the change in area, the result can only be considered valid if it is obtained either: against the anticipated direction of the bias for wound size, or where percentage area change and absolute area change are in the same direction. If baseline data are not given then it is not possible to determine the direction of bias and the validity of the result cannot be determined. Only two trials (D'Hemecourt 1998; Markevich 2000) demonstrated that their treatment groups were balanced for ulcer area at baseline.

Use of intention-to-treat analysis

An intention-to-treat analysis analyses participants in the groups to which they were

randomised, irrespective of the treatment received. Three of the five trials (D'Hemecourt 1998; Markevich 2000; Vandeputte 1997) explicitly used an intention-to-treat analysis.

Power of the studies to find clinically important effects

Small sample size was the major deficiency of most of these trials. Two of the trials (D'Hemecourt 1998; Markevich 2000) recruited 140 patients or more. D'Hemecourt (D'Hemecourt 1998) conducted a three arm trial, involving 172 patients and was the largest study included. The other 3 trials each recruited fewer than 50 patients (median: 42; range: 29-197).

Extent of loss of follow up

Four of the five trials addressed loss of follow up. Two studies reported no withdrawals (Piaggessi 1998; Vandeputte 1997) and two studies accounted for the withdrawals that had taken place (D'Hemecourt 1998; Jensen 1998). This is important because excluding those people who withdrew from a study may lead to a misleading estimate of effectiveness as patients withdraw for non random reasons, including treatment failure.

Blinded outcome assessment

Of the five RCTs in this review, we could be confident that blinded outcome assessment had been used in one trial (D'Hemecourt 1998). Markevich 2000 reported that the study was double blinded, although they did not report who was blinded (it may be any or all of outcome assessor, patient, clinician or data analyst). The other three trials (Jensen 1998; Piaggessi 1998; Vandeputte 1997) did not use blinded outcome assessments. Vandeputte (Vandeputte 1997) photographed the wounds every four weeks although it was unclear if and how these photographs were used in the analysis.

Results

Results of dichotomous variables are presented as relative risk (RR) with 95% confidence intervals (CI). Relative risk has been used rather than odds ratios as the event rates are high in these trials and odds ratios would give an inflated impression of the magnitude of effect (Deeks 1998). Relative risk of healing is the healing rate in the experimental group divided by the healing rate in the control group. The relative risk indicates the relative benefit of a therapy, but not the actual benefit, i.e. it does not take into account the number of people whose ulcer would have healed without therapy.

Comparison 1: Surgical debridement compared with conventional nonsurgical management

This comparison was made in only one trial (Piaggessi 1998) (42 participants). The surgical debridement group underwent surgical excision, eventual debridement or removal of bone segments underlying the lesion and surgical closure. The conventional management group received pressure relief and regular dressings (the type of dressing was not reported).

Primary outcomes

Proportion of ulcers completely healed (Figure Comparison 01, Outcome 01)

Conservative care healed 19/24 (79%) ulcers, compared with 21/22 (95%) of ulcers treated by surgical debridement, RR 1.21 (95% CI 0.96 to 1.51) (P = 0.1) (no statistically significant difference).

Time to complete healing (Figure Comparison 01, Outcome 02)

The ulcers treated with conservative methods took longer to heal on average; 129 (+/- 87 days) compared with the surgically treated group whose healing time was 47 (+/- 39 days). It was unclear in the trial whether the figures in parentheses were the range, SEM or standard deviation values. There were insufficient data provided to determine whether this difference was statistically significant. Baseline data were collected for the type and duration of diabetes, the age of patients and their HBA1c. From the reported data each group seemed balanced for baseline variables.

Secondary outcomes

Proportion of ulcers recurring after healing (Figure Comparison 01, Outcome 04)

In the conservative treatment group 8/24 (33%) ulcers recurred within six months, compared with 3/22 (14%) in the surgical treatment group; RR 0.41 (95%CI 0.12 to 1.35) (no statistically significant difference).

Number of complications/adverse events reported (Figure Comparison 01, Outcome 05)

In the conservative treatment group 3/24 (13%) patients became infected compared with 1/22 (5%) of patients in the surgical group; RR 0.33 (95% CI 0.03 to 3.47). This difference was not statistically significant. The abstract did not report how infection was diagnosed.

Patients' quality of life (Figure Comparison 01, Outcome 06)

No data were shown for this outcome. [Piaggessi 1998](#) claimed that patients reported a higher degree of satisfaction with surgical debridement as well as lower discomfort, but did not report how this outcome was measured and whether a valid scale was used.

Comparison 2: Larvae compared with hydrogel

This comparison was made in only one trial, ([Markevich 2000](#)). Only one outcome was reported, number of outcomes completely healed. The trial involved 140 patients all with diabetic neuropathic foot lesions

Proportion of ulcers completely healed (Figure Comparison 02, Outcome 01)

In the larvae group 5/70 (7%) patients achieved complete healing, compared with 2/70 (3%) patients from the hydrogel group; RR 2.5 (95% CI 0.5 to 12.4) (no statistically significant difference). It is unclear from the abstract how long it took to achieve wound healing in either group. The duration of follow up was also unclear.

Comparison 3: Hydrogel compared with gauze/standard care

Trial 1: Hydrogel (Carrasyn, CHWD) compared with wet to moist saline gauze

Only one trial reported this comparison (Jensen 1998). The trial recruited 31 diabetic patients with foot ulcers of at least 1 cm diameter with no evidence of infection in the ulcer or peri-wound tissue.

Primary outcomes

Proportion of ulcers completely healed (Figure Comparison 03, Outcome 01)

In the hydrogel group 12/14 (86%) patients healed completely compared with 6/17(46%) in the control group, RR 2.43 (95% CI 1.23 to 4.79) (a statistically significant difference in favour of hydrogel). The average duration of ulceration was longer in the hydrogel group (8.9 months) than in the saline control group (3 months), and since ulcer duration is prognostic for healing, the bias at baseline is working against the direction of the results, giving us more confidence in them.

Time to complete healing (Figure Comparison 03, Outcome 02)

Those ulcers treated with the hydrogel achieved healing in an average of 10 weeks. The control group healed in an average of 12 weeks (no statistically significant difference).

Rate of reduction in wound size (Figure Comparison 03, Outcome 03)

At the end of 16 weeks the wound closure rate with hydrogel was 85% (11/14) and 46% (6/17) with the saline control group (P = 0.05). It is unclear whether these figures relate to the mean or median value.

Secondary outcomes

Number of complications/adverse events reported (Figure Comparison 03, Outcome 05)

In the hydrogel group 2/14 people had complications (14%), compared with 4/17 (24%) in the control group. Complications were as follows: a) worsened and required amputation, b) increased eschar formation, c) developed cellulitis, d) worsened with increased eschar formation), RR 0.61 (95%CI 0.13 to 2.84) (no statistically significant difference).

Cost effectiveness (Figure Comparison 03, Outcome 07)

Insufficient data prevented us from determining whether there was any statistically significant

difference between the apparent difference in cost effectiveness (hydrogel cost \$7/day compared with \$12/day for the control treatment).

Trial 2: Hydrogel (NaCMC aqueous based gel) compared with good wound care alone

Only one trial reported this comparison ([D'Hemecourt 1998](#)). The intention-to-treat population consisted of 172 patients. Baseline comparisons were documented for patient demographic characteristics, gender, race, age, height and weight.

Primary outcomes

Proportion of ulcers completely healed (Figure Comparison 03, Outcome 01)

Within a 20 week study period 15/68 (22%) of patients healed with good wound care alone, whilst 25/70 (36%) of patients healed with hydrogel, RR 1.62 (95% CI 0.94 to 2.80) (no statistically significant difference).

Time to complete healing (Figure Comparison 03, Outcome 02)

Complete healing was achieved in an average of 141 days with good wound care alone and in an average of 98 days with hydrogel. No variance data were provided for this outcome.

Secondary outcomes

Number of complications/adverse events reported (Figure Comparison 03, Outcome 05)

In the good wound care (GWC) alone group 25/68 (37%) patients developed an infection (it is unclear how infection was defined in the paper), compared with 19/70 (27%) patients in the hydrogel group, RR 0.74 (95%CI 0.45 to 1.21) (no statistically significant difference).

Quality of life/increase in pain (Figure Comparison 03, Outcome 06)

In the control group 10/68 (15%) patients reported an increase in pain compared with 11/70 (16%) in the hydrogel group, RR 1.07 (95% CI 0.49 to 2.35) (no statistically significant difference). It is not clear in the reporting of the trial how pain was measured.

Trial 3: 'Immunomodulating' hydrogel compared with dry gauze

Only [Vandeputte 1997](#) made this comparison. The trial recruited 29 patients with diabetic foot ulcers. Patient characteristics collected at baseline were gender, age, number completely mobile, number less than completely mobile, number of neuropathic ulcers and number of patients with infection before the trial. There were only two outcome measures identified.

Primary outcomes

Proportion of ulcers completely healed (Figure Comparison 03, Outcome 01)

After three months 14/15 (93%) patients completely healed with hydrogel, compared with 7/14 (50%) patients healed in the dry gauze group (statistically significant difference). RR 1.87 (95% CI 1.09 to 3.21). However, this trial lacked power due to its small size.

Secondary outcomes

Number of complications/adverse events reported (Figure Comparison 03, Outcome 05)

One person in the hydrogel group (7%) developed a wound infection (it is unclear in the paper how infection was defined) compared with 7/14 (50%) in the dry gauze group RR 0.13 (95% CI 0.02 to 0.95) (no statistically significant difference).

Hydrogel compared with gauze/good wound care alone (Figure Comparison 03, Outcome 01)

The three trials (D'Hemecourt 1998; Jensen 1998; Vandeputte 1997) comparing hydrogel with either gauze dressing or good wound care (dressing not specified) were considered sufficiently similar to pool (in the absence of significant heterogeneity ($P = 0.65$, $I^2 = 0\%$), using a fixed-effects model. Pooling the three hydrogel trials yielded a relative risk of healing with hydrogel of 1.84 (95% CI 1.3 to 2.61). This translates to an absolute increase in the risk of healing with hydrogel of 23%, (95% CI 10% to 36%) and a number needed to treat of five (95% CI 2 to 10), that is for one additional patient to heal their diabetic foot ulcer, five patients must be treated with hydrogel instead of gauze or standard care (treatment time varied from 12 to 20 weeks).

Number of complication/adverse events reported (Figure Comparison 03, Outcome 05)

All three trials (D'Hemecourt 1998; Jensen 1998; Vandeputte 1997) reported the incidence of complications/adverse events. There was a total of 22 events in the hydrogel groups, compared with 36 events in the comparison groups. It was decided to pool these trials and although there was some evidence of heterogeneity ($I^2 = 31\%$) a fixed effects model was applied RR 0.60 (95% CI 0.38 to 0.95) showing a statistically significant difference in favour of hydrogel. If a random effects model is applied there is no statistically significant difference between the two groups RR 0.56 (95% CI 0.25 to 1.25).

Discussion

Many clinicians believe that debridement or cleaning the wound by the removal of necrotic tissue aids wound closure and therefore promotes wound healing. It is because of this belief that an outcome measure based on wound healing is valid. The common outcome identified by all the trials was complete wound healing. Two methods of debridement were employed by the included studies but the confidence with which we can draw firm conclusions from this review is greatly tempered by:

- (1) the poor quality of many of the trials;

- (2) the diversity of the debriding agents being compared;
- (3) small sample sizes; and
- (4) lack of replication studies.

Most of the trials undertaken were small and under powered, running a risk of failing to detect clinically significant differences as statistically significant. Other common methodological flaws such as open randomisation, lack of baseline comparability and lack of blind outcome assessment further reduce the confidence with which we can regard many of the individual study findings. It is possible to minimise bias in outcome assessment by having an assessor who is unaware of the treatment allocation, either in person, or by presenting photographic evidence of the ulcer. Future trials should address these deficiencies.

Firstly, debridement by surgical treatment compared with conventional nonsurgical management was considered by one small study ([Piaggessi 1998](#)). Whilst the study authors concluded that surgical treatment of neuropathic foot ulcers in diabetic patients is more effective compared with conventional treatment, this conclusion was not based on a statistically significant effect and the study was low in power due to its small size. Therefore there is no evidence from RCTs that surgical debridement heals diabetic foot ulcers more rapidly than conservative care.

Secondly, trials comparing the effects of hydrogels were considered. Two trials showed a statistically significant benefit of hydrogel on ulcer healing ([Jensen 1998](#); [Vandeputte 1997](#)). [Jensen 1998](#) compared hydrogel with wet to moist saline gauze found a statistically significant benefit for the hydrogel intervention. However, the trial is hampered both by methodological flaws. A comparison of a hydrogel with dry gauze ([Vandeputte 1997](#)) found a significant benefit associated with the hydrogel. Again this trial is hampered by methodological faults. The largest trial included in this review compared hydrogel with good wound care ([D'Hemecourt 1998](#)) in 172 patients: the only study to report using a blinded assessor. D'Hemecourt concludes that hydrogel may have a beneficial effect on wound healing when compared with good wound care alone. Although the results of the trial favoured the hydrogel treatment, the difference was not statistically significant.

The three trials ([D'Hemecourt 1998](#); [Jensen 1998](#); [Vandeputte 1997](#)) that compared hydrogel with either gauze ([Jensen 1998](#); [Vandeputte 1997](#)) or 'good wound care' ([D'Hemecourt 1998](#)) were sufficiently similar to pool, resulting in a statistically significant benefit for healing associated with hydrogel.

The final comparison of larvae with hydrogel in 140 patients, is reported in abstract form only, and found no difference ([Markevich 2000](#)).

A trial by Steed et al ([Steed 1996](#)), which was excluded from the review on the grounds that it was not a randomised comparison of debridement strategies, raises some important issues. The trial makes a connection between debridement and an increased rate of wound healing. The trial was designed to assess the effects of topically applied growth factor with regard to the healing of diabetic foot ulcers. Before randomisation, all patients underwent aggressive, sharp debridement of callous and necrotic tissue. The influence of this debridement was evaluated by correlating

healing rates with debridement. Whilst the results showed that, in general, there was a lower rate of healing in centres where less frequent debridement was performed, these results must be viewed with caution, as they constitute a post hoc analysis of a non-randomised comparison and it cannot be concluded that the only difference between the patients who healed was the extent of debridement received (Steed 1996).

In summary, this review has demonstrated that hydrogel appears to result in better healing rates for diabetic foot ulcers than gauze or standard care, however since hydrogel functions by increasing the moisture of the wound environment, it is not clear whether this effect is mediated through debridement per se. More rigorous research is required to clarify whether debridement aids the healing of diabetic foot ulcers, and if so which is the optimum method.

Authors' conclusions

Implications for practice

The RCTs on debridement of diabetic foot ulcers are in general small and of poor methodological quality. The evidence suggests that hydrogel increases the healing of diabetic foot ulcers compared with gauze or standard wound care. It is not clear whether this effect is due to debridement.

Implications for research

Well designed RCTs of sufficient size are needed to assess the effectiveness of debridement of diabetic foot ulcers. Future trials evaluating debridement need to be properly randomised with concealed allocation, adequate sample size, blinding of outcome assessors, unbiased, and objective in their assessment of ulcer healing. The review strongly suggests that more good quality RCTs are needed to determine the clinical effect of debridement on healing.

Potential conflict of interest

None known.

Acknowledgements

The Cochrane Wounds group for their continual support and guidance throughout and specifically to Andrea Nelson. Cochrane Wounds Group referees (Andrew Boulton, Sue O'Meara and Donald Cameron) and Editors (Nicky Cullum, David Margolis and Raj Mani) for their comments to improve the review.

For the update of the review, Wendy Milborrow (Asst RGC) provided comments on the draft update; incorporated copy editor's recommendations into the review and reformatted references, with the agreement of the author.

Notes

This review was originally published in the Cochrane Library, Issue 4, 2002, with five included

studies.

For this first update, new searches were carried out in May 2005. Eight studies were identified, of which four were excluded. Three studies (Capillas 2002, Dolnychuck 200, Whalley 2001) are awaiting assessment. One duplicate publication has been added as a secondary reference.

One study (Mulder 1994b), which was awaiting assessment in the original review, has now been excluded.

The reviewers conclusions remain unchanged.

Characteristics of included studies

Study D'Hemecourt 1998

Methods RCT

Multi-centred (10 sites)

Evaluator-blind

Participants 172 patients

A) 68

B) 70

C) 34

45 women/127 men

19 years or older

Type 1 / Type 2 diabetes.

Wound size (area and depth) measured at baseline.

Interventions A) Good wound care

B) Good wound care & NaCMC hydrogel

C) Good wound care & becaplermin

Off loading of pressure and systemic control of infection for all wounds.

Outcomes 1. Complete wound healing at 20 weeks

A) 15 / 68 (22%)

B) 25 / 70 (36%)

2. Time to complete healing

A) 141 days *

B) 98 days *

5. Complications & adverse events

A) 25 / 68 (37%)

B) 19 / 70 (27%)

6. Quality of life (pain reported as adverse event)

A) 10 / 68 (15%)

B) 11 / 70 (16%)

Notes 1. RCT

2. Lower extremity diabetic ulcers

3. NaCMC hydrogel

4. Complete healing

5. Largest trial with regard to patient numbers

Allocation concealment A - Adequate

Study Jensen 1998

Methods RCT

Randomised into 2 groups.

Participants 31 patients

A) 14

B) 17

No description of age, sex or type of diabetes.

Wound area measured at baseline.

Average duration of ulceration

A) 8.9 months

B) 3 months

Interventions A) Carrasyn hydrogel wound dressing (CHWD)

B) Wet-to-moist saline gauze

All patients received custom made healing sandals for pressure redistribution

Outcomes 1. Complete wound healing at 16 weeks

A) 12 / 14 (86%)

B) 6 / 17 (35%)

2. Healing time

A) 10.3 weeks *

B) 11.69 weeks *

3. Healing rate (reduction in wound area)

A) 84.6% *

B) 46.1% * P=0.05

5. Complications

A) 2/14 (14%)

B) 4/17 (24%)

7. Cost effectiveness

A) 7.01 - (\$/day)

B) 12.28 - (\$/day)

Notes 1. RCT - No randomisation method reported

2. Diabetic foot ulcer

3. Use of hydrogel

4. Complete wound closure as outcome

5. Small patient numbers

6. No intention-to -treat analysis

Allocation concealment B - Unclear

Study Markevich 2000

Methods RCT

Multi-centred

Double-blind

Participants 140 patients,

A) 70

B) 70

Average age 53.6+/-15.4 years.

No description of sex or type of diabetes.

Wound depth measured at baseline.

Interventions A) Larval therapy for 72 hours

B) Hydrogel (no data on frequency of dressing change)

Outcomes 1. Complete healing (no data as to time this took)

A) 5/70 (7%)

B) 2/70 (3%)

(no statistical difference)

Notes 1. RCT - Not clear whether allocation was concealed

2. Diabetic foot ulcer

3. Treatment with debriding agent

4. Outcome - healing mentioned

5. Duration of follow up unclear

Allocation concealment B - Unclear

Study Piaggessi 1998

Methods Randomised into 2 groups

Participants 42 patients with 46 ulcers

A) 21 patients, 24 ulcers

B) 21 patients 22 ulcers

No description of age, sex or type of diabetes.

Baseline wound area measurement not reported.

Interventions A) Control - Non-surgical conservative treatment and pressure relief

B) Treatment - Surgical debridement

Outcomes 1. Complete healing at 6 months

A) 19/24 (79%)

B) 21/22 (95%)

2. Healing time

A) 128.9 days *

B) 46.7 days *

4. Reccurence rate

A) 8/24 (33%)

B) 3/22 (14%)

5. Infective complications

A) 3/24 (13%)

B) 1/22 (5%)

Notes 1. RCT - No randomisation method reported

2. Diabetic foot ulcers

3. Surgical debridement

4. Healing as an outcome

Allocation concealment B - Unclear

Study Vandeputte 1997

Methods Pre-prepared randomisation listing

Participants 29 patients with 30 wounds

A) 15 patients (15 wounds)

B) 14 patients (15 wounds)

No description of age, sex or type of diabetes.

Baseline wound area measurement not reported.

Interventions A) Hydrogel

B) Dry gauze (control)

Outcomes 1. Complete Healing at 3 months

A) 14/15 (93%)

B) 7/14 (50%)

5. Infective complications

A) 1/15 (7%)

B) 7/14 (50%)

Notes 1. RCT -

2. Preprepared randomisation listings

3. Diabetic foot ulcers

4. Glycerine-based hydrogel

5. Healing times

Allocation concealment B - Unclear

D'Hemecourt study - a three arm trial with the third arm concerned with good wound care and the use of Becaplermin gel - this arm was considered ineligible for the review.

* It is unclear if these are mean or median times to healing

Characteristics of excluded studies

Study Reason for exclusion

Armstrong 2000 Although all wounds were debrided the primary intervention measured was a foot compression system, there was no comparison or conclusions drawn regarding the debridement methods used.

Gottrup 2001 This is a cost evaluation paper. The full paper (Capillas) is in 'studies awaiting assessment'

Gough 1997 RCT which compares granulocyte stimulating factor, with a placebo, there is no debriding agent included in the trial.

Grayson 1994 RCT assessing the effectiveness of imipenem / cilastatin against ampicillin / sulbactam in the treatment of pedal infections in diabetic. No debriding agent was considered.

Krupski 1991 RCT which compared platelet derived wound healing with a placebo. Although all wounds were extensively debrided initially, there were no debriding agents included in the trial. The trial sample was 'mixed ulcers' - with leg ulcers mainly identified.

Martinez-de-Jesus 97 RCT where all foot ulcers under went surgical debridement and were then treated with either topical ketanserine or normal saline (placebo). Excluded as the topical treatment, although gel based was compounded by the fact that it contained ketanserine gel.

Mulder 1994a RCT comparing Iamin gel with standard care and vehicle gel. The Iamin gel contains a peptide copper complex, which has been shown to be a chemoattractant for capillary

endothelial cells and is angiogenic, it is therefore not a debriding agent.

Mulder 1994b Report available as abstract only. Letters to authors have failed to elicit further information.

Piaggese 2001 RCT with diabetic patients. The type of dressing used in the intervention, however, is not a debridement agent, the use of hydro-fibres allows the dressing to absorb exudate and is concerned with maintaining a moist environment at the wound surface.

Pollak 1997 RCT which assesses the effectiveness of human dermis replacement against conventional treatment. There is initially sharp debridement, but there is no debriding agent assessed in the trial.

Razzak 1997 RCT including 24 patients, dividing patients into treatment with either antibiotics or local insulin application. No debriding agent was assessed in this trial.

Saap 2002 Fulfils the inclusion criteria for RCT and diabetic foot ulcers. The paper, however, is concerned with measuring the standard of debridement and the effectiveness of a debridement scale, rather than the effectiveness of debridement as a treatment.

Seidel 1994 RCT which assess the use of short term retrograde transvenous leg perfusion. The trial is concerned with infection of foot ulcers, wound healing was not an outcome.

Steed 1996 RCT of 118 patients which compares treatment of human derived growth factor against a placebo. The influence of debridement was evaluated by reviewing the records of the office. This paper was used in the discussion section of this review.

Wieman 1998 RCT of 382 patients which assessed the efficacy and safety of topically applied recombinant human platelet derived growth factor at two strengths, either becaplermin 30mg or becaplermin 100mg.

Additional tables

Table 01

Table 02

Table 03

Analyses

Comparison 01

Comparison 02

Comparison 03

Sources of support

External sources of support

* No sources of support supplied

Internal sources of support

* Diabetes Centre, York District Hospital, York UK

* Department of Health Sciences, University of York, York UK

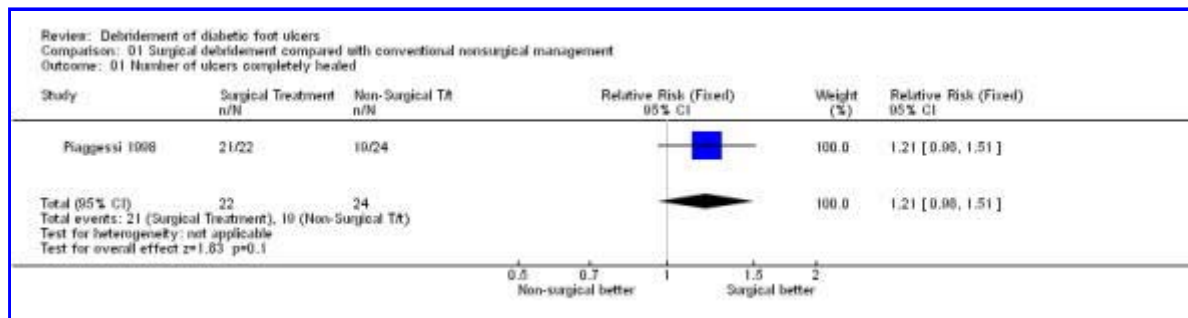
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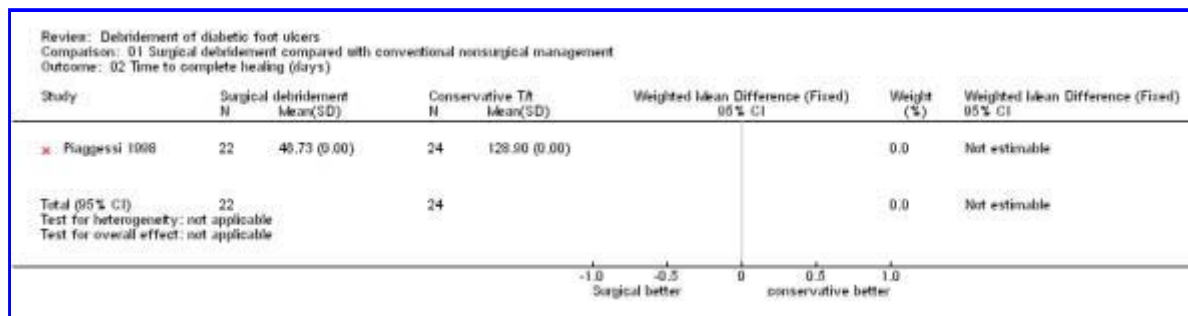
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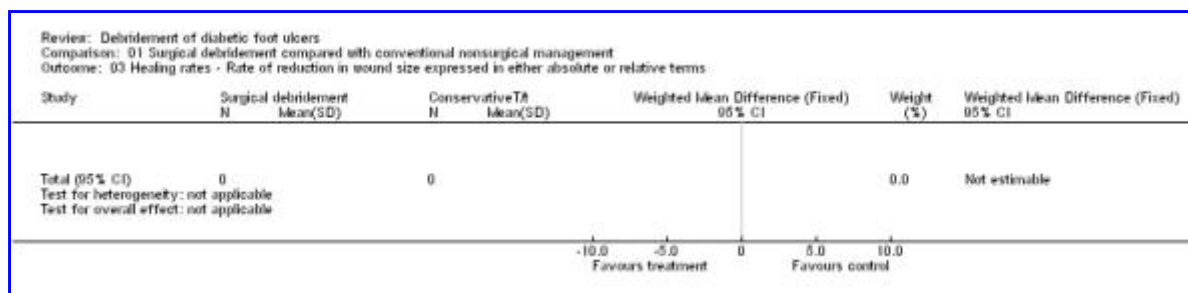
The reviewers conclusions remain unchanged.



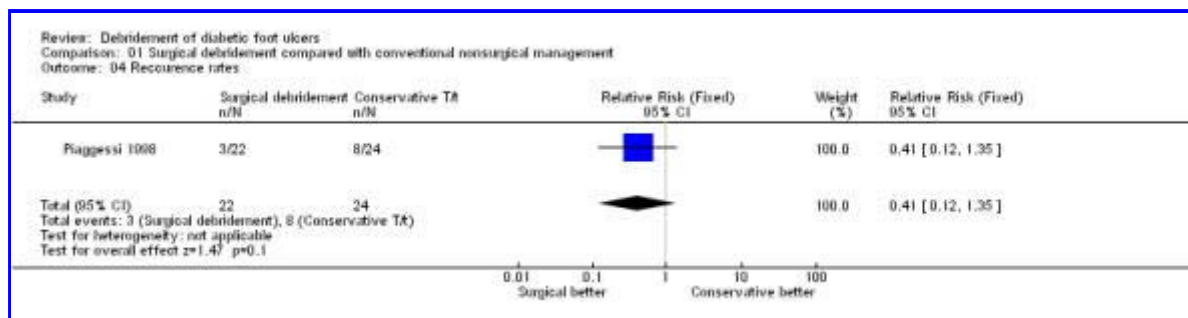
Comparison 01 Surgical debridement compared with conventional nonsurgical management, Outcome 01 Number of ulcers completely healed



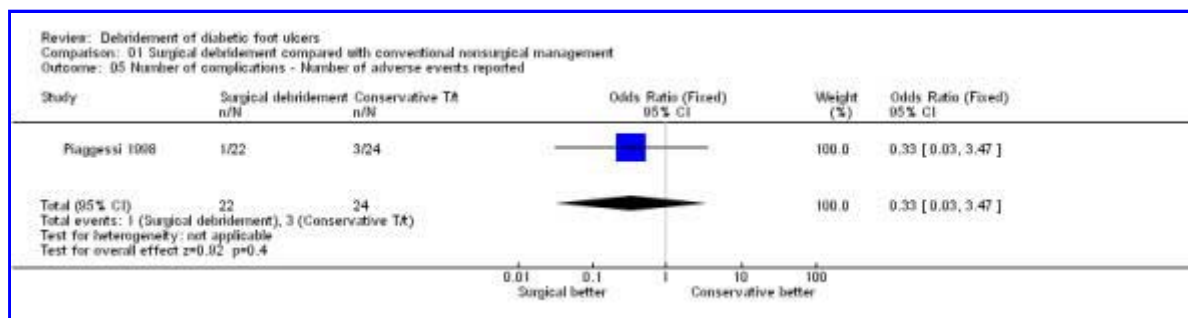
Comparison 01 Surgical debridement compared with conventional nonsurgical management, Outcome 02 Time to complete healing (days)



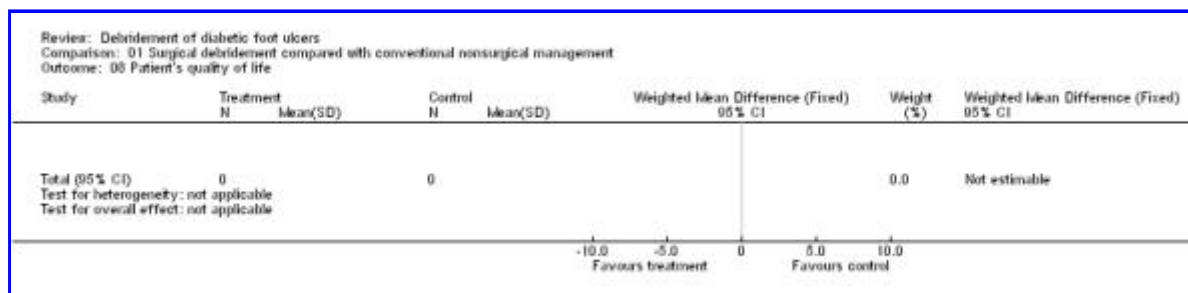
Comparison 01 Surgical debridement compared with conventional nonsurgical management, Outcome 03 Healing rates - Rate of reduction in wound size expressed in either absolute or relative terms



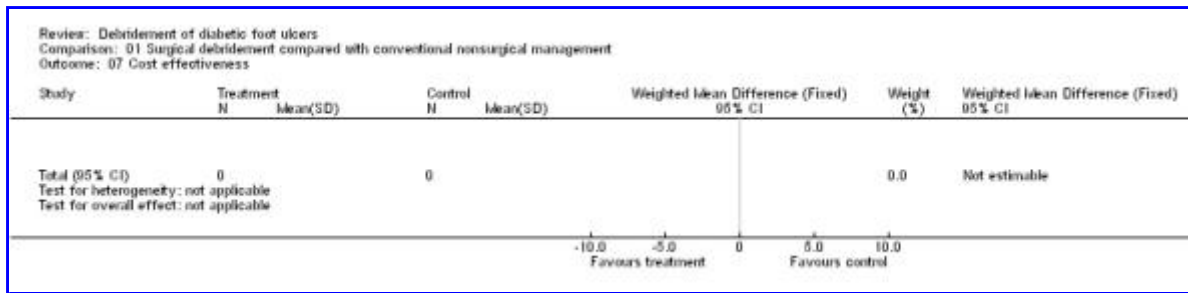
Comparison 01 Surgical debridement compared with conventional nonsurgical management, Outcome 04 Recurrence rates



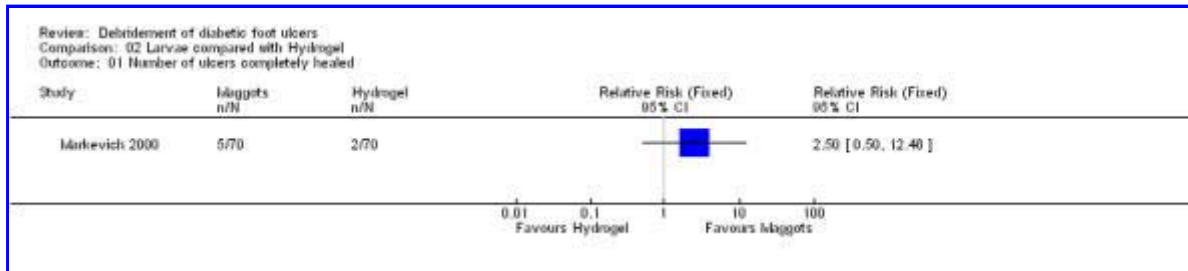
Comparison 01 Surgical debridement compared with conventional nonsurgical management, Outcome 05 Number of complications - Number of adverse events reported



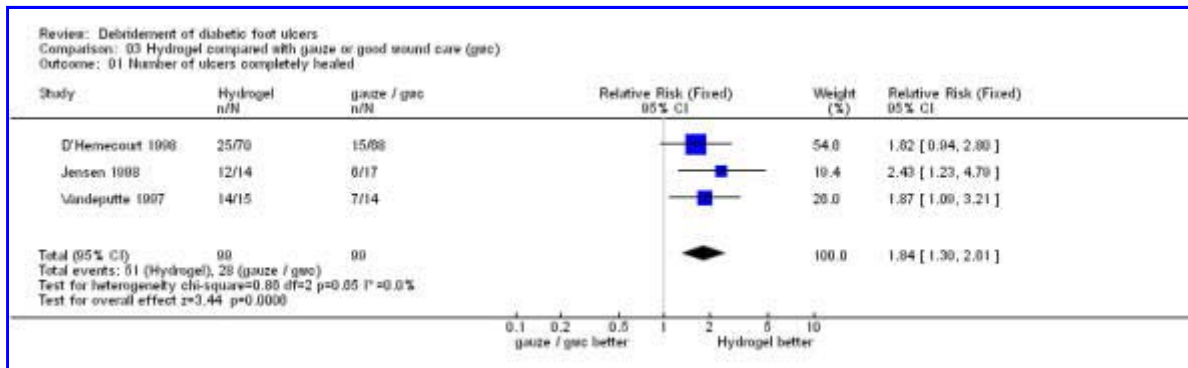
Comparison 01 Surgical debridement compared with conventional nonsurgical management, Outcome 06 Patient's quality of life



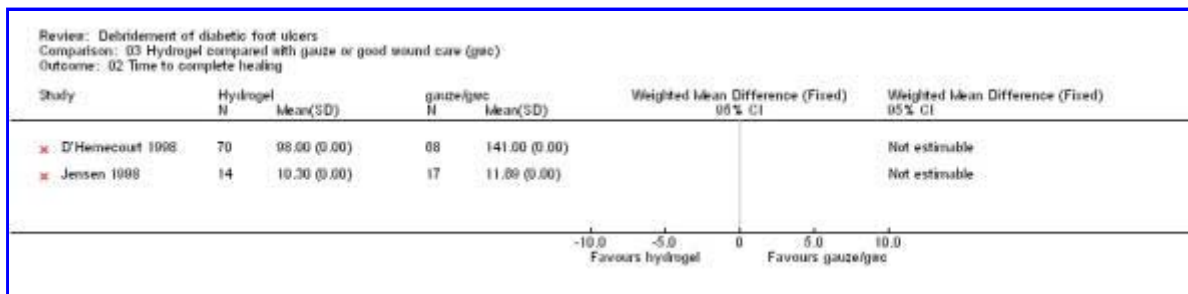
Comparison 01 Surgical debridement compared with conventional nonsurgical management, Outcome 07 Cost effectiveness



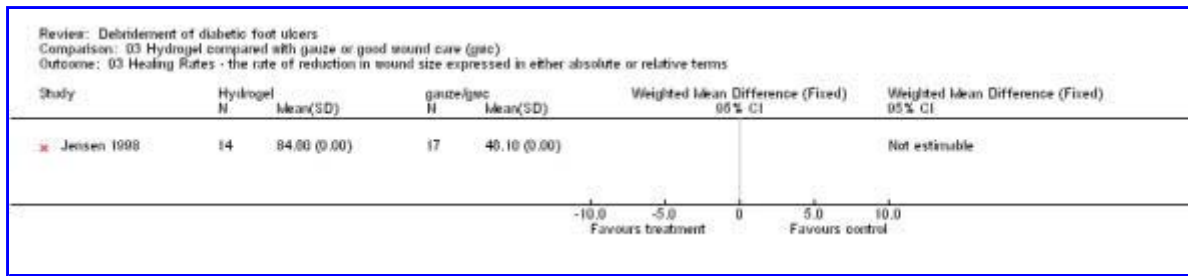
Comparison 02 Larvae compared with Hydrogel, Outcome 01 Number of ulcers completely healed



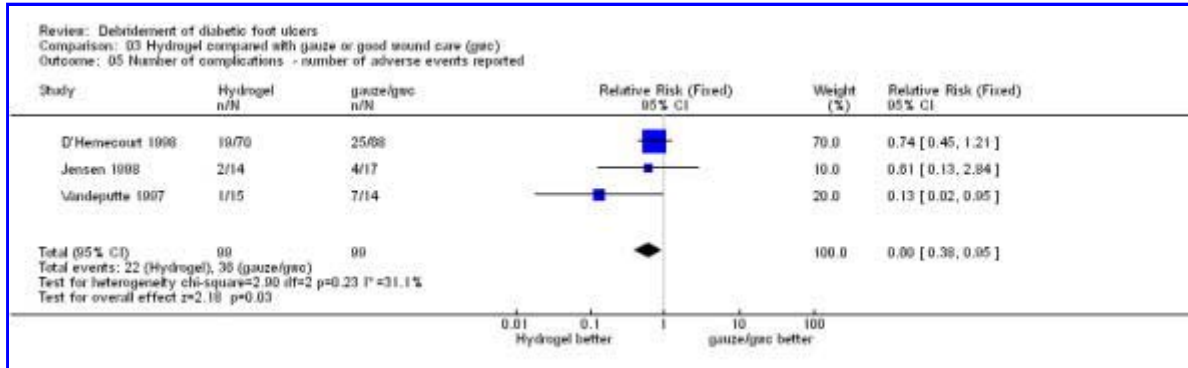
Comparison 03 Hydrogel compared with gauze or good wound care (gwc), Outcome 01 Number of ulcers completely healed



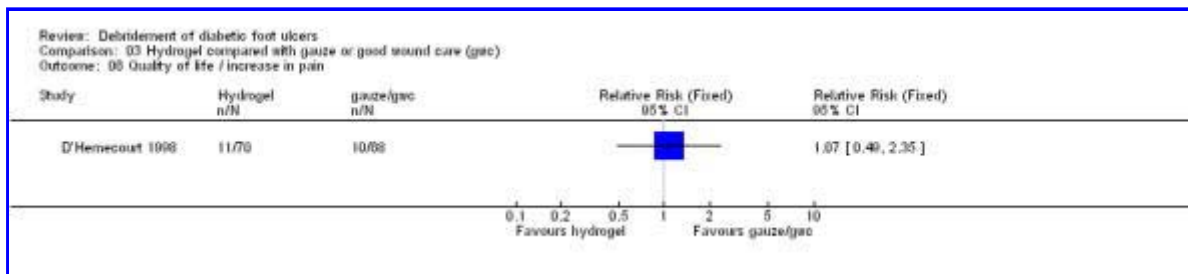
Comparison 03 Hydrogel compared with gauze or good wound care (gwc), Outcome 02 Time to complete healing



Comparison 03 Hydrogel compared with gauze or good wound care (gwc), Outcome 03 Healing Rates - the rate of reduction in wound size expressed in either absolute or relative terms



Comparison 03 Hydrogel compared with gauze or good wound care (gwc), Outcome 05 Number of complications - number of adverse events reported



Comparison 03 Hydrogel compared with gauze or good wound care (gwc), Outcome 06 Quality of life / increase in pain

Methods of debridement

Debridement Method: Mechanical

Explanation:

Advantages:

Disadvantages:

Debridement Method: Surgical (scalpel)

Explanation: The technique is simple, requiring the use of only sterile scissors or a scalpel,

but it does require a certain amount of skill to prevent enlarging the wound.

Advantages: Quick

Disadvantages: Can make the wound bigger

Debridement Method: Wet-to dry

Explanation: The wound is soaked in saline to moisten hard material before the application of a moist gauze pad over the affected area. As the devitalised tissue dries it re-hardens and becomes attached to the gauze, when the dressing is changed the adhered material is pulled free.

Advantages: Allows removal of hardened necrosis Inexpensive

Disadvantages: It is not discriminating and may remove granulating tissue. It also may be painful for the patient.

Debridement Method: Bio-Surgery

Explanation: Sterile maggots of the green bottle fly *Lucilia sericata* are placed directly on to the affected area and held in place by a close net dressing. The larvae have a ferocious appetite for necrotic material while actively avoiding newly formed healthy tissue.

Advantages: They discriminate between the necrotic and the granulating tissue.

Disadvantages: There is at present no conclusive evidence of effectiveness in foot ulcers, there may also be a reluctance to use this treatment by patients and clinicians, there is a cost implication

Debridement Method: Non-Mechanical - These treatments are easy to apply and have additional properties that may be beneficial for wound healing

Explanation:

Advantages:

Disadvantages:

Debridement Method: Enzyme Preparations

Explanation: The only formulation available in the UK contains Streptokinase and Streptodornase (Varidase Topical(R) Wyeth Laboratories). This enzyme aggressively digests the proteins fibrin, collagen & elastin, which are commonly found in the necrotic exudate of a wound. Other enzymatic preparations include trypsin and collagenase, are licensed in other countries.

Advantages: They can be applied directly onto the necrotic area

Disadvantages: Streptokinase can be systemically absorbed and is therefore contraindicated in patients at risk of an MI. There is a cost implication

Debridement Method: Polysaccharide beads or paste

dextranomer polysaccharide

Explanation: Is supplied as anhydrous porous beads or as a paste. The beads are highly hydrophilic and rapidly absorb exudate from a necrotic sloughy mass. The beads are removed by washing and the trapped necrotic material is removed.

Advantages: They can be applied directly onto the necrotic area. Minimal level of skill required.

Disadvantages:

Debridement Method: Hydrogels

Explanation: These gels are biologically inert and have significant water content. They complement the body's natural debriding process by providing a moist environment, which promotes autolysis, while still acting to preserve living healthy tissue. (Bradley 1999)

Advantages: They can be applied to a wound at any stage, as they promote moist wound healing they will do the wound no harm. Minimal level of skill required.

Disadvantages: They can be seen as the minimum level of debridement for a sloughy wound. If not masked properly they may macerate the surrounding tissue

Inclusion & exclusion criteria for included trials

Trial Author: D'Hemecourt (1998): written consent needed

Inclusion Criteria: 19 years or older, type 1 or type 2 diabetes, at least 1 full thickness ulcer (stage 3 or 4), ulcer present 8 weeks prior to study, 1cm²-10cm² post debridement, TcpO₂ >/ 30mmHg, chronic diabetic ulcer of lower extremity.

Exclusion Criteria: Ostoemyelitis, outside 1cm² -10cm² range, patient has more than 3 ulcers, cause of ulcer was not diabetes e.g electrical, chemical or radiation, patients with cancer, concomitant medication to affect wound healing, women who were pregnant, nursing or of child bearing potential.

Trial Author: Jensen (1997): written consent needed

Inclusion Criteria: Diabetic, foot ulcer of at least 1cm diameter, no evidence of infection in ulcer or peri-wound tissue, Wagner grade 2 ulcer - full thickness into subcutaneous tissue, but not involving tendon joint capsule or bone, documented blood supply consistent with the ability to

heal (palpable pulses, non-invasive vascular study), willingness to comply with protocol.

Exclusion Criteria: No exclusion criteria listed

Trial Author: Markevich (2000)

Inclusion Criteria: No inclusion criteria listed

Exclusion Criteria: No exclusion criteria listed

Trial Author: Vandeputte (1997): written consent needed

Inclusion Criteria: Diabetic, wound on foot

Exclusion Criteria: Patient receiving systemic antibiotics

Trial Author: Piagessi (1998)

Inclusion Criteria: All patients who came to the diabetic foot clinic between January - December 1995, diabetic neuropathic ulcer, uncomplicated.

Exclusion Criteria: No exclusion criteria listed

Trials reporting baseline wound statistics

Area (cm²) of wound: D'Hemecourt (1998) target area between 1.0 - 10cm² post debridement

Depth (cm²) of wound: D'Hemecourt (1998)

Duration of ulcer: D'Hemecourt (1998)

Area (cm²) of wound: Markevich (2000) average surface area in the maggot group = 14.9cm² and 15.14 cm² in the hydrogel group

Depth (cm²) of wound: Markevich (2000)

Duration of ulcer: Markevich (2000)

Area (cm²) of wound: Jensen (1997) All ulcers had to measure at least 1cm²

Depth (cm²) of wound:

Duration of ulcer: Jensen (1997)

Surgical debridement compared with conventional nonsurgical

management

Outcome title: 01 Number of ulcers completely healed

No. of studies: 1

No. of participants: 46

Statistical method: Relative Risk (Fixed) 95% CI

Effect size: 1.21 [0.96, 1.51]

Outcome title: 02 Time to complete healing (days)

No. of studies: 1

No. of participants: 46

Statistical method: Weighted Mean Difference (Fixed) 95% CI

Effect size: Not estimable

Outcome title: 03 Healing rates - Rate of reduction in wound size expressed in either absolute or relative terms

No. of studies: 0

No. of participants: 0

Statistical method: Weighted Mean Difference (Fixed) 95% CI

Effect size: Not estimable

Outcome title: 04 Recurrence rates

No. of studies: 1

No. of participants: 46

Statistical method: Relative Risk (Fixed) 95% CI

Effect size: 0.41 [0.12, 1.35]

Outcome title: 05 Number of complications - Number of adverse events reported

No. of studies: 1

No. of participants: 46

Statistical method: Odds Ratio (Fixed) 95% CI

Effect size: 0.33 [0.03, 3.47]

Outcome title: 06 Patient's quality of life

No. of studies: 0

No. of participants: 0

Statistical method: Weighted Mean Difference (Fixed) 95% CI

Effect size: Not estimable

Outcome title: 07 Cost effectiveness

No. of studies: 0

No. of participants: 0

Statistical method: Weighted Mean Difference (Fixed) 95% CI

Effect size: Not estimable

Larvae compared with Hydrogel

Outcome title: 01 Number of ulcers completely healed

No. of studies:

No. of participants:

Statistical method: Relative Risk (Fixed) 95% CI

Effect size: Totals not selected

Hydrogel compared with gauze or good wound care (gwc)

Outcome title: 01 Number of ulcers completely healed

No. of studies: 3

No. of participants: 198

Statistical method: Relative Risk (Fixed) 95% CI

Effect size: 1.84 [1.30, 2.61]

Outcome title: 02 Time to complete healing

No. of studies:

No. of participants:

Statistical method: Weighted Mean Difference (Fixed) 95% CI

Effect size: Totals not selected

Outcome title: 03 Healing Rates - the rate of reduction in wound size expressed in either absolute or relative terms

No. of studies:

No. of participants:

Statistical method: Weighted Mean Difference (Fixed) 95% CI

Effect size: Totals not selected

Outcome title: 04 Recurrence rates

No. of studies: 0

No. of participants: 0

Statistical method: Odds Ratio (Fixed) 95% CI

Effect size: Not estimable

Outcome title: 05 Number of complications - number of adverse events reported

No. of studies: 3

No. of participants: 198

Statistical method: Relative Risk (Fixed) 95% CI

Effect size: 0.60 [0.38, 0.95]

Outcome title: 06 Quality of life / increase in pain

No. of studies:

No. of participants:

Statistical method: Relative Risk (Fixed) 95% CI

Effect size: Totals not selected

Outcome title: 07 Cost effectiveness

No. of studies: 0

No. of participants: 0

Statistical method: Odds Ratio (Fixed) 95% CI

Effect size: Not estimable

Contribution of Reviewer(s)

JS initiated the review, performed the data extraction, analysed the data and wrote the report.

JS is the guarantor for the review

Most recent changes

This review was originally published in the Cochrane Library, Issue 4, 2002.

For this first update, new searches were carried out in May 2005. Eight studies were identified, of which four were excluded. Three studies (Capillas 2002, Dolnychuck 2001, Whalley 2001) are awaiting assessment. One duplicate publication has been added as a secondary reference.

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References to studies included in this review

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Piaggessi A, Rizzo L, Campi F, Schipani E. Conservative surgical approach versus non-operative treatment for diabetic neuropathic foot ulcers: a randomized trial. *Journal of Endocrinological Investigation* 1998;21(7):193.

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Armstrong DG, Nguyen HC. Improvement in healing with aggressive edema reduction after debridement of foot infection in persons with diabetes. *Archives of Surgery* 2000;135:1405-9. [Ovid Full Text](#) | [Bibliographic Links](#) | [\[Context Link\]](#)

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Gough A, Clapperton M, Rolando N, Foster AV, Philpott-Howard J, Edmonds ME. Randomised placebo-controlled trial of granulocyte-colony stimulating factor in diabetic foot infection. *Lancet* 1997;350:855-9. [Bibliographic Links](#) |

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