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Foam dressings for healing diabetic foot ulcers

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First published:
6 June 2013

Editorial Group:
Cochrane Wounds Group

DOI:
10.1002/14651858.CD009111.pub3 View/save citation

Cited by (CrossRef):
2 articles Check for updates | Citation tools

Abstract

Background

Foot ulcers in people with diabetes are a prevalent and serious global health issue. Dressings form a key part of ulcer treatment, with clinicians and patients having many different types to choose from. A clear and current overview of current evidence is required to facilitate decision-making regarding dressing use.

Objectives

The review aimed to evaluate the effects of foam wound dressings on the healing of foot ulcers in people with diabetes.

Search methods

For this first update we searched the following databases the Cochrane Wounds Group Specialised Register; The Cochrane Central Register of Controlled Trials (CENTRAL) (*The*

Cochrane Library); Ovid MEDLINE; Ovid MEDLINE (In-Process & Other Non-Indexed Citations); Ovid EMBASE; and EBSCO CINAHL in April 2013. There were no restrictions based on language or date of publication.

Selection criteria

Published or unpublished randomised controlled trials (RCTs) that evaluated the effects on ulcer healing of one or more foam wound dressings in the treatment of foot ulcers in people with diabetes.

Data collection and analysis

Two review authors independently performed study selection, risk of bias assessment and data extraction.

Main results

We included six studies (157 participants) in this review. Meta analysis of two studies indicated that foam dressings do not promote the healing of diabetic foot ulcers compared with basic wound contact dressings (RR 2.03, 95%CI 0.91 to 4.55). Pooled data from two studies comparing foam and alginate dressing found no statistically significant difference in ulcer healing (RR 1.50, 95% CI 0.92 to 2.44). There was no statistically significant difference in the number of diabetic foot ulcers healed when foam dressings were compared with hydrocolloid (matrix) dressings. All included studies were small and/or had limited follow-up times.

Authors' conclusions

Currently there is no research evidence to suggest that foam wound dressings are more effective in healing foot ulcers in people with diabetes than other types of dressing however all trials in this field are very small. Decision makers may wish to consider aspects such as dressing cost and the wound management properties offered by each dressing type e.g. exudate management.

Plain language summary

Foam dressings for healing foot ulcers in people with diabetes

Diabetes, a condition which leads to high blood glucose concentrations, is a common condition with around 2.8 million people affected in the UK (approximately 3% of the population). Dressings are a widely used treatment when caring for foot ulcers in people with diabetes. There are many types of dressings that can be used, which also vary considerably in cost. Existing reviews have not found evidence that one dressing type is more effective than other types in healing foot ulcers in people with diabetes. This review (157 participants) confirms that currently there is no research evidence to suggest that foam wound dressings are more effective in healing diabetic foot ulcers than other types of dressing. Current decisions on choice of wound dressing if any, should be based where

possible, on dressing costs and selecting the most useful management properties offered by each dressing type, for example, the management of wound discharge.

Summary of findings (Explanation)

Summary of findings for the main comparison. Foam dressings compared to basic wound contact dressings for foot ulcers in people with diabetes

Foam dressings compared to basic wound contact dressings for foot ulcers in people with diabetes

Patient or population: patients with foot ulcers in people with diabetes
Settings:
Intervention: Foam dressings
Comparison: Basic wound contact dressings

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Basic wound contact dressings	Foam dressings				
Nunber of ulcers healed Follow-up: mean 10 weeks	Low risk of healing[1]		RR 2.03 (0.91 to 4.55)	49 (2 studies)	⊕⊕⊖⊖ low [2,3]	
	340 per 1000	690 per 1000 (309 to 1000)				
	Moderate risk of healing[1]					
	530 per 1000	1000 per 1000 (482 to 1000)				
	High risk of healing[1]					
	650 per 1000	1000 per 1000 (592 to 1000)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate

of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Baseline risk of healing obtained from external source in which data from 27,630 patients with a diabetic neuropathic foot ulcer was used to develop a simple prognostic model to predict likelihood of ulcer healing (Margolis DJ, Allen-Taylor L, Hoffstad O, Berlin JA. Diabetic neuropathic foot ulcers: predicting which ones will not heal. Am J Med. 2003;115:627-31). It is important to note that given an outcome of ulcer healing, low risk refers to a low risk of healing and thus reflects the most severe patient populations. Conversely high risk refers to a high risk of healing.
[2] The two studies reported insufficient information to make any judgement regarding quality of study design and associated risk of bias.
[3] Very small samples sizes and short follow up times which limited the number of healing events resulted in large imprecision. 19 participants achieved the endpoint of healing in the two studies, this is an underpowered comparison. The confidence interval around the estimate of relative risk is consistent with a 9% relative reduction in healing with foam and a 450% relative increase in healing with foam.

Summary of findings 2 Foam dressings compared to alginate dressings for foot ulcers in people with diabetes

Summary of findings 2. Foam dressings compared to alginate dressings for foot ulcers in people with diabetes

Foam dressings compared to alginate dressings for foot ulcers in people with diabetes

Patient or population: patients with foot ulcers in people with diabetes
Settings:
Intervention: Foam dressings
Comparison: Alginate dressings

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Algiante dressings	Foam dressings				
	Low risk of healing[1]					

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[2] 30 participants achieved the endpoint of healing in the two studies, this is an underpowered comparison. The confidence interval around the estimate of relative risk is consistent with a 8% relative reduction in healing with foam and a 244% relative increase in healing with foam.

Number of ulcers healed Follow-up: mean 10 weeks	**340 per 1000**	**510 per 1000** (313 to 830)	**RR 1.50** (0.92 to 2.44)	50 (2 studies)	⊕⊕⊖⊖ **low** [2]	
	Moderate risk of healing[1]					
	530 per 1000	**795 per 1000** (488 to 1000)				
	High risk of healing[1]					
	650 per 1000	**975 per 1000** (598 to 1000)				
Adverse events Follow-up: 8 weeks	See comment	See comment	Not estimable	0 (1 study)	See comment	One study reported limited adverse event data: no events in the foam-dressed group and four events in the alginate-dressed group.

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CI: Confidence interval; **RR:** Risk ratio.

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High quality: Further research is very unlikely to change our confidence in the estimate of effect.
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Summary of findings 3 Foam dressings compared to hydrocolloid matrix dressings for foot ulcers in people with diabetes

Summary of findings 3. Foam dressings compared to hydrocolloid matrix dressings for foot ulcers in people with diabetes

Foam dressings compared to hydrocolloid matrix dressings for foot ulcers in people with diabetes

Patient or population: patients with foot ulcers in people with diabetes
Settings:
Intervention: Foam dressings
Comparison: Hydrocolloid matrix dressings

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Hydrocolloid matrix dressings	Foam dressings				
Number of ulcers healed Follow-up: 16 weeks	**Low risk of healing**[1]		**RR 0.88** (0.61 to 1.26)	40 (1 study)	⊕⊖⊖⊖ **very low** [2,3]	
	340 per 1000	**299 per 1000** (207 to 428)				
	Moderate risk of healing[1]					
	530 per 1000	**466 per 1000** (323 to 668)				
	High risk of healing[1]					
	650 per 1000	**572 per 1000** (397 to 819)				
Adverse events Follow-up: 16 weeks	**Study population**		Not estimable	0 (1)	See comment	Limited data from one study. Five events reported in the foam dressed group compared with
	See comment	See comment				
	Moderate					

[1] Baseline risk of healing obtained from external source in which data from 27,630 patients with a diabetic neuropathic foot ulcer was used to develop a simple prognostic model to predict likelihood of ulcer healing (Margolis DJ, Allen-Taylor L, Hoffstad O, Berlin JA. Diabetic neuropathic foot ulcers: predicting which ones will not heal. Am J Med. 2003;115:627-31). It is important to note that given an outcome of ulcer healing, low risk refers to a low risk of healing and thus reflects the most severe patient populations. Conversely high risk refers to a high risk of healing.
[2] In total six participants were withdrawn, or 15% of the study population. The study states that withdrawals were excluded from the analysis.
[3] 30 participants achieved the endpoint of healing in the study, this is an underpowered comparison. The confidence interval around the estimate of relative risk is consistent with a 39% relative reduction in healing with foam and a 26% relative increase in healing with foam.

				one event in the hydrocolloid matrix group.

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio.

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High quality: Further research is very unlikely to change our confidence in the estimate of effect.
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Background

Description of the condition

Diabetes, a condition which leads to high blood glucose concentrations, is common and affects around 2.8 million people in the UK (approximately 4.3% of the population) (Diabetes UK 2011). This number is set to increase over the next 25 years as the incidence of diabetes increases rapidly (WHO 2005). Global projections suggest that the worldwide prevalence of diabetes is expected to rise to 4.4% by 2030, meaning that approximately 366 million people will be affected (Wild 2004).

Success in treating diabetes has improved the life expectancy of patients. However, the increased prevalence of diabetes coupled with the extended time people live with the disease has led to a rise in the number of diabetes-related complications, such as neuropathy (damage to the nerves of the peripheral nervous system) and peripheral arterial disease (PAD). It is estimated that lower extremity PAD is twice as common in people with diabetes compared with people without diabetes (Gregg 2004). Both neuropathy and PAD are risk factors for diabetic foot ulceration (Pecoraro 1990; Reiber 1999), which is a problem reported to affect 15% or more of the diabetic population at some time in their lives (Reiber 1996; Singh 2005). Around 1% to 4% of people with diabetes have foot ulcers at any given

time (Abbott 2002; Kumar 1994). An ulcer forms as a result of damage to the epidermis and subsequent loss of underlying tissue. Specifically, the International Consensus on the Diabetic Foot defines a foot ulcer as a wound extending through the full thickness of the skin below the level of the ankle (Apelqvist 2000a). This is irrespective of duration and the ulcer can extend to muscle, tendon and bone. The Wagner wound classification system is well-established and widely used for grading diabetic foot ulcers. The system assesses ulcer depth and the presence of osteomyelitis or gangrene in the following grades: grade 0 (pre- or post-ulcerative lesion), grade 1 (partial/full thickness ulcer), grade 2 (probing to tendon or capsule), grade 3 (deep with osteitis (inflammation of the bone)), grade 4 (partial foot gangrene) and grade 5 (whole foot gangrene) (Wagner 1981). However, newer grading systems, such as the PEDIS system (Schaper 2004) and the University of Texas Wound Classification System (Oyibo 2001) have been developed.

Peripheral arterial disease and neuropathy can occur separately (ischaemic foot and neuropathic foot) or in combination (in the neuroischaemic foot). The over-arching term 'diabetic neuropathy' refers to a number of neuropathic syndromes. Chronic distal sensorimotor symmetrical neuropathy (abbreviated to distal symmetrical neuropathy) is the most common, affecting around 28% of people with diabetes. It can lead to ulceration through the following route(s) (Tesfaye 1996).

- Sympathetic autonomic neuropathy leads to decreased sweating causing anhidrotic (dry) skin, which is prone to cracks and fissures causing a break in the dermal barrier (Tesfaye 1996).
- Motor neuropathy causes wasting of the small, intrinsic muscles of the foot by de-enervation. As the muscles waste they cause retraction of the toes and lead to a subsequent deformity. The abnormal foot shape can promote ulcer development due to an increase in plantar pressures (Murray 1996).
- Sensory neuropathy results in impaired sensation, making the patient unaware of potentially dangerous foreign bodies and injuries.

People with diabetes-related foot ulceration are treated in a variety of settings, for example, community clinics, surgeries and their own homes, by a variety of practitioners; this can make data collection challenging. A UK study estimated that 2% of community-based diabetic patients develop new foot ulcers each year (Abbott 2002). In terms of healing, a meta-analysis of trials in which people with neuropathic ulcers received good wound care reported that 24% of ulcers attained complete healing by 12 weeks and 31% by 20 weeks (Margolis 1999). However, the risk of ulcer recurrence post-healing is high. Pound 2005 reported that 62% of ulcer patients (n = 231) became ulcer-free at some stage over a 31-month observation period. However, of the ulcer-free group, 40% went on to develop a new or recurrent ulcer after a median of 126 days. The ulcer recurrence rate over five years can be as high as 70% (Dorresteijn 2010; Van Gils 1999).

Diabetic foot ulcers can seriously impact on an individual's quality of life and as many as 85% of foot-related amputations are preceded by ulceration (Apelqvist 2000b; Pecoraro 1990). Patients with diabetes have a 10 to 20-fold higher risk of losing a lower limb or part of a lower limb due to non-traumatic amputation than those without diabetes (Morris 1998; Wrobel 2001).

Diabetic foot ulcers represent a major use of health resources, incurring costs not only for dressings applied, but also staff costs (for podiatry, nurses, doctors), tests and investigations, antibiotics and specialist footwear. Currie 1998 estimated the cost of healing a foot ulcer in a patient with diabetes at around £1451. Hospital admissions add further to the costs. Ten years ago the cost of diabetic foot ulceration to the UK National Health Service was believed to be about £12.9 million per year (Lewis 2013) and this figure is likely to have increased significantly. The economic impact is also high in terms of the personal costs to patients and carers, for example costs associated with lost work time and productivity while the patient is non-weight bearing or hospitalised.

Description of the intervention

Broadly, the treatment of diabetic foot ulcers includes pressure relief (or off-loading) by resting the foot or wearing special footwear or shoe inserts (or both); the removal of dead cellular material from the surface of the wound (debridement or desloughing); infection control; and the use of wound dressings. Other general strategies in the treatment of diabetic foot ulcers include: patient education; optimisation of blood glucose control; correction (where possible) of arterial insufficiency; and surgical interventions (debridement, drainage of pus, revascularisation, amputation).

Dressings are widely used in wound care, both to protect the wound and to promote healing. Classification of a dressing normally depends on the key material used. Several attributes of an ideal wound dressing have been described (BNF 2010), including:

- the ability of the dressing to absorb and contain exudate without leakage or strike-through;
- lack of particulate contaminants left in the wound by the dressing;
- thermal insulation;
- permeability to water and bacteria;
- avoidance of wound trauma on dressing removal;
- frequency with which the dressing needs to be changed;
- provision of pain relief; and
- comfort.

There is a vast choice of dressings available to treat chronic wounds such as diabetic foot ulcers. For ease of comparison this review has categorised dressings according to the British National Formulary 2010 (BNF 2010) which is freely available via the Internet. We used 'generic' names where possible, also providing UK trade names and manufacturers where these are available to allow cross referencing with the BNF. However, it is important to note that the way dressings are categorised as well as dressing names, manufacturers and distributors of dressings may vary from country to country, so these are provided as a guide only. Below is a description of all categories of dressings and includes the category of dressing (foam) which is the focus of this review:

Basic wound contact dressings

Low-adherence dressings and wound contact materials: usually cotton pads which are placed directly in contact with the wound. They can be either non-medicated (e.g. paraffin gauze dressing) or medicated (e.g. containing povidone iodine or chlorhexidine). Examples are paraffin gauze dressing, BP 1993 and Xeroform (Covidien) dressing - a non-adherent petrolatum blend with 3% bismuth tribromophenate on fine mesh gauze.

Absorbent dressings: applied directly to the wound or used as secondary absorbent layers in the management of heavily exuding wounds. Examples include Primapore (Smith & Nephew), Mepore (Mölnlycke) and absorbent cotton gauze (BP 1988).

Advanced wound dressings

Foam dressings: normally contain hydrophilic polyurethane foam and are designed to absorb wound exudate and maintain a moist wound surface. There are various versions and some foam dressings include additional absorbent materials, such as viscose and acrylate fibres or particles of superabsorbent polyacrylate, or which are silicone-coated for non-traumatic removal. Examples are: Allevyn (Smith & Nephew), Biatain (Coloplast) and Tegaderm (3M).

Hydrogel dressings: consist of cross-linked insoluable polymers (i.e. starch or carboxymethylcellulose) and up to 96% water. These dressings are designed to absorb wound exudate or rehydrate a wound depending on the wound moisture levels. They are supplied in either flat sheets, an amorphous hydrogel or as beads. Examples are: ActiformCool (Activa) and Aquaflo (Covidien).

Films - permeable film and membrane dressings: permeable to water vapour and oxygen but not to water or microorganisms. Examples are Tegaderm (3M) and Opsite (Smith & Nephew).

Soft polymer dressings: dressings composed of a soft silicone polymer held in a non-adherent layer. They are moderately absorbent. Examples are: Mepitel (Mölnlycke) and Urgotul (Urgo).

Hydrocolloid dressings: are occlusive dressings usually composed of a hydrocolloid matrix bonded onto a vapour-permeable film or foam backing. When in contact with the wound surface this matrix forms a gel to provide a moist environment. Examples are: Granuflex (ConvaTec) and NU DERM (Systagenix). Fibrous alternatives have been developed which resemble alginates and are not occlusive but which are more absorbant than standard hydrocolloid dressings: Aquacel (ConvaTec).

Alginate dressings: highly absorbent and come in the form of calcium alginate or calcium sodium alginate and can be combined with collagen. The alginate forms a gel when in contact with the wound surface which can be lifted off with dressing removal or rinsed away with sterile saline. Bonding to a secondary viscose pad increases absorbency. Examples are: Curasorb (Covidien), SeaSorb (Coloplast) and Sorbsan (Unomedical).

Capillary-action dressings: consist of an absorbent core of hydrophilic fibres held between two low-adherent contact layers. Examples are: Advadraw (Advancis) and Vacutx (Protex).

Odour-absorbent dressings: dressings that contain charcoal and are used to absorb wound odour. Often these types of wound dressings are used in conjunction with a secondary dressing to improve absorbency. Example: CarboFLEX (ConvaTec).

Anti-microbial dressings

Honey-impregnated dressings: contain medical-grade honey which is proposed to have antimicrobial and anti-inflammatory properties and can be used for acute or chronic wounds. Examples are: Medihoney (Medihoney) and Activon Tulle (Advancis).

Iodine-impregnated dressings: release free iodine when exposed to wound exudate, which is thought to act as a wound antiseptic. Examples are Iodoflex (Smith & Nephew) and Iodozyme (Insense).

Silver-impregnated dressings: used to treat infected wounds as silver ions are thought to have antimicrobial properties. Silver versions of most dressing types are available (e.g. silver foam, silver hydrocolloid etc). Examples are: Acticoat (Smith & Nephew) and Urgosorb Silver (Urgo).

Other antimicrobial dressings: these dressings are composed of a gauze or low-adherent dressing impregnated with an ointment thought to have antimicrobial properties. Examples are: chlorhexidine gauze dressing (Smith & Nephew) and Cutimed Sorbact (BSN Medical).

Specialist dressings

Protease-modulating matrix dressings: alter the activity of proteolytic enzymes in chronic wounds. Examples are: Promogran (Systagenix) and Sorbion (H & R).

The diversity of dressings available to clinicians (including variation within each type, listed above) makes evidence-based decision-making difficult when deciding the best treatment regimen for the patient. In a UK survey undertaken to determine treatments used for debriding diabetic foot ulcers, a diversity of treatments was reported (Smith 2003). It is possible that a similar scenario is true for dressing choice. A survey of Diabetes Specialist Nurses found that low/non-adherent dressings, hydrocolloids and alginate dressings were the most popular for all wound types, despite a paucity of evidence for either of these dressing types (Fiskin 1996). However, several new dressing types have been made available and heavily promoted in recent years. Some dressings now have an 'active' ingredient such as silver that are promoted as dressing treatment options to reduce infection and thus possibly also promote healing in this way. With increasingly sophisticated technology being applied to wound care, practitioners need to know how effective these often expensive dressings are compared with more traditional dressings.

How the intervention might work

Animal experiments conducted over 40 years ago suggest that acute wounds heal more quickly when their surface is kept moist, rather than left to dry and scab (Winter 1963). A moist environment is thought to provide optimal conditions for the cells involved in the healing process as well as allowing autolytic debridement, which is thought to be an important part of the healing pathway (Cardinal 2009). The desire to maintain a moist wound environment is a key driver for the use of wound dressings. Different wound

dressings vary in their level of absorbency so that a very wet wound can be treated with an absorbent dressing (such as a foam dressing) to draw excess moisture away from the wound to avoid skin damage, while a drier wound can be treated with a more occlusive dressing to maintain a moist environment. Foam dressings are composed of polyurethane (or sometimes silicone) foam, that is highly absorbent and thus able to manage wound exudate.

Why it is important to do this review

Diabetic foot ulcers are a prevalent and serious global issue. Treatment with dressings forms a key part of the treatment pathway when caring for diabetic foot ulcers and there are many types of dressings that can be used, which also vary considerably in cost. Guidelines for the treatment of diabetic ulcer (e.g. Steed 2006) maintain that clinical judgement should be used to select a moist wound dressing.

However, previous reviews of the evidence for wound dressings as treatments for diabetic foot ulcers have not found evidence to support a specific dressing choice. Ten trials were eligible for inclusion in a UK Health Technology Assessment (HTA) review of wound dressings published in 2000 (O'Meara 2000). The review included nine trials that investigated a dressing or topical treatment for healing diabetic foot ulcers. The review did not find any evidence to suggest that one dressing type was more or less effective in terms of treating diabetic foot ulcers. The methodological quality of trials was poor and all were small. Only one comparison was repeated in more than one trial. A further systematic review conducted some years ago reported similar findings (Mason 1999). A more recent systematic review on the effectiveness of interventions to enhance the healing of chronic ulcers of the foot (Hinchliffe 2008) (search date December 2006) included only eight trials (randomised and non-randomised) did not identify any evidence that one dressing type was superior to another in terms of promoting ulcer healing. A Cochrane Review of silver-based wound dressings and topical agents for treating diabetic foot ulcers (Bergin 2006; search date 2010) did not find any studies that met its inclusion criteria. Finally, a review of antimicrobial treatments for diabetic foot ulcers (Nelson 2006) included dressings and found that existing evidence was too weak to recommend any antimicrobial product.

This review is part of a suite of Cochrane reviews investigating the use of dressings in the treatment of foot ulcers in people with diabetes. Each review will focus on a particular dressing type which in this review is the foam dressing. These reviews will be summarised in an overview of reviews (Higgins 2011) which will draw together all existing Cochrane review evidence regarding the use of dressings to treat foot ulcers in people with diabetes. While other existing review evidence may also be included in this overview, following Cochrane guidance, this will only occur in the absence of a relevant Cochrane Intervention review (Higgins 2011).

Objectives

To determine the effects of foam wound dressings on the healing of foot ulcers in people with diabetes.

Methods

Criteria for considering studies for this review

Types of studies

Published or unpublished randomised controlled trials (RCTs) that evaluated the effects of any type of foam wound dressing in the treatment of diabetic foot ulcers, irrespective of publication status or language.

Types of participants

Trials recruiting people with Type 1 or Type 2 diabetes, with an open foot ulcer. Since study-specific classifications of ulcer diagnosis were likely to be too restrictive, we accepted the study authors' definitions of what was classed a diabetic foot ulcer. There was no restriction in relation to the aetiology of the ulcer; trials recruiting people with ulcers of neuropathic, ischaemic or neuroischaemic causes were all eligible for inclusion.

We included trials that involved participants of any age. We excluded trials which included patients with a number of different wound aetiologies in addition to diabetic foot ulcers (e.g. pressure ulcers, mixed arterial/venous arterial) unless the results for the subgroup of patients with a diabetic foot ulcer were reported separately or were available from the authors on contact.

Types of interventions

The primary intervention was the foam wound dressing (**BNF 2010**). We included any RCT in which the presence or absence of a foam dressing was the only systematic difference between treatment groups. We anticipated that likely comparisons would include foam dressings compared with other dressing types or other interventions, or both (which could be non-dressing treatments i.e. topical applications).

Types of outcome measures

Primary outcomes

- Time to ulcer healing.
- Number of ulcers completely healed within a specific time period (we assumed that the period of time in which healing occurred was the duration of the trial unless otherwise stated).

We also included studies reporting surrogate healing outcomes expressed as absolute changes (e.g. surface area changes in cm^2 since baseline) or relative changes (e.g. percentage change in area relative to baseline). However, we did not consider these surrogate measures as a proxy for the treatment effect of complete ulcer healing since there is no evidence of such a relationship in the context of an RCT and thus while data were extracted and included in data tables, we did not report them unless no other healing data were available.

Secondary outcomes

- Health-related quality of life (measured using a standardised generic questionnaire such as EQ-5D, SF-36, SF-12 or SF-6 or disease-specific questionnaire). We did not include ad-hoc measures of quality of life which are likely not to be validated and will not be common to multiple trials.
- Number and level of amputations.
- Adverse events, including pain (measured using survey/questionnaire/data capture process or visual analogue scale).
- Cost (including measurements of resource use such as number of dressing changes and nurse time).
- Ulcer recurrence.

Search methods for identification of studies

Electronic searches

For this first update we searched the following databases in April 2013.

- The Cochrane Wounds Group Specialised Register (searched 11 April 2013)
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2013, Issue 3);
- Ovid MEDLINE (1950 to March Week 4 2013);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations, April 10, 2013);
- Ovid EMBASE (1980 to 2011 April 05);
- EBSCO CINAHL (1982 to 4 April 2013).

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) using the following exploded MeSH headings and keywords:

#1 MeSH descriptor Occlusive Dressings explode all trees
#2 MeSH descriptor Biological Dressings explode all trees
#3 MeSH descriptor Alginates explode all trees
#4 MeSH descriptor Hydrogels explode all trees
#5 MeSH descriptor Silver explode all trees
#6 MeSH descriptor Honey explode all trees
#7 (dressing* or alginate* or hydrogel* or "foam" or "bead" or "film" or "films" or tulle or gauze or non-adherent or "non adherent" or silver or honey or matrix):ti,ab,kw
#8 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)
#9 MeSH descriptor Foot Ulcer explode all trees
#10 MeSH descriptor Diabetic Foot explode all trees
#11 diabet* NEAR/3 ulcer*:ti,ab,kw

#12 diabet* NEAR/3 (foot or feet):ti,ab,kw
#13 diabet* NEAR/3 wound*:ti,ab,kw
#14 (#9 OR #10 OR #11 OR #12 OR #13)
#15 (#8 AND #14)

The search strategies used in Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in Appendix 1, Appendix 2 and Appendix 3 respectively. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (**Lefebvre 2011**). We also combined the EMBASE and CINAHL searches with the trial filters developed by the Scottish Intercollegiate Guidelines Network (**SIGN 2009**). There were no restrictions on the basis of date or language of publication.

We also searched for on-going studies on the ISRCTN register (http://www.controlled-trials.com/isrctn/) (last searched 25nd April 2013).

Searching other resources

We attempted to contact researchers to obtain any unpublished data when needed. We also searched the reference lists of the included studies and previous systematic reviews. We contacted appropriate manufacturers (Smith & Nephew, Convatec Ltd, Mölnlycke Health Care, 3M Healthcare, Coloplast Ltd) for details of any unpublished studies.

Data collection and analysis

Selection of studies

Two review authors independently assessed the titles and abstracts of retrieved studies for relevance. After this initial assessment, we obtained the full text of all studies felt to be potentially relevant. Two review authors then independently checked the full papers for eligibility, with disagreements resolved by discussion and, where required, the input of a third review author. We recorded all reasons for exclusion.

Data extraction and management

We extracted and summarised details of the eligible studies using a data extraction sheet. Two review authors extracted data independently and resolved disagreements by discussion. Where data were missing from reports, we attempted to contact the study authors to obtain the missing information. We included studies published in duplicate once but maximally extracted data. We extracted the following data:

- country of origin;
- type of ulcer;
- unit of investigation (per patient) - single ulcer or foot or patient or multiple ulcers on the same patient;
- care setting;
- number of participants randomised to each trial arm;

- eligibility criteria and key baseline participant data;
- details of the dressing/treatment regimen received by each group;
- details of any co-interventions;
- primary and secondary outcome(s) (with definitions);
- outcome data for primary and secondary outcomes (by group);
- duration of follow-up;
- number of withdrawals (by group);
- adverse events, including amputation; and
- source of funding.

Assessment of risk of bias in included studies

Two review authors independently assessed each included study using The Cochrane Collaboration tool for assessing risk of bias (**Higgins 2011**). This tool addresses six specific domains, namely sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues (e.g. extreme baseline imbalance, issues with unit of investigation) (see Appendix 4 for details of the criteria on which the judgement was based). We assessed blinding and completeness of outcome data for each outcome separately. We completed a 'Risk of bias' table for each eligible study. We resolved disagreements about risk of bias assessment by discussion. Where a lack of reported information resulted in an unclear decision, where possible we contacted authors for clarification.

We have presented our assessment of risk of bias findings using a 'Risk of bias' summary figure, which presents all of the judgements in a cross-tabulation of study by entry. This display of internal validity indicates the weight the reader may give the results of each study. We also aimed to present this assessment in the narrative review.

We classified trials as being at high risk of bias if they were rated 'high' for any of three key criteria (randomisation sequence, allocation concealment and blinded outcome assessment).

Measures of treatment effect

Where possible, we presented the outcome results for each trial with 95% confidence intervals (CI). We reported estimates for dichotomous outcomes (e.g. ulcers healed during time period) as risk ratio (RR). We used the RR rather than odds ratio (OR), since ORs (when interpreted as RR) can give an inflated impression of the effect size when event rates are high, as is the case for many trials reporting healing of chronic wounds (**Deeks 2002**). We planned to report outcomes relating to continuous data (e.g. percentage change in ulcer area) as mean difference (MD) and overall effect size (with 95% CI calculated). Where a study reported time to healing data (the probability of healing over a consecutive time period), we planned to report and plot these data (where possible) using hazard ratio estimates. If studies reporting time to event data (e.g. time to healing) did not report a hazard ratio or reported these data incorrectly as a continuous variable then, where feasible, we planned to

estimate this using other reported outcomes such as the numbers of events through the application of available statistical methods (Tierney 2007).

Unit of analysis issues

We recorded whether trials measured outcomes in relation to an ulcer, a foot, a participant or whether multiple ulcers on the same participant were studied. We also recorded where multiple ulcers on a participant had been (incorrectly) treated as individual ulcers in a study, rather than within-patient analysis methods being applied. We have recorded this as part of the risk of bias assessment. Unless otherwise stated, where the number of wounds appeared to equal the number of participants, we treated the ulcer as the unit of analysis in this review.

Dealing with missing data

Missing data are common in trial reports. Excluding participants post-randomisation from the analysis or ignoring those participants lost to follow-up can, in effect, compromise the process of randomisation and thus potentially introduce bias into the trial. In individual studies, where "proportion of ulcers healed" data were presented, we assumed that where randomised participants were not included in an analysis, their wound did not heal (that is, they were considered in the denominator but not the numerator). Where a trial did not specify participant group numbers prior to dropout, we planned to present only complete case data. We planned to present data for time to healing, area change and for all secondary outcomes as a complete case analysis.

Assessment of heterogeneity

We considered both clinical and statistical heterogeneity. Wherever appropriate, we pooled data using meta-analysis (conducted using RevMan 5.1 (RevMan 2011), that is where studies appeared similar in terms of the clinical status of participants, intervention type and duration and outcome type. We assessed statistical heterogeneity using the Chi^2 test (a significance level of $P < 0.1$ was considered to indicate heterogeneity) and the I^2 statistic (Higgins 2003). The I^2 statistic examines the percentage of total variation across studies due to heterogeneity rather than to chance. Values of I^2 over 50% indicate a high level of heterogeneity. In the absence of clinical heterogeneity and in the presence of statistical heterogeneity (I^2 over 50%), we used a random-effects model. However, we did not pool studies where heterogeneity was very high (I^2 over 50%). Where there was no clinical or statistical heterogeneity, we envisaged using a fixed-effect model.

Data synthesis

We combined studies using a narrative overview with meta-analyses of outcome data where appropriate (in RevMan 5). The decision to include studies in a meta-analysis depended on the availability of treatment effect data and assessment of heterogeneity. For time to event data, we planned to plot log rank observed minus expected events estimates using a fixed-effect model (a random-effects model is not available for this analysis in RevMan 5). Where relevant and possible, we planned to conduct a sensitivity analysis to investigate the potential impact of studies at high risk of bias on pooled results.

Results

Description of studies

See Characteristics of included studies; Characteristics of excluded studies.

Results of the search

The systematic search yielded 346 abstracts which we screened for potential inclusion in the review. Of these, we obtained 103 reports in full (84 studies) for a more detailed assessment; six studies were eligible for inclusion in the review. We did not obtain any eligible studies from the five commercial companies that we contacted. The search for this first update was conducted in April 2013 and yielded 116 citations of which one study was obtained in full text for further assessment (**Turns 2012**) and was subsequently excluded. We are not aware of any relevant on-going studies (checked ISRCTN register 25nd April 2013). Five studies awaiting assessment from the original review are now excluded from the review and have been added to the Characteristics of excluded studies.

Included studies

We included six studies (157 participants) in this review (**Baker 1993**; **Blackman 1994**; **Clever 1995**; **Foster 1994**; **Mazzone 1993**; **Roberts 2001**). Dressings evaluated are detailed in Table 1. Two studies were single-centred (**Baker 1993**; **Blackman 1994**) and the remaining studies did not detail the number of centres. Two studies were undertaken in the USA (**Blackman 1994**; **Mazzone 1993**); three were undertaken in the UK (**Baker 1993**; **Foster 1994**; **Roberts 2001**) and one was undertaken in Germany (**Clever 1995**). We note that the **Blackman 1994** and **Mazzone 1993** studies appeared similar in design and conduct (similar number of participants, same interventions evaluated) with both lead authors being referenced on the alternate study however, the outcome data varied. Attemps to contact the authors for clarification were unsuccessful.

Table 1. Summary of studies

First Author	Group A	Group B	Duration of follow-up	% healed data
Baker 1993	Foam dressing (Allevyn,Smith & Nephew)	Calcium-alginate dressing (Sorbsan, Aspen Medical)	12 weeks	yes
Blackman 1994	Foam dressing (PolyMem, Ferris)	Wet-to-dry saline gauze dressing	24 weeks	yes
Clever 1995	Foam dressing (Allevyn, Smith & Nephew)	Hydrocolloid (polyurethane matrix) dressing (Cutinova Hydro, Smith & Nephew)	16 weeks	yes
Foster 1994			8 weeks	yes

	Foam dressing (Allevyn, Smith & Nephew).	Calcium- alginate dressing (Kaltostat, ConvaTec)		
Mazzone 1993	Foam dressing (PolyMem, Ferris)	Wet to dry saline gauze	8 weeks	yes
Roberts 2001	Foam dressing (Allevyn, Smith & Nephew).	Saline soaked low adherence dressing (Tricotex, Smith & Nephew).	13 weeks	yes

All studies were undertaken in adults with diabetes. One study included people with both Type 1 and Type 2 diabetes (**Blackman 1994**) and one specified that only people with Type 1 diabetes were included (**Roberts 2001**). One study specified that it only included participants with Wagner grade 1 or 2 ulcers (**Blackman 1994**) and three studies specified that they only included participants with ulcers that were neuropathic or neuroischaemic in origin or specified that participants had to have an ankle brachial pressure index (ABPI) above a certain value (0.8), or both (**Baker 1993**; **Clever 1995**; **Roberts 2001**). Three studies excluded participants who had infected, sloughy or deep ulcers (**Baker 1993**; **Clever 1995**; **Foster 1994**). In general, it seems that studies aimed to include participants with non-complex diabetic foot ulcers. The duration of trial follow-up ranged from four weeks (**Ahroni 1993**) to 24 weeks (**Blackman 1994**).Full details are presented in Table 1. All six included studies were two-arm trials and all reported the number of ulcers healed. Mean time to healing was reported in one study (**Clever 1995**) and the more appropriate summary measure, median time to healing, in three studies (**Baker 1993**; **Clever 1995**; **Foster 1994**). The reporting of secondary outcomes was limited.

Excluded studies

We excluded a total of 79 studies from the review, this included six studies excluded in this update (**Munter 2006**; **Novinscak 2010**; **Ogce 2007**; **Sibbald 2011**; **Turns 2012**; **Woo 2010**). In summary, the main reasons for exclusion were: the study was not randomised (n = 10), no single, identifiable dressing type was evaluated (n = 10); another intervention, not a dressing, differed between study groups (n = 29); dressing was not a foam dressing (n = 22). Other reasons were recorded for the remaining eight studies.

Risk of bias in included studies

We classified studies rated 'High Risk' for any of three key domains: randomisation sequence, allocation concealment and blinded outcome assessment, as being at high risk of bias. (Characteristics of included studies; Figure 1; Figure 2). We rated all studies as being at unclear risk of bias due to poor reporting.

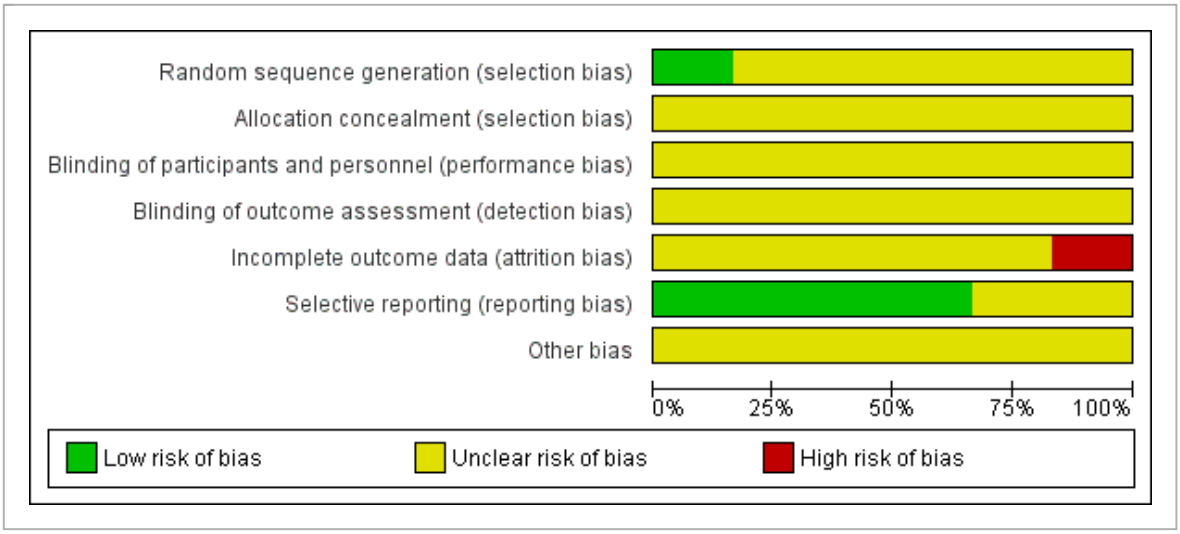

Figure 1.

Open in figure viewer

Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

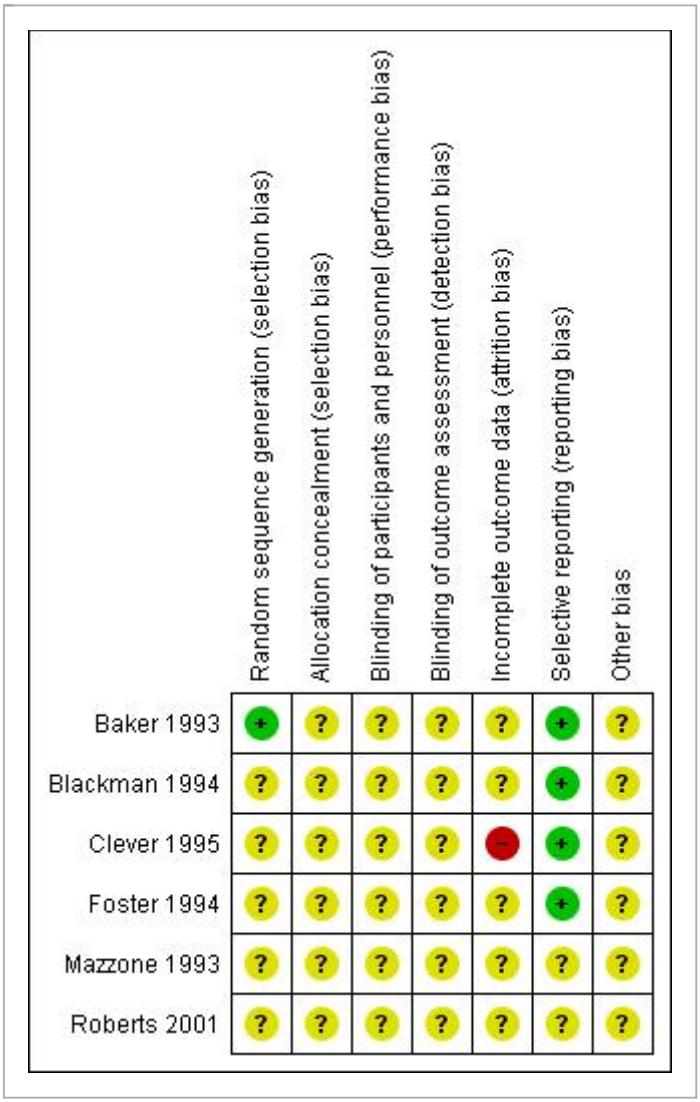

Figure 2.

Open in figure viewer

Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Allocation

Adequacy of randomisation process

All included studies were described as "randomised" however, only one reported the method used: computer-generated randomisation (Baker 1993). The randomisation method was not reported in the remaining five studies.

Allocation Concealment

None of the six included studies clearly reported the allocation procedure such that we could assess the degree of concealment.

Blinding

Assessment of wound healing can be subjective and thus has the potential to be influenced if the outcome assessor is aware of the treatment allocation. In this review we focused on whether the studies had conducted blinded outcome assessment. None of the six included studies reported that blinded outcome assessment had been conducted.

Incomplete outcome data

One study was judged to have a high loss to follow-up (Clever 1995). Clever 1995 reported six of forty participants (15%) were lost to follow-up and stated that withdrawals were excluded from the analyses. We considered this trial to be at high risk of bias for this domain. The remaining five studies did not report enough information to make a judgement about ITT analysis and so we classed these as unclear.

Selective reporting

There was no evidence of selective reporting and we considered studies to be at unclear or low risk of bias. However, it is important to note that judgement for this domain may be of limited value given it was made at face value based on the reporting of outcomes in the results that were described in the methods. We did not compare study reports with study protocols, which we did not actively seek out.

Other potential sources of bias

Two studies did not report their funding source (Baker 1993; Foster 1994). The remaining studies were funded by commercial organisations and we recorded these studies as being unclear in terms of bias for this domain since there is research which suggests that commercially funded trials are more likely to find and/or conclude in favour their products

rather than comparators (Als-Nielsen 2003; Bhandari 2004). Two studies (Blackman 1994; Foster 1994) reported some baseline imbalances for different baseline characteristics.

Effects of interventions

See: **Summary of findings for the main comparison** Foam dressings compared to basic wound contact dressings for foot ulcers in people with diabetes; **Summary of findings 2** Foam dressings compared to alginate dressings for foot ulcers in people with diabetes; **Summary of findings 3** Foam dressings compared to hydrocolloid matrix dressings for foot ulcers in people with diabetes

Dressing compared with dressing

Advanced wound dressings compared with basic wound contact dressing

Comparison 1: Foam dressings compared with basic wound contact dressings (three trials; 67 participants)

Three studies (Blackman 1994; Mazzone 1993; Roberts 2001) involving a total of 67 participants compared foam dressings with basic wound contact dressings (all gauze/low adherence dressings soaked in saline). Blackman 1994 and Mazzone 1993 compared the same brand of foam dressing (Table 1) with wet-to-dry saline gauze. Roberts 2001 compared an alternative foam dressing brand with saline-soaked low-adherent dressing.

Primary outcome: ulcer healing

Blackman 1994 had a follow-up time until healing or six months, however, we used only the two-month healing data due to treatment cross-over following this point. There was no statistically significant difference in the number of ulcers healed between the foam-dressed group (3/11; 27%) and the basic wound contact-dressed group (0/7; 0%): RR 4.67, 95% CI 0.28 to 78.68 (Analysis 1.1). It is unclear whether this study excluded four participants post-randomisation.

Mazzone 1993 had a follow-up time of eight weeks. We took the data from a conference abstract only. There was no statistically significant difference in the number of ulcers healed in the foam-dressed group (7/11; 64%) compared with the basic wound contact-dressed group (2/8; 25%): RR 2.55, 95% CI 0.71 to 9.16 (Analysis 1.1). We note that the Blackman 1994 and Mazzone 1993 studies appeared similar in design and conduct (similar number of participants, same interventions evaluated) with both lead authors being referenced on the alternate study. However, the outcome data varied. We have not been able to confirm the independence of the studies with the authors hence, we have reported data from these studies separately and have not pooled these data.

Roberts 2001 had a follow-up time of 13 weeks. We took the data from a conference abstract only. There was no statistically significant difference in the number of ulcers healed in the foam-dressed group (6/14; 43%) compared with the basic wound contact dressed-group (4/16; 25%): RR 1.71, 95% CI 0.60 to 4.86 (Analysis 1.1).

We pooled data from Mazzone 1993 (as it had a clearer follow-up time than Blackman 1994) with Roberts 2001. The studies had follow-up times of 8 and 13 weeks respectively but there was no evidence of heterogeneity (Chi²: P value = 0.64); I^2 = 0%) so we used a fixed-effect

model. There was no statistically significant difference in the number of ulcers healed in the foam-dressed groups compared with the basic wound contact group: RR:2.03, 95%CI 0.91 to 4.55 (Analysis 1.2).

Secondary outcomes

Blackman 1994, Mazzone 1993 and Roberts 2001: None reported.

Summary: foam dressings compared with basic wound contact dressings

There was no evidence of any difference in the number of diabetic foot ulcers healed when treated with foam dressings compared with saline-soaked gauze/low adherence dressings. There were no relevant secondary outcome data presented thus, we could not draw any conclusions on the advantages or disadvantages of these treatments in terms of cost, health-related quality of life, adverse events or ulcer recurrence. It is important to note that all studies in this comparison were small and at unclear risk of bias.

Advanced dressing compared with advanced dressing

Comparison 2: Foam dressing compared with alginate dressing (two trials; 50 participants)

Two studies (Baker 1993; Foster 1994), involving a total of 50 participants compared foam dressings with alginate dressings. Both studies compared the same foam dressing, but with different brands of calcium-alginate dressings (Table 1).

Primary outcome: ulcer healing

Baker 1993 had a maximum follow-up of 12 weeks. The difference in the number of ulcers healed in the foam-dressed group (9/10; 90%) compared with the alginate-dressed group (4/10; 40%) was statistically significant. RR 2.25, 95% CI 1.02 to 4.94 in favour of the foam dressing (Analysis 2.1). The study report also notes that a Cox's proportional hazards model adjusted for initial ulcer size and duration of ulcer at baseline (as well as treatment effect) returned a hazard ratio of 4.04 in favour of foam dressing (95% CI 1.18 to 13.84). We do not have the raw data to replicate this analysis. However, the median time to healing was reported as 28 days in the foam-dressed group and was not reached by 84 days in the alginate-dressed group (i.e. less than half of participants in this group had healed by the end of the follow-up period so the median could not be calculated). We classed this study as being at unclear risk of bias due to limited information in the study report.

Foster 1994 had a maximum follow-up of eight weeks. There was no statistically significant difference in the number of ulcers healed in the foam-dressed group (9/15; 60%) compared with the alginate-dressed group (8/15; 53%): RR 1.13, 95% CI 0.60 to 2.11 (Analysis 2.1). We estimated the median time to healing from a graph presented in the study report as 40 days for the foam-dressed group and 42 days for the alginate-dressed group. We noted differences in baseline characteristics between groups i.e. mean age 61 years in foam-dressed group and 70 years in the alginate-dressed group. We classed this study as being at unclear risk of bias due to limited information in the study report.

We pooled the data from Baker 1993 and Foster 1994 using a fixed effect model (Chi²: P = 0.18; I^2 = 45%). The difference in the number of ulcers healed in the foam-dressed groups

compared with the alginate-dressed groups was not statistically significant: RR 1.50, 95% CI 0.92 to 2.44.

Secondary outcomes

Baker 1993: None reported.

Foster 1994: There was limited reporting of adverse events, with no events reported in the foam-dressed group and four events in the alginate-dressed group.

Summary: Foam dressings compared with alginate dressings

Limited data from two small studies at unclear risk of bias found no statistically significant difference in ulcer healing between foam and alginate dressings. It is important to note the limited follow-up times for these trials that were also small.

Comparison 3: Foam dressing compared with hydrocolloid (matrix) dressing (one trial; 40 participants)

Clever 1995 recruited 40 participants and compared a foam dressing with a hydrocolloid-matrix dressing (Table 1).

Primary outcome: ulcer healing

Clever 1995 had a maximum follow-up of 16 weeks. There was no statistically significant difference in the number of ulcers healed in the foam-dressed group (14/20; 70%) compared with the hydrocolloid-matrix dressed group (16/20; 80%): RR 0.88, 95% CI 0.61 to 1.26 (Analysis 3.1). The median time to healing was similar in both groups: 16.5 (range 4 to 52) days in the foam-dressed group compared with 15.5 (range 4 to 76) days for the hydrocolloid-matrix dressed group.

Secondary outcomes

Clever 1995: There was limited reporting of adverse events, with five events reported in the foam-dressed group and one event in the hydrocolloid-matrix-dressed group. The mean number of dressing changes between clinical visits was similar for both groups: 2.37 changes in the foam-dressed group compared with 2.23 in the hydrocolloid-matrix-dressed group.

Summary: Foam dressing compared with hydrocolloid (matrix) dressing

Limited data from one small study at high risk of bias found no difference in healing between ulcers treated with foam and hydrocolloid matrix dressings.

Summary of Findings Table

We have included a Summary of Findings table (Summary of findings for the main comparison; Summary of findings 2; Summary of findings 3): this aims to give a concise overview and synthesis of the volume and quality of the evidence for this comparison. The Summary of Findings table confirm our conclusion that the quality of evidence is of low quality and on balance there is no evidence of a benefit of using foam dressings for healing foot ulcers in people with diabetes.

Discussion

Summary of main results

This review has identified, appraised and presented all available RCT evidence (six studies) regarding the clinical effectiveness of foam wound dressings in the treatment of diabetic foot ulcers.

We found no evidence that foam dressings promote the healing of diabetic foot ulcer compared with basic wound contact dressings. When data from two studies (eight and 12 weeks follow-up) were pooled, there was no statistically significant difference in ulcer healing between alginate and foam dressings. Similarly there was no evidence of a difference in the number of diabetic foot ulcers healed between foam and hydrocolloid (matrix) dressings. We note that most included studies were evaluating treatments on participants with non-complex foot ulcers. This means the body of literature presented may be of limited use to health professional in the treatment of patients with harder to heal foot ulcers as it is difficult to generalise from the included studies to patients with more co-morbidities or complications; this is a limitation of the RCTs that have been undertaken in this field thus far. Included trials were small and therefore statistically underpowered to detect important treatment differences should they exist.

Quality of the evidence

We deemed all studies as being at unclear risk of bias due to poor reporting. In general studies did not follow good practice conduct and reporting guidelines e.g. CONSORT (Schulz 2010). Key areas of good practice are the robust generation of a randomisation sequence, for example, computer generated, robust allocation concealment, for example the use of a telephone randomisation service and blinded outcome assessment where possible. All this information should be clearly stated in the study report as all trial authors should anticipate the inclusion of their trials in systematic reviews. In terms of analysis, where possible, data from all participants should be included, that is an ITT analysis should be conducted. Steps should be taken during trial conduct to prevent missing data as far as is possible. Where missing data are an issue, imputation methods should be considered and clearly reported when implemented. Finally, where possible robust economic data should be collected.

Potential biases in the review process

The review considered as much evidence as it was possible to obtain, including studies that were not published in English-language journals. We contacted relevant pharmaceutical companies but did not receive any RCT data from them. There is the potential for publication bias, however, this is likely to be a limited issue in this review given the large number of negative findings that have been published. It is important to note that we excluded one study that compared an ibuprofen-releasing foam dressing against local best practice in the treatment of multiple wound types, including an unspecified number of foot ulcers in people with diabetes. The primary outcome for this study was pain, and the follow-up was limited to 7 days. As healing data was not reported the authors were contacted and no further information was obtained. We anticipate that given the short follow-up time healing data

would be limited. It is also important to note that five studies are awaiting assessment and may be included in future reviews, and updates of this review. However, we anticipate this is unlikely for the majority of these studies.

Agreements and disagreements with other studies or reviews

The existing evidence-base to help clinicians in their decision-making processes suggests that there is no evidence to suggest that foam dressings are better than other dressing treatments for diabetic foot ulcers. This agrees with the most recent systematic review in the area prior to this (Hinchliffe 2008), which did report any evidence that any one dressing type was more effective in healing diabetic foot ulcers than other types of dressing; the review did not comment on foam dressings specifically. Furthermore Hinchliffe 2008 included only one trial of foam dressings, compared with the five studies that were included in this review.

Authors' conclusions

Implications for practice

Based on a comprehensive review of current evidence, foam dressings do not appear to increase healing rates of diabetic foot ulcers compared with alternative dressings. Practitioners may therefore elect to consider other characteristics such as costs and symptom management properties when choosing between alternatives.

Implications for research

Current evidence suggests that there is no difference in ulcer healing between foam dressings and alternatives. The importance of including robust cost-effectiveness analyses is highlighted by Jeffcoate 2009, which did not find that treatment with advanced wound management dressings reduced the number of clinic visits. In terms of dressing choice, any investment in future research must maximise its value to decision makers. Given the large number of dressing options, the design of future trials should be driven by the questions of high priority to patients and other decision makers. It is also important for research to ensure that the outcomes that are collected in research studies are those that matter to patients, carers and health professionals. It may be that dressings should be viewed as management tools and that other treatments that address patient lifestyle issues deserve attention. Where trials are conducted, good practice guidelines must be followed in their design, implementation and reporting. Further reviews are being conducted to synthesis evidence regarding

the effect of other dressings on the treatment of diabetic foot ulcers. It would then be useful to conduct further evidence synthesis (an overview of reviews or mixed treatment or comparisons) to aid decision making about the choice of dressings for diabetic foot ulcers across all dressing options.

Acknowledgements

The authors would like to thank the following people who reviewed the protocol for clarity, readability and rigour: Wounds Group editors (Julie Bruce, Andrea Nelson and Gill Worthy) and peer referees (David Armstrong, Duncan Chambers and Janet Yarrow). In addition, copy editor Jenny Bellorini.

Data and analyses

Download statistical data

Comparison 1. Foam dressing compared with basic wound contact dressing

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of ulcers healed	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2 Number of ulcers healed - pooled data	2	49	Risk Ratio (M-H, Fixed, 95% CI)	2.03 [0.91, 4.55]

Comparison 2. Foam dressing compared with alginate dressing

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of ulcers healed	2	50	Risk Ratio (M-H, Fixed, 95% CI)	1.5 [0.92, 2.44]

Comparison 3. Foam dressing compared with hydrocolloid (matrix) dressing

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of ulcers healed	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Comparison 4. Trial data

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Trial data			Other data	No numeric data

Appendices

Appendix 1. Ovid MEDLINE search strategy

1 exp Occlusive Dressings/
2 exp Biological Dressings/
3 exp Alginates/
4 exp Hydrogels/
5 exp Silver/
6 exp Honey/
7 (dressing* or hydrocolloid* or alginate* or hydrogel* or foam or bead or film*1 or tulle or gauze or non-adherent or non adherent or silver or honey or matrix).tw.
8 or/1-7
9 exp Foot Ulcer/
10 exp Diabetic Foot/
11 (diabet* adj3 ulcer*).tw.
12 (diabet* adj3 (foot or feet)).tw.
13 (diabet* adj3 wound*).tw.
14 or/9-13
15 8 and 14

Appendix 2. Ovid EMBASE search strategy

1 exp wound dressing/
2 exp alginic acid/
3 exp hydrogel/
4 exp SILVER/
5 exp HONEY/
6 (dressing* or hydrocolloid* or alginate* or hydrogel* or foam or bead or film*1 or tulle or gauze or non-adherent or non adherent or silver or honey or matrix).tw.
7 or/1-6
8 exp foot ulcer/
9 exp diabetic foot/
10 (diabet* adj3 ulcer*).tw.
11 (diabet* adj3 (foot or feet)).tw.
12 (diabet* adj3 wound*).tw.

13 or/8-12
14 7 and 13

Appendix 3. EBSCO CINAHL search strategy

S11 S4 and S10
S10 S5 or S6 or S7 or S8 or S9
S9 TI diabet* N3 wound* or AB diabet* N3 wound*
S8 TI (diabet* N3 foot OR diabet* N3 feet) or AB (diabet* N3 foot OR diabet* N3 feet)
S7 TI diabet* N3 ulcer* or AB diabet* N3 ulcer*
S6 (MH "Foot Ulcer+")
S5 (MH "Diabetic Foot")
S4 S1 or S2 or S3
S3 TI (dressing* or alginate* or hydrogel* or foam or bead or film or films or tulle or gauze or non-adherent or non adherent or honey or silver or matrix) or AB (dressing* or alginate* or hydrogel* or foam or bead or film or films or tulle or gauze or non-adherent or non adherent or honey or silver or matrix)
S2 (MH "Honey")
S1 (MH "Bandages and Dressings+")

Appendix 4. Risk of bias criteria

1. Was the allocation sequence randomly generated?

Low risk of bias

The investigators describe a random component in the sequence generation process such as: referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots.

High risk of bias

The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

Unclear

Insufficient information about the sequence generation process to permit judgement of low or high risk of bias.

2. Was the treatment allocation adequately concealed?

Low risk of bias

Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central

allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially-numbered drug containers of identical appearance; sequentially-numbered, opaque, sealed envelopes.

High risk of bias

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

Unclear

Insufficient information to permit judgement of low or high risk of bias. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

3. Blinding - was knowledge of the allocated interventions adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

Unclear

Any one of the following.

- Insufficient information to permit judgement of low or high risk of bias.
- The study did not address this outcome.

4. Were incomplete outcome data adequately addressed?

Low risk of bias

Any one of the following.

- No missing outcome data.
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size.
- Missing data have been imputed using appropriate methods.

High risk of bias

Any one of the following.

- Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size.
- 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Any one of the following.

- Insufficient reporting of attrition/exclusions to permit judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided).
- The study did not address this outcome.

5. Are reports of the study free of suggestion of selective outcome reporting?

Low risk of bias

Any of the following.

- The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
- The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

High risk of bias

Any one of the following.

- Not all of the study's pre-specified primary outcomes have been reported.
- One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified.
- One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear

Insufficient information to permit judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

6. Other sources of potential bias

Low risk of bias

The study appears to be free of other sources of bias.

High risk of bias

There is at least one important risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- had extreme baseline imbalance; or
- has been claimed to have been fraudulent; or
- had some other problem.

Unclear

There may be a risk of bias, but there is either:

- insufficient information to assess whether an important risk of bias exists; or
- insufficient rationale or evidence that an identified problem will introduce bias.

What's new

Date	Event	Description
14 May 2013	New citation required but conclusions have not changed	Summary of findings table completed, no change to conclusions of the review.
14 May 2013	New search has been performed	First update, new search, five studies awaiting assessment added to the table of excluded studies plus one study included from the new search.

Contributions of authors

Jo Dumville developed the protocol and review and co-ordinated development, completed the first draft of the review, made an intellectual contribution, approved the final version prior to submission and is the guarantor of the review.
Sohan Deshpande completed the first draft of the protocol, made an intellectual contribution and approved the final version of the protocol and review prior to submission.
Susan O'Meara edited the protocol and review, made an intellectual contribution and approved the final version of the protocol and review prior to submission.
Katharine Speak made an intellectual contribution to the protocol, advised on the protocol and approved the final version of the review prior to submission.

Contributions of editorial base

Nicky Cullum: edited the review, advised on methodology, interpretation and review content. Approved the final review prior to submission.

Sally Bell-Syer: coordinated the editorial process. Advised on methodology, interpretation and content. Edited and the review and the updated review.
Ruth Foxlee: designed the search strategy, ran the searches and edited the search methods section.

Declarations of interest

This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Grant Reference Number RP-PG-0407-10428). The views expressed are those of the authors (Susan O'Meara and Jo Dumville) and not necessarily those of the NHS, the NIHR or the Department of Health.

Sohan Deshpande and Katherine Speak none declared.

Sources of support

Internal sources

- Department of Health Sciences, University of York, UK.

External sources

- NIHR Programme Grants for Applied Research, UK.
- NIHR/Department of Health (England), (Cochrane Wounds Group), UK.

Characteristics of studies

Characteristics of included studies [ordered by study ID]

Baker 1993

Methods	Single centre, two-arm RCT comparing a foam dressing (Allevyn, Smith & Nephew) with a calcium alginate dressing (Sorbsan, Aspen Medical) undertaken in the UK. Duration of follow-up: Until the wound healed or for a maximum period of 12 weeks.
Participants	20 participants Inclusion criteria: Patients above 18 years of age with clean diabetic foot ulcers that were neuropathic in origin located on weight bearing areas of the foot. Patients who were able to give informed consent and willingly compliant to study protocol. Patients geographically able to comply with the study's demands. Exclusion criteria: Patients with necrotic, sloughy ulcers or peripheral vascular disease, presence of infection in ulcerative foot, patients with history of poor

	compliance, patients unable to attend regularly, unable to follow simple instructions and those who could not comprehend to the nature of the trial.
Interventions	Group A (n = 10): Foam dressing (Allevyn, Smith & Nephew). No secondary dressing was applied . Group B (n = 10): Calcium alginate dressing (Sorbsan, Aspen Medical). A secondary low adherent absorbant dressing was used. In both groups, dressings were cut to the required size but they did not overlap the wound margins by more than 3 cm or less than 0.5 cm. The dressings were secured by standard podiatric methods; e.g. padding and or strapping. Frequency of dressing changes depended on the quantity of exudate produced by the ulcers. If upon removal either dressing should appear to be stuck, they were to be irrigated as necessary with sterile saline. Co-intervention: Ulcers were cleansed with warm sterile saline only and debridement was undertaken where required.
Outcomes	Primary outcome: Ulcer healing (number of ulcers healed at 12 weeks; median healing times *).* Secondary outcome: Not reported.
Notes	Trial data: Analysis 4.1 Funding source not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	**Quote:** " *Each subject will be randomly allocated to one of the two treatment groups either to the Allevyn or the Sorbsan group. This will be determined by the randomisation code which is computer generated* ." **Comment:** Method of generation of random schedule reported.
Allocation concealment (selection bias)	Unclear risk	**Comment:** The process of randomising participants, including who did this is not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	**Comment:** No mention of blinding in study report.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	**Comment:** No mention of blinding in study report.
Incomplete outcome data	Unclear risk	**Comment:** One withdrawal (1/20 = 5%). Viewed as limited attrition.

(attrition bias) All outcomes		
Selective reporting (reporting bias)	Low risk	**Comment:** Based on paper only, protocol not obtained.
Other bias	Unclear risk	**Comment:** Funding source not reported.

Blackman 1994

Methods	Single centre, two-arm RCT comparing a foam dressing (PolyMem, Ferris) with wet-to-dry saline gauze dressing undertaken in the USA. Duration of follow-up: Until healed or until 6 months after the treatment was started. Five participants initially treated with saline gauze (Group B) conventional therapy CROSSED OVER to the polymeric membrane after 2 months. It is difficult to interpret 6 month healing data because of this cross over thus it has not been presented here.
Participants	18 participants However, four participants (two in each arm) were excluded under the criterion: ulcers progressed to Wagner grade 3 or higher. It is not clear if these were post-randomisation exclusions and in fact 22 participants were randomised. Inclusion criteria: Diabetic patients (Type 1 and Type 2) with foot ulcers free of hard eschar. Exclusion criteria: Participants needing vascular surgical therapy, participants with ulcers from Charcot joints, participants with ulcers of non-diabetic origin.
Interventions	Group A (n = 11): Foam dressing (PolyMem, Ferris). Instructed to change dressing once daily as a minimum or when dressing was saturated. In keeping with manufacturers directions - those using the polymeric dressing were instructed not to use topical antibiotics of disinfectants. Group B (n = 7): Wet-to-dry saline gauze dressings. Instructed to change dressing once daily as a minimum or when dressing was saturated. Co-intervention: All participants were encouraged to obtain orthotic footwear and minimise weight bearing as much as possible.
Outcomes	Primary outcome: Ulcer healing (number of ulcers healed at 2 months; average size of ulcer at 2 months compared to baseline; substantial improvement noted in ulcer size *).* Secondary outcomes: Not reported.
Notes	Trial data: Analysis 4.1 Source of funding: Ferris manufacturing corporation (Burr Ridge, IL).

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
	Unclear risk	**Quote:** *"After qualifying for the study subjects were randomly assigned to conventional or polymeric membrane treatment".*

Random sequence generation (selection bias)		**Comment:** Method of generating the random schedule not reported.
Allocation concealment (selection bias)	Unclear risk	**Comment:** The process of randomising participants, including who did this is not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	**Comment:** No mention of blinding in study report.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	**Comment:** No mention of blinding in study report.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	**Comment:** Four participants (2 in each group) were excluded under the criterion "ulcers progressed to Wagner stage 3 or higher" We are not clear if these participants were post-randomisation exclusion meaning that 22 participants were randomised.
Selective reporting (reporting bias)	Low risk	**Comment:** Based on paper only, protocol not obtained.
Other bias	Unclear risk	**Comment:** Some differences in baseline characteristics between groups e.g. mean age 51 years in Group A and 59 years in group Group B. Small sample size means trial is at high risk of chance imbalance. Funded by commercial organisation.

Clever 1995

Methods	Two-arm RCT (not clear if single centre or multi-centred) comparing a foam dressing (Allevyn, Smith & Nephew) with a hydrocolloid (polyurethane matrix) dressing (Cutinova Hydro, Smith & Nephew, previously Beiersdorf) undertaken in Germany. Duration of follow-up: Until healing occurred or for a maximum of 16 weeks.
Participants	40 participants Inclusion criteria: Patients aged 18 to 80 years with a pure neuropathic superficial ulcer 1 to 5 cm in diameter and with no clinical and radiological signs of osteomyelitis or tendon involvement. Exclusion criteria: Patients an ABPI < 0.8 (measured using doppler ultrasound) and with clinical or radiological signs of osteomyelitis or tendon involvement. Ulcers requiring topical treatment were also excluded, as were patients with know allergies to any product being used.
Interventions	Group A (n = 20): Foam dressing (Allevyn, Smith & Nephew). Group B (n = 20): Hydrocolloid (polyurethane matrix) dressing (Cutinova

	Hydro, Smith & Nephew). In both groups, dressing changes were performed as often as required but at least once a week. Co-intervention: Pressure relief comprising a half-shoe or so-called 'heal sandal', therapeutic footwear with cushioned insoles, and crutches as required to meet individual needs, infection control with systemic antibiotics if required, wound cleansing with Ringer's solution and debridement with removal of callus if needed.
Outcomes	Primary outcome: Ulcer healing (number of ulcers healed; mean time to healing; median time to healing; wound size at 4 weeks mm^2). Secondary outcomes: Adverse events; costs (mean number of dressing changes between clinical visits *).* Health-related quality of life; amputations, ulcer recurrence not reported.
Notes	Trial data: Analysis 4.1 Source of funding: Beiersdorf AG, Hamburg.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	**Quote:** *"Conducted an open, randomised, controlled study".* **Comment:** Method of generation of random schedule not reported.
Allocation concealment (selection bias)	Unclear risk	**Comment:** The process of randomising participants, including who did this is not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	**Quote:** " *Conducted an open, randomised, controlled study* ". **Comment:** This was labelled an open trial not clear if blinded evaluation was conducted.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	**Quote:** *"Conducted an open, randomised, controlled study* ". **Comment:** This was labelled an open trial not clear if blinded evaluation was conducted.
Incomplete outcome data (attrition bias) All outcomes	High risk	**Comment:** In total six participants were withdrawn, or 15% of the total study population. The study report states that withdrawals were excluded from the analyses.
Selective reporting (reporting bias)	Low risk	**Comment:** Based on paper only, protocol not obtained.
Other bias	Unclear risk	**Comment:** Funded by commercial organisation.

Foster 1994

Methods	Two-arm RCT (not clear if single centre or multi-centred) comparing a foam dressing (Allevyn, Smith & Nephew) with a calcium-alginate dressing (Kaltostat, ConvaTec) undertaken in the UK. Duration of follow-up: Until ulcer healed or for a maximum of 8 weeks.
Participants	30 participants Inclusion criteria: Patients above the age of 18 years with clean diabetic foot ulcers and who were willing and able to comply with study protocol. Exclusion criteria: Ulcer was sloughy, necrotic or infected.
Interventions	30 participants Group A (n = 15): Foam dressing (Allevyn, Smith & Nephew). Where surrounding skin was in good condition the dressing was secured with hypo-allergic tape. If the skin was atrophic or fragile then no tape was applied but a conforming bandage was used to secure the dressing. To apply the dressing to the patients' lesser toes, a strip of polyurethane foam dressing was doubled over and fastened at the sides to form a sleeve that fitted over the toe. Group B (n = 15): Calcium-alginate dressing (Kaltostat, ConvaTec). The dressing was moistened with saline. A perforated film absorbent dressing was used as a secondary dressing, as before this was secured with hypo-allergic tape or a conforming bandage, depending on the state of the skin. Co-interventions: None reported.
Outcomes	Primary outcome: Ulcer healing (number of ulcers healed; ulcers improved; median time to healing). Secondary outcomes: Adverse events. Health-related quality of life; amputations; costs; amputations, ulcer recurrence not reported.
Notes	The dressing performance parameters such as patient comfort and ease of removal were assessed using the three-point graded categorical scores. For each parameter the mean category score for each patient over the repeated dressing assessment was calculated. These data were not extracted as this approach has not been validated and does not facilitate comparison between studies. Trial data: Analysis 4.1 Funding source not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	**Quote:** *"Thirty out patients entered study and 15 were randomised to each dressing".* **Comment:** Method of generation of random schedule not reported.
Allocation concealment (selection bias)	Unclear risk	**Comment:** The process of randomising participants, including who did this is not reported.

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	**Comment:** No mention of blinding in study report.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	**Comment:** No mention of blinding in study report.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	**Comment:** Four participants were withdrawn from the alginate group (4/30 = 13%). There were no withdrawals from the foam group. It is not clear how data from the withdrawn participants were used.
Selective reporting (reporting bias)	Low risk	**Comment:** Based on paper only, protocol not obtained.
Other bias	Unclear risk	**Comment:** Some differences in baseline characteristics between groups e.g. mean age 61 years in Group A and 70 years in group Group B. Small sample size means trial is at high risk of chance imbalance. Funding source not reported.

Mazzone 1993

Methods	Two-arm RCT (not clear if single or multi-centred) comparing a foam dressing (PolyMem, Ferris) with wet-to-dry saline gauze dressing undertaken in the USA. Duration of follow-up: 8 weeks.
Participants	19 participants Inclusion criteria: Diabetic foot ulcer. Exclusion criteria: Not reported.
Interventions	Group A (n = 11): Foam membrane dressing (PolyMem, Ferris). No other details. Group B (n = 8): Wet-to-dry saline gauze dressings. No other details. Co-interventions: None reported.
Outcomes	Primary outcome: Ulcer healing (number of ulcers healed; % reduction in wound size). Secondary outcomes: Not reported.
Notes	Trial data: Analysis 4.1 Conference abstract. Funding source: Ferris manufacturing corporation (Burr Ridge,IL).
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	**Quote:** *"..were randomly assigned..."* **Comment:** Method of generation of random schedule not reported.
Allocation concealment (selection bias)	Unclear risk	**Comment:** The process of randomising participants, including who did this is not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	**Comment:** No mention of blinding in study report.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	**Comment:** No mention of blinding in study report.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	**Comment:** Not clear (conference abstract).
Selective reporting (reporting bias)	Unclear risk	**Comment:** Based on conference abstract, protocol not obtained.
Other bias	Unclear risk	**Comment:** Funded by commercial organisation.

Roberts 2001

Methods	Two-arm RCT (not clear if single or multi-centred) comparing a foam dressing (Allevyn, Smith & Nephew) with saline-soaked low adherent wound contact dressings (Tricotex, Smith & Nephew) undertaken in the UK. Duration of follow-up: 13 weeks.
Participants	30 participants Inclusion criteria: Type 1 diabetes with neuropathic ulcer. Exclusion criteria: ABPI < 0.8.
Interventions	Group A (n = 14): Foam dressing (Allevyn, Smith & Nephew). Group B (n = 16): Saline-soaked low adherent wound contact dressings (Tricotex, Smith & Nephew). Dressings were changed weekly. Co-interventions: Standard podiatric care (no other details given).
Outcomes	Primary outcome: Ulcer healing (number of ulcers healed; % ulcers reduced by 50% in size) Secondary outcomes: Not reported.

[a] ABPI: ankle-brachial pressure index
RCT: randomised controlled trial

Notes	Trial data: Analysis 4.1 Conference abstract. Time to healing reported as not significantly different but values not reported. Funding source: Smith and Nephew.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	**Comment:** Described in title as randomised controlled trial but method of generation of random schedule not reported.
Allocation concealment (selection bias)	Unclear risk	**Comment:** The process of randomising participants, including who did this is not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	**Comment:** No mention of blinding in conference abstract.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	**Comment:** No mention of blinding in study report.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	**Comment:** Not clear (conference abstract).
Selective reporting (reporting bias)	Unclear risk	**Comment:** Based on conference abstract, protocol not obtained.
Other bias	Unclear risk	**Comment:** Funded by commercial organisation.

[a] ABPI: ankle-brachial pressure index
RCT: randomised controlled trial

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Agas 2006	Study did not randomise participants.
Ahroni 1993	The dressing groups evaluated in this study were not foam dressings.
Altman 1993	No single, identifiable dressing type evaluated.

Study	Reason for exclusion
Alvarez 2003	The dressing groups evaluated in this study were not foam dressings.
Apelqvist 1990	The dressing groups evaluated in this study were not foam dressings.
Apelqvist 1996	No single, identifiable dressing type evaluated.
Apelqvist 2004	No single, identifiable dressing type evaluated.
Armstrong 2004	No single, identifiable dressing type evaluated.
Belcaro 2010	The dressing groups evaluated in this study were not foam dressings.
Bogaert 2004	Study did not randomise participants.
Bradshaw 1989	Trial stopped after recruiting six participants. No data presented. Authors not contacted for healing data.
Caravaggi 2003	Other intervention, not dressings, differ between trial arms.
Chang 2000	Study did not include diabetic foot ulcers.
Chauhan 2003	Other intervention, not dressings, differ between trial arms.
Chirwa 2010	Study did not randomise participants.
Cuevas 2007	No single, identifiable dressing type evaluated.
D'Hemecourt 1998	The dressing groups evaluated in this study were not foam dressings.
Dash 2009	Other intervention, not dressings, differ between trial arms
Diehm 2005	Study did not randomise participants
Donaghue 1998	The dressing groups evaluated in this study were not foam dressings
Driver 2006	Other intervention, not dressings, differ between trial arms
Edmonds 2009	Other intervention, not dressings, differ between trial arms
Eginton 2003	No single, identifiable dressing type evaluated.
Etoz 2004	Study did not randomise participants.
Farac 1999	Author contacted: study not suitable for inclusion due to data quality issues.
Foo 2004	The dressing groups evaluated in this study were not foam dressings.

Study	Reason for exclusion
Foster 1999	Other intervention, not dressings, differ between trial arms.
Gao 2007	Other intervention, not dressings, differ between trial arms.
Gentzkow 1996	Other intervention, not dressings, differ between trial arms.
Gottrup 2011	The dressing groups evaluated in this study were not foam dressings.
Hanft 2002	Other intervention, not dressings, differ between trial arms.
Jeffcoate 2009	The dressing groups evaluated in this study were not foam dressings.
Jeffery 2008	Study did not randomise participants.
Jensen 1998	The dressing groups evaluated in this study were not foam dressings.
Jude 2007	The dressing groups evaluated in this study were not foam dressings.
Kordestani 2008	The dressing groups evaluated in this study were not foam dressings.
Lalau 2002	The dressing groups evaluated in this study were not foam dressings.
Landsman 2010	Other intervention, not dressings, differ between trial arms.
Lazaro-Martinez 2007	Other intervention, not dressings, differ between trial arms.
Lipkin 2003	Other intervention, not dressings, differ between trial arms.
Markevich 2000	The dressing groups evaluated in this study were not foam dressings.
Marston 2001	Other intervention, not dressings, differ between trial arms.
McCallon 2000	Study did not randomise participants.
Mody 2008	Study did not include diabetic foot ulcers.
Moretti 2009	Other intervention, not dressings, differ between trial arms.
Mueller 1989	Other intervention, not dressings, differ between trial arms.
Mulder 1994	The dressing groups evaluated in this study were not foam dressings.
Munter 2006	Study included a range of wound types, with data not reported separately for diabetic foot ulcers. We were unsuccessful in contacting the authors to query the availability of relevant data.
Novinscak 2010	No single, identifiable dressing type evaluated.

Study	Reason for exclusion
Ogce 2007	The dressing groups evaluated in this study were not foam dressings.
Palao i Domenech 2008	Study included a range of wound types, with data not reported separately for diabetic foot ulcers. The control arm of the study received 'local best practice' with no further information provided. The primary ou come was ulcer pain and the follow-up period was seven days only. We were unsuccessful in contacting the authors to query the availability of relevant healing data.
Parish 2009	Other intervention, not dressings, differ between trial arms.
Pham 1999	Other intervention, not dressings, differ between trial arms.
Piaggesi 1997	Study did not randomise participants.
Piaggesi 2001	The dressing groups evaluated in this study were not foam dressings.
Reyzelman 2009	No single, identifiable dressing type evaluated.
Robson 2005	Other intervention, not dressings, differ between trial arms.
Robson 2009	Study did not include diabetic foot ulcers.
Sabolinski 2000	Other intervention, not dressings, differ between trial arms.
Sabolinski 2001	Other intervention, not dressings, differ between trial arms.
Shaw 2010	Other intervention, not dressings, differ between trial arms.
Shukrimi 2008	Other intervention, not dressings, differ between trial arms.
Sibbald 2011	Study included a range of wound types, with data not reported separately for diabetic foot ulcers. We were unsuccessful in contacting the authors to query the availability of further information.
Solway 2011	Study did not randomise participants.
Steed 1992	Other intervention, not dressings, differ between trial arms.
Steed 1995	Other intervention, not dressings, differ between trial arms.
Steed 1996	Other intervention, not dressings, differ between trial arms.
Subrahmanyam 1993	The dressing groups evaluated in this study were not foam dressings.
Trial 2010	The dressing groups evaluated in this study were not foam dressings.
Turns 2012	Study did not randomise participants.

Study	Reason for exclusion
Urbaneie-Rovan 1999	No single, identifiable dressing type evaluated.
Vandeputte 1997	The dressing groups evaluated in this study were not foam dressings.
Varma 2006	No single, identifiable dressing type evaluated.
Veves 2001	Other intervention, not dressings, differ between trial arms.
Veves 2002	The dressing groups evaluated in this study were not foam dressings.
Whalley 2001	The dressing groups evaluated in this study were not foam dressings.
Woo 2010	Study included a range of wound types, with data not reported separately for diabetic foot ulcers. We were unsuccessful in contacting the authors to query the availability of further information.
Yao 2007	Other intervention, not dressings, differ between trial arms.
Zimny 2003	Other intervention, not dressings, differ between trial arms.

References

Version History

Citing Literature

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