

# Debridement for surgical wounds (Review)

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[Intervention Review]

# Debridement for surgical wounds

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**Editorial group:** Cochrane Wounds Group.

**Publication status and date:** New search for studies and content updated (no change to conclusions), published in Issue 9, 2013.

**Review content assessed as up-to-date:** 13 June 2013.

**Citation:** Smith F, Dryburgh N, Donaldson J, Mitchell M. Debridement for surgical wounds. *Cochrane Database of Systematic Reviews* 2013, Issue 9. Art. No.: CD006214. DOI: 10.1002/14651858.CD006214.pub4.

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## ABSTRACT

### Background

Surgical wounds that become infected are often debrided because clinicians believe that removal of this necrotic or infected tissue will expedite wound healing. There are numerous methods available but no consensus on which one is most effective for surgical wounds.

### Objectives

To determine the effect of different methods of debridement on the rate of debridement and healing of surgical wounds.

### Search methods

In March 2013, for this third update, we searched 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.

### Selection criteria

We included randomised controlled trials (RCTs) with outcomes including at least one of the following: time to complete debridement or time to complete healing.

### Data collection and analysis

Two review authors independently reviewed the abstracts and titles obtained from the search, extracted data independently using a standardised extraction sheet and independently assessed methodological quality. One review author was involved in all stages of the data collection and extraction process, thus ensuring continuity.

### Main results

Five RCTs (159 participants) were eligible for inclusion; all compared treatments for infected surgical wounds and reported time required to achieve a clean wound bed (complete debridement). One trial compared an enzymatic agent (streptokinase/streptodornase) with saline-soaked dressings. Four trials compared the effectiveness of dextranomer beads or paste with other products (different comparator in each trial) to achieve complete debridement. Meta-analysis was not possible due to the unique comparisons within each trial. One trial reported that dextranomer achieved a clean wound bed significantly more quickly than Eusol, and one trial comparing enzymatic debridement with saline-soaked dressings reported that the enzyme-treated wounds were cleaned more quickly. However, methodological quality was poor in these two trials.

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## Authors' conclusions

There is a lack of large, high-quality published RCTs evaluating debridement *per se*, or comparing different methods of debridement for surgical wounds, to guide clinical decision-making.

## PLAIN LANGUAGE SUMMARY

### Debridement for surgical wounds

Following surgery most surgical wounds heal naturally with no complications. However, complications such as infection and wound dehiscence (opening) can occur which may result in delayed healing or wound breakdown. Infected surgical wounds may contain dead (devitalised) tissue. Removal of this dead tissue (debridement) from surgical wounds is believed to enable wound healing. Many methods are available to clinicians to debride surgical wounds. This review showed that there is insufficient valid research evidence to recommend any one particular method.

There is a clear need for more research into which method is most effective in removing dead tissue from surgical wounds that have become infected.

## BACKGROUND

Surgical wounds, by definition, are initially acute and most heal naturally without delay or complications (Bale 1997; Baxter 2003). However, complications such as infection and wound dehiscence (opening) may occur, and may result in either delayed wound healing or wound breakdown, or both. Wounds with surgical site infections may contain devitalised (dead) tissue. The appearance, colour and texture of this tissue may vary from hard, black tissue (necrotic or eschar) to a soft fibrous yellow or green tissue (slough) (Thomas 1999; Vowden 1999a; Ramundo 2000; Stotts 2000; O'Brien 2003a). This may be accompanied by increased production of fluid (exudate) and the presence of an odour (Dealey 1994; O'Brien 2003a).

There is a widely held belief that wound healing is impeded by the presence of devitalised, necrotic tissue and wounds containing such material do not heal successfully (Baharestani 1999; Lewis 2000; Stotts 2000; NICE 2001; O'Brien 2002). Non-viable tissue not only inhibits the growth of epithelial tissue, but also increases the production of exudate, impairs assessment of the wound bed, and makes it more difficult to achieve wound closure, thus having an adverse effect on quality of life (Baharestani 1999). Although Baharestani 1999 details a number of reasons for the removal of the dead tissue (as detailed above), these reasons do not appear to be supported by robust, scientific evidence.

Debridement is the process whereby foreign material and dead or damaged tissue and debris are removed from a wound (Vowden 1999a; O'Brien 2002; O'Brien 2003c). Debridement of wounds

includes any method that removes infected or contaminated tissue, cell debris or dead, devitalised, fibrous material (frequently classified as eschar or slough) to create a clean wound bed (Vowden 1999a; NICE 2001; O'Brien 2002). Debridement is thought to provide a foundation for the subsequent healing of wounds (O'Brien 2003b).

Debridement may be achieved by a variety of methods including: surgery; biosurgical (larvae) debridement; autolytic debridement; mechanical debridement; chemical debridement and enzymatic debridement.

### Surgical or sharp debridement

Surgical debridement may be achieved by the aggressive excision of all devitalised tissue using surgical techniques (Thomas 1999; Vowden 1999b; Sibbald 2000; Schultz 2003). Disadvantages associated with this method are the requirement for hospital admission, the administration of an anaesthetic with associated complications, and time in the operating theatre. It is also associated with pain, bleeding and excision of healthy tissue and, as such, is not suitable or desirable for all patients (Baharestani 1999; Thomas 1999; Vowden 1999b; Sibbald 2000; Schultz 2003). On the other hand, sharp debridement involves the excision of small quantities of dead tissue by a clinician using scissors or a scalpel (O'Brien 2003a; O'Brien 2003c). This procedure may be performed in a community or hospital setting (Poston 1996). However, for both surgical and sharp procedures, issues of patient consent, training and skill of the clinician must be considered (Ashworth 2002).

## Biosurgical/biological debridement

In biosurgical or biological debridement, sterile larvae (maggots) of the *Lucilia sericata* species of greenbottle fly are applied to a sloughy wound. There, the larvae are capable of producing powerful proteolytic enzymes that destroy the dead tissue by liquefying and ingesting it. Healthy tissue in the wound bed is not damaged and, although there are aesthetic considerations, larvae are increasingly being used for wound debridement (Baharestani 1999; Lewis 2000; O'Brien 2003a).

## Autolytic debridement

Over time, naturally occurring enzymes will eventually break down and dissolve dead or sloughy tissue in wounds. This natural process is promoted by the maintenance of a moist environment through judicious use of dressings and topical agents (e.g. hydrogels, semi-occlusive and occlusive wound dressings). Many of these dressings hydrate and remove black, necrotic tissue and slough (Baharestani 1999; Vowden 1999a; Lewis 2000). Dextranomer is an example of a hydroscopic dressing which has a high absorptive capacity and is capable of removing bacteria, debris and absorbing wound exudate, thereby facilitating autolytic debridement. However worldwide production of dextranomer beads and paste was discontinued in 2007, with the exception of the paste which is still available in South Africa.

## Mechanical debridement

Mechanical methods of debridement are non-selective and may result in damage to healthy tissue (Baharestani 1999). These methods include: wet to dry debridement, wound cleansing debridement and whirlpool debridement (Vowden 1999a; Ramundo 2000; O'Brien 2003a; Stotts 2004; Falabella 2006).

## Wet to dry debridement

The wet to dry method of debridement involves the application of a saline-soaked gauze dressing to a wound. The moist dressing induces separation of the devitalised tissue and, once dry, the dressing is removed, together with the slough and necrotic tissue. This process is continued until all the devitalised tissue is removed. This is reported to be a painful procedure and may damage healthy tissue; fibres may be left in the wound and the dressing does not provide a barrier to bacterial contamination (Baharestani 1999; Ramundo 2000; O'Brien 2003a; Stotts 2004).

## Wound cleansing debridement

Wound cleansing debridement involves irrigating a wound with a continuous or intermittent flow of fluid delivered under high pressure. The force of the fluid is between 8 and 12 pounds per

square inch (psi), and is sufficient to remove devitalised tissue and wound bacteria (Baharestani 1999; Ramundo 2000). Newer wound cleansing systems use pressurised saline delivered via a nozzle at between 12,800 and 15,000 psi (Granick 2006).

## Whirlpool debridement

Whirlpool debridement is used for large wounds on the trunk or extremities. The affected person is immersed in a whirlpool bath, where the vigorous action of the water and its hydrating effect loosen the surface bacteria and devitalised tissue, and allow them to be washed away (Baharestani 1999; Ramundo 2000).

## Chemical debridement

A range of chemical agents, including hypochlorites such as EU-SOL (Edinburgh University Solution of Lime) and Dakin's Solution (sodium hypochlorite), hydrogen peroxide and iodine, have been used to promote debridement of wounds. The use of chemical agents remains a controversial area, in which any benefits need to be judged against any detrimental effects on the process of healing (Brennan 1985; Baharestani 1999; Hofman 2002; Ayello 2004).

## Enzymatic debridement

Topical enzymatic preparations are applied to moist (or moistened) devitalised tissue. Such preparations include: streptokinase/streptodornase (Lewis 2000; O'Brien 2003a), collagenase (Ramundo 2000; Stotts 2004), papain/urea, and a combination of fibrinolysin and deoxyribonuclease (Ramundo 2000; Stotts 2004). This method has a number of disadvantages, including a requirement for frequent dressing changes and a slow rate of debridement. Worldwide production of the enzymatic preparation of streptokinase/streptodornase has now been discontinued.

## Overview

There is considerable debate about the appropriateness and efficacy of debridement methods (Ashworth 2002). A systematic review published in 1999 indicated that there were no studies comparing non debridement with debridement and therefore the benefits of debridement on wound healing were unclear (Bradley 1999). A guidance document on the use of debriding agents for difficult-to-heal surgical wounds highlighted the lack of sufficient evidence (and the corresponding absence of randomised controlled trials (RCTs)) to support any particular method of debridement (NICE 2001). However a Cochrane Review on the debridement of diabetic foot ulcers found evidence suggesting that the rate of healing increased when a hydrogel dressing was used in comparison to a gauze dressing (Edwards 2010). The choice of debriding agent and method is usually made on the basis of the clinician's expertise

and knowledge, the available resources and cost (Flanagan 1999). Since wound management choices, however, continue to increase, as do the cost of products, the choice of debridement method or agent should be guided by good evidence (Lewis 2000). An up-to-date review of debridement for surgical wounds is therefore necessary, to enable evidence-based clinical decision-making.

## OBJECTIVES

To determine the effects of different debriding methods on the rate of debridement and healing of surgical wounds.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We included all RCTs evaluating debridement in the management of surgical wounds.

#### Types of participants

We included studies on people of any age, in any care setting, with a surgical wound that required debridement, but excluded studies of wounds that were not caused by surgery (i.e. trauma wounds, burns, abscesses or sinuses, pressure ulcers, leg ulcers, diabetic foot ulcers, fungating tumours and wounds caused by the removal of foreign bodies).

#### Types of interventions

We considered any method of debridement compared with a control regimen (a placebo, an alternative method of debridement, any other therapy or no treatment) including:

- surgical, such as the excision of all devitalised tissue, or sharp, such as the excision of small quantities of non-viable tissue using a scalpel or scissors;
- biosurgical, such as the use of sterile larvae;
- autolytic, such as the use of hydrogels/hydrocolloids to promote a moist environment;
- mechanical, such as wet to dry debridement, high-pressure irrigation or whirlpool debridement;
- chemical, such as the use of Eusol or Dakin's Solution; and
- enzymatic debridement, such as topical enzymatic preparations (e.g. collagenase).

### Types of outcome measures

A trial report had to provide at least one of the primary outcomes to be included in the review.

#### Primary outcomes

- Time to complete debridement.
- The proportion of wounds completely debrided during the trial period.
- The rate of reduction in wound size expressed in either absolute or relative terms.
- The proportion of wounds completely healed during the trial period.
- Time to complete healing.

#### Secondary outcomes

When reported, we recorded the following secondary outcomes:

- patient satisfaction (e.g. pain associated with treatment as recorded using a recognised pain scale);
- rate of infection;
- quality of life;
- length of hospital stay;
- cost-effectiveness (e.g. as presented in a cost-effectiveness analysis, which may include: nursing time; time taken to change dressing; number of dressing changes required; cost of dressing materials);
- serious adverse events (life-threatening or those leading to hospitalisation);
- other adverse events (those leading to discontinuation of treatment).

### Search methods for identification of studies

The search methods used in the second review update can be found in Appendix 1.

#### Electronic searches

In March 2013, for this third update, we searched the following databases for reports of eligible trials:

- the Cochrane Wounds Group Specialised Register (searched 28 March 2013);
- the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2013, Issue 2);
- Ovid MEDLINE (2011 to March Week 2 2013);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations, March 26, 2013);
- Ovid EMBASE (2011 to 2013 Week 12); and
- EBSCO CINAHL (2011 to 22 March 2013).

We used the following strategy in the Cochrane Central Register of Controlled Trials (CENTRAL):

#1 MeSH descriptor Debridement explode all trees  
 #2 debrid\*  
 #3 MeSH descriptor Larva explode all trees  
 #4 (larva\* or maggot\* or biosurgery or bio-surgery)  
 #5 wound\* NEXT irrigat\*  
 #6 wound\* NEXT cleans\*  
 #7 whirlpool  
 #8 collagenase\* or fibrinolytic\* or proteolytic\* or trypsin or streptokinase or streptodornase or varidase  
 #9 hypochlorite or hydrogen NEXT peroxide  
 #10 malic NEXT acid or benzoid NEXT acid or salicylic NEXT acid or propylene NEXT glycol  
 #11 dakin solution  
 #12 dextranomer\* or cadexomer or xerogel or eusol or debrisan  
 #13 polysaccharide NEXT bead\* or polysaccharide NEXT paste\*  
 #14 iodoflex or iodisorb  
 #15 intrasite NEXT gel or intrasitgel or sterigel or granugel or nugel or purilon NEXT gel or purilon or vigilon  
 #16 gauze NEXT dressing\* or adherent NEXT dressing\* or absorbent NEXT dressing\* or tulle NEXT dressing\* or polysaccharide NEXT dressing\* or hydrofibre NEXT dressing\* or “wet to dry dressing” or “wet to dry dressings”  
 #17 hydrocolloid\* or granuflex or tegasorb or aquacel or hydrocoll or combiderm or duoderm  
 #18 alginate NEXT dressing\* or foam NEXT dressing\* or hydrogel\* or saline NEXT gauze  
 #19 MeSH descriptor Honey explode all trees  
 #20 honey\*  
 #21 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20)  
 #22 MeSH descriptor Surgical Wound Infection explode all trees  
 #23 MeSH descriptor Surgical Wound Dehiscence explode all trees  
 #24 surg\* NEAR/5 infection\*  
 #25 surg\* NEAR/5 wound\*  
 #26 (postoperative or post-operative) NEAR/5 infection\*  
 #27 exudat\* NEAR/5 wound\*  
 #28 exudat\* NEAR/5 cavit\*  
 #29 necrot\* NEAR/5 wound  
 #30 necrot\* NEAR/5 cavit\*  
 #31 (#22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30)  
 #32 (#21 AND #31)

The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in Appendix 2; Appendix 3 and Appendix 4 respectively. We combined the MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision); Ovid format (Lefebvre 2011). We combined the EMBASE and CINAHL searches with the trial filters developed by the Scottish Intercollegiate Guidelines Network

(SIGN 2007). There were no restrictions with respect to language, date of publication or study setting.

### Searching other resources

We contacted manufacturers of wound products by e-mail for details of published, unpublished and ongoing trials (Smith & Nephew Healthcare Ltd; Convatec Ltd; Johnston & Johnston; Medihoney). To date we have identified no new citations for this review through these contacts. We checked the citations within obtained studies to identify additional papers.

### Data collection and analysis

#### Selection of studies

Two review authors (ND and FS) independently assessed for relevance and design the titles and abstracts of studies identified. They obtained full versions of articles that met the inclusion criteria of this initial assessment. A third review author (MM) was consulted for adjudication on some abstracts. All rejected titles and abstracts were reviewed by (MM).

#### Data extraction and management

We used a standardised extraction sheet to record and summarise details of the studies. Two review authors (ND and JD) independently performed data extraction. Discrepancies were resolved by discussion and referred to a third review author (FS).

We extracted the following data:

- general information: author(s), title, source, contact address, year of study, country of study, language of publication, year of publication;
- trial characteristics: design (RCT), randomisation method, manner of recruitment, sampling method, duration of intervention period, length of follow up, reason for and number of dropouts and withdrawals, adverse events;
- participants: baseline characteristics such as sex, age, type of wound, wound size, duration of wound, method of debridement, prevalence of co-morbidities (e.g. diabetes), study inclusion and exclusion criteria, all by treatment group;
- intervention: detailed description of the comparison dressing/method, co-interventions, duration;
- outcome measures;
- primary outcomes: time to complete debridement, proportion of wounds completely debrided, reduction in wound size, proportion of wound completely healed, time to complete healing;
- secondary outcomes: patient satisfaction (pain assessment), rate of infection, quality of life, length of hospital stay, cost-effectiveness, serious/other adverse events;

- any co-interventions; and
- where trials were sponsored by the dressing manufacturer.

### **Assessment of risk of bias in included studies**

For the update of this review we assessed each included study for risk of bias, without blinding to journal or authorship, using the Cochrane Collaboration tool (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) (see

Appendix 5 for details of the criteria on which the judgements were based). We assessed blinding and completeness of outcome data for each outcome separately. We completed a 'Risk of bias' table for each eligible study.

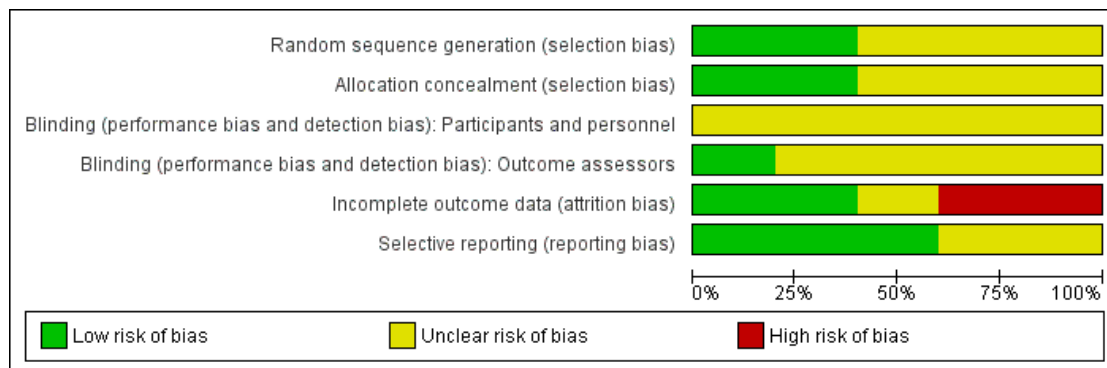
We presented an assessment of risk of bias using a 'Risk of bias' summary figure (Figure 1 and Figure 2), which presents all of the judgements in a cross-tabulation of study by entry. This display of the internal validity indicates the weight the reader may give the results of each study. We classed studies as being at high risk of bias overall if any one of the criteria were judged to be at high risk of bias.



Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias): Participants and personnel	Blinding (performance bias and detection bias): Outcome assessors	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Goode 1979	?	?	?	+	+	+
Michiels 1990	+	?	?	?	?	+
Poulson 1983	?	+	?	?	-	?
Sondergaard 1982	+	+	?	?	-	?
Young 1982	?	?	?	?	+	+

**Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**



### Assessment of heterogeneity

Should data be available in future updates, we will explore both clinical and statistical heterogeneity. In the absence of clinical and statistical heterogeneity we will apply a fixed-effect model to pool data, if appropriate. In the presence of statistical heterogeneity (as estimated by the  $I^2$  statistic where values of  $I^2$  over 75% indicate a high level of heterogeneity) (Higgins 2003) we will apply a random-effects model for meta-analysis. Where synthesis is inappropriate we will undertake a narrative overview. If there are any cost-effectiveness data then these will be summarised narratively.

### Data synthesis

Where appropriate data were entered into RevMan 5 by one review author (ND) and checked by two others (JD) and (FS). We converted continuous data (e.g. total area healed, or changes in volume of ulcers) to the standardised mean difference (or a weighted mean difference, when plausible) and calculated overall effect size (with 95% CI). We analysed time to wound healing and time to return to work as survival (time to event) data, using the appropriate analytical method (as per the *Cochrane Handbook for Systematic Reviews of Interventions* version 5.0 (Higgins 2011)).

### Subgroup analysis and investigation of heterogeneity

Should data be available in future updates, we may use subgroup analysis to investigate the effect of pre-existing pathology (e.g. diabetes), or ages of subjects (e.g. below or above age 14 years), or

location of wound (e.g. abdominal, thoracic wounds) on surgical wound debridement.

## RESULTS

### Description of studies

None of the titles or abstracts (425 citations) retrieved in the updated search were relevant to this review.

Our original 2008 search identified 2087 titles and abstracts. A total of 30 abstracts were potentially relevant and we obtained the full publications of these. Five of these publications were in languages other than English and after translation it was apparent that only one of these was a RCT. Two authors (ND and MM) independently read the publications and applied the inclusion and exclusion criteria. They made referral to a third author (JD) regarding three trials. Six RCTs were initially identified as having met the inclusion criteria (see 'Characteristics of included studies' table); the randomisation status of one was unclear and the author did not respond to requests for further information (Zeitani 2004) therefore we excluded this trial (see 'Characteristics of excluded studies' table), leaving five included trials (Goode 1979; Sondergaard 1982; Young 1982; Poulson 1983; Michiels 1990). All identified trials were published between 1979 and 1990; trial sizes ranged from 18 to 50 participants and, where reported, ages ranged from three years to 91 years. Small sample size was the main deficiency of the five trials and none of the trials reported an *a priori* sample size calculation.

All the trials compared treatments for infected post surgical wounds and, although the term debridement was mentioned in only one of the five trials (Michiels 1990), each trial reported the time required to obtain a clean wound bed. As the debridement of wounds includes any method that removes infected or contaminated tissue, cell debris or devitalised material to create a clean bed, we considered the five trials eligible for inclusion in the review. The five trials entered people with post surgical wounds all described as infected, or at risk of infection, and reported that the wounds were either left open, or required opening and drainage for infection. Reporting of the type and site of the surgery and extent of the wound was variable. Poulson 1983 provided the most detailed breakdown of the type of surgery performed and inclusion criteria indicating the minimum length and depth of the wounds. Sondergaard 1982 reported inclusion of wounds involving the subcutaneous tissue and Young 1982 included wounds left open from the muscle layer outwards. Exclusion criteria was not reported in the trials by Goode 1979 and Young 1982.

Four of the trials evaluated the effectiveness of dextranomer beads or paste in providing a clean wound bed. One compared the effectiveness of dextranomer with Eusol-soaked dressings (Goode 1979). Michiels 1990 compared dextranomer paste with 10% aqueous polyvinylpyrrolidone. Dextranomer beads were compared with 0.1% chloramine soaked packs in the trial by Sondergaard 1982 and with a polymer foam dressing in another trial (Young 1982). One trial compared the enzyme preparation of streptokinase/streptodornase with saline-soaked dressings (Poulson 1983). Time to a clean wound bed was reported in all trials and was the primary outcome prior to wound closure or discharge from hospital (Goode 1979; Poulson 1983; Michiels 1990). Time to complete healing was reported in two trials (Sondergaard 1982; Young 1982).

Small sample size was the major deficiency of the five trials. The sample sizes ranged from 18 to 50.

### Risk of bias in included studies

We classified studies as being at high risk of bias overall if any of the following four criteria were judged to be at high risk of bias: randomisation sequence generation, allocation concealment, blinding and incomplete outcome data addressed.

All five included trials (Goode 1979; Sondergaard 1982; Young 1982; Poulson 1983; Michiels 1990) were classified as 'unclear' for the majority of the four key criteria (see 'Risk of bias' tables for each study).

### Allocation

#### Adequacy of the randomisation process

All studies reported that allocation was randomised but the method of generating the randomisation sequence was not always clear. We judged sequence generation to be adequate in two studies: Michiels 1990 reported the use of a randomisation list and Sondergaard 1982 randomised patients in blocks of four. Hence, we judged these two studies to be at low risk of bias for this domain. We judged the remaining three studies as at unclear risk of bias as they did not report sufficient information to make a judgement with respect to the method of sequence generation: Goode 1979 and Young 1982 used a randomised card system, whilst Poulson 1983 arranged for the hospital pharmacy to control the randomisation but none of them stated how the sequence was generated.

#### Adequacy of allocation concealment

Two studies reported adequate allocation concealment and were judged to be at low risk of bias for this domain. Poulson 1983 reported that the hospital pharmacy prepared and provided the ampoules of the treatment and control solutions (treatment and control solutions were both 20 ml vials of clear fluid). Sondergaard 1982 reported the use of numbered sealed envelopes which, although not described as opaque, we have judged it to be adequate allocation concealment. The extent of the allocation concealment in the remaining trials was unclear either because insufficient information was provided or studies did not state that allocation was concealed.

### Blinding

#### Blinding of outcome assessors

Studies were regarded as at lower risk of bias if the outcome assessor was blinded to the intervention. Only one trial (Goode 1979) reported that the outcome assessor was blinded to treatment and the assessment was carried out using photographs rather than a visual inspection. The remaining trials did not report if the outcome assessors were blinded and were judged as at unclear risk of bias for this domain (Sondergaard 1982; Young 1982; Poulson 1983; Michiels 1990).

#### Blinding of participants and personnel

None of the included studies reported blinding of participants or personnel involved in the care of the participants. It would be difficult to blind the personnel involved in applying the wound dressings where the control and treatment dressings had very different properties; the same would apply to the participants. It is reasonable to argue that blinding of these two would not adversely influence the outcomes measured within the trials, however the judgement remains as at unclear risk of bias.

## Incomplete outcome data

Goode 1979 and Young 1982 do not record any withdrawals or dropouts and the number of participants included at the start of each trial is reflected in the results and therefore were judged to be at low risk of bias for this domain. Two studies were classified to be at high risk of bias for this domain: Poulson 1983 reported three withdrawals which were excluded from the final analysis and Sondergaard 1982 reported six withdrawals and in the tables of results indicated that these participants were excluded. It is not clear if these were also excluded from the final analysis. Also, the dropout rate in Sondergaard 1982 was 21% (we originally prespecified greater than 80%) and hence was judged to be unacceptable. The remaining trial reported limited information and was judged to be 'unclear' for risk of bias in this domain (Michiels 1990).

## Selective reporting

No study protocols were available. However, we judged Goode 1979, Michiels 1990 and Young 1982 to be at low risk of bias for this domain because they adequately reported the expected study outcomes. We judged Sondergaard 1982 and Poulson 1983 'unclear' due to poor reporting.

## Effects of interventions

### Comparison 1: Dextranomer beads compared with Eusol gauze (one RCT, 20 participants)

Goode 1979 compared dextranomer beads (an autolytic debridement agent) with Eusol-soaked ribbon gauze in 20 patients with infected surgical wounds, following appendectomy or bowel surgery.

#### Primary outcomes

- Outcome 1 - Time to a clean wound bed and secondary wound closure:

Resolution of erythema and oedema, absence of pus or slough and the formation of granulation tissue, were used as the criteria to determine a clean wound bed. Mean time to a clean wound bed was significantly shorter with dextranomer; 8.1 days compared with 11.6 days for Eusol ( $P < 0.05$ , Mann-Whitney U-test).

- Outcome 2 - Time to complete healing:

The time to complete healing was not reported, although the trialists report that one wound in each group healed without secondary closure.

#### Secondary outcomes

- Outcome 1 - Patient satisfaction: not reported.
- Outcome 2 - Rate of infection: not reported.
- Outcome 3 - Quality of life: not reported.
- Outcome 4 - Length of hospital stay:

Patients in the dextranomer group were described as having a shorter stay by a median of 2.2 days than the Eusol group, however no data for the control group were reported.

- Outcome 5 - Cost-effectiveness: not reported:

Goode 1979 commented on the higher cost of dextranomer (£3.40 per twice-daily dressing) but that the shorter hospital stay in the treatment group compensated for this. This claim was not supported by any data.

While Goode 1979 demonstrated methodological adequacy in allocation concealment and blinding of outcome assessment, an unclear randomisation process, a small sample size and insufficient data mean it is difficult to place much weight on these results. Furthermore the comparator (Eusol) is rarely used due to fears of harmful effects on healthy tissue (Morgan 1991; Morgan 2004).

### Comparison 2: Dextranomer paste compared with 10% aqueous polyvinylpyrrolidone (one RCT, 40 participants)

Michiels 1990 compared dextranomer paste with gauze dressings soaked in 10% aqueous polyvinylpyrrolidone (an iodine-based chemical debridement agent) in people with infected surgical wounds following osteosynthesis, microsurgery and reconstructive procedures.

#### Primary outcomes

- Outcome 1 - Time to clean wound bed:

The disappearance or resolution of erythema, pus and debris, oedema, necrotic tissue and the presence of granulation tissue were used as the criteria to determine a clean wound bed. The results for each variable were assessed subjectively and presented individually. The development, validity and reliability of the assessment systems used was not reported, but the trialists did acknowledge that the evaluation was an approximation. The trial reported no significant difference between the treatment and control groups for the resolution of erythema, oedema, necrotic tissue and the development of granulation tissue. The handling and reporting of the data for the pus and debris criteria were unclear and subjective and the groups were not comparable at baseline with respect to the amount of pus and debris. Michiels 1990 reports that dextranomer significantly reduced the time taken to clean the wound bed compared with polyvinylpyrrolidone. A P value of less than 0.05 was reported (Student's *t*-test), however no data were provided, the outcome was subjective and the outcome assessment was not reported as masked to treatment.

- Outcome 2 - Time to complete healing:

The duration of the trial was 12 days and treatment was discontinued when the wound was clean and had new granulation tissue. Time to complete healing was not reported.

### Secondary outcomes

No secondary outcomes were reported in this trial. The methodological quality of this trial was poor with only the completeness of follow up adequate. The validity of the results is questionable.

### Comparison 3: Streptokinase/streptodornase compared with saline-soaked dressing (one RCT, 21 participants)

One small randomised trial compared enzymatic debridement with streptokinase/streptodornase with saline-soaked dressings in people with infected abdominal surgical wounds following a range of operations (Poulson 1983).

### Primary outcomes

- Outcome 1 - Time to clean wound bed:

The trial reported the number of days required for a clean wound bed and secondary suture. Statistical analysis of the data demonstrated that time to a clean wound bed or secondary suture was significantly shorter for the streptokinase/streptodornase group (mean 5 days (SD 2.16)) compared with the saline-soaked dressings group (mean 13.45 days (SD 6.77),  $P < 0.05$  by both Student's *t*-test and Mann-Whitney U-test). Time to clean wound bed was analysed using the Student's *t*-test and Mann Whitney U-test. Time to debridement or discharge of the patient are time to event outcomes and so the treatment effect should have been expressed as a hazard ratio.

- Outcome 2 - Time to complete healing not reported.

### Secondary outcomes

- Outcome 1 - Patient satisfaction: not reported.
- Outcome 2 - Rate of infection: not reported.
- Outcome 3 - Quality of life:

The trial reported that no patients in either group complained of significant discomfort from the wound.

- Outcome 4 - Length of hospital stay:

Patients in the streptokinase/streptodornase group were described as having a had a shorter stay by 8.5 days than the saline-soaked dressings group, however no data or statistics were included in the trial report.

- Outcome 5 - Cost-effectiveness: not reported.

Methodological adequacy is reported in the randomisation process, allocation concealment, blinded outcome assessment and completeness of follow up. However, poor handling and analysis of the data and a small sample size are deficiencies in this trial. The validity of the results is therefore questionable.

### Comparison 4: Dextranomer beads compared with 0.1% chloramine-soaked dressings (one RCT, 28 participants)

Sondergaard 1982 randomised 28 patients with infected open surgical wounds to the dextranomer or 0.1% chloramine group.

### Primary outcomes

- Outcome 1 - Time to clean wound bed:

The number of days until the wounds were clinically clean were reported as a median of six days with dextranomer and five days with chloramine-soaked dressings (described as no significant difference, however no data provided). The criteria used to determine when the wound was clinically clean were not reported.

- Outcome 2 - Time from the start of the treatment until the patient was assessed as ready for outpatient treatment:

This was reported as a median of nine days for dextranomer and seven days for chloramine; the difference between the two groups was reported as not significant, however no variance data were reported.

- Outcome 3 - Time to complete healing:

The time to complete healing was reported as a median of 27 days for the dextranomer group and 20 days for the chloramine group (no variance data provided). This was described by the trialists as no significant difference between the groups.

### Secondary outcomes

- Outcome 1 - Patient satisfaction:

The trialists reported that the dextranomer dressing was less painful as it was easier to remove. However, no data were included.

- Outcome 2 - Rate of infection: not reported.
- Outcome 3 - Quality of life: not reported.
- Outcome 4 - Length of hospital stay: not reported.
- Outcome 5 - Cost-effectiveness:

The average cost per change of dressing for the dextranomer group was 123 Danish Kroner compared with approximately 1.50 Danish Kroner for the chloramine group, however no further cost analysis was reported.

Methodological quality was poor and none of the adequacy criteria were met by this trial.

### Comparison 5: Dextranomer beads compared with elastomer foam (one RCT, 50 participants)

Young 1982 randomised 50 people with open, infected surgical wounds between treatment with dextranomer beads and a foam elastomer dressing.

#### Primary outcomes

- Outcome 1 - Time to clean wound bed: not reported.
- Outcome 2 - Time to complete healing:

There was no statistically significant difference in mean time to healing (40.92 days (SD = 3.98) with dextranomer compared with 36.90 days (SD = 3.18) for elastomer foam). Time to clean wound bed was analysed as continuous data, using the Student's *t*-test ( $P > 0.05$ ). Time to a clean wound bed is a time to event outcome and so the treatment effect should have been expressed as a hazard ratio.

#### Secondary outcomes

- Outcome 1 - Patient satisfaction:

The trialists reported that comfort of the dressing was assessed by questioning the patient. Pain of the wound was graded and the mean time to a pain-free wound was reduced with dextranomer at 5.32 days (SD = 0.55) compared with 5.64 days (SD = 0.45) for foam. Once again the analysis of the data of time to a pain-free wound should have been expressed as a hazard ratio.

- Outcome 2 - Rate of infection: not reported.
- Outcome 3 - Quality of life: not reported.
- Outcome 4 - Length of hospital stay: not reported.
- Outcome 5 - Cost-effectiveness:

Young 1982 discussed the cost of the dressings reporting that dextranomer was markedly less cost-effective than elastomer foam. However, no cost analysis data was included and only approximate costings from another dextranomer trial by Goode 1979 were quoted.

The trial is poorly conducted and fails to meet the methodological quality criteria. Poor handling and analysis of the data and a small sample size are deficiencies in this trial. The validity of the results presented is therefore questionable.

It was not possible to undertake any subgroup analyses.

## DISCUSSION

Despite the availability of a range of debridement methods (see [Background](#)) and an increasing number of modern dressings, we identified only five poor-quality randomised controlled trials (RCTs), all conducted prior to 1990. Two methods of debridement

were employed in the included studies: autolytic debridement using dextranomer and enzymatic debridement using streptokinase/streptodornase. It is important to note that no trials were identified by the search that compared debridement with no debridement of surgical wounds. This reflects earlier findings by Bradley 1999 and apart from the findings of Edwards 2010, who showed that the rate of healing of diabetic foot ulcers increased with a hydrogel dressing when compared with gauze, this review of the evidence would indicate that there is still little evidence to support the belief that debridement promotes wound healing. Also the merit of using gauze as a comparator could be questioned, as Pollard 2008 would argue that most, if not all modern dressings would demonstrate improvement in healing when compared with gauze. However, in contrast Ubbink 2006 found that time to complete wound healing was similar when comparing occlusive with gauze-based dressings for surgical wounds. It is beyond the scope of this review to postulate reasons for the lack of trials comparing debridement with no debridement: perceived ethical considerations may be a barrier to the conducting of such RCTs.

Although only five RCTs conducted prior to 1990 met the inclusion criteria for this review, a range of more recent research papers were identified but following closer scrutiny were all excluded (see 'Characteristics of excluded studies' table). It is apparent from these excluded studies that a range of debridement methods are being used in clinical practice, including surgical debridement (Zeitani 2004) and mechanical debridement (Allie 2004; Granick 2006), however these studies are not RCTs and therefore are highly susceptible to selection bias. It is disappointing that recently published studies are not employing more rigorous research methods that aim to minimise bias and therefore increase the confidence with which we can view the findings. The cost of conducting a RCT may be one consideration. Manufacturers of existing and new wound debridement products appear to use controlled trials, retrospective analysis of patient case notes and case studies as evidence of effectiveness.

The common outcome for the five included trials was time to a clean wound bed for infected post surgical wounds. Three out of the four trials comparing dextranomer with other products reported shorter time to a clean wound bed for dextranomer. The trial comparing streptokinase/streptodornase with saline dressings reported a shorter time to a clean wound bed with streptokinase/streptodornase.

However, a number of trial deficiencies reduce the confidence by which we can draw any conclusions to inform practice. These deficiencies include:

1. poor quality of the trials;
2. small sample sizes;
3. limited range of treatments;
4. different control groups for each trial;



5. lack of replication studies; and
6. inappropriate statistical analysis (time to event data not being analysed as such).

The methodological quality of the trials was variable, with small sample sizes, method of randomisation not always being clear, and inadequate allocation concealment. Data and statistical information were incomplete in three of the five trials. Blinding of the independent assessors would have been possible, but this was only clearly demonstrated in two studies (Goode 1979; Poulson 1983).

A limited range of treatments was identified with dextranomer beads or paste and different comparisons used in each trial, therefore it was not possible to pool the results. The rationale for choosing dextranomer for the treatment groups was not clear, apart from in Young 1982, who identified this as a new dressing, the trial being supported financially by the manufacturer. Dextranomer was significantly better than Eusol-soaked dressings (Goode 1979) but this result must be viewed with caution, as there were insufficient statistical data included in the small trial and methodological flaws in the trial. As worldwide production of dextranomer products has been discontinued, except for dextranomer paste (which is currently only available in South Africa), the impact on clinical practice of these findings is extremely limited.

The enzymatic agent streptokinase/streptodornase demonstrated a statistically significant reduction in the time to a clean wound bed when compared with saline-soaked dressings. Poor handling and analysis of the data was a limitation of this trial and it should be noted that this enzyme is no longer available worldwide.

There is a complete absence of adequately powered, methodologically robust RCTs evaluating contemporary debridement interventions for surgical wounds. The trials included in this review investigate treatments that are no longer available and the trials were of poor quality. Trials reflecting the wider range of surgical, biosurgical, mechanical, chemical and autolytic debridement methods, and agents for surgical wounds were not identified.

## AUTHORS' CONCLUSIONS

### Implications for practice

Existing RCTs of methods of debridement for surgical wounds are small, evaluate outdated products and are of poor methodological

quality. Currently there is no RCT evidence to support any particular debridement method or agent for surgical wounds.

### Implications for research

Current innovations in wound debridement strategies increase the options available to the practitioner. Adequately powered, methodologically robust RCTs evaluating contemporary debridement interventions for surgical wounds are needed to guide clinical decision-making. Future trials should compare current debridement methods, for example surgical debridement compared to high-powered saline jet (at high pressure up to 15,000 pounds per square inch) or honey compared with low-cost established alternatives such as hydrogel dressings. These studies should: report time to healing as well as time to a clean wound bed; use valid measures of wound healing; assess quality of life; cost-effectiveness and be reported in accordance with CONSORT requirements.

## ACKNOWLEDGEMENTS

We would like to thank the Cochrane Wounds Group for their continual support and guidance throughout, specifically Sally Bell-Syer for her comments on the protocol and review and Ali Baba-Akbari Sari and Ruth Foxlee for their assistance with the search strategy. We would like to thank the peer referees for their comments on the protocol and review and also the Editors (Nicky Cullum, David Margolis and Dirk Ubbink), the referees (Roy Buffery, Lois Orton, Jude Edwards and Alan Holloway), the statistician editor (Gill Worthy) and the copy editors (Elizabeth Royle, Margaret Carver and Jenny Bellorini). We would like to thank Oleg Borisenko and Jannie Hedegaard for their assistance with the translation of studies in Russian and Danish.

We would also like to acknowledge the support provided by the following people:

Heather Maxwell, Cochrane Peripheral Vascular Diseases Group, for her advice with the preparation of the review; Robert Rush, Statistician, Centre for Integrated Healthcare Research, Edinburgh, for statistical advice; Sheena Moffat, Information Services Advisor, Edinburgh Napier University, for her assistance with the search strategy; and Kay Penny, Lecturer, Edinburgh Napier University, for her assistance with the statistics.

This review has been part-funded by a research grant from the Centre for Integrated Health Care Research, Edinburgh.

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\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

#### Goode 1979

Methods	RCT Setting: hospital and outpatients, UK
Participants	n = 20 (A) 10 (B) 10 13 men/7 women Age: 24 to 91 years Post surgical wounds, infected wounds left open for delayed closure, or closed wounds requiring opening and drainage following infection Inclusion criteria: patients at risk from wound infection, following abdominal surgery for appendicitis or bowel surgery; wounds heavily contaminated at surgery and left open for delayed primary closure; wounds closed at surgery but developed an abscess and required removal of sutures and wound drainage Exclusion criteria: none listed
Interventions	All patients were given antibiotic cover prior to surgery for 48 to 72 hours postoperatively Each wound was photographed at the start, during and at the end of the trial (A) Twice daily dressings of dextranomer granules covered with a light pack (B) Twice daily dressings of Eusol and paraffin-soaked ribbon gauze All other wound procedures were identical for both groups Independent assessor decided when the wound was clean and could be closed by secondary suture
Outcomes	Primary outcomes: (1) Mean time to wound closure (SD not reported): (A) 8.1 days (B) 11.6 days Statistical difference $P < 0.05$ (Mann-Whitney U-test) (2) Time to complete healing not reported Secondary outcomes: (1) Patient satisfaction: not reported (2) Rate of infection: not reported (3) Quality of life: not reported (4) Length of hospital stay (median): (A) 2.2 days less than group B (B) Not reported (5) Cost-effectiveness: (A) Approximately £3.40 per day (B) Not reported (6) Adverse events: not reported
Notes	Trial did report that 1 patient in each group was left to heal by granulation but the time to healing was not reported

<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	"...each patient was allocated to treatment with either Debrisan or Eusol by means of cards drawn from a sealed envelope" (p325). However, the method used for generating the randomisation sequence for the cards was not reported. Hence, it was judged to be unclear
Allocation concealment (selection bias)	Unclear risk	Although "sealed envelopes" are documented no further details are given
Blinding (performance bias and detection bias) Participants and personnel	Unclear risk	Participants - blinding not stated but lack of blinding unlikely to influence results Personnel - blinding not stated but unlikely to be achievable due to different properties (beads versus ribbon gauze). Lack of blinding unlikely to influence results
Blinding (performance bias and detection bias) Outcome assessors	Low risk	Outcome assessor - blinded to treatment "an independent assessor decided when the wound was clean" using photographs of the wound (p325)
Incomplete outcome data (attrition bias) All outcomes	Low risk	20 patients studied, 20 patients "mean time to secondary wound closure reported" reported within table 1 (p325). One patient in each treatment group did not achieve wound secondary wound closure
Selective reporting (reporting bias)	Low risk	No study protocol available but expected outcomes reported "Efficacy of treatment assessed by time taken to allow secondary skin closure, by the condition of the wound after closure and the number of days in hospital" (p328) all reported on although limited details given for the later 2

**Michiels 1990**

Methods	RCT Setting: hospital, Belgium
Participants	n = 40 (A) 20 (10 men, 10 women) (B) 20 (10 men, 10 women) Age: 3 to 89 years Infected post surgical wounds, oozing, covered in pus and debris Patients all gave informed consent Inclusion criteria: patients hospitalised in the surgical unit presenting with infected postoperative wounds, covered in pus and debris Surgery: ranged from osteosynthesis, microsurgery, reconstructive procedures; surgical site not reported Exclusion criteria: patients with diabetes, vascular insufficiency, severe anaemia and serum albumin less than 30 g/L
Interventions	Duration of the trial was 12 days (A) Dressing changed daily: wound cleansed - no details of the technique given; a saline-soaked compress was applied and this was covered by a 3 mm layer of dextranomer paste, covered with a compress and bandaged (B) Dressing changed daily; wound cleansed; then a gauze dressing soaked in 10% aqueous polyvinylpyrrolidone was applied, covered with a dry dressing and bandaged Further changes of the dressings for groups A and B were dictated by the degree of soakage of the dressings
Outcomes	Primary outcomes: (1) Time to a clean wound bed - changes evaluated using specific variables; degree of erythema; degree of pus and debris; oedema; necrosis; granulation tissue. The results for each variable were assessed subjectively and presented individually Degree of erythema (reported using a 0 to 3 degree table): no significant difference reported (2 wounds in group A and 2 in group B did not have any erythema and were excluded from the evaluation of this variable) Oedema (reported using a 0 to 3 degree table): no significant difference (2 wounds in group A and 2 in group B did not have any oedema and were excluded from the evaluation) Necrosis (reported as a percentage of the total area of the wound): no significant difference (4 wounds in group A and 10 in group B did not exhibit any necrotic material and were excluded from the evaluation) Pus and debris (reported as a percentage of the total area of the wound): (1 wound in group B did not have any pus or debris and was excluded from the evaluation) No significant difference between the days of treatment or cleaning of the wounds. However, the trial also reported a further division of group A and B for evaluation of this variable, but it was unclear as to when this division was made and the handling and reporting of the data was unclear, subjective and the groups were not comparable at baseline. So while the subgroup of group A showed a higher degree of improvement in the removal of pus and debris and this was reported as significant ( $P < 0.05$ , Student's t-test) the poor handling and subjective nature of the data makes this outcome unreliable. The subgroup of group B did not demonstrate a significant difference Granulation tissue:

	<p>Mean time to a clean wound bed (SD not reported):</p> <p>(A) mean 6.5 days</p> <p>(B) mean 5.2 days</p> <p>No significant difference (1 wound in group A and 2 in Group B did not have any granulation tissue by the end of the trial and were excluded from the evaluation)</p> <p>(2) Time to complete healing: not reported</p> <p>Secondary outcomes:</p> <p>(1) Patient satisfaction: not reported</p> <p>(2) Rate of infection: not reported</p> <p>(3) Quality of life: not reported</p> <p>(4) Length of hospital stay: not reported</p> <p>(5) Cost-effectiveness: not reported</p> <p>(6) Adverse events: 1 patient in group B had an allergic reaction with oedema and erythema after 10 days and the treatment was discontinued</p>
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Notes	The development and testing of the comparison tables was not reported, therefore it is not possible to determine the reliability and validity of these tables. While the mean days for granulation tissue was reported, no other data or statistics were presented
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The patients were allotted to one or other of the preparations according to a randomisation list" (p284)
Allocation concealment (selection bias)	Unclear risk	No details given about allocation concealment
Blinding (performance bias and detection bias) Participants and personnel	Unclear risk	Participants - blinding not stated but blinding unlikely to influence outcome Personnel - blinding not stated but unlikely to be achievable due to different properties (application of paste versus soaked dressings). Lack of blinding unlikely to influence results
Blinding (performance bias and detection bias) Outcome assessors	Unclear risk	Outcome assessor - blinding not stated, p284 states that the "status of the wound was recorded each day by the same doctor when the dressing was changed" but no further detail is given
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of the 5 criteria to be reported on (granulation, pus and debris, erythema, oedema and necrosis) data are included within report on all 5 with missing data accounted for (for example within 'necrosis' 4 patients in one arm had no necrosis at the start or during so not reported) One patient in the control group exhibited an allergic reaction to treatment therefore treatment was dis-

**Michiels 1990** (Continued)

		continued (p288); it is not clear how this withdrawal was dealt with in the data presented
Selective reporting (reporting bias)	Low risk	No study protocol available but expected outcomes reported States that “aim of study was to assess and compare the clinical effects of dextranomer paste and a control treatment with polyvinylpyrrolidone (PVP) in a trial of patients with infected post-operative wounds. All variables dealing with cleansing, inflammation reducing effect, and different signs of ongoing healing were studied” (p284). Reporting of granulation, pus and debris, erythema, oedema and necrosis is given within the report

**Poulson 1983**

Methods	RCT Setting: hospital, Denmark
Participants	n = 21 started the trial; 18 completed the trial (A) 7 (B) 11 5 men/13 women Age: 26 to 86 years Patients with infected laparotomy wounds, a minimum of 7 cm, requiring opening and drainage Inclusion criteria: wound infection following laparotomy surgery; operations included: appendicectomy, bowel surgery, cholecystectomy, hysterectomy, repair of ventral hernia, wound infection which necessitated opening and drainage of the wound Minimum length of wound 7 cm Maximum depth of wound 7 cm Exclusion criteria: patients with burst abdomen, stoma or fistula in the vicinity of the wounds, because this increased the risk of continuous wound contamination
Interventions	A and B: initial drainage and removal of necrotic tissue method of removal not stated All wounds dressed with saline dressings to secure haemostasis (A) Twice-daily dressings, necrotic tissue removed; dressing soaked in 20 ml solution (streptokinase/streptodornase) applied; solution provided by hospital pharmacy (B) Twice-daily dressings, necrotic tissue removed; dressing soaked in 20 ml solution applied; solution provided by hospital pharmacy (saline)
Outcomes	Primary outcome: mean time to clean wound bed and closure by secondary suture: (A) 5.00 days (SD = 2.16) (B) 13.45 days (SD = 6.77) Statistically significant ( $P < 0.05$ , both Student's t-test and Mann-Whitney U-test) Secondary outcomes: (1) Patient satisfaction: neither group of patients complained of significant wound dis-

	<p>comfort; no data or statistics presented                  (2) Rate of infection: not reported                  (3) Quality of life: not reported                  (4) Length of hospital stay (median):                  (A) 2.2 days less than group B                  (B) Not reported                  (5) Cost-effectiveness: not reported                  (6) Adverse events: 3 patients were excluded from the evaluation for non completion of the treatment; in group A 1 patient died of a pulmonary embolism and the other required further surgery for intra-abdominal sepsis; 1 patient in group B was withdrawn as a result of abdominal dehiscence</p>	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	"Pharmacy undertook the randomization" (p245) , however no details are given regarding how this randomisation was done
Allocation concealment (selection bias)	Low risk	Pharmacy prepared the solutions (20 ml Varidase or 20 ml saline)
Blinding (performance bias and detection bias) Participants and personnel	Unclear risk	Not explicitly stated and therefore judged as unclear. However, it would be highly unlikely that participants and personnel would have been able to tell which solution was being applied as both ampoules contained 20 ml of clear solution, so unlikely to influence results. On p246 the authors state "only when the code was broken 11 patients were found to have saline and 7 had Varidase"
Blinding (performance bias and detection bias) Outcome assessors	Unclear risk	Not explicitly stated and therefore judged as unclear. However, it would be highly unlikely that outcome assessors would have been able to tell which solution was being applied as both ampoules contained 20 ml of clear solution, so unlikely to influence results. On p246 the authors state "only when the code was broken 11 patients were found to have saline and 7 had Varidase"
Incomplete outcome data (attrition bias) All outcomes	High risk	From the 21 originally recruited, 3 were withdrawn: 2 from the placebo group and one from the Varidase group. These 3 were excluded from the results presented and therefore no ITT analysis was undertaken. Rationales were given for the withdrawal



Selective reporting (reporting bias)	Unclear risk	No study protocol available The stated aim of the trial was “to show, by means of a prospective clinical trial with randomised double blind procedure if Varidase is superior to conventional management of infected laparotomy wounds” (p245). However, they do not state what constitutes ‘superior’ and how this would be measured. The study reports number of days required for wound dressing and number of days in hospital (within discussion section). Size of wound and type of bacterial growth recorded at the start of the trial; this is not reported on again within the results
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**Sondergaard 1982**

Methods	RCT Setting: hospital inpatient and outpatient, Denmark
Participants	n = 28 started the trial and 22 completed the trial (A) 10 (B) 12 Numbers of men and women not reported Participants ages not reported Consent was not reported but patients were provided with oral and written objectives of the study Study was in accordance with the Helsinki declaration, 1975 Inclusion criteria: patients with suppurating infected surgical wounds involving subcutaneous tissue Exclusion criteria: patients prescribed systemic steroid therapy; patients receiving another local wound intervention; patients with substantial wound revision and if there was peritoneal communication
Interventions	A microbiological swab was taken from the bottom of each wound at the start of the trial and on every 7th day until the wound was clean; this was to document the bacterial flora to register any favourable influences of the dressings (A) Wound irrigated with saline; dextranomer beads made into a paste and applied to the wound; covered with a sterile compress; dressing changed at least daily and before it became fully saturated (B) Dressing soaked in 0.1% chloramine solution; covered with a sterile compress; changed once daily and 2 or 3 times if saturated; dressings changed by senior registrars; trial authors undertook assessment of the wounds
Outcomes	Primary outcomes: (1) Time to clean wound bed (reported as the median: mean, SD or SEM not reported for any of the results): (A) 6 days (B) 5 days (2) Time until the wound was clinically assessed as ready for outpatient treatment (me-

Sondergaard 1982 (Continued)

	<p>dian):</p> <p>(A) 9 days</p> <p>(B) 7 days</p> <p>(3) Time to wound healing (median):</p> <p>(A) 27 days</p> <p>(B) 20 days</p> <p>Observed results were compared and assessed using the Mann-Whitney U-test; no significant difference reported; detailed data and statistics not included</p> <p>Secondary outcomes:</p> <p>(1) Patient satisfaction: dressing changes were less painful in group A; no data or statistics presented</p> <p>(2) Rate of infection: not reported; results of microbiological wound swabs not reported</p> <p>(3) Quality of life: not reported</p> <p>(4) Length of hospital stay: not reported</p> <p>(5) Cost-effectiveness:</p> <p>(A) Approximately 123 Danish Kroner per dressing change</p> <p>(B) Approximately 1.50 Danish Kroner per dressing change</p> <p>Cost analysis not presented</p> <p>(6) Adverse events: 4 patients excluded from group A: 2 patients died, cause of death not reported; 1 had peritoneal communication; in 1 the wound was too undermined for application of the paste; 2 excluded from group B: 1 had heavy growth of bacteria and the dressing was changed to acetic alumina; 1 had a total wound rupture</p>	
Notes	<p>The trial authors did observe more granulation tissue; less irritation and less pain on dressing changes with the dextranomer dressing. Blinding of assessors (trial authors) is not reported. The original paper was in German and the data were extracted after being translated into English</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Although the trial reports that the patients were allocated by a "random sequence generated in blocks of 4" (p1523) no further information is given regarding the blocks of 4. However, this is judged to be adequate sequence generation
Allocation concealment (selection bias)	Low risk	"...sealed, numbered envelopes" (p1523) is reported to conceal allocation, however it is not stated if these envelopes were opaque. However, this is judged to be adequate allocation concealment
Blinding (performance bias and detection bias) Participants and personnel	Unclear risk	It is not stated if the participants were blinded however this would be unlikely to influence findings. It is not stated if the personnel involved in redressing the wounds

**Sondergaard 1982** (Continued)

		(senior registrars) were blinded or not
Blinding (performance bias and detection bias) Outcome assessors	Unclear risk	It is unclear from the trial if the assessors (the study authors) were blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	A total of 6 patients were excluded from the study (2 from the chloramine and 4 from the Debrisan), a rationale for the exclusions is given and exclusions are mentioned in the presented in results tables. It is not clear if these were also excluded from the final analysis. Also, the dropout rate was 21% (> 10%) and hence judged to be unacceptable
Selective reporting (reporting bias)	Unclear risk	No study protocol is available. No study aims or outcomes are stated in the paper. Results reported include: number of days from start of treatment to a clean wound; number of days until wound assessed as ready for outpatient treatment; number of days until wound healed. It is apparent that the intention was also to examine the number of daily wound dressing changes required but this was abandoned due to insufficient recording (p1524)

**Young 1982**

Methods	RCT Setting: hospital and outpatient clinic, UK
Participants	n = 50 (A) 25 (B) 25 Numbers of men and women not reported Mean age (years): (A) 44.48, SD 5.17 (B) 49.64, SD 4.57 Patients with surgical wound breakdown Consent not reported Inclusion criteria: patients undergoing surgery for perforated or gangrenous appendix, where the wound was left open from the muscle layer outwards; patients with surgical wound breakdown postoperatively No exclusion criteria listed
Interventions	Each wound was measured at the start of the trial: Mean length (cm): (A) 5.53, SD 0.55

	<p>(B) 6.57, SD 0.89  Mean breadth (cm):  (A) 2.25, SD 0.33  (B) 2.48, SD 0.32  Mean depth (cm):  (A) 1.80, SD 0.20  (B) 2.24, SD 0.29  Mean volume (ml):  (A) 4.92, SD 1.15  (B) 6.37, SD 1.30  Individual wounds were photographed  All wounds were initially treated with gauze packing for the first 48 hours  (A) Dextranomer beads applied twice-daily: reduced to once a day when the discharge reduced  (B) Silastic foam dressing applied, and this was removed and cleaned twice a day; reduced to once a day with reduction in the discharge  All wounds were reviewed on 1st, 3rd and 7th days and then weekly. Patients discharged home had their wounds reviewed weekly  The review included: photograph, measurement of the wound, review of erythema, oedema, rash, odour and slough  Comfort of the dressing was assessed by questioning the patient  Pain was graded using an ordinal scale (0 = no pain to 3 = severe pain)</p>
<p>Outcomes</p>	<p>Primary outcomes:  (1) Time to disappearance of erythema, oedema and slough: similar in group A and group B; data and statistics not reported  (2) Mean time to complete healing (days):  (A) 40.92, SD 3.98  (B) 36.96, SD 3.18  Results subjected to analysis using the Student's t-test  Secondary outcomes:  (1) Patient satisfaction: mean days until pain free dressings  (A) 5.32, SD 0.55 days  (B) 5.64, SD 0.45 days  Results subjected to analysis using the Student's t-test  Wound pain reported as similar for both groups  (2) Rate of infection: not reported  (3) Quality of life: not reported  (4) Length of hospital stay: not reported  (4) Cost-effectiveness: authors quoted the costs as calculated in a previous study (Goode 1979):  (A) Approximately £3.40 per day  (B) Approximately £0.75 per week; no data or statistical evidence reported  (6) Adverse events: not reported</p>
<p>Notes</p>	<p>An ordinal scale is used to assess the pain at dressing changes. This may result in skewed data, so a non parametric Mann-Whitney U-test may have been more appropriate than the Student's t-test. Also there was a methodological flaw in the analysis of the data and time to complete healing and time to a pain-free wound, which should have been</p>

expressed as a hazard ratio and not as continuous data		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were allocated to receive either Debrisan or Silastic foam elastomer by means of a random card system" (p33). Not clear if the cards were randomised. However, the method used for generating the randomisation sequence for the cards was not reported. Hence, it was judged to be unclear
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not stated
Blinding (performance bias and detection bias) Participants and personnel	Unclear risk	It is not reported if participants were blinded to treatment, however blinding would be unlikely to affect results. Blinding or not of personnel to treatment is not reported, however due to the different properties of the dressings this would be unachievable
Blinding (performance bias and detection bias) Outcome assessors	Unclear risk	Limited information given within the paper: "wounds were reviewed" (p33) but it is not stated by whom and if they were blinded to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow up reported, 50 patients completed the trial (25 in each arm)
Selective reporting (reporting bias)	Low risk	No study protocol is available but appropriate study outcomes reported The aim of the trial was to "compare the efficacy of these two dressings in surgical wounds that have either broken down or have been left open postoperatively" (p33). It is not stated how "efficacy" will be measured at the outset. Time to heal and time to pain-free are reported within the trial; presence of erythema, odour, slough and rash were also reported

A = intervention group  
 B = control group  
 ITT = intention-to-treat

RCT = randomised controlled trial  
 SD = standard deviation  
 SEM = standard error of the mean

### Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Allie 2004	Non-randomised retrospective method
Bethell 2003	Literature review, not a research study
Cannavo 1998	RCT: comparison of alginate with gauze dressings for healing of surgical wounds, not of debridement
Capasso 2003	Non-experimental retrospective chart review
Cohn 2004	Comparison of hydrofibre to wet to dry dressings for healing rates of surgical wounds, not of debridement
De Feo 2001	Retrospective chart review of wound infections over 20 years
De Feo 2003	Retrospective non-randomised study
Doughty 2005	Management of surgical wound dehiscence and not a research paper
Douville 2004	Retrospective review of managing sternal wound complications
Edwards 1967	Clean surgical wound healing by primary intention - no debridement required
Foster 2000	Abscess wounds
Gliantsev 1996	In vitro study
Gottrup 2005	A review, not RCT
Granick 2006	Retrospective study of patients records: debridement of a range of wounds, including pressure ulcers, trauma wounds and surgical wound complications
Guest 2005	Not RCT: models used to estimate the cost of 2 dressings
Kuleshov 1992	Not RCT: chronic wounds
Moore 2000	Included abscesses; did not measure debridement
Moore 2001	Systematic review
Moues 2004	Wounds treated prior to surgical closure

*(Continued)*

Mulder 1995	Non-randomised study; debridement of chronic wounds
Rand 1998	Compared methods of wound closure for dehiscence, rather than debridement methods
Soul 1978	Not RCT: study included a range of wounds including pressure ulcers
Tolstykh 1987	Not RCT: no randomisation method identified
Williams 1995	Abscess wounds
Zeitani 2004	Not RCT: controlled study

RCT = randomised controlled trial

## DATA AND ANALYSES

This review has no analyses.

## WHAT'S NEW

Last assessed as up-to-date: 13 June 2013.

Date	Event	Description
13 June 2013	New citation required but conclusions have not changed	No new studies identified for inclusion. The conclusions remain the same
13 June 2013	New search has been performed	Third update, new search.

## HISTORY

Protocol first published: Issue 4, 2006

Review first published: Issue 3, 2008

Date	Event	Description
13 April 2011	New citation required but conclusions have not changed	New lead author and contact person
13 April 2011	New search has been performed	Second update, new search, no new studies included. Risk of bias assessment completed on all included studies. The conclusions remain unchanged
12 January 2011	New search has been performed	First update, new searches, no new studies identified, conclusions remain unchanged
17 February 2010	Amended	Contact details updated.
24 April 2008	Amended	Converted to new review format.



## CONTRIBUTIONS OF AUTHORS

ND and MM researched and developed the background information.

ND, JD, MM and FS contributed to the formulation of the objective and criteria for considering studies for the review.

ND prepared the search strategy for the review.

JD and FS completed the methods of the review.

ND and FS independently assessed the titles and abstracts of studies identified for relevance and design. The authors obtained full versions of articles that met the inclusion criteria of this initial assessment. MM was consulted for adjudication on some abstracts and she reviewed all rejected titles and abstracts.

Data extraction using a standard extraction sheet was performed by ND and JD independently. Any discrepancies were resolved by discussion and referred to FS.

Quality of studies was assessed independently by ND and MM.

ND and JD extracted the data from the studies, ND undertook initial analysis and interpreted the data. The review was drafted by ND and FS with some editing by MM. Responses and amendments following peer review were undertaken by ND and FS.

FS and JD independently reviewed the titles and abstracts following the updated searches.

FS completed the risk of bias assessment for included trials and updated the review.

### Contributions of editorial base:

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

Sally Bell-Syer: coordinated the editorial process. Advised on methodology, interpretation and content. Edited and the review and the updated reviews.

Ruth Foxlee: designed the search strategy, ran the searches and edited the search methods section for the updates.

## DECLARATIONS OF INTEREST

None known.

## SOURCES OF SUPPORT

### Internal sources

- School of Nursing, Midwifery and Social Care, UK.

## **External sources**

- NIHR/Department of Health (England), (Cochrane Wounds Group), UK.
- Grant worth £15,000, from the Centre for Integrated Healthcare Research, UK.

## **INDEX TERMS**

### **Medical Subject Headings (MeSH)**

Bandages; Debridement [\*methods]; Dextrans [therapeutic use]; Randomized Controlled Trials as Topic; Sodium Chloride [administration & dosage]; Streptodornase and Streptokinase [therapeutic use]; Surgical Wound Infection [\*surgery]; Wound Healing

### **MeSH check words**

Humans