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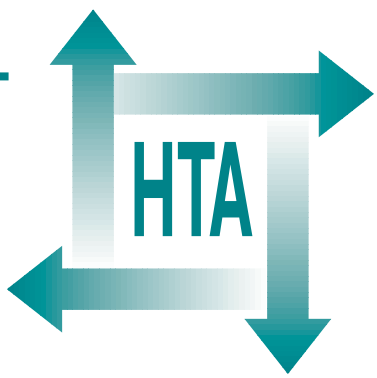
Rapid review

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention

R Lewis
P Whiting
G ter Riet
S O'Meara
J Glanville

Health Technology Assessment
NHS R&D HTA Programme



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A rapid and systematic review of the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention

R Lewis[1*]
P Whiting[1]
G ter Riet[1,2]
S O'Meara[1]
J Glanville[1]

[1] NHS Centre for Reviews and Dissemination, University of York, UK
[2] Department of Epidemiology, Maastricht University, The Netherlands

[*] Corresponding author

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Contents

Glossary and list of abbreviations

Technical terms and abbreviations are used throughout this report. The meaning is usually clear from the context, but a glossary is provided for the non-specialist reader. In some cases usage differs in the literature, but the term has a constant meaning throughout this review.

Glossary

Bias A tendency to produce results that depart systematically from the 'true' results. Unbiased results are internally valid.

Confidence interval (CI) The range within which the 'true' value of the effect of an intervention is expected to lie with a given degree of certainty. Confidence intervals represent the distribution probability of random errors, but not systematic errors (bias).

Cost–benefit analysis (CBA) An attempt is made to give the consequences of the alternative interventions a monetary value. In this way, the consequences can be more easily compared with the costs of the intervention. This can involve measuring individuals' 'willingness to pay' for given outcomes.

Cost–consequence analysis (CCA) Where multiple outcome measures and costs for each alternative are presented, clinical outcomes may vary in direction and effect. This is sometimes considered a subtype of cost-effectiveness analysis.

Cost-effectiveness analysis (CEA) The consequences of the alternatives are measured in natural units (e.g. postoperative infections prevented, years of life gained). The consequences are not given a value.

Cost-minimisation analysis (CMA) Where two alternatives are found to have equal clinical efficacy or outcomes (consequences). Therefore, the only difference between the two is cost. This is considered to be a subtype of cost-effectiveness analysis.

Cost–utility analysis (CUA) The consequences of alternatives are measured in 'health state preferences', which are given a weighting score. In this type of analysis, different consequences are values in comparison to each other, and the outcomes (e.g. life-years gained) are adjusted by assigning weightings. In this way, an attempt is made to value the quality of life associated with the outcome, so that life-years gained become quality-adjusted life-years gained.

Debridement The removal of devitalised, necrotic tissue or fibrin from a wound.[1]

Dehiscence The splitting or bursting open of a wound.[2]

Effect size/measure (treatment effect, estimate of effect) The observed relationship between an intervention and an outcome. This could be summarised as a *p* value, an odds ratio, a relative risk, a risk difference, the number needed to treat or a standardised mean difference, or weighted mean difference for pooled data.

Family Practitioner Form (FP 10) The form used for prescriptions within general practice.

Generalisability The extent to which the effects observed in a study truly reflect what can be expected in a target population beyond the sample recruited in that study. It refers to the applicability of the results to non-study subjects.

Granulation The outgrowth of new capillaries and connective tissue from the surface of an open wound.[2]

Healing by primary intention When the edges of a clean wound are accurately held together, healing occurs with the minimum of scarring and deformity.[2]

Healing by secondary intention When the edges of a wound are not held together, the gap is filled by granulation tissue before epithelium can grow over the wound.[2]

continued

Glossary *contd*

Heterogeneity The variability or differences between studies in key characteristics (clinical heterogeneity), quality (methodological heterogeneity) and effects (heterogeneity of results). Statistical tests of heterogeneity may be used to assess whether the observed variability in study results (effect sizes) is greater than that expected to occur by chance.

Meta-analysis The use of statistical techniques to combine the results of studies addressing the same question into a summary measure.

Modern dressings A collective term used in this review to represent the different types of dressings evaluated by the included trials (i.e. foam, alginate, hydrofibre, hydrocolloid and dextranomer beads dressings). It is, however, acknowledged that these dressings cannot be categorised as one type as they all have different properties and functions.

Moist wound healing Healing achieved by the application of an occlusive, semi-permeable dressing, which permits the exudate to collect under the film[2] and therefore maintains a moist interface with the wound surface.

Primary care Basic, general healthcare services that are intended to prevent disease, detect illness at an early stage, and to treat routine, uncomplicated conditions. Primary care is usually the patient's initial contact point with the healthcare system.

Primary research Studies in which data are first collected.

Publication bias A bias in the research literature where the likelihood of publication of a study is influenced by the significance of its results. Studies in which an intervention is found to be ineffective, or where there are no clear results, may be less likely to be published. Because of this, systematic reviews that fail to identify such studies may overestimate the true effect of an intervention.

***p* value (statistical significance)** The probability of finding a treatment of this magnitude or larger given that the null hypothesis is correct, in an unbiased study. Put simply, the probability that the observed results in a study could have occurred by chance. A p value of less than 5% (i.e. $p < 0.05$) is generally regarded as statistically significant.

Quality-adjusted life-year (QALY) An index of survival that is weighted or adjusted by the patient's quality of life during the survival period.

Relative risk (RR) The ratio of risk in the intervention group to the risk in the control group. A relative risk of one indicates no difference between comparison groups. For undesirable outcomes a relative risk that is less than one indicates that the intervention was effective in reducing the risk of that outcome.

Secondary care Medical interventions intended to prevent a worsening of a condition or the development of complications in a patients suffering from illness or injury. Secondary care is often rendered by a specialist after referral from a primary care provider.

Systematic review A review of the evidence on a clearly formulated question. It uses systematic and explicit methods to identify, select and critically appraise relevant primary research, and to extract and analyse data from the studies that are to be included in the review. Statistical methods (meta-analysis) may or may not be used to pool data from individual studies.

List of abbreviations

ANOVA	one-way analysis of variance
ARC	Academic Reference Centre
CCTR	Cochrane Controlled Trials Register
CBA	cost–benefit analysis*
CCA	cost–consequence analysis*
CEA	cost-effectiveness analysis*
CI	confidence interval
CMA	cost-minimisation analysis*
CUA	cost–utility analysis*
CRD	NHS Centre for Reviews and Dissemination
DARE	Database of Abstracts of Reviews of Effectiveness
FP 10	Family Practitioner Form 10
HEED	Health Economic Evaluations Database
HMIC	Health Management Information Consortium
ITT	intention to treat
MD	mean difference
MRSA	methicillin-resistant *Staphylococcus aureus*
NHS EED	NHS Economic Evaluation Database
NICE	National Institute for Clinical Excellence
NRR	National Research Register
QALY	quality-adjusted life-year*
RCT	randomised controlled trial
RR	relative risk
SD	standard deviation
VAS	visual analogue scale*

* Used only in tables

Executive summary

Background

Most surgically sutured wounds heal without any complication. However, in some cases wound healing can be delayed due to the presence of infection or wound breakdown. This can result in the wounds becoming cavity wounds and thus necessitate healing by secondary intention. Other surgical wounds that are not sutured but left to heal by secondary intention include abscess cavities such as perianal abscesses or breast abscesses.

Surgical wounds healing by secondary intention are thought to heal more slowly than wounds healing by primary intention, especially if infection is present or healing is compromised by factors such as decreased blood supply, poor nutritional status or a general suppression of the immune response. Such wounds may contain dead tissue and have a moderate or high level of exudate.

Debridement involves the removal of devitalised, necrotic tissue or fibrin from a wound. There are many different methods that can be used to debride a wound, which are broadly classified as surgical/sharp, biosurgical, mechanical, chemical, enzymatic and autolytic. Although it is generally agreed that the management of surgical wounds which contain devitalised tissue and are healing by secondary intention requires debridement, it is not always clear as to what is the best method or agent to use. There is currently a large selection of products with debriding properties available on the market, which vary considerably in cost. It is important that the choice of both debriding method and product is based on the best scientific evidence available, taking into account both cost and effectiveness data.

Objectives

The review had two main objectives:

- To determine the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention.
- To evaluate the clinical effectiveness and cost-effectiveness of treating patients with surgical wounds healing by secondary intention at specialised wound care clinics as compared to conventional care.

The review incorporated all debriding methods and any agent that is considered to have a debriding property.

Methods

The following databases were searched using strategies designed specifically for each database: MEDLINE, EMBASE, CINAHL, HMIC (Health Management Information Consortium), CCTR via the Cochrane Library, the National Research Register (NRR), the NHS Economic Evaluation Database (NHS EED), and the Health Economic Evaluations Database (HEED). Additional references were identified through reviewing manufacturer and sponsor submissions made to NICE, the bibliographies of retrieved articles, and conferences proceedings on the Internet.

Only randomised controlled trials (RCTs) or non-randomised controlled trials with concurrent controls and full economic evaluations were considered for inclusion. Only studies that evaluated some sort of debriding method or a specialised wound care clinic (a nurse with specialist training in wound care; care being provided by a multidisciplinary team; a fast-track referral system to other professions (e.g. dermatologist); or access to the latest health technology) were included in the review. Studies had to include participants with surgical wounds healing by secondary intention (e.g. cavity wounds, the consequences of wound dehiscence and abscesses) and report an objective measure of wound healing.

Data were extracted by one reviewer and checked by a second. Quality assessment was conducted independently by two reviewers. Disagreements were resolved by consensus and, when necessary, by recourse to a third reviewer. The primary outcomes of interest were wound healing and cost. Results of data extraction and quality assessment were presented in structured tables and also as a narrative summary. In addition, where feasible,

the results of individual studies were presented as forest plots. Studies were grouped according to the type of wound, debriding method and outcome measure used.

Results

Clinical effectiveness

Seventeen trials met the inclusion criteria, all of which used the autolytic method of debridement. No studies were found that investigated sharp/surgical, biosurgical, mechanical, chemical or enzymatic debridement in the treatment of surgical wounds healing by secondary intention. No studies were found which investigated specialised wound care clinics that included the provision of care within a clinical setting (based in either primary or secondary care). The type of surgical wounds investigated by studies included in the review were those that had broken down postoperatively, perineal wounds resulting from proctolectomy or rectal excision, and those left open after pilonidal sinus excision or abscess incision, or wounds following a laparotomy. Four additional studies investigated treatment of postoperative wounds from toenail avulsions. The debriding agents investigated included foam dressings (silicone elastomer foam dressings and polyurethane foam dressings), alginate dressings, hydrocolloid dressings, and dextranomer polysaccharide bead dressings. For the purposes of this review these are referred to collectively as modern dressings. Most were compared to plain or impregnated gauze dressings. However, there was a great variation between trials with respect to the type of antiseptic solution that the gauze was soaked in or the type of gauze-based dressing used. Three trials included a direct comparison of two types of modern dressings. One trial compared polyurethane foam with alginate dressings and another trial compared it with silicone foam. The third trial compared dextranomer polysaccharide with silicone foam dressings. The heterogeneous nature of the included studies precluded statistical pooling of results.

Methodological quality of clinical effectiveness data

On the whole, included trials tended to have a small sample size (median = 43 participants) and the majority suffered from methodological flaws. The total number of participants included in the trials was 783. Detailed information relating to the randomisation procedure and blinding was not reported in most trials. Many trials failed to report the initial wound size and baseline characteristics of included participants. The majority of trials that used the outcome measure 'time to complete healing' reported mean values instead of median values. Mean healing times may not represent the healing events in an appropriate way as they are greatly affected by outliers and, unlike median times, cannot be calculated if some wounds fail to heal. Almost half of the included trials did not report the results in sufficient detail to calculate a summary estimate of the treatment effect, for one or more outcome measures. The statistical test used to compare the treatment groups was often not reported or no statistical test was used.

Overall findings of clinical effectiveness

In summary, there is a suggestion that modern dressings have a beneficial effect on healing compared to traditional gauze dressings, especially for toenail avulsions, where significant benefits of modern dressings were found. However, these results should be interpreted with caution due to the poor quality of the studies, the fact that the direction of bias is unclear and the unknown effects of potential publication bias.

There is some evidence to suggest a beneficial effect of modern dressings for surgical wounds on other outcomes, such as pain, dressing performance and resource use, although a beneficial effect for these outcomes was not found for studies of toenail avulsions. However, in addition to the methodological problems highlighted above, these outcome measures are very difficult to assess and are particularly subject to bias, especially in unblinded studies.

In view of the lack of data and the poor methodological quality of the trials, there is no evidence to support the superiority of one type of modern dressing over another.

Cost-effectiveness

Four economic evaluations met the inclusion criteria. All four studies included a cost-effectiveness analysis of an autolytic debriding method compared with traditional gauze dressings soaked in various antiseptic solutions. The dressings investigated were silicone elastomer foam dressings, polyurethane foam dressings and calcium alginate dressings. No economic evaluations that compared the cost-effectiveness of two different types of modern dressings were found. No economic evaluations investigating specialised wound care clinics were found.

Conclusions

The results of the cost-effectiveness data suggest partial dominance in favour of the intervention, and only the cost data support the use of the intervention dressings (modern dressings were found to have lower costs than the gauze dressings, but with no difference in the outcome measures). However, the quality of the clinical effectiveness and cost-effectiveness analyses are poor.

Generalisability of the review findings

The majority of included studies were UK based, within the NHS setting. Two of the included trials were based in a military hospital and five trials were based outside the UK (Australia, USA, France, Italy and Spain). Studies were published between 1979 and 2000, four before 1984 and the remainder between 1991 and 2000.

Implications for future research

The review identified the following areas for future research:

- Large multicentre trials of good methodological quality comparing foam, alginate, hydrofibre, hydrocolloid or dextranomer bead dressings with standard treatment or, preferably, to each other. It is acknowledged that it may be difficult to recruit sufficient numbers of patients with similar wounds from a single centre/hospital.
- More good-quality economic evaluations of modern dressings that are based on sound scientific evidence, such as good-quality primary RCTs. This would mean that information relating to such outcome measures as time taken to change the dressings, number of dressing changes required and number of nursing visits could be measured accurately. Economic evaluations would also need to utilise sensitivity analyses that investigate the effect on the overall findings of adjusting these variables.
- RCTs of other autolytic debriding methods not covered by included trials, such as hydrogels.
- Further research, in both clinical effectiveness and cost-effectiveness, into the use of other debriding methods, such as enzymatic, biosurgical and surgical methods, in the treatment of surgical wounds healing by secondary intention.
- Because there is no research available on the organisation of care, such as the use of specialist wound care clinics, research that includes studies looking at both the clinical effectiveness and cost-effectiveness of the use of specialised wound care clinics is required.
- Further epidemiological studies to evaluate the extent of the problem (i.e. the prevalence and cost to the NHS of treating surgical wounds healing by secondary intention where there is a delay in the healing process).

Chapter 1

Aims

The main objectives of the review were:

- to determine the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention
- to evaluate the clinical effectiveness and cost-effectiveness of treating patients with surgical wounds healing by secondary intention at specialised wound care clinics compared to conventional care.

The review included all debriding methods and any agent considered to have a debriding property (see appendix 1).

Specialised wound clinics included the provision of care within a clinical setting (based in either primary or secondary care) with the addition of one or more of the following criteria:

- a nurse with specialist training in wound care
- care provided by a multidisciplinary team, or a fast-track referral system to other professionals (e.g. a dermatologist)
- access to the latest health technology (e.g. dressings not available on the drug tariff or not included in local formularies).

Conventional care included the management of wounds within the hospital or community, or shared between the two.

Chapter 2
Background

Description of wounds

Most surgically sutured wounds heal without any complication. However, in some cases wound healing can be delayed due to the presence of infection, wound dehiscence (partial or complete separation of the wound) or the presence of a foreign body.[3,4] This can result in the wounds becoming cavity wounds and thus necessitate healing by secondary intention.[5] Other surgical wounds that are not sutured but left to heal by secondary intention include abscess cavities such as perianal abscesses or breast abscesses. Wounds healing by secondary intention will need to be filled with new tissue. This process includes granulation, epithelialisation and the contraction of the wound.[6,7]

Surgical wounds healing by secondary intention are thought to heal more slowly than wounds healing by primary intention, especially if infection is present. Such wounds may contain dead tissue and have a moderate or high level of exudate, although it is acknowledged that some wounds healing by secondary intention may be clean granulating wounds. Dehisced wounds usually contain devitalised necrotic material.[4]

During the inflammatory process of wound healing, devitalised tissue, debris and bacteria are removed by a process of phagocytosis mediated by macrophages, which are derived from monocytes and phagocytotic white blood cells.[7–10] However, as the area of non-viable tissue expands it can impede the body's natural healing process, since it serves to stimulate ongoing inflammation and leucocyte infiltration, which delays progression to the formation of granulation tissue and re-epithelialisation.[1] Necrotic tissue also provides an ideal environment for bacterial growth[11] and interferes with the mechanism of wound contraction.[12] There are also a number of other local and systemic factors that can impinge upon the wound healing process and thus cause further delay. These include factors such as decreased blood supply, poor nutritional status and a general suppression of the immune response.[7] In such circumstances, the local tissue defences may not be able to cope with the increase in the bacterial load, which may be present in the necrotic tissue. It is therefore considered that wound healing can be accelerated by debridement (i.e. the removal of any devitalised tissue from the wound).[10,12]

Current service provision

Service delivery

More than 6 million operations were undertaken in the NHS in England between 1998 and 1999.[13] However, there is no official figure available on how many of these operations result in surgical wounds healing by secondary intention. Furthermore, there are no data available on how many of the resulting surgical wounds healing by secondary intention are 'clean' granulating wounds and how many wounds would be deemed to require debridement due to the presence of devitalised or necrotic material. One study that included an economic evaluation of two types of dressings in the management of acute surgical wounds left to heal by secondary intention, calculated that an average UK district health authority with a catchment population of 300,000 would have potentially 120 patients per year with an open acute surgical wound left to heal by secondary intention.[14] However, this information was based on the theatre register data for five general surgeons at a single NHS trust hospital with an average catchment population (190,000), which means that the information is probably an underestimation of the incidence of such wounds, as the figures did not include patients from other specialities (e.g. orthopaedics and gynaecology) with suitable wounds.

The actual cost of treating surgical wounds left to heal by secondary intention has not been systematically evaluated. The net cost of selected dressings (alginate, hydrocolloids, hydrogels and polyurethane dressings) dispensed in the community via Family Practitioner Form 10 (FP 10) in England in 1998 was £37 million.[15] However, the majority of this expenditure is likely to have been in the treatment of chronic wounds, especially venous leg ulcers, rather than

in the treatment of surgical wounds. These figures give very little information about the full cost of patient management or the cost of treating surgical wounds healing by secondary intention. In addition, many NHS trusts and primary care groups purchase directly from manufacturers and wholesalers, for which data relating to cost are not available. The highest costs incurred when treating surgical wounds left to heal by secondary intention include the cost of hospital stay and staffing costs,[14] for which there are no official figures available.

Modern materials designed to provide the optimum conditions to promote healing, such as occlusive and semi-occlusive dressings, are more expensive than traditional products such as gauze dressings. However, many of the newer products require less frequent dressing changes, and may lead to a reduction in healing time.[16] This means that an expensive dressing may incur less cost than a cheaper dressing when the complete episode of care is taken into account.[17] A decrease in healing time is also likely to promote both social and economic advantages for patients, in terms of ensuring a shorter duration of pain and discomfort, as well as early mobilisation and therefore return to work or usual activities.

Service delivery and organisation of care

The management of patients with surgical wounds healing by secondary intention is shared by both the hospital and the community. However, due to an increase in the number of surgical procedures being undertaken in primary care and outpatient clinics and the general decrease in the length of hospital stay, the number of patients treated in the community is increasing. Patients are also increasingly expected to have a greater involvement in their own care.[17]

Ideally, when patients are discharged from acute or secondary care into the community their care should continue without interruption. For some patients, however, 'seamless' care is not possible. For example, hospital staff and those working in the community may not have access to the same range of wound care products. It has been noted that secondary care has access to more advanced products than primary care, which is limited to those available on the Drug Tariff through prescription.[18] However, hospital staff may also be restricted to products available on local formularies.

Professionals working in the community may have less access to the advice of other specialists, with referral for a multidisciplinary opinion being more accessible within a hospital setting. Timely referral protocols to other specialities (e.g. dermatologists, dieticians and plastic surgeons) is very important, because the older a wound becomes the longer it takes to heal.[19] This means that a fast-track referral system has the potential to reduce the number of surgical wounds healing by secondary intention that are slow to heal.

Specialist practitioners, such as tissue viability nurse specialists, with specific training in wound care would potentially have greater knowledge and skills to treat surgical wounds where there is a delay in healing than would other practitioners. The efficacy of wound management products depends on whether they are used appropriately (e.g. a dressing that is considered to have some debriding properties that is not used correctly will not debride the wound). Therefore, knowledge and skills in the use of various products is essential. The product industry is often the only available source of education and advice for generic practitioners such as nurses, both in the community and in the private sector.[19] With a growing number of products available, the level of knowledge required to make the right choice of treatment is also greater. In addition, the management of one type of wound is not transferable to another (e.g. the treatment of venous leg ulcers will differ greatly from that of surgical wounds).

Specialised wound care clinics with access to the best available practices and interventions and/or a fast-track referral system to a multidisciplinary team could potentially lead to a reduction in healing time. They may also prove to be a more cost-effective method of wound care management in terms of both labour and service costs.

The implementation of specialised clinics in the treatment of other chronic wound types (e.g. venous leg ulcers) has proceeded without robust evidence to show that they make a difference. This has been largely due to the fact that evaluations have tended to be single pre- and post-audits, with only one cluster randomised trial. In addition, a raft of interventions is generally implemented simultaneously (e.g. clinic plus new treatment plus new referral pattern plus educational services), which means that the effectiveness of individual items has not been considered.[20]

Description of intervention

Debridement involves the removal of devitalised, necrotic tissue or fibrin from a wound.[1,7] The effectiveness of debridement has not been confirmed by clinical research, although it is generally agreed that wounds that contain devitalised and necrotic tissue require debriding.[10,12]

There are many different methods that can be used to debride a wound. These are broadly classified as surgical/sharp, biosurgical, mechanical, chemical, enzymatic and autolytic (see appendix 1).

Surgical/sharp debridement

This involves the removal of devitalised tissue using a sharp instrument such as scissors or a scalpel. This method can be painful to the patient. Surgical/sharp debridement can be undertaken in two ways. First, the excision or wide resection of all dead or damaged tissue can be carried out by a surgeon in theatre with general or local anaesthetic.[21] This method is quick and is essential when the presence of devitalised tissue becomes life-threatening to the patient. However, it is considered to be a non-selective method of debridement, as healthy tissue lying at the margin of the wound adjacent to dead tissue is also removed.[8,22] Alternatively, smaller quantities of dead tissue lying just above the level of viable tissue can be removed by a clinician using sharp scissors or a blade in the ward or home environment.[21] This method is time consuming and requires skill and patience, but it is considered to be more specific.

Biosurgical debridement

Sterile maggots (greenbottle larvae) may be used to debride wounds. Greenbottle (*Lucilia sericata*) larvae destroy dead tissue by liquefying it with enzymes and ingesting it.[12] Larvae are about 2 mm long and are applied directly to the wound and held in place with a dressing.[23] Maggots may also have the added benefit of ingesting bacteria, thus reducing the risk of clinical infection developing or proceeding in a wound.[23] They have also been used to eliminate antibiotic-resistant strains of bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA).[24–26] It has been suggested that larval therapy stimulates the production of granulation tissue and thus promotes wound healing.[27,28] However, as yet, there does not appear to be any clinical evidence to support this in the healing of surgical wounds. Maggot therapy is likely to be considered unpleasant by some people, and patient acceptability is therefore a key consideration in its use. The enzymes that the maggots produce have the potential to damage keratinised epidermis if applied in excess, or left in place for too long after debridement has been completed.[28]

Mechanical debridement

This involves the physical removal of devitalised tissue from the wound bed by applying a mechanical scrubbing force or by using wet-to-dry dressings.[22] Wet-to-dry debridement involves the application of a saline-moistened gauze pad to an area of necrotic tissue presoftened with saline. As the dressing dries, necrotic tissue becomes attached to the gauze and is removed along with the dressing. This method is generally painful to the patient because patient structures that are attached to the necrotic tissue are disrupted/removed from the wound.[22] There are other methods of mechanical debridement that use water to loosen necrotic debris. High-pressure irrigation and whirlpool baths mechanically debride wounds using jets of water.[12] The disadvantage of mechanical debridement is that it may damage the healthy wound bed.[12]

Chemical debridement

This involves the use of chemicals such as hypochlorite solutions (e.g. Eusol™) and caustic agents (e.g. Aserbine™ and hydrogen peroxide) for the debridement of wounds.[12,29]

Enzymatic debridement

This involves the topical application of enzymes to devitalised tissue.[12] These agents are activated in the presence of moisture and bring about the breakdown/digestion of the unwanted tissue. This method is thought to be a selective method of debridement, as healthy cells may contain enzyme inhibitors that protect the tissues from the action of these enzymes.[22] Various types of enzymes target specific necrotic tissues such as protein, fibrin and collagen.[11] Enzymes commonly used in wound debridement include streptokinase and streptodornase.[29]

Autolytic debridement

The body will naturally debride dead tissue with enzymes generated by the inflammatory and other cells.[22] This process can be speeded up by the creation of a moist environment.[23] Many of the dressings available, the main function of which is to provide a moist wound environment, are also recognised as having debriding properties (e.g. occlusive and semi-occlusive dressings).

Summary

It is generally agreed that the management of surgical wounds that contain sloughy necrotic tissue healing by secondary intention requires debridement.[10,12] However, this is not supported by research evidence. There is currently a large selection of products with debriding properties available on the market, which vary considerably in cost. It is important that the choice of both debriding method and product is based on the best scientific evidence available, taking into account both cost and effectiveness data.

Chapter 3
Methods

Search strategy

The following databases were searched:

- MEDLINE (SilverPlatter), 1966 to June 2000
- EMBASE (SilverPlatter), 1980 to June 2000
- CINAHL (SilverPlatter), 1982 to May 2000
- Health Management Information Consortium (HMIC), 2000 disk
- Cochrane Controlled Trials Register (CCTR) (via Cochrane Library, 2000, Issue 2)
- National Research Register (NRR), Issue 1:2000
- NHS Economic Evaluation Database (NHS EED), June 2000
- Health Economic Evaluations Database (HEED), June 2000.

Searches of conference paper databases and world wide web conference sites were also undertaken. More detailed information about the search strategies used is presented in appendix 7.

The bibliographies of all retrieved articles, including the recent Health Technology Assessment reviews on the debridement and treatment of chronic wounds, were searched for any additional references that met relevance criteria. Manufacturer and sponsor submissions made to the National Institute for Clinical Excellence (NICE) were reviewed to identify any additional studies.

Inclusion and exclusion criteria

Titles (and where possible abstracts) of studies identified from all searches and sources were assessed independently by two reviewers for relevance. If either reviewer considered the paper to be potentially relevant, a full copy of the manuscript was obtained.

Each full copy was reassessed for inclusion. Two reviewers independently decided whether the primary studies met each criterion and any disagreements were discussed to obtain a consensus. If no agreement was reached a third reviewer was consulted. Studies that did not meet one or more of the inclusion criteria were excluded and the reason for exclusion was recorded (appendices 2 and 8).

Surgical wounds

Studies had to evaluate the management of surgical wounds healing by secondary intention (e.g. surgical wounds that have 'broken down' into cavities, the consequences of wound dehiscence and cavities following incision and drainage of abscesses). Excised pilonidal sinuses that were left to heal by secondary intention were also included. Such wounds usually contain necrotic or sloughy material and may have a high or low level of exudate. Studies of surgical toenail avulsion that involved the destruction of the germinal matrix with phenol or sodium hydroxide in order to prevent the regrowth of the nail were also included. These wounds are left to heal by secondary intention and the acid burn results in the formation of slough. It is acknowledged, however, that the healing process of these wounds may differ from that of wounds treated with more radical surgical interventions. Consequently, the results of these studies are presented separately.

Studies of patients undergoing any form of surgery, other than corneal or dental surgery, were considered for inclusion in the review, and information regarding the type of operation undertaken was recorded.

The review did not specifically investigate infected wounds, but information on the presence or absence of infection, as well as the use of antibiotic therapy was recorded.

Studies of chronic wounds, such as venous leg ulcers and pressure sores, and those that included surgical wounds healing by primary intention were excluded. Studies that included the donor sites of skin grafts were also excluded, as they were considered to be 'clean' granulating wounds and were therefore not deemed to require debridement.

Type of intervention

Any method or agent that can be used for the debridement of surgical wounds was included

in the review (see appendix 1). Many dressings have debriding properties, as any dressing that maintains a moist environment will, in theory, promote autolytic debridement.[7] However, it is very difficult to differentiate specific debriding agents from those that have been developed simply to promote healing. Therefore, as the review was primarily interested in wound healing, a very broad classification was used that incorporated most types of dressings considered to have any form of debriding property (e.g. providing a moist environment for autolytic debridement).

The review did not investigate the antimicrobial treatment of surgical wounds *per se*. However, a number of agents have both antimicrobial and debriding properties (e.g. hypochlorites, hydrogen peroxide and cadexomer iodine), and studies investigating such agents were included in the review. Studies that included only treatment protocols for surgical wounds other than debridement, such as drug therapy to promote healing, growth factors, tissue engineering and ultrasound, were excluded.

Study design

Only randomised controlled trials (RCTs) or non-randomised controlled trials with concurrent controls were considered. Any relevant full economic evaluations where the costs and consequences of two or more alternatives were considered were also included. Only human studies were included in the review.

Outcome measures

Healing is considered to be the most important outcome measure.[30] Only studies that reported an objective measurement of wound healing were included in the review. Such outcome measures could include time to wound healing (or the time it takes for a certain proportion, say 50%, of wounds to heal), the number (proportion) of wounds completely healed within a certain time period, healing rate, or change in wound size or volume (expressed as absolute or relative values). Studies in which the investigator made a subjective decision on how much the wound had healed based on clinical experience were excluded. However, all studies that investigated complete healing were included, even if the decision was made subjectively by the investigator.

Information relating to other outcome measures reported by included studies was also collected.

Language restrictions

Only studies reported in English, German, Dutch or French were considered for the review. However, the search strategy included all languages, and the bibliographic details of other non-English studies are presented in the table of excluded studies (see appendix 2).

Data extraction strategy

Data were extracted by one reviewer using predefined data extraction forms (appendix 3) and checked by a second reviewer. Any disagreement was resolved by consensus and, if this was not reached, a third reviewer was consulted.

Quality assessment strategy

The methodological quality of each included study was assessed using a predefined checklist (appendix 4). Two reviewers conducted this process independently. Any disagreement was resolved by consensus and, if this was not obtained, a third reviewer was consulted.

A published checklist[32] was used to assess the quality of studies that included an economic evaluation of either specialised wound clinics or debriding agents.

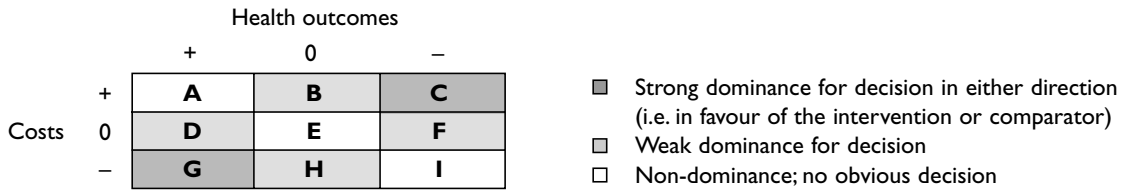
Data synthesis

Where sufficient data were presented, an estimation of the treatment effect along with the 95% confidence interval (CI) was calculated for each individual study. Where possible this was done on an intention-to-treat (ITT) basis. For dichotomous outcome measures the relative risk (RR) was calculated and for continuous outcomes the mean difference (MD) was used.

The results of data extraction and quality assessment are presented in structured tables and also as a narrative summary. Studies were grouped according to the type of debriding agent used (e.g. hydrocolloid, alginate or polyurethane foam dressings). However, it is important to note that individual products within the different debriding agent categories can also vary considerably in the way that they function, and this may or may not be clinically significant. Where sufficient data were available, the results of individual studies are presented as Forest

plots. Heterogeneity was investigated statistically using a *Q*-test and visually by examination of the Forest plot. Due to the heterogeneity present, pooling of results was deemed inappropriate. Studies varied in terms of wound type, study design and the nature of the comparator.

In order to assess the economic data in terms of the clinical effectiveness of the intervention (i.e. the direction of the cost-effectiveness data and the magnitude of clinical effectiveness data), each study was given a summary grading (A to I) according to the level and direction of dominance (i.e. whether the intervention of interest should be preferred over the comparator). Extended dominance indicates that both the effectiveness data and the economic data support the use of either the intervention or the comparator and the decision on resource allocation is clear. When either the economic or the effectiveness data support the intervention/comparator, but not both, the dominance is said to be 'partial' or 'weak' and a decision can still be made. However, if no dominance is indicated, further incremental cost analysis may be required in order to estimate the incremental cost-effectiveness ratio. This is important to help the decision-making process. The matrix shown in *Figure 1* was used to assign a summary grading to each study.



Code	Implication for intervention	Direction of the cost-effectiveness data and the magnitude of the clinical effectiveness data
A	Trade-off	Higher costs but better outcomes (incremental analysis required)
B	Reject	Higher costs and no difference in outcomes (partial dominance in favour of the comparator)
C	Reject	Higher costs and poorer outcomes (extended dominance in favour of the comparator)
D	Accept	No difference in costs and improved outcomes (partial dominance in favour of the intervention)
E	Neutral	No difference in costs and no difference in outcomes
F	Reject	No difference in costs and poorer outcomes (partial dominance in favour of comparator)
G	Accept	Lower costs and improved outcomes (extended dominance in favour of the intervention)
H	Accept	Lower costs and no difference in outcomes (partial dominance in favour of the intervention)
I	Trade-off	Lower costs but poorer outcomes (incremental analysis required)

FIGURE 1 *Incremental cost of treatment compared with control*[32,33]

Chapter 4

Results: clinical effectiveness

Quantity and quality of research available

Included studies

Seventeen studies met the inclusion criteria, all of which used autolytic methods of debridement.[34–50] No studies were included that investigated sharp/surgical, biosurgical, mechanical or enzymatic debridement. All studies were published studies; no additional studies identified for inclusion from the company submission data presented to NICE met the inclusion criteria. Additional information for one included trial was provided by the company submission data.[41]

No studies were found that investigated specialised wound care clinics, which included the provision of care within a clinical setting (based in either primary or secondary care).

Fifteen of the included studies were RCTs,[34,35,37–43,46–51] one was a quasi-RCT[45] and one was a non-randomised controlled trial.[44] Information relating to three trials was derived from two publications.[37,41,43,52–54] Two trials were published as abstracts[52,53] as well as full reports,[37,43] and one trial was published as a poster[54] as well as an abstract.[41] For the purpose of this review these trials will be referred to as one publication.[37,41,43]

Five of the included studies looked at surgical wounds healing by secondary intention after pilonidal abscess excision,[34,37,44,47,49] one of which also included participants who had abdominal surgical wounds.[37] Three studies[38,41,43] investigated healing after abscess incision followed by light packing of the wound, and one study included the incision of either a sinus or abscess with the excision of granulation tissue.[48] One of these studies also included wounds healing by secondary intention following a laporotomy.[43] One study included perineal wounds resulting from procolectomy or rectal excision,[42] and three studies[36,40,50] included surgical wounds that had broken down postoperatively, but did not specify the type of surgery that was undertaken. The remaining four studies investigated treatment of postoperative wounds from toenail avulsions.[35,39,45,46]

Four different types of debriding agents were investigated in the included studies. These included foam dressings (silicone elastomer foam dressings and polyurethane foam dressings), alginate dressings, hydrocolloid dressings and dextranomer polysaccharide beads dressings. These will be referred to as **modern dressings** for the purpose of this review. However, it is acknowledged that they all have different properties and functions. The results are presented according to the type of debriding agent used.

Gauze or gauze based dressings, impregnated or otherwise, were used as the comparator in 14 trials.[35–49] However, there was great variation between trials with respect to the type of antiseptic solution that the gauze was soaked in or the type of gauze-based dressing used. Gauze dressings impregnated with an antiseptic solution do not provide an environment for moist wound healing unless a secondary occlusive or semi-occlusive dressing is used. Three trials using gauze dressings impregnated with antiseptic solution used a simple dry gauze dressing as the secondary dressing, which means that a moist wound environment was not provided as the gauze dressing can dry out.[38,43,44] Five trials using gauze dressings impregnated with antiseptic solution did not report what secondary dressing was used, and therefore it is not possible to ascertain if a moist wound environment was provided.[40–42,47,48] Gauze dressings may act as mechanical debriding agents and the antiseptic solutions in which the gauze is soaked could act as chemical debriding agents. However, as these were used as the comparators in trials rather than as the intervention, the effects of mechanical or chemical debriding agents could not be investigated.

One trial compared polyurethane foam to alginate dressings[34] and another trial compared it to silicone foam.[37] A third study compared dextranomer polysaccharide to silicone foam.[50]

The majority of included studies were UK based, within an NHS setting. Two of the included trials were based in a military hospital[41,48] and five trials were based outside the UK.[36,41,44,46,47] The countries of origin for these trials were Australia,[36] the USA,[46] France,[41] Italy[44] and Spain.[47] Studies were

published between 1979 and 2000, four before 1984[7,40,42,49] and the remainder between 1991 and 2000.

Excluded studies

In total, 136 studies identified by the main searches were excluded, as they did not meet inclusion criteria. The specific reason why each study was excluded is presented in appendix 2. The reasons for exclusion of studies reported in the manufacturer and sponsor submissions made to NICE are presented separately in appendix 8.

Twenty-three studies were excluded because they were not reported in one of the languages considered for inclusion. It was not possible to ascertain if they met any of the other inclusion criteria, such as the appropriate study design, intervention, wound type or outcome measure. Fifteen of these studies were reported in Russian, with the year of publication ranging from 1976 to 1993. Three of the studies were reported in Italian and the year of publication ranged from 1984 to 1992. The remaining studies were published in Danish (1985), Japanese (1992), Portuguese (1981) or Spanish (1994) and one study was from Scandinavia (1983).

The reason for exclusion for the majority of the remaining studies was that they did not investigate surgical wounds healing by secondary intention. Most looked at either sutured wounds or chronic wounds such as venous leg ulcers, pressure sores and diabetic foot ulcers.

Quality of included studies

A summary of the quality of individual studies is presented in *Tables 1* and *2*.

Randomisation and concealment of treatment allocation

Only three of the 14 trials of surgical wounds reported information relating to the method used to randomise participants to different intervention groups. Two trials used cards contained in sealed envelopes[36,40] and one trial reported using a random card system, but gave no further details.[50] There was insufficient information for all three trials to ascertain whether treatment allocation had been adequately concealed from the clinicians and participants.

Information relating to the randomisation procedure used was only reported by one of the four trials of toenail avulsion.[45] Participants were allocated numbers, and those with even numbers were treated with the intervention dressing while the others received the standard dressing. Treatment allocation is therefore unlikely to have been concealed from those conducting the procedure.

Follow-up

Relatively complete follow-up (≥ 80%) was achieved in ten of the 13 trials of surgical wounds.[36–38,40,41,43,44,47,48,50] Insufficient information was presented to judge the completeness of follow-up in two trials.[42,49] Of these, one trial reported the number of participants that were followed to complete healing, but did not state if this was the number of participants that were randomised.[49] Another trial reported that on completion there were 25 participants in each treatment group.[42] However, three participants in each group were reported to have died before the end of the trial and it was therefore assumed that these participants were not included in the final analysis. For this trial it was unclear how many participants were initially randomised and it was therefore not possible to calculate the percentage lost to follow-up. The last trial, an RCT with a small sample size, reported a loss to follow-up of 30% (6/20).[34]

None of the seven trials[38,40,41,44,47,48,50] of surgical wounds that were deemed to have no drop-outs reported using an ITT analysis or a per protocol analysis. It was therefore not possible to ascertain if non-compliers had been included in the analysis correctly, or if any participants that had received the intervention for which they had not been randomised, were included in the analysis according to their randomised treatment group.

Four of the trials in surgical wounds reported having some participants lost to follow-up. Two of these did not report the reason for withdrawal.[37,43] One of these trials did not include those that were lost to follow-up in the final analysis[37] and this information was unclear for the second trial.[43] Two trials reported the reason for withdrawal, presenting the information according to the two treatment groups to which participants had been randomised.[34,36] However, neither of these trials reported the number of participants that were included in the final analysis and therefore it was not possible to ascertain if an ITT or per protocol analysis had been conducted. Neither trial reported having conducted an ITT analysis. The study that did not achieve complete follow-up reported that three participants dropped out from each treatment group, although the reasons for withdrawal do not appear to be related to the

TABLE 1 *Quality assessment of included trials: surgical wounds healing by secondary intention*

Study	Sample size (No. of arms)	Random. procedure adequate	Allo-cation con-cealed	Follow-up ≥ 80%	Loss to follow-up (%)	Out-comes of with-drawals*	ITT	Blinding of outcome assessors	Blinding of admin-istrators	Partic-ipants blinded	Success of blinding checked	Appropriate baseline character-istics†	Comparable baseline character-istics‡	Co-inter-ventions stated	Correct analysis
Silicone foam versus traditional gauze dressings															
Macfie and McMahon, 1980[42]	50 (2)	?	?	?	?	✔a	✘	?	?	?	?	✔c	✔d	✘	✘
Walker *et al.*, 1991[48]	75 (4)	?	?	✔	0	NA	?	?	?	?	?	✔	?	✘	✘
Williams *et al.*, 1981[49]	80 (2)	?	?	?	?	✘	?	?	?	?	?	✔c	✔d	✘	✘
Ricci *et al.*, 1998[44]	12 (2)	NA	?	✔	0	NA	?	?	?	?	?	✔c	✘	✘	✘
Polyurethane foam versus traditional gauze dressings															
Meyer, 1997[43]	43 (2)	?	?	✔	7	✘	?	?	?	?	?	✔c	✘	✘	?
Polyurethane foam versus silicone foam dressings															
Butterworth *et al.*, 1992[37]	80 (2)	?	?	✔	7.5	✘	✘	✘	✘	✘	?	✔c	✔d	✔	✘
Polyurethane versus alginate dressings															
Berry, 1996[34]	20 (2)	?	?	✘	30	✔a	?	?	?	?	?	✔c	✘	✔	✘
Alginate versus traditional gauze dressings															
Cannavo *et al.*, 1998[36]	36 (3)	✔	?	✔	17	✔a	?	✔	?	?	?	✔c	✘	✘	✔
Dawson *et al.*, 1992[38]	34 (2)	?	?	✔	0	NA	?	✘	?	?	?	✔/✘	?	✔	✔
Guillotreau *et al.*, 1996[41]	70 (2)	?	?	✔	0	NA	?	?	?	?	?	✔c	✘	✘	✔
Hydrocolloid versus traditional gauze dressings															
Viciano *et al.*, 2000[47]	38 (2)	?	?	✔	0	NA	?	?	?	?	?	✔	?	✘	✔
Dextranomer polysaccharide versus traditional gauze dressings															
Goode, 1979[40]	20 (2)	✔	?	✔	0	NA	?	?	?	?	?	✔	✔	✔	✔
Dextranomer polysaccharide versus silicone foam dressings															
Young *et al.*, 1982[50]	50 (2)	✔	?	✔	0	NA	?	?	?	?	?	✔c	✔d	✘	✘

✔, Yes; ✘, no; ✔/✘, partially covered; ?, not stated, not enough information or unclear; NA, not appropriate (controlled trial) (see appendix 4)

**✔a, Numbers reported by group and reason*

†✔, One or more appropriate baseline characteristics stated, but not initial wound size; ✔c, initial wound size stated

‡✔, According to one or more of the characteristics stated, but not initial wound size; ✔d, including wound size

TABLE 2 *Quality assessment of included trials: wounds from toenail avulsion surgery*

Study	Sample size (No. of arms)	Random. procedure adequate	Allo-cation con-cealed	Follow-up ≥ 80%	Loss to follow-up (%)	Out-comes of with-drawals*	ITT	Blinding of outcome assessors	Blinding of admin-istrators	Partic-ipants blinded	Success of blinding checked	Appropriate baseline character-istics†	Comparable baseline character-istics‡	Co-inter-ventions stated	Correct analysis
Bruce *et al.*, 1991[35]	18 (2)	?	?	✘	56	✔b	✘	?	?	?	?	✘	?	✘	?
Foley *et al.*, 1994[39]	70 (2)	?	?	✔	0	NA	?	?	?	?	?	✔	✔	✘	?
Smith *et al.*, 1992[45]	67 (2)	✘	✘	✔	7	✘	✘	?	?	?	?	✔/✘	?	✘	✘
Van Gils *et al.*, 1998[46]	20 (2)	?	?	✔	5	✔b	✘	✘	✘	?	?	✔	✔	✔/✘	✔

✔, Yes; ✘, no; ✔/✘, partially covered; ?, not stated, not enough information or unclear; NA, not appropriate (controlled trial) (see appendix 4)

**✔b, Withdrawals reported, but not by group or reason not given*

†✔, One or more appropriate baseline characteristics stated, but not initial wound size

‡✔, According to one or more of the characteristics stated, but not initial wound size

intervention. Two participants were withdrawn due to perceived discomfort at having biopsies taken (one in each treatment group), three because of recurrent infection (one in the foam group, two in the alginate group) and one required further surgery.[34]

Three of the four toenail avulsion studies reported that relatively complete follow-up (≥ 80%) was achieved.[39,45,46] There were no drop-outs in one trial,[39] one trial did not report any information on participants lost to follow-up[45] and the third trial did not state which treatment group the one participant that was lost to follow-up was allocated to.[46] Ten participants withdrew from a small RCT which had an initial sample size of 18 participants.[35] Four participants were reported to have failed to return for redressing, for which the reasons could not be ascertained, and the treatment group was not stated. None of the trials with withdrawals conducted an ITT analysis, using techniques such as last observation carried forward or more sophisticated methods. The trial that had no drop-outs did not report using an ITT analysis and therefore it was not possible to ascertain if bad compliers were correctly analysed.[39]

Blinding

Only one of the trials of surgical wounds reported the blinding of the outcome assessors to treatment allocation.[36] None of the trials reported having blinded the administrators (those who administered the intervention) or participants to the type of dressings being used, although this may be difficult to achieve in practice. One trial was reported as being an 'open parallel' study, and was therefore deemed not to be blind.[37] One trial reported that one of the authors supervised the dressing changes, which was undertaken by a member of the nursing staff.[38] It was therefore suspected that the assessor was not blinded to the intervention.

None of the trials that investigated wounds relating to toenail avulsions reported on the blinding of outcome assessors or participants to the type of intervention used. One trial reported that the authors conducted all the nail surgery as well as administering the dressing protocols.[46] It was therefore considered that blinding of the administrators had not been undertaken for this trial.

Baseline characteristics

The types of baseline characteristics most frequently reported by included studies were age, sex, wound type and wound measurements.

Nine of the 14 trials of surgical wounds reported information on baseline characteristics, which included the initial wound size.[34,36,37,41–44,49,50] There was no difference in wound size or other reported baseline characteristics for four of these trials (this was judged using an 'eye test' rather than relying solely on reported p values or the findings of statistical tests).[37,42,49,50] Three of the studies reported a greater mean baseline wound size in the intervention group,[34,41,43] while the other two studies found a greater mean wound size in the control group.[36,44] Three of these trials used the outcome measure reduction in wound size,[55–57] but only two reported the results of both absolute and relative values.[55,57] Three further trials reported one or more relevant baseline characteristics, but did not specify wound size.[40,47,48] One of these trials reported no baseline differences between groups.[40] It was not possible to assess the comparability of the treatment groups for the remaining two trials, as these were not reported per group.[47,48] One trial merely stated that none of the patients were diabetic or receiving steroid treatment.[38]

Two of the four trials of toenail avulsions reported baseline data on one or more important patient characteristic for which the treatment groups were considered to be comparable.[39,46] However, no trial reported any information relating to the initial wound size.

Reporting of co-interventions

Only four of the 14 trials reported any other co-interventions that participants were receiving, such as drugs (e.g. steroids).[34,37,38,40]

None of the trials of toenail avulsions reported whether participants were receiving any co-interventions.

Appropriate analysis

Seven of the 14 trials of surgical wounds were judged to have used an appropriate statistical test to analyse the data.[36,38,40–42,47,50] Three trials did not report what statistical test was used, and therefore it was not possible to assess the appropriateness of the test.[37,43,48] Eleven[34,35,37,39,40,42,44,45,48–50] of 13[34,35,37,39,40,42,44–50] trials summarised healing times using mean values instead of survival analysis or medians. Eight trials of surgical wounds did not report the results in sufficient detail to calculate a summary estimate of the treatment effect, for one or more outcome measures.[34,38,40,41,43,44,47,48]

Eight trials of surgical wounds used the outcome measure 'time to complete healing',[34,37,42,44,47–50]

seven of which reported mean values rather than medians.[34,37,42,44,48–50] Mean values are greatly affected by outliers and, unlike the median, cannot be calculated if some wounds fail to heal. One trial reported the rate of full epithelialisation, which was calculated from the initial wound volume divided by the number of days required to achieve each end-point.[58] None of the included trials of surgical wounds used survival analysis (where survival includes wounds not healed at any point of time during follow-up) or reported hazard ratios.

The change in wound area or volume can be expressed as either the percentage change or the absolute change. The absolute measure of change over time is dependent on the initial wound size. However, any change in wound area or volume presented as a percentage takes into account the initial wound size but is dependent on the length of follow-up. It is therefore important that studies that report incompatibility with regard to initial wound size should present the results on a change in wound area as both the percentage change and the absolute change. Of the nine trials of surgical wounds that reported baseline wound measurements,[34,36,41–44,49,50,59] five reported incomparability with regard to initial wound size.[34,36,41,43,44] Four of these trials reported on the outcome measure reduction in wound size,[36,41,43,44] of which only two trials reported both the absolute and the percentage change.[43,56]

Only one of the four trials of toenail avulsions was deemed to have used an appropriate statistical test.[46] However, this trial used mean values to summarise healing times.[46] Two trials did not report the statistical test used to compare data,[35,39] and in one trial no statistical analysis was performed.[45] One trial of toenail avulsions did not report the results in sufficient detail to calculate a summary estimate of the treatment effect for one or more outcomes.[45]

Four trials of toenail avulsions reported on the outcome measure time to complete healing.[35,39,45,46] However, only one of these used median values.[46] None of the included trials of toenail avulsions used survival analysis or reported hazard ratios.

Overall quality of included studies

On the whole, included trials tended to have a small sample size (median 43 participants) and the majority suffered from methodological flaws. The total number of participants included in the trials was 783. Detailed information relating to the randomisation procedure and blinding were not reported in most trials. Many trials failed to report the initial wound size and baseline characteristics of included participants. The majority of trials that used time to complete healing as the outcome measure reported mean instead of median values. Mean healing times may not represent the healing events in an appropriate way, as they are greatly affected by outliers, and unlike median values cannot be calculated if some wounds fail to heal. Almost half of the included trials did not report their results in sufficient detail to calculate a summary estimate of the treatment effect, for one or more outcome measures. The statistical test used to compare the treatment groups was often not reported or no test was used.

Assessment of clinical effectiveness

Included trials were considered to be heterogeneous with regard to type of wounds, type of dressing, comparator used and results presented, and so it was not possible to formally assess heterogeneity across trials. As statistical pooling of results was not feasible, and was considered inappropriate, the results are presented according to dressing type, with the results of studies of toenail avulsions presented separately within each dressing type. The results of outcomes relating to wound healing are presented first, and results of other outcomes investigated are presented in a separate section. Where the text states that a 'significant' difference was found this refers to statistical, not clinical, significance.

Measures of healing

Foam dressings

Two types of foam dressings were investigated by included studies. The first was silicone elastomer foam, which is prepared by mixing a base material and a catalyst in different proportions to form liquid foam. This is poured into the wound where it expands to 3–4 times its original volume and forms a soft pliable foam stent that conforms to the contour of the wound cavity.[60] The foam stent can be removed, disinfected and reinserted. However, the foam stent needs to be remodelled when the wound changes shape, usually about once a week.[61] The alternative foam dressing was a contoured honeycomb polymer membrane filled with hydrocellular chips.[37] This pliable polyurethane foam comes in various preformed shapes that can be moulded and inserted into a cavity wound. Unlike silicone foam, these are disposable and the dressings are replaced rather than disinfected and reused.

Silicone foam dressings versus traditional gauze dressings

Surgical wounds healing by secondary intention

Four included studies investigated the use of silicone elastomer foam versus traditional moist gauze dressings.[42,44,48,49] These included three RCTs, two of which looked at pilonidal wounds[48,49] (one of which also included incised abscess wounds[48]), and one looked at perineal wounds.[42] The fourth study was a controlled trial that looked at excised pilonidal sinus wounds.[44] The comparator gauze dressing was soaked in a different solution for each trial. The antiseptic solution included Eusol,[48] 0.5% chlorhexidine,[49] mercuric chloride[42] and povidone iodine solution.[44] All four studies followed participants until complete wound healing.

Results for the two RCTs that presented mean and variance data are presented in *Figure 2*.[42,49] Both trials found no significant difference between the two groups with regard to the mean time to healing, although both point estimates favour silicone foam. The third RCT did not provide a measure of variance and so could not be included in the Forest plot. This study stated that no significant difference with respect to mean time to wound healing was found.[48] One RCT also reported on the outcome of 'number of days packed' and found there was no significant difference between the two groups.[49] One trial reported on time to dry dressing, which was found to be significantly shorter in the foam group.[42] This study also reported the rates of healing. This was calculated by dividing the initial wound volume by the number of days required to achieve each end-point (full epithelialisation and dry dressing). No significant differences were found between the treatment groups. These measures are more appropriate as they take into account the initial wound volume, which will affect healing time.

The controlled trial reported both a longer mean cavity filling time and time to complete healing among participants in the iodine and dry gauze dressings group as compared to silicone foam (4.3 weeks versus 9.5 weeks, and 33.5 days versus 73 days, respectively) (see *Table 3* and appendix 5).[44] The trial also reported that the reduction in wound volume after 15 days was higher in the silicone group than in the gauze group (46% versus 22%). No data on statistical variability were provided, precluding the calculation of a CI.

Summary

There was no significant difference in the healing time between silicone foam elastomer dressing and conventional gauze dressing. All three trials included a relatively small sample size ranging from 50 to 80 participants (205 participants in total) (see *Table 4*).

Polyurethane foam dressings versus traditional gauze dressings

Surgical wounds healing by secondary intention

One RCT compared the use of polyurethane foam to moist gauze after abdominal surgery or surgical incision of an abscess.[43] No information

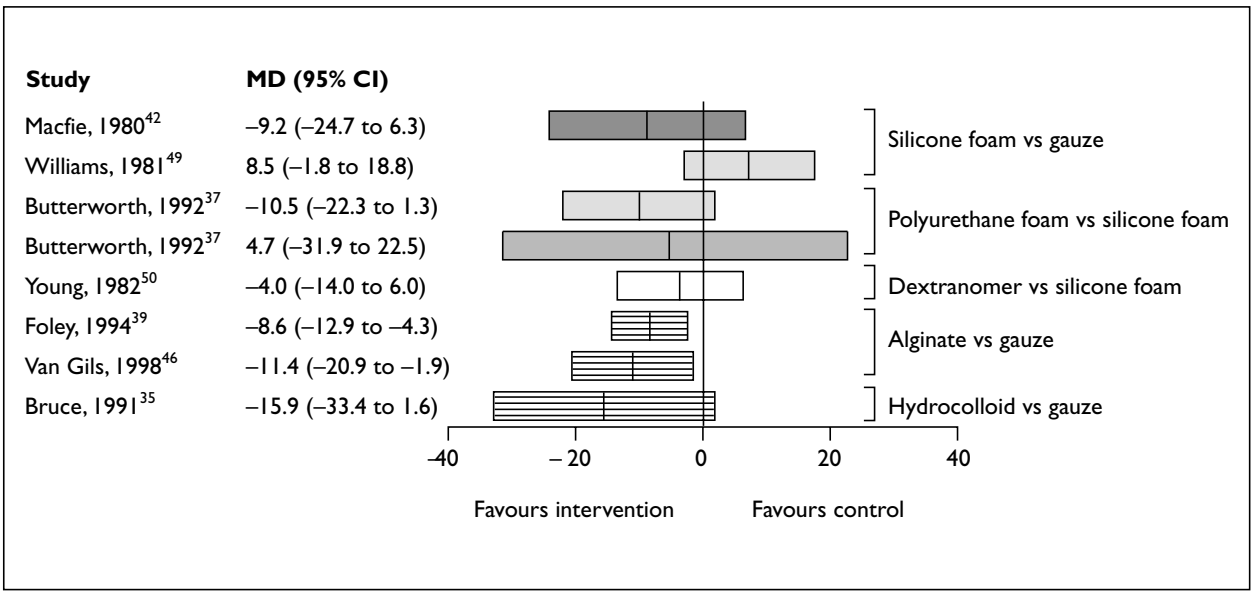


FIGURE 2 *Forest plot illustrating the mean difference in time to complete healing (days) between intervention and control groups (■, perineal; □, pilonidal; ■, abdominal; □, broken down surgical; ▤, toenail avulsion)*

TABLE 3 *Results for measures of healing*

Study	Condition	Duration	Proportion healed (including number of wounds closed surgically)	Per cent wound area reduction; wound volume	Time to complete healing (days); time to dry dressing
Silicone foam versus traditional gauze dressings					
Macfie and McMahon, 1980[42] RCT	Perineal wounds	Until healing			**Mean time to full epithelialisation**: no significant differences between the groups (60.3 days in foam group, 69.5 days in gauze group; MD = –9.2; 95% CI, –24.7 to 6.3) **Mean time to dry dressing**: significantly ($p < 0.05$) shorter in the foam group (47.5 days in foam group, 62.6 days in gauze group; MD = –15.10; 95% CI, –28.6 to –1.34) **Rate to full epithelialisation**: no significant differences (0.94 in foam group, 0.98 in gauze group; MD = –0.04; 95% CI, –0.31 to 0.23) **Rate to dry dressing**: no significant difference (1.24 in foam group, 1.07 in gauze group; MD = 0.17; 95% CI, –0.19 to 0.53)
Walker *et al.*, 1991[48] RCT	Pilonidal sinus wounds Incised abscesses	Until healing Until healing			**Mean time to healing**: no significant difference ($p > 0.05$) between the groups (30 days in foam group, 33 days in gauze group; no measure of variance) **Mean time to healing**: no significant difference ($p > 0.05$) between the groups (39.8 days in foam group, 39.6 days in gauze group; no measure of variance)
Williams *et al.*, 1981[49] RCT	Pilonidal sinus wounds	Until healing			**Mean time to healing**: no significant difference ($p > 0.05$) between the groups (66.2 days in foam group, 57.7 days in gauze group; MD = –8.5; 95% CI, –18.8 to 1.8) **Mean number of days packed**: no significant difference ($p > 0.05$) between groups (41.5 days in foam group, 41.8 days in gauze group; MD = –0.3; 95% CI, –10.79 to 10.19)
Ricci *et al.*, 1998[44] Controlled trial	Pilonidal sinus wounds	Until healing		**Reduction in cavity volume after 15 days**: higher in the silicone group (46%) than the gauze group (22%); no measure of variance or significance	**Mean time to healing**: higher in the gauze group (73 days) than in the silicone group (33.5 days); no measure of variance or significance **Mean time for cavity to fill**: shorter in silicone group (4.3 weeks) than gauze group (9.5 weeks); no measure of variance or significance

continued

TABLE 3 contd *Results for measures of healing*

Study	Condition	Duration	Proportion healed (including number of wounds closed surgically)	Per cent wound area reduction; wound volume	Time to complete healing (days); time to dry dressing
Polyurethane foam versus traditional gauze dressings					
Meyer, 1997[43] RCT	Abdominal surgery or abscess incision	4 weeks	**Proportion healed**: significantly greater (p = 0.04) in Cutinova group (48%) than in gauze group (18%); RR = 2.6 (95% CI, 1.0 to 7.1) **Overall healing (total healed or closed surgically)**: significantly greater (p = 0.01) in the Cutinova group (67%) than in gauze group (27%); RR = 2.44 (95% CI, 1.23 to 5.31)	**Reduction in wound volume**: significantly greater (p < 0.05) in Cutinova group (75.6%) than in gauze group (50.1%); no measure of variance **Epithelialisation and granulation**: faster in Cutinova group, also earlier reduction of fibrinous coats	
Polyurethane foam versus silicone foam dressings					
Butterworth *et al.*, 1992[37] RCT	Abdominal wounds	Until healing			**Mean time to healing**: no significant differences (p = 0.05) between groups (51.9 days in polyurethane foam group, 56.6 days in silicone foam group; MD = –10.5; 95% CI, –22.3 to 1.3)
	Pilonidal wounds	Until healing			**Mean time to healing**: no significant differences (p = 0.05) between groups (51.4 days in polyurethane foam group, 61.9 days in silicone foam group; MD = –4.7; 95% CI, –31.9 to 22.5)
Polyurethane foam versus alginate dressings					
Berry *et al.*, 1996[34] RCT	Pilonidal sinus excision	Until healing			**Mean time to healing**: 56.7 days in foam group, 65.5 days in gauze group; no measure of variance or significance
Alginate versus traditional gauze dressings					
Cannavo *et al.*, 1998[36] RCT	Dehisced surgical abdominal wounds	Until healing		**Reduction in wound area and volume**: no significant difference between any of the three groups	
Dawson *et al.*, 1992[38] RCT	Abscess incision	4 weeks	**Proportion healed**: no significant difference between groups (p > 0.05); at 2 week review 75% in alginate group, 72% in control group; all wounds healed at 4 weeks; RR = 1.0 (95% CI, 0.8 to 1.2)		

continued

TABLE 3 contd *Results for measures of healing*

Study	Condition	Duration	Proportion healed (including number of wounds closed surgically)	Per cent wound area reduction; wound volume	Time to complete healing (days); time to dry dressing
***Alginate versus traditional gauze dressings* contd**					
Guillotreau *et al.*, 1996[41] RCT	Abscess incision	3 weeks	**Proportion epithelialised**: no significant differences between groups (RR = 1.9; 95% CI, 0.9 to 4.5) **Proportion filled**: no significant differences ($p > 0.05$) between groups (59% in alginate group, 48% in gauze group; RR = 1.2; 95% CI, 0.8 to 1.9)	**Wound area reduction**: significantly ($p < 0.05$) higher in alginate group than gauze group at weeks 1, 2 and 3; no measure of variance	
Foley and Allen, 1994[39] RCT	Toenail avulsion	Until healing			**Mean time to healing**: significantly ($p < 0.05$) less in alginate-treated group (25.8 days) than in gauze group (34.4 days) (MD = –8.6; 95% CI, –12.9 to –4.3)
Van Gils *et al.*, 1998[46] RCT	Toenail avulsion	8 weeks	**Proportion healed**: one patient in control group had not healed at end of follow-up		**Median/mean time to healing**: significantly ($p = 0.03$) less in Fibracol-treated group (26/24.4 days) compared to control (42/35.8 days) (MD = –11.4; 95% CI, –20.9 to –1.9)
Smith, 1992[45] Quasi-RCT	Toenail avulsion	Until healing			**Mean time to healing**: shorter in Sorbsan treatment group (43 days) than Anaflex group (52 days); significant ($p < 0.05$) for total nail avulsions (45 days versus 69 days), but not for partial nail avulsion (40 days on Sorbsan, 39 days on control); no measure of variance
Hydrocolloid versus traditional gauze dressings					
Viciano *et al.*, 2000[47] RCT	Pilonidal sinus wounds	Until healing			**Median healing time**: no significant ($p > 0.05$) differences between the groups (65 days in hydrocolloid group, 68 days in gauze group; no measure of variance)
Bruce, 1991[35] RCT	Toenail avulsion	Until healing			**Mean time to healing**: 49.3 days in hydrocolloid group, 65.2 days in gauze group (MD = –15.9; 95% CI, –33.4 to 1.6)

continued

TABLE 3 contd *Results for measures of healing*

Study	Condition	Duration	Proportion healed (including number of wounds closed surgically)	Per cent wound area reduction; wound volume	Time to complete healing (days); time to dry dressing
Dextranomer polysaccharide versus traditional gauze dressings					
Goode *et al.*, 1979[40] RCT	Broken down surgical wounds	Until healing or suture	**Proportion healed**: no significant ($p > 0.05$) differences between groups; 1 wound healed in each group (RR = 1.0; 95% CI, 0.1 to 8.8)		**Mean time to secondary closure**: significantly ($p < 0.05$) less in beads group (8.1 days) than gauze (11.6 days) group; no measure of variance and therefore unable to check this calculation
Dextranomer polysaccharide versus silicone foam dressings					
Young and Wheeler, 1982[50] RCT	Broken down surgical wounds	Until healing			**Mean time to healing**: no significant ($p > 0.05$) differences between the groups (41 days on beads, 37 days on control; MD = –4.0; 95% CI, –14.0 to 6.0)

TABLE 4 *Results for measures of healing according to intervention and wound type**

Intervention	Pilonidal sinus excision	Perineal wound	Abscess incisions	Abdominal wounds	Broken down surgical wounds	Toenail avulsion
Silicone foam versus gauze	*N* = 3: no significant differences in mean time to healing or reduction in cavity size, small suggestion in favour of foam	*N* = 1: no significant differences in mean time to healing or reduction in cavity size, small suggestion in favour of foam	*N* = 1: no difference between two treatment groups in mean time to healing			
Polyurethane foam versus gauze			**N = 1: significantly greater proportion healed in foam group than gauze group, also significantly greater reduction in wound volume**			
Polyurethane versus silicone foam	*N* = 1: no significant differences in mean time to healing, although shorter in foam group			*N* = 1: no significant differences in mean time to healing, although shorter in foam group		
Polyurethane foam versus alginate	*N* = 1: no measure of variance or significance; shorter mean time to healing in foam group					
Alginate versus gauze			*N* = 2: no significant difference in proportion epithelialised or healed; suggestion in favour of alginate. No measure of variance: significantly greater wound area reduction in alginate group	*N* = 1: no significant difference between the groups in mean time to healing		**N = 3: significantly shorter mean time to healing in alginate group**
Hydrocolloid versus gauze	*N* = 1: no significant difference in median healing time					*N* = 1: no significant difference in mean time to healing, shorter in hydrocolloid group
Dextranomer versus gauze					**N = 1: mean time to secondary closure significantly less in dextranomer group**	
Dextranomer versus silicone foam					*N* = 1: no significant differences in mean time to healing, slightly longer in dextranomer group	

N, *The number of trials reporting on this intervention and wound type*

** Studies which show significant benefits of the intervention compared to the control are highlighted in bold*

was presented as to whether the gauze had been moistened with saline or an antiseptic solution. The duration of follow-up for this trial was 4 weeks. During this time period the proportion of wounds healed completely was found to be significantly higher in the foam group than in the gauze dressing group. The results are presented in *Figure 3* (see also *Table 3* and appendix 5). The reduction in wound volume was also reported to be greater for participants who were in the foam group compared to gauze, and baseline wound volume was greater in the foam group. However, the authors did not report the standard deviation or give an exact *p* value, and therefore the CI could not be calculated. The authors also failed to present the statistical test used to compare the treatment groups.

Summary

According to a single RCT, the number of wounds healed at 4 weeks was significantly higher for those treated with polyurethane foam compared to moist gauze dressings. However, this trial included a very small sample. In addition, the initial mean wound volume was significantly greater in the foam group (27.9 cm^3) compared to the gauze group (21.0 cm^3) (see *Table 4*).

Polyurethane foam dressings versus alginate dressings

Surgical wounds healing by secondary intention

One RCT compared the use of polyurethane foam with a calcium sodium alginate dressing.[34] The type of operation was pilonidal sinus excision and participants were followed up until complete healing had been achieved. The mean healing time for the alginate group was found to be slightly higher than that of the foam group (65.5 days versus 56.7 days). However, no measure of variance or of the significance of the difference was provided. When wounds became superficial or had no significant depth, the dressing protocols were changed. Wounds that were previously dressed with polyurethane foam were treated with polyurethane sheets (Allevyn™) and those in the alginate group were dressed with a different type of polyurethane sheet dressing (Lyofoam™). The time at which dressing protocols were changed was not reported.

Summary

No conclusions could be drawn, with regard to the wound dressings used initially, from the results of a single trial comparing polyurethane foam and calcium sodium alginate dressings. Wounds in both groups were treated with polyurethane sheet dressings when they became superficial or had no significant depth (see *Table 4*).

Polyurethane foam dressings versus silicone foam dressings

Surgical wounds healing by secondary intention

One RCT compared the use of polyurethane foam to silicone foam dressings.[37] Participants had cavity wounds that had resulted from either pilonidal surgery excision or abdominal surgery. Participants were followed up until complete healing had occurred. There was no significant difference in mean time to complete healing between the two groups for either abdominal or pilonidal surgery wounds. The results are presented in *Figure 2* (see also *Table 3* and appendix 5).

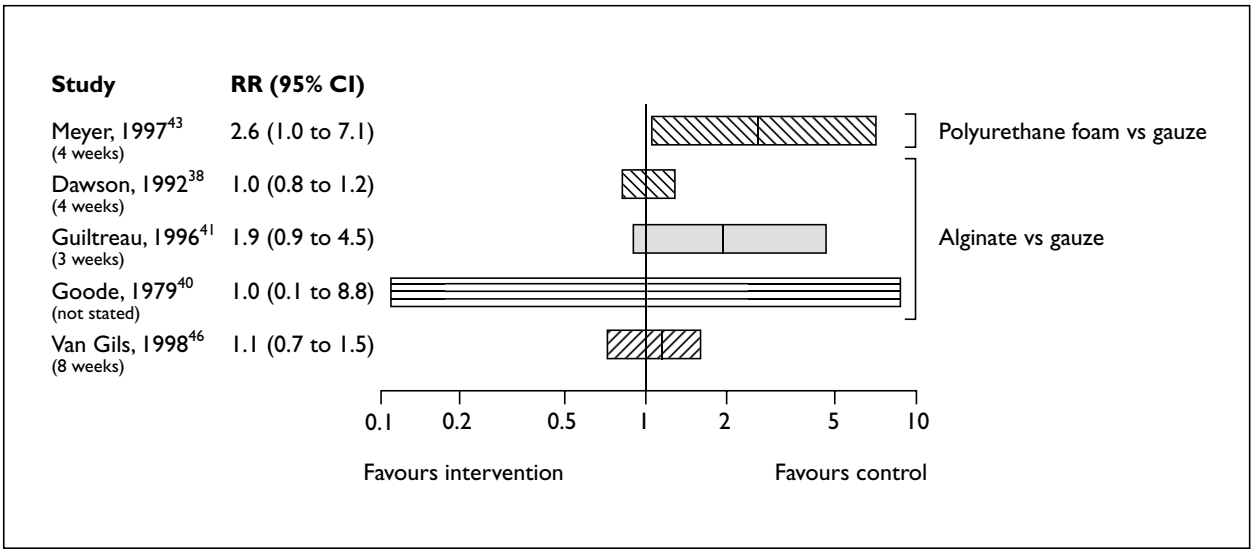


FIGURE 3 *Forest plot illustrating the relative risk for the number of wounds healed between intervention and control groups (▨, abscess; □, pilonidal; ▤, broken down surgical wounds; ▨, toenail avulsion)*

Summary
According to a single open RCT (n = 80), there was no significant difference in the mean healing time for wounds treated with either polyurethane foam or silicone foam dressings. However, the CIs were relatively large and thus the study may have lacked the power to detect differences between the two treatment groups (see *Table 4*).

Alginate dressings versus traditional gauze dressings

Surgical wounds healing by secondary intention
Two RCTs compared the use of calcium alginate to traditional moist gauze dressings in the packing of wounds following the incision and drainage of abscesses.[38,41] The follow-up periods were 3 weeks[41] and 4 weeks.[38] The comparator gauze dressing was soaked in saline for one trial[38] and povidone iodine in the other.[41] There was no significant difference in outcome between the two dressing protocols for the proportion of wounds healed at either 3 or 4 weeks, although one of the trials tended to favour alginate. The results are presented in *Figure 3* (see also *Table 3* and appendix 5). One trial also reported that the percentage reduction in the mean wound surface area was significantly higher at weeks 1, 2 and 3 in the alginate group compared to those dressed with gauze.[41] One RCT compared the performance of three dressings in the management of dehisced surgical abdominal wounds.[36] The three dressing protocols included calcium alginate dressings and a Combine dressing pad (an absorbent wound dressing that consists of cotton wool and gauze) with or without a 0.05% sodium hypochlorite solution moistened gauze. Participants were followed up until complete healing had been achieved. There was no significant difference between any of the groups with regard to the reduction in wound area and volume.

Wounds resulting from toenail avulsion surgery
Three RCTs compared the use of alginate dressings to conventional treatment on wounds produced by toenail avulsion followed by chemical destruction of the germinal matrix and nailbed.[39,45,46] The comparator treatment used in the trials included a cotton and acrylic fibre pad bonded to a low-adherent polyester film (Melolin™),[39] Melolin dressing with Anaflex™ powder[46] and no additional wound dressing (all wounds were dressed with a thin layer of sulfadiazine silver cream and covered with sterile compressive gauze).[45] The length of follow-up was 8 weeks in one trial,[46] and participants were followed up until complete healing had been achieved in the other two trials.[39,45]

All three trials reported that for participants who had received a total nail avulsion, as opposed to partial nail avulsion, time to complete healing was significantly less in the alginate group compared to the traditional gauze dressing group (see *Table 3* and appendix 5). Two of the three trials provided sufficient information to calculate a mean difference and the 95% CI (see *Figure 2*).[39,50] Both trials found a significantly shorter mean time to healing in the alginate compared to the gauze group. One trial reported the median healing time, but did not report a measure of variance (median healing time of 26 days in the alginate group versus 42 in the control group).[46] This trial also reported on the number of wounds healed at 8 weeks.[46] All wounds, except that of one participant in the control group, had healed at 8 weeks.

Summary
There was no significant difference, in terms of the proportion of wounds healed at 3 or 4 weeks between surgical wounds packed with calcium alginate and those dressed using the conventional gauze dressings. The trials included only small sample sizes, ranging from 20 to 70 (152 participants in total). No initial wound size or any other baseline characteristics were reported (see *Table 4*).

Time to complete healing for wounds resulting from total nail avulsion surgery was found to be significantly shorter in the alginate dressings group compared to traditional gauze dressings. The trials included only small sample sizes, ranging from 20 to 70 (157 participants in total). No baseline wound area was reported. Two trials reported only age and sex as baseline characteristics[39,45,46] (see *Table 4*).

Hydrocolloid versus traditional gauze dressings

Surgical wounds healing by secondary intention
One RCT compared the use of hydrocolloid dressings with traditional gauze dressings soaked in povidone iodine in the treatment of excised pilonidal wounds.[47] Two types of hydrocolloid dressings were investigated, Comfeel™ and Varihesive™. Participants were followed up until complete healing had occurred. There was no significant difference in median healing time between the hydrocolloid groups combined and the gauze treatment group (65 days versus 68 days).

Wounds resulting from toenail avulsion surgery
One RCT compared the use of hydrocolloid dressings with chlorohexidine acetate impregnated dressing (Serotulle™) for the treatment of wounds

produced by toenail avulsion followed by the phenolisation of the germinal matrix and nailbed.[35] Participants were followed up until their wounds had completely healed. The sample size was very small (n = 11) and there was no significant difference in the mean healing time between wounds treated with hydrocolloid dressing and those dressed with Serotulle. The results are presented in *Figure 2* (see also *Table 3* and appendix 5).

The trial reported the reason for withdrawal according to the intervention group, which included pain (n = 1), developed allergies (n = 3) and the decision of the chiropodist (n = 2).

Summary
One trial reported no significant difference in median healing time between excised pilonidal wounds dressed with hydrocolloid dressings and those treated with conventional gauze soaked with povidone iodine. No baseline wound size was reported and the trial had a very small sample size (n = 38) (see *Table 4*).

The findings of a very small single RCT (n = 11) showed no significant difference in mean healing time for wounds resulting from toenail avulsion surgery treated with hydrocolloid dressing compared to traditional gauze dressings. No baseline characteristics were reported (see *Table 4*).

Dextranomer polysaccharide beads versus traditional gauze dressings

Surgical wounds healing by secondary intention
One small RCT (n = 20) compared the use of dextranomer polysaccharide beads to that of traditional gauze dressings soaked in Eusol, in the treatment of contaminated or infected wounds following bowel surgery or appendectomy.[40] When the wounds were deemed to be 'clean' (see appendix 5) wounds were closed by secondary suture. One wound in each group healed by granulation and therefore did not require suturing. The time to complete healing of these two wounds was not reported. There was no significant difference in the mean time to wound closure by secondary suture between the two intervention groups.

Summary
No conclusions could be drawn from the results of a single small RCT (n = 20) (see *Table 4*).

Dextranomer polysaccharide beads versus silicone dressings

Surgical wounds healing by secondary intention
One RCT (n = 50) compared dextranomer polysaccharide beads and silicone foam elastomer dressings in the treatment of surgical wounds that had either broken down or been left open postoperatively.[50] The type of surgery undertaken was not specified. Participants were followed up until complete healing had occurred. There was no significant difference in the mean time to complete healing between the two dressings. The results are presented in *Figure 2* (see also *Table 3* and appendix 5).

Summary
According to a single trial (n = 50), there was no significant difference in the mean healing time for wounds treated with either dextranomer polysaccharide beads or silicone foam dressings (see *Table 4*).

Other outcomes

The results for outcome measures other than healing reported by the included studies are presented below. These results should be interpreted with extreme caution for two reasons. To be included in the review studies had to report an objective measure of healing, and thus any trial which reported on other outcome measures but did not report an objective healing measure was not included in the review. The results below are therefore derived from a subset of studies looking at these outcomes. The second problem with these results relates to the quality of the study. As highlighted above, the methodological quality of the included studies is low, with very few studies blinding investigators or participants. This is a particular problem for the outcome measures presented below, which are generally very subjective, difficult to assess and subject to bias. Results for these outcomes are presented in *Table 5* and appendix 5.

Silicone foam dressings versus traditional gauze dressings

Surgical wounds healing by secondary intention
Three RCTs and one controlled trial compared silicone foam dressings to traditional gauze dressings. Other outcome measures reported on by the RCTs were pain,[42] duration of hospital stay,[42,48,49] number of visits by the district nurse,[42,49] work lost[49] and level of discomfort on dressing removal.[49] One study found a significantly greater number of visits by the district nurse in the gauze group compared to the foam group, and a significantly greater requirement for analgesia in the gauze group.[42] Another study also found a significantly greater number of home nursing visits in the gauze group compared to the foam group, as well as significantly greater discomfort on dressing change in the gauze group.[49] No significant differences were found for any of the other outcomes

TABLE 5 *Results for other outcome measures*

Study	Condition	Duration	Resource use	Dressing comfort	Dressing performance	Other outcomes
Silicone foam versus traditional gauze dressings						
Macfie and McMahon, 1980[42] RCT	Perineal wounds	Until healing	**Number of inpatient days**: no significant ($p > 0.05$) differences between the groups (23.8 days in foam group, 22.8 days in gauze group (excluding convalescence); MD = 1.00; 95% CI, –3.85 to 5.85) **Number of visits by district nurse**: significantly ($p < 0.001$) less in foam group (14.1) compared to gauze group (46.9); MD = –32.8; 95% CI, –45.1 to –20.5)	**Pain**: 15 patients in gauze group and 4 patients in foam group required analgesia (RR = 0.27; 95% CI, 0.1 to 0.63)		
Walker *et al.*, 1991[48] RCT	Pilonidal sinus wounds and incised abscesses	Until healing	**Days to hospital discharge**: no significant ($p > 0.05$) difference between groups; no measure of variance			
Williams *et al.*, 1981[49] RCT	Pilonidal sinus wounds	Until healing	**Mean time to hospital discharge**: no significant ($p > 0.05$) difference between groups (8.5 days in foam group, 7.3 days in gauze group (MD = 1.2; 95% CI, –3.22 to 5.62) **Number of home nursing visits**: significantly ($p < 0.05$) greater in gauze group (35.1) than foam group (4.6) (MD = –30.5; 95% CI, –35.7 to –25.3)	**Discomfort on dressing removal (measured using VAS)**: significantly greater in gauze group (2.9) than foam group (1.4) (MD = –1.5; 95% CI, –2.3 to –0.7)		**Work lost**: no significant ($p > 0.05$) difference between groups (45.4 days in foam group, 38.6 days in gauze group; MD = –6.8; 95% CI, –16.8 to 3.2)
Ricci *et al.*, 1998[44] Controlled trial	Pilonidal sinus wounds	Until healing	**Number of dressings used**: less in foam group (20) than gauze group (868); no measure of variance and therefore cannot determine whether statistically significant	**Pain**: authors reported dressing was pain free in foam group, while in gauze group it was painful and bleeding occurred, but no data were presented to allow judgements to be made about clinical or statistical significance		**Time before return to work**: shorter in foam group (12 days) than gauze group (23 days); no measure of variance

VAS, Visual analogue scale

continued

TABLE 5 contd *Results for other outcome measures*

Study	Condition	Duration	Resource use	Dressing comfort	Dressing performance	Other outcomes
Polyurethane foam versus traditional gauze dressings						
Meyer, 1997[43] RCT	Abdominal surgery or abscess incision	4 weeks	**Number of dressing changes**: about three times more frequent in gauze group than foam group at weeks 3 (mean 0.28/0.69) and 4 (mean 0.14/0.39)	**Pain (VAS) at week 4**: significantly ($p < 0.05$) greater in gauze group (1.82) than foam group (0.86); no measure of variance **Erythema**: significant reduction after 1 week of treatment for Cutinova group, 3 weeks for reduction in gauze group	**Necrotic tissue, odour and putrid secretion and itching**: no difference between dressings as they were not frequently reported at any time during study	**Number of wounds closed surgically**: 4 in Cutinova group and 2 in gauze group (RR = 2.1; 95% CI, 0.5 to 9.15) **Infection**: significant reduction after 1 week of treatment for Cutinova group, 3 weeks for reduction in gauze group
Polyurethane foam versus alginate dressings						
Berry *et al.*, 1996[34] RCT	Pilonidal sinus wounds	Until healing			**Dressing leakage and absorbency capacity**: no significant difference between groups **Dressing performance (clinician assessed)**: no differences between groups	
Polyurethane foam versus silicone foam dressings						
Butterworth *et al.*, 1992[37] RCT	Abdominal and pilonidal sinus wounds	Until healing	**Mean time for dressing change**: shorter in polyurethane group (203 s) than silicone group (263 s); no measure of variance	**Comfort**: no difference between groups (90% painless for both dressings; RR = 0.99; 95% CI, 0.96 to 1.03)	**Ease of application**: significantly ($p = 0.03$) easier in silicone foam group (84% easy) than polyurethane foam group (67% easy) (RR = 1.25; 95% CI, 1.18 to 1.33) **Ease of removal**: no difference between groups (97% easily removed in both groups; RR = 0.99; 95% CI, 0.97 to 1.01) **Conformability**: no significant differences between groups (99% in silicone group and 93% in polyurethane group conformed well); no measure of variance	

VAS, Visual analogue scale

continued

TABLE 5 contd *Results for other outcome measures*

Study	Condition	Duration	Resource use	Dressing comfort	Dressing performance	Other outcomes
Alginate versus traditional gauze dressings						
Cannavo *et al.*, 1998[36] RCT	Dehisced surgical abdominal wounds	Until healing		**Maximum pain**: significantly greater for gauze compared to alginate or combined dressing; no significant difference between alginate and combined dressing groups	**Satisfaction during dressing change**: no significant differences between alginate and combined dressing at week 1; gauze significantly ($p < 0.02$) less than alginate and combined dressing during dressing changes and at other times; no statistically significant difference in satisfaction between the three groups at the last assessment visit	
Dawson *et al.*, 1992[38] RCT	Abscess incision	4 weeks		**Pain of dressing removal**: alginate dressing was significantly ($p < 0.01$) less painful than gauze dressing; no further data provided	**Ease of removal**: alginate dressing was significantly ($p < 0.01$) easier than gauze dressing; no further data provided	
Guillotreau *et al.*, 1996[41] RCT	Abscess incision	3 weeks		**Pain**: less in alginate group than gauze group ($p = 0.001$); no further data provided	**Ease of use**: alginate dressing easier than gauze dressing ($p = 0.011$); no further data provided	**Bacteria cultured**: no difference between groups; no further data provided
Foley and Allen, 1994[39] RCT	Toenail avulsion	Until healing	**Mean number of dressing changes**: no significant differences between groups (3.6 in alginate group, 4.5 in gauze group; MD = –0.9; 95% CI, –1.8 to 0.0)			
Van Gils *et al.*, 1998[46] RCT	Toenail avulsion	8 weeks	No secondary outcomes			
Smith, 1992[45] Quasi-RCT	Toenail avulsion	Until healing	**Number of visits**: similar in both groups (6 in alginate group, 7 in gauze group); no measure of variance or significance		**Problems after operation**: no significant ($p > 0.05$) differences between groups (71% in alginate group, 86% in gauze group; RR = 0.82; 95% CI, 0.61 to 1.09)	**Postoperative infection**: 1 in gauze group, 0 in alginate group (RR = 0.0; 95% CI, 0.0 to 3.1)

continued

TABLE 5 contd *Results for other outcome measures*

Study	Condition	Duration	Resource use	Dressing comfort	Dressing performance	Other outcomes
Hydrocolloid versus traditional gauze dressings						
Viciano *et al.*, 2000[47] RCT	Pilonidal sinus wounds	Until healing	**Number of dressings used**: greater in gauze group (68) than hydrocolloid group (23); no measure of variance or significance	**Local intolerance**: 3 in hydrocolloid group, 1 in control group (RR = 2; 95% CI, 0.3 to 13.2) **Pain**: significantly (p = 0.05) less in hydrocolloid group during first 4 weeks than in control group; median difference in pain between groups only significant during week 1	**Scar quality, tolerance of dressing, smell**: no differences among groups	**Postoperative culture that grew pathogen**: 1 in hydrocolloid group, 5 in control group (p = 0.03; RR = 0.13; 95% CI, 0.02 to 0.75)
Bruce, 1991[35] RCT	Toenail avulsions	Until healing	**Mean dressing time**: no significant differences between groups (Serotulle 10 min, Comfeel 9 min); no measure of variance	**Patient comfort during and after dressing change**: no significant difference between groups	**Patient satisfaction**: presence of the hydrated gel from the dressing was often offensive to the patient, along with its smell **Leakage**: gel frequently leaked from wound site	
Dextranomer polysaccharide versus traditional gauze dressings						
Goode *et al.*, 1979[40] RCT	Broken down surgical wounds	Until healing or suture	**Hospital stay**: shorter in Debrisan group by median of 2.2 days; no measure of variance or significance			**Serous discharge**: 3 patients in Eusol group continued to have serious discharge for up to 5 days after wound closure, this did not occur in Debrisan group
Dextranomer polysaccharide versus silicone foam dressings						
Young and Wheeler, 1982[50] RCT	Broken down surgical wounds	Until healing				**Mean time to pain-free days**: no difference between groups (5.32 days in beads group, 5.64 days in foam group; MD = –0.3; 95% CI, –1.8 to 1.2)

investigated. The controlled trial investigated the number of dressings used, level of pain on dressing removal and time before return to work.[44] No statistical analysis was undertaken and variance data were not provided, and thus it is difficult to interpret these results. These results are presented in *Table 5* and appendix 5.

Polyurethane foam dressings versus traditional gauze dressings

Surgical wounds healing by secondary intention

One RCT compared foam dressings to traditional gauze dressings. Other outcome measures reported by the trial included the evaluation of the level of putrid secretion, odour, extent of necrosis, erythema, infection, itching and pain, as well as the rate of epithelialisation and granulation. The trial also investigated the frequency of dressing changes. The results are presented in *Table 5* and appendix 5. Pain was found to be significantly greater in the gauze group at week 4 compared to that in the silicone foam group. A significant reduction in the level of infection and erythema was also reported to be present at the end of week 1 in the silicone elastomer foam group as compared to week 3 in the conventional gauze group. However, no actual figures were presented for these results.

Polyurethane foam dressings versus alginate dressings

Surgical wounds healing by secondary intention

One RCT compared the use of polyurethane foam with a calcium sodium alginate dressing.[34] The trial reported on other outcome measures, including ease of dressing application, ease of dressing removal, ease of dressing use, dressing leakage, absorbency capacity of the dressing and patient comfort. These results are presented in *Table 5* and appendix 5. No significant difference was found between the treatment groups for any outcome measure.

Polyurethane foam dressings versus silicone foam dressings

Surgical wounds healing by secondary intention

One RCT compared the use of polyurethane foam to silicone foam dressings.[37] The trial reported on other outcome measures that included ease of dressing application, ease of dressing removal by clinical staff, patient comfort and the time taken by clinical staff to change the dressing. The results are presented in *Table 5* and in appendix 5. A greater number of clinical staff considered the application of silicone dressing easier than polyurethane foam. The time taken to apply the cavity wound dressing was, on average, one minute less for silicone foam than for the polyurethane foam dressings. However, dressing times were recorded for clinic dressing changes only, which were undertaken at a specialised wound clinic. Here the equipment to make the silicone foam dressing was laid out in advance, whereas a nurse in a community setting would take additional time to prepare the foam dressing. The polyurethane foam dressing is simply removed from its packet and placed in the wound.

Alginate dressings versus traditional gauze dressings

Surgical wounds healing by secondary intention

Two RCTs compared the use of calcium alginate to traditional gauze dressings in the packing of wounds following the incision and drainage of abscesses.[38,41] One RCT compared the performance of three dressings in the management of dehisced surgical abdominal wounds.[36] The three RCTs reported on other outcome measures, which included pain,[36,38,41] patient satisfaction with the dressing process,[36] ease of dressing removal,[38] ease of dressing use[41] and bacterial culture.[41] The results are presented in *Table 5* and appendix 5. All three trials reported that alginate dressings were significantly less painful than conventional gauze dressings. Ease of use[41] and ease of removal[38] were reported to be significantly better in the alginate group compared to gauze. However, no actual figures were presented for either outcome.

Wounds resulting from toenail avulsion surgery

Three RCTs compared the use of alginate dressings to conventional treatment on wounds produced by toenail avulsion followed by chemical destruction of the germinal matrix and nailbed.[39,45,46] Two of the RCTs[39,45] reported on other outcome measures, which included the number of dressing changes,[39] number of follow-up visits,[45] any volunteered complaints by the patients and the incidence of post-operative infection.[45] The results are presented in *Table 5* and appendix 5. The mean number of dressing changes was found to be significantly fewer for participants in the alginate treatment group compared to those treated with conventional gauze dressings.[39] No difference was found between the treatment groups with regard to the remaining outcome measures.

Hydrocolloid versus traditional gauze dressings

Surgical wounds healing by secondary intention

One RCT compared the use of hydrocolloid dressings with traditional gauze dressings soaked in povidone iodine, in the treatment of excised pilonidal wounds.[47] Two types of hydrocolloid dressings were investigated, Comfeel and

Varihesive. The trial reported on infection rate, number of dressings used, dressing intolerance, level of pain, level of odour, scar quality, tolerance and smell. The results are presented in *Table 5* and appendix 5. The level of pain was reported to be significantly less during the first 4 weeks post-operatively in the hydrocolloid treatment group compared to gauze. However, there were no data on the magnitude of the effect. There were five postoperative cultures in the hydrocolloid group that grew pathogens, compared to one in the gauze treatment group. This difference was found to be statistically significant. There was no difference between the treatment groups for any other outcome measure.

Wounds resulting from toenail avulsion surgery
One RCT compared the use of hydrocolloid dressings with a chlorhexidine acetate impregnated dressing (Serotulle) for the treatment of wounds produced by toenail avulsion followed by the phenolisation of the germinal matrix and nail-bed.[35] The trial reported no difference between the treatment groups with regard to the mean time to change of the dressing and the level of patient comfort during and after the change of dressing.

Dextranomer polysaccharide beads versus traditional gauze dressings

Surgical wounds healing by secondary intention
One small RCT ($n = 20$) compared the use of dextranomer polysaccharide beads to that of traditional gauze dressings soaked in Eusol, in the treatment of contaminated or infected wounds following bowel surgery or appendectomy.[40] The trial reported on the length of hospital stay and the level of serous wound discharge. Hospital stay was reported to be shorter in the dextranomer beads group compared to gauze. However, no measure of significance was provided. Participants in the gauze treatment group continued to have serious discharge for up to 5 days after wound closure. This did not occur in the dextranomer beads group.

Dextranomer polysaccharide beads versus silicone dressings

Surgical wounds healing by secondary intention
One RCT ($n = 50$) compared dextranomer polysaccharide beads and silicone foam elastomer dressings in the treatment of surgical wounds that had either broken down or been left open post-operatively.[50] The trial also reported on the time to pain-free wounds and time to the disappearance of erythema, oedema and slough. There was no difference between the groups with regard to these outcome measures.

Summary of clinical effectiveness data

Studies were judged as having an effect if they reported any significant difference between the intervention groups for either the measures of healing or other measures. Studies were judged as showing an overall effect if they showed a significant difference between treatments for more than two outcome measures, or, if only one outcome measure was reported, if they showed a significant difference for that outcome. However, the results presented in *Table 6* may be affected by type I error (false-positive result), where the conclusion that the intervention is better than the control may in fact be incorrect, and have occurred due to chance, especially in studies which reported a large number of outcome measures. It is also important to note that some of the other outcome measures are in fact related (i.e. not truly independent, e.g. pain, comfort, ease of use and time taken to change the dressing). The results of all outcome measures should be interpreted with caution due to the methodological problems highlighted above. This is particularly the case for the 'other outcome measures'. Due to the very subjective nature of the majority of these outcomes their measurement is particularly susceptible to bias, especially in unblinded studies.

On the whole, included trials tended to have a small sample size (median 43 participants) and the majority suffered from methodological flaws. The total number of participants included in the trials was 783. Detailed information relating to the randomisation procedure and blinding was not reported in most trials. Many trials failed to report the initial wound size and baseline characteristics of included participants. The majority of trials that used the outcome measure of time to complete healing reported mean values instead of median values. Mean healing times may not represent the healing events in an appropriate way as they are greatly affected by outliers and, unlike median values, cannot be calculated if some wounds fail to heal. Almost half of the included trials did not report their results in sufficient detail to calculate a summary estimate of the treatment effect, for one or more outcome measures. The statistical test used to compare the treatment groups was often not reported or no statistical test was used.

Modern dressings versus gauze

Eleven of the 13 studies of surgical wounds compared modern dressings to traditional gauze

TABLE 6 *Overall results of the assessment of effectiveness*

Study	Condition	Healing outcomes		Other outcomes	
		Overall effect	**Any effect**	**Overall effect**	**Any effect**
Modern dressings versus gauze					
Surgical wounds					
Silicone foam versus traditional gauze dressings					
Macfie and McMahon, 1980[42]	Perineal wounds	–*	✔	–*	✔
Walker *et al.*, 1991[48]	Pilonidal wounds	–*	–*	–*	–*
	Incised abscesses	–*	–*	–*	–*
Williams *et al.*, 1981[49]	Pilonidal wounds	–*	–*	✔	✔
Ricci *et al.*, 1998[44]	Pilonidal wounds	–*	✔	–*	–*
Polyurethane foam versus traditional gauze dressings					
Meyer, 1997[43]	Abdominal surgery or abscess incision	✔	✔	✔	✔
Alginate versus traditional gauze dressings					
Cannavo *et al.*, 1999[36]	Dehisced surgical abdominal wounds	–*	–*	–*	✔
Dawson *et al.*, 1992[38]	Abscess incision	–*	–*	✔	✔
Guillotreau *et al.*, 1996[41]	Abscess incision	–*	✔	✔	✔
Hydrocolloid versus traditional gauze dressings					
Viciano *et al.*, 2000[47]	Pilonidal wounds	–*	–*	✔	✔
Dextranomer polysaccharide versus traditional gauze dressings					
Goode *et al.*, 1979[40]	Broken down surgical wounds	–*	✔	–*	–*
Toenail avulsion					
Alginate versus traditional gauze dressings					
Foley and Allen, 1994[39]		✔	✔	–*	–*
Smith, 1992[45]		✔	✔	–*	–*
Van Gils *et al.*, 1998[46]		✔	✔	None investigated	
Hydrocolloid versus traditional gauze dressings					
Bruce, 1991[35]		✔	✔	–*	–*
Direct comparison of modern dressings					
Surgical wounds					
Polyurethane foam versus alginate dressings					
Berry *et al.*, 1996[34]	Pilonidal wounds	–*	–*	–*	–*
Polyurethane foam versus silicone foam dressings					
Butterworth *et al.*, 1992[37]	Abdominal and pilonidal wounds	–*	–*	–*	✔
Dextranomer polysaccharide versus silicone foam dressings					
Young and Wheeler, 1982[50]	Broken down surgical wounds	–*	–*	–*	–*

✔, *Positive effect of intervention (i.e. intervention shows greater benefit than control)*

**No significant effect reported*

dressings. Only one study found an overall effect on healing in favour of modern dressings.[43] A further four studies found some significant benefit of the modern dressings compared to traditional gauze dressings.[40–42,44] The study which found an overall beneficial effect in terms of healing also found an overall beneficial effect for the other outcomes investigated; this study compared polyurethane foam to gauze dressing.[43] Two of the four studies which found some significant effect of the modern dressing (alginate and silicone foam) on healing outcomes also found some significant effect on other outcomes.[41,42] One of these studies found an overall beneficial effect of alginate dressing compared to gauze for the other outcomes considered.[41] Three studies which did not find any difference between treatment groups for healing outcomes found an overall significant effect of the modern dressing on the other outcomes investigated.[38,47,49] These studies looked at silicone foam,[49] alginate dresings[38] and hydrocolloid dressings.[47] One further study found some significant benefit of the modern dressing (alginate) for outcomes other than healing.[36]

The four studies of toenail avulsions all found a significant difference in favour of modern dressings compared to gauze for the outcomes relating to healing but not for the other outcomes,[35,39,45,46] although one of these studies did not investigate any other outcomes.[46] Three of these studies compared alginate to gauze,[39,45,46] and the fourth compared hydrocolloid to gauze.[35]

In summary, there is a suggestion that modern dressings have a beneficial effect compared to traditional gauze dressings, especially for toenail avulsions, where significant benefits of modern dressings were found. This suggestion should be seen in the context of the poor quality of the studies, the fact that the direction of bias is unclear and the unknown effects of publication bias. There is some evidence to suggest a beneficial effect of modern dressings on other outcomes, such as pain, dressing performance and resource use, for surgical wounds, although a beneficial effect for these outcomes was not found for studies of toenail avulsions. However, in addition to the methodological problems highlighted above, these outcome measures are very difficult to assess and are particularly subject to bias, especially in unblinded studies.

Direct comparison of modern dressings

Only two studies compared different types of modern dressing. One study compared a polyurethane foam to silicone foam[37] and the second compared polyurethane foam to alginate.[34] Neither of these studies found any overall significant difference in healing outcomes or other outcomes between the two groups, although one of the studies did find a significant difference in favour of the polyurethane foam group for one of the other outcomes investigated.[37] In view of the lack of data, there is no evidence to support the superiority of one type of modern dressing over another.

Chapter 5

Results: cost-effectiveness

Quantity and quality of research available

Included studies

Three economic evaluations that met the inclusion criteria were identified.[36,48,51,60] Information relating to one study was derived from two publications.[51,60] For the purpose of this review the economic evaluation is referenced according to the latest publication.[51] Two further economic evaluations, included in the company submission data presented to NICE, met the inclusion criteria.[62,63]

There was heterogeneity between studies with regard to the type of debriding agent investigated, the comparator dressing and the type of study populations examined.

All included economic evaluations investigated the cost-effectiveness of the autolytic debriding method compared to traditional gauze dressings soaked in various antiseptic solutions. The type of dressings investigated varied, with two studies looking at silicone elastomer foam dressings,[48,51] one at polyurethane foam dressings[62] and one at calcium alginate dressings.[36]

The study population included in the economic evaluations varied. One study included patients from a gastrointestinal surgical unit with surgical abdominal wound breakdown,[36] one study included patients with granulating perineal wounds following abdominal excision of the rectum[51] and another study looked at patients who had received surgery for either pilonidal sinus or abscess.[48] Both economic evaluations submitted by pharmaceutical companies looked at participants with difficult to heal surgical wounds healing by secondary intention.[62,63] Neither study provided information on the type of surgical procedures that were undertaken.

All five studies were cost-effectiveness analyses. The source of effectiveness data for three of the economic evaluations was a single RCT with a small sample size.[36,48,51] All three RCTs are included in the effectiveness section of this review; they reported no significant difference between the interventions with regard to wound healing.[36,42,48] Two trials reported no significant difference between the treatment groups with regard to time to hospital discharge.[48,51] One trial reported significantly fewer district nurse visits among participants in the intervention group (silicone foam) compared to those in the control group.[51] Of the economic evaluations submitted by the pharmaceutical companies, the effectiveness data for one[62] were based on the findings of a single small RCT, one case study and a small NHS hospital survey. The RCT is included in the effectiveness section of this review; it reported a significant difference with regard to healing in favour of the intervention (polyurethane foam).[43] However, the decision to conduct a cost-minimisation analysis for the economic evaluation was based on the findings of a published systematic review of the literature on the debriding of chronic wounds, including surgical wounds healing by secondary intention.[30] The review concluded that, pending the availability of improved relative effectiveness data, other considerations, such as cost minimisation, may reasonably guide decisions on the use of debriding agents.[62]

All the included economic evaluations investigated costs from the perspective of either a single hospital or the health service (the NHS). The type of direct costs considered included dressing costs,[36,48,51,62,63] drug costs,[63] inpatient hospital stay (which includes nursing time),[36,48,51,62,63] costs incurred after discharge (outpatient and district nurse visits)[48,51,63] and travel time (for clinic or district nurse visits after discharge).[51,63]

Most economic evaluations were set in the UK and considered the cost in pounds sterling.[36,48,62,63] One economic evaluation was carried out in Australia and presented cost data in Australian dollars.[51] The cost years, where specified, were 1996,[36] 1989–1990[48] and 1982.[51]

Only one study used stochastic data, which were analysed using a one-way analysis of variance (ANOVA).[36]

Detailed information about the included economic evaluations is presented in appendix 6.

Quality of included economic evaluations

A summary of the quality assessment of the economic evaluations is presented in *Table 7*.

Question

All included economic evaluations reported clear objectives, and detailed information about the alternative dressing protocols was presented. Two economic evaluations did not specify the price year that was used.[62,63] One economic evaluation used staff costs based on 1998–1999 data and dressing acquisition costs in 1996 prices and did not describe how these were combined.[62]

Important costs

All economic evaluations were undertaken from the perspective of the NHS, and therefore only costs relating to the NHS were considered. The economic evaluations were considered to have incorporated the relevant costs and outcome measures for this perspective. None of the studies covered the patient viewpoint or conducted the evaluation from a societal view point. However, one study quantified lost productivity, reporting that some patients who received silicone elastomer foam dressings were able to return to work within one day of discharge, although this outcome was not costed.[48,51]

Source of clinical effectiveness data

The effectiveness data for four economic evaluations were obtained from small RCTs with uncertain results, and therefore a moderate or high risk of bias is present.[36,48,51,62] One economic evaluation also incorporated clinical effectiveness data from a very small hospital survey ($n = 5$) and one case study.[62] The variation in both cost-effectiveness and clinical effectiveness data cannot be reliably established from such small samples, and a number of assumptions would have had to be made. The study also failed to present information on how the data from the two sources were combined.

Outcome measures

Only economic evaluations that incorporated healing as an outcome measure were included in the review, and therefore all included studies were considered to have included important outcome measures. The healing rate of one trial also included surgical wounds that had been closed with secondary suture.[43,62] Two trials reported time to complete healing,[42,48,51] and one trial included healing rate (reduction in wound size).[36] Two studies also included the outcome measure of time to hospital discharge.[48,51] However, this is an intermediate outcome measure, as follow-up appointments or visits are usually still required. One economic evaluation included the number of nurse visits[51] and one incorporated information on the number of dressing changes.[62] Two economic evaluations also reported on pain as an outcome measure[36,62] and one included patient satisfaction with the dressing process.[36]

Accurate measurements of costs and outcomes

Costs were considered to have been measured accurately in all economic evaluations. The trials from which the clinical effectiveness data were derived suffered from validity problems (see page 12).[36,42,43,48] Problems included lack of blinding, no information reported on the method of randomisation and no ITT analysis. Subjective decisions, such as time to discharge, means that proper blinding is essential. Only one trial reported blinded outcome measures.[36] However, wound size and pain were the only outcome measures blinded. It was reported that three experienced surgical nurses, who were not working in the gastro-intestinal surgical unit, but were instructed in and familiar with the study protocol, conducted all 'blinded' assessments. No further information was provided on how the assessors were blinded and the success of blinding was not checked. This study also reported on the outcomes of time to discharge and patient satisfaction with dressings. The same trial measured wound depth using a depth gauge at the deepest point. Wound volume was then calculated from this single measurement. No reliability test for measuring wound depth was conducted. The initial wound size of the treatment groups in two trials was not comparable at baseline.[36,43] One trial did not present information on the baseline comparability of the intervention groups with regard to wound size.[48]

Prospective analysis

Ideally, costing should be undertaken prospectively (i.e. as part of the clinical trial) in order to ensure that all the important data relevant to the economic evaluation are collected and that appropriate statistical analysis is used. Costing was undertaken retrospectively in three of the economic evaluations.[48,51,62]

Valuation of costs

Costs were considered to have been valued credibly in all economic evaluations.

Sensitivity analysis

Issues of uncertainty can be dealt with using sensitivity analysis. Ideally, these should be multiway, include other variables and 95% CIs

TABLE 7 *Quality assessment of included economic evaluations**

Study	Type of economic evaluation†	Matrix letter‡	Question	Description of alternatives	Important costs/ outcomes identified	Clinically effective	Costs/ outcomes measured accurately	Prospective costing	Costs/ outcomes valued	Costs/ outcomes adjusted for timing	Incremental analysis	Sensitivity analysis	Included all issues of interest	Generalisabilitiy
Beiersdorf, 2000[62]	CEA/CMA	G	✔	✔	✔/✘	✔/✘	✔	✘	✔	NA	NA	✔	✔	✘
Cannavo *et al.*, 1988[36]	CEA/CCA	H	✔	✔	✔/✘	✔/✘	✔	✔	✔	NA	NA	✘	✔/✘	✔
ConvaTec, 2000[63]	_§	_§	_§	_§	_§	_§	_§	_§	_§	_§	_§	_§	_§	_§
Culyer and Wagstaff, 1984[51]	CEA	H	✔	✔	✔	✔	✔	✘	✔	NA	NA	✔	✔/✘	✔
Walker *et al.*, 1991[48]	CEA/CMA	H	✔	✔	✔/✘	✔/✘	✔	✘	✔	NA	NA	✘	✔/✘	✔/✘

✔, *Yes;* ✔, *no;* ✔/✔, *partially covered; NA, not appropriate*

**More detailed information relating to the questions used to assess quality of economic evaluations is presented in appendix 4*

† *CCA, Cost–consequence analysis; CEA, cost-effectiveness analysis; CMA, cost-minimisation analysis*

‡ *For classification of matrix score see* Figure 1

§ *Commercial in confidence data omitted*

should be incorporated. However, only three of the economic evaluations conducted such an analysis.[51,62,63] The remaining two studies used a sensitivity analysis that was limited to one-way and which included a worst-case/best-case scenario. One study recalculated the cost data while doubling the frequency of the intervention dressing changes (polyurethane foam)[62] and one study presented three estimates of cost for each variable (high, medium and low).[51]

Generalisability

The setting for two studies differed from that of a typical UK NHS setting and this should be taken into consideration when generalising the findings. One study was based in a naval hospital where participants were mainly servicemen living far outside the immediate hospital vicinity. This means that participants were discharged when healing was well advanced, as regular follow-up was difficult to arrange.[48] One trial was based in Australia, where staffing arrangements may differ from those in the UK.[36]

Assessment of cost-effectiveness

Silicone foam dressings versus traditional gauze dressings

Two economic evaluations investigated the cost-effectiveness of silicone foam dressings as compared to traditional gauze dressings.[48,51] One economic evaluation looked at participants who had received surgery for either pilonidal sinus or abscess[48] and the second included patients with granulating perineal wounds following abdominal excision of the rectum.[51] The type of costing reported by both studies included dressing costs, hospital stay and other costs incurred after discharge, such as district nurse visits. One study also incorporated travel costs.[51] There was no significant difference between the dressings in terms of either healing rate or time to discharge; silicone foam was found to be less expensive than traditional gauze dressings by both economic evaluations. Both studies therefore reported partial dominance in favour of the silicone foam dressing.

However, there are a few important methodological issues, in addition to the quality issues previously reported, that need to be considered when interpreting these results. The cost of hospital stay in one economic evaluation was calculated based on participants being discharged 3 days earlier in the silicone foam group.[48] This difference was not found to be significant. Another reasonable approach, therefore, would have been to assume zero days difference and use, for example, the 3 days difference in the sensitivity analysis. The cost year for one economic evaluation was 1982, and both clinical practice and costs will have changed since this date.[48,51]

Polyurethane foam versus traditional gauze dressings

One economic evaluation investigated the cost-effectiveness of polyurethane dressings as compared to traditional gauze dressings.[62] The study included patients with difficult to heal surgical wounds and demonstrated that the polyurethane dressing was dominant (less costly and more effective).

However, the economic evaluation had methodological problems. The findings of a small RCT[55] (n = 43) was used to show that patients treated with polyurethane foam experience more rapid wound healing as compared to gauze. Two sources were used for the cost data (a case study (n = 1) and a hospital survey (n = 5)) and no information was presented on how these were combined. Staff costs were based on 1998–1999 data and acquisition costs were based on 1996 prices. It was not stated how these were combined. Costing was undertaken retrospectively and was not conducted on the sample used in the effectiveness study, and therefore included a number of assumptions.

Calcium alginate dressings versus traditional gauze dressings

One economic evaluation investigated the cost-effectiveness of three dressing types in the management of dehisced surgical abdominal wounds.[36] Dressing protocols included calcium alginate dressings, sodium hypochlorite moistened gauze with Combine dressing pads (an absorbent wound dressing that consists of cotton wool and gauze), or Combine dressing pads alone. No significant difference was found between the interventions in terms of healing time, but both the alginate dressings and the Combine dressing pad were found to be economically advantageous.

The effectiveness trial had a small sample size (n = 36) as well as some validity problems, which should be taken into consideration when interpreting the results. The economic evaluation did not include a sensitivity analysis.

Modern semi-occlusive and occlusive dressings versus traditional gauze dressings

Paragraphs removed: commercially in confidence.

Summary of cost-effectiveness data

The conservative assumptions made by the economic evaluations from the effectiveness data are in agreement with the findings of the review. This assumes that publication bias would not affect the results. In other words, if the economic evaluations were based on a systematic review the same assumptions with regard to healing outcomes and length of hospital stay (i.e. no difference between the modern dressings and traditional gauze dressings) would have been made. This means that the decision to undertake cost-minimisation analysis is reasonable in light of our findings.

However, one economic study evaluated the cost of hospital stay using a cost-minimisation analysis based on the fact that the participants in the silicone foam dressing group had been discharged from hospital 3 days earlier than those in the gauze intervention group.[48] This was despite the fact that there was no significant difference between the two treatment groups with regard to length of hospital stay. This means that the results of this study may be too optimistic.

The results of the cost-effectiveness data lie within the region of grade H on the matrix presented in *Figure 1*. This represents partial dominance in favour of the intervention. However, it is important to note that the quality of the clinical effectiveness and cost-effectiveness analysis is poor.

Chapter 6
Discussion

Main results

Clinical effectiveness

The 17 studies that met the inclusion criteria all promoted autolytic debridement. No studies were found that investigated sharp/surgical, biosurgical, mechanical or enzymatic debridement, and no studies were found that evaluated the use of specialised wound clinics. The type of surgical wounds evaluated by the included studies were those that had broken down postoperatively, perineal wounds resulting from proctolectomy or rectal excision, and those left open after pilonidal excision or abscess incision, or wounds following a laparotomy. Four studies investigated treatment of postoperative wounds from toenail avulsions. The debriding agents investigated included foam dressings (silicone elastomer foam dressings and polyurethane foam dressings), alginate dressings, hydrocolloid dressings and dextranomer polysaccharide beads dressings. Most were compared to traditional gauze dressings, impregnated or otherwise. However, there was a great variation between trials with respect to the type of antiseptic solution with which the gauze was soaked and the type of gauze dressing used. Three trials included a direct comparison of modern dressings. One trial compared polyurethane foam to alginate dressings, and one trial included the comparison of polyurethane foam and silicone foam. The third trial compared dextranomer polysaccharide to silicone foam. No difference between the dressings was found with regard to healing.

As the included studies varied with respect to wound type and debriding agent used, as well as the type of comparator, statistical pooling of study results was deemed inappropriate. Most trials found no significant difference between modern dressings and conventional gauze dressings with regard to healing, but a number of studies showed modern dressings to be better than conventional gauze. The overall findings of the effectiveness data therefore suggest a beneficial effect in favour of the modern dressings compared to gauze, especially for toenail avulsions, where significant benefits of modern dressings were found. This suggestion should be seen in the context of the poor quality of the studies, the fact that the direction of bias is unclear and the unknown effects of potential publication bias. None of the included studies found traditional gauze dressings to be more effective than modern dressings. However, this could also be an indication that publication bias is present, especially as all the included trials were relatively small, or if bias is operating in the same direction in all trials in favour of modern dressings.

Cost-effectiveness

All the included economic evaluations investigated the cost-effectiveness of autolytic debriding compared with traditional gauze dressings soaked in various antiseptic solutions. The type of dressings investigated varied, with two studies looking at silicone elastomer foam dressings, one study investigating polyurethane dressings and one study looking at calcium alginate dressings. No economic evaluations that compared the cost-effectiveness of two different types of modern dressings were found. No economic evaluations investigating specialised wound care clinics were found.

All four studies were cost-effectiveness analyses and two studies went on to undertake a cost-minimisation analysis. For three of the economic evaluations the sources of effectiveness data were single small RCTs.

However, the conservative assumptions made by the economic evaluations on the effectiveness data are in agreement with the findings of the review, assuming that publication bias would not affect the results. This means that the decision to undertake cost-minimisation analysis is reasonable in the light of our findings.

The results of the cost-effectiveness data suggest partial dominance in favour of the intervention, with only the cost data supporting the use of the intervention dressings (modern dressings found to have lower costs compared to the gauze dressings, but with no difference in the outcome measures). However, the quality of the clinical effectiveness and cost-effectiveness analysis is poor.

Assumptions, limitations and uncertainties

Effectiveness data

Included trials were generally very small and the majority had methodological problems. There were also problems with regard to poor reporting. It is important that trials are not only conducted well but are also reported adequately. Readers should not have to infer what was probably done, they should be told explicitly.[64]

Information relating to secondary dressings used by included trials was very poorly reported, and it was therefore difficult to ascertain if a moist wound environment had been provided in the comparator group. The interventions evaluated by some included trials may not be suitable for wound management to the end-point of complete healing. If the intervention is changed (e.g. where the wound becomes filled with granulation tissue or exudate levels become very low (e.g. too low for the use of alginate dressings)) then the dressing protocol needs to be described explicitly. It was generally not clear when decisions were made to change dressing protocols and to what type of dressing. In order to associate any treatment differences with a particular product one has to assume that all patients in all treatment groups received identical wound management with the exception of the intervention under investigation.

Most included trials (76%) failed to state the method of randomisation procedure used and none of the trials reported any allocation concealment. Proper randomisation ensures that selection bias is avoided by ensuring that participants have a pre-specified (very often an equal) chance of being assigned to the experimental or control group.[65] An adequate procedure for generating a random number list should therefore be used. None of the studies reported on concealment of treatment allocation. Prior knowledge of group assignments leaves the allocation sequence subject to manipulation by researchers and participants.[65] Concealed random allocation of treatments, by an independent person not responsible for determining the eligibility of patients, is therefore essential. Previous research has demonstrated that RCTs and non-randomised controlled trials may produce different results.[66] RCTs that have used an inadequate randomisation procedure or have not clearly demonstrated allocation concealment may overestimate the treatment effect size.[66]

The majority of included trials (94%) did not report using blinding of outcome assessors, and none of the trials reported blinding of treatment administrators. Blinding is very important in that it avoids observer bias, and it is therefore essential for any subjective outcome measures such as the assessment of the wound being completely healed and the exact timing of healing, pain, comfort and granulation. Previous research has shown that non-blinded studies can overestimate the treatment effect.[66,67] Non-blindness of administrators can also result in the biased administration of co-interventions.

The details of the initial wound size were not reported by almost half (47%) of the included trials. Information relating to the comparability of groups with regard to other important baseline characteristics was also very limited. Prognostic similarity at baseline is important for drawing causal differences in therapeutic effects found.[68] If there are any baseline differences between treatment groups, which favour either group, then this should be adjusted for in the analysis. Five trials reported differences between the treatment groups with regard to the initial wound size. None of these trials reported making any allowances for this during data analysis.

Information relating to the methods used to measure wound size were poorly reported. Only nine trials reported information on wound measurement.[35–37,40–43,45,50] Eight trials reported using a photographic record of wounds, but none stated any further details on how the photographs were interpreted.[35–37,40,41,43,45,50] Two trials reported using tracings of the wound, but again no further description of the method was given.[35,41] Two trials used a stick and a ruler, one trial reported using sterile swabs and one trial filled the wound with sterile saline, but gave no further details.[36,37] One trial reported taking volumetric measurements using impression material (type not stated) or saline,[43] but gave no further details and did not state how many wounds were measured with each method, and one trial reported using silicone elastomer foam dressing to measure the volume of water displacement.[42]

Only one trial reported testing the reliability of the wound measurements taken.[36] This was conducted by correlating ruler and photographic measurements on a sample of the wounds assessed. However, only the measurement of wound diameter was tested. Wound depth was measured using a depth gauge at a single point, which was considered to be the deepest point. The reliability of this measurement was not

assessed, but it was used to calculate the wound volume. The results were analysed with respect to wound volume.

Most other outcome measures evaluated by the trials, such as pain, comfort and dressing performance, were subjective in nature. In addition, some trials included a subjective outcome measure of healing (this is in addition to an objective outcome measure required for inclusion), such as time to dry dressing and time to cavity fill. Subjective outcome measures are unlikely to be measured consistently between wounds.[30] None of the included studies validated the measurement of these measures or tested the reliability of the measurements taken (either inter-rater or intra-rater reliability). This is likely to lead to misleading results. It is also considered that subjective measures usually overestimate the relative effectiveness of the experimental treatment compared to objective measurements in the same trial.[30]

The change in wound area (or volume) can be expressed as either the percentage change or the absolute change. The percentage change takes into account the initial size of the wound. For two wounds healing at the same linear rate (as measured by the diameter reduction), the percentage area calculation will show a larger change for a small wound than a big wound.[30] The opposite is true when reporting the absolute change in wound area, as a bigger reduction in the wound radius will occur for larger wounds. It is therefore important that studies that report incompatibility with regard to initial wound size should present the results on a change in wound area as both the percentage change and the absolute change. This will enable the reader to ascertain that the change data are in the same direction for both measurements. Of the nine trials that reported baseline wound measurements, five reported incomparability with regard to initial wound size. Four of these trials used reduction in wound size as an outcome measure, of which only two trials reported both the absolute and the percentage change.

Wounds rarely heal at a linear rate, with some wounds enlarging prior to healing while others initially decrease rapidly in size before experiencing a slower rate of healing.[30] Therefore, the percentage change in wound area or volume based on a linear rate would not give an accurate estimate of the rate of healing. Complete healing is therefore seen as the most valid outcome in studies of wound healing.[30]

The majority of included trials (70%) followed up participants until complete healing had occurred, using the healing time as an outcome measure. All but two trials reported mean values for time to complete healing. Mean values are greatly affected by outliers and, unlike median values, cannot be calculated if some wounds fail to heal. None of the included trials of surgical wounds used survival analysis (where survival indicates the proportion of wound survival, i.e. not healed, at any point of time during follow-up)[68] or reported hazard ratios (the ratio of the wound closure probabilities per unit time).[68]

Four of the included trials reported number of wounds healed over a specific time period (i.e. at the end of the study). These trials included a relatively short follow-up period (range 3–8 weeks). It was unlikely that all participants underwent the surgical procedure at the same time, and therefore a short follow-up period may not have been adequate. However, if the length of follow-up is too long then most wounds will have completely healed at the end of the trial. The use of a survival analysis which takes into account both whether and when the wound healed would have been a more appropriate analysis to use. None of the trials used a survival analysis.

Study results should be presented in enough detail to enable the reader to re-analyse the data. For surgical wounds, only 50% of included trials reported sufficient data to calculate a summary estimate of the treatment effect for one or more healing outcome measures, and only 15% for one or more other outcome measures. For toenail avulsion surgery, 80% of included trials reported sufficient data on healing outcome measures and 33% for other outcome measures.

Twenty-eight per cent of the included trials did not undertake a statistical analysis to compare the treatment groups and 44% did not report what statistical test was used to analyse the data. It was therefore not possible to ascertain whether the correct statistical test was undertaken in almost half of the included trials. Ideally, studies should report which statistical test they were planning on using to analyse the data. The reader can then be more confident that a significant result was obtained using the planned test.

None of the trials reported using an ITT analysis, where participants are analysed according to the groups to which they were initially randomly allocated, regardless of whether or not they dropped out, fully complied with the treatment,

or crossed over and received the other treatment. Such an analysis protects against attrition bias.[65] Ignoring the findings of all withdrawals, drop-outs and non-responders means that only those who fully complied with treatment were included in the analysis, which could lead to an over-estimation of the treatment effect.

Some of the included trials reported a large number of outcome measures. Five trials reported on more than five outcome measures. The trial that reported the greatest number of outcomes reported nine measures. If trials investigate a sufficient number of outcome measures it becomes more probable that a significant result will be found by chance.

The included trials had small sample sizes, ranging from 12 to 80 participants (median 43). A small sample size means that the randomisation process is unlikely to ensure that initial wound measurements, as well as other important prognostic factors, will be comparable at baseline. Small trials are unlikely to measure any treatment effects with good precision (i.e. the CI will be wide).

Many factors affect wound healing, such as underlying medical conditions that can impede the body's defence system (e.g. diabetes and rheumatoid arthritis), concurrent medical treatment (e.g. immunosuppressant drugs and steroids), the risk of infection due to the type of surgery that was undertaken and the nutritional status of the patient. This means that much larger trials, with careful consideration given to the type of inclusion and exclusion criteria used, are needed to show the effectiveness of specific interventions.

Twenty-three studies were excluded because they were not reported in one of the languages considered for inclusion. It was not possible to ascertain if they met inclusion criteria (appropriate study design, intervention, wound type and outcome measure). Fifteen of these studies were reported in Russian. Three studies were reported in Italian and the remaining studies were published in Danish, Japanese, Portuguese or Spanish, and one study was from Scandinavia. Authors whose first language is not English may be more likely to publish positive findings in English-language journals, because they are considered to have a greater international impact.[69] This means that the exclusion of non-English studies could lead to overoptimistic conclusions. The language restrictions used in this review were due to the time constraints and it is acknowledged that some publication bias may therefore be present.

Another source of publication bias is where trials that do not show the intervention to be effective, or do not report significant findings, do not get published. This may be due to the reluctance of the authors themselves or due to the editorial policies of editors.[70] This can be a particular problem with industry-sponsored studies, with companies often only wanting to publish positive results relating to their products. Five of the 17 included studies reported being sponsored by a pharmaceutical company, although it is possible that others were industry sponsored but did not report this.

Due to the poor reporting of outcome measures and the different outcome measures used by included studies it was not possible to investigate the effect of publication bias either graphically or statistically.

Economic evaluation

The valid application of a cost-minimisation analysis requires that the patient outcomes associated with each procedure are the same. All four economic evaluations undertook a cost-effectiveness analysis and two went on to undertake a cost-minimisation analysis. Considering the overall findings of the effectiveness part of the review, this type of analysis is considered appropriate, as modern dressings were found to be marginally more effective than conventional gauze dressings.

However, three of the included economic evaluations made assumptions based on the findings of very small single RCTs that found no significant difference between the treatment groups with regard to wound healing. A non-significant finding does not mean that the interventions were equivalent. For equivalence to be 'proven' the CIs of the summary effect have to be quite narrow. This means that small trials showing a non-significant difference between the interventions do not prove equivalence, as such studies may lack the power to detect significant difference.

It is also important to remember that the poor quality of effectiveness trials is reflected in the economic evaluations. There were also some methodological problems in the economic evaluations themselves, including lack of sensitivity analysis, absence of statistical analysis and the use of retrospective costing.

Need for further research

The review has identified the following areas for future research:

- Large multicentre trials of good methodological quality comparing foam, alginate, hydrofibre, hydrocolloid or dextranomer beads dressings to standard treatment or, preferably, to each other. It is acknowledged that it may be difficult to recruit sufficient numbers with similar wounds from a single centre or hospital.
- More good-quality economic evaluations of modern dressings that are based on sound scientific evidence, such as good-quality primary RCTs. This means that information relating to such outcome measures as the time taken to change dressings, the number of dressing changes required and the number of nursing visits is measured accurately. Economic evaluations would also need to utilise sensitivity analyses that investigate the effect of adjusting these variables on the overall findings.
- RCTs of other autolytic debriding methods not covered by included trials, such as hydrogels.
- Further research, on both clinical effectiveness and cost-effectiveness, into the use of other debriding methods, such as enzymatic, biosurgical and surgical methods, in the treatment of surgical wounds healing by secondary intention.
- Because there is no research available on the organisation of care, such as the use of specialist wound care clinics, research that includes studies looking at both the clinical effectiveness and cost-effectiveness of the use of specialised wound care clinics is required.
- Further epidemiological studies to evaluate the extent of the problem (i.e. the prevalence and cost to the NHS of treating surgical wounds healing by secondary intention where there is a delay in the healing process).

It is recommended that future research be independently funded. It is also suggested that the association of professional organisations may take the responsibility of organising such research.

Chapter 7

Conclusions

The majority of included studies were UK based, within the NHS setting. Two of the included trials were based in a military hospital and five trials were based outside the UK. The countries of origin for these trials were Australia, the USA, France, Italy and Spain.

In summary, there is a suggestion that modern dressings have a beneficial effect compared to traditional gauze dressings, especially for toenail avulsions, where significant benefits of modern dressings were found. This suggestion should be seen in the context of the poor quality of the studies, the fact that the direction of bias is unclear and the unknown effects of potential publication bias. There are insufficient data to support the superiority of one type of modern dressing over another.

The results of the cost-effectiveness data suggest partial dominance in favour of the intervention. However, the poor quality of the clinical effectiveness and cost-effectiveness analysis limits the full endorsement of this interpretation.

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External advisory panel

Nicky Cullum, Reader/Co-ordinating Editor, Cochrane Wounds Group, Centre for Evidence Based Nursing, Department of Health Studies, University of York, Genesis 6, York Science Park, Heslington, York YO10 5DQ, UK.

Andrea Nelson, Research Fellow/Review Group Co-ordinator, Cochrane Wounds Group, Centre for Evidence Based Nursing, Department of Health Studies, University of York, Genesis 6, York Science Park, Heslington, York YO10 5DQ, UK.

Peter Moore, Consultant Surgeon, Scunthorpe General Hospital, Cliff Gardens, Scunthorpe DN15 7BH, UK.

Liz Scanlon, Nurse Consultant – Tissue Viability, Centre for the Analysis of Nursing Practice, Leeds Community and Mental Health Trust, Mansion House, Meanwood Park Hospital, Tongue Lane, Leeds LS6 4QB, UK.

Christine Moffatt, Professor of Nursing, The Centre for Research and Implementation of Clinical Practice (CRICP) (part of Thames Valley University), Wolfson Institute of Health Sciences, 32–38 Uxbridge Road, London W5 2BS, UK.

Assistance with economics data

Boyka Stoykova, Research Fellow (NHS EED Project), NHS Centre for Reviews and Dissemination, University of York, Heslington, York YO10 5DD, UK.

John Nixon, Research Fellow (NHS EED Project), NHS Centre for Reviews and Dissemination, University of York, Heslington, York YO10 5DD, UK.

Reading draft copies of the report

Jos Kleijnen, Director, NHS Centre for Reviews and Dissemination, University of York, Heslington, York YO10 5DD, UK.

Conducting initial literature searches

Ruth Frankish, Information Specialist, Appraisals, National Institute for Clinical Excellence, 11 Strand, London WC2N 5HR, UK.

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Appendix 1

Classification of debriding methods and agents

TABLE 8 *Classification of debriding methods and agents*

Classification	Selectiveness*	Method of debridement	Type of debriding agent/dressings	Examples of products
Surgical	Non-selective[8]	Sharp instrument	**Scalpel** – quick but imprecise	
Biosurgical	Selective	Biosurgery	**Maggot larvae** – the maggots destroy dead tissue by liquefying it with enzymes and ingesting it[12]	'LarvE' (Biosurgical Research Unit)
Mechanical	Non-selective	Wet-to-dry dressing	**Gauze dressing soaked in saline** – drying dressings debride mechanically by taking tissue from the wound surface indiscriminately[12]	
		Pressurised wound irrigation (for small wounds)		
		Whirlpool – using jets of water (large wounds)		
		Adherent dressings	**Gauze dressings**	
			Gauze-based dressings – non- or low-adherent gauze derivatives (developed to overcome the problem of adherence associated with tulle dressings):[71]	(These dressings may not be specifically used for debriding)
			perforated film absorbent dressing	Melolin, Mepore, Release, Skintact
			knitted viscous primary dressing	N-A Dressing
			povidone iodine fabric dressing	Inadine
			Tulle dressings: tulles (non-medicated) are made of open-weave cotton or rayon impregnated with soft paraffin	Jelonet, Paratulle, Unitulle
			tulles (medicated) are impregnated with either antiseptics or antibiotics	The commonest type of antiseptic is chlorhexidine, present in Bactigras, Chlorhexitulle and Serotulle. Two tulles are impregnated with antibiotics, Fucidin Intertulle and Sofra-Tulle. The use of these dressings is not recommended because of the problems of sensitivity and resistance of bacteria

* *Selective debridement removes only necrotic tissue, whereas non-selective debridement does not discriminate between viable and non-viable tissue and removes both from the wound*[8]

continued

TABLE 8 contd *Classification of debriding methods and agents*

Classification	Selectiveness*	Method of debridement	Type of debriding agent/dressings	Examples of products
Chemical	Selective method	Hypochlorite solution	Sodium hypochlorite, hydrogen peroxide	Dakin's solution, Eusol
		Caustic agents	Malic acid, benzoic acid, salicylic acid, propylene glycol	Aserbine (Goldshield)
Enzymatic	Selective method	Topical enzymes (target-specific necrotic tissue):	**Streptokinase and streptodornase** (in powder form):	
		proteolytics	trypsin	Varidase (Lederle Laboratories)
		fibrinolytics		
		collagenase	collagenase	Crab collagenase, krill
Autolytic	Highly selective method	Dressings to support wound healing – moisture retention dressing. The body will naturally debride dead tissue with enzymes generated by inflammatory and other cells. The process can be speeded up by the creation of a moist environment[12]	**Hydrocolloids/hydrocolloid wafers (occlusive dressings)** – hydrocolloids are a type of dressing containing gel-forming agents, such as sodium carboxymethylcellulose (NaCMC) and gelatine. In many products, these are combined with elastomers and adhesives and applied to a carrier (usually poly-urethane foam or film) to form an absorbent, self-adhesive, waterproof wafer In the presence of wound exudate, hydrocolloids absorb liquid and form a gel, the properties of which are determined by the nature of the formulation. Some dressings form a cohesive gel, which is largely contained within the adhesive matrix; others form more mobile, less viscous gels which are not retained within the dressing structure. In the intact state most hydrocolloids are impermeable to water vapour, but as the gelling process takes place the dressing becomes progressively more permeable Also available in the form of powders, fibre and paste. Powder forms are also available as an ointment or slab of ointment	Flat dressing sheets: Improved Formulation Granuflex, Comfeel Plus, Tegasorb, Tegasorb Advanced Formulation, Cutinova Foam, Hydrocoll, CombiDERM (ConvaTec), Hydrocoll Basic, DuoDerm Extra Thin, Hydrocoll Extra Thin, Aquacel (Convatec Ltd) Cavity dressings: Aquacel Ribbon

* *Selective debridement removes only necrotic tissue, whereas non-selective debridement does not discriminate between viable and non-viable tissue and removes both from the wound*[8]

continued

TABLE 8 contd *Classification of debriding methods and agents*

Classification	Selectiveness*	Method of debridement	Type of debriding agent/dressings	Examples of products
Autolytic *contd*			**Polysaccharide beads or paste** (sometimes referred to as dextranomers, xerogels or codexomer iodine) – consist of powder or beads, which swell and gel in the presence of exudate	Debrisan (Pharmacia Ltd) – a polysaccharide bead dressing Iodosorb (Perstorp), similar to Debrisan but contains an element of iodine, Iodoflex
			Hydrogels/gels (virtually impermeable to moisture) – made from insoluble polymers and have a large water content. Most share a common basic structure of about 2–3% of a gel-forming polymer such as NaCMC, modified starch or sodium alginate, together with 20% propylene glycol as a humecant, and preservative. The balance (about 80%) consists of water[72]	Intrasite Gel (Smith and Nephew Medical Ltd), Granugel Hydrocolloid Gel (Convatec Ltd), Sterigel (Seton Health Care Ltd), Nu-gel (Johnson and Johnson Medical Ltd), Purilon Gel (Coloplast), Aquaform Hydrogel, Gel sheets – 2nd Skin, Vigilon
			Alginate dressings – produced from the calcium and sodium salts of alginic acid, a polymer derived from seaweed. These are activated by wound exudate to produce a hydrophilic-like gel, which is believed to promote wound healing.[17] Available in a variety of formats (flat dressing, rope or ribbon)	Flat dressing sheets: Sorbsan (Maersk), Sorbsan Plus (Maersk), Tegagen (3M Health Care Ltd), Kaltostat (Convatec Ltd), Kaltogel (Convatec Ltd), Comfeel SeaSorb (Coloplast), Algisite M, Algosteril, Kaltogel, Meligsorb Cavity dressings: Algisite M Rope, Algosteril Rope, Cutinova Cavity, Kaltostat, Megisorb Cavity, Seasorb Filler, Sorbsan Packing, Sorbsan Ribbon
			Foam dressings – may be made from polyurethane or silicone. Absorb liquid by capillary action	Flat foam dressing: Allevyn (Smith & Nephew), Lyfoam (Seton), Tielle (Johnson & Johnson), Flexipore (Polymedia), Lyofoam Extra (Seton), Spyrosorb (Perstrop) Filler for cavity wounds: Allevyn Cavity Wound Dressing (Cavi-care), Silastic (Dow Corning Ltd)
			Vapour-permeable adhesive films and membranes – these allow the passage of water vapour and oxygen, but not of water or micro-organisms, and are suitable for mildly exudating wounds.[71] Commonly used as secondary dressings over alginates and hydrogels	Bioclusive, Cutifilm, EpiView, Mefilm, Opsite Flexigrid, Tegaderm, Spyrosorb, Flexipore, Omiderm, Surfasoft or Tegapore

* *Selective debridement removes only necrotic tissue, whereas non-selective debridement does not discriminate between viable and non-viable tissue and removes both from the wound*[8]

Appendix 2

List of excluded studies

To be included in the review, studies had to fulfil all the following criteria:

- The study design must be an RCT, controlled trial (with concurrent control) or a full economic evaluation (cost-effectiveness/cost-minimisation analysis, cost–utility analysis or cost–benefit analysis).
- The study must evaluate some sort of debriding method (which may include products noted to have debriding properties, see appendix 1) or a specialised wound care clinic (a nurse with specialist training in wound care; care being provided by a multidisciplinary team, or by a fast-track referral system to other professions (e.g. dermatologist); or access to the latest health technology).
- The study must include patients with surgical wounds healing by secondary intention.
- The study must include an objective outcome measure of wound healing.

TABLE 9 *Summary of excluded studies*

Study	Study design	Intervention	Wound type	Outcome	Comments
Abasov *et al.*, 1982[73]	?	?	?	?	Russian
Ahmed *et al.*, 1997[74]	No	Yes	No	No	Catheter site wound
Akesson *et al.*, 1984[75]	No	Yes	No	No	No control group or measure of healing; mixture of appropriate wounds and ulcers, not analysed separately
Alsbjorn *et al.*, 1990[76]	Yes	Yes	No	Yes	Wounds left by removal of drainage tubes
Anon., 1991[77]	Yes	No	Yes	Yes	Aloe vera used as intervention, which is reported to have anti-inflammatory properties and therefore is not considered to be a debriding agent
Aragona *et al.*, 1984[78]	?	?	?	?	Italian
Arnold, 1992[79]	No	No	Yes	Yes	Retrospective study of wound care at home
Arnold and Weir, 1994[80]	No	Yes	No	Yes	Retrospective study of enterostomal nurse versus staff nurse in the home; mixture of appropriate wounds and ulcers, not analysed separately
Bale *et al.*, 1994[81]	Yes	Yes	No	Yes	Mixture of appropriate wounds and ulcers, not analysed separately, mainly chronic
Banks *et al.*, 1995[82]	Yes	Yes	No	No	Chronic wounds; no measure of healing
Banks *et al.*, 1995[83]	Yes	Yes	No	Yes	Chronic wounds
Banks *et al.,* 1997[84]	Yes	Yes	No	No	Mixed wound types reported together; no measure of healing
Bridel-Nixon *et al.*, 1998[85]	Yes	No	No	No	Incidence of postoperative pressure sores
Briggs, 1996[86]	Yes	No	No	No	Sutured wounds; inappropriate intervention and no measure of healing
Brown *et al.*, 1991[87]	Yes	No	No	Yes	Epidermal growth factor investigated in ulcers
Calligaro *et al.*, 1994[88]	No	Yes	No	Yes	No control group
Cassino, 1998[208]	Yes	Yes	No	Yes	Chronic wounds
Cassino, 1998[209]	Yes	Yes	No	Yes	Chronic wounds
Cespa et al., 1984[89]	No	?	?	?	Italian
Chalmers and Turner, 1996[90]	No	Yes	Yes	Yes	Case study
Chevretton *et al.*, 1991[91]	No	Yes	Yes	No	Retrospective study, control not concurrent; no measure of wound healing
Church, 1995[92]	No	Yes	No	No	Report of other studies using maggots
Coerper *et al.*, 1999[93]	No	Yes	No	Yes	Chronic wounds
Creese *et al.*, 1986[94]	Yes	Yes	No	Yes	Mixture of appropriate wounds and ulcers, not analysed separately
Dahlstrom, 1995[95]	Yes	Yes	No	No	Split skingraft, no measure of wound healing
Davis *et al.*, 1987[96]	No	No	No	Yes	Animal study on aloe vera
Di Maggio *et al.*, 1994[97]	?	?	?	?	Spanish
Donnelly and Maxwell, 1997[98]	No	Yes	Yes	Yes	Case history
Drago *et al.*, 1983[99]	Yes	Yes	Yes	No	No information on healing (only data on pain, drainage, exudate, infection, days to wearing normal shoes presented)
Efendiev *et al.*, 1991[100]	?	?	?	?	Russian
Eldrup, 1985[101]	?	?	?	?	Danish
Ersh, 1984[102]	?	?	?	?	Russian
Estienne *et al.*, 1989[103]	Yes	Yes	Yes	Yes	Italian

continued

TABLE 9 contd *Summary of excluded studies*

Study	Study design	Intervention	Wound type	Outcome	Comments
Flanagan, 1995[104]	Yes	Yes	No	Yes	Chronic and traumatic wounds
Fleishmann *et al.*, 1999[105]	No	Yes	Yes	No	No control group
Foster *et al.*, 2000[106]	Yes	Yes	Yes	No	No measure of healing
Foster and Moore, 1997[107]	Yes	Yes	Yes	No	No measure of healing
Foster and Moore, 1997[108]	No	Yes	Yes	Yes	Case study
Foster and Moore, 1997[109]	Yes	Yes	Yes	No	No measure of healing
Foster and Moore, 1997[110]	Yes	Yes	Yes	No	No measure of healing
Freeman *et al.*, 1981[111]	Yes	Yes	No	No	Chronic wounds; no measure of healing (bacterial growth measured)
Gainant *et al.*, 1989[112]	Yes	No	No	Yes	Looked at method of preventing wound dehiscence
Gardezi *et al.*, 1983[113]	Yes	Yes	No	Yes	Sutured wounds
Gates and Holloway, 1992[114]	Yes	Yes	Yes	No	No objective measure of wound healing
Goode *et al.*, 1985[115]	Yes	Yes	Yes	No	No objective measure of wound healing
Gostishchev *et al.*, 1985[116]	?	?	?	?	Russian
Gostishchev *et al.*, 1985[117]	?	?	?	?	Russian
Gostishchev *et al.*, 1993[118]	?	?	?	?	Russian
Gostishchev *et al.*, 1983[119]	?	?	?	?	Russian
Gostitshchev *et al.*, 1985[120]	?	?	?	?	Russian
Grabski *et al.*, 1995[121]	No	Yes	No	No	Descriptive study
Gupta *et al.*, 1991[122]	Yes	Yes	Yes	No	No measure of healing (pain level and analgesic use presented)
Hancevic *et al.*, 1980[123]	No	Yes	No	No	Croatian; no control group
Heng *et al.*, 2000[124]	No	No	No	Yes	Feasibility study of hypertonic oxygen
Hermans, 1993[125]	Yes	Yes	No	Yes	Sutured wounds
Herzberg, 1985[126]	No	Yes	Not clear	Yes	No control group; not clear if wounds were of appropriate type
Hien *et al.*, 1988[127]	Yes	Yes	No	Yes	Clean wounds, did not require debriding
Hughes, 1986[128]	Yes	Yes	Not clear	No	No measure of healing; not clear whether wounds were of appropriate type
Hulkko *et al.*, 1981[129]	Yes	Yes	No	Yes	Mixture of wounds, including venous leg ulcers, results not presented separately
Ingram *et al.*, 1998[130]	Yes	Yes	Yes	No	No measure of wound healing (pain assessed as primary outcome)
Johnson *et al.*, 1985[131]	Yes	Yes	No	Yes	Sutured wounds
Johnson and Jones, 1988[132]	No	Yes	Yes	Yes	No control group
Joshi *et al.*, 1986[133]	No	Yes	No	Yes	No control; chronic wounds
Kallehave *et al.*, 1994[134]	No	Yes	Yes	Yes	No control group
Kauer and Siodmak, 1984[135]	No	Yes	No	No	No control group; chronic wounds; no measure of healing
Kavkalo, 1984[136]	?	?	?	?	Russian
Krupski *et al.*, 1991[137]	Yes	No	No	Yes	Platelet derived wound healing factor in chronic wounds
Kubatov *et al.*, 1984[138]	?	?	?	?	Russian
Kulikov *et al.*, 1983[139]	?	?	?	?	Russian
Lang, 1981[140]	No	?	?	?	Not an RCT or controlled trial; case studies
Lees *et al.*, 1991[141]	Yes	Yes	Yes	No	No measure of healing (pain used as outcome measure)

continued

TABLE 9 contd *Summary of excluded studies*

Study	Study design	Intervention	Wound type	Outcome	Comments
Legray and Greco, 1979[142]	No	Yes	No	No	Chronic wounds; no measure of healing
Levine *et al.*, 1976[143]	Yes	Yes	No	No	Burn wounds; no measure of healing
Linke *et al.*, 1986[144]	Yes	Yes	Yes	No	No measure of wound healing (assessed physician and nurse assessment of superiority, and acceptance of patients)
Lippert and Zeh, 1991[145]	No	Yes	Yes	No	No control group or measure of healing
Marks *et al.,* 1985[146]	Yes	No	Yes	Yes	Antibiotic therapy, no debridement
Mateev *et al.*, 1976[147]	?	?	?	?	Russian
McCulloch and Kemper, 1993[148]	No	No	Yes	Yes	Case report of vacuum compression
Michie and Hugill, 1994[149]	Yes	Yes	No	No	Wounds sutured; no measure of healing
Michiels and Christiaens, 1990[150]	Yes	Yes	Yes	No	No measure of healing
Moore and Foster, 2000[14]	Yes	Yes	Yes	No	No measure of healing
Moore *et al.*, 1999[151]	No	Yes	Yes	Yes	Case study
Moore and Foster, 1996[152]	Yes	Yes	Yes	No	No results for an objective measure of healing presented
Morgan *et al.*, 1980[153]	No	Yes	Yes	Yes	No control group
Moshakis *et al.*, 1984[154]	Yes	Yes	No	No	Sutured wounds; no measure of healing
Mosher *et al.,* 1999[155]	No	Yes	No	Yes	Chronic wounds
Mulder and Andrews, 1993[156]	Yes	Yes	No	Yes	Chronic wounds
Mulder, 1995[157]	Yes	Yes	No	Yes	Mixture of wounds (venous, trauma and pressure)
Mulder, 1995[158]	Yes	Yes	No	No	Chronic wounds, no measure of healing
Muller *et al.*, 1994[159]	No	Yes	Yes	Yes	Description of a trial to be conducted
Nash *et al.*, 1994[160]	No	Yes	Yes	Yes	No control group
Nepi, 1992[161]	No	?	?	?	Italian
Niinkoski and Renvall, 1980[162]	No	Yes	No	Yes	Animal study
Paul, 1990[163]	No	Yes	No	Yes	No control group; inappropriate wound (ulcer)
Pendse *et al.*, 1993[164]	Yes	Yes	No	Yes	Chronic wounds
Petrosian, 1993[165]	?	?	?	?	Russian
Phan *et al.*, 1993[166]	Yes	Yes	Yes	No	No measure of healing (wound infection primary outcome)
Philbeck *et al.,* 1999[167]	No	No	No	Yes	Descriptive study; vacuum therapy (not a debriding agent) in chronic wounds
Platt and Becknall, 1984[168]	No	No	No	Yes	Animal study
Plaumann *et al.*, 1985[169]	Yes	Yes	Yes	No	No measure of healing (bacterial counts only)
Pogosov *et al.*, 1991[170]	?	?	?	?	Russian
Ponnighaus and Kowalzick, 1999[171]	Yes	Yes	Yes	No	No measure of healing
Ponzio *et al.*, 1981[172]	?	?	?	?	Portuguese
Poulsen *et al.*, 1983[173]	Yes	Yes	Yes	No	No measure of healing
Rasmussen *et al.*, 1993[174]	Yes	Yes	No	No	Wounds did not require debridement; no measure of wound healing
Rees and Hirshberg, 1999[175]	No	Yes	No	No	Not a trial; chronic wounds; no measure of healing
Regan, 1992[176]	No	Yes	Yes	Yes	Case studies; no control

continued

TABLE 9 contd *Summary of excluded studies*

Study	Study design	Intervention	Wound type	Outcome	Comments
Ricci *et al.*, 1995[177]	No	Yes	No	Yes	No control or surgical wound
Ricci *et al.*, 1998[178]	No	Yes	No	Yes	No control; chronic wounds
Sakai *et al.*, 1992[179]	?	?	?	?	Japanese
Schmidt *et al.*, 1991[180]	Yes	No	Yes	Yes	Aloe vera used as intervention, which is reported to have anti-inflammatory properties and therefore is not considered to be a debriding agent
Schmitt *et al.*, 1996[181]	Yes	No	No	Yes	Sutured wounds
Schwarz, 1981[182]	No	Yes	Yes	Yes	No control group
Shukla, 1983[183]	No	Yes	Yes	Yes	No control group
Soul, 1978[184]	No	Yes	Yes	Yes	No control group
Steed *et al.*, 1996[185]	No	Yes	No	No	Not a controlled trial or RCT; chronic wounds; no measure of wound healing
Stuwe, 1983[186]	Yes	Yes	Yes	No	No measure of wound healing
Suomalainen, 1983[187]	Yes	Yes	No	Yes	Traumatic ulcer
Sutherland, 1997[188]	No	Yes	Yes	Yes	Case report of gangrene after total hip replacement surgery
Stuwe, 1983[186]	Yes	Yes	No	Yes	Not surgical wounds
Taranenko *et al.*, 1984[189]	?	?	?	?	Russian
Thomas *et al.,* 1997[190]	Yes	Yes	No	No	No measure of healing; mixture of appropriate wounds and ulcers, not analysed separately
Tolstykh *et al.*, 1987[191]	?	?	?	?	Russian
Treusch and Kohnlein, 1985[192]	No	Yes	No	No	No control group; chronic wounds
Turner *et al.*, 1994[193]	No	Yes	No	No	Observational study of home wounds managed by contract nurses; mixture of appropriate wounds and ulcers, not analysed separately
Vogel and Lenz, 1992[194]	Yes	No	Yes	Yes	Wounds closed surgically
Wahlby and Hedberg, 1983[195]	?	?	?	?	Foreign language – Scandinavian
Watts and Lee, 1994[196]	Yes	Yes	Yes	No	No measure of healing
Weise and Evers, 1988[197]	No	Yes	No	Yes	No control group; sutured wounds
Wernet *et al.*, 1992[198]	No	No	Yes	Yes	No control group; intervention (collagenous sponge containing gentamicin) was not a debriding agent
Westrate, 1996[199]	No	Yes	Yes	No	Retrospective study; no control group
Wikblad and Anderson, 1995[200]	Yes	Yes	No	Yes	Sutured wounds
Williams *et al.*, 1995[201]	Yes	Yes	Yes	No	No measure of healing
Wollina, 1997[202,203]	No	Yes	Yes	Yes	No control group
Wood and Hughes, 1975[204]	No	Yes	Yes	Yes	Retrospective study
Wood *et al.*, 1977[205]	No	Yes	Yes	Yes	No control group

Appendix 3

Data extraction forms

TABLE 10 *An example of a data extraction form for reports of trials investigating clinical effectiveness*

Study and design	Participants	Intervention details	Baseline characteristics	Results	Withdrawals	Comments
Author, year **Country of origin** **Study design** (i.e. RCT or controlled trial) **Method of randomisation** (if applicable) **Setting** (if multicentre, number of sites, outpatients, in hospital) **Objective** (authors' objective)	**Type of operation** **Inclusion criteria** **Exclusion criteria** **Bacterial growth**	**Intervention** (description of intervention and sample size) **Comparator** (description of comparator(s), including sample size) **Concurrent treatment** (e.g. any additional dressings used) **Duration of follow-up** **Measure of healing** (includes information relating to the method used to measure healing) **Other outcome measures**	Details of baseline comparability of intervention groups	**Statistical test used to compare groups** **Results** (summary of results)	Details of withdrawals	**Authors' conclusions** (authors' own comments) **Other comments** (limitations of the study, biases not reported by authors, generalisability and other comments)

TABLE 11 *An example of a data extraction form for reports of trials evaluating economic outcomes*

Study details	Source of data	Method used to estimate benefits/costs	Results	Sensitivity analysis	Comments
Author, year **Objective** (objectives of the economic evaluation) **Type of economic evaluation** (CEA, CUA, CBA) **Country/currency** (currency data and year to which data relate) **Perspective** (health service, societal, hospital, third-party payer, patient) **Study population** **Interventions** (including comparator)	**Source of efficacy data** (data derived from a single study, based on a review or synthesis of previously completed studies or on expert opinion; consider classification according to hierarchy of effectiveness evidence) **Source of cost data** (literature or data from actual sources; consider strength of link between cost and effectiveness data (i.e. prospective concurrent will be the strongest link, retrospective disconnected will be the weakest link))	**Valuation for clinical outcomes or benefit** (basic methods of valuation of health states (e.g. direct measurements based on primary study or estimates based on certain clinical assumptions); instruments used to value health states (e.g. QALY in CUA, monetary value in CBA)) **Estimates of cost** (including both direct and indirect costs, determined by chosen prospective) **Modelling** (if modelling used, type of model, purpose of model and components that were integrated in the model)	**Clinical outcome/benefit** (summary estimates of clinical outcome/benefits) **Costs** (summary cost results) **Synthesis of costs and benefits** (outcome measure used in economic evaluation (e.g. incremental cost-effectiveness in CEA, cost per QALY gained in CUA, net benefit or cost in CBA)) **Statistical analysis** (appropriate statistical test according to data characteristics; appropriate method for chosen time frame (e.g. discounting, inflating, deflating cost data))	**Sensitivity analysis** (appropriate sensitivity analysis of results to assess variability in the data)	**Authors' conclusions** **Magnitude and direction of results** (determine if extended dominance can be established) **Comments**

CBA, cost–benefit analysis; CEA, cost-effectiveness analysis; CUA, cost–utility analysis; QALY, quality-adjusted life-year

Appendix 4

Quality checklists

Quality checklist for clinical trials

An adaptation of the checklist presented in CRD Report 4[65] was used. The criteria used for assessing the quality of clinical trials were as follows:

- Was the method of randomisation adequate? (Computer-generated random numbers and random number tables will be accepted as adequate, while inadequate approaches will include the use of alternation, case record numbers, birth dates or days of the week.)
- Was the randomisation of participants blinded (allocation concealment)? (Concealment will be deemed adequate where randomisation is centralised or pharmacy-controlled, or where the following are used: serially numbered containers, on-site computer-based systems where assignment is unreadable until after allocation, other methods with robust methods to prevent prior knowledge of the allocation sequence to clinicians and patients. Inadequate approaches will include: the use of alternation, case record numbers, days of the week, open random number lists and serially numbered envelopes, even if opaque.)
- Was a relatively complete follow-up achieved?
- Were the outcomes of people who withdrew described?
- Was an ITT analysis conducted?
- Were those assessing outcomes blinded to the treatment allocation?
- Were administrators (those who administered the intervention) blinded?
- Were participants blinded?
- Was success of blinding checked?
- Were appropriate baseline characteristics reported?
- Were the control and treatment groups comparable at entry?
- Was there registration of any co-interventions that may influence the outcome for each group?
- Was the analysis appropriate? (Analysis will be considered appropriate if the authors: (a) report healing times using either survival analysis or medians to summarise such data, and (b) report carrying out a statistical test and state what test they used. The test must be appropriate for comparing the outcome measures reported, such as a *t*-test, analysis of variance, χ^2 test for categorical data, Wilcoxon, Fisher's exact or Mann–Whitney test. Where the authors report carrying out a statistical test but do not state what test was used, the study will be given a question mark. All other studies will be classified as not having carried out an appropriate analysis.)

Each item was graded as follows:

✔	yes
✘	no
✔/✘	partially covered
?	not stated, not enough information or unclear
NA	not appropriate (information relating to the method of randomisation in non-randomised controlled trials).

For ticked items under withdrawals:

✔a	numbers reported by group and reason
✔b	withdrawals reported, but not by group or reason not given.

For ticked items under appropriateness of baseline characteristics:

✔	one or more appropriate baseline characteristics stated (but not initial wound size)
✔c	initial wound size stated.

For ticked items under comparability of baseline characteristics:

✔	according to one or more of the characteristics stated (but not initial wound size)
✔d	including wound size.

Quality checklist for economic evaluations

An adaptation of the checklist published by Drummond and co-workers[32] was used. The criteria used for assessing the quality of economic evaluations were as follows:

- Is there a well-defined question?
- Is there a comprehensive description of alternatives?
- Are all the important and relevant costs and outcomes for each alternative identified?
- Has clinical effectiveness been established?
- Are costs and outcomes measured accurately?
- If economic data are from a trial, was the costing analysed either concurrently or prospectively?
- Are costs and outcomes valued credibly?
- Are costs and outcomes adjusted for differential timing?
- Is there an incremental analysis of costs and consequences?
- Were sensitivity analyses conducted to investigate uncertainty in estimates of cost or consequences?
- How far do study results include all issues of concern to users?
- Are the results generalisable to the setting of interest in the review?

Each item was graded as:

✔	yes
✘	no
✔/✘	partially covered
?	unclear or not enough information
NA	not appropriate.

Appendix 5

Summary of included clinical trials

TABLE 12 *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Berry *et al.*, 1996,[34] UK **Study design**: RCT **Method of randomisation**: not stated **Setting**: community and outpatient clinic **Objective**: to compare two treatment protocols in the management of cavity wounds	**Type of operation**: pilonidal sinus excision **Inclusion criteria**: patients with standard pilonidal sinus excision wounds **Exclusion criteria**: not stated **Bacterial growth**: wounds were examined at each clinic visit to exclude the presence of infection, weekly biopsies (6 mm punch biopsies 1 cm from the wound edge) and regular bacteriological swabs were taken	**Intervention**: polyurethane foam hydrophilic dressing (Allevyn cavity wound dressing), followed by polyurethane foam sheet dressing (Allevyn) when the wound no longer had significant depth (n = 10) **Comparator**: calcium sodium alginate dressing (Kaltostat) followed by a polyurethane foam sheet dressing (Lyofoam) when the wound no longer had significant depth (n = 10) **Concurrent treatment**: none reported **Duration of follow-up**: wound assessment carried out at weekly clinic visits. Results collected from time of surgery until re-epithelialisation had occurred and cavity wound dressings were no longer suitable for use **Measure of healing**: time to complete healing **Other outcome measures**: ease of use, application and removal (classified as easy/difficult), patient conformability (good or poor) and dressing performance	**Wound details:** mean ± SD Length: foam 68.2 ± 26.4 mm; alginate 53.7 ± 19.8 mm Width: foam 22.6 ± 11.1 mm; alginate 11 ± 6.2 mm Depth: foam 28.5 ± 10.4 mm; alginate 28.0 ± 12.6 mm **Patient details:** Mean age: foam 26.5 years; alginate 28.1 years Gender (male/female): foam 7/3; alginate 8/2 Mean weight: foam 72.7 kg; alginate 84.2 kg Mean duration before inclusion: foam 13.2 days; alginate 9.3 days	**Statistical test used to compare groups**: no statistical analysis was undertaken **Results**: presented as mean (range) *Time to healing*: foam 56.7 days (36–78 days); alginate 65.5 days (43–106 days) *Ease of application*: foam 42% easy; alginate 85% easy *Ease of removal*: foam 85% easy; alginate 92% easy *Ease of use*: foam 86% easy; alginate 100% easy *Patient conformability*: foam 86% good; alginate 79% good *Absorption capacity*: foam 85% good; alginate 86% good *Dressing leakage*: foam 81% nil/slight; alginate 73% nil/slight No differences between the two treatment arms for clinician observation of dressing performance (measured as ease of application, conformability and ease of removal; > 80% for both groups)	**Foam**: 1 participant because of perceived discomfort at having biopsies taken, 1 because of recurrent infection, 1 required further surgery **Alginate**: 1 participant because of perceived discomfort at having biopsies taken, 2 because of recurrent infection	**Authors' conclusions**: both dressings were easy to use, effective, and acceptable to patients and clinicians. Direct comparison in performance between the polyurethane foam hydrophilic dressing and the alginate dressing in relation to healing is limited because of the introduction of other materials when the wounds became superficial or had no significant depth **Other comments**: the number of patients included in the trial was small, and thus the study may have lacked power to detect significant associations. The wounds were larger at baseline in the foam group compared to the alginate group, which may have confounded the results. No statistical analysis was undertaken and the results are presented graphically so it is difficult to draw conclusions from the results. The authors state that an ITT analysis was conducted, but it is not clear from the results whether they did this **Study sponsor**: Smith and Nephew, who produce Allevyn

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Bruce, 1991,[35] UK **Study design**: RCT **Method of randomisation**: not stated **Setting**: chiropody clinic **Objective**: to compare the efficacy of Comfeel Ulcer Dressing (hydrocolloid dressing) with a chlorhexidine acetate impregnated dressing on iatrogenic wounds produced by toenail avulsion followed by phenolisation of the germinal matrix and nailbed	**Type of operation**: toenail avulsion and phenolisation of the germinal matrix for 3 minutes **Inclusion criteria**: patients aged 10–60 years in good general health **Exclusion criteria**: diabetes and rheumatoid arthritis, severe peripheral vascular disease, anticoagulant and corticosteroid therapy, pregnancy **Bacterial growth**: not stated	**Intervention**: Comfeel Ulcer Dressing (Coloplast Ltd), a hydrocolloid dressing (n = 3, final number) **Comparator**: Serotulle, chlorhexidine acetate impregnated dressing (gauze derivative) (n = 8, final number) **Concurrent treatment**: irrigated with normal saline and dressed accordingly **Duration of follow-up**: redressing and assessment appointments were made for 3, 7, 10 and 14 days from the first procedure date; subsequent assessment and redressing done every 7 days until full healing or patient withdrawal **Measure of healing**: healing time and an estimate of the percentage re-epithelialisation of the wound. Wounds were photographed and traced. On days 3 and 10 the wound was traced and not photographed **Other outcome measures**: patient comfort (score of 1 to 4 for nil, slight, moderate and severe discomfort) prior to dressing change, during dressing change, and 15 minutes following dressing change. Mean time to replace dressing	18 subjects randomised	**Statistical test used to compare groups**: not stated **Results**: presented as mean ± SD *Healing time*: hydrocolloid 49.3 ± 21.5 days; gauze 65.2 ± 9.63 days ($p < 0.05$) *Dressing time*: hydrocolloid 9 min; gauze 10 min ($p > 0.05$) *Comfort prior to dressing change*: hydrocolloid 1.4; gauze 1.2 ($p > 0.05$) *Comfort during dressing change*: hydrocolloid 1.1; gauze 1.1 ($p > 0.05$) *Comfort 15 minutes following dressing change*: hydrocolloid 1.1; gauze 1.0 ($p > 0.05$) The presence of the hydrated gel from the dressing was often offensive to the patient, as was the smell. The gel frequently leaked from the wound	Four patients failed to attend for redressing and no reason was ascertained (group not stated) **Gauze**: 1 participant reported pain, 1 interfered with dressing, 1 was a chiropodist's decision **Hydrocolloid**: 3 participants developed allergies, 1 patient interfered with dressing, 1 was a chiropodist's decision	**Authors' conclusions**: the trial is seen to be inconclusive because of the small sample number and the number of patients withdrawn from the trial. However, Comfeel Ulcer Dressing is not proven to be contraindicated except for the three patients who may have developed an allergy to the dressing **Other comments**: the sample size was very small and so the study will have lacked the power to detect significant differences between the groups

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Butterworth *et al.*, 1992,[37] UK **Study design**: RCT **Method of randomisation**: not stated **Setting**: wound clinic at a university hospital **Objective**: to compare Allevyn cavity wound dressings and silastic foam in the treatment of surgical granulating cavity wounds	**Type of operation**: pilonidal sinus excision or abdominal surgery **Inclusion criteria**: patients entered into study at first visit to wound clinic, usually within one week of surgery; patients of both sexes aged 16 years or over attending Cardiff wound clinic; patients with a cavity wound; permission from referring consultant and patient **Exclusion criteria**: patients with wounds that showed obvious signs of clinical infection, if they were immunosuppressed, pregnant or receiving cytotoxic therapy or radiotherapy **Bacterial growth**: wounds swabbed for bacterial culture at a weekly wound clinic; wounds that were judged to be either clinically or bacteriologically infected were treated with systemic antibiotics according to the usual policy of the clinic	**Intervention**: polyurethane foam (Allevyn cavity wound dressing); more than one dressing used, as appropriate; dressing supplied in sterile form and patients advised to change dressing when soaked with exudate and at least every 3 days (n = 40: pilonidal sinus wounds n = 30; abdominal wall wounds n = 10) **Comparator**: silicone foam (Silastic foam); dressings cleansed and sterilised twice daily; held in place with surgical tape covered with an absorbent pad (n = 40: pilonidal sinus wounds n = 32; abdominal wall wounds n = 8) **Concurrent treatment**: wounds judged to be either clinically or bacteriologically infected were treated with systemic antibiotics according to the usual practice of the clinic **Duration of follow-up**: until complete healing; patients were reviewed weekly at the wound care clinic, where their wound healing progress was reported **Measure of healing**: time to wound healing; wound dimensions (length, width, depth) were recorded at baseline examination; measured with a stick and ruler; a photograph was taken of each wound **Other outcome measures**: ease of application and removal, time for dressing change, dressing comfort, wound leakage and pain, and a general quality-of-life assessment by patients and clinicians	**Wound details**: mean (range) Length: Allevyn 63.0 mm (23–148 mm); foam 62.3 mm (25–160 mm) Width: Allevyn 19.8 mm (0–59 mm); foam 18.9 mm (0–51 mm) Depth: Allevyn 26.1 mm (8–82 mm); foam 26.6 mm (5–65 mm) **Patient details**: Age: Allevyn 30.4 years (16–72 years); foam 28.2 years (16–76 years)	**Statistical test used to compare groups**: not stated **Results**: mean ± SE (range) *Time to wound healing* Pilonidal: Allevyn 51.4 ± 20.9 days (14–112 days); foam 61.9 ± 26.1 days (28–110 days) Abdominal: Allevyn 51.9 ± 20.5 days (27–84 days); foam 56.6 ± 37.6 days (28–138 days) All wounds: Allevyn 51.5 ± 20.5 days (14–112 days); foam 60.8 ± 28.4 days (28–138 days) $p < 0.05$ **Results of measures assessed by patients**: *Comfort at dressing change* Allevyn: 90% painless, 10% acceptable, 0.1% painful Foam: 90% painless, 9% acceptable, 1% painful *Ease of application* Allevyn: 67% easy, 26% acceptable, 7% difficult Foam: 84% easy, 16% acceptable, 0.6% difficult *Ease of removal* Allevyn: 97% came out of wound spontaneously, 3% easily removed Foam: 97% came out of wound spontaneously, 3% easily removed *Mean (range) time for dressing change*: Allevyn 203 s (60–480 s); foam 263 s (120–600 s) *Percentage of dressings that conformed well*: Allevyn 93%; foam 99%	**Allevyn**: 1 with pilonidal wound, 2 with abdominal wounds **Foam**: 3 with pilonidal wounds Reasons for withdrawals not discussed	**Authors' conclusions**: Allevyn cavity wound dressing is similar to Silastic foam cavity wound dressing for most parameters of wound healing, progress and patient comfort, with some advantages from its disposable format and ease of use by patients **Other comments**: the sample size was small, so the study may have lacked the power to detect significant differences between the two treatments

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Cannavo *et al.*, 1998,[36] Australia **Study design**: RCT **Method of randomisation**: cards contained in sealed envelopes **Setting**: gastrointestinal surgical unit **Objective**: to compare the performance of three dressings in the management of dehisced surgical abdominal wounds	**Type of operation**: type of operation not specified **Inclusion criteria**: resident in the catchment area; 18 years of age or over; had a surgical abdominal suture line with a breakdown of greater than 3 cm; no known allergies to dressings **Exclusion criteria**: not stated **Bacterial growth**: not stated	**Intervention**: calcium alginate dressing (Sorbsan); dressing not changed until gelled (approximately once daily) (n = 13) **Comparator**: sodium hypochlorite 0.05% solution moistened gauze dressing and Combine dressing pack Dressing changed 2 or 3 times daily until wound granulation; solution then changed to normal saline (0.09%), 2 or 3 times daily (n = 10) Combine dressing pad (absorbent wound dressing consisting of cotton wool and gauze) applied to wound surface; dressing changed 2 or 3 times daily (n = 13) **Concurrent treatment**: secondary film dressing (Tegaderm) applied with 3 cm margin; once exudate was low, study dressing was ceased and hydrocolloid (Duoderm) applied until healing end-point **Duration of follow-up**: until healing end-point (up to 38 days) **Measure of healing**: healing rate; wound photographed and length and width of each wound measured using a ruler; wound depth measured using a sterile depth gauge at the deepest point; reliability of surface area measurements was established by correlating ruler and photograph measurements on a sample of the wounds assessed; assessment also included exudate evaluation, standard wound photography and a swab; participants returned to the gastrointestinal surgical unit for 'blinded' wound measurement at weekly intervals, by three surgical nurses not working on the unit, until healing achieved **Other outcome measures**: patient comfort (questionnaire), pain (visual analogue scale) and nutritional status measured weekly	39 participants recruited to trial **Wound details**: mean ± SD Initial surface area (cm^2): alginate 6.9 ± 1.2 cm^2); gauze 9.9 ± 2.2 cm^2; Combine 10.7 ± 3.0 cm^2 Initial volume: alginate 14.9 ± 3.6 cm^3; gauze 19.4 ± 5.7 cm^3; Combine dressing 23.7 ± 6.6 cm^3 **Patient details**: mean ± SD Weight: alginate 71.6 ± 3.6 kg; gauze 72.1 ± 4.5 kg; Combine dressing 78.9 ± 4.7 kg Age: alginate: 61 ± 3.4 years; gauze 72 ± 2.9 years; Combine dressing 67 ± 5.0 years	**Statistical test used to compare groups**: rates were compared using ANOVA **Results**: mean ± SD *Wound area reduction*: alginate 0.55 ± 0.144 cm^2/day; gauze 0.51 ± 0.164 cm^2/day; Combine dressing 0.79 ± 0.144 cm^2/day ($p > 0.05$) *Percentage change in area*: alginate 9.5 ± 2.8%; gauze 5.6 ± 3.2%; Combine dressing 9.2 ± 2.8% ($p > 0.05$) *Wound volume reduction*: alginate 0.57 ± 0.15 cm^3/day; gauze 0.50 ± 0.17 cm^3/day; Combine dressing: 0.90 ± 0.15 cm^3/day ($p > 0.05$) *Percentage change in volume*: alginate 4.4 ± 1.4%; gauze 3.1 ± 1.6%; Combine dressing 6.3 ± 1.4% ($p > 0.05$) *Maximum pain reported:* Gauze vs alginate: difference 2.6 (95% CI, 0.64 to 4.6), favouring alginate Gauze vs Combine dressing: difference 2.3 (95% CI, 0.27 to 4.3), favouring gauze No significant difference in maximum pain between alginate and Combine dressing groups *Satisfaction with dressing process:* Alginate and Combine dressing groups: similar in the first week Gauze vs alginate: $p = 0.01$ Gauze vs Combine dressing: $p < 0.03$ No statistically significant difference in satisfaction between the three groups at last assessment visit *> 10% weight loss in 6 months to trial exit:* alginate 38%; gauze 37%; Combine dressing 38% *Usual oral intake not resumed by trial exit:* alginate 23%; gauze 50%; Combine dressing 33%	Three participants withdrawn before trial started, 1 who withdrew consent and 2 required further surgery; 36 were included in final study **Alginate**: 1 participant went on holiday, 1 participant's wound developed into sinus that required further surgery, and 1 participant's wound showed significant overgranulation after 3 weeks of hospital care **Gauze**: 2 participants' wounds developed sinuses, 1 participant developed a cerebral vascular accident Minor deviations in dressing protocols by community nurses were documented for two participants (one in alginate and one in gauze group); these involved the application of copper sulphate crystals to a small area of overgranulation 1–2 weeks prior to healing end-point	**Authors' conclusions**: the study's findings would support the view of advocates for the abandonment of the use of hypochlorite dressing protocols for surgical wounds, as hypochlorite caused more patients discomfort without yielding any healing rate or cost benefits. The healing rates appeared to be similar but this study did not have the power to detect moderate differences in healing rates. The findings regarding the combine dressing pad protocol demonstrated that it performed well in comparison with calcium alginate dressing in terms of healing time, patient comfort and cost **Other comments**: no information was presented on how the levels of exudate were judged to be sufficiently low to change the dressing protocol, and no information was given on for how long hydrocolloid dressings were used. Wound size at baseline varied between the 3 groups, which may have confounded the results. Results for some outcomes were not reported adequately, with, for example, the authors only reporting p values for differences between the groups for some outcomes

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Dawson *et al.*, 1992,[38] UK **Study design**: RCT **Method of randomisation**: not stated **Setting**: outpatient clinic **Objective**: to examine the use of calcium alginate as a dressing for abscess cavities compared to saline-soaked gauze packs (conventional treatment)	**Type of operation**: incision and drainage of abscess **Inclusion criteria**: over 16 years of age **Exclusion criteria**: none stated **Bacterial growth**: pus from abscess sent for examination, culture and determination of antibiotic sensitivity; it was confirmed that the principal organisms encountered were coliforms and *Bacteroides* sp. in the perianal abscesses and *Staphylococcus pyogenes* in the remainder	**Intervention**: wound packed lightly with calcium alginate dressing (n = 16) **Comparator**: gauze soaked in saline, lightly packed into wound (n = 18) **Concurrent treatment**: wound was covered with a gauze pad; patients given 2 Co-proxamol (dextropropoxyphene hydrochloride plus paracetamol) tablets 1 hour before dressing change; dressing change on first day after operation; followed up 2 weeks later **Duration of follow-up**: outcomes assessed at 2 week review; patients were not seen again if wound had healed. If required, dressings were continued by the district nurse. Final follow-up at 4 weeks **Measure of healing**: complete healing at 2 weeks **Other outcome measures**: patient and nurse assessed level of pain on removal of dressing and ease of removal; measured on a linear analogue scale (0, great ease/no pain; 10, great difficulty/severe pain)	None of the patients were diabetic or receiving steroid treatment *Abscess types – alginate group* Perianal/pilonidal: 8 (50%) Breast: 3 (19%) Other: 5 (31%) *Abscess types – gauze group* Perianal/pilonidal: 14 (78%) Breast: 2 (11%) Other: 2 (11%)	**Statistical test used to compare groups**: statistical analysis of the scores was performed using the Wilcoxon rank-sum test **Results**: *Number of wounds healed at 2 week review*: alginate 12/16 (75%); gauze 13/18 (72%) ($p > 0.05$) All wounds healed by 4 weeks *Pain and ease of dressing removal*: significantly less in alginate group than gauze group ($p < 0.01$) Good correlation between ease of removal of dressing and pain experienced ($r = 0.63$, $p < 0.005$)	None reported	**Authors' conclusions**: calcium alginate dressings are preferable to traditional saline-soaked gauze dressings in the initial treatment of abscess cavities and raw surfaces that typically require packing. There seems little place in modern surgical practice for the continued use of dry or saline soaked gauze dressings **Other comments**: the authors did not report sufficient baseline details, such as the age of the patients included in the trial and initial wound size. The sample size was small and thus the study may have lacked the power to detect any difference in wound healing between the two groups **Study sponsor**: calcium alginate dressings were provided by BritCair UK

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Foley and Allen, 1994,[39] UK **Study design**: RCT **Method of randomisation**: predetermined random sequence **Setting**: chiropody outpatient department **Objective**: to investigate factors which influence the rate of healing after toenail avulsion and phenolisation, including a comparison of an alginate wound dressing and a non-adherent dry dressing	**Type of operation**: partial or total nail avulsion **Inclusion criteria**: patients referred by GP to the chiropody department for toenail surgery **Exclusion criteria**: mycotic nail infection; undergoing treatment with antibiotics, steroids or immunosuppressants; diabetes; absent foot pulses or peripheral neuropathy **Bacterial growth**: none stated	**Intervention**: Kaltostat (BritCair) (calcium sodium alginate flat dressing); dressing replaced with moistened Kaltostat at first outpatient review; at subsequent follow-up visits could use dry sterile gauze instead of Kaltostat if wound was no longer sufficiently moist for alginate to be an appropriate choice (n = 35: partial nail avulsion n = 32; total nail avulsion n = 3) **Comparator**: Melolin (Smith & Nephew) (cotton and acrylic fibre pad bonded to perforated low-adherent polyester film) used throughout trial (n = 35: partial nail avulsion n = 30; total nail avulsion n = 5) **Concurrent treatment**: dressings in both groups were soaked with sterile normal saline prior to removal, and the site swabbed with saline and blotted dry. The use of topical antiseptics was discouraged, and if these were used on two consecutive visits the patient was excluded **Duration of follow-up**: until complete healing; patients were reviewed the day after surgery and the wound then dressed once a week **Measure of healing**: time to re-epithelialisation (complete healing) **Other outcome measures**: wounds were assessed weekly for signs of infection, pain or tenderness around the operation site, exudate, swelling inflammation or irritation at the operation site, and whether sensation in the operation area had returned to normal; at each postoperative appointment patients were asked to rate the dressings for comfort, acceptability and pain on dressing removal	Mean ± SD age: alginate 23.7 ± 14 years; gauze 29.8 ± 17 years Gender (male/female): alginate 23/11; gauze 20/10 Sex not recorded: alginate 1; gauze 5 Non-smokers/smokers: alginate 32/2; gauze 31/4 Smoking not recorded: alginate 1; gauze 0 Mean ± SD ischaemic index: alginate 1.08 ± 0.12; gauze 1.08 ± 0.14 The two groups were similar for all the characteristics recorded	**Statistical test used to compare groups**: not stated **Results**: mean ± SD *Time to healing*: alginate 25.8 ± 12.9 days; gauze 34.4 ± 15.2 days (p < 0.05) *Number of dressing changes*: alginate 3.6 ± 1.8; gauze 4.5 ± 2.2 (p < 0.05) *Total nail avulsion time to healing*: alginate 20.3 ± 6.7 days; gauze 43.0 ± 16.9 days (p < 0.05) *Partial nail avulsion time to healing*: alginate 26.3 ± 13.2 days; gauze 32.9 ± 14.8 days (p = 0.069) **Cost data**: the additional dressing cost of Kaltostat was between £1.60 and £2.20 per patient in the study (3 or 4 alginate dressings per patient); no data were presented for the cost of Melolin dressings; the reduction in healing time represents a saving of one or two clinic appointments	None reported	**Authors' conclusions**: nail avulsion and phenolisation are now widely accepted as the best treatment for recurring onychocryptosis and onychogryphosis. Kaltostat offers considerable advantages both in terms of faster healing time and in reducing the number of dressings needed **Other comments**: baseline details on wound size were not reported. The main focus of the study was to investigate factors which influence the rate of healing after toenail avulsion and phenolisation; the comparison of dressing types was a secondary objective. This may have affected the design of the study and could have resulted in biased results **Study sponsor**: BritCair Division of CV Laboratories; the second author is an employee of BritCair Division

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Goode *et al.*, 1979,[40] UK **Study design**: RCT **Method of randomisation**: cards drawn from sealed envelopes **Setting**: hospital and outpatients **Objective**: to examine the cost-effectiveness of dextranomer and Eusol in the treatment of infected surgical wounds	**Type of operation**: appendectomy or bowel surgery **Inclusion criteria**: wounds either heavily contaminated at operation and left open for delayed primary suture, or wounds which were closed primarily, but which subsequently developed an abscess requiring removal of sutures and drainage **Exclusion criteria**: none stated **Bacterial growth**: bacteriological slides showed that the predominant infective organisms were *Escherichia coli* and *Pseudomonas*, with no particular difference between groups	**Intervention**: dextranomer polysaccharide beads (Debrisan) (n = 10) **Comparator**: Eusol ribbon gauze (n = 10) **Concurrent treatment**: all patients were given prophylactic antibiotic cover of Cephazolin and Metronidazole with the premedication and for 48–72 hours postoperatively **Duration of follow-up**: not stated **Measure of healing**: time taken to secondary skin closure. An independent assessor decided when the wound was clean according to the following criteria: resolution of erythema and oedema, absence of pus, slough at the base, and the formation of granulation tissue. Such wounds were then closed by secondary suture. Each wound was photographed at the start, during and at the end of treatment **Other outcome measures**: number of days in hospital	**Patient details**: Mean (range) age: dextranomer 52.9 years (24–91 years); gauze 50.9 years (27–71 years) Gender (male/female): dextranomer 7/3; gauze 6/4 **Wound details**: Appendectomy/ paramedian (near the middle): dextranomer 6/4; gauze 7/3 Delayed primary suture: dextranomer 4; gauze 6 Wound abscess: dextranomer 6; gauze 4	**Statistical test used to compare data**: Mann–Whitney *U*-test **Results**: *Number of wounds that healed by granulation*: dextranomer 1; gauze 1 (duration of time not stated) *Mean time to wound closure by secondary suture*: dextranomer 8.1 days; gauze 11.6 days ($p < 0.05$) 3 patients in the gauze group continued to have a serous discharge for up to 5 days after wound closure, but this did not occur in the dextranomer group Patients treated with dextranomer had a shorter hospital stay by a median of 2.2 days (no measure of significance provided) **Cost data**: the cost of Debrisan is £3.40 (trial published in 1979) for the twice-daily dressing of a 10 cm wound. However, the high cost was compensated for by the saving in the total cost of hospital care resulting from the shorter hospital stay	Not reported	**Authors' conclusions**: Debrisan was found to be more effective than Eusol in the patients studied **Other comments**: there were no baseline details on wound size and the length of follow-up was not stated. The authors were inconsistent in reporting the summary measure, as both means and medians were given. It is not clear from the data presented which measure is the most appropriate

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TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Guillotreau *et al.*, 1996,[41] France **Study design**: RCT (multicentre) **Method of randomisation**: not stated **Setting**: 7 general surgery departments of military hospitals **Objective**: to compare the efficacy and safety of calcium alginate dressing and povidone iodine pack in the management of infected post-operative wounds	**Type of operation**: incision and drainage of pilonidal abscess **Inclusion criteria**: not stated **Exclusion criteria**: not stated **Bacterial growth**: bacterial swabs were taken; there was no difference between the bacteria cultured in the two groups	**Intervention**: calcium alginate rope (n = 37) **Comparator**: packing with gauze soaked in povidone iodine (n = 33) **Concurrent treatment**: none reported **Duration of follow-up**: 3 weeks; wounds were evaluated weekly; treatment begun 1 day after incision **Measure of healing**: wound healing was evaluated using wound cavity volume, area tracings, photographs and clinical observation **Other outcome measures**: wound infection using bacterial swabs; pain and ease of use of use were measured using visual analogue scales	**Wound details**: mean (range) Area: alginate 472.6 mm^2 (81–2314 mm^2); gauze 269.4 mm^2 (44–863 mm^2) Volume: alginate 7.4 ml (0.5–50 ml); gauze 5.6 ml (0.6–25 ml) **Patient details**: mean (range) Age: alginate 21.2 years (18–37 years); gauze 22.2 years (18–35 years) Weight: alginate 75.5 kg (57–110 kg); gauze 79.6 kg (60–110 kg) Height: alginate 117 cm (167–190 cm); gauze 176 cm (168–190 cm)	**Statistical test used to compare groups**: χ^2 test for categorical data, Student's t-test or Wilcoxon test for continuous data **Results**: *Number of subjects with completely healed wounds*: alginate 13 (35%); gauze 6 (18%) *Number of subjects in which wound cavity completely filled*: alginate 22 (59%); gauze 16 (48%) ($p > 0.05$) *Reduction in wound area at week 3*: alginate 67.1%; gauze 44.8% *Reduction in wound area at week 2*: alginate 58.2%; gauze 38% *Reduction in wound area at week 1*: alginate 32.8%; gauze 20.3% The percentage mean wound surface reduction in the alginate group was higher at weeks 1, 2 and 3 ($p < 0.05$). The calcium alginate rope was painless ($p = 0.0001$) and easier to use ($p = 0.011$) than povidone iodine	None reported; there were no adverse reactions in either of the 2 treatment groups	**Authors' conclusions**: these results confirm that alginate rope is effective and can be used safely in the management of infected wounds **Other comments**: the study was conducted in military hospitals, and thus the results may not be generalisable to the general population

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Macfie and McMahon, 1980,[42] UK **Study design**: RCT **Method of randomisation**: not stated; randomised on postoperative day 14 **Setting**: hospital and surgical outpatient department clinic; a district nurse was arranged for all patients on discharge **Objective**: to assess the value of foam elastomer, a catalysed silicone polymer dressing, in the management of the perineal wound after abdominal excision of the rectum	**Type of operation**: procolectomy or rectal excision **Inclusion criteria**: consecutive participants with open perineal wound at postoperative day 14 **Exclusion criteria**: none stated **Bacterial growth**: not stated	**Intervention**: silicone foam elastomer (Silastic, Dow Corning Ltd) (n = 25 completed trial) **Comparator**: ribbon gauze soaked in mercuric chloride antiseptic solution, loosely packed into the perineal wound (n = 25 completed trial) **Concurrent treatment**: perineal wound irrigation was performed in both groups when necessary; when no cavity remained a dry dressing was applied as the sole dressing in both groups; participants instructed to remove dressings at least once daily and take a salt bath while dressing was removed **Duration of follow-up**: until complete healing; participants reviewed weekly in surgical outpatient department; assessment of participant's progress was always made by the same person **Measure of healing**: initial wound volume calculated by forming a foam dressing, and the volume measured by displacement of water; time to dry dressing and full epithelialisation; rate of healing calculated from initial wound volume divided by the number of days required to achieve each end-point **Other outcome measures**: analgesic requirements of patients to cover the dressing change and while dressing was in position; number of days as inpatient, either in hospital or in a convalescent home; number of visits made by the district nurse recorded each week from the patient at weekly clinic attendance	Mean ± SE initial wound volume on day 14: foam 55.5 ± 4.5 ml; gauze 61.5 ± 5.3 ml Mean ± SD age: foam 54 ± 17.0 years; gauze 59 ± 17.5 years Gender (male/female): foam: 14/11; gauze 16/9 *Reasons for surgery (number of subjects)*: Ulcerative colitis: foam 8; gauze 6 Crohn's disease: foam 5; gauze 3 Carcinoma: foam 10; gauze 14 Villous papilloma: foam 1; gauze 0 Irradiation colitis: foam 1; gauze 1 Diverticulitis: foam 0; gauze 1 *Number of wounds that resulted from breakdown of attempt at primary suture*: foam 14; gauze 16	**Statistical test used to compare groups**: unpaired Student's t-test **Results**: mean ± SE *Time to full epithelialisation*: foam 60.3 ± 3.0 days; gauze 69.5 ± 7.3 ($p > 0.05$) *Rate to full epithelialisation (time to full epithelialisation/initial wound size)*: foam 0.94 ± 0.11; gauze 0.98 ± 0.08 ($p > 0.05$) *Time to dry dressing*: foam 47.5 ± 3.1 days; gauze 62.6 ± 6.3 days ($p < 0.05$) *Rate to dry dressing*: foam 1.24 ± 0.15; gauze 1.07 ± 0.11 ($p < 0.02$) *Assessment of pain*: 4 patients (16%) in the foam group required analgesia (all had Entonox); 15 patients (60%) in the gauze group required some form of analgesia (10 by Entonox, 5 by intramuscular pethidine) *Number of inpatient days, including convalescence*: foam 29.4 ± 3.6; gauze 29.9 ± 2.8 ($p > 0.05$) *Number of inpatient days, excluding convalescence*: foam 23.8 ± 1.8; gauze 22.8 ± 1.7 ($p > 0.05$) *Number of visits by district nurse*: foam 14.1 ± 2.4; gauze 46.9 ± 5.8 ($p < 0.001$) *Complication of treatment*: one patient in the foam group complained of severe vaginal odour 2 months postoperatively; on examination a piece of foam stent was discovered lying high in the vault of the vagina; the foam was removed under general anaesthetic	**Foam**: 1 participant had proven recurrent carcinoma and 1 failed to heal following rectal excision for irradiation colitis **Gauze**: 1 participant had recurrent carcinoma and 1 had Crohn's involvement of the perineum **Persistent sinuses**: 3 in gauze group and 1 in foam group (present in otherwise healed perineum and necessitated further minor surgery) **Death**: 3 patients in each group died before complete healing of wound; complication of wound not thought to be a contributory factor	**Authors' conclusions**: this study suggests that foam elastomer dressing is a more comfortable alternative to gauze pack in the management of the perineal wound and substantially reduces the amount of nursing supervision which is required. We recommend its routine use in the management of the open perineal wounds particularly in the young and co-operative patient **Other comments**: it is unclear if patients who died before complete healing occurred or whose wounds failed to heal were included in the trial. The authors noted that there were no exclusions; however, the outcome measures included the number of days until complete healing and epithelialisation, which would not have been available for these patients **Study sponsor**: foam dressings were supplied by Dow Corning Ltd

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Meyer, 1997,[43] UK **Study design**: RCT **Method of randomisation**: not stated **Setting**: hospital **Objective**: to compare a new hydroactive dressing to traditional therapy for the treatment of secondary healing wounds after abdominal surgery and abscess cavities	**Type of operation**: laparotomy or surgical incision of an abscess **Inclusion criteria**: patients with a deep secondary healing wound **Exclusion criteria**: allergic reactions to the applied products; diabetes; immunodeficiency; wounds consisting of a big subcutaneous cavity with a small ostium; receiving steroids, radiation or chemotherapy **Bacterial growth**: not stated	**Intervention**: polyurethane foam containing hydroactive particles (Cutinova cavity dressing, Beiersdorf AG); the dressing was covered with a thin film dressing (n = 21) **Comparator**: moist cotton gauze (the traditional therapy) covered by a simple surgical dressing; solution used to moisten the gauze was not stated (n = 22) **Concurrent treatment**: dressings were changed as often as necessary, but at least once a week; the wound was cleansed and then the dressing applied; no additional topical medication was allowed **Duration of follow-up**: 4 weeks **Measure of healing**: reduction in wound size and depth; healing process was measured using photography and volumetric measurement (using impression material or saline); subjective evaluation of epithelialisation and formation of granulation tissue **Other outcome measures**: for the evaluation of fibrinous coats, putrid secretion, odour, extent of necrosis, erythema and infection a scale of 'none' to 'severe' was used; itching was evaluated to be present or not present; pain was evaluated using a visual analogue scale	Mean (range) initial mean wound volume: foam 27.9 cm^3 (9.2–54.8 cm^3); gauze 21.0 cm^3 (11.4–27.6 cm^3) Secondary healing after abdominal surgery: foam 15; gauze 16 Secondary healing after surgical incision of an abscess: foam 6; gauze 6 Level of pain at the beginning of treatment: foam 5.54; gauze 5.11	**Statistical test used to compare groups**: not stated **Results**: mean (range) *Wound volume at 4 weeks*: foam 6.8 cm^3 (0.0–10.4 cm^3); gauze 10.5 cm^3 (0.0–15.0 cm^3) *Reduction in wound size*: foam 76%; gauze 50% ($p < 0.05$) *Number of wounds completely healed*: foam 10; gauze 4 *Number of wounds closed surgically after 4 weeks*: foam 4; gauze 2 *Overall healing rate (number of patients who either healed during the 4 weeks treatment or whose wounds could be secondarily closed)*: foam 14; gauze 6 *Pain at week 4 (visual analogue scale)*: foam 0.86; gauze 1.82 ($p < 0.05$) *Epithelialisation and granulation*: faster epithelialisation and granulation and also an earlier reduction of fibrinous coats reported for the foam dressing *Time to significant reduction in infection and erythema*: foam 1 week; gauze 3 weeks *Necrotic tissue, odour, putrid secretion and itching*: not generally observed at any time during the study, so no difference between groups *Mean number of dressing changes (gauze/foam)*: week 1, 1.77/0.97 = 1.83; week 2, 1.20/0.56 = 2.16; week 3, 0.69/0.28 = 2.48; week 4, 0.39/0.14 = 2.76	**Foam**: 1 participant due to no further improvement and start of a local antibiotic treatment **Gauze**: 2 participants due to deterioration of wound and non-acceptance of dressing	**Authors' conclusions**: this study shows a significant difference with regard to the healing of deep cavity wounds in favour of the hydroactive dressing. After 4 weeks there was a difference in reduction of wound size of approximately 25% between the two dressings. There also appears to be a lower degree of inflammation during the treatment with the hydroactive dressing. Patients found the hydroactive dressing more comfortable due to the significant reduction in pain. Looking at the earlier time point of wound closure and the reduced frequency of dressing changes in the Cutinova cavity group, this treatment might also be more cost-effective. However, more detailed analysis is necessary **Other comments**: the authors did not state what statistical test was used to analyse the data

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Ricci *et al.*, 1998,[44] Italy **Study design**: controlled trial **Method of randomisation**: not applicable **Setting**: hospital **Objective**: to evaluate the healing time of surgical wounds healing by secondary intention using two different types of dressing (traditional and advanced)	**Type of operation**: pilonidal sinus removal **Inclusion criteria**: not stated **Exclusion criteria**: not stated **Bacterial growth**: no presence of infection was seen in either group	**Intervention**: reconstituted silicone foam (CaviCare, Smith & Nephew); each day, the foam was disinfected with 10% chlorohexidine, rinsed with sterile saline solution and replaced (n = 6) **Comparator**: 10% iodopovidone solution and dry gauze, changed twice daily (n = 6) **Concurrent treatment**: all patients received an antiseptic dressing (Inadine, Johnson & Johnson) on the first postoperative day; in both groups dressings were changed if dirty, contaminated or displaced; wounds cleansed with sterile saline solution **Duration of follow-up**: treatment was continued until wound reduction or rupture **Measure of healing**: healing time **Other outcome measures**: granulating time, comfort and infection	All patients were younger than 40 years of age and had no other pathologies other than pilonidal sinus Average volume of wound cavity: foam 91 cm^3; gauze 114 cm^3	**Statistical test used to compare groups**: no statistical analysis was undertaken **Results**: mean (range) *Time to complete healing*: foam 33.5 days (21–52 days); gauze 73 days (38–102 days) *Cavity reduction after 15 days*: foam 46%; gauze 22% *Cavity filling time*: foam 4.3 weeks; gauze 9.5 weeks *Time before return to work*: foam 12 days; gauze 23 days *Number of dressings used per patient*: foam 20; gauze 868 For the foam group, dressings were pain-free, while in the gauze group they were painful and bleeding occurred	None reported	**Authors' conclusions**: this study indicates that the advanced dressing (foam) is easy to use with better results in pilonidal sinus wounds **Other comments**: the sample size was very small and so the study may have lacked the power to detect significant differences between the groups; no statistical analysis was undertaken

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Smith, 1992,[45] UK **Study design**: quasi-RCT **Method of randomisation**: participants were allocated numbers and those with even numbers were treated with Sorbsan, while the others received the standard dressing **Setting**: acute hospital, chiropody department **Objective**: to compare the use of two dressing regimens, Sorbsan and polynoxylin/ Melolin, after toenail removal in terms of healing time and postoperative complications	**Type of operation**: total or partial nail avulsion with phenolisation (80% liquefied phenol) **Inclusion criteria**: none stated **Exclusion criteria**: cases in which treatment other than Sorbsan or Melolin/ Anaflex was used or where an emergency avulsion had to be performed; no participants were excluded for medical reasons **Bacterial growth**: not stated	**Intervention**: calcium alginate dressing (Sorbsan) (n = 34, final number: total nail avulsion n = 17; partial nail avulsion n = 17) **Comparator**: gauze derivative (Melolin dressing and Anaflax powder) (n = 28, final number: total nail avulsion n = 13; partial nail avulsion n = 15) **Concurrent treatment**: dressings held in place with tubular gauze; advice leaflet **Duration of follow-up**: when complete healing had occurred; the first follow-up session was held 3 or 4 days after surgery and then weekly until healing had occurred; on following visits the condition of the nailbed and matrix was recorded **Measure of healing**: time to healing and number of visits; complete healing was defined as when the eschar had resolved; photographic evidence was taken at all stages of the procedure **Other outcome measures**: any volunteered complaints were recorded	No participants with insulin-dependent diabetes were included in the trial. Participants in both groups were reported to have been evenly matched for sex and age. No further details were reported	**Statistical test used to compare groups**: not stated, and no statistical data presented **Results**: mean *Healing time*: alginate 43 days; gauze 52 days *Total nail avulsion – healing time*: alginate 45 days; gauze 69 days *Partial nail avulsion – healing time*: alginate 40 days; gauze 39 days *Number of visits per patient to complete healing*: alginate 6; gauze 7 *Number of participants reporting problems after the operation*: alginate 24 (71%); gauze 24 (86%) *Number of participants with infection postoperatively that required antibiotics*: alginate 0; gauze 1 (4%)	67 participants entered the trial and 62 were included in the analysis; no information presented on those lost to follow-up	**Authors' conclusions**: the results of the study indicate that Sorbsan, used after nail matrix phenolisation, reduced median healing time and the number of patient complaints when compared with the control treatment. As a result, the number of follow-up visits required was significantly less in the Sorbsan group, saving considerable chiropody staff time and allowing treatment of more patients **Other comments**: the initial number of participants in each group was not presented; no baseline information on participants was given, and therefore it is not possible to assess the comparability of the groups. The authors' conclusions do not seem to follow from the results in that the differences between Sorbsan and Anaflex appear to be marginal, especially in terms of the mean number of visits per patient and side-effects **Study sponsor**: materials were provided by Steriseal

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Van Gils *et al.*, 1998,[46] USA **Study design**: RCT **Method of randomisation**: not stated **Setting**: podiatry clinic **Objective**: to evaluate the efficacy of a collagen–alginate wound dressing in the postoperative management of chemical matricectomies	**Type of operation**: toenail avulsion utilising 10% sodium hydroxide was performed; area irrigated with 5% acetic acid to neutralise chemical **Inclusion criteria**: 20 consecutive patients who presented to the podiatry clinic; patients with infected or chronic ingrown toenails **Exclusion criteria**: arterial insufficiency; failure to demonstrate palpable pedal pulses; history of peripheral vascular disease; unable or unwilling to commit to the full treatment plan **Bacterial growth**: none of the patients in the 2 groups experienced post-operative infection	**Intervention**: collagen–alginate wound dressing (Fibracol) applied directly to exposed area of nail matrix, cuticle tissue and nailbed; patients given cut sections of the alginate dressing to apply at every dressing change (n = 9) (10 separate procedures: partial nail avulsion n = 5; total nail avulsion n = 5) **Comparator**: no additional wound dressing (n = 11) (13 separate procedures: partial nail avulsion n = 9; total nail avulsion n = 4) **Concurrent treatment**: all wounds were dressed with a thin layer of sulfadiazine silver cream, applied over a Fibracol dressing in the treatment group, and covered with sterile gauze; all patients told to soak the surgical site in a dilute salt solution, clean the nail border with a cotton-tipped applicator, apply one drop of otic Cortisporin solution to the nailbed and cover with a bandage twice daily **Duration of follow-up**: 8 weeks; patients were seen weekly until healing had occurred or until the 8 week end-point was reached **Measure of healing**: average time to healing; healing defined as absence of drainage, erythema, oedema and pain at wound site	Gender (male/female): alginate 1/2; control 1/1 Mean (range) age: alginate 42 years (12–79 years); control 40 years (12–63 years)	**Statistical test used to compare groups**: a t-test was conducted for comparison of independent group means **Results**: mean (range), median *Time to healing*: alginate 24.4 days (14–35 days), 26 days; control 35.8 days (19–56 days), 42 days (p = 0.03) One of the control group patients had not 'healed' fully at the end of the 8 week trial	One patient was not available for follow-up and was excluded from the analysis	**Authors' conclusions**: the Fibracol collagen–alginate dressing was found to be an effective adjunct in the post-operative treatment protocol, shortening healing time and increasing patient satisfaction with this common procedure **Other comments**: the authors only reported on patient satisfaction with the Fibracol treatment, not with the control treatment, and so conclusions cannot be drawn regarding patient satisfaction. Twenty patients were randomised to two treatment groups; however, the data were analysed according to the number of wounds[23]

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Viciano *et al.*, 2000,[47] Spain **Study design**: RCT **Method of randomisation**: not stated **Setting**: outpatient department **Objective**: to assess the efficacy of hydrocolloid dressings in wound management after excision of pilonidal sinus	**Type of operation**: surgery under local anaesthetic; an elliptical incision was made to remove the cyst en bloc to the presacral fascia, leaving the wound open to heal by secondary intention **Inclusion criteria**: none stated **Exclusion criteria**: patients with pilonidal abscesses **Bacterial growth**: bacteriological cultures made of bed of wound during surgery and on cure; specimens collected from the wounds during operation failed to grow pathogens; during follow-up 5 positive cultures from control group and 1 from the combined hydrocolloid group grew pathogens ($p = 0.03$); bacterial contamination had no clinical effect on wound healing	**Intervention**: hydrocolloid dressings (groups combined in analysis), Comfeel (Coloplast) ($n = 12$) and Varihesive (Convatec) ($n = 11$) **Comparator**: conventional gauze with povidone iodine ($n = 15$) **Concurrent treatment**: washing of wound in saline and replacement of dressing **Duration of follow-up**: the median postoperative hospital stay was 1 day (range 1–3 days); no further details on duration of follow-up stated **Measure of healing**: time to healing **Other outcome measures**: infection rate, intolerance, odour, pain (during and between care sessions, rated on a visual analogue scale), comfort, ease of management, leakage and recurrence **Cost-effectiveness**: cost per patient and unit dressing cost	31 men and 7 women Mean age 24 years (range 16–48 years) None of the patients presented with associated disease No differences between groups in sex, age or size of resected area of tissue	**Statistical test used to compare groups**: Fisher's exact test and Mann–Whitney test **Results**: median (range) *Healing time*: hydrocolloid 65 days (40–137 days); gauze 68 days (33–168 days) ($p > 0.05$) *Number of dressings used*: hydrocolloid 23 (13–36); gauze 68 (33–168) *Local intolerance (dermal folliculitis at wound margins)*: hydrocolloid 3 (13%); gauze 1 (7%) *Postoperative culture grew pathogen*: hydrocolloid 1; gauze 5 ($p = 0.03$) *Scar quality, tolerance of dressing, smell*: no significant differences among groups *Recurrence*: none after median follow-up of 74 months (range 59–77 months) *Pain*: less in hydrocolloid group during first 4 weeks postoperatively than in gauze group ($p = 0.05$); median weekly difference in pain between groups was only significant during week 1 *Leakage*: 14 of the hydrocolloid dressings leaked as a result of poor attachment of the edges of the dressing; however, they were reported to be easy to apply and remove; there was no significant difference between the two types of hydrocolloid dressings used **Cost data**: Euros (July 1999) Unit dressing: hydrocolloid 4.0; control 1.3 Cost per patient: hydrocolloid 93.6; control 101.1 ($p > 0.05$)	None reported	**Authors' conclusions**: hydrocolloid dressings lessen pain and increase comfort for patients after excision of pilonidal sinus, though time to healing is no shorter than when a conventional gauze dressing is used **Other comments**: the sample size was small and so the study may have lacked the power to detect significant differences between the groups

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Walker *et al.*, 1991,[48] UK **Study design**: RCT **Method of randomisation**: not stated **Setting**: naval hospital and community (seen by district nurse) **Objective**: to compare Eusol and Silastic foam dressing in the postoperative management of pilonidal sinus	**Type of operation**: acute abscesses and chronic sinuses were treated similarly: incision of sinus, and excision of chronic granulation tissue and hair; wounds initially dressed with ribbon gauze (2.5 cm wide) and soaked in half-strength Eusol; patients randomised to treatments 48 hours after the operation **Inclusion criteria**: consecutive patients admitted to the Royal Naval Hospital, Gosport, with either pilonidal sinus or abscess; patients grouped into 2 groups depending on whether they had pilonidal sinus or abscess **Exclusion criteria**: none stated **Bacterial growth**: not stated	**Intervention**: silicone foam sponge (Silastic); patients removed and washed sponge twice daily; new sponge constructed when the existing one no longer fitted easily into the cavity (n = 34: abscess n = 17; sinus n = 17) **Comparator**: half-strength Eusol soaked gauze dressing laid into cavity twice daily initially, then once daily when wound was considered clean enough by nursing staff (n = 41: abscess n = 20; sinus n = 21) **Concurrent treatment**: not stated **Duration of follow-up**: patients discharged when only required once daily dressing changes as an outpatient or were managing their own Silastic foam **Measure of healing**: time to full healing **Other outcome measures**: time to discharge	Mean age: men 25 years; women 19 years Age range: 16–33 years 96% male	**Statistical test used to compare groups**: not stated **Results**: mean (range) *Time to full healing – sinus*: foam 30.0 days (21–39 days); gauze 33.0 days (20–46 days) (p > 0.05) *Time to hospital discharge – sinus*: foam 12.8 days (6–20 days); gauze 15.2 days (3–27 days) (p > 0.05) *Time to full healing – abscess*: foam 39.8 days (26–54 days); gauze 39.6 days (27–53 days) (p > 0.05) *Time to hospital discharge – abscess*: foam 11.5 days (4–13 days); gauze 14.6 days (10–19 days) (p > 0.05)	None reported	**Authors' conclusions**: there was not a statistically significant difference in hospital discharge times for Eusol dressing or Silastic foam in either group. The authors advocate that pilonidal sinus disease should be treated by simple incision and Silastic foam dressing reducing hospital stay time and nursing expenditure **Other comments**: no baseline details reported; the sample size was small and so the study may lack the power to detect significant differences between the treatment groups; 75 consecutive participants were recruited, with no specific exclusion criteria specified See also *Table 13*

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Williams *et al.*, 1981,[49] UK **Study design**: RCT **Method of randomisation**: not stated **Setting**: multicentre study set in hospitals and the community **Objective**: to investigate the advantages of using a silastic foam dressing in the management of open granulating wounds	**Type of operation**: excision of pilonidal sinus **Inclusion criteria**: not stated **Exclusion criteria**: not stated **Bacterial growth**: not stated	**Intervention**: silicone foam elastomer dressing (Silastic) refashioned at weekly intervals (n = 44, final number) **Comparator**: daily packing with gauze soaked in a 0.5% aqueous solution of chlorhexidine (Habitant) (n = 36, final number) **Concurrent treatment**: each wound was packed for 4 days in a gauze roll soaked in flavine emulsion prior to randomisation **Duration of follow-up**: patients were reviewed weekly until the wound was completely epithelialised **Measure of healing**: time to complete healing of wound (when surface was completely epithelialised), and time until packing was no longer required **Other outcome measures**: duration of hospital stay; work days lost; number of home nursing visits; discomfort on dressing removal (score reported by patient: extreme 3, moderate 2, mild 1, none 0); the degree of discomfort experienced when the dressing was changed in week 1 was obtained by dividing the total score for that week by the number of dressing changes undertaken	Mean ± SD wound volume: foam 59 ± 57.7 ml; gauze 64 ± 74.5 ml	**Statistical test used to compare groups**: no statistical analysis was undertaken **Results**: mean ± SD *Number of days to complete healing*: foam 66.2 ± 26.1; gauze 57.7 ± 19.6 *Number of days packed*: foam 41.5 ± 21.2; gauze 41.8 ± 26.7 *Duration of hospital stay*: foam 8.5 ± 12.3 days; gauze 7.3 ± 6.2 days *Work lost*: foam 38.6 ± 24.9 days; gauze 45.4 ± 19.9 days *Number of home nursing visits*: foam 4.6 ± 1.5; gauze 35.1 ± 17.4 *Discomfort on dressing removal*: foam 1.4 ± 0.6, mild; gauze 2.9 ± 2.6, severe	Not stated; not clear from results presented	**Authors' conclusions**: the wounds dressed with Silastic foam did not heal more quickly than those managed with a moistened gauze pack. Silastic foam dressing has undoubted advantages for the nurse, purse and patient **Other comments**: the authors only reported the results for the participants followed up; it is not clear whether a greater number were randomised and whether drop-outs occurred; no inclusion and exclusion criteria were specified

continued

TABLE 12 contd *Details of the clinical trials included in the review*

Study and design	Participants	Intervention and study details	Baseline characteristics	Results	Withdrawals	Comments
Young and Wheeler, 1982,[50] UK **Study design**: RCT **Method of randomisation**: random card system **Setting**: hospital setting with patients discharged home **Objective**: to compare the efficacy of dextranomer beads (Debrisan) and silicone foam elastomer (Silastic) in patients with surgical wounds that had either broken down or had been left open postoperatively	**Type of operation**: appendectomy for a gangrenous or perforated appendix with free peritoneal pus **Inclusion criteria**: all patients who developed a surgical breakdown; wounds left open after surgery in the superficial part from the muscle layers outwards **Exclusion criteria**: not stated **Bacterial growth**: bacteriological swabs were taken of any wounds that were odorous, contained excess slough or discharged frank pus; the findings were not presented	**Intervention**: dextranomer polysaccharide beads (Debrisan, Pharmacia); changed twice daily initially, and then once daily when reduction in discharge permitted (n = 25) **Comparator**: silicone foam elastomer (Silastic, Dow Corning Ltd); foam dressing was removed and cleaned twice daily initially, and then once daily when the discharge decreased; new foam stents were made weekly (n = 25) **Concurrent treatment**: all wounds were initially treated with conventional gauze packing for 48 hours **Duration of follow-up**: until complete healing; wounds were reviewed on days 1, 3 and 7 following breakdown, and thereafter weekly **Measure of healing**: length, breadth and depth of each wound measured and volume recorded; the latter measurement was obtained by filling the wound with sterile saline; a photographic record of individual wounds was obtained, taken at a standard distance of 0.45 m; time taken to complete healing in each patient was recorded **Other outcome measures**: wounds were examined for erythema, oedema, rash, odour and slough; the comfort of the dressing was assessed by asking the patient; the pain of the wound was graded as 0–3 (0, no pain; 3, severe pain)	Number of wounds left open primarily: dextranomer 8; foam 8 Mean ± SD age: dextranomer 44.48 ± 5.17 years; foam 49.64 ± 4.57 years *Types of wound in the two treatment groups (difference not significant):* Midline: dextranomer 3; foam 8 Upper paramedian: dextranomer 2; foam 1 Lower paramedian: dextranomer 7; foam 10 Subcostal: dextranomer 3; foam 0 Grid iron: dextranomer 9; foam 5 Other: dextranomer 1; foam 1 *Mean ± SD wound measurements:* Length: dextranomer 5.53 ± 0.55 cm; foam 6.57 ± 0.89 cm Breadth: dextranomer 2.25 ± 0.33 cm; foam 2.48 ± 0.32 cm Depth: dextranomer 1.80 ± 0.20 cm; foam 2.24 ± 0.29 cm Volume: dextranomer 4.92 ± 1.15 ml; foam 6.37 ± 1.30 ml	**Statistical test used to compare groups**: Student's t-test **Results**: mean ± SE *Time to complete healing*: dextranomer 40.92 ± 3.98 days; foam 36.90 ± 3.18 days ($p > 0.05$) *Time to pain-free wounds*: dextranomer 5.32 ± 0.55 days; foam 5.64 ± 0.45 days The time taken for disappearance of erythema, oedema and slough was similar in the two treatment groups	None reported	**Authors' conclusions**: the results indicate that the time taken for wounds to heal is comparable with both methods of treatment. Wound pain appears to be similar for both groups treated. The incidence of erythema, oedema and slough was similar for both our groups and there were no late adverse skin reactions **Other comments**: the small sample size would have made it difficult to detect any difference between the groups

Appendix 6

Summary of included economic evaluations

TABLE 13 *Details of the economic evaluations included in the review*

Study details	Source of data	Method for estimation of benefits/costs	Results/statistical analysis	Sensitivity analysis	Comments
Beiersdorf, 2000[62] (Part of the manufacturer and sponsor submission made to NICE by Beiersdorf UK Ltd) **Research question**: what is the cost-effectiveness of Cutinova in the management of difficult to heal surgical wounds as compared to gauze dressings? **Type of economic evaluation**: CEA (CMA) **Country/currency**: UK, pounds sterling; price year (a single financial year to which the economic evaluations relate) not specified **Perspective**: health service, hospital **Study population**: patients with difficult to heal surgical wounds **Interventions (including comparator)**: polyurethane dressings (Cutinova, Beiersdorf UK Ltd); comparator, gauze	**Source of effectiveness data**: a decision to conduct a CMA was based on the findings of a published systematic review of the literature on the debridement of chronic wounds, including surgical wounds healing by secondary intention[30] Effectiveness data for the CMA were based on the findings of a RCT of Cutinova and gauze in 43 patients with secondary healing wounds after a laparotomy or surgical incision of an abscess[43] (see *Table 12*) The duration of the trial was 4 weeks **Source of cost data**: a case study of a patient who had postoperative wound infection following colorectal surgery[206] and a survey conducted at an NHS hospital looking at nursing time and costs of disposables involved in the dressing of (difficult to heal) surgical wounds in consecutive patents over a 1-week period For the case study, initial postoperative dressings were used for 20 days, then Cutinova cavity and Cutinova hydro were used for 23 days; dressings were changed on alternate days Cost data were collected retrospectively	**Valuation for clinical outcomes or benefits**: interpretation of surgical team. The nursing time per week per dressing was calculated from information regarding the nursing time per dressing (in minutes) and the mean number of dressing changes per week taken from the randomised comparative data[43] and the survey data from 5 patients **Estimation of costs**: costs that were considered included acquisition costs of dressings and nursing time per dressing Staff costs were based on 1998–1999 NHS costs and dressing costs were from the drug tariff in February 2000. The acquisition costs per dressing in the case study[206] was based on 1996 prices **Modelling**: NA	**Clinical outcome/benefits**: Cutinova patients experienced more rapid wound healing and less pain on changing dressings. The dressing time per wound was shorter with Cutinova and this group needed fewer dressings per week (no statistical analysis was undertaken). The shorter nursing times were also found in the survey conducted in a NHS hospital **Costs**: *Cost per week of nursing time:* Week 1: gauze £19.18, Cutinova £9.49; saving £9.69 Week 2: gauze £13.08, Cutinova £5.48; saving £7.61 Week 3: gauze £7.44, Cutinova £2.72; saving £4.73 Week 4: gauze £4.21, Cutinova £1.38; saving £2.83 *Estimation of acquisition cost per week:* Week 1: gauze £16.35, Cutinova £5.90; saving £10.44 Week 2: gauze £11.15, Cutinova £3.41; saving £7.74 Week 3: gauze £6.34, Cutinova £1.69; saving £4.65 Week 4: gauze £3.58, Cutinova £0.86; saving £2.73 **Synthesis of costs and benefits**: *Potential saving per week from using Cutinova:* Week 1: £20.14 (gauze £35.53, Cutinova £15.39) Week 2: £15.35 (gauze £24.23, Cutinova £8.88) Week 3: £9.38 (gauze £13.78, Cutinova £4.41) Week 4: £5.55 (gauze £7.79, Cutinova £2.24) **Statistical analysis**: no statistical calculation was conducted to compare the costs of the two treatments	**Sensitivity analysis**: if the frequency of Cutinova dressings is doubled the savings almost, but not quite, disappear, suggesting that the conclusion of cost saving is robust *Potential savings if Cutinova dressings are changed twice as often:* Week 1: £2.38 (gauze £17.76, Cutinova £15.39) Week 2: £3.23 (gauze £12.11, Cutinova £8.88) Week 3: £2.49 (gauze £6.89, Cutinova £4.41) Week 4: £1.66 (gauze £3.90, Cutinova £2.24) *If the Cutinova price is increased by a factor of 3 the cost advantage is retained:* Week 1: £8.34 (gauze £35.53, Cutinova £27.19) Week 2: £8.54 (gauze £24.23, Cutinova £15.69) Week 3: £6.00 (gauze £13.78, Cutinova £7.79) Week 4: £3.84 (gauze £7.79, Cutinova £3.95)	**Authors' conclusions**: this simple analysis suggests that the use of Cutinova in preference to moist gauze in the dressing of difficult-to-heal surgical wounds will save NHS resources and reduce costs both by decreasing the spend on disposables and by reducing the nursing time involved in dressing changes. Although the potential savings will vary from patient to patient, the reduction in costs is likely to be £5–20 per week for each patient **Magnitude and direction of result**: the authors' findings suggest that Cutinova is dominant (less costly and more effective) **Comments**: data (acquisition costs and nursing time) from one patient from the survey who had a deep wound were not included in the economic evaluation as the data were considered outliers. When considering the data from this patient the mean Cutinova cost from the survey was higher than the 'other dressings'. The sample size was small for both effectiveness and cost data. No statistical analysis was undertaken. The sensitivity analysis was only one-way and the uncertainty of the effectiveness data was not considered. Two sources were used for the cost data (case study and hospital survey) and no information was presented on how these were combined. Staff costs were based on 1998–1999 data and acquisition costs on 1996 prices. It was not stated how these were combined. Costing was undertaken retrospectively and not conducted on the sample used in the effectiveness study, and therefore included a number of assumptions. Given the above limitations the authors' conclusions do not seem to be justified

continued

TABLE 13 contd *Details of the economic evaluations included in the review*

Study details	Source of data	Method for estimation of benefits/costs	Results/statistical analysis	Sensitivity analysis	Comments
Cannavo *et al.*, 1998[36] **Research question**: to compare the performance of three dressing protocols in the management of dehisced surgical abdominal wounds **Type of economic evaluation**: CEA (CCA) **Country/currency**: Australia, Australian dollars, 1996 **Perspective**: hospital **Study population**: patients from a gastrointestinal surgical unit with surgical abdominal wound breakdown **Interventions (including comparator)**: calcium alginate dressing (Sorbsan); comparator included sodium hypochlorite (0.05%) solution moistened gauze dressing with a Combine dressing pad (an absorbent wound dressing that consists of cotton wool and gauze) or a Combine dressing pad alone	**Source of effectiveness data**: data derived from a single RCT (n = 36) (see also appendix 5)[36] **Source of cost data**: costs prior to hospital discharge were measured by calculating material costs and nursing time expended in completing the dressing protocol for each patient. The cost of materials was derived from the purchase cost by the Australian hospital. Nursing costs were based on a midpoint hourly pay rate for surgical registered nurse (Australian $15.60). Alginate dressing was costed on the basis of use among those in the alginate treatment group: flat dressing (n = 3, Australian $2.89; packing ($n$ = 10), Australian $10.44 Cost was considered prospectively	**Valuation for clinical outcomes or benefits**: interpreted by surgical team **Estimation of costs**: *Direct costs*: materials used, which include basic dressing pack (dressing pack, gloves, normal saline sachet, forceps, scissors), intervention dressing and film dressing (Tegaderm) Cost incurred per day during hospital stay (material cost plus nursing time) *Indirect costs*: no indirect costs were included **Modelling**: not applicable	**Clinical outcome/benefits**: no statistically significant differences in healing rates were observed. The maximum pain reported for each dressing type was found to be significantly higher in the sodium hypochlorite group protocol than either the alginate treatment group or the Combine dressing protocol group. During the first week participants in the sodium hypochlorite protocol group reported significantly less satisfaction with the dressing process than either those in the alginate treatment group or those in the Combine dressing protocol. There was no statistically significant difference between the three groups at the last assessment visit **Costs**: *Total cost per dressing:* Alginate dressing protocol: Australian $12.94 (dressing changed once per day) Sodium hypochlorite protocol: Australian $11.54 (dressing changed twice per day) Combine dressing protocol: Australian $8.78 (dressing changed twice per day). *Total cost per day (mean ± SD):* Alginate dressing protocol: Australian $15.25 ± 1.26 Sodium hypochlorite protocol: Australian $19.36 ± 4.12; difference from alginate dressing 4.12 (95% CI, –0.35 to 8.58; p = 0.069) Combine dressing protocol: Australian $14.14 ± 1.71; difference from alginate dressing –1.10 (95% CI, –5.49 to 3.29; p = 0.636) The results indicate that costs during this phase were no different between the alginate treatment group and the Combine dressing protocol group, and that dressings in the sodium hypochlorite protocol group were substantially more expensive than in either the alginate or the Combine dressing protocol groups (sodium hypochlorite protocol versus alginate dressing, p = 0.069; sodium hypochlorite protocol versus Combine dressing protocol, p = 0.052). The principal reason for higher costs in the sodium hypochlorite protocol group was the greater amount of nursing time needed to carry out the dressing protocol **Synthesis of costs and benefits**: not applicable **Statistical analysis**: ANOVA was used to compare maximum cost variables for the three intervention groups	**Sensitivity analysis**: none reported	**Authors' conclusions**: the study's findings would support the view of advocates for the abandonment of the use of sodium hypochlorite dressing protocols for surgical wounds, as hypochlorite caused more patient discomfort without yielding any healing rate or cost benefits. The healing rates appeared to be similar but this study did not have the power to detect moderate differences in healing rate **Magnitude and direction of result**: no significant difference was found between the interventions in terms of healing time, but both the alginate dressing and the Combine dressing pad were found to be economically advantageous **Comments**: the effectiveness trial had validity problems (see *Table 1*). Subjective decisions, such as time to discharge and time to wound exudate being low, means that proper blinding is essential. Wound size and pain were the only blinded outcome measures. It was reported that three experienced surgical nurses, who were not working in the gastrointestinal surgical unit and were instructed in and familiar with the study protocol, conducted all 'blinded' assessments. No further information was provided on how the assessors were blinded and the success of blinding was not checked. Wound depth was measured by using a depth gauge at the deepest point. Wound volume was then calculated from this single measurement. No reliability test was conducted for measuring wound depth. The initial wound size was not comparable between the treatment groups

continued

TABLE 13 contd *Details of the economic evaluations included in the review*

Study details	Source of data	Method for estimation of benefits/costs	Results/statistical analysis	Sensitivity analysis	Comments
ConvaTec, 2000[63] (Commercial in confidence data – omitted)					

continued

TABLE 13 contd *Details of the economic evaluations included in the review*

Study details	Source of data	Method for estimation of benefits/costs	Results/statistical analysis	Sensitivity analysis	Comments
Culyer and Wagstaff, 1984;[51] Culyer *et al.*, 1984[60] **Research question**: to compare the cost per case of treating wounds with conventional gauze dressings versus elastomer foam dressings **Type of economic evaluation**: CEA **Country/ currency**: UK, pounds sterling, 1982 **Perspective**: hospital and health service **Study population**: patients with granulating perineal wounds following abdominoperineal excision of the rectum **Interventions (including comparator)**: silicone foam elastomer (FE) dressings (Silastic, Dow-Corning); comparator included conventional gauze dressing (GD)	**Source of efficacy data**: data were derived from a single RCT (n = 50) (see also appendix 5)[42] **Source of cost data**: the resources costed fall into three categories of reliability: 1. The data relating to use of materials for which the standard deviations (SDs) were available were collected during the trial. Information regarding the number of district nurse visits per group and the SD was also available 2. Data relating to nursing time in hospital, which were obtained from a small sample of 10 patients in the trial. For these, only ranges were available 3. Data for which there were only informed guesses. This included the time estimated to have been spent by district nurses on travel and patient care The quantity of FE dressing was calculated based on wound volume data from the trial plus 15% extra volume for wastage and handling. New elastomer stents were fashioned weekly The decision to include an economic component in the analysis was taken after the final trial design had been established and carried out (retrospective cost analysis) The quantity of GD used was not calculated directly and the cost estimate was based on a formula discussed in the text The nursing cost per minute was calculated using the salary of a staff nurse at the midpoint of the salary scale (31 March 1982) and adding employer's national insurance (NI) and superannuation (SA) contributions, and the salary of a student nurse, also at the midpoint of the salary scale. Costs per mile were estimated taking into account petrol, depreciation and interest rates for a small car of about 1000 cc capacity. Taxation was excluded. District nurse time was calculated from the midpoint of the relevant salary scale, including employer's NI and SA contributions Outpatient clinic costs included transport, driver's time (salaries based on average earnings), clerical staff (midpoint of the clerical officers' pay scale) and nursing time For GD treatment the costs included the district nursing cost and the cost of the dressings (patients in the GD group were not required to attend the outpatient clinic)	**Valuation for clinical outcomes or benefits**: not applicable **Estimation of costs**: *FE dressing* – items costed included: Material costs of the treatments (FE dressings, dry dressing pads, syringes and standard dressing packs) Other inpatient hospital costs (hotel costs, nursing costs). Other costs incurred after discharge (district nurse costs and outpatient clinic costs) Morbidity costs due to complications arising were excluded on account of the expected morbidity costs per case being so small (not more than £0.50) Outpatient clinic costs included transport. In the absence of details of mode of transport (e.g. private car, bus or ambulance) the same cost per mile was used as for district nurse transport. *GD* – items costed included: District nursing costs Costs of dressing It was thought that these two items alone were sufficiently costly to establish the result concerning the relative cost-effectiveness of the FE dressing. Patients in the gauze group were not required to attend the outpatient clinic for wound dressing (All inclusive items would also include dressing pads, analgesia (pethidine), dressing packs, inpatient nursing costs and district nurse transport costs) The procedure throughout was conducted to bias the costing procedure against the FE dressing treatment **Modelling**: not applicable	**Clinical outcomes/benefits**: there was no statistically significant difference in the initial wound volumes between the groups, or in the time until full epithelialisation or the length of inpatient stay. However, patients receiving the FE dressing required significantly fewer district nurse visits ($p < 0.001$) **Costs**: *Total material cost per case for FE dressing group*: low, £47.90; medium, £77.80; high, £109.70 *Total non-material cost per case for FE dressing group*: low, £20.80; medium, £80.60; high, £305.90 *GD cost per case*: low, £32.78; medium, £61.31; high, £89.91 *District nurse time*: low, £54.72; medium, £196.98; high, £455.40 *Comparisons of the total cost per case for FE dressings (all inclusive) and GDs (selective):* Low: FE, £68.70; GD, £87.50 Medium: FE, £158.40; GD, £258.30 High: FE, £415.60; GD, £545.30 *Comparison of the cost per case for FE dressings and GD (all inclusive items, also includes cost of analgesia):* Low: FE, £70.50; GD, £146.10 Medium: FE, £162.10; GD, £417.60 High: FE, £422.00; GD, £984.40 **Synthesis of costs and benefits**: none reported **Statistical analysis of quantities/cost**: no statistical calculation was conducted to compare the costing of the two treatments	A form of sensitivity analysis was performed. Three estimates of cost were presented throughout: a mean estimate (or 'medium' value where calculations do not permit an estimate of the true mean), a high estimate and a low estimate	**Authors' conclusions**: bearing in mind the qualifications concerning the resources costed (which are characteristic of studies in which the economic component was not incorporated into the initial research design) and given also that the costs attributed seem to favour FE, while omissions in the analysis suggest that the relative costs of FE are even lower than we have suggested, we conclude that the relative cheapness of FE is a fairly robust result: the medium cost per case for the FE method is only the gauze method, while the medium cost per case for the gauze method is only marginally lower than the highest of our estimates of the cost per case of the FE method **Magnitude and direction of results**: the study demonstrates at a minimum that the FE intervention is equally effective and less costly. At best, FE is dominant (less costly and more effective). As such, no incremental CEA was performed **Comments**: the trial that the effectiveness data was derived from suffered from validity problems, which carry over to the economic evaluation (see *Table 1*).[42] Problems include lack of blinding, no information reported on method of randomisation and no ITT. The price year was 1982 and the methods of clinical practice may have changed over time

continued

TABLE 13 contd *Details of the economic evaluations included in the review*

Study details	Source of data	Method for estimation of benefits/costs	Results/statistical analysis	Sensitivity analysis	Comments
Walker *et al.*, 1991[48] **Research question**: to compare Eusol and Silastic foam dressing in the management of pilonidal sinus **Type of economic evaluation**: CEA (CMA) **Country/ currency**: UK, pounds sterling, 1989–1990 **Perspective**: hospital and health service **Study population**: participants who had received surgery for either a pilonidal sinus or an abscess **Interventions (including comparator)**: silicone foam elastomer dressing (Silastic, Dow-Corning); comparator included a half-strength Eusol soaked gauze dressing	**Source of effectiveness data**: data derived from a single RCT (n = 75) (see also appendix 5)[48] **Source of cost data**: the cost of hospital stay and community nursing was derived from the District Treasurer, Portsmouth and South Hampshire Health Authority. Trade prices (1990) were used for the cost of dressings Cost was considered retrospectively	**Valuation for clinical outcomes or benefits**: interpreted by a surgical team and district nurse **Estimation of costs**: *Direct costs:* Cost of hospital bed days Gross district nurse costs (including travelling) Dressing cost *Indirect costs:* Lost productivity (not actually assessed but estimated) **Modelling**: not applicable	**Clinical outcome/benefits**: there were no statistically significant differences between the two groups for the outcomes of time to full healing and time to hospital discharge. Although the difference was not statistically significant, the patients in both the simple sinus and abscess groups were discharged from hospital on average 3 days earlier if treated with Silastic foam Silastic foam treated patients required only 2 or 3 visits by the district nurse to allow refashioning of new foam dressings. Eusol-treated patients required daily visits for up to 4 weeks **Costs**: Cost of 3 hospital bed days: £400 Gross district nurse cost: £8.50/hour, not including travel The cost saving to the community nursing service could be between £100 and £200 per patient Each 20 g pack of Silastic foam suitable to make one dressing costs £5.87. Eusol and ribbon gauze alone are not expensive; 18 daily treatments equate to three Silastic foam changes It was reported that patients treated with Silastic foam are able to return to work earlier as they are able to change their own dressings **Synthesis of costs and benefits**: not applicable **Statistical analysis**: no statistical calculation was conducted to compare the costing of the two treatments	**Sensitivity analysis**: none reported	**Authors' conclusions**: by using Silastic foam, an average total saving of over £500 per patient can be made **Magnitude and direction of result**: there was no significant difference between the interventions in terms of healing time, but the silastic foam dressing was found to be economically advantageous **Comments**: the cost results were based on non-significant effectiveness data (time to hospital discharge). The effectiveness trial also suffered from methodological problems (see *Table 1*). Discharge and complete healing are very subjective outcome measures, which means that blinding is essential. Blinding was not reported in the trial The cost of hospital stay was calculated based on participants being discharged 3 days earlier in the silicone foam group. This difference was not found to be significant. A better approach, therefore, would have been to assume zero days difference and use, for example, the 3 days difference in the sensitivity analysis. 95% CIs should be part of the sensitivity analysis (multiway, together with other variables)

CCA, cost–consequence analysis; CEA, cost-effectiveness analysis; CMA, cost-minimisation analysis

Appendix 7

Search strategies

Identifying research for the review

The following databases were searched:

- MEDLINE (SilverPlatter), 1966 to June 2000
- EMBASE (SilverPlatter), 1980 to June 2000
- CINAHL (SilverPlatter), 1982 to May 2000
- Health Management Information Consortium, Issue 2000
- CCTR (Cochrane Library), Issue 2, 2000
- National Research Register, Issue 1, 2000
- NHS Economic Evaluation Database, June 2000
- HEED, June 2000.

Search strategies were developed using an iterative process; additional terms were added as they were identified and the strategies re-run. Note that searches are presented as runs: spelling mistakes in early searches were rectified in later iterations.

Searches for relevant conference papers in conference proceedings were also conducted by searching conference databases and the world wide web.

Topic 1: effectiveness of debridement for difficult to heal surgical wounds

The search strategies used are given below.

MEDLINE

The MEDLINE search was done via Academic Reference Centre (ARC)/SilverPlatter, as follows.

First iteration

1. explode "Surgical-Procedures-Operative"/ all subheadings
2. (surgery or surgical)in ti, ab
3. #1 or #2
4. "surgical-wound-infection"/ all subheadings
5. "surgical-wound-dehiscence"/ all subheadings
6. "Postoperative-Complications"/ all subheadings
7. (wound* or cavit*)in ti, ab
8. #6 and #7
9. #4 or #5 or #8
10. explode "infection"/ all subheadings
11. "bacterial infections"/ all subheadings
12. (#10 or #11) and #9
13. (infect* near surg* near (wound* or cavit*)) in ti, ab
14. dehiscen* near ((wound* or cavit*) in ti, ab)
15. sepsis near ((wound* or cavit*) in ti, ab)
16. exudat* near ((wound* or cavit*) in ti, ab)
17. nectrot near ((wound* or cavit*) in ti, ab)
18. necrot* near ((wound* or cavit*) in ti, ab)
19. slough* near ((wound* or cavit*) in ti, ab)
20. (((non-heal*) or (non heal*) or nonheal* or problem or difficult* or complic*) near (wound* or cavit*)) in ti, ab
21. #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20
22. #3 and #21
23. #9 or #22
24. "Debridement"/ all subheadings
25. debrid* in ti, ab
26. "larva"/ all subheadings
27. larva* in ti, ab
28. maggot* in ti, ab
29. ((bio-surg* or (bio surg*) or biosurg*)) in ti, ab
30. ((trypsin or collagenase or streptokinase or streptodornase) and (wound* or cavit*)) in ti, ab
31. (varidase near topical) in ti, ab
32. (wet to dry dress*) in ti, ab
33. (saline gauz*) in ti, ab
34. (dextranomer polysaccharid*) in ti, ab
35. (polysaccharid* (bead or paste)) in ti, ab
36. dextranomer* in ti, ab
37. xerogel* in ti, ab
38. (cadexomer iodine) in ti, ab
39. (iodoflex or iodosorb) in ti, ab
40. hydrogel* in ti, ab
41. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ti, ab
42. (pressur* wound* irrigation*) in ti, ab
43. woorlpool
44. hydrochlorite solution
45. ((sodium hypochlorite) near (wound* or cavit*)) in ti, ab
46. ((dakin* solution) near (wound* or cavit)) in ti, ab
47. eusol near ((wound* or cavit*) in ti, ab)
48. (((malic acid) or (benzoic acid) or (salicylic acid) or (propylene glycol)) near (wound* or cavit*)) in ti, ab

49. (proteolytic* or fibrinolytic* or collagenase*) near ((wound* or cavit*) in ti, ab)
50. ((hydrocholloid* or granuflex or (comfeel plus) or tegasorb or hydrocoll or aqualcel or combiderm or duoderm) near (wound* or cavit*)) in ti, ab
51. ((polysaccharid* dress*) near (wound* or cavit*)) in ti, ab
52. hydrofibre dress*
53. debrisan in ti, ab
54. (bioclusive of cutifilm or epiview of mefilm or (opsite flexigrid) or tegaderm) in ti, ab
55. ((polyurethane foam dress*) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
56. ((alginat* dress*) or sorbsan or tegagel or kaltostat or kaltogel or (comfeel seasorb) or algisite or algosteril or megisorb or (cutinova cavity) or (seasorb filler)) in ti, ab
57. ((parafin gauze dress*) or (tulle gras) or jelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ti, ab
58. (((vapour permeable (membrane or membranes)) or spyrosorb or flexipore or omiderm or surfasoft or tegapore) near (wound* or cavit*)) in ti, ab
59. #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55 or #56 or #57 or #58
60. #23 and #59

The above was combined with the Cochrane Collaboration's MEDLINE search for trials.[207]

Second iteration

1. explode "Surgical-Procedures-Operative"/ all subheadings
2. (surgery or surgical)in ti, ab
3. #1 or #2
4. "surgical-wound-infection"/ all subheadings
5. "surgical-wound-dehiscence"/ all subheadings
6. "Postoperative-Complications"/ all subheadings
7. (wound* or cavit*) in ti, ab
8. #6 and #7
9. #4 or #5 or #8
10. explode "infection"/ all subheadings
11. "bacterial infections"/ all subheadings
12. (#10 or #11) and #9
13. (infect* near surg* near (wound* or cavit*)) in ti, ab
14. dehiscen* near ((wound* or cavit*) in ti, ab)
15. sepsis near ((wound* or cavit*) in ti, ab)
16. exudat* near ((wound* or cavit*) in ti, ab)
17. nectrot near ((wound* or cavit*) in ti, ab)
18. necrot* near ((wound* or cavit*) in ti, ab)
19. slough* near ((wound* or cavit*) in ti, ab)
20. (((non-heal*) or (non heal*) or nonheal* or problem or difficult* or complic*) near (wound* or cavit*)) in ti, ab
21. #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20
22. #3 and #21
23. #9 or #22
24. explode "health facilities"/ all subheadings
25. explode "health services"/ all subheadings
26. explode "delivery of health care"/ all subheadings
27. "postoperative care"/ all subheadings
28. "Aftercare"/ all subheadings
29. tissue viability nurs* in ti, ab
30. ((post operative care) or (postoperative care) or aftercare) in ti, ab
31. ((nurse or nurses or doctor* or physician or gp or practitioner or (health visit*) or staff or personnel) near (wound* or cavit*)) in ti, ab
32. ((setting or hospital or hospitals or community or clinic or clinics or home or centre* or center* or department* or unit or units) near (wound* or cavit*)) in ti, ab
33. ((facilit* or location or outpatient* or inpatient* or rehabilitation or acute) near (wound* or cavit*)) in ti, ab
34. ((management or treatment* or program* or service* or delivery or care) near (wound* or cavit*)) in ti, ab
35. #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34
36. #23 and #35
37. explode "Health-Care-Evaluation-Mechanisms"/ all subheadings
38. explode "Evaluation-Studies"/ all subheadings
39. (trial* or stud* or evaluat* or examin*) in ti, ab
40. #37 or #38 or #39
41. #36 and #40
42. alginate
43. granulating wound*
44. enzymes or enzymotic
45. (secondary or film or gauze or fibre or fiber or occlusive or wound) dressing*
46. (paraffin or impregnated) gauze
47. aquacel or aloe vera or wound gel or hydrocolloid or polynoxylin
48. melolin or emsol or silastic foam or hydrofibre or hydrofiber
49. polyurethane or hydrocellular or foam elastomer or cellulose
50. alginate near (wound* or cavit*)
51. granulating wound* near (wound* or cavit*)

52. (enzymes or enzymotic) near (wound* or cavit*)
53. (secondary or film or gauze or fibre or fiber or occlusive or wound) dressing*
54. (paraffin gauze or impregnated gauze) near (wound* or cavit*)
55. (aquacel or aloe vera or wound gel or hydrocolloid or polynoxylin) near (wound* or cavit*)
56. (melolin or emsol or silastic foam or hydrofibre or hydrofiber) near (wound* or cavit*)
57. (polyurethane or hydrocellular or foam elastomer or cellulose) near (wound* or cavit*)

Third (set 72) and fourth (set 80) iterations

1. explode "Surgical-Procedures-Operative"/ all subheadings
2. surgery or surgical
3. #1 or #2
4. "surgical-wound-infection"/ all subheadings
5. "surgical-wound-dehiscence"/ all subheadings
6. "Postoperative-Complications"/ all subheadings
7. (wound* or cavit* or incision*)in ti, ab
8. #6 and #7
9. #3 or #4 or #5 or #8
10. (dehiscen* or sepsis or exudat* or necrot* or slough*) in ti, ab
11. (non-heal* or non heal* or nonheal*) in ti, ab
12. (problem or difficult* or complic*) near (wound* or cavit* or incision*) in ti, ab
13. (chronic wound*) in ti, ab
14. (granulating wound*) in ti, ab
15. (postoperative near wound*) in ti, ab
16. (pilonidal sinus* or pilonidal abcess*) in ti, ab
17. #10 or #11 or #12 or #13 or #14 or #15 or #16
18. #9 or #17
19. "Debridement"/ all subheadings
20. debrid* in ti, ab
21. "larva"/ all subheadings
22. larva* in ti, ab
23. (maggot or maggots) in ti, ab
24. (bio-surg* or bio surg* or biosurg*) in ti, ab
25. (trypsin or collagenase or streptokinase or streptodornase) in ti, ab
26. (varidase near topical) in ti, ab
27. (wet near dry near dress*) in ti, ab
28. (polysaccharid* or dextranomer* or xerogel or cadexomer iodine) in ti, ab
29. (iodoflex or iodosorb or hydrogel*) in ti, ab
30. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ti, ab
31. (pressur* wound* irrigation*) in ti, ab
32. whirlpool in ti, ab
33. (hydrochlorite solution) in ti, ab
34. (sodium hypochlorite) in ti, ab
35. (dakin* solution) in ti, ab
36. eusol in ti, ab
37. (malic acid or benzoic acid or salicylic acid or propylene glycol) in ti, ab
38. (proteolytic* or fibrinolytic* or collagenase*) in ti, ab
39. (hydrocholloid* or granuflex or comfeel or tegasorb or hydrocolloid* or aqualcel or combiderm or duoderm) in ti, ab
40. (hydrofibre or debrisan) in ti, ab
41. (bioclusive or cutifilm or epiview of mefilm or (opsite flexigrid) or tegaderm) in ti, ab
42. ((polyurethane foam) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
43. (alginate* or sorbsan or tegagel or kaltostat or kaltogel or seasorb or algisite or algosteril or megisorb or cutinova cavity) in ti, ab
44. (tulle gras or jelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ti, ab
45. (vapour permeable membrane* or spyrosorb or flexipore or omiderm or surfasoft or tegapore) in ti, ab
46. (enzymes or enzymotic) in ti, ab
47. (secondary dressing* or film or films or gauze or fibre or fiber or occlusive dressing*) in ti, ab
48. (aquacel or aloe vera or wound gel* or polynoxylin) in ti, ab
49. (melolin or emsol or silastic foam* or hydrofibre* or hydrofiber*) in ti, ab
50. (polyurethane or hydrocellular or foam elastomer or cellulose) in ti, ab
51. #19 or #20 or #21 or #22 or #23
52. #24 or #25 or #26 or #27
53. #28 or #29 or #30 or #31
54. #32 or #33 or #34 or #35
55. #36 or #37 or #38 or #39
56. #40 or #41 or #42 or #43
57. #44 or #45 or #46 or #47 or #48 or #49 or #50
58. #51 or #52 or #53 or #54 or #55 or #56 or #57
59. #18 and #58
60. wound or wounds or cavity or cavities or abscess* or sinus or sinuses or incision or incisions
61. #59 and #60
62. sutur* near wound*
63. skin graft*
64. explode "Burns"/ all subheadings
65. explode "Eye-Diseases"/ all subheadings
66. explode "Dentistry"/ all subheadings
67. #62 or #63 or #64 or #65 or #66
68. #61 not #67

69. exact{ANIMAL} in TG
70. exact{HUMAN} in TG
71. #69 not (#69 and #70)
72. #68 not #71
73. mesalt
74. sodium chloride near dressing*
75. hypergel or normlgel or mepilex or mepitel
76. silicone near dressing*
77. alldress or mepore or mesorb or (cellulose near dressing*)
78. #73 or #74 or #75 or #76 or #77
79. #18 and #78
80. #79 not #72

Fifth iteration

1. explode "Surgical-Procedures-Operative"/ all subheadings
2. surgery or surgical
3. #1 or #2
4. "surgical-wound-infection"/ all subheadings
5. "surgical-wound-dehiscence"/ all subheadings
6. "Postoperative-Complications"/ all subheadings
7. (wound* or cavit* or incision*)in ti, ab
8. #6 and #7
9. #3 or #4 or #5 or #8
10. (dehiscen* or sepsis or exudat* or necrot* or slough*) in ti, ab
11. (non-heal* or non heal* or nonheal*) in ti, ab
12. (problem or difficult* or complic*) near (wound* or cavit* or incision*) in ti, ab
13. (chronic wound*) in ti, ab
14. (granulating wound*) in ti, ab
15. (postoperative near wound*) in ti, ab
16. (pilonidal sinus* or pilonidal abcess*) in ti, ab
17. #10 or #11 or #12 or #13 or #14 or #15 or #16
18. #9 or #17
19. "Debridement"/ all subheadings
20. debrid* in ti, ab
21. "larva"/ all subheadings
22. larva* in ti, ab
23. (maggot or maggots) in ti, ab
24. (bio-surg* or bio surg* or biosurg*) in ti, ab
25. (trypsin or collagenase or streptokinase or streptodornase) in ti, ab
26. (varidase near topical) in ti, ab
27. (wet near dry near dress*) in ti, ab
28. (polysaccharid* or dextranomer* or xerogel or cadexomer iodine) in ti, ab
29. (iodoflex or iodosorb or hydrogel*) in ti, ab
30. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ti, ab
31. (pressur* wound* irrigation*) in ti, ab
32. whirlpool in ti, ab
33. (hydrochlorite solution) in ti, ab
34. (sodium hypochlorite) in ti, ab
35. (dakin* solution) in ti, ab
36. eusol in ti, ab
37. (malic acid or benzoic acid or salicylic acid or propylene glycol) in ti, ab
38. (proteolytic* or fibrinolytic* or collagenase*) in ti, ab
39. (hydrocholloid* or granuflex or comfeel or tegasorb or hydrocolloid* or aqualcel or combiderm or duoderm) in ti, ab
40. (hydrofibre or debrisan) in ti, ab
41. (bioclusive or cutifilm or epiview of mefilm or (opsite flexigrid) or tegaderm) in ti, ab
42. ((polyurethane foam) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
43. (alginate* or sorbsan or tegagel or kaltostat or kaltogel or seasorb or algisite or algosteril or megisorb or cutinova cavity) in ti, ab
44. (tulle gras or jelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ti, ab
45. (vapour permeable membrane* or spyrosorb or flexipore or omiderm or surfasoft or tegapore) in ti, ab
46. (enzymes or enzymotic) in ti, ab
47. (secondary dressing* or film or films or gauze or fibre or fiber or occlusive dressing*) in ti, ab
48. (aquacel or aloe vera or wound gel* or polynoxylin) in ti, ab
49. (melolin or emsol or silastic foam* or hydrofibre* or hydrofiber*) in ti, ab
50. (polyurethane or hydrocellular or foam elastomer or cellulose) in ti, ab
51. #19 or #20 or #21 or #22 or #23
52. #24 or #25 or #26 or #27
53. #28 or #29 or #30 or #31
54. #32 or #33 or #34 or #35
55. #36 or #37 or #38 or #39
56. #40 or #41 or #42 or #43
57. #44 or #45 or #46 or #47 or #48 or #49 or #50
58. #51 or #52 or #53 or #54 or #55 or #56 or #57
59. #18 and #58
60. wound or wounds or cavity or cavities or abscess* or sinus or sinuses or incision or incisions
61. #59 and #60
62. sutur* near wound*
63. skin graft*
64. explode "Burns"/ all subheadings
65. explode "Eye-Diseases"/ all subheadings
66. explode "Dentistry"/ all subheadings
67. #62 or #63 or #64 or #65 or #66
68. #61 not #67
69. exact{ANIMAL} in TG
70. exact{HUMAN} in TG

71. #69 not (#69 and #70)
72. #68 not #71
73. mesalt
74. sodium chloride near dressing*
75. hypergel or normlgel or mepilex or mepitel
76. silicone near dressing*
77. alldress or mepore or mesorb or (cellulose near dressing*)
78. #73 or #74 or #75 or #76 or #77
79. #18 and #78
80. #79 not #72
81. enzymatic
82. hypochlorite
83. solution
84. enzymatic or hypochlorite solution
85. #84 and #18
86. #85 and #60

EMBASE

The EMBASE search was done via ARC/ SilverPlatter, as follows.

First iteration

1. explode "surgery"/ all subheadings
2. (surgery or surgical) in ts, ab
3. #1 or #2
4. "surgical-wound"/ all subheadings
5. "wound-dehiscence"/ all subheadings
6. "wound-infection"/ all subheadings
7. "postoperative-complication"/ all subheadings
8. (wound* or cavit*) in ts, ab
9. #7 and #8
10. #4 or #5 or #6 or #9
11. explode "infection"/ all subheadings
12. "bacterial-infection"/ all subheadings
13. (#11 or #12) and #10
14. (infect* near surg* near (wound* or cavit*)) in ts, ab
15. (dehiscen* near (wound* or cavit*)) in ts, ab
16. sepsis near ((wound* or cavit*) in ts, ab)
17. exudat* near ((wound* or cavit*) in ts, ab)
18. necrot* near ((wound* or cavit*) in ts, ab)
19. slough* near ((wound* or cavit*) in ts, ab)
20. (((non-heal*) or (non heal*) or nonheal* or problem or difficult* or complic*) near (wound* or cavit*)) in ts, ab
21. #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20
22. #3 and #21
23. #10 or #22
24. "debridement"/ all subheadings
25. debrid* in ts, ab
26. "larva"/ all subheadings
27. larva* or (maggot* in ts, ab)
28. ((bio-surg*) or (bio surg*) or biosurg*) in ts, ab
29. ((trypsin or collagenase or streptokinase or streptodornase) and (wound* or cavit*)) in ts, ab
30. (varidase near topical) in ts, ab
31. (wet to dry dress*) in ts, ab
32. (saline gauz*) in ts, ab
33. (dextranomer polysaccharid*) in ts, ab
34. (polysaccharid* (bead or paste)) in ts, ab
35. dextranomer* or (xerogel* in ts, ab)
36. (cadexomer iodine) in ts, ab
37. (iodoflex or iodosorb) in ts, ab
38. hydrogel* in ts, ab
39. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ts, ab
40. (pressur* wound* irrigation*) in ts, ab
41. woorlpool
42. hydrochlorite solution
43. ((sodium hypochlorite) near (wound* or cavit*)) in ts, ab
44. ((dakin* solution) near (wound* or cavit*)) in ts, ab
45. eusol near ((wound* or cavit*) in ts, ab)
46. (((malic acid) or (benzoic acid) or (salicylic acid) or (propylene glycol)) near (wound* or cavit*)) in ts, ab
47. (proteolytic* or fibrinolytic* or collagenase*) near ((wound* or cavit*) in ts, ab)
48. ((hydrocholloid* or granuflex or (comfeel plus) or tegasorb or hydrocoll or aqualcel or combiderm or duoderm) near (wound* or cavit*)) in ts, ab
49. ((polysaccharid* dress*) near (wound* or cavit*)) in ts, ab
50. (bioclusive or cutifilm or epiview or mefilm or (opsite flexigrid) or tegaderm) in ts, ab
51. ((polyurethane foam dress*) or allevyn or lyfoam or tielle or lyofoam) in ts, ab
52. ((alginat* dress*) or sorbsan or tegagel or kaltostat or kaltogel or (comfeel seasorb) or algisite or algosteril or megisorb or (cutinova cavity) or (seasorb filler)) in ts, ab
53. ((parafin gauze dress*) or (tulle gras) or jelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ts, ab
54. (((vapour permeable (membrane or membranes)) or spyrosorb or flexipore or omiderm or surfasoft or tegapore) near (wound* or cavit*)) in ts, ab
55. #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54
56. #23 and #55

Second iteration

1. explode "surgery"/ all subheadings
2. surgery or surgical
3. #1 or #2
4. "surgical-wound"/ all subheadings
5. "wound-dehiscence"/ all subheadings
6. "wound-infection"/ all subheadings
7. "postoperative-complication"/ all subheadings
8. (wound* or cavit*) in ts, ab
9. #7 and #8
10. #3 or #4 or #5 or #6 or #9
11. (dehiscen* or sepsis or exudat* or necrot* or slough*) in ti, ab
12. (non-heal* or non heal* or nonheal* or problem or difficult* or complic*) near (wound* or cavit* or incision*) in ti, ab
13. (chronic wound*) in ti, ab
14. (granulating wound*) in ti, ab
15. (postoperative near wound*) in ti, ab
16. (pilonidal sinus* or pilonidal abcess*) in ti, ab
17. #10 or #11 or #12 or #13 or #14 or #15 or #16
18. "Debridement"/ all subheadings
19. debrid* in ti, ab
20. "larva"/ all subheadings
21. larva* in ti, ab
22. (maggot or maggots) in ti, ab
23. (bio-surg* or bio surg* or biosurg*) in ti, ab
24. (trypsin or collagenase or streptokinase or streptodornase) in ti, ab
25. (varidase near topical) in ti, ab
26. (wet near dry near dress*) in ti, ab
27. (polysaccharid* or dextranomer* or xerogel or cadexomer iodine) in ti, ab
28. (iodoflex or iodosorb or hydrogel*) in ti, ab
29. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ti, ab
30. (pressur* wound* irrigation*) in ti, ab
31. whirlpool in ti, ab
32. (hydrochlorite solution) in ti, ab
33. (sodium hypochlorite) in ti, ab
34. (dakin* solution) in ti, ab
35. eusol in ti, ab
36. (malic acid or benzoic acid or salicylic acid or propylene glycol) in ti, ab
37. (proteolytic* or fibrinolytic* or collagenase*) in ti, ab
38. (hydrocholloid* or granuflex or comfeel or tegasorb or hydrocolloid* or aqualcel or combiderm or duoderm) in ti, ab
39. (hydrofibre or debrisan) in ti, ab
40. (bioclusive or cutifilm or epiview of mefilm or (opsite flexigrid) or tegaderm) in ti, ab
41. ((polyurethane foam) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
42. (alginate* or sorbsan or tegagel or kaltostat or kaltogel or seasorb or algisite or algosteril or megisorb or cutinova cavity) in ti, ab
43. (tulle gras or jelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ti, ab
44. (vapour permeable membrane* or spyrosorb or flexipore or omiderm or surfasoft or tegapore) in ti, ab
45. (enzymes or enzymotic) in ti, ab
46. (secondary dressing* or film or films or gauze or fibre or fiber or occlusive dressing*) in ti, ab
47. (aquacel or aloe vera or wound gel* or polynoxylin) in ti, ab
48. (melolin or emsol or silastic foam* or hydrofibre* or hydrofiber*) in ti, ab
49. (polyurethane or hydrocellular or foam elastomer or cellulose) in ti, ab
50. #18 or #19 or #20 or #21 or #22 or #23
51. #24 or #25 or #26 or #27 or #28 or #29
52. #30 or #31 or #32 or #33 or #34 or #35
53. #36 or #37 or #38 or #39 or #40 or #41
54. #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49
55. #50 or #51 or #52 or #53 or #54
56. #55 and #17
57. wound or wounds or cavity or cavities or abscess* or sinus or sinuses or incision or incisions
58. #56 and #57
59. sutur* near wound*
60. explode "burn"/all subheadings
61. "burn-dressing"/all subheadings
62. explode "eye-disease"/all subheadings
63. explode "dentistry"/all subheadings
64. explode "dental-care"/all subheadings
65. #59 or #60 or #61 or #62 or #63 or #64
66. #58 not #65
67. "case-report"/ all subheadings
68. "case-study"/ all subheadings
69. "retrospective-study"/ all subheadings
70. #67 or #68 or #69
71. #66 not #70

Third (set 71) and fourth (set 79) iterations

1. explode "surgery"/ all subheadings
2. surgery or surgical
3. #1 or #2
4. "surgical-wound"/ all subheadings
5. "wound-dehiscence"/ all subheadings
6. "wound-infection"/ all subheadings
7. "postoperative-complication"/ all subheadings
8. (wound* or cavit*) in ts,ab
9. #7 and #8
10. #3 or #4 or #5 or #6 or #9

11. (dehiscen* or sepsis or exudat* or necrot* or slough*) in ti, ab
12. (non-heal* or non heal* or nonheal* or problem or difficult* or complic*) near (wound* or cavit* or incision*) in ti, ab
13. (chronic wound*) in ti, ab
14. (granulating wound*) in ti, ab
15. (postoperative near wound*) in ti, ab
16. (pilonidal sinus* or pilonidal abcess*) in ti, ab
17. #10 or #11 or #12 or #13 or #14 or #15 or #16
18. "Debridement"/ all subheadings
19. debrid* in ti, ab
20. "larva"/ all subheadings
21. larva* in ti, ab
22. (maggot or maggots) in ti, ab
23. (bio-surg* or bio surg* or biosurg*) in ti, ab
24. (trypsin or collagenase or streptokinase or streptodornase) in ti, ab
25. (varidase near topical) in ti, ab
26. (wet near dry near dress*) in ti, ab
27. (polysaccharid* or dextranomer* or xerogel or cadexomer iodine) in ti, ab
28. (iodoflex or iodosorb or hydrogel*) in ti, ab
29. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ti, ab
30. (pressur* wound* irrigation*) in ti, ab
31. whirlpool in ti, ab
32. (hydrochlorite solution) in ti, ab
33. (sodium hypochlorite) in ti, ab
34. (dakin* solution) in ti, ab
35. eusol in ti, ab
36. (malic acid or benzoic acid or salicylic acid or propylene glycol) in ti, ab
37. (proteolytic* or fibrinolytic* or collagenase*) in ti, ab
38. (hydrocholloid* or granuflex or comfeel or tegasorb or hydrocolloid* or aqualcel or combiderm or duoderm) in ti, ab
39. (hydrofibre or debrisan) in ti, ab
40. (bioclusive or cutifilm or epiview of mefilm or (opsite flexigrid) or tegaderm) in ti, ab
41. ((polyurethane foam) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
42. (alginate* or sorbsan or tegagel or kaltostat or kaltogel or seasorb or algisite or algosteril or megisorb or cutinova cavity) in ti, ab
43. (tulle gras or jelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ti, ab
44. (vapour permeable membrane* or spyrosorb or flexipore or omiderm or surfasoft or tegapore) in ti, ab
45. (enzymes or enzymotic) in ti, ab
46. (secondary dressing* or film or films or gauze or fibre or fiber or occlusive dressing*) in ti, ab
47. (aquacel or aloe vera or wound gel* or polynoxylin) in ti, ab
48. (melolin or emsol or silastic foam* or hydrofibre* or hydrofiber*) in ti, ab
49. (polyurethane or hydrocellular or foam elastomer or cellulose) in ti, ab
50. #18 or #19 or #20 or #21 or #22 or #23
51. #24 or #25 or #26 or #27 or #28 or #29
52. #30 or #31 or #32 or #33 or #34 or #35
53. #36 or #37 or #38 or #39 or #40 or #41
54. #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49
55. #50 or #51 or #52 or #53 or #54
56. #55 and #17
57. wound or wounds or cavity or cavities or abscess* or sinus or sinuses or incision or incisions
58. #56 and #57
59. sutur* near wound*
60. explode "burn"/all subheadings
61. "burn-dressing"/all subheadings
62. explode "eye-disease"/all subheadings
63. explode "dentistry"/all subheadings
64. explode "dental-care"/all subheadings
65. #59 or #60 or #61 or #62 or #63 or #64
66. #58 not #65
67. "case-report"/ all subheadings
68. "case-study"/ all subheadings
69. "retrospective-study"/ all subheadings
70. #67 or #68 or #69
71. #66 not #70
72. mesalt
73. sodium chloride near dressing*
74. hypergel or normlgel or mepilex or mepitel
75. silicone near dressing*
76. alldress or mepore or mesorb or (cellulose near dressing*)
77. #72 or #73 or #74 or #75 or #76
78. #17 and #77
79. #78 not #71

Fifth iteration

1. explode "surgery"/ all subheadings
2. surgery or surgical
3. #1 or #2
4. "surgical-wound"/ all subheadings
5. "wound-dehiscence"/ all subheadings
6. "wound-infection"/ all subheadings
7. "postoperative-complication"/ all subheadings
8. (wound* or cavit*) in ts,ab
9. #7 and #8
10. #3 or #4 or #5 or #6 or #9
11. (dehiscen* or sepsis or exudat* or necrot* or lsough*) in ti, ab

12. (non-heal* or non heal* or nonheal* or problem or difficult* or complic*) near (wound* or cavit* or incision*) in ti, ab
13. (chronic wound*) in ti, ab
14. (granulating wound*) in ti, ab
15. (postoperative near wound*) in ti, ab
16. (pilonidal sinus* or pilonidal abcess*) in ti, ab
17. #10 or #11 or #12 or #13 or #14 or #15 or #16
18. "Debridement"/ all subheadings
19. debrid* in ti, ab
20. "larva"/ all subheadings
21. larva* in ti, ab
22. (maggot or maggots) in ti, ab
23. (bio-surg* or bio surg* or biosurg*) in ti, ab
24. (trypsin or collagenase or streptokinase or streptodornase) in ti, ab
25. (varidase near topical) in ti, ab
26. (wet near dry near dress*) in ti, ab
27. (polysaccharid* or dextranomer* or xerogel or cadexomer iodine) in ti, ab
28. (iodoflex or iodosorb or hydrogel*) in ti, ab
29. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ti, ab
30. (pressur* wound* irrigation*) in ti, ab
31. whirlpool in ti, ab
32. (hydrochlorite solution) in ti, ab
33. (sodium hypochlorite) in ti, ab
34. (dakin* solution) in ti, ab
35. eusol in ti, ab
36. (malic acid or benzoic acid or salicylic acid or propylene glycol) in ti, ab
37. (proteolytic* or fibrinolytic* or collagenase*) in ti, ab
38. (hydrocholloid* or granuflex or comfeel or tegasorb or hydrocolloid* or aqualcel or combiderm or duoderm) in ti, ab
39. (hydrofibre or debrisan) in ti, ab
40. (bioclusive or cutifilm or epiview of mefilm or opsite flexigrid or tegaderm) in ti, ab
41. (polyurethane foam or allevyn or lyfoam or tielle or lyofoam) in ti, ab
42. (alginate* or sorbsan or tegagel or kaltostat or kaltogel or seasorb or algisite or algosteril or megisorb or cutinova cavity) in ti, ab
43. (tulle gras or jelonet or bactigras or chlorhexitulle or serotulle or fucidin intertulle or sofra tulle) in ti, ab
44. (vapour permeable membrane* or spyrosorb or flexipore or omiderm or surfasoft or tegapore) in ti, ab
45. (enzymes or enzymotic) in ti, ab
46. (secondary dressing* or film or films or gauze or fibre or fiber or occlusive dressing*) in ti, ab
47. (aquacel or aloe vera or wound gel* or polynoxylin) in ti, ab
48. (melolin or emsol or silastic foam* or hydrofibre* or hydrofiber*) in ti, ab
49. (polyurethane or hydrocellular or foam elastomer or cellulose) in ti, ab
50. #18 or #19 or #20 or #21 or #22 or #23
51. #24 or #25 or #26 or #27 or #28 or #29
52. #30 or #31 or #32 or #33 or #34 or #35
53. #36 or #37 or #38 or #39 or #40 or #41
54. #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49
55. #50 or #51 or #52 or #53 or #54
56. #55 and #17
57. wound or wounds or cavity or cavities or abscess* or sinus or sinuses or incision or incisions
58. #56 and #57
59. sutur* near wound*
60. explode "burn"/all subheadings
61. "burn-dressing"/all subheadings
62. explode "eye-disease"/all subheadings
63. explode "dentistry"/all subheadings
64. explode "dental-care"/all subheadings
65. #59 or #60 or #61 or #62 or #63 or #64
66. #58 not #65
67. "case-report"/ all subheadings
68. "case-study"/ all subheadings
69. "retrospective-study"/ all subheadings
70. #67 or #68 or #69
71. #66 not #70
72. mesalt
73. sodium chloride near dressing*
74. hypergel or normlgel or mepilex or mepitel
75. silicone near dressing*
76. alldress or mepore or mesorb or (cellulose near dressing*)
77. #72 or #73 or #74 or #75 or #76
78. #17 and #77
79. #78 not #71
80. enzymatic
81. hypochlorite
82. solution
83. enzymatic or hypochlorite solution
84. #17 and #83
85. #84 and #57
86. #85 not #58

CINAHL

The CINAHL search was done via ARC/ SilverPlatter, as follows.

First iteration

1. explode "Surgery-Operative"/ all topical subheadings / all age subheadings
2. surgery or (surgical in ti, ab)
3. #1 or #2

4. "Surgical-Wound"/ all topical subheadings / all age subheadings
5. "Surgical-Wound-Dehiscence"/ all topical subheadings / all age subheadings
6. "Surgical-Wound-Infection"/ all topical subheadings / all age subheadings
7. "Postoperative-Complications"/ all topical subheadings / all age subheadings
8. wound* or (cavit* in ti, ab)
9. #7 and #8
10. #4 or #5 or #6 or #9
11. explode "Infection"/ all topical subheadings / all age subheadings
12. "Bacterial-Infections"/ all topical subheadings / all age subheadings
13. (#11 or #12) and #8
14. (infect* near surg* near (wound* or cavit*)) in ti, ab
15. dehiscen* near ((wound* or cavit*) in ti, ab)
16. sepsis near ((wound* or cavit*) in ti, ab)
17. necrot* near ((wound* or surg*) in ti, ab)
18. slough* near ((wound* or cavit*) in ti, ab)
19. (((non-heal*) or (non heal*) or nonheal* or problem* or difficult* or complic*) near (wound* or cavit*)) in ti, ab
20. #13 or #14 or #15 or #16 or #17 or #18 or #19
21. #3 and #20
22. #10 or #21
23. "Debridement"/ all topical subheadings / all age subheadings
24. debrid* in ti, ab
25. larva* or (maggot* in ti, ab)
26. ((bio-surg*) or (bio surg*) or biosurg*) in ti, ab
27. ((trypsin or collagenase or streptokinase or streptodornase) and (wound* or cavit*)) in ti, ab
28. (varidase near topical) in ti, ab
29. wet to dry dress* in ti, ab
30. (saline gauz*) in ti, ab
31. (dextranomer polysaccharid*) in ti, ab
32. (polysaccharid* (bead* or paste)) in ti, ab
33. dextranomer in ti, ab
34. xerogel* in ti, ab
35. (cadexomer iodine) in ti, ab
36. (iodoflex or iodosorb) in ti, ab
37. hydrogel* in ti, ab
38. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ti, ab
39. (pressur* wound* irrigation*) in ti, ab
40. woorlpool
41. hydrochlorite solution
42. (sodium hypochlorite) near ((wound* or cavit*) in ti, ab)
43. (dakin* solution) in ti, ab
44. eusol near ((wound* or cavit*) in ti, ab)
45. (((malic acid) or (benzoic acid) or (salicylic acid) or (propylene glycol)) near (wound* or cavit*)) in ti, ab
46. (proteolytic* or fibrinolytic* or collagenase*) near ((wound* or cavit*) in ti, ab)
47. ((hydrocholloid* or granuflex or (comfeel plus) or tegasorb or hydrocoll or aqalcel or combiderm or duoderm) near (wound* or cavit*)) in ti, ab
48. (polysaccharid* dress*) in ti, ab
49. hydrofibre dress* in ti, ab
50. debrisan in ti, ab
51. (bioclusive or cutifilm or epiview or mefilm or (opsite flexigrid) or tegaderm) in ti, ab
52. ((polyurethane foam dress*) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
53. ((alginat* dress*) or sorbsan or tegagel or kaltostat or kaltogel or (comfeel seasorb) or algisite or algosteril or megisorb or (cutinova cavity) or (seasorb filler)) in ti, ab
54. ((parafin gauze dress*) or (tulle gras) or gelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ti, ab
55. #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54
56. #22 and #55

Second iteration

1. explode "Surgery-Operative"/ all topical subheadings / all age subheadings
2. surgery or (surgical in ti, ab)
3. #1 or #2
4. "Surgical-Wound"/ all topical subheadings / all age subheadings
5. "Surgical-Wound-Dehiscence"/ all topical subheadings / all age subheadings
6. "Surgical-Wound-Infection"/ all topical subheadings / all age subheadings
7. "Postoperative-Complications"/ all topical subheadings / all age subheadings
8. wound* or (cavit* in ti, ab)
9. #7 and #8
10. #4 or #5 or #6 or #9
11. explode "Infection"/ all topical subheadings / all age subheadings
12. "Bacterial-Infections"/ all topical subheadings / all age subheadings
13. (#11 or #12) and #8
14. (infect* near surg* near (wound* or cavit*)) in ti, ab

15. dehiscen* near ((wound* or cavit*) in ti, ab)
16. sepsis near ((wound* or cavit*) in ti, ab)
17. necrot* near ((wound* or surg*) in ti, ab)
18. slough* near ((wound* or cavit*) in ti, ab)
19. (((non-heal*) or (non heal*) or nonheal* or problem* or difficult* or complic*) near (wound* or cavit*)) in ti, ab
20. #13 or #14 or #15 or #16 or #17 or #18 or #19
21. #3 and #20
22. #10 or #21
23. "Debridement"/ all topical subheadings / all age subheadings
24. debrid* in ti, ab
25. larva* or (maggot* in ti, ab)
26. ((bio-surg*) or (bio surg*) or biosurg*) in ti, ab
27. ((trypsin or collagenase or streptokinase or streptodornase) and (wound* or cavit*)) in ti, ab
28. (varidase near topical) in ti, ab
29. wet to dry dress* in ti, ab
30. (saline gauz*) in ti, ab
31. (dextranomer polysaccharid*) in ti, ab
32. (polysaccharid* (bead* or paste)) in ti, ab
33. dextranomer in ti, ab
34. xerogel* in ti, ab
35. (cadexomer iodine) in ti, ab
36. (iodoflex or iodosorb) in ti, ab
37. hydrogel* in ti, ab
38. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ti, ab
39. (pressur* wound* irrigation*) in ti, ab woorlpool
40. hydrochlorite solution
41. (sodium hypochlorite) near ((wound* or cavit*) in ti, ab)
42. (dakin* solution) in ti, ab
43. eusol near ((wound* or cavit*) in ti, ab)
44. (((malic acid) or (benzoic acid) or (salicylic acid) or (propylene glycol)) near (wound* or cavit*)) in ti, ab
45. (proteolytic* or fibrinolytic* or collagenase*) near ((wound* or cavit*) in ti, ab)
46. ((hydrocholloid* or granuflex or (comfeel plus) or tegasorb or hydrocoll or aqalcel or combiderm or duoderm) near (wound* or cavit*)) in ti, ab
47. (polysaccharid* dress*) in ti, ab
48. hydrofibre dress* in ti, ab
49. debrisan in ti, ab
50. (bioclusive or cutifilm or epiview or mefilm or (opsite flexigrid) or tegaderm) in ti, ab
51. ((polyurethane foam dress*) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
52. ((alginat* dress*) or sorbsan or tegagel or kaltostat or kaltogel or (comfeel seasorb) or algisite or algosteril or megisorb or (cutinova cavity) or (seasorb filler)) in ti, ab
53. ((parafin gauze dress*) or (tulle gras) or gelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ti, ab
54. #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53
55. #22 and #53

Third (set 72) and fourth (set 80) iterations

1. explode "Surgery-Operative"/ all topical subheadings / all age subheadings
2. surgery or (surgical in ti, ab)
3. #1 or #2
4. "Surgical-Wound"/ all topical subheadings / all age subheadings
5. "Surgical-Wound-Dehiscence"/ all topical subheadings / all age subheadings
6. "Surgical-Wound-Infection"/ all topical subheadings / all age subheadings
7. "Postoperative-Complications"/ all topical subheadings / all age subheadings
8. wound* or (cavit* in ti, ab)
9. #7 and #8
10. #3 or #4 or #5 or #6 or #9
11. (dehiscen* or sepsis or exudat* or necrot* or slough*) in ti, ab
12. (non-heal* or non heal* or nonheal*) in ti, ab
13. (problem or difficult* or complic*) near (wound* or cavit* or incision*) in ti, ab
14. (chronic wound*) in ti, ab
15. (granulating wound*) in ti, ab
16. (postoperative near wound*) in ti, ab
17. (pilonidal sinus* or pilonidal abcess*) in ti, ab
18. #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17
19. "Debridement"/ all topical subheadings / all age subheadings
20. debrid* in ti, ab
21. "larva"/ all subheadings
22. larva* in ti, ab
23. (maggot or maggots) in ti, ab
24. (bio-surg* or bio surg* or biosurg*) in ti, ab
25. (trypsin or collagenase or streptokinase or streptodornase) in ti, ab
26. (varidase near topical) in ti, ab
27. (wet near dry near dress*) in ti, ab
28. (polysaccharid* or dextranomer* or xerogel or cadexomer iodine) in ti, ab
29. (iodoflex or iodosorb or hydrogel*) in ti, ab

30. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ti, ab
31. (pressur* wound* irrigation*) in ti, ab
32. whirlpool in ti, ab
33. (hydrochlorite solution) in ti, ab
34. (sodium hypochlorite) in ti, ab
35. (dakin* solution) in ti, ab
36. eusol in ti, ab
37. (malic acid or benzoic acid or salicylic acid or propylene glycol) in ti, ab
38. (proteolytic* or fibrinolytic* or collagenase*) in ti, ab
39. (hydrocholloid* or granuflex or comfeel or tegasorb or hydrocolloid* or aqualcel or combiderm or duoderm) in ti, ab
40. (hydrofibre or debrisan) in ti, ab
41. (bioclusive or cutifilm or epiview or mefilm or (opsite flexigrid) or tegaderm) in ti, ab
42. ((polyurethane foam) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
43. (alginate* or sorbsan or tegagel or kaltostat or kaltogel or seasorb or algisite or algosteril or megisorb or cutinova cavity) in ti, ab
44. (tulle gras or jelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ti, ab
45. (vapour permeable membrane* or spyrosorb or flexipore or omiderm or surfasoft or tegapore) in ti, ab
46. (enzymes or enzymotic) in ti, ab
47. (secondary dressing* or film or films or gauze or fibre or fiber or occlusive dressing*) in ti, ab
48. (aquacel or aloe vera or wound gel* or polynoxylin) in ti, ab
49. (melolin or emsol or silastic foam* or hydrofibre* or hydrofiber*) in ti, ab
50. (polyurethane or hydrocellular or foam elastomer or cellulose) in ti, ab
51. #19 or #20 or #21 or #22 or #23
52. #24 or #25 or #26 or #27
53. #28 or #29 or #30 or #31
54. #32 or #33 or #34 or #35
55. #36 or #37 or #38 or #39
56. #40 or #41 or #42 or #43
57. #44 or #45 or #46 or #47 or #48 or #49 or #50
58. #51 or #52 or #53 or #54 or #55 or #56 or #57
59. #18 and #58
60. wound or wounds or cavity or cavities or abscess* or sinus or sinuses or incision or incisions
61. #59 and #60
62. sutur* near wound*
63. skin graft*
64. explode "Burns"/ all subheadings
65. explode "Eye-Diseases"/ all subheadings
66. explode "Dentistry"/ all subheadings
67. #62 or #63 or #64 or #65 or #66
68. #61 not #67
69. "Case-Studies"/ all topical subheadings / all age subheadings
70. "Retrospective-Design"/ all topical subheadings / all age subheadings
71. #69 or #70
72. #68 not #71
73. mesalt
74. sodium chloride near dressing*
75. hypergel or normlgel or mepilex or mepitel
76. silicone near dressing*
77. alldress or mepore or mesorb or (cellulose near dressing*)
78. #73 or #74 or #75 or #76 or #77
79. #18 and #78
80. #79 not #72

Fifth iteration

1. explode "Surgery-Operative"/ all topical subheadings / all age subheadings
2. surgery or (surgical in ti, ab)
3. #1 or #2
4. "Surgical-Wound"/ all topical subheadings / all age subheadings
5. "Surgical-Wound-Dehiscence"/ all topical subheadings / all age subheadings
6. "Surgical-Wound-Infection"/ all topical subheadings / all age subheadings
7. "Postoperative-Complications"/ all topical subheadings / all age subheadings
8. wound* or (cavit* in ti, ab)
9. #7 and #8
10. #3 or #4 or #5 or #6 or #9
11. (dehiscen* or sepsis or exudat* or necrot* or slough*) in ti, ab
12. (non-heal* or non heal* or nonheal*) in ti, ab
13. (problem or difficult* or complic*) near (wound* or cavit* or incision*) in ti, ab
14. (chronic wound*) in ti, ab
15. (granulating wound*) in ti, ab
16. (postoperative near wound*) in ti, ab
17. (pilonidal sinus* or pilonidal abcess*) in ti, ab
18. #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17
19. "Debridement"/ all topical subheadings / all age subheadings
20. debrid* in ti, ab
21. "larva"/ all subheadings
22. larva* in ti, ab
23. (maggot or maggots) in ti, ab
24. (bio-surg* or bio surg* or biosurg*) in ti, ab
25. (trypsin or collagenase or streptokinase or streptodornase) in ti, ab

26. (varidase near topical) in ti, ab
27. (wet near dry near dress*) in ti, ab
28. (polysaccharid* or dextranomer* or xerogel or cadexomer iodine) in ti, ab
29. (iodoflex or iodosorb or hydrogel*) in ti, ab
30. ((intrasite gel) or intrasitegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilon gel) or vigilon or (2nd skin) or (second skin)) in ti, ab
31. (pressur* wound* irrigation*) in ti, ab
32. whirlpool in ti, ab
33. (hydrochlorite solution) in ti, ab
34. (sodium hypochlorite) in ti, ab
35. (dakin* solution) in ti, ab
36. eusol in ti, ab
37. (malic acid or benzoic acid or salicylic acid or propylene glycol) in ti, ab
38. (proteolytic* or fibrinolytic* or collagenase*) in ti, ab
39. (hydrocholloid* or granuflex or comfeel or tegasorb or hydrocolloid* or aqualcel or combiderm or duoderm) in ti, ab
40. (hydrofibre or debrisan) in ti, ab
41. (bioclusive or cutifilm or epiview or mefilm or (opsite flexigrid) or tegaderm) in ti, ab
42. ((polyurethane foam) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
43. (alginate* or sorbsan or tegagel or kaltostat or kaltogel or seasorb or algisite or algosteril or megisorb or cutinova cavity) in ti, ab
44. (tulle gras or jelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ti, ab
45. (vapour permeable membrane* or spyrosorb or flexipore or omiderm or surfasoft or tegapore) in ti, ab
46. (enzymes or enzymotic) in ti, ab
47. (secondary dressing* or film or films or gauze or fibre or fiber or occlusive dressing*) in ti, ab
48. (aquacel or aloe vera or wound gel* or polynoxylin) in ti, ab
49. (melolin or emsol or silastic foam* or hydrofibre* or hydrofiber*) in ti, ab
50. (polyurethane or hydrocellular or foam elastomer or cellulose) in ti, ab
51. #19 or #20 or #21 or #22 or #23
52. #24 or #25 or #26 or #27
53. #28 or #29 or #30 or #31
54. #32 or #33 or #34 or #35
55. #36 or #37 or #38 or #39
56. #40 or #41 or #42 or #43
57. #44 or #45 or #46 or #47 or #48 or #49 or #50
58. #51 or #52 or #53 or #54 or #55 or #56 or #57
59. #18 and #58
60. wound or wounds or cavity or cavities or abscess* or sinus or sinuses or incision or incisions
61. #59 and #60
62. sutur* near wound*
63. skin graft*
64. explode "Burns"/ all subheadings
65. explode "Eye-Diseases"/ all subheadings
66. explode "Dentistry"/ all subheadings
67. #62 or #63 or #64 or #65 or #66
68. #61 not #67
69. "Case-Studies"/ all topical subheadings / all age subheadings
70. "Retrospective-Design"/ all topical subheadings / all age subheadings
71. #69 or #70
72. #68 not #71
73. mesalt
74. sodium chloride near dressing*
75. hypergel or normlgel or mepilex or mepitel
76. silicone near dressing*
77. alldress or mepore or mesorb or (cellulose near dressing*)
78. #73 or #74 or #75 or #76 or #77
79. #18 and #78
80. #79 not #72
81. enzymatic
82. hypochlorite
83. solution
84. enzymatic or hypochlorite solution
85. #84 and #18
86. #85 and #60

CCTR/CENTRAL and NRR

The CCTR/CENTRAL and NRR search was done on CD-ROM, the former via the Cochrane Library, as follows.

First iteration

1. SURGICAL-PROCEDURES-OPERATIVE*:ME
2. (SURGERY or SURGICAL)
3. (#1 or #2)
4. POSTOPERATIVE-COMPLICATIONS:ME
5. (WOUND* or CAVIT*)
6. (#4 and #5)
7. SURGICAL-WOUND-DEHISCENCE:ME
8. SURGICAL-WOUND-INFECTION:ME
9. ((#6 or #7) or #8)
10. INFECTION*:ME
11. BACTERIAL-INFECTIONS:ME
12. (#10 or #11)
13. (#6 and #12)
14. ((INFECT* near SURG*) near WOUND*)
15. ((INFECT* near SURG*) near CAVIT*)
16. (DEHISCEN* near WOUND*)
17. (DEHISCEN* near CAVIT*)
18. (SEPSIS near WOUND*)

19. (SEPSIS near CAVIT*)
20. (EXUDAT* near WOUND*)
21. (EXUDAT* near CAVIT*)
22. (NECROT* near WOUND*)
23. (NECROT* near CAVIT*)
24. (SLOUGH* near WOUND*)
25. (SLOUGH* near CAVIT*)
26. ((((((NON-HEAL* or (NON next HEAL*)) OR NONHEAL*) OR DIFFICULT*) OR PROBLEM*) OR COMPLIC*) AND (WOUND* OR CAVIT*))
27. ((((((((((((#13 or #14) or #15) or #16) or #17) or #18) or #19) or #20) or #21) or #22) or #23) or #24) or #25) or #26)
28. (#3 and #27)
29. (#9 or #28)
30. DEBRIDEMENT*:ME
31. DEBRID*
32. LARVA*:ME
33. (LARVA* or MAGGOT*)
34. ((BIO-SURG* or (BIO next SURG*)) OR BIOSURG*)
35. ((((TRYPSIN or COLLAGENASE) or STREPTOKINASE) or STREPTODORNASE) and (WOUND* or CAVIT*))
36. (VARIDASE near TOPICAL)
37. ((WET near DRY) near DRESS*)
38. (SALINE next GAUZ*)
39. (DEXTRANOMER next POLYSACCHARID*)
40. (POLYSACCHARIDE next BEAD*)
41. (POLYSACCHARIDE next PASTE)
42. DEXTRANOMER*
43. XEROGEL*
44. (CADEXOMER next IODINE)
45. (IODOFLEX or IODOSORB)
46. HYDROGEL*
47. (((((((((INTRASITE next GEL) or INTRASITEGEL) OR STERIGEL) OR GRANUGEL) OR (AQUAFORM NEXT HYDROGEL)) OR NUGEL) OR (PURILON NEXT GEL)) OR VIGILON) OR (SECOND NEXT SKIN))
48. (PRESSUR* next (WOUND* next IRRIGATION*))
49. WOORLPOOL
50. (HYDROCHLORITE next SOLUTION)
51. (SODIUM next HYPOCHLORITE)
52. (DAKIN* next SOLUTION)
53. EUSOL
54. (((((MALIC next ACID) or (BENZOID next ACID)) OR (SALICYLIC NEXT ACID)) OR (PROPYLENE NEXT GLYCOL)) AND (WOUND* OR CAVIT*))
55. (((PROTEOLYTIC* or FIBRINOLYTIC*) or COLLAGENASE*) and (WOUND* or CAVIT*))
56. ("HYDROCHOLLOID* OR GRANUFLEX OF "COMFEEL PLUS" OR TEGASORB OR HYDROCOLL OR AQUALCEL OR COMBIDERM OR DUODERM) AND (WOUND* OR CAVIT*)
57. ("HYDROCHOLLOID* OR GRANUFLEX OF "COMFEEL PLUS" OR TEGASORB OR HYDROCOLL OR AQUALCEL OR COMBIDERM OR DUODERM) AND (WOUND* OR CAVIT*)
58. ("HYDROCHOLLOID* OR GRANUFLEX OR "COMFEEL PLUS" OR TEGASORB OR HYDROCOLL OR AQUALCEL OR COMBIDERM OR DUODERM) AND (WOUND* OR CAVIT*)
59. (((((((HYDROCHOLLOID* or GRANUFLEX) OR (COMFEEL next PLUS)) OR TEGASORB) OR HYDROCOLL) OR AQUALCEL) OR COMBIDERM) OR DUODERM) AND (WOUND* OR CAVIT*))
60. ((POLYSACCHARID* next DRESS*) near WOUND*)
61. ((POLYSACCHARID* next DRESS*) near CAVIT*)
62. (HYDROFIBRE next DRESS*)
63. DEBRISAN
64. (((((BIOCLUSIVE or CUTIFILM) or EPIVIEW) or MEFILM) OR (OPSITE next FLEXIGRID)) OR TEGADERM)
65. (((((POLYURETHAN* next (FOAM next DRESS*)) or ALLEVYN) OR LYFOAM) OR TIELLE) OR LYOFOAM)
66. ((((((((((ALGINAT* next DRESS*) or SORBSAN) OR TEGAGEL) OR KALTOSTAT) OR KALTOGEL) OR (COMFEEL NEXT SEASORB)) OR ALGISITE) OR ALGOSTERIL) OR MEGISORB) OR (CUTINOVA NEXT CAVITY)) OR (SEASORB NEXT FILLER))
67. (((((((PARAFIN next (GAUZE next DRESS*)) or (TULLE next GRAS)) OR JELONET) OR BACTIGRAS) OR CHLORHEXITULLE) OR SEROTULLE) OR (FUCIDIN NEXT INTERTULLE)) OR (SOFRA NEXT TULLE))
68. (((((((VAPOUR next (PERMEABLE next MEMBRANE)) or (VAPOUR next (PERMEABLE next MEMBRANES))) OR SYPROSORB) OR FLEXIPORE) OR OMIDERM) OR SURFASOFT) OR TEGAPORE) AND (WOUND* OR CAVIT*))
69. (((((((((#30 or #31) or #32) or #33) or #34) or #35) or #36) or #37) or #38) or #39)
70. (((((((((#40 or #41) or #42) or #43) or #44) or #45) or #46) or #47) or #48) or #49)
71. (((((((((#50 or #51) or #52) or #53) or #54) or #55) or #56) or #57) or #58) or #59)

72. (((((((#60 or #61) or #62) or #63) or #64) or #65) or #66) or #67) or #68)
73. (((#69 or #70)or #71) or #72)
74. (#29 and #73)

Second iteration

1. SURGICAL-PROCEDURES-OPERATIVE*:ME
2. SURGICAL-WOUND-INFECTION*:ME
3. SURGICAL-WOUND-DEHISCENCE*:ME
4. POSTOPERATIVE-COMPLICATIONS*:ME
5. ((WOUND* or CAVIT*) or INCISION*)
6. (SURGICAL or SURGERY)
7. ((((DEHISCEN* or SEPSIS) or EXUDAT*) or NECORT*) or SLOUGH*)
8. (NECROT* or NONHEAL*)
9. (PROBLEM near ((WOUND* or CAVIT*) or INCISION*))
10. (DIFFICULT near ((WOUND* or CAVIT*) or INCISION*))
11. (COMPLICAT* near ((WOUND* or CAVIT*) or INCISION*))
12. (CHRONIC and WOUND*)
13. (GRANULATING and WOUND*)
14. (POSTOPERATIVE near WOUND*)
15. ((PILONIDAL and SINUS*) or (PILONIDAL and ABSCESS*))
16. (((#4 or #1) or #6) and #5)
17. ((((((((((#2 or #3) or #7) or #8) or #9) or #10) or #11) or #12) or #13) or #14) or #15) or #16)
18. DEBRIDEMENT:ME
19. (((DEBRID* or LARVA*) or MAGGOT) or MAGGOTS)
20. LARVA:ME
21. (((BIOSURG* or BIO-SURG*) or TRYPSIN) or COLLAGENASE)
22. ((STREPTOKINASE or STREPTODORNASE) not THROMBOLY*)
23. (VARIDASE near TOPICAL*)
24. (((POLYSACCHARID* or DEXTRANOMER*) or XEROGEL) OR (CADEXOMER next IODINE))
25. ((((IODOFLEX or IODOSORB) or HYDROGEL*) or INTRASITE*) or STERIGEL)
26. ((((GRANUGEL or NUGEL) or NU-GEL) OR (PURILON next GEL)) OR VIGILON)
27. ((((SECOND next SKIN) or IRRIGATION) OR WHIRLPOOL) OR (HYDROCHLORITE NEXT SOLUTION))
28. (((((SODIUM next HYPOCHLORITE) or DAKIN*) OR EUSOL) OR (MALIC NEXT ACID)) OR (BENZOIC NEXT ACID))
29. ((salicylic next acid) or (propylene next glycol))
30. (((proteolytic* or fibrinolytic*) or hydrocholloid*) or granuflex)
31. (((comfeel or tegasorb) or hydrocolloid*) or aqualcel)
32. (((combiderm or duoderm) or hydrofibre) or debrisan)
33. (((bioclusive or cutifilm) or epiview) or mefilm)
34. (((opsite next flexigrid) or tegaderm) or (polyurethane next foam))
35. (((allevyn or lyfoam) or tielle) or lyofoam)
36. (((alginate* or sorbsan) or tegagel) or kaltostat)
37. (((kaltogel or seasorb) or algisite) or algosteril)
38. (((megisorb or cutinova) or tulle) or jelonet)
39. (((bactigras or chlorhexitulle) or serotulle) or intertulle)
40. (((sofra or spyrosorb) or flexipore) or omiderm)
41. (vapour next permeable next membrane*)
42. (((surfasoft or tegapore) or enzyme*) or enzymatic)
43. (((secondary next dressing*) or film) or films)
44. (((gauze or fiber) or fibre) or (occlusive next dressing*))
45. (((aquacel or aloe) or (wound next gel*)) or polynoxylin)
46. (((melolin or emsol) or silastic) or hydrofib*)
47. (((polyurethane or hydrocellular) or cellulose) or (foam next elastomer))
48. (((((((wound or wounds) or cavity) or cavities) or abscess*) or sinus) or sinuses) or incision) or incisions)
49. ((((((((((((((((((((((((((((((#18 or #19) or #20) or #21) or #22) or #23) or #24) or #25) or #26) or #27) or #28) or #29) or #30) or #31) or #32) or #33) or #34) or #35) or #36) or #37) or #38) or #39) or #40) or #41) or #42) or #43) or #44) or #45) or #46)
50. (#17 and #49)
51. (#47 and #50)

Third iteration

The following terms were added to the second iteration search terms; previous results were excluded:

- MESALT
- ((SODIUM next CHLORIDE) near DRESSING*)
- ((HYPERGEL or NORMLGEL) or MEPILEX)
- ((HYPERGEL or NORMLGEL) or MEPILEX)
- (SILICONE near DRESSING*)
- (((MEPITEL or ALLDRESS) or MEPORE) or MESORB)

Topic 2: settings of care for difficult to heal surgical wounds

MEDLINE

The MEDLINE search was done via ARC/ SilverPlatter, as follows. (Searches 1–23 were as for the debridement search, first iteration.)

24. explode "health facilities"/ all subheadings
25. explode "health services"/ all subheadings
26. explode "delivery of health care"/ all subheadings
27. "postoperative care"/ all subheadings
28. "Aftercare"/ all subheadings
29. tissue viability nurs* in ti, ab
30. ((post operative care) or (postoperative care) or aftercare) in ti, ab
31. ((nurse or nurses or doctor* or physician or gp or practitioner or (health visit*) or staff or personnel) near (wound* or cavit*)) in ti, ab
32. ((setting or hospital or hospitals or community or clinic or clinics or home or centre* or center* or department* or unit or units) near (wound* or cavit*)) in ti, ab
33. ((facilit* or location or outpatient* or inpatient* or rehabilitation or acute) near (wound* or cavit*)) in ti, ab
34. ((management or treatment* or program* or service* or delivery or care) near (wound* or cavit*)) in ti, ab
35. #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34
36. #23 and #35
37. explode "Health-Care-Evaluation-Mechanisms"/ all subheadings
38. explode "Evaluation-Studies"/ all subheadings
39. (trial* or stud* or evaluat* or examin*) in ti, ab
40. #37 or #38 or #39
41. #36 and #40

EMBASE

The MEDLINE search was done via ARC/ SilverPlatter, as follows. (Searches 1–23 were as for the debridement search, first iteration.)

24. explode "health-care-facilities-and-services"/ all subheadings
25. explode "health-care-delivery"/ all subheadings
26. "postoperative-care"/ all subheadings
27. explode "aftercare"/ all subheadings
28. tissue viability nurs* in ti, ab
29. (((post operative care) or (postoperative care) or aftercare) near (wound* or cavit*)) in ts, ab
30. ((nurse or nurses or doctor* or physician or gp or practitioner or (health visit*) or staff or personnel) near (wound* or cavit*)) in ts, ab
31. ((setting or hospital or hospitals or community or clinic or clinics or home or centre* or center* or department* or unit or units) near (wound* or cavit*)) in ts, ab
32. ((facilit* or location or outpatient* or inpatient* or rehabilitation or acute) near (wound* or cavit*)) in ts, ab
33. ((management or treatment* or program* or service* or delivery or care) near (wound* or cavit*)) in ts, ab
34. #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33
35. #23 and #34
36. explode "health-care-quality"/ all subheadings
37. explode "evaluation-and-follow-up"/ all subheadings
38. explode "comparative-study"/ all subheadings
39. explode "controlled-study"/ all subheadings
40. explode "methodology"/ all subheadings
41. "feasibility-study"/ all subheadings
42. "theoretical-study"/ all subheadings
43. (trial* or stud* or evaluat* or examin*) in ts, ab
44. #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43
45. #35 and #44

CINAHL

The CINAHL search was done via ARC/ SilverPlatter, as follows. (Searches 1–22 were as for the debridement search, first iteration.)

23. explode "Health-Facilities"/ all topical subheadings / all age subheadings
24. explode "Health-Services"/ all topical subheadings / all age subheadings
25. explode "Health-Care-Delivery"/ all topical subheadings / all age subheadings
26. explode "Postoperative-Care"/ all topical subheadings / all age subheadings
27. explode "Patient-Care" tree: 2/ all topical subheadings / all age subheadings
28. "After-Care"/ all topical subheadings / all age subheadings
29. tissue viability nurs* in ti, ab
30. ((post operative care) or (postoperative care) or aftercare) in ti, ab
31. ((nurse or nurses or doctor* or physician or gp or practitioner or (health visit*) or staff or personnel) near (wound* or cavit*)) in ti, ab
32. ((setting or hospital or hospitals or community or clinic or clinics or home or centre* or center* or department* or unit or units) near (wound* or cavit*)) in ti, ab

33. ((facilit* or location or outpatient* or inpatient* or rehabilitation or acute) near (wound* or cavit*)) in ti, ab
34. ((management or treatment* or program* or service* or delivery or care) near (wound* or cavit*)) in ti, ab
35. #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34
36. #22 and #35
37. explode "Quality-Assessment"/ all topical subheadings / all age subheadings
38. "Program-Evaluation"/ all topical subheadings / all age subheadings
39. "Evaluation"/ all topical subheadings / all age subheadings
40. (trial* or stud* or evaluat* or examin*) in ti, ab
41. #37 or #38 or #39 or #40
42. #36 and #41

HMIC

The HMIC search was done via ARC/SilverPlatter, as follows.

1. (wound* or cavit*) in ti, ab, de
2. postoperative complic* in ti, ab, de
3. postoperative problem* in ti, ab de
4. infection* in ti, ab, de
5. (#2 or #3 or #4) and #1
6. (dehiscen* near (wound* or cavit*)) in ti, ab, de
7. (sepsis near (wound* or cavit*)) in ti, ab, de
8. exudat* near ((wound* or cavit*) in ti, ab, de)
9. (necrot* near (wound* or cavit*)) in ti, ab, de
10. (slough* near (wound* or cavit*)) in ti, ab, de
11. (((non-heal*) or (non heal*) or nonheal* or problem* or difficult* or complic*) near (wound* or cavit*)) in ti, ab, de
12. (infect* near (wound* or cavit*)) in ti, ab, de
13. #6 or #7 or #8 or #9 or #10 or #11 or #12
14. #5 or #13
15. tissue viability nurs* in ti, ab
16. ((post operative care) or (postoperative care) or aftercare) in ti, ab, de
17. ((nurse or nurses or doctor* or physician or gp or practitioner or (health visit*) or staff or personnel) near (wound* or cavit*)) in ti, ab, de
18. ((setting or hospital or hospitals or community or clinic or clinics or home or centre* or center* or department* or unit or units) near (wound* or cavit*)) in ti, ab, de
19. ((facilit* or location or outpatient* or inpatient* or rehabilitation or acute) near (wound* or cavit*)) in ti, ab, de
20. ((management or treatment* or program* or service* or delivery or care) near (wound* or cavit*)) in ti, ab, de
21. #15 or #16 or #17 or #18 or #19 or #20
22. #14 and #21

NRR

The NRR search was done using the CD-ROM, 2000, Issue 1, as follows:

1. POSTOPERATIVE-COMPLICATIONS:ME
2. (WOUND* or CAVIT*)
3. (#1 and #2)
4. SURGICAL-WOUND-DEHISCENCE:ME
5. SURGICAL-WOUND-INFECTION:ME
6. ((#3 or #4) or #5)
7. INFECTION*:ME
8. BACTERIAL-INFECTIONS:ME
9. (#7 or #8)
10. (#2 and #9)
11. ((INFECT* near SURG*) near WOUND*)
12. ((INFECT* near SURG*) near CAVIT*)
13. (DEHISCEN* near WOUND*)
14. (DEHISCEN* near CAVIT*)
15. (SEPSIS near WOUND*)
16. (SEPSIS near CAVIT*)
17. (EXUDAT* near WOUND*)
18. (EXUDAT* near CAVIT*)
19. (NECROT* near WOUND*)
20. (NECROT* near CAVIT*)
21. (SLOUGH* near WOUND*)
22. (SLOUGH* near CAVIT*)
23. ((((((NON-HEAL* or (NON next HEAL*)) OR NONHEAL*) OR DIFFICULT*) OR PROBLEM*) OR COMPLIC*) AND (WOUND* OR CAVIT*))
24. ((((((((((#10 or #11 or #12 or #13 or #14) or #15) or #16) or #17) or #18) or #19) or #20) or #21) or #22) or #23)
25. (#6 or #24)

Topic 3: economic evaluations

MEDLINE

The MEDLINE search was done via ARC/SilverPlatter. The following search was appended to the bottom of the search for the effectiveness of debridement, first iteration.

61. "Economics"/ all subheadings
62. explode "Costs-and-Cost-Analysis"/ all subheadings
63. "Economic-Value-of-Life"
64. explode "Economics-Hospital"/ all subheadings
65. explode "Economics-Medical"/ all subheadings
66. "Economics-Nursing"/ all subheadings
67. "Economics-Pharmaceutical"/ all subheadings

68. explode "Fees-and-Charges"/ all subheadings
69. explode "Budgets"/ all subheadings
70. explode "Models-Economic"/ all subheadings
71. #61 or #62 or #63 or #64 or #65 or #66 or #67 or #68 or #69 or #70
72. (cost or costs or costed or costly or costing) in ti, ab
73. (economic* or pharmacoeconomic* or price or prices or pricing or qaly*) in ti, ab
74. #71 or #72 or #73
75. #60 and #74

EMBASE

The EMBASE search was done via ARC/ SilverPlatter. The following search was appended to the bottom of the search for the effectiveness of debridement, first iteration.

57. explode "health-economics"/ all subheadings
58. "cost"/ all subheadings
59. explode "health-care-cost"/ all subheadings
60. #57 or #58 or #59
61. explode "economic-evaluation"/ all subheadings
62. (cost or costs or costing or costed or costly) in ti, ab
63. (economic* or pharmaceconomic* or price or prices or pricing) in ti, ab
64. #60 or #61 or #62 or #63
65. #56 and #64

CINAHL

The CINAHL search was done via ARC/ SilverPlatter. The following search was appended to the bottom of the search for the effectiveness of debridement, first iteration.

57. "Economics"/ all topical subheadings / all age subheadings
58. explode "Costs-and-Cost-Analysis"/ all topical subheadings / all age subheadings
59. "Economic-Aspects-of-Illness"/ all topical subheadings / all age subheadings
60. "Economics-Pharmaceutical"/ all topical subheadings / all age subheadings
61. "Economic-Value-of-Life"/ all topical subheadings / all age subheadings
62. explode "Fees-and-Charges"/ all topical subheadings / all age subheadings
63. "Budgets"/ all topical subheadings / all age subheadings
64. #57 or #58 or #59 or #60 or #61 or #62 or #63
65. (cost or costs or costed or costly or costing) in ti, ab
66. (economic* or pharmacoeconomic* or price or prices or pricing) in ti, ab
67. #64 or #65 or #66
68. #56 and #67

Search for conference proceedings

Named wound care conferences and wound care organisations were identified by searching the Inside Conferences and Index to Conference Proceedings database on the Dialog Service. The world wide web was also searched for conference proceedings and web pages that might provide records of conference papers. The findings are summarised in *Table 14*.

TABLE 14 *Results of search for conference proceedings*

Conference	Inside Conferences database	Index to Conference Proceedings	Web page
World Conference of Phlebology	No references	No references	No details of past conferences on that web site or on that of the International Union (parent organisation)
European Venous Forum	No references	No references	http://www.esvs.org/esvs/evf2000.html
European Wound Management Conferences	References identified and downloaded	References identified and downloaded	EWMA web site: http://www.leahcim.demon.co.uk/ewma.htm. However, no conference listings
European Tissue Repair Society	References identified and downloaded	No references	http://www.leahcim.demon.co.uk/etrs.htm 1996–1997 meeting abstracts on web site, but not updated since
European Advisory Panel on Pressure Ulceration	No references	No references	Meeting abstracts: http://www.leahcim.demon.co.uk/epuap/
Tissue Viability Conference	References identified and downloaded	No references	Tissue Viability Society: http://www.tvs.org.uk/
Wound Care Society Conferences	No references	No references	WCS home page: http://www.leahcim.demon.co.uk/wcs/wcs_hp.htm (old); http://www.woundcaresociety.org/ (new)
Symposium on advanced wound care and medical research forum on wound care	References identified and downloaded	No references	15th conference: http://www.woundcarenet.com/wcsymp00/program.htm 12th symposium: http://www.medscape.com/HMP/wounds/1999/woundConf/public/toc-woundsConf.html 1997 symposium: http://www.medexpo.com/Pages/schedule.html. conf15
American Wound Healing Society	No references	No references	http://www.leahcim.demon.co.uk/whs-usa/whs.htm No abstracts
Canadian Association of Wound Care	No references	No references	No home page identified
Australian Wound Management Association	No references	No references	http://www.awma.com.au/pages/about.html

Appendix 8

Manufacturer and sponsor submissions made to NICE

TABLE 15 *Manufacturer and sponsor submissions made to NICE*

Company	Information provided	Clinical data	Cost data	Action
Beiersdorf UK Ltd (Medical Division) **Products**: Cutinova™ (foam, hydro, cavity and thin), polyurethane hydroactive dressings	Product description	RCT (*n* = 1): Cutinova vs moist gauze, treatment of ulcers Controlled study (*n* = 1): Cutinova hydro and Allevyn™ in diabetic foot ulcers Clinical evaluation (*n* = 1): Cutinova cavity in secondary healing deep wounds, not clear if controlled Clinical article (*n* = 1): insufficient details Uncontrolled study (*n* = 1): Cutinova cavity in heavily exuding wounds Case studies and series (*n* = 4) *In vitro* (*n* = 5)	Cost per dressing data reported Cost-effectiveness study (*n* = 2),[206] based on a case report of cavity wounds Meyer,[43] based on cavity wound in 43 patients	Cost-minimisation study of Cutinova in difficult to heal surgical wounds Included: cost-minimisation study,[62] RCT[43] Excluded: studies with inappropriate designs (uncontrolled studies, case studies and *in vitro* investigations), RCT and controlled studies because they looked at chronic non-surgical wounds; other cost studies as based on non-surgical wounds
Biosurgical Research Unit **Products**: LarvE™ (sterile larvae of *Lucilia sericata*)	Wound details Debridement Product information General papers	RCT (*n* = 1): looked at venous leg ulcers, no measure of healing Controlled studies (*n* = 2): looked pressure sores and ischaemic ulcers Published case histories (*n* = 16) Unpublished case studies (*n* = 6)	Some cost data provided (the RCT looking at venous leg ulcers also included cost data)	Excluded: all other studies due to inappropriate wound type or study design
Coloplast **Products**: Purilon gel™ (alginate) Comfeel Plus™ (hydrocolloid) SeaSorb™ (flat alginate dressing) Biatain™ (flat foam dressing)	Wound healing and management Product details Wider implications	RCTs (*n* = 5): Purilon vs control in pressure sores (*n* = 1), Comfeel vs Varihesive™ or Granuflex™ in leg ulcers (*n* = 2), SeaSorb vs Kaltostat™ in leg ulcers (*n* = 1) and Biatain vs Allevyn in leg ulcers (*n* = 1) Controlled trials (*n* = 4): Purilon vs Intrasite™ in diabetic foot ulcers (*n* = 1), SeaSorb vs Kaltostat in leg ulcers (*n* = 1), SeaSorb vs gauze in exuding cavity wounds (*n* = 1) and Comfeel vs gauze in leg ulcers (*n* = 1) *In vitro* (*n* = 2)	Cost-effectiveness analysis presented, used data from trials of chronic wounds	Excluded: all other studies due to inappropriate wound type or study design. Cost-effectiveness analysis excluded because data relate to chronic wounds

continued

TABLE 15 contd *Manufacturer and sponsor submissions made to NICE*

Company	Information provided	Clinical data	Cost data	Action
ConvaTec (Commercial in confidence data, omitted)	Wider NHS implications Description of products			Included: economic evaluation[63]
Johnson and Johnson Medical **Products**: NU-GEL™ (hydrogel with alginate) Actisorb-Plus™	Debridement Product description	Refers to HTA report for clinical effectiveness data[30,31] RCT (n = 1): compared NU-GEL to Intrasite™ in pressure sores Case study (n = 2)	Refers to HTA report, no additional data	Excluded: inappropriate wound types and study designs
Kinetic Concepts Inc. **Products**: Vacuum Assisted Closure therapy (VAC™)	Description Mechanism of action Indications, contraindications and precautions	RCTs (n = 2): VAC vs wet-to-dry in mainly chronic wounds Controlled trials (n = 3): VAC vs surgical intervention (post-sternotomy mediastinitis) (n = 1) or gauze (in chronic wounds) (n = 2) Uncontrolled studies (n = 3): VAC in skin graft donor sites (n = 2), wounds not stated (n = 1) Case studies and series (n = 7)	Cost-effectiveness studies reported, mainly on chronic wounds (n = 3)	Excluded: VAC was not considered as a debriding agent. Most studies included inappropriate wound types or study design
Les Laboratoires Brothier **Products**: Algosteril™ (alginate dressing)	Debridement Dressing description Wider NHS implications	RCT (n = 1): Algosteril vs povidone iodine for infected pilonidal abscesses Controlled studies (n = 4): Algosteril vs dextranomer paste for pressure ulcers (n = 1), alginate for treating abscess cavities (n = 1), Algosteril vs gauze in skin grafts (donor sites) (n = 1) and alginate + zinc for leg ulcers (n = 1) *In vitro* studies (n = 2) Case studies and series (n = 1)	Cost-minimisation analysis: used data from decubitus ulcers	Included: controlled trial on alginate for abscess cavities[38] and RCT of Algosteril (calcium alginate) vs povidone iodine for infected pilonidal abscesses[41] Excluded: all other studies, either inappropriate designs or wound types. Cost-minimisation study excluded as used data on ulcers
Maersk Medical **Products**: Aquaform™	Product description and use	RCT (n = 1): Aquaform vs Intrasite, mixed wounds, all chronic, no objective measures of healing Case studies and series (n = 3) *In vitro* (n = 2)	Some cost information, but no analysis	Excluded: inappropriate wound types or study designs

continued

TABLE 15 contd *Manufacturer and sponsor submissions made to NICE*

Company	Information provided	Clinical data	Cost data	Action
Mölnlycke Healthcare **Products**: Mesalt™ (high sodium chloride non-woven dressing) Hypergel™ (high sodium chloride hypergel) NormIgel™ (normal sodium chloride hypergel) Mepilex™ (soft silicone dressing with foam backing) Mepitel™ (soft silicone wound dressing) Mefilm™ (vapour-permeable dressing) Melgisorb™ (alginate dressing)	Dressing details Wound healing Debridement	RCT (n = 1): Hypergel vs enzymatic debridement in dermal ulcers Controlled trials (n = 3): old vs new Mesalt in dermal wounds (n = 1), Mesalt vs saline in pressure ulcers (n = 1) and Mesalt vs benzoyl peroxide gel in ulcers Case studies and series (n = 12)	Cost analysis looking at pressure sores	Excluded: inappropriate wound types and study designs. Cost analysis excluded because it looked at pressure sores
Smith and Nephew **Products**: Cadexomer iodine in the form of Iodoflex™ Iodoflex™ Iodosorb™ powder and ointment Intrasite™ gel (hydrogel)	Surgical practice Wound healing Debridement Product description	Most references come from HTA reports,[30,31] other studies: RCTs (n = 5): Intrasite vs Debrisan for pressure sores (n = 2) and cadexomer iodine vs standard treatment for venous leg ulcers (n = 2) Case studies and series (n = 6)	Iodosorb/Iodoflex, effectiveness data for chronic wounds	Excluded: inappropriate wound types or study designs. Cost analysis did not include healing as an outcome measure and effectiveness data are based on chronic paste, wounds
SSL International plc **Products**: Sterige™	Debridement Management	No additional data, present their own review of the literature RCTs (n = 2): Sterigel vs gauze in treatment of leg ulcers (n = 1) and Sterigel vs Intrasite in pressure sores (n = 1) *In vitro* (n = 1): tests of Sterigel		Excluded: inappropriate wound types and study designs

continued

TABLE 15 contd *Manufacturer and sponsor submissions made to NICE*

Company	Information provided	Clinical data	Cost data	Action
TG Eakin Ltd **Products**: Eakin™ (fistula and wound pouches)	Eakin cohesive Rationale for inclusion Wider implications	Controlled trial (*n* = 1): Eakin cohesive vs other pastes, all surgical wounds, used paste then Eakin, no measure of healing Case studies (*n* = 8)	Present data on cost of dressings. Some cost information provided, but no direct analysis	Excluded: inappropriate study designs or no measure of healing provided, fistula and wound pouches not considered to be debriding agents
Tyco Healthcare (UK) Ltd **Products**: Ultec*Pro™ (alginate hydrocolloid) Curafil gel™ Aquaflo™ (hydrogel)	Debridement	Uncontrolled study (*n* = 1): Aquaflo in chronic and acute wounds Case study (*n* = 1) *In vitro* (*n* = 1)	None reported	Excluded: studies with inappropriate designs

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Department of Health, London

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Director, Health Services
Research Unit
University of Oxford

Dr Gillian Vivian
Consultant in Nuclear
Medicine & Radiology
Royal Cornwall Hospitals Trust
Truro

Mrs Joan Webster
Former Chair
Southern Derbyshire
Community Health Council
Nottingham

Feedback

The HTA programme and the authors would like to know your views about this report.

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We look forward to hearing from you.

Copies of this report can be obtained from:

The National Coordinating Centre for Health Technology Assessment,
Mailpoint 728, Boldrewood,
University of Southampton,
Southampton, SO16 7PX, UK.
Fax: +44 (0) 23 8059 5639 Email: hta@soton.ac.uk
http://www.ncchta.org

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