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

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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

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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.

**Dehiscence** The splitting or bursting open of a wound.

**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.

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

**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.

*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 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

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

* Used only in tables
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 proctectomy 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. 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. Wounds healing by secondary intention will need to be filled with new tissue. This process includes granulation, epithelialisation and the contraction of the wound.

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.

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 phagocytic white blood cells. 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. Necrotic tissue also provides an ideal environment for bacterial growth and interferes with the mechanism of wound contraction. 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. 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).

Current service provision

Service delivery

More than 6 million operations were undertaken in the NHS in England between 1998 and 1999. 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. 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. 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, 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. This means that an expensive dressing may incur less cost than a cheaper dressing when the complete episode of care is taken into account. 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.

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 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. 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. 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.
Description of intervention

Debridement involves the removal of devitalised, necrotic tissue or fibrin from a wound. 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.

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. 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. 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. 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. Larvae are about 2 mm long and are applied directly to the wound and held in place with a dressing. Maggots may also have the added benefit of ingesting bacteria, thus reducing the risk of clinical infection developing or proceeding in a wound. They have also been used to eliminate antibiotic-resistant strains of bacteria such as methicillin-resistant Staphylococcus aureus (MRSA). It has been suggested that larval therapy stimulates the production of granulation tissue and thus promotes wound healing. 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.

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. Wet-to-dry debridement involves the application of a saline-moistened gauze pad to an area of necrotic tissue presofterned 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. 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. The disadvantage of mechanical debridement is that it may damage the healthy wound bed.

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.

Enzymatic debridement

This involves the topical application of enzymes to devitalised tissue. 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. Various types of enzymes target specific necrotic tissues such as protein, fibrin and collagen. Enzymes commonly used in wound debridement include streptokinase and streptodornase.

Autolytic debridement

The body will naturally debride dead tissue with enzymes generated by the inflammatory and other cells. This process can be speeded up by the creation of a moist environment. 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. 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.
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
Methods

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. 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. 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 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.

![Figure 1: Incremental cost of treatment compared with control](image)

**Figure 1** Incremental cost of treatment compared with control

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

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, one was a quasi-RCT and one was a non-randomised controlled trial. Information relating to three trials was derived from two publications. Two trials were published as abstracts as well as full reports, and one trial was published as a poster as well as an abstract. For the purpose of this review these trials will be referred to as one publication.

Five of the included studies looked at surgical wounds healing by secondary intention after pilonidal abscess excision, one of which also included participants who had abdominal surgical wounds. Three studies 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. One of these studies also included wounds healing by secondary intention following a laparotomy. One study included perineal wounds resulting from procolectomy or rectal excision, and three studies 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.

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. 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. 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.

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 and another trial compared it to silicone foam. A third study compared dextranomer polysaccharide to silicone foam.

The majority of included studies were UK based, within an 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. Studies were

**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 and one trial reported using a random card system, but gave no further details. 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. 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. Insufficient information was presented to judge the completeness of follow-up in two trials. 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. Another trial reported that on completion there were 25 participants in each treatment group. 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).

None of the seven trials 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. One of these trials did not include those that were lost to follow-up in the final analysis and this information was unclear for the second trial. Two trials reported the reason for withdrawal, presenting the information according to the two intervention groups. 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 did not appear to be related to the
<table>
<thead>
<tr>
<th>Study Description</th>
<th>Sample Size</th>
<th>Random Procedure Adequate</th>
<th>Allocation Concealed</th>
<th>Follow-up %</th>
<th>Loss to Follow-up (%)</th>
<th>Outcome of Withdrawals</th>
<th>ITT Blinding</th>
<th>Blinding of Outcome Assessors</th>
<th>Blinding of Administrators</th>
<th>Participants Blinded</th>
<th>Success of Blinding Checked</th>
<th>Appropriate Baseline Characteristics</th>
<th>Comparable Baseline Characteristics</th>
<th>Co-interventions Stated</th>
<th>Correct Analysis</th>
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</tr>
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</table>

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

a, Numbers reported by group and reason

b, One or more appropriate baseline characteristics stated, but not initial wound size; c, initial wound size stated
d, According to one or more of the characteristics stated, but not initial wound size; e, including wound size
## TABLE 2  
Quality assessment of included trials: wounds from toenail avulsion surgery

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample size (No. of arms)</th>
<th>Random. procedure adequate</th>
<th>Allocation concealed</th>
<th>Follow-up ≥ 80%</th>
<th>Loss to follow-up (%)</th>
<th>ITT</th>
<th>Blinding of outcome assessors</th>
<th>Blinding of administrators</th>
<th>Participants blinded</th>
<th>Success of blinding checked</th>
<th>Appropriate baseline characteristics(^1)</th>
<th>Comparable baseline characteristics(^1)</th>
<th>Co-interventions stated</th>
<th>Correct analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruce et al., 1991(^25)</td>
<td>18 (2)</td>
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<td></td>
<td>♦</td>
<td>X</td>
<td>❌</td>
<td>❌</td>
<td>✘</td>
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<tr>
<td>Foley et al., 1994(^27)</td>
<td>70 (2)</td>
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<tr>
<td>Smith et al., 1992(^28)</td>
<td>67 (2)</td>
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<td>✗</td>
<td>?</td>
<td>7</td>
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<td>✘/X</td>
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<tr>
<td>Van Gils et al., 1998(^29)</td>
<td>20 (2)</td>
<td>?</td>
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<td>5</td>
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</tr>
</tbody>
</table>
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-up45 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.59

Blinding
Only one of the trials of surgical wounds reported the blinding of the outcome assessors to treatment allocation.56 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 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).57,42,44,50 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.46 It was not possible to assess the comparability of the treatment groups for the remaining two trials, as these were not reported per group.37,38 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.57,43,44 Eleven of 13 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.34,36,40,41,43,44,47,48 Eight trials of surgical wounds used the outcome measure ‘time to complete healing’.34,37,42,44,47–50
Results: clinical effectiveness

Seven of which reported mean values rather than medians. 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. 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, five reported incomparability with regard to initial wound size. Four of these trials reported on the outcome measure reduction in wound size, of which only two trials reported both the absolute and the percentage change.

Only one of the four trials of toenail avulsions was deemed to have used an appropriate statistical test. However, this trial used mean values to summarise healing times. Two trials did not report the statistical test used to compare data, and in one trial no statistical analysis was performed. 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.

Four trials of toenail avulsions reported on the outcome measure time to complete healing. However, only one of these used median values. 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. 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. The alternative foam dressing was a contoured honeycomb polymer membrane filled with hydrocellular chips. 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 wounds48,49 (one of which also included incised abscess wounds48), 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 chloride42 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

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**TABLE 3**

<table>
<thead>
<tr>
<th>Study</th>
<th>MD (95% CI)</th>
<th>Silicone foam vs gauze</th>
<th>Polyurethane foam vs silicone foam</th>
<th>Dextranomer vs silicone foam</th>
<th>Alginate vs gauze</th>
<th>Hydrocolloid vs gauze</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macfie, 198042</td>
<td>-9.2 (-24.7 to 6.3)</td>
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<td></td>
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<tr>
<td>Williams, 198149</td>
<td>8.5 (-1.8 to 18.8)</td>
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<tr>
<td>Butterworth, 199237</td>
<td>-10.5 (-22.3 to 1.3)</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Butterworth, 199237</td>
<td>4.7 (-31.9 to 22.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Young, 198248</td>
<td>-4.0 (-14.0 to 6.0)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Foley, 199439</td>
<td>-8.6 (-12.9 to -4.3)</td>
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<tr>
<td>Van Gils, 199846</td>
<td>-1.4 (-20.9 to -1.9)</td>
<td></td>
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<tr>
<td>Bruce, 199135</td>
<td>-15.9 (-33.4 to 1.6)</td>
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</table>

**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>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Duration</th>
<th>Proportion healed (including number of wounds closed surgically)</th>
<th>Per cent wound area reduction; wound volume</th>
<th>Time to complete healing (days); time to dry dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Silicone foam versus traditional gauze dressings</strong></td>
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<tr>
<td></td>
<td>Perineal wounds</td>
<td>Until healing</td>
<td>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)</td>
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<td></td>
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<td><strong>Mean time to dry dressing</strong>: significantly ($p&lt;0.05$) 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)</td>
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<td></td>
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<td></td>
<td><strong>Rate to full epithelialisation</strong>: no significant differences (0.94 in foam group, 0.98 in gauze group; MD = -0.04; 95% CI, -0.31 to 0.23)</td>
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<td></td>
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<td><strong>Rate to dry dressing</strong>: no significant difference (1.24 in foam group, 1.07 in gauze group; MD = 0.17; 95% CI, -0.19 to 0.53)</td>
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<td></td>
<td><strong>Walker et al., 1991</strong></td>
<td>Pilonidal sinus wounds</td>
<td>Until healing</td>
<td>Mean time to healing: no significant difference ($p&gt;0.05$) between the groups (30 days in foam group, 33 days in gauze group; no measure of variance)</td>
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<td><strong>Mean time to healing</strong>: no significant difference ($p&gt;0.05$) between the groups (39.8 days in foam group, 39.6 days in gauze group; no measure of variance)</td>
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<td><strong>Williams et al., 1981</strong></td>
<td>Pilonidal sinus wounds</td>
<td>Until healing</td>
<td>Mean time to healing: no significant difference ($p&gt;0.05$) 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)</td>
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<td></td>
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<td><strong>Mean number of days packed</strong>: no significant difference ($p&gt;0.05$) between groups (41.5 days in foam group, 41.8 days in gauze group; MD = -0.3; 95% CI, -10.79 to 10.19)</td>
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<td></td>
<td><strong>Ricci et al., 1998</strong></td>
<td>Pilonidal sinus wounds</td>
<td>Until healing</td>
<td>Reduction in cavity volume after 15 days: higher in the silicone group (46%) than the gauze group (22%); no measure of variance or significance</td>
<td>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</td>
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<td></td>
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<td></td>
<td><strong>Mean time for cavity to fill</strong>: shorter in silicone group (4.3 weeks) than gauze group (9.5 weeks); no measure of variance or significance</td>
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continued
# TABLE 3 contd Results for measures of healing

<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Duration</th>
<th>Proportion healed (including number of wounds closed surgically)</th>
<th>Per cent wound area reduction; wound volume</th>
<th>Time to complete healing (days); time to dry dressing</th>
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</thead>
<tbody>
<tr>
<td><strong>Polyurethane foam versus traditional gauze dressings</strong></td>
<td>Meyer, 1997&lt;sup&gt;13&lt;/sup&gt;</td>
<td>Abdominal surgery</td>
<td>4 weeks</td>
<td>Proportion healed: significantly greater (&lt;i&gt;p&lt;/i&gt; = 0.04) in Cutinova group (48%) than in gauze group (18%); RR = 2.6 (95% CI 1.0 to 7.1)</td>
<td>Reduction in wound volume: significantly greater (&lt;i&gt;p&lt;/i&gt; &lt; 0.05) in Cutinova group (75.6%) than in gauze group (50.1%); no measure of variance</td>
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<td></td>
<td>RCT</td>
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<tr>
<td><strong>Polyurethane foam versus silicone foam dressings</strong></td>
<td>Butterworth et al., 1992&lt;sup&gt;27&lt;/sup&gt;</td>
<td>Abdominal wounds</td>
<td>Until healing</td>
<td>Mean time to healing: no significant differences (&lt;i&gt;p&lt;/i&gt; = 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)</td>
<td>Mean time to healing: no significant differences (&lt;i&gt;p&lt;/i&gt; = 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)</td>
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<td>Pilonidal wounds</td>
<td>Until healing</td>
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<td><strong>Polyurethane foam versus alginate dressings</strong></td>
<td>Berry et al., 1996&lt;sup&gt;36&lt;/sup&gt;</td>
<td>Pilonidal sinus excision</td>
<td>Until healing</td>
<td></td>
<td>Mean time to healing: 56.7 days in foam group, 65.5 days in gauze group; no measure of variance or significance</td>
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<tr>
<td></td>
<td>RCT</td>
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<td><strong>Alginate versus traditional gauze dressings</strong></td>
<td>Cannavo et al., 1998&lt;sup&gt;40&lt;/sup&gt;</td>
<td>Dehisced surgical abdominal wounds</td>
<td>Until healing</td>
<td>Proportion healed: no significant difference between any of the three groups</td>
<td>Reduction in wound area and volume: no significant difference between any of the three groups</td>
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<td>Dawson et al., 1992&lt;sup&gt;46&lt;/sup&gt;</td>
<td>Abscess incision</td>
<td>4 weeks</td>
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<td></td>
<td>RCT</td>
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### TABLE 3 contd  Results for measures of healing

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<tr>
<th>Study</th>
<th>Condition</th>
<th>Duration</th>
<th>Proportion healed (including number of wounds closed surgically)</th>
<th>Per cent wound area reduction; wound volume</th>
<th>Time to complete healing (days); time to dry dressing</th>
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</thead>
<tbody>
<tr>
<td><strong>Alginate versus traditional gauze dressings contd</strong></td>
<td>Abscess incision</td>
<td>3 weeks</td>
<td>Proportion epithelialised: no significant differences between groups (RR = 1.9; 95% CI 0.9 to 4.5)</td>
<td>Wound area reduction: significantly (p &lt; 0.05) higher in alginate group than gauze group at weeks 1, 2 and 3; no measure of variance</td>
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<tr>
<td>Guillotreau et al., 1996</td>
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<td>Proportion filled: no significant differences (p &gt; 0.05) between groups (59% in alginate group, 48% in gauze group; RR = 1.2; 95% CI 0.8 to 1.9)</td>
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<tr>
<td>Foley and Allen, 1994</td>
<td>Toenail avulsion</td>
<td>Until healing</td>
<td>Mean time to healing: significantly (p &lt; 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)</td>
<td>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)</td>
<td>Mean time to healing: shorter in Sorbsan treatment group (43 days) than Anaflex group (52 days); significant (p &lt; 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</td>
</tr>
<tr>
<td>Van Gils et al., 1998</td>
<td>Toenail avulsion</td>
<td>8 weeks</td>
<td>Median/mean time to healing: significantly (p &lt; 0.05) differences between the groups (65 days in hydrocolloid group, 68 days in gauze group; no measure of variance)</td>
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</tr>
<tr>
<td>Smith, 1992</td>
<td>Toenail avulsion</td>
<td>Until healing</td>
<td>Median/mean time to healing: significantly (p = 0.03) differences between the groups (65 days in hydrocolloid group, 68 days in gauze group; no measure of variance)</td>
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<tr>
<td>Quasi-RCT</td>
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<td>Median/mean time to healing: significantly (p = 0.03) differences between the groups (65 days in hydrocolloid group, 68 days in gauze group; no measure of variance)</td>
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<tr>
<td><strong>Hydrocolloid versus traditional gauze dressings</strong></td>
<td>Pilonidal sinus wounds</td>
<td>Until healing</td>
<td>Mean time to healing: shorter in Sorbsan treatment group (43 days) than Anaflex group (52 days); significant (p &lt; 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</td>
<td>Mean time to healing: no significant (p &gt; 0.05) differences between the groups (65 days in hydrocolloid group, 68 days in gauze group; no measure of variance)</td>
<td>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)</td>
</tr>
<tr>
<td>Vicario et al., 2000</td>
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<tr>
<td>Bruce, 1991</td>
<td>Toenail avulsion</td>
<td>Until healing</td>
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<td></td>
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</tbody>
</table>

*continued*
**TABLE 3 contd** Results for measures of healing

<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Duration</th>
<th>Proportion healed (including number of wounds closed surgically)</th>
<th>Per cent wound area reduction; wound volume</th>
<th>Time to complete healing (days); time to dry dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dextranomer polysaccharide versus traditional gauze dressings</strong></td>
<td>Goode et al., 1979&lt;sup&gt;60&lt;/sup&gt;</td>
<td>Broke down surgical wounds</td>
<td>Proportion healed: no significant differences between groups (p &gt; 0.05); 1 wound healed in each group (RR = 1.0; 95% CI: 0.1 to 8.8)</td>
<td>Mean time to secondary closure: significantly less in beads group (8.1 days) than gauze group (11.6 days); no measure of variance and therefore unable to check this calculation</td>
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</tr>
<tr>
<td>RCT</td>
<td></td>
<td>Until healing or suture</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dextranomer polysaccharide versus silicone foam dressings</strong></td>
<td>Young and Wheeler, 1982&lt;sup&gt;50&lt;/sup&gt;</td>
<td>Broke down surgical wounds</td>
<td>Mean time to healing: no significant (p &gt; 0.05) differences between the groups (41 days on beads, 37 days on control; MD = –4.0; 95% CI: –14.0 to 6.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td>Until healing</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
TABLE 4 Results for measures of healing according to intervention and wound type

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

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.

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).
Results: clinical effectiveness

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. The follow-up periods were 3 weeks and 4 weeks. The comparator gauze dressing was soaked in saline for one trial and povidone iodine in the other. 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. One RCT compared the performance of three dressings in the management of dehisced surgical abdominal wounds. The three dressing protocols included calcium alginate dressings and a Comfeel 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. The comparator treatment used in the trials included a cotton and acrylic fibre pad bonded to a low-adherent polyester film (Melolin™), Melolin dressing with Anaflex™ powder and no additional wound dressing (all wounds were dressed with a thin layer of sulfadiazine silver cream and covered with sterile compressive gauze). The length of follow-up was 8 weeks in one trial, and participants were followed up until complete healing had been achieved in the other two trials.

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). 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). This trial also reported on the number of wounds healed at 8 weeks. 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 initial wound area was reported. Two trials reported only age and sex as baseline characteristics (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. 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.\textsuperscript{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.\textsuperscript{39} 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.\textsuperscript{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,\textsuperscript{42} duration of hospital stay,\textsuperscript{42,48,49} number of visits by the district nurse,\textsuperscript{42,49} work lost\textsuperscript{49} and level of discomfort on dressing removal.\textsuperscript{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.\textsuperscript{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.\textsuperscript{49} No significant differences were found for any of the other outcomes
### TABLE 5 Results for other outcome measures

<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Duration</th>
<th>Resource use</th>
<th>Dressing comfort</th>
<th>Dressing performance</th>
<th>Other outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Silicone foam versus traditional gauze dressings</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Macfie and McMahon, 1980&lt;sup&gt;12&lt;/sup&gt;</td>
<td>Perineal wounds</td>
<td>Until healing</td>
<td><strong>Number of inpatient days:</strong> no significant ($p &gt; 0.05$) 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)</td>
<td>Pain: 15 patients in gauze group and 4 patients in foam group required analgesia (RR = 0.27, 95% CI, 0.1 to 0.63)</td>
<td></td>
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<tr>
<td>RCT</td>
<td></td>
<td></td>
<td><em>Number of visits by district nurse:</em> significantly ($p &lt; 0.001$) less in foam group (14.1) compared to gauze group (46.9); MD = –32.8; 95% CI, –45.1 to –20.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Walker et al., 1991</strong>&lt;sup&gt;40&lt;/sup&gt;</td>
<td>Pilonidal sinus wounds and incised abscesses</td>
<td>Until healing</td>
<td><strong>Days to hospital discharge:</strong> no significant ($p &gt; 0.05$) difference between groups; no measure of variance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td></td>
<td><strong>Mean time to hospital discharge:</strong> no significant ($p &gt; 0.05$) 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)</td>
<td>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)</td>
<td></td>
<td>Work lost: no significant ($p &gt; 0.05$) 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)</td>
</tr>
<tr>
<td>Williams et al., 1981&lt;sup&gt;19&lt;/sup&gt;</td>
<td>Pilonidal sinus wounds</td>
<td>Until healing</td>
<td><strong>Number of home nursing visits:</strong> significantly ($p &lt; 0.05$) greater in gauze group (35.1) than foam group (4.6) (MD = –30.5; 95% CI, –35.7 to –23.3)</td>
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<tr>
<td>RCT</td>
<td></td>
<td></td>
<td><strong>Number of dressings used:</strong> less in foam group (20) than gauze group (868); no measure of variance and therefore cannot determine whether statistically significant</td>
<td>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</td>
<td></td>
<td>Time before return to work: shorter in foam group (12 days) than gauze group (23 days); no measure of variance</td>
</tr>
<tr>
<td>Ricci et al., 1998&lt;sup&gt;44&lt;/sup&gt;</td>
<td>Pilonidal sinus wounds</td>
<td>Until healing</td>
<td></td>
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<tr>
<td>Controlled trial</td>
<td></td>
<td></td>
<td><strong>Number of dressings used:</strong> less in foam group (20) than gauze group (868); no measure of variance and therefore cannot determine whether statistically significant</td>
<td></td>
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</tbody>
</table>

**VAS, Visual analogue scale**
### TABLE 5 contd Results for other outcome measures

<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Duration</th>
<th>Resource use</th>
<th>Dressing comfort</th>
<th>Dressing performance</th>
<th>Other outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyurethane foam versus traditional gauze dressings&lt;br&gt;Meyer, 1997^a&lt;br&gt;RCT</td>
<td>Abdominal surgery or abscess incision</td>
<td>4 weeks</td>
<td>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)</td>
<td>Pain (VAS) at week 4: significantly ($p &lt; 0.05$) greater in gauze group (1.82) than foam group (0.86); no measure of variance</td>
<td>Necrotic tissue, odour and putrid secretion and itching: no difference between dressings as they were not frequently reported at any time during study</td>
<td>Number of wounds closed surgically: 4 in Cutinova group and 2 in gauze group (RR = 2.1; 95% CI, 0.5 to 9.15)</td>
</tr>
<tr>
<td>Polyurethane foam versus alginate dressings&lt;br&gt;Berry et al., 1996^b</td>
<td>Pilonidal sinus wounds</td>
<td>Until healing</td>
<td>Dressing leakage and absorbency capacity: no significant difference between groups</td>
<td>Dressing performance (clinician assessed): no differences between groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyurethane foam versus silicone foam dressings&lt;br&gt;Butterworth et al., 1992^c</td>
<td>Abdominal and pilonidal sinus wounds</td>
<td>Until healing</td>
<td>Mean time for dressing change: shorter in polyurethane group (203 s) than silicone group (263 s); no measure of variance</td>
<td>Comfort: no difference between groups (90% painless for both dressings; RR = 0.99; 95% CI, 0.96 to 1.03)</td>
<td>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)</td>
<td>Ease of removal: no difference between groups (97% easily removed in both groups; RR = 0.99; 95% CI, 0.97 to 1.01)</td>
</tr>
</tbody>
</table>

VAS, Visual analogue scale
<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Duration</th>
<th>Resource use</th>
<th>Dressing comfort</th>
<th>Dressing performance</th>
<th>Other outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alginate versus traditional gauze dressings</strong>&lt;br&gt;Cannavo et al., 1998&lt;sup&gt;10&lt;/sup&gt;&lt;br&gt;RCT</td>
<td>Dehisced surgical abdominal wounds</td>
<td>Until healing</td>
<td></td>
<td><strong>Maximum pain</strong>: significantly greater for gauze compared to alginate or combined dressing; no significant difference between alginate and combined dressing groups</td>
<td><strong>Satisfaction during dressing change</strong>: no significant differences between alginate and combined dressing at week 1; gauze significantly (p &lt; 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</td>
<td></td>
</tr>
<tr>
<td><strong>Dawson et al., 1992&lt;sup&gt;1&lt;/sup&gt;</strong>&lt;br&gt;RCT</td>
<td>Abscess incision</td>
<td>4 weeks</td>
<td></td>
<td><strong>Pain of dressing removal</strong>: alginate dressing was significantly (p &lt; 0.01) less painful than gauze dressing; no further data provided</td>
<td><strong>Ease of removal</strong>: alginate dressing was significantly (p &lt; 0.01) easier than gauze dressing; no further data provided</td>
<td></td>
</tr>
<tr>
<td><strong>Guillotreau et al., 1996&lt;sup&gt;11&lt;/sup&gt;</strong>&lt;br&gt;RCT</td>
<td>Abscess incision</td>
<td>3 weeks</td>
<td></td>
<td><strong>Pain</strong>: less in alginate group than gauze group (p = 0.001); no further data provided</td>
<td><strong>Ease of use</strong>: alginate dressing easier than gauze dressing (p = 0.011); no further data provided</td>
<td><strong>Bacteria cultured</strong>: no difference between groups; no further data provided</td>
</tr>
<tr>
<td><strong>Foley and Allen, 1994&lt;sup&gt;12&lt;/sup&gt;</strong>&lt;br&gt;RCT</td>
<td>Toenail avulsion</td>
<td>Until healing</td>
<td>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)</td>
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<tr>
<td><strong>Van Gils et al., 1998&lt;sup&gt;13&lt;/sup&gt;</strong>&lt;br&gt;RCT</td>
<td>Toenail avulsion</td>
<td>8 weeks</td>
<td></td>
<td>No secondary outcomes</td>
<td></td>
<td></td>
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<tr>
<td><strong>Smith, 1992&lt;sup&gt;14&lt;/sup&gt;</strong>&lt;br&gt;Quasi-RCT</td>
<td>Toenail avulsion</td>
<td>Until healing</td>
<td>Number of visits: similar in both groups (6 in alginate group, 7 in gauze group); no measure of variance or significance</td>
<td></td>
<td>Problems after operation: no significant (p &gt; 0.05) differences between groups (71% in alginate group, 86% in gauze group; RR = 0.82; 95% CI, 0.61 to 1.09)</td>
<td><strong>Postoperative infection</strong>: 1 in gauze group, 0 in alginate group (RR = 0.0; 95% CI, 0.0 to 3.1)</td>
</tr>
<tr>
<td>Study</td>
<td>Condition</td>
<td>Duration</td>
<td>Resource use</td>
<td>Dressing comfort</td>
<td>Dressing performance</td>
<td>Other outcomes</td>
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<tr>
<td><strong>Hydrocolloid versus traditional gauze dressings</strong></td>
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</tr>
<tr>
<td>Viciano et al., 2000</td>
<td>Pilonidal sinus wounds</td>
<td>Until healing</td>
<td>Number of dressings used: greater in gauze group (68) than hydrocolloid group (23); no measure of variance or significance</td>
<td>Local intolerance: 3 in hydrocolloid group, 1 in control group (RR = 2; 95% CI, 0.3 to 13.2)</td>
<td>Scar quality, tolerance of dressing, smell: no differences among groups</td>
<td>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)</td>
</tr>
<tr>
<td>RCT</td>
<td></td>
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<tr>
<td>Bruce, 1991</td>
<td>Toenail avulsions</td>
<td>Until healing</td>
<td>Mean dressing time: no significant differences between groups (Serotulle 10 min, Comfeel 9 min); no measure of variance</td>
<td>Patient comfort during and after dressing change: no significant difference between groups</td>
<td>Patient satisfaction: presence of the hydrated gel from the dressing was often offensive to the patient, along with its smell</td>
<td>Leakage: gel frequently leaked from wound site</td>
</tr>
<tr>
<td>RCT</td>
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<tr>
<td><strong>Dextranomer polysaccharide versus traditional gauze dressings</strong></td>
<td></td>
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</tr>
<tr>
<td>Goode et al., 1979</td>
<td>Broken down surgical wounds</td>
<td>Until healing or suture</td>
<td>Hospital stay: shorter in Debrisan group by median of 2.2 days; no measure of variance or significance</td>
<td></td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dextranomer polysaccharide versus silicone foam dressings</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Young and Wheeler, 1982</td>
<td>Broken down surgical wounds</td>
<td>Until healing</td>
<td>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)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
investigated. The controlled trial investigated the number of dressings used, level of pain on dressing removal and time before return to work. 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. 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. 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. One RCT compared the performance of three dressings in the management of dehisced surgical abdominal wounds. The three RCTs reported on other outcome measures, which included pain, patient satisfaction with the dressing process, ease of dressing removal, ease of dressing use and bacterial culture. 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 and ease of removal 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. Two of the RCTs reported on other outcome measures, which included the number of dressing changes, number of follow-up visits, any volunteered complaints by the patients and the incidence of postoperative infection. 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. 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. 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

<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Healing outcomes</th>
<th>Other outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Overall effect</td>
<td>Any effect</td>
</tr>
<tr>
<td><strong>Modern dressings versus gauze</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Surgical wounds</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical wounds</td>
<td>Perineal wounds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walker et al., 1991[^38]</td>
<td>Pilonidal wounds</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Incised abscesses</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Williams et al., 1981[^9]</td>
<td>Pilonidal wounds</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Ricci et al., 1998[^44]</td>
<td>Pilonidal wounds</td>
<td>—</td>
<td>✔</td>
</tr>
<tr>
<td>Polyurethane foam versus traditional gauze dressings</td>
<td>Meyer, 1997[^73]</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Surgical wounds</td>
<td>Abdominal surgery or abscess incision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alginate versus traditional gauze dressings</td>
<td>Cannavo et al., 1999[^36]</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Dehisced surgical abdominal wounds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dawson et al., 1992[^38]</td>
<td>Abscess incision</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Guillotreau et al., 1996[^41]</td>
<td>Abscess incision</td>
<td>—</td>
<td>✔</td>
</tr>
<tr>
<td>Hydrocolloid versus traditional gauze dressings</td>
<td>Viciano et al., 2000[^37]</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Pilonidal wounds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dextranomer polysaccharide versus traditional gauze dressings</td>
<td>Goode et al., 1979[^90]</td>
<td>—</td>
<td>✔</td>
</tr>
<tr>
<td>Broken down surgical wounds</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Toenail avulsion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alginate versus traditional gauze dressings</td>
<td>Foley and Allen, 1994[^14]</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Smith, 1992[^45]</td>
<td>✔</td>
<td>✔</td>
<td>—</td>
</tr>
<tr>
<td>Van Gils et al., 1998[^46]</td>
<td>✔</td>
<td>✔</td>
<td>None investigated</td>
</tr>
<tr>
<td>Hydrocolloid versus traditional gauze dressings</td>
<td>Bruce, 1991[^35]</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td><strong>Direct comparison of modern dressings</strong></td>
<td>Surgical wounds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyurethane foam versus alginate dressings</td>
<td>Berry et al., 1996[^34]</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Pilonidal wounds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyurethane foam versus silicone foam dressings</td>
<td>Butterworth et al., 1992[^27]</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Abdominal and pilonidal wounds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Broken down surgical wounds</td>
<td></td>
<td></td>
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</tbody>
</table>

[^2]: Positive effect of intervention (i.e. intervention shows greater benefit than control)
[^3]: No significant effect reported
dressings. Only one study found an overall effect on healing in favour of modern dressings. A further four studies found some significant benefit of the modern dressings compared to traditional gauze dressings. 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. 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. One of these studies found an overall beneficial effect of alginate dressing compared to gauze for the other outcomes considered. 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. These studies looked at silicone foam, alginate dressings and hydrocolloid dressings. One further study found some significant benefit of the modern dressing (alginate) for outcomes other than healing.

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, although one of these studies did not investigate any other outcomes. Three of these studies compared alginate to gauze, and the fourth compared hydrocolloid to gauze.

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 and the second compared polyurethane foam to alginate. 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. 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.52,63

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 dressings62 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 abdominocision of the rectum48 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 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 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 one62 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).62

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 debridging 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

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 1989–199048 and 1982.51

Only one study used stochastic data, which were analysed using a one-way analysis of variance (ANOVA).56

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.62,65 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.36,51 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 visits51 and one incorporated information on the number of dressing changes.62 Two economic evaluations also reported on pain as an outcome measure50,62 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.56 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 gastrointestinal 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.36,51,62

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of economic evaluation</th>
<th>Matrix letter</th>
<th>Question of alternatives</th>
<th>Description identified</th>
<th>Important costs/outcomes measured</th>
<th>Clinically effective</th>
<th>Prospective costing</th>
<th>Costs/outcomes adjusted for timing</th>
<th>Costs/outcomes</th>
<th>Incremental analysis</th>
<th>Sensitivity analysis</th>
<th>Included all issues of interest</th>
<th>Generalisability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beiersdorf, 2000</td>
<td>CEA/CMA</td>
<td>G</td>
<td>✓</td>
<td>✓/X</td>
<td>✓/X</td>
<td>✓</td>
<td>X</td>
<td>✓/X</td>
<td>NA</td>
<td>NA</td>
<td>✔</td>
<td>✔</td>
<td>✘</td>
</tr>
<tr>
<td>Cannavo et al., 1988</td>
<td>CEA/CCA</td>
<td>H</td>
<td>✓</td>
<td>✓/X</td>
<td>✓/X</td>
<td>✓</td>
<td>✔</td>
<td>✓/X</td>
<td>✘/X</td>
<td>✔/X</td>
<td>✔</td>
<td>✔</td>
<td>✘/X</td>
</tr>
<tr>
<td>Conva Tec, 2000</td>
<td>CEA/CCA</td>
<td>H</td>
<td>✓</td>
<td>✓/X</td>
<td>✓/X</td>
<td>✓</td>
<td>✔</td>
<td>✓/X</td>
<td>✘/X</td>
<td>✔/X</td>
<td>✔</td>
<td>✔</td>
<td>✘/X</td>
</tr>
<tr>
<td>Culyer and Wagstaff, 1984</td>
<td>CEA</td>
<td>H</td>
<td>✓</td>
<td>✓/X</td>
<td>✓/X</td>
<td>✓</td>
<td>✘</td>
<td>✓/X</td>
<td>✘/X</td>
<td>✔/X</td>
<td>✔</td>
<td>✔</td>
<td>✘/X</td>
</tr>
<tr>
<td>Walker et al., 1991</td>
<td>CEA/CMA</td>
<td>H</td>
<td>✓</td>
<td>✓/X</td>
<td>✓/X</td>
<td>✓</td>
<td>✘</td>
<td>✓/X</td>
<td>✘/X</td>
<td>✔/X</td>
<td>✔</td>
<td>✔</td>
<td>✘/X</td>
</tr>
</tbody>
</table>

*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

✔ Yes; ✘ no; ✗/✘, partially covered; NA, not appropriate
should be incorporated. However, only three of the economic evaluations conducted such an analysis.\textsuperscript{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)\textsuperscript{62} and one study presented three estimates of cost for each variable (high, medium and low).\textsuperscript{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.\textsuperscript{48} One trial was based in Australia, where staffing arrangements may differ from those in the UK.\textsuperscript{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.\textsuperscript{48,51} One economic evaluation looked at participants who had received surgery for either pilonidal sinus or abscess\textsuperscript{48} and the second included patients with granulating perineal wounds following abdominal excision of the rectum.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{48,51}

**Polyurethane foam versus traditional gauze dressings**

One economic evaluation investigated the cost-effectiveness of polyurethane dressings as compared to traditional gauze dressings.\textsuperscript{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\textsuperscript{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.\textsuperscript{36} Dressing protocols included calcium alginate dressings, sodium hypochlorite moistened gauge 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. 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.
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 post-operatively, perineal wounds resulting from proctectomy 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 debridement 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.65,66 Non-blinding 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.35–37,40,43,45,50 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,35 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.35 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.

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) 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,
Discussion

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

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References


Appendix 1

Classification of debriding methods and agents
### TABLE 8 Classification of debriding methods and agents

<table>
<thead>
<tr>
<th>Classification</th>
<th>Selectiveness</th>
<th>Method of debridement</th>
<th>Type of debriding agent/dressings</th>
<th>Examples of products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical</td>
<td>Non-selective</td>
<td>Sharp instrument</td>
<td>Scalpel – quick but imprecise</td>
<td></td>
</tr>
<tr>
<td>Biosurgical</td>
<td>Selective</td>
<td>Biosurgery</td>
<td>Maggot larvae – the maggots destroy dead tissue by liquefying it with enzymes and ingesting it12</td>
<td>‘LarVÉ’ (Biosurgical Research Unit)</td>
</tr>
<tr>
<td>Mechanical</td>
<td>Non-selective</td>
<td>Wet-to-dry dressing</td>
<td>Gauze dressing soaked in saline – drying dressings debride mechanically by taking tissue from the wound surface indiscriminately2</td>
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<td></td>
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<td></td>
<td>Pressurised wound irrigation (for small wounds)</td>
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<td></td>
<td></td>
<td></td>
<td>Whirlpool – using jets of water (large wounds)</td>
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<tr>
<td></td>
<td></td>
<td>Adherent dressings</td>
<td>Gauze dressings</td>
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<td></td>
<td></td>
<td></td>
<td><strong>Gauze-based dressings</strong> – non- or low-adherent gauze derivatives (developed to overcome the problem of adherence associated with tulle dressings):2</td>
<td>(These dressings may not be specifically used for debriding)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>perforated film absorbent dressing</td>
<td>Melolin, Mepore, Release, Skintact</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>knitted viscous primary dressing</td>
<td>N-A Dressing</td>
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<td></td>
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<td>povidone iodine fabric dressing</td>
<td>Inadine</td>
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<td></td>
<td></td>
<td></td>
<td><strong>Tulle dressings</strong>: tulle (non-medicated) are made of open-weave cotton or rayon impregnated with soft paraffin</td>
<td>Jelonet, Paratulle, Unitulle</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>tulle (medicated) are impregnated with either antiseptics or antibiotics</td>
<td>The commonest type of antiseptic is chlorhexidine, present in Bactigras, Chlorhexitulle and Serotulle. Two tullies are impregnated with antibiotics, Fusidin Interstelle and Sofra-Tulle. The use of these dressings is not recommended because of the problems of sensitivity and resistance of bacteria</td>
</tr>
</tbody>
</table>

* 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*
### TABLE 8 contd Classification of debriding methods and agents

<table>
<thead>
<tr>
<th>Classification</th>
<th>Selectiveness*</th>
<th>Method of debridement</th>
<th>Type of debriding agent/dressings</th>
<th>Examples of products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical</td>
<td>Selective method</td>
<td>Hypochlorite solution</td>
<td>Sodium hypochlorite, hydrogen peroxide</td>
<td>Dakin's solution, Eusol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Caustic agents</td>
<td>Malic acid, benzoic acid, salicylic acid, propylene glycol</td>
<td>Aserine (Goldshield)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>proteolytics</td>
<td>trypsin</td>
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<tr>
<td></td>
<td></td>
<td>fibrinolytics</td>
<td>collagenase</td>
<td>Crab collagenase, krill</td>
</tr>
<tr>
<td></td>
<td></td>
<td>collagenase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Autolytic</td>
<td>Highly selective method</td>
<td>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.</td>
<td>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 polyurethane 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</td>
<td>Flat dressing sheets: Improved Formulation Granuflex, Comfeel Plus, Tegasorb, Tegasorb Advanced Formulation, Cuti Nova Foam, Hydrocoll, CombiDERM (Convatec), Hydrocoll Basic, DuoDerm Extra Thin, Hydrocoll Extra Thin, Aquacel (Convatec Ltd) Cavity dressings: Aquacel Ribbon</td>
</tr>
</tbody>
</table>

* 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.
<table>
<thead>
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<th>Examples of products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autolytic contd</td>
<td></td>
<td></td>
<td>Polysaccharide beads or paste</td>
<td>Debrisan (Pharmacia Ltd) – a polysaccharide bead dressing</td>
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<td></td>
<td></td>
<td></td>
<td>(sometimes referred to as dextranomers, xerogels or codexomer iodine) – consist</td>
<td>Iodosorb (Perstorp), similar to Debrisan but contains an element of iodine, Iodoflex</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>of powder or beads, which swell and gel in the presence of exudate</td>
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<td></td>
<td></td>
<td></td>
<td>Hydrogels/gels (virtually impermeable to moisture) – made from insoluble polymers</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>and have a large water content. Most share a common basic structure of about 2–3%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>of a gel-forming polymer such as NaCMC, modified starch or sodium alginate, together with 20% propylene glycol as a humectant, and preservative. The balance (about 80%) consists of water.</td>
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<td></td>
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<td></td>
<td>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.</td>
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<td></td>
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<td></td>
<td>Available in a variety of formats (flat dressing, rope or ribbon)</td>
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<td></td>
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<td></td>
<td>Foam dressings – may be made from polyurethane or silicone. Absorb liquid by capillary action</td>
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<td></td>
<td></td>
<td></td>
<td>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 exuding wounds. Commonly used as secondary dressings over alginates and hydrogels</td>
<td></td>
</tr>
</tbody>
</table>

* 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.
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.

Appendix 2

List of excluded studies
<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Intervention</th>
<th>Wound type</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abasov et al., 1982&lt;sup&gt;73&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Russian</td>
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<tr>
<td>Ahmed et al., 1997&lt;sup&gt;74&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No control group or measure of healing; mixture of appropriate wounds and ulcers, not analysed separately</td>
</tr>
<tr>
<td>Akesson et al., 1984&lt;sup&gt;75&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Wounds left by removal of drainage tubes</td>
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<tr>
<td>Alsbrjorn et al., 1990&lt;sup&gt;76&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Aloe vera used as intervention, which is reported to have anti-inflammatory properties and therefore is not considered to be a debriding agent</td>
</tr>
<tr>
<td>Anon., 1991&lt;sup&gt;77&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Retrospective study of enterostomal nurse versus staff nurse in the home; mixture of appropriate wounds and ulcers, not analysed separately</td>
</tr>
<tr>
<td>Aragona et al., 1984&lt;sup&gt;78&lt;/sup&gt;</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Retrospective study of wound care at home</td>
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<td>Arnold, 1992&lt;sup&gt;79&lt;/sup&gt;</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Retrospective study at home; mixture of appropriate wounds and ulcers, not analysed separately</td>
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<td>Arnold and Weir, 1994&lt;sup&gt;80&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Mixed wound types reported together; no measure of healing</td>
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<tr>
<td>Bale et al., 1994&lt;sup&gt;81&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Mixture of appropriate wounds and ulcers, not analysed separately, mainly chronic</td>
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<tr>
<td>Banks et al., 1995&lt;sup&gt;82&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Chronic wounds; no measure of healing</td>
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<tr>
<td>Banks et al., 1995&lt;sup&gt;83&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Chronic wounds</td>
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<td>Banks et al., 1994&lt;sup&gt;84&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Mixture of appropriate wounds and ulcers, not analysed separately</td>
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<td>Bridel-Nixon et al., 1998&lt;sup&gt;85&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Incidence of postoperative pressure sores</td>
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<td>Briggs, 1996&lt;sup&gt;86&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Sutured wounds; inappropriate intervention and no measure of healing</td>
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<tr>
<td>Brown et al., 1991&lt;sup&gt;87&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Epidermal growth factor investigated in ulcers</td>
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<td>Calligaro et al., 1994&lt;sup&gt;88&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No control group</td>
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<tr>
<td>Cassino, 1998&lt;sup&gt;89&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Chronic wounds</td>
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<tr>
<td>Cassino, 1998&lt;sup&gt;90&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Chronic wounds</td>
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<tr>
<td>Cespa et al., 1984&lt;sup&gt;91&lt;/sup&gt;</td>
<td>No</td>
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<td>?</td>
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<td>Italian</td>
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<td>Chalmers and Turner, 1996&lt;sup&gt;92&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Case study</td>
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<td>Chevretton et al., 1991&lt;sup&gt;93&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Retrospective study, control not concurrent; no measure of wound healing</td>
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<td>Church, 1995&lt;sup&gt;94&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Report of other studies using maggots</td>
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<td>Coerper et al., 1999&lt;sup&gt;95&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Chronic wounds</td>
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<td>Creese et al., 1986&lt;sup&gt;96&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Mixture of appropriate wounds and ulcers, not analysed separately</td>
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<td>Dahlstrom, 1995&lt;sup&gt;97&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Split skin graft, no measure of wound healing</td>
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<td>Davis et al., 1987&lt;sup&gt;98&lt;/sup&gt;</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Animal study on aloe vera</td>
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<td>Donnelly and Maxwell, 1997&lt;sup&gt;100&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
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<td>Yes</td>
<td>Case history</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No information on healing (only data on pain, drainage, exudate, infection, days to wearing normal shoes presented)</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Italian</td>
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<td>Study design</td>
<td>Intervention</td>
<td>Wound type</td>
<td>Outcome</td>
<td>Comments</td>
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<td>Flanagan, 1995&lt;sup&gt;104&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Chronic and traumatic wounds</td>
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<td>Fleishmann et al., 1999&lt;sup&gt;105&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No control group</td>
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<tr>
<td>Foster et al., 2000&lt;sup&gt;106&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing</td>
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<td>Foster and Moore, 1997&lt;sup&gt;107&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing</td>
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<td>Foster and Moore, 1997&lt;sup&gt;108&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Case study</td>
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<td>Foster and Moore, 1997&lt;sup&gt;109&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing</td>
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<td>Foster and Moore, 1997&lt;sup&gt;110&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<td>Freeman et al., 1981&lt;sup&gt;111&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Chronic wounds; no measure of healing (bacterial growth measured)</td>
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<td>Gainant et al., 1989&lt;sup&gt;112&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Looked at method of preventing wound dehiscence</td>
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<td>Gardezi et al., 1983&lt;sup&gt;113&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Sutured wounds</td>
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<tr>
<td>Gates and Holloway, 1992&lt;sup&gt;114&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No objective measure of wound healing</td>
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<tr>
<td>Goode et al., 1985&lt;sup&gt;115&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No objective measure of wound healing</td>
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<tr>
<td>Grabski et al., 1995&lt;sup&gt;120&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Descriptive study</td>
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<tr>
<td>Gupta et al., 1991&lt;sup&gt;121&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing (pain level and analgesic use presented)</td>
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<tr>
<td>Hancevic et al., 1980&lt;sup&gt;122&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Croatian; no control group</td>
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<tr>
<td>Heng et al., 2000&lt;sup&gt;123&lt;/sup&gt;</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Feasibility study of hypertonic oxygen</td>
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<td>Hermans, 1993&lt;sup&gt;124&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Sutured wounds</td>
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<tr>
<td>Herzberg, 1985&lt;sup&gt;125&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Not clear</td>
<td>Yes</td>
<td>No control group; not clear if wounds were of appropriate type</td>
</tr>
<tr>
<td>Hien et al., 1988&lt;sup&gt;126&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Clean wounds, did not require debridng</td>
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<tr>
<td>Hughes, 1986&lt;sup&gt;127&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Not clear</td>
<td>No measure of healing; not clear whether wounds were of appropriate type</td>
</tr>
<tr>
<td>Hulkko et al., 1981&lt;sup&gt;128&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Mixture of wounds, including venous leg ulcers, results not presented separately</td>
</tr>
<tr>
<td>Ingram et al., 1998&lt;sup&gt;129&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of wound healing (pain assessed as primary outcome)</td>
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<tr>
<td>Johnson et al., 1985&lt;sup&gt;130&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Sutured wounds</td>
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<tr>
<td>Johnson and Jones, 1988&lt;sup&gt;131&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No control group</td>
</tr>
<tr>
<td>Joshi et al., 1986&lt;sup&gt;132&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No control; chronic wounds</td>
</tr>
<tr>
<td>Kallehave et al., 1994&lt;sup&gt;133&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No control group</td>
</tr>
<tr>
<td>Kauer and Siodmak, 1984&lt;sup&gt;134&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No control group; chronic wounds; no measure of healing</td>
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<tr>
<td>Krupski et al., 1991&lt;sup&gt;136&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Platelet derived wound healing factor in chronic wounds</td>
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<td>Lang, 1981&lt;sup&gt;139&lt;/sup&gt;</td>
<td>No</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>Not an RCT or controlled trial; case studies</td>
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<tr>
<td>Lees et al., 1991&lt;sup&gt;140&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing (pain used as outcome measure)</td>
</tr>
</tbody>
</table>

*continued*
### TABLE 9 contd Summary of excluded studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Intervention</th>
<th>Wound type</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legray and Greco, 1979&lt;sup&gt;142&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Chronic wounds; no measure of healing</td>
</tr>
<tr>
<td>Levine et al., 1976&lt;sup&gt;43&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Burn wounds; no measure of healing</td>
</tr>
<tr>
<td>Linke et al., 1986&lt;sup&gt;44&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of wound healing (assessed physician and nurse assessment of superiority, and acceptance of patients)</td>
</tr>
<tr>
<td>Lippert and Zeh, 1991&lt;sup&gt;145&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No control group or measure of healing</td>
</tr>
<tr>
<td>Marks et al., 1985&lt;sup&gt;144&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Antibiotic therapy, no debridement</td>
</tr>
<tr>
<td>McCulloch and Kemper, 1993&lt;sup&gt;146&lt;/sup&gt;</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Case report of vacuum compression</td>
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<td>Michie and Hugill, 1994&lt;sup&gt;19&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Wounds sutured; no measure of healing</td>
</tr>
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<td>Michiels and Christiaens, 1990&lt;sup&gt;16&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing</td>
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<tr>
<td>Moore and Foster, 2000&lt;sup&gt;18&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing</td>
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<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Case study</td>
</tr>
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<td>Moore and Foster, 1996&lt;sup&gt;12&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No results for an objective measure of healing presented</td>
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<td>Morgan et al., 1980&lt;sup&gt;133&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No control group</td>
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<td>Mosshakis et al., 1984&lt;sup&gt;144&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Sutured wounds; no measure of healing</td>
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<tr>
<td>Mosher et al., 1999&lt;sup&gt;113&lt;/sup&gt;</td>
<td>No</td>
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<td>No</td>
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<td>Chronic wounds</td>
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<td>Mulder and Andrews, 1993&lt;sup&gt;133&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<td>Chronic wounds</td>
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<td>Mulder, 1995&lt;sup&gt;17&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Mixture of wounds (venous, trauma and pressure)</td>
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<td>Mulder, 1995&lt;sup&gt;133&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Chronic wounds, no measure of healing</td>
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<td>Muller et al., 1994&lt;sup&gt;39&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Description of a trial to be conducted</td>
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<td>Nash et al., 1994&lt;sup&gt;40&lt;/sup&gt;</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No control group</td>
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<td>Nepi, 1992&lt;sup&gt;141&lt;/sup&gt;</td>
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<td>Italian</td>
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<td>Niinkoski and Renvall, 1980&lt;sup&gt;142&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Animal study</td>
</tr>
<tr>
<td>Paul, 1990&lt;sup&gt;163&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No control group; inappropriate wound (ulcer)</td>
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<td>Pendse et al., 1993&lt;sup&gt;144&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Chronic wounds</td>
</tr>
<tr>
<td>Phan et al., 1993&lt;sup&gt;146&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing (wound infection primary outcome)</td>
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<td>Philbeck et al., 1999&lt;sup&gt;147&lt;/sup&gt;</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Descriptive study; vacuum therapy (not a debriding agent) in chronic wounds</td>
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<td>Platt and Becknall, 1984&lt;sup&gt;148&lt;/sup&gt;</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Animal study</td>
</tr>
<tr>
<td>Plaumann et al., 1985&lt;sup&gt;149&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing (bacterial counts only)</td>
</tr>
<tr>
<td>Ponnighaus and Kowalzick, 1999&lt;sup&gt;171&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing</td>
</tr>
<tr>
<td>Poulsen et al., 1983&lt;sup&gt;173&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing</td>
</tr>
<tr>
<td>Rasmussen et al., 1993&lt;sup&gt;174&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Wounds did not require debridement; no measure of wound healing</td>
</tr>
<tr>
<td>Rees and Hirshberg, 1999&lt;sup&gt;175&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Not a trial; chronic wounds; no measure of healing</td>
</tr>
<tr>
<td>Regan, 1992&lt;sup&gt;176&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Case studies; no control</td>
</tr>
</tbody>
</table>

*continued*
<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Intervention</th>
<th>Wound type</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ricci et al., 1995&lt;sup&gt;177&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No control or surgical wound</td>
</tr>
<tr>
<td>Ricci et al., 1998&lt;sup&gt;178&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No control; chronic wounds</td>
</tr>
<tr>
<td>Schmidt et al., 1991&lt;sup&gt;180&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Aloe vera used as intervention, which is reported to have anti-inflammatory properties and therefore is not considered to be a debriding agent</td>
</tr>
<tr>
<td>Schmitt et al., 1996&lt;sup&gt;181&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Sutured wounds</td>
</tr>
<tr>
<td>Schwarz, 1981&lt;sup&gt;182&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No control group</td>
</tr>
<tr>
<td>Shukla, 1983&lt;sup&gt;183&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No control group</td>
</tr>
<tr>
<td>Soul, 1978&lt;sup&gt;184&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No control group</td>
</tr>
<tr>
<td>Steed et al., 1996&lt;sup&gt;185&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Not a controlled trial or RCT; chronic wounds; no measure of wound healing</td>
</tr>
<tr>
<td>Stuwe, 1983&lt;sup&gt;186&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of wound healing</td>
</tr>
<tr>
<td>Suomalainen, 1983&lt;sup&gt;187&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Traumatic ulcer</td>
</tr>
<tr>
<td>Sutherland, 1997&lt;sup&gt;188&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Case report of gangrene after total hip replacement surgery</td>
</tr>
<tr>
<td>Stuwe, 1983&lt;sup&gt;188&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Not surgical wounds</td>
</tr>
<tr>
<td>Taranenko et al., 1984&lt;sup&gt;189&lt;/sup&gt;</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>Russian</td>
</tr>
<tr>
<td>Thomas et al., 1997&lt;sup&gt;190&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No measure of healing; mixture of appropriate wounds and ulcers, not analysed separately</td>
</tr>
<tr>
<td>Treusch and Kohnlein, 1985&lt;sup&gt;192&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No control group; chronic wounds</td>
</tr>
<tr>
<td>Turner et al., 1994&lt;sup&gt;193&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Observational study of home wounds managed by contract nurses; mixture of appropriate wounds and ulcers, not analysed separately</td>
</tr>
<tr>
<td>Vogel and Lenz, 1992&lt;sup&gt;194&lt;/sup&gt;</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Wounds closed surgically</td>
</tr>
<tr>
<td>Watts and Lee, 1994&lt;sup&gt;196&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing</td>
</tr>
<tr>
<td>Weise and Evers, 1988&lt;sup&gt;197&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No control group; sutured wounds</td>
</tr>
<tr>
<td>Weneret et al., 1992&lt;sup&gt;198&lt;/sup&gt;</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No control group; intervention (collagenous sponge containing gentamicin) was not a debriding agent</td>
</tr>
<tr>
<td>Weststrate, 1996&lt;sup&gt;199&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Retrospective study; no control group</td>
</tr>
<tr>
<td>Wikblad and Anderson, 1995&lt;sup&gt;200&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Sutured wounds</td>
</tr>
<tr>
<td>Williams et al., 1995&lt;sup&gt;201&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No measure of healing</td>
</tr>
<tr>
<td>Wollina, 1997&lt;sup&gt;202,203&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No control group</td>
</tr>
<tr>
<td>Wood and Hughes, 1975&lt;sup&gt;204&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Retrospective study</td>
</tr>
<tr>
<td>Wood et al., 1977&lt;sup&gt;205&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No control group</td>
</tr>
</tbody>
</table>
Appendix 3

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

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author, year</td>
<td>Type of operation</td>
<td>Intervention (description of intervention and sample size)</td>
<td>Details of baseline comparability of intervention groups</td>
<td>Statistical test used to compare groups</td>
<td>Details of withdrawals</td>
<td>Authors' conclusions (authors' own comments)</td>
</tr>
<tr>
<td>Country of origin</td>
<td>Inclusion criteria</td>
<td>Comparator (description of comparator(s), including sample size)</td>
<td>Results (summary of results)</td>
<td></td>
<td></td>
<td>Other comments (limitations of the study; biases not reported by authors, generalisability and other comments)</td>
</tr>
<tr>
<td>Study design (i.e. RCT or controlled trial)</td>
<td>Exclusion criteria</td>
<td>Concurrent treatment (e.g. any additional dressings used)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Method of randomisation (if applicable)</td>
<td>Bacterial growth</td>
<td>Duration of follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Setting (if multicentre, number of sites, outpatients, in hospital)</td>
<td></td>
<td>Measure of healing (includes information relating to the method used to measure healing)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Objective (authors' objective)</td>
<td></td>
<td>Other outcome measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study details</td>
<td>Source of data</td>
<td>Method used to estimate benefits/costs</td>
<td>Results</td>
<td>Sensitivity analysis</td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td>----------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>---------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Author, year</td>
<td>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)</td>
<td>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))</td>
<td>Clinical outcome/benefit (summary estimates of clinical outcome/benefits)</td>
<td>Sensitivity analysis (appropriate sensitivity analysis of results to assess variability in the data)</td>
<td>Authors’ conclusions</td>
<td></td>
</tr>
<tr>
<td>Objective (objectives of the economic evaluation)</td>
<td>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))</td>
<td>Estimates of cost (including both direct and indirect costs, determined by chosen prospective)</td>
<td>Costs (summary cost results)</td>
<td>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))</td>
<td>Magnitude and direction of results (determine if extended dominance can be established)</td>
<td></td>
</tr>
<tr>
<td>Type of economic evaluation (CEA, CUA, CBA)</td>
<td></td>
<td>Modelling (if modelling used, type of model, purpose of model and components that were integrated in the model)</td>
<td>Statistical analysis (appropriate statistical test according to data characteristics; appropriate method for chosen time frame (e.g. discounting, inflating, deflating cost data))</td>
<td></td>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td>Country/currency (currency data and year to which data relate)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perspective (health service, societal, hospital, third-party payer, patient)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interventions (including comparator)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CBA, cost–benefit analysis; CEA, cost-effectiveness analysis; CUA, cost–utility analysis; QALY, quality-adjusted life-year
Quality checklist for clinical trials

An adaptation of the checklist presented in CRD Report 4 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, \( \chi^2 \) 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 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>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Berry et al., 1996</strong>, UK</td>
<td>Concrete details included in the table</td>
<td><strong>Intervention:</strong> 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)</td>
<td><strong>Wound details:</strong> 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</td>
<td><strong>Statistical test used to compare groups:</strong> no statistical analysis was undertaken</td>
<td>Foam: 1 participant because of perceived discomfort at having biopsies taken, 1 because of recurrent infection, 1 required further surgery</td>
<td></td>
</tr>
<tr>
<td>Study and design</td>
<td>Participants</td>
<td>Intervention and study details</td>
<td>Baseline characteristics</td>
<td>Results</td>
<td>Withdrawals</td>
<td>Comments</td>
</tr>
<tr>
<td>-----------------</td>
<td>--------------</td>
<td>-------------------------------</td>
<td>--------------------------</td>
<td>---------</td>
<td>-------------</td>
<td>----------</td>
</tr>
<tr>
<td>Bruce, 1991, UK</td>
<td>Type of operation: toenail avulsion and phenolisation of the germinal matrix for 3 minutes</td>
<td><strong>Intervention</strong>: Comfeel Ulcer Dressing (Coloplast Ltd), a hydrocolloid dressing (n = 3, final number)</td>
<td>18 subjects randomised</td>
<td><strong>Statistical test used to compare groups</strong>: not stated</td>
<td>Four patients failed to attend for redressing and no reason was ascertained (group not stated)</td>
<td><strong>Authors’ conclusions</strong>: 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.</td>
</tr>
<tr>
<td>Study design: RCT</td>
<td>Study design: RCT</td>
<td>Comparator: Serotulle, chlorhexidine acetate impregnated dressing (gauze derivative) (n = 8, final number)</td>
<td></td>
<td><strong>Results</strong>: presented as mean ± SD</td>
<td><strong>Gauze</strong>: 1 participant reported pain, I interfered with dressing, I was a chiropodist’s decision</td>
<td></td>
</tr>
<tr>
<td>Method of randomisation: not stated</td>
<td>Setting: chiropody clinic</td>
<td>Concurrent treatment: irrigated with normal saline and dressed accordingly</td>
<td></td>
<td><strong>Gauze</strong>: 1 participant reported pain, 1 interfered with dressing, 1 was a chiropodist’s decision</td>
<td><strong>Hydrocolloid</strong>: 3 participants developed allergies, 1 patient interfered with dressing, I was a chiropodist’s decision</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td>Inclusion criteria: patients aged 10–60 years in good general health</td>
<td><strong>Concurrent treatment</strong>: irrigated with normal saline and dressed accordingly</td>
<td></td>
<td><strong>Hydrocolloid</strong>: 3 participants developed allergies, 1 patient interfered with dressing, I was a chiropodist’s decision</td>
<td><strong>Other comments</strong>: the sample size was very small and so the study will have lacked the power to detect significant differences between the groups.</td>
<td></td>
</tr>
<tr>
<td>Exclusion criteria: diabetes and rheumatoid arthritis, severe peripheral vascular disease, anticoagulant and corticosteroid therapy, pregnancy</td>
<td>Concurrent treatment: irrigated with normal saline and dressed accordingly</td>
<td><strong>Duration of follow-up</strong>: 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</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacterial growth: not stated</td>
<td>Measurement 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</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>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</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

continued
### TABLE 12 contd Details of the clinical trials included in the review

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of operation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pilonidal sinus excision or abdominal surgery</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Inclusion criteria</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Exclusion criteria</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>patients with wounds that showed obvious signs of clinical infection, if they were immunosuppressed, pregnant or receiving cytotoxic therapy or radiotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bacterial growth</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>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 practice of the clinic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Duration of follow-up</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>until complete healing; patients were reviewed weekly at the wound care clinic, where their wound healing progress was reported</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Measure of healing</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>time to wound healing; wound dimensions (length, width, depth) were recorded at baseline examination; measured with a stock and ruler; a photograph was taken of each wound</td>
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<tr>
<td><strong>Other outcome measures</strong></td>
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<tr>
<td>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</td>
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<td><strong>Wound details</strong></td>
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<tr>
<td>mean (range)</td>
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<td>Length: Allevyn 63.0 mm (23–148 mm); foam 62.3 mm (23–160 mm)</td>
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<td>Width: Allevyn 19.8 mm (0–59 mm); foam 18.9 mm (0–51 mm)</td>
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<td>Depth: Allevyn 26.1 mm (8–82 mm); foam 26.6 mm (5–65 mm)</td>
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<td><strong>Patient details</strong></td>
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<tr>
<td>Age: Allevyn 30.4 years (16–72 years); foam 28.2 years (16–76 years)</td>
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<td><strong>Statistical test used to compare groups</strong></td>
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<tr>
<td>not stated</td>
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<tr>
<td><strong>Results</strong></td>
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<tr>
<td>mean ± SE (range)</td>
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<tr>
<td>Time to wound healing</td>
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<td>Pilonidal: Allevyn 51.4 ± 20.9 days (14–112 days); foam 61.9 ± 26.1 days (28–110 days)</td>
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<td>Abdominal: Allevyn 51.9 ± 20.5 days (27–84 days); foam 56.6 ± 37.6 days (28–138 days)</td>
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<tr>
<td>All wounds: Allevyn 51.5 ± 20.5 days (14–112 days); foam 60.8 ± 28.4 days (28–138 days)</td>
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<tr>
<td><strong>Concurrent treatment</strong></td>
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<td>wounds judged to be either clinically or bacteriologically infected were treated with systemic antibiotics according to the usual practice of the clinic</td>
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<tr>
<td><strong>Percentage of dressings that conformed well</strong></td>
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<tr>
<td>Allevyn: 93%; foam 99%</td>
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</tbody>
</table>

**Other comments:** the sample size was small, so the study may have lacked the power to detect significant differences between the two treatments.
TABLE 12 contd Details of the clinical trials included in the review

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannava et al.</td>
<td>1998. Australia</td>
<td>Type of operation: type of operation not specified</td>
<td>Comparator: sodium hypochlorite 0.05%</td>
<td>Statistical test used to compare groups: rates were compared using ANOVA</td>
<td>Three participants withdrawn before trial started, 1 who withdrew consent and 2 required further surgery; 36 were included in final study</td>
<td>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 protocol demonstrated that it performed well in comparison with calcium alginate dressing in terms of healing time, patient comfort and cost.</td>
</tr>
</tbody>
</table>

**Study design:** RCT

**Method of randomisation:** cards contained in sealed envelopes

**Setting:** gastrointestinalsurgical unit

**Objective:** to compare the performance of three dressings in the management of dehisced surgical abdominal wounds

**Inclusion criteria:** resident in the catchment area; 18 years of age or over; had a surgical abdominal suture line with a break-down of greater than 3 cm; no known allergies to dressings

**Exclusion criteria:** not stated

**Type of operation:** defunctionalisation of the rectum; split-thickness skin grafting

**Intervention:** calcium alginate dressing (Sorbsan); dressing not changed until gelled (approximately once daily) (n = 13)

**Comparator:** sodium hypochlorite 0.05% solution moistened gauze dressing

**Dressing: calcium alginate dressing (Sorbsan); dressing not changed until gelled (approximately once daily) (n = 13)**

**Dressing:** calcium alginate dressing (Sorbsan); dressing not changed until gelled (approximately once daily) (n = 13)

**Comparison:** calcium alginate dressing vs sodium hypochlorite 0.05% solution moistened gauze dressing

**Dressing change:** 2 or 3 times daily until wound granulation; solution then changed to normal saline (0.09%); 2 or 3 times daily (n = 10)

**Dressing:** calcium alginate dressing (Sorbsan); dressing not changed until gelled (approximately once daily) (n = 13)

**Comparison:** calcium alginate dressing vs sodium hypochlorite 0.05% solution moistened gauze dressing

**Dressing change:** 2 or 3 times daily until wound granulation; solution then changed to normal saline (0.09%); 2 or 3 times daily (n = 10)

**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

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**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
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<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Dawson et al., 1992, UK</td>
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<tr>
<td>Study design: RCT</td>
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<tr>
<td>Method of randomisation: not stated</td>
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<tr>
<td>Setting: outpatient clinic</td>
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<tr>
<td>Objective: to examine the use of calcium alginate as a dressing for abscess cavities compared to saline-soaked gauze packs (conventional treatment)</td>
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<tr>
<td>Type of operation: incision and drainage of abscess</td>
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<tr>
<td>Inclusion criteria: over 16 years of age</td>
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<tr>
<td>Exclusion criteria: none stated</td>
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<tr>
<td>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</td>
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<tr>
<td>Intervention: wound packed lightly with calcium alginate dressing (n = 16)</td>
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<td>None of the patients were diabetic or receiving steroid treatment</td>
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<td>Comparator: gauze soaked in saline, lightly packed into wound (n = 18)</td>
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<td>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</td>
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<tr>
<td>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</td>
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<tr>
<td>Measure of healing: complete healing at 2 weeks</td>
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<tr>
<td>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)</td>
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<tr>
<td>Statistical test used to compare groups: none reported</td>
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<tr>
<td>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</td>
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<tr>
<td>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</td>
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<tr>
<td>Study sponsor: calcium alginate dressings were provided by BritCair UK</td>
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</table>

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

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Foley and Allen, 1994, UK</strong></td>
<td><strong>Type of operation:</strong> partial or total nail avulsion</td>
<td><strong>Intervention:</strong> 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)</td>
<td><strong>Mean ± SD age:</strong> alginate 23.7 ± 14 years; gauze 29.8 ± 17 years</td>
<td><strong>Statistical test used to compare groups:</strong> not stated</td>
<td>None reported</td>
<td><strong>Authors' conclusions:</strong> 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</td>
</tr>
<tr>
<td><strong>Study design:</strong> RCT</td>
<td><strong>Inclusion criteria:</strong> patients referred by GP to the chiropody department for toenail surgery</td>
<td><strong>Comparator:</strong> Melolin (Smith &amp; 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)</td>
<td><strong>Mean ± SD ischaemic index:</strong> alginate 1.08 ± 0.12; gauze 1.08 ± 0.14</td>
<td><strong>Results:</strong> mean ± SD</td>
<td><strong>Other comments:</strong> 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</td>
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<tr>
<td><strong>Method of randomisation:</strong> predetermined random sequence</td>
<td><strong>Exclusion criteria:</strong> mycotic nail infection; undergoing treatment with antibiotics, steroids or immunosuppressants; diabetes; absent foot pulses or peripheral neuropathy</td>
<td><strong>Duration of follow-up:</strong> until complete healing; patients were reviewed the day after surgery and the wound then dressed once a week</td>
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<td><strong>Study sponsor:</strong> BritCair Division of CV Laboratories; the second author is an employee of BritCair Division</td>
</tr>
<tr>
<td><strong>Setting:</strong> chiropody outpatient department</td>
<td><strong>Bacterial growth:</strong> none stated</td>
<td><strong>Measure of healing:</strong> time to re-epithelialisation (complete healing)</td>
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<tr>
<td><strong>Objective:</strong> 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</td>
<td><strong>Duration of follow-up:</strong> until complete healing; patients were reviewed the day after surgery and the wound then dressed once a week</td>
<td><strong>Other outcome measures:</strong> 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</td>
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</table>

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

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
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<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Goode et al., 1979,</strong> UK</td>
<td><strong>Type of operation:</strong> appendectomy or bowel surgery</td>
<td><strong>Intervention:</strong> dextranomer polysaccharide beads (Debrisan) ((n = 10))</td>
<td><strong>Patient details:</strong> Mean (range) age dextranomer 52.9 years ((24–91) years); gauze 50.9 years ((27–71) years)</td>
<td><strong>Statistical test used to compare data:</strong> Mann-Whitney (U)-test</td>
<td>Not reported</td>
<td><strong>Authors' conclusions:</strong> Debrisan was found to be more effective than Eusol in the patients studied</td>
</tr>
<tr>
<td><strong>Study design:</strong> RCT</td>
<td><strong>Method of randomisation:</strong> cards drawn from sealed envelopes</td>
<td><strong>Comparator:</strong> Eusol ribbon gauze ((n = 10))</td>
<td>Gender (male/female): dextranomer 7/3; gauze 6/4</td>
<td><strong>Results:</strong> Number of wounds that healed by granulation: dextranomer 1; gauze 1 ((\text{duration of time not stated}))</td>
<td></td>
<td><strong>Other comments:</strong> 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</td>
</tr>
<tr>
<td><strong>Setting:</strong> hospital and outpatients</td>
<td><strong>Inclusion criteria:</strong> 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</td>
<td><strong>Concurrent treatment:</strong> all patients were given prophylactic antibiotic cover of Cephalixin and Metronidazole with the premedication and for 48–72 hours postoperatively</td>
<td><strong>Wound details:</strong> Appendectomy/paramedian ((\text{near the middle})): dextranomer 6/4; gauze 7/3</td>
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<tr>
<td><strong>Objective:</strong> to examine the cost-effectiveness of dextranomer and Eusol in the treatment of infected surgical wounds</td>
<td><strong>Exclusion criteria:</strong> none stated</td>
<td><strong>Delayed primary suture:</strong> dextranomer 4; gauze 6</td>
<td><strong>Mean time to wound closure by secondary suture:</strong> dextranomer 8.1 days; gauze 11.6 days ((p &lt; 0.05))</td>
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<td></td>
<td><strong>Bacterial growth:</strong> bacteriological slides showed that the predominant infective organisms were Escherichia coli and Pseudomonas, with no particular difference between groups</td>
<td><strong>Wound abscess:</strong> dextranomer 6; gauze 4</td>
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<tr>
<td></td>
<td><strong>Duration of follow-up:</strong> not stated</td>
<td><strong>Other outcome measures:</strong> number of days in hospital</td>
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<td></td>
<td><strong>Measure of healing:</strong> 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</td>
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</table>

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

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Guillotreau et al., 1996.</strong></td>
<td>France</td>
<td><strong>Intervention:</strong> calcium alginate rope (n = 37)</td>
<td><strong>Wound details:</strong> mean (range)</td>
<td><strong>Statistical test used to compare groups:</strong> χ² test for categorical data, Student's t-test or Wilcoxon test for continuous data</td>
<td>None reported; there were no adverse reactions in either of the 2 treatment groups</td>
<td><strong>Authors’ conclusions:</strong> these results confirm that alginate rope is effective and can be used safely in the management of infected wounds</td>
</tr>
<tr>
<td><strong>Study design:</strong> RCT (multicentre)</td>
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<td><strong>Comparator:</strong> packing with gauze soaked in povidone iodine (n = 33)</td>
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<tr>
<td><strong>Method of randomisation:</strong> not stated</td>
<td></td>
<td><strong>Duration of follow-up:</strong> 3 weeks; wounds were evaluated weekly; treatment begun 1 day after incision</td>
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<tr>
<td><strong>Setting:</strong> 7 general surgery departments of military hospitals</td>
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<td><strong>Bacterial growth:</strong> bacterial swabs were taken; there was no difference between the bacteria cultured in the two groups</td>
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<tr>
<td><strong>Objective:</strong> to compare the efficacy and safety of calcium alginate dressing and povidone iodine pack in the management of infected postoperative wounds</td>
<td></td>
<td><strong>Measure of healing:</strong> wound healing was evaluated using wound cavity volume, area tracings, photographs and clinical observation</td>
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<tr>
<td></td>
<td></td>
<td><strong>Other outcome measures:</strong> wound infection using bacterial swabs; pain and ease of use of use were measured using visual analogue scales</td>
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</tbody>
</table>

- **Type of operation:** incision and drainage of pilonidal abscess

- **Inclusion criteria:** not stated

- **Exclusion criteria:** not stated

- **Concurrent treatment:** none reported

- **Bacterial swabs:** bacterial swabs were taken; there was no difference between the bacteria cultured in the two groups

- **Volume of swabs:** 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 17 cm (167–190 cm); gauze 176 cm (168–190 cm)

- **Statistical test used to compare groups:** χ² test for categorical data, Student's t-test or Wilcoxon test for continuous data

- **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**
### Appendix 5

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

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macfie and McMahon, 1982, UK</td>
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<tr>
<td>Study design: RCT</td>
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<tr>
<td>Method of randomisation: not stated; randomised on postoperative day 14</td>
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<tr>
<td>Setting: hospital and surgical outpatient clinic; a district nurse was arranged for all patients on discharge</td>
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<tr>
<td>Objective: to assess the value of foam elastomer, a catalysed silicone polymer dressing, in the management of the perineal wound after abdominopelvic excision of the rectum</td>
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<tr>
<td>Inclusion criteria: consecutive participants with open perineal wound at postoperative day 14</td>
<td>Type of operation: proctectomy or rectal excision</td>
<td>Intervention: silicone foam elastomer (Silastic, Dow Corning Ltd) (n = 25 completed trial)</td>
<td>Mean ± SE initial wound volume on day 14: foam 55.5 ± 4.5 ml; gauze 61.5 ± 5.3 ml</td>
<td>Statistical test used to compare groups: unpaired Student’s t-test</td>
<td>Foam: 1 participant had proven recurrent carcinoma and 1 failed to heal following rectal excision for irradiation colitis</td>
<td>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</td>
</tr>
<tr>
<td>Exclusion criteria: none stated</td>
<td>Comparator: ribbon gauze soaked in mercuric chloride antiseptic solution, loosely packed into the perineal wound (n = 25 completed trial)</td>
<td>Mean ± SD age: foam 54 ± 17.0 years; gauze 59 ± 17.5 years</td>
<td>Time to full epithelialisation: foam 60.3 ± 3.0 days; gauze 69.5 ± 7.3 (p &gt; 0.05)</td>
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<tr>
<td>Bacterial growth: not stated</td>
<td>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</td>
<td>Gender (male/female): foam: 14/11; gauze: 16/9</td>
<td>Rate to full epithelialisation (time to full epithelialisation/initial wound size): foam 0.94 ± 0.11; gauze 0.98 ± 0.08 (p &gt; 0.05)</td>
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<td></td>
<td>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</td>
<td>Reasons for surgery (number of subjects): ulcerative colitis: foam 8; gauze 6</td>
<td>Time to dry dressing: foam 47.5 ± 3.1 days; gauze 62.6 ± 6.3 days (p &lt; 0.05)</td>
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<td></td>
<td>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</td>
<td>Crohn’s disease: foam 5; gauze 3</td>
<td>Rate to dry dressing: foam 1.24 ± 0.15; gauze 1.07 ± 0.11 (p &lt; 0.02)</td>
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<td>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</td>
<td>Carcinoma: foam 10; gauze 14</td>
<td>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)</td>
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<td></td>
<td>Inclusion criteria: consecutive participants with open perineal wound at postoperative day 14</td>
<td>Villous papilloma: foam 1; gauze 0</td>
<td>Number of inpatient days, including convalescence: foam 29.4 ± 3.6; gauze 29.9 ± 2.8 (p &gt; 0.05)</td>
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<td></td>
<td>Exclusion criteria: none stated</td>
<td>Irradiation colitis: foam 1; gauze 1</td>
<td>Number of inpatient days, excluding convalescence: foam 23.8 ± 1.8; gauze 22.8 ± 1.7 (p &gt; 0.05)</td>
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<td></td>
<td>Bacterial growth: not stated</td>
<td>Diverticulitis: foam 0; gauze 1</td>
<td>Number of visits by district nurse: foam 14.1 ± 2.4; gauze 14.9 ± 5.8 (p &lt; 0.001)</td>
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<td>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</td>
<td>Number of wounds that resulted from breakdown of attempt at primary suture: foam 14; gauze 16</td>
<td>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</td>
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<td>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</td>
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<td></td>
<td>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</td>
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<td>Inclusion criteria: consecutive participants with open perineal wound at postoperative day 14</td>
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<td>Exclusion criteria: none stated</td>
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<td></td>
<td>Bacterial growth: not stated</td>
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<td>Exclusion criteria: none stated</td>
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<td>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</td>
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<td>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</td>
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<td>Inclusion criteria: consecutive participants with open perineal wound at postoperative day 14</td>
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<td>Exclusion criteria: none stated</td>
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<td></td>
<td>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</td>
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<td></td>
<td>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</td>
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</table>
| | 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 | | | | | continued
### TABLE 12 contd Details of the clinical trials included in the review

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Meyer, 1997, 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; immuno-deficiency; wounds consisting of a big subcutaneous cavity with a small ostium; receiving steroids, radiation or chemotherapy | 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 | 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  
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 | 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 | 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' conclusion: 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 |
<table>
<thead>
<tr>
<th>Study and design</th>
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<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ricci et al., 1998, Italy</td>
<td>Type of operation: pilonidal sinus removal</td>
<td><strong>Intervention:</strong> reconstituted silicone foam (CaviCare, Smith &amp; Nephew); each day, the foam was disinfected with 10% chlorohexidine, rinsed with sterile saline solution and replaced (n = 6)</td>
<td>All patients were younger than 40 years of age and had no other pathologies other than pilonidal sinus</td>
<td>Statistical test used to compare groups: no statistical analysis was undertaken</td>
<td>None reported</td>
<td>Authors’ conclusions: this study indicates that the advanced dressing (foam) is easy to use with better results in pilonidal sinus wounds</td>
</tr>
<tr>
<td>Study design: controlled trial</td>
<td>Inclusion criteria: not stated</td>
<td><strong>Comparator:</strong> 10% iodopovidone solution and dry gauze, changed twice daily (n = 6)</td>
<td>Average volume of wound cavity: foam 91 cm³; gauze 114 cm³</td>
<td>Results: mean (range)</td>
<td></td>
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</tr>
<tr>
<td>Method of randomisation: not applicable</td>
<td>Exclusion criteria: not stated</td>
<td><strong>Concurrent treatment:</strong> all patients received an antiseptic dressing (Inadine, Johnson &amp; Johnson) on the first postoperative day; in both groups dressings were changed if dirty, contaminated or displaced; wounds cleansed with sterile saline solution</td>
<td><strong>Time to complete healing:</strong> foam 33.5 days (21–52 days); gauze 73 days (38–102 days)</td>
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<tr>
<td>Setting: hospital</td>
<td>Bacterial growth: no presence of infection was seen in either group</td>
<td><strong>Cavity reduction after 15 days:</strong> foam 46%; gauze 22%</td>
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<tr>
<td>Objective: to evaluate the healing time of surgical wounds healing by secondary intention using two different types of dressing (traditional and advanced)</td>
<td>Duration of follow-up: treatment was continued until wound reduction or rupture</td>
<td><strong>Cavity filling time:</strong> foam 4.3 weeks; gauze 9.5 weeks</td>
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<td></td>
<td>Measure of healing: healing time</td>
<td><strong>Time before return to work:</strong> foam 12 days; gauze 23 days</td>
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<tr>
<td></td>
<td>Other outcome measures: granulating time, comfort and infection</td>
<td><strong>Number of dressings used per patient:</strong> foam 20; gauze 868</td>
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<td></td>
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<td>For the foam group, dressings were pain-free, while in the gauze group they were painful and bleeding occurred</td>
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</tbody>
</table>

continued
### Table 12 contd: Details of the clinical trials included in the review

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith, 1992, UK</td>
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<tr>
<td><strong>Study design:</strong></td>
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<tr>
<td>quasi-RCT</td>
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<td><strong>Method of randomisation:</strong></td>
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<tr>
<td>participants were allocated numbers and those with even numbers were treated with Sorbsan, while the others received the standard dressing</td>
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<tr>
<td><strong>Setting:</strong></td>
<td>acute hospital, chiropody department</td>
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<tr>
<td><strong>Objective:</strong></td>
<td>to compare the use of two dressing regimens, Sorbsan and polyoxymelatin/Melolin, after toenail removal in terms of healing time and postoperative complications</td>
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<tr>
<td><strong>Type of operation:</strong></td>
<td>total or partial nail avulsion with phenolisation (80% liquefied phenol)</td>
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<tr>
<td><strong>Inclusion criteria:</strong></td>
<td>none stated</td>
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<tr>
<td><strong>Exclusion criteria:</strong></td>
<td>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</td>
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<tr>
<td><strong>Concurrent treatment:</strong></td>
<td>dressings held in place with tubular gauze; advice leaflet</td>
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<tr>
<td><strong>Duration of follow-up:</strong></td>
<td>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</td>
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<tr>
<td><strong>Measure of healing:</strong></td>
<td>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</td>
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<tr>
<td><strong>Other outcome measures:</strong></td>
<td>any volunteered complaints were recorded</td>
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</tbody>
</table>

**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 Anaflex powder) (n = 28, final number: total nail avulsion n = 13; partial nail avulsion n = 15)

**Results:**
- Mean healing time (total nail avulsion):
  - Alginate: 43 days
  - Gauze: 52 days
- Mean healing time (partial nail avulsion):
  - 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: 6
- 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

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*continued*
<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Van Gils et al., 1998, USA</td>
<td>Type of operation: toenail avulsion utilising 10% sodium hydroxide was performed; area irrigated with 5% acetic acid to neutralise chemical</td>
<td>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)</td>
<td>Gender (male/female): alginate 1/2; control 1/1 Mean (range) age: alginate 42 years (12–79 years); control 40 years (12–63 years)</td>
<td>Statistical test used to compare groups: a t-test was conducted for comparison of independent group means Results: mean (range), median</td>
<td>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</td>
<td>Authors' conclusions: the Fibracol collagen–alginate dressing was found to be an effective adjunct in the postoperative 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</td>
</tr>
<tr>
<td>Study design: RCT</td>
<td>Method of randomisation: not stated</td>
<td>Setting: podiatry clinic</td>
<td>Objective: to evaluate the efficacy of a collagen–alginate wound dressing in the postoperative management of chemical matricectomies</td>
<td>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</td>
<td>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</td>
<td>One patient was not available for follow-up and was excluded from the analysis</td>
</tr>
<tr>
<td>Setting: podiatry clinic</td>
<td>Objective: to evaluate the efficacy of a collagen–alginate wound dressing in the postoperative management of chemical matricectomies</td>
<td>Inclusion criteria: 20 consecutive patients who presented to the podiatry clinic; patients with infected or chronic ingrown toenails</td>
<td>Bacterial growth: none of the patients in the 2 groups experienced post-operative infection</td>
<td>Duration of follow-up: 8 weeks; patients were seen weekly until healing had occurred or until the 8 week end-point was reached</td>
<td>Measure of healing: average time to healing; healing defined as absence of drainage, erythema, oedema and pain at wound site</td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vicano et al., 2000, Spain</td>
<td>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</td>
<td>Comparator: conventional gauze with povidone iodine (n = 15)</td>
<td>31 men and 7 women Mean age 24 years (range 16–48 years)</td>
<td>Statistical test used to compare groups: Fisher’s exact test and Mann–Whitney test</td>
<td>None reported</td>
<td>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</td>
</tr>
<tr>
<td>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</td>
<td>Intervention: hydrocolloid dressings (groups combined in analysis). Comfeel (Coloplast) (n = 12) and Varihesive (Convatec) (n = 11)</td>
<td>Concurrent treatment: washing of wound in saline and replacement of dressing</td>
<td>No differences between groups in sex, age or size of resected area of tissue</td>
<td>Results: median (range) Healing time: hydrocolloid 65 days (40–137 days); gauze 68 days (33–168 days) (p &gt; 0.05)</td>
<td>Number of dressings used hydrocolloid 23 (13–36); gauze 68 (33–168)</td>
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<tr>
<td></td>
<td>Inclusion criteria: none stated</td>
<td>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</td>
<td>Local intolerance (dermal folliculitis at wound margins): hydrocolloid 3 (13%); gauze 1 (7%)</td>
<td></td>
<td>Local intolerance (dermal folliculitis at wound margins): hydrocolloid 3 (13%); gauze 1 (7%)</td>
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<tr>
<td></td>
<td>Exclusion criteria: patients with pilonidal abscesses</td>
<td>Measure of healing: time to healing</td>
<td>Scar quality, tolerance of dressing, smell: no significant differences among groups</td>
<td></td>
<td>Scar quality, tolerance of dressing, smell: no significant differences among groups</td>
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<tr>
<td></td>
<td>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</td>
<td>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</td>
<td>Recurrence: none after median follow-up of 74 months (range 59–77 months)</td>
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<td>Recurrence: none after median follow-up of 74 months (range 59–77 months)</td>
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<td>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</td>
<td></td>
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<td></td>
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<td>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</td>
<td></td>
<td>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</td>
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<td></td>
<td>Cost data: Euros (July 1999) Unit dressing: hydrocolloid 4.0; control 1.3 Cost per patient: hydrocolloid 93.6; control 101.1 (p &gt; 0.05)</td>
<td></td>
<td>Cost data: Euros (July 1999) Unit dressing: hydrocolloid 4.0; control 1.3 Cost per patient: hydrocolloid 93.6; control 101.1 (p &gt; 0.05)</td>
<td></td>
</tr>
</tbody>
</table>

continued
### TABLE 12 contd  Details of the clinical trials included in the review

<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walker et al., 1991, UK</td>
<td>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</td>
<td><strong>Type of operation:</strong> 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 <strong>Inclusion criteria:</strong> 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 <strong>Exclusion criteria:</strong> none stated <strong>Bacterial growth:</strong> not stated</td>
<td><strong>Intervention:</strong> 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 $n = 17$) <strong>Comparator:</strong> 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 $n = 21$) <strong>Concurrent treatment:</strong> not stated <strong>Duration of follow-up:</strong> patients discharged when only required once daily dressing changes as an outpatient or were managing their own Silastic foam <strong>Measure of healing:</strong> time to full healing <strong>Other outcome measures:</strong> time to discharge</td>
<td>Mean age: men 25 years; women 19 years Age range: 16–33 years 96% male</td>
<td>Statistical test used to compare groups: not stated Results: mean (range)</td>
<td>Time to full healing – sinus: foam 30.0 days (21–39 days); gauze 33.0 days (20–46 days) ($p &gt; 0.05$) Time to hospital discharge – sinus: foam 12.8 days (6–20 days); gauze 15.2 days (3–27 days) ($p &gt; 0.05$) Time to full healing – abscess: foam 39.8 days (26–54 days); gauze 39.6 days (27–53 days) ($p &gt; 0.05$) Time to hospital discharge – abscess: foam 11.5 days (4–13 days); gauze 14.6 days (10–19 days) ($p &gt; 0.05$)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study design</th>
<th>Participants</th>
<th>Intervention and study details</th>
<th>Baseline characteristics</th>
<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Williams et al., 1981, 49 UK</td>
<td><strong>Type of operation:</strong> excision of pilonidal sinus</td>
<td><strong>Intervention:</strong> silicone foam elastomer dressing (Silastic) refashioned at weekly intervals (n = 44, final number)</td>
<td><strong>Mean ± SD wound volume:</strong> foam 59 ± 57.7 ml; gauze 64 ± 745 ml</td>
<td><strong>Statistical test used to compare groups:</strong> no statistical analysis was undertaken</td>
<td>Not stated; not clear from results presented</td>
<td><strong>Authors’ conclusions:</strong> 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</td>
</tr>
<tr>
<td><strong>Study design:</strong> RCT</td>
<td><strong>Inclusion criteria:</strong> not stated</td>
<td><strong>Comparator:</strong> daily packing with gauze soaked in a 0.5% aqueous solution of chlorhexidine (Habitant) (n = 36, final number)</td>
<td></td>
<td><strong>Results:</strong> mean ± SD</td>
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<tr>
<td><strong>Method of randomisation:</strong> not stated</td>
<td></td>
<td><strong>Concurrent treatment:</strong> each wound was packed for 4 days in a gauze roll soaked in flavine emulsion prior to randomisation</td>
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<tr>
<td><strong>Setting:</strong> multicentre study set in hospitals and the community</td>
<td><strong>Exclusion criteria:</strong> not stated</td>
<td><strong>Duration of follow-up:</strong> patients were reviewed weekly until the wound was completely epithelialised</td>
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<tr>
<td>Objective: to investigate the advantages of using a silastic foam dressing in the management of open granulating wounds</td>
<td><strong>Bacterial growth:</strong> not stated</td>
<td><strong>Measure of healing:</strong> time to complete healing of wound (when surface was completely epithelialised), and time until packing was no longer required</td>
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<td><strong>Other outcome measures:</strong> duration of hospital stay; work days lost; number of home nursing visits; discomfort on dressing removal; 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</td>
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</table>

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<table>
<thead>
<tr>
<th>Study and design</th>
<th>Participants</th>
<th>Intervention and study details</th>
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<th>Results</th>
<th>Withdrawals</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young and Wheeler, 1982</td>
<td>UK</td>
<td><strong>Type of operation:</strong> appendectomy for a gangrenous or perforated appendix with free peritoneal pus</td>
<td>Number of wounds left open primarily: dextranomer 8; foam 8</td>
<td><strong>Statistical test used to compare groups:</strong> Student’s t-test</td>
<td>None reported</td>
<td>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</td>
</tr>
<tr>
<td><strong>Study design:</strong> RCT</td>
<td></td>
<td><strong>Method of randomisation:</strong> random card system</td>
<td>Mean ± SD age: dextranomer 44.48 ± 5.17 years; foam 49.64 ± 4.57 years</td>
<td><strong>Results:</strong> mean ± SE</td>
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</tr>
<tr>
<td><strong>Setting:</strong> hospital setting with patients discharged home</td>
<td></td>
<td><strong>Inclusion criteria:</strong> all patients who developed a surgical breakdown; wounds left open after surgery in the superficial part from the muscle layers outwards</td>
<td>Types of wound in the two treatment groups (difference not significant): Midline: dextranomer 3; foam 8</td>
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<tr>
<td><strong>Objective:</strong> 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</td>
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<td><strong>Exclusion criteria:</strong> not stated</td>
<td>Upper paramedian: dextranomer 2; foam 1</td>
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<td><strong>Bacterial growth:</strong> bacteriological swabs were taken of any wounds that were odorous, contained excess slough or discharged frank pus; the findings were not presented</td>
<td>Lower paramedian: dextranomer 7; foam 10</td>
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<td></td>
<td><strong>Duration of follow-up:</strong> until complete healing; wounds were reviewed on days 1, 3 and 7 following breakdown, and thereafter weekly</td>
<td>Subcostal: dextranomer 3; foam 0</td>
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<td><strong>Measure of healing:</strong> 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</td>
<td>Grid iron: dextranomer 9; foam 5</td>
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<td><strong>Other outcome measures:</strong> 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)</td>
<td>Other: dextranomer 1; foam 1</td>
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<td></td>
<td><strong>Mean ± SD wound measurements:</strong> Length: dextranomer 5.53 ± 0.55 cm; foam 6.57 ± 0.89 cm</td>
<td><strong>Mean ± SD wound measurements:</strong></td>
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<td>Breadth: dextranomer 2.25 ± 0.33 cm; foam 2.48 ± 0.32 cm</td>
<td>Length: dextranomer 5.53 ± 0.55 cm; foam 6.57 ± 0.89 cm</td>
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<tr>
<td></td>
<td></td>
<td>Depth: dextranomer 1.80 ± 0.20 cm; foam 2.24 ± 0.29 cm</td>
<td>Breadth: dextranomer 2.25 ± 0.33 cm; foam 2.48 ± 0.32 cm</td>
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<tr>
<td></td>
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<td>Volume: dextranomer 4.92 ± 1.15 ml; foam 6.37 ± 1.30 ml</td>
<td>Depth: dextranomer 1.80 ± 0.20 cm; foam 2.24 ± 0.29 cm</td>
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</tbody>
</table>
Appendix 6
Summary of included economic evaluations
TABLE 13: Details of the economic evaluations included in the review

<table>
<thead>
<tr>
<th>Study details</th>
<th>Source of data</th>
<th>Method for estimation of benefits/costs</th>
<th>Results/statistical analysis</th>
<th>Sensitivity analysis</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beiersdorf, 2000*</td>
<td>(Part of the manufacturer and sponsor submission made to NICE by Beiersdorf UK Ltd)</td>
<td>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.</td>
<td>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 and the survey data from 5 patients.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Research question:</td>
<td>What is the cost-effectiveness of Cutinova in the management of difficult to heal surgical wounds as compared to gauze dressings?</td>
<td>Estimation of costs: costs that were considered included acquisition costs of dressings and nursing time per dressing.</td>
<td>Potential savings if Cutinova dressings are changed twice as often:</td>
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<tr>
<td>Type of economic evaluation: CEA (CMA)</td>
<td></td>
<td>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** was based on 1996 prices.</td>
<td>Week 1: £2.38 (gauze £19.18, Cutinova £17.76, £15.39) Week 2: £3.23 (gauze £17.76, £15.39) Week 3: £2.49 (gauze £12.11, £8.89, Cutinova £4.41) Week 4: £1.66 (gauze £6.89, £5.24) If the Cutinova price is increased by a factor of 3 the cost advantage is retained:</td>
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<tr>
<td>Country/currency: UK, pounds sterling; price year (a single financial year to which the economic evaluations relate) not specified</td>
<td></td>
<td>Modelling: NA</td>
<td>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)</td>
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<tr>
<td>Perspective: health service, hospital</td>
<td></td>
<td>Statistical analysis: no statistical calculation was conducted to compare the costs of the two treatments</td>
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<tr>
<td>Study population: patients with difficult to heal surgical wounds</td>
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<tr>
<td>Interventions (including comparator): polyurethane dressings (Cutinova, Beiersdorf UK Ltd); comparator, gauze</td>
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<tr>
<td>Study details</td>
<td>Source of data</td>
<td>Method for estimation of benefits/costs</td>
<td>Results/statistical analysis</td>
<td>Sensitivity analysis</td>
<td>Comments</td>
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<tr>
<td>Cannavo et al., 1998</td>
<td>Source of effectiveness data: data derived from a single RCT (n = 36) (see also appendix 5)</td>
<td>Valuation for clinical outcomes or benefits: interpreted by surgical team</td>
<td>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.</td>
<td>Sensitivity analysis: none reported</td>
<td>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.</td>
</tr>
<tr>
<td>Research question: to compare the performance of three dressing protocols in the management of dehisced surgical abdominal wounds</td>
<td>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).</td>
<td>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)</td>
<td>Costs:</td>
<td>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.</td>
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<tr>
<td>Type of economic evaluation: CEA (CCA)</td>
<td>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</td>
<td>Cost incurred per day during hospital stay (material cost plus nursing time)</td>
<td>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).</td>
<td>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.</td>
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<tr>
<td>Country/currency: Australia, Australian dollars, 1996</td>
<td>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</td>
<td>Indirect costs: no indirect costs were included</td>
<td>Modelling: not applicable.</td>
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<tr>
<td>Perspective: hospital</td>
<td>Study population: patients from a gastrointestinal surgical unit with surgical abdominal wound breakdown</td>
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<tr>
<td>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</td>
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<td></td>
<td>Cost was considered prospectively</td>
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<td></td>
<td>Valuation for clinical outcomes or benefits: interpreted by surgical team</td>
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<td>Estimation of costs:</td>
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<td></td>
<td>Cost incurred per day during hospital stay (material cost plus nursing time)</td>
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<td></td>
<td>Indirect costs: no indirect costs were included</td>
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<td></td>
<td>Modelling: not applicable</td>
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<td></td>
<td>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.</td>
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<td>Costs:</td>
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<td>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).</td>
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<td>Total cost per day (mean ± SD): Alginate dressing protocol: Australian $15.25 ± 1.26 Sodium hypochlorite protocol: Australian $14.14 ± 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)</td>
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<td></td>
<td>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</td>
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<td></td>
<td>Synthesis of costs and benefits: not applicable</td>
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<td></td>
<td>Statistical analysis: ANOVA was used to compare maximum cost variables for the three intervention groups</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study details</th>
<th>Source of data</th>
<th>Method for estimation of benefits/costs</th>
<th>Results/statistical analysis</th>
<th>Sensitivity analysis</th>
<th>Comments</th>
</tr>
</thead>
</table>

A form of sensitivity analysis was performed. Three estimates of cost were presented through-out: a low estimate, a medium estimate, and a high estimate. 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, £330.90. Total non-material cost per case for GD dressing group: low, £20.80; medium, £80.60; high, £330.90. GD cost per case: low, £32.78; medium, £196.98; high, £455.40. Other costs incurred after discharge (district nurse costs and outpatient clinic costs). Outpatient clinic costs included: not applicable. Synthesis of costs and benefits: none reported. Clinical outcomes/benefits: no statistical calculation was conducted to compare the costing of the two treatments. Modelling: not applicable.

**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 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 I). 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.

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**Table 13 cont** Details of the economic evaluations included in the review

<table>
<thead>
<tr>
<th>Study details</th>
<th>Source of data</th>
<th>Method for estimation of benefits/costs</th>
<th>Results/statistical analysis</th>
<th>Sensitivity analysis</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culyer and Wagstaff, 1984</td>
<td>Source of efficacy data: data were derived from a single RCT (n = 59) (see also appendix 5)</td>
<td>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.</td>
<td>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 &lt; 0.001).</td>
<td>A form of sensitivity analysis was performed. Three estimates of cost were presented through-out: a low estimate, a medium estimate, and a high estimate.</td>
<td>A high estimate and a low estimate.</td>
</tr>
<tr>
<td>Culyer et al., 1984</td>
<td>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 vashtage and handling. New elalstomer 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, doctor’s time (salaries based on average earnings), clerical staff (mid-point 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).</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study details</th>
<th>Source of data</th>
<th>Method for estimation of benefits/costs</th>
<th>Results/statistical analysis</th>
<th>Sensitivity analysis</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walker et al., 1991</td>
<td>Source of effectiveness data: data derived from a single RCT (n = 75) (see also appendix 5)</td>
<td>Valuation for clinical outcomes or benefits: interpreted by a surgical team and district nurse</td>
<td><strong>Clinical outcome/benefits:</strong> 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</td>
<td><strong>Sensitivity analysis:</strong> none reported</td>
<td><strong>Authors’ conclusions:</strong> by using Silastic foam, an average total saving of over £500 per patient can be made</td>
</tr>
<tr>
<td>Research question: to compare Eusol and Silastic foam dressing in the management of pilonidal sinus</td>
<td>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</td>
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<td><strong>Magnitude and direction of result:</strong> there was no significant difference between the interventions in terms of healing time, but the silastic foam dressing was found to be economically advantageous</td>
</tr>
<tr>
<td>Type of economic evaluation: CEA (CMA)</td>
<td>Cost was considered retrospectively</td>
<td></td>
<td></td>
<td></td>
<td><strong>Comments:</strong> 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</td>
</tr>
<tr>
<td>Country/currency: UK, pounds sterling, 1989–1990</td>
<td>Estimation of costs:</td>
<td></td>
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<td></td>
<td>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 (multivariable together with other variables)</td>
</tr>
<tr>
<td>Perspective: hospital and health service</td>
<td>Direct costs: Cost of hospital bed days Gross district nurse costs (including travelling) Dressing cost</td>
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<td>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 (multivariable together with other variables)</td>
</tr>
<tr>
<td>Study population: participants who had received surgery for either a pilonidal sinus or an abscess</td>
<td>Indirect costs: Lost productivity (not actually assessed but estimated)</td>
<td></td>
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<td></td>
<td>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 (multivariable together with other variables)</td>
</tr>
<tr>
<td>Interventions (including comparator): silicone foam elastomer dressing (Silastic, Dow-Corning); comparator included a half-strength Eusol soaked gauze dressing</td>
<td>Modelling: not applicable</td>
<td></td>
<td></td>
<td></td>
<td>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 (multivariable together with other variables)</td>
</tr>
<tr>
<td></td>
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<td><strong>Clinical outcome/benefits:</strong> 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</td>
<td></td>
<td></td>
<td><strong>Authors’ conclusions:</strong> by using Silastic foam, an average total saving of over £500 per patient can be made</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Magnitude and direction of result:</strong> there was no significant difference between the interventions in terms of healing time, but the silastic foam dressing was found to be economically advantageous</td>
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<tr>
<td></td>
<td></td>
<td><strong>Comments:</strong> 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</td>
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</table>

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
- 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. maggott* 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 (aquiform 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. ((hydrochloroion* or granuflex or (comfeel plus) or tegafob or hydrocoll or aquacel or comibiderm 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 or 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 season) 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 surafos 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 #39

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. (infec* 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 polynxylin
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. (aqualcel 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 abscess*) 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. (hydrocolloid* or granuflex or comfeel or tegasor 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 opsit flexigrid or tegaderm) in ti, ab
42. ((polyurethane foam) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
43. (alginate* or sorbana or tegatol or kaltostat or kaltogel or searosb or algisite or algosteril or megisorb or cutinova cavity) in ti, ab
44. (tulle gras or kelon or bactigras or chlorhexitule or sorotulle or (fuscidin 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 enzymatic) in ti, ab
47. (secondary dressing* or film or films or gauze or fibre or fiber or occlusive dressing*) in ti, ab
48. (aqualcel 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
Appendix 7

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. (dehiscenc* 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 stergel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nugel or (purilong 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 granulflex or comfeel or tegasorb or hydrocolloid* or aqualcal or comiderm or duoderm) in ti, ab
40. (hydrofibre or debrisan) in ti, ab
41. (bioclusive or cutifilm or epiview of mefilm or (opiste flexigrid) or tegaderm) in ti, ab
42. ((polyurethane foam) or alleyn or lyfoam or tielle or lyfofoam) in ti, ab
43. (alginate* or sorbans 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 syrosorb or flexipore or omiderm or surfasoft or tegapore) in ti, ab
46. (enzymes or enzymatic) in ti, ab
47. (secondary dressing* or film or films or gauze or fibre or fiber or occlusive dressing*) in ti, ab
48. (aqualcel or aloe vera or wound gel* or polynoxylan) 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 #65 or #64 or #65 or #66
68. #61 not #67
69. exact{ANIMAL} in TG
70. exact{HUMAN} in TG
1. #69 not (#69 and #70)
2. #68 not #71
3. mesalt
4. sodium chloride near dressing*
5. hypergel or normigel or mepilex or mepitel
6. silicone near dressing*
7. alldress or mepore or mesorb or (cellulose near dressing*)
8. #73 or #74 or #75 or #76 or #77
9. #18 and #78
10. #79 not #72
11. enzymatic
12. hypochlorite
13. solution
14. enzymatic or hypochlorite solution
15. #84 and #18
16. #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* (head or paste)) in ts, ab
35. dextranomer* or (xerogel* in ts, ab)
36. (cadoexomer iodine) in ts, ab
37. (iodoflex or iodosorb) in ts, ab
38. hydrogel* in ts, ab
39. ((intratise gel) or intratisegel or sterigel or granugel or (aquaform hydrogel) or (nu-gel) or (nu gel) or nigel 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 epview or mefilm or (opsite flexigrid) or tegaderm) in ts, ab
51. ((polyurethane foam dress*) or alleyn or lyfoam or tielle or lyfoam) in ts, ab
52. ((alginat* dress*) or sorbsan or tegagel or kaltostat or kaltogel or (comfeel seasonb) 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 tegapone) 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
Appendix 7

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 abscess*) 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 xeroglue or cadexomer iodine) in ti, ab
28. (iodoflex or iodosorb or hydrogel*) in ti, ab
29. ((intrasite gel) or intrasitegel or sterigel or (aquaform hydrogel) or (nu-gel) or (nu gel) 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. (biocclusive or cutifilm or epiview of mefilm or (opsite flexigrid) or tegaderm) in ti, ab
41. ((polypurathane foam) or allevyn or lyfoam or tielle or lyofoam) in ti, ab
42. (alginate* or sorbsan or tegadelt or kaltostat or kaltogel or seashorel or algisite or algosteril or megisorb or cutinova cavity) in ti, ab
43. (tulle gras or jelonet or bactigras or chlorhexitulite or serotulle or (fucidin intesttule) or (sofra tulle)) in ti, ab
44. (vapour permeable membrane* or spyrorsorb 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. (aquel 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. (dehiscence or sepsis or exudate or necrosis or slough) in ti, ab
12. (non-heal or non heal or nonheal or problem or difficult or complic) near (wound or cavitate 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 abscess) 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-surgery or biosurgery) 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. (polysaccharide 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 tegason 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 lyfoam) in ti, ab
42. (alginate or sorbsan or tegagel or kaltostat or kaltogel or searsorb or algisite or algosteril or megisorb or cutinova cavity) in ti, ab
43. (tulle gras or jelonet or bactigras or chlorhexitulle or serotulle or (fuscidin intertulle) or (sofra tulle)) in ti, ab
44. (vapour permeable membrane or spyrosoar or flexipore or omiderm or surfasoft or tegapore) in ti, ab
45. (enzymes or enzymatic) 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 polynoxyn) 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 #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 normgel 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 cavitate) in ti, ab
9. #7 and #8
10. #3 or #4 or #5 or #6 or #9
11. (dehiscence or sepsis or exudate or necrosis or slough) in ti, ab
12. (non-heal* or non heal* or nonheal* or problem or difficult* or complic*) near (wound* or cavity* 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 abscess*) 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 biosurg* 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 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. (hydrocolloid* 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. (alginate* or sorbsan or tegagel or kaltostat or kaltogel or searsorb or algisite or algosteril or mesgsorb or cutinova cavity) in ti, ab
41. (tulle gras or jelonet or bactigras or chlorhexitulle or serotulle or fucidin intertulle or sofra tulle) in ti, ab
42. (vapour permeable membrane* or spyrasorb or flexipore or omiderm or surfasoft or tegapore) in ti, ab
43. (enzymes or enzymatic) in ti, ab
44. (secondary dressing* or film or films or gauze or fibre or fiber or occlusive dressing*) in ti, ab
45. (aquecel or aloe vera or wound gel* or polynoxylin) in ti, ab
46. (melolin or emsol or silastic foam* or hydrofibre* or hydrofiber*) in ti, ab
47. (polyurethane or hydrocellular or foam elastomer or cellulose) in ti, ab
48. #18 or #19 or #20 or #21 or #22 or #23
49. #24 or #25 or #26 or #27 or #28 or #29
50. #30 or #31 or #32 or #33 or #34 or #35
51. #36 or #37 or #38 or #39 or #40 or #41
52. #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49
53. #50 or #51 or #52 or #53 or #54
54. #55 and #17
55. wound or wounds or cavity or cavities or abscess* or sinus or sinuses or incision or incisions
56. #56 and #57
57. sutur* near wound*
58. #58 and #57
59. explode “burn”/all subheadings
60. “burn-dressing”/all subheadings
61. “eye-disease”/all subheadings
62. explode “dentistry”/all subheadings
63. explode “dental-care”/all subheadings
64. “case-report”/ all subheadings
65. “case-study”/ all subheadings
66. “retrospective-study”/ all subheadings
67. #67 or #68 or #69
68. #66 not #70
69. #65 not #65
70. #72 or #73 or #74 or #75 or #76
71. #77 or #78 or #79
72. #78 not #71
73. mesalt
74. sodium chloride near dressing*
75. hypergel or nornigel or mepilex or mepitel
76. silicone near dressing*
77. alldress or mepore or mesorb or (cellulose near dressing*)
78. #77 or #78 or #79
79. #79 and #77
80. enzymatic
81. hypochlorite
82. solution
83. enzymatic or hypochlorite solution
84. #17 and #88
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. (infec* 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* (head* or paste)) in ti, ab
33. dextranomer in ti, ab
34. xerogel* in ti, ab
35. ((parafin gauze dress*) or (tulle gras) or gelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofra tulle)) in ti, ab
36. (pressur* wound* irrigation*) in ti, ab
37. hydrofibre dress* in ti, ab
38. (dakin* solution) in ti, ab
39. eusol near ((wound* or cavit*) in ti, ab)
40. (((malic acid) or (benzoic acid) or (salicylic acid) or (propylene glycol)) near (wound* or cavit*)) in ti, ab
41. (proteolytic* or fibrinolytic* or collagenase*) near ((wound* or cavit*) in ti, ab)
42. (hydrocholloid* or granulflex or (comfeel plus) or tegasorb or hydrocoll or aquacel or combiderm or duoderm) near (wound* or cavit*) in ti, ab
43. (polysaccharid* dress*) in ti, ab
44. hydrofibre dress* in ti, ab
45. debrisan in ti, ab
46. (biolusive or cutifilm or epiview or melfilm or (opsite flexgrid) or tegaderm) in ti, ab
47. ((polyurethane foam dress*) or allelyn or lyfoam or tielle or lyfoam) in ti, ab
48. (alginate* dress*) or sorbsan or tegagel or kaltostat or kaltogel or (comfeel searose) or algisite or algosteril or megisorb or (cutinova cavity) or (searose filler)) in ti, ab
49. (parafin gauze dress*) or (tulle gras) or gelonet or bactigras or chlorhexitulle or serotulle or (fucidin intertulle) or (sofratulle) in ti, ab
50. #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
51. #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. (infec* near surg* near (wound* or cavit*)) in ti, ab
15. dehiscence near ((wound* or cavity*) in ti, ab)
16. sepsis near ((wound* or cavity*) in ti, ab)
17. necrosis near ((wound* or surgery*) in ti, ab)
18. slough near ((wound* or cavity*) in ti, ab)
19. (((non-heal*) or (non heal*) or nonheal*) or problem* or difficult* or complic*) near (wound* or cavity*) 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. ((trypsin or collagenase or streptokinase or streptodornase) and (wound* or cavity*)) in ti, ab
27. (wet near dry near dress*) in ti, ab
28. (saline gauze*) in ti, ab
29. (xerogel*) in ti, ab
30. (polysaccharide* (bead* or paste)) in ti, ab
31. dextranomer in ti, ab
32. (iodoflex or iodosorb) in ti, ab
33. hydrogel* in ti, ab
34. (intrasite gel) or intrasitegel or sterigel or (aquaform hydrogel) or (nu-gel) or (second skin) in ti, ab
35. (parafin gauze dress*) or (tulle gras) or gelonet or bactigras or chlorhexidine or serotulle or (fucidin intertulle) or (sofra tulle) in ti, ab
36. (debrid* or (cavity* in ti, ab)
37. (pressur* wound* irrigation*) in ti, ab
38. hydrochlorite solution
39. (sodium hypochlorite) near ((wound* or cavity*) in ti, ab)
40. (dakin* solution) in ti, ab
41. (malic acid) or (benzoic acid) or (salicylic acid) or (propylene glycol) near (wound* or cavity*) in ti, ab
42. (chronic wound*) in ti, ab
43. (granulating wound*) in ti, ab
44. (pilonidal sinus* or pilonidal abscess*) in ti, ab
45. (debrid* or (cavity* in ti, ab)
46. (hydrocholloid* or granuflex or (comfeel plus) or tegasorb or hydrocoll or aquacel or combiderm or duoderm) near (wound* or cavity*) in ti, ab
47. (debrisan in ti, ab
48. hydrofibre dress* in ti, ab
49. (biohesive or cutifilm or epiview or mefilm or (opsite flexigrid) or tegaderm) in ti, ab
50. ((polyurethane foam dress*) or alleyvn or lyofoam or tielle or lyofoam) in ti, ab
51. (iodoflex or iodosorb or hydrogel*) in ti, ab
52. (alginate* dress*) or sorbsan or tegagel or kaltostat or kaltogel or (comfeel searorb) or algisite or algosteril or megosorb or (cutinova cavity) or (searorb filler)) in ti, ab
53. ((paraffin gauze dress*) or (tulle gras) or gelonet or bactigras or chlorhexidine 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 (cavity* in ti, ab)
9. #7 and #8
10. #3 or #4 or #5 or #6 or #9
11. (dehiscence* or sepsis or exudate* or necrosis* 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 cavity* 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 abscess*) 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-surge* or bio surg* or biosurge*) in ti, ab
25. (trypsin or collagenase or streptokinase or streptodornase) in ti, ab
26. (varidase near topical) in ti, ab
27. (wet to dry dress*) in ti, ab
28. (saline gauze*) in ti, ab
29. (dextranomer polysaccharide*) in ti, ab
30. (iodoflex or iodosorb) in ti, ab
31. (iodine gauze*) in ti, ab
32. (polysaccharide* (bead* or paste)) in ti, ab
33. dextranomer in ti, ab
34. xerogel* in ti, ab
35. (parafin gauze dress*) or (tulle gras) or gelonet or bactigras or chlorhexidine or serotulle or (fucidin intertulle) or (sofra tulle) in ti, ab
36. (alginate* dress*) or sorbsan or tegagel or kaltostat or kaltogel or (comfeel searorb) or algisite or algosteril or megosorb or (cutinova cavity) or (searorb filler)) in ti, ab
30. ((intrasite gel) or inrasitegel or sterigel or grannulgel or (aquaf orm 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 sear sor 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 spysorobs 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. (aquelar or aloe vera or wound gel* or polynoxylin) in ti, ab
49. (melin or emsol or silastic foam* or hydrofibre* or hydrofiber*) in ti, ab
50. (polyurethane or hydrocellular or foam elastomer or cellulos) 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
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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 negligent gel 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 chlorhexiltule or serotulle or (fucidin intertulle) or (sofre 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. (aqualcel or aloe vera or wound gel* or polyoxynil) in ti, ab
49. (melolin or emsol or silastic foam* or hydrofibra* 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. ((#6 or #7) or #8)
7. INFECTION*:ME
8. BACTERIAL-INFECTIONS:ME
9. #9 and #10
10. WOUND-DEHISCENCE:ME
11. WOUND-DEHISCENCE:ME
12. (INFECT* near SURG*) near WOUND*
13. (INFECT* near SURG*) near CAVIT*
14. (DEHISCEN* near WOUND*)
15. (DEHISCEN* near CAVIT*)
16. (SEPSIS near WOUND*)

**Second iteration**

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

**Third iteration**

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

**Fourth iteration**

1. SURGICAL-PROCEDURES-OPERATIVE*:ME
2. (SURGERY or SURGICAL)
3. (#1 or #2)
4. POSTOPERATIVE-COMPLICATIONS:ME
5. (WOUND* or CAVIT*)
6. ((#6 or #7) or #8)
7. INFECTION*:ME
8. BACTERIAL-INFECTIONS:ME
9. #9 and #10
10. WOUND-DEHISCENCE:ME
11. WOUND-DEHISCENCE:ME
12. (INFECT* near SURG*) near WOUND*
13. (INFECT* near SURG*) near CAVIT*
14. (DEHISCEN* near WOUND*)
15. (DEHISCEN* near CAVIT*)
16. (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 NON-HEAL*) 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 POLYSAACCHARID*)
40. (POLYSAACCHARIDE next BEAD*)
41. (POLYSAACCHARIDE next PASTE)
42. DEXTRANOMER*
43. XEROGEL*
44. (CADEXOMER next IODINE)
45. (IODOFLEX or IODOSORB)
46. HYDROGEL*
47. (((((TRYPsin or COLLAGENASE) or
    STREPTOKINASE) or STERIGEL) OR
    GRANUGEL) OR (AQUAFORM NEXT
    HYDROGEL) OR (PURILON NEXT GEL))
    OR (SECOND SKIN))
48. (PRESSUR* next (WOUND* next
    IRRIGATION*))
49. WOORLPOL
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
    OF "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. (((BIOCLIUSIVE 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 LYFOAM)
66. (((ALGINAT* next DRESS*) or
    SORBASAN) 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
    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
    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)
Appendix 7

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) or 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 (BENOZIC 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. (((comiderm 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. (((alteyn or lyfoam) or tielle) or lyfoam)
36. (((alginate* or sorbsan) or tegagel) or kaltostat)
37. (((kaltogel or searso) or algisite) or algosteril)
38. (((megisorb or cutinova) or tulle) or jelonet)
39. (((bactigras or chlorhexitulule) or sorotulle) or intertulle)
40. (((sofra or spyrosorb) or flexipore) or omiderm)
41. (vapour next permeable next membrane*)
42. (((surfosoft 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. (((aquelcol 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 sinuses) or incision) or incisions)
49. ((((((((((((wound or #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 NORMGEL) or MEPILEX)
- ((SILCONE near DRESSING*)
- (((MEPITEL or ALLDRESS) or MEPOR) 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 cavity*)) 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 cavity*)) in ti, ab
33. ((facilit* or location or outpatient* or inpatient* or rehabilitation or acute) near (wound* or cavity*)) in ti, ab
34. ((management or treatment* or program* or service* or delivery or care) near (wound* or cavity*)) in ti, ab
35. #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33
36. #23 and #34
37. explode “health-care-quality”/ all subheadings
38. explode “evaluation-and-follow-up”/ all subheadings
39. explode “comparative-study”/ all subheadings
40. explode “controlled-study”/ all subheadings
41. explode “methodology”/ all subheadings
42. “theoretical-study”/ all subheadings
43. (trial* or stud* or evaluat* or examin*) in ti, ab
44. #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43
45. #35 and #44

**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 cavity*)) in ti, ab
30. ((nurse or nurses or doctor* or physician or gp or practitioner or (health visit*) or staff or personnel) near (wound* or cavity*)) 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 cavity*)) in ts, ab
32. ((facilit* or location or outpatient* or inpatient* or rehabilitation or acute) near (wound* or cavity*)) in ts, ab
33. (management or treatment* or program* or service* or delivery or care) near (wound* or cavity*)) 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 cavity*)) 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 cavity*)) in ti, ab
Appendix 7

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 #25
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 next HEAL*)) or nonheal* or difficult* or problem* or complic*) and (wound* or cavit*)) in ti, ab, de
12. (infec* 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 pharmacoeconomic* 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

<table>
<thead>
<tr>
<th>Conference</th>
<th>Inside Conferences database</th>
<th>Index to Conference Proceedings</th>
<th>Web page</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Conference of Phlebology</td>
<td>No references</td>
<td>No references</td>
<td>No details of past conferences on that web site or on that of the International Union (parent organisation)</td>
</tr>
<tr>
<td>European Venous Forum</td>
<td>No references</td>
<td>No references</td>
<td><a href="http://www.esvs.org/esvs/evf2000.html">http://www.esvs.org/esvs/evf2000.html</a></td>
</tr>
<tr>
<td>European Wound Management Conferences</td>
<td>References identified and downloaded</td>
<td>References identified and downloaded</td>
<td>EWMA web site: <a href="http://www.leahcim.demon.co.uk/ewma.htm">http://www.leahcim.demon.co.uk/ewma.htm</a>. However, no conference listings</td>
</tr>
<tr>
<td>European Tissue Repair Society</td>
<td>References identified and downloaded</td>
<td>No references</td>
<td><a href="http://www.leahcim.demon.co.uk/etrs.htm">http://www.leahcim.demon.co.uk/etrs.htm</a></td>
</tr>
<tr>
<td>European Advisory Panel on Pressure Ulceration</td>
<td>No references</td>
<td>No references</td>
<td>1996–1997 meeting abstracts on web site, but not updated since</td>
</tr>
<tr>
<td>Tissue Viability Conference</td>
<td>References identified and downloaded</td>
<td>No references</td>
<td>Tissue Viability Society: <a href="http://www.tvs.org.uk/">http://www.tvs.org.uk/</a></td>
</tr>
<tr>
<td>Wound Care Society Conferences</td>
<td>No references</td>
<td>No references</td>
<td>WCS home page: <a href="http://www.leahcim.demon.co.uk/wcs/wcs_hp.htm">http://www.leahcim.demon.co.uk/wcs/wcs_hp.htm</a> (old); <a href="http://www.woundcaresociety.org/">http://www.woundcaresociety.org/</a> (new)</td>
</tr>
<tr>
<td>Symposium on advanced wound care and medical research forum on wound care</td>
<td>References identified and downloaded</td>
<td>No references</td>
<td>15th conference: <a href="http://www.woundcarenet.com/wcsymp00/program.htm">http://www.woundcarenet.com/wcsymp00/program.htm</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1997 symposium: <a href="http://www.medexpo.com/Pages/schedule.html">http://www.medexpo.com/Pages/schedule.html</a>. conf15</td>
</tr>
<tr>
<td>American Wound Healing Society</td>
<td>No references</td>
<td>No references</td>
<td><a href="http://www.leahcim.demon.co.uk/whs-usa/whs.htm">http://www.leahcim.demon.co.uk/whs-usa/whs.htm</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No abstracts</td>
</tr>
<tr>
<td>Canadian Association of Wound Care</td>
<td>No references</td>
<td>No references</td>
<td>No home page identified</td>
</tr>
</tbody>
</table>
Appendix 8

Manufacturer and sponsor submissions made to NICE
### TABLE 15 Manufacturer and sponsor submissions made to NICE

<table>
<thead>
<tr>
<th>Company</th>
<th>Information provided</th>
<th>Clinical data</th>
<th>Cost data</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beiersdorf UK Ltd</td>
<td>Product description</td>
<td>RCT (n = 1): Cutinova vs moist gauze, treatment of ulcers</td>
<td>Cost per dressing data reported</td>
<td>Cost-minimisation study of Cutinova in difficult to heal surgical wounds</td>
</tr>
<tr>
<td>(Medical Division)</td>
<td></td>
<td>Controlled study (n = 1): Cutinova hydro and Allevyn™ in diabetic foot ulcers</td>
<td>Cost-effectiveness study (n = 2), based on a case report of cavity wounds</td>
<td>Included: cost-minimisation study, RCT</td>
</tr>
<tr>
<td><strong>Products:</strong></td>
<td></td>
<td>Clinical evaluation (n = 1): Cutinova cavity in secondary healing deep wounds, not clear if controlled</td>
<td>Meyer, based on cavity wound in 43 patients</td>
<td>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</td>
</tr>
<tr>
<td>Cutinova™ (foam, hydro, cavity and thin), polyurethane hydroactive dressings</td>
<td></td>
<td>Clinical article (n = 1): insufficient details</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Uncontrolled study (n = 1): Cutinova cavity in heavily exuding wounds</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Case studies and series (n = 4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>In vitro (n = 5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biosurgical Research Unit</td>
<td>Wound details</td>
<td>RCT (n = 1): looked at venous leg ulcers, no measure of healing</td>
<td>Some cost data provided (the RCT looking at venous leg ulcers also included cost data)</td>
<td>Excluded: all other studies due to inappropriate wound type or study design</td>
</tr>
<tr>
<td><strong>Products:</strong></td>
<td>Debridement</td>
<td>Controlled studies (n = 2): looked pressure sores and ischaemic ulcers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LarvE™ (sterile larvae of Lucilia sericata)</td>
<td>Product information</td>
<td>Published case histories (n = 16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>General papers</td>
<td>Unpublished case studies (n = 6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coloplast</td>
<td>Wound healing and management</td>
<td>RCTs (n = 5): Purilon vs control in pressure sores (n = 1), Comfeel vs Varishe™ or Granuflex™ in leg ulcers (n = 2), SeaSorb vs Kaltostat™ in leg ulcers (n = 1) and Biatain vs Allevyn in leg ulcers (n = 1)</td>
<td>Cost-effectiveness analysis presented, used data from trials of chronic wounds</td>
<td>Excluded: all other studies due to inappropriate wound type or study design, Cost-effectiveness analysis excluded because data relate to chronic wounds</td>
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<tr>
<td><strong>Products:</strong></td>
<td>Product details</td>
<td>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)</td>
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<tr>
<td>Purilon gel™ (alginate)</td>
<td>Wider implications</td>
<td>In vitro (n = 2)</td>
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<tr>
<td>Comfeel Plus™ (hydrocolloid)</td>
<td></td>
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<td>SeaSorb™ (flat alginate dressing)</td>
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<td>Biatain™ (flat foam dressing)</td>
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*continued*
### TABLE 15 contd  Manufacturer and sponsor submissions made to NICE

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<tr>
<th>Company</th>
<th>Information provided</th>
<th>Clinical data</th>
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<th>Action</th>
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<tbody>
<tr>
<td>ConvaTec</td>
<td>Wider NHS implications</td>
<td>Refers to HTA report for clinical effectiveness data</td>
<td>Refers to HTA report, no additional data</td>
<td>Included: economic evaluation</td>
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<tr>
<td>(Commercial in confidence data, omitted)</td>
<td>Description of products</td>
<td>RCT (n = 1); compared NU-GEL to Intrasite™ in pressure sores</td>
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<tr>
<td></td>
<td></td>
<td>Case study (n = 2)</td>
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<tr>
<td>Johnson and Johnson Medical</td>
<td>Debridement</td>
<td>Refers to HTA report for clinical effectiveness data</td>
<td>Refers to HTA report, no additional data</td>
<td>Excluded: inappropriate wound types and study designs</td>
</tr>
<tr>
<td>Products:</td>
<td>Product description</td>
<td>RCT (n = 1): compared NU-GEL to Intrasite™</td>
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<tr>
<td>NU-GEL™ (hydrogel with alginate)</td>
<td></td>
<td>Delayed wound closure</td>
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<tr>
<td>Actisorb-Plus™</td>
<td></td>
<td>RCT (n = 1): compared NU-GEL to Intrasite™</td>
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<tr>
<td>Kinetic Concepts Inc.</td>
<td>Description</td>
<td>RCTs (n = 2): VAC vs wet-to-dry in mainly chronic wounds</td>
<td>Cost-effectiveness studies reported, mainly on chronic wounds (n = 3)</td>
<td>Excluded: VAC was not considered as a debriding agent. Most studies included inappropriate wound types or study design</td>
</tr>
<tr>
<td>Products:</td>
<td>Mechanism of action</td>
<td>Controlled trials (n = 3): VAC vs surgical intervention (post-sternotomy mediastinitis) (n = 1) or gauze (in chronic wounds) (n = 2)</td>
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<tr>
<td>Vacuum Assisted Closure therapy (VAC™)</td>
<td>Indications, contraindications and precautions</td>
<td>Uncontrolled studies (n = 3): VAC in skin graft donor sites (n = 2), wounds not stated (n = 1)</td>
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<td>Case studies and series (n = 7)</td>
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<tr>
<td>Les Laboratoires Brothier</td>
<td>Debridement</td>
<td>RCT (n = 1): Algosteril vs povidone iodine for infected pilonidal abscesses</td>
<td>Cost-minimisation analysis: used data from decubitus ulcers</td>
<td>Included: controlled trial on alginate for abscess cavities and RCT of Algosteril (calcium alginate) vs povidone iodine for infected pilonidal abscesses</td>
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<tr>
<td>Products:</td>
<td>Dressing description</td>
<td>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)</td>
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<tr>
<td>Algosteril™ (alginate dressing)</td>
<td>Wider NHS implications</td>
<td>In vitro studies (n = 2)</td>
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<td></td>
<td>Case studies and series (n = 1)</td>
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<tr>
<td>Maersk Medical</td>
<td>Product description and use</td>
<td>RCT (n = 1): Aquaf orm vs Intrasite, mixed wounds, all chronic, no objective measures of healing</td>
<td>Some cost information, but no analysis</td>
<td>Excluded: inappropriate wound types or study designs</td>
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<td>Products:</td>
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<td>Case studies and series (n = 3)</td>
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<td>Aquaform™</td>
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<td>In vitro (n = 2)</td>
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continued
### TABLE 15 contd Manufacturer and sponsor submissions made to NICE

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<th>Company</th>
<th>Information provided</th>
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<th>Cost data</th>
<th>Action</th>
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<tbody>
<tr>
<td>Mölnlycke Healthcare</td>
<td></td>
<td>RCT (&lt;i&gt;n&lt;/i&gt; = 1): Hypergel vs enzymatic debridement in dermal ulcers</td>
<td>Cost analysis looking at pressure sores</td>
<td>Excluded: inappropriate wound types and study designs. Cost analysis excluded because it looked at pressure sores</td>
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<tr>
<td><strong>Products:</strong> Mesalt™ (high sodium chloride non-woven dressing)</td>
<td>Dressing details</td>
<td>Controlled trials (&lt;i&gt;n&lt;/i&gt; = 3): old vs new Mesalt in dermal wounds (&lt;i&gt;n&lt;/i&gt; = 1), Mesalt vs saline in pressure ulcers (&lt;i&gt;n&lt;/i&gt; = 1) and Mesalt vs benzoyl peroxide gel in ulcers</td>
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<tr>
<td>Hypergel™ (high sodium chloride hypergel)</td>
<td>Wound healing</td>
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<tr>
<td>Normigel™ (normal sodium chloride hypergel)</td>
<td>Debridement</td>
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<tr>
<td>Mepilex™ (soft silicone dressing with foam backing)</td>
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<tr>
<td>Mepitel™ (soft silicone wound dressing)</td>
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<tr>
<td>Megil™ (vapour-permeable dressing)</td>
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<td>Melgisorb™ (alginate dressing)</td>
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<tr>
<td>Smith and Nephew</td>
<td></td>
<td>Most references come from HTA reports, other studies:</td>
<td>Iodosorb/Iodoflex, effectiveness data for chronic wounds</td>
<td>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</td>
</tr>
<tr>
<td><strong>Products:</strong> Cadexomer iodine in the form of Iodoflex™ Iodoflex™ Iodosorb™ powder and ointment</td>
<td>Surgical practice</td>
<td>RCTs (&lt;i&gt;n&lt;/i&gt; = 5): Intrasite vs Debrisan for pressure sores (&lt;i&gt;n&lt;/i&gt; = 2) and cadexomer iodine vs standard treatment for venous leg ulcers (&lt;i&gt;n&lt;/i&gt; = 2)</td>
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<tr>
<td>Intrasite™ gel (hydrogel)</td>
<td>Wound healing</td>
<td>Case studies and series (&lt;i&gt;n&lt;/i&gt; = 6)</td>
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<td>Sterigel™</td>
<td>Debridement</td>
<td>No additional data, present their own review of the literature</td>
<td>Excluded: inappropriate wound types and study designs</td>
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<tr>
<td>SSL International plc</td>
<td>Management</td>
<td>RCTs (&lt;i&gt;n&lt;/i&gt; = 2): Sterigel vs gauze in treatment of leg ulcers (&lt;i&gt;n&lt;/i&gt; = 1) and Sterigel vs Intrasite in pressure sores (&lt;i&gt;n&lt;/i&gt; = 1)</td>
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<td>In vitro (&lt;i&gt;n&lt;/i&gt; = 1): tests of Sterigel</td>
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<tr>
<td>Company</td>
<td>Information provided</td>
<td>Clinical data</td>
<td>Cost data</td>
<td>Action</td>
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<tr>
<td>TG Eakin Ltd</td>
<td>Eakin cohesive</td>
<td>Controlled trial (n = 1): Eakin cohesive vs other pastes, all surgical wounds, used paste then Eakin, no measure of healing</td>
<td>Present data on cost of dressings. Some cost information provided, but no direct analysis</td>
<td>Excluded: inappropriate study designs or no measure of healing provided, fistula and wound pouches not considered to be debriding agents</td>
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<tr>
<td><strong>Products:</strong> Eakin™ (fistula and wound pouches)</td>
<td>Rationale for inclusion</td>
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<td></td>
<td>Wider implications</td>
<td>Case studies (n = 8)</td>
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<tr>
<td>Tyco Healthcare (UK) Ltd</td>
<td>Debridement</td>
<td>Uncontrolled study (n = 1): Aquaflo in chronic and acute wounds</td>
<td>None reported</td>
<td>Excluded: studies with inappropriate designs</td>
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<tr>
<td><strong>Products:</strong> Utec®Pro™ (alginate hydrocolloid)</td>
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<tr>
<td>Curafl™ gel™</td>
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<tr>
<td>Aquaflo™ (hydrogel)</td>
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# Health Technology Assessment Programme

## Prioritisation Strategy Group

<table>
<thead>
<tr>
<th>Members</th>
<th>Members</th>
</tr>
</thead>
</table>
| **Chair** | **Professor Shah Ebrahim**  
Professor of Epidemiology of Ageing  
University of Bristol  
| **Dr Ron Zimmer**  
Director, Public Health Genetics Unit  
Strangeways Research Laboratories, Cambridge |
| **Professor Bruce Campbell**  
Consultant General Surgeon  
Royal Devon & Exeter Hospital  
| **Dr John Reynolds**  
Clinical Director  
Acute General Medicine SDU  
Oxford Radcliffe Hospital |

## HTA Commissioning Board

<table>
<thead>
<tr>
<th>Members</th>
<th>Members</th>
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</thead>
</table>
| **Programme Director** | **Ms Christine Clark**  
Freelance Medical Writer  
Bury, Lancs  
| **Professor Jenny Hewison**  
Senior Lecturer  
School of Psychology  
University of Leeds |
| **Professor Kent Woods**  
Director, NHS HTA Programme, &  
Professor of Therapeutics  
University of Leicester  
| **Professor Martin Eccles**  
Professor of Clinical Effectiveness  
University of Newcastle-upon-Tyne  
| **Professor Alison Kitson**  
Director, Royal College of Nursing Institute, London |
| **Dr Andrew Farmer**  
General Practitioner & NHS R&D Clinical Scientist  
Institute of Health Sciences  
University of Oxford  
| **Dr Donna Lamping**  
Head, Health Services Research Unit  
London School of Hygiene & Tropical Medicine  
| **Professor David Neal**  
Professor of Surgery  
University of Newcastle-upon-Tyne  
| **Professor Gillian Parker**  
Nuffield Professor of Community Care  
University of Leicester |
| **Professor Jon Nicholl**  
Director, Medical Care Research Unit  
University of Sheffield  
| **Professor Adrian Grant**  
Director, Health Services Research Unit  
University of Aberdeen  
| **Dr Tim Peters**  
Reader in Medical Statistics  
University of Bristol  
| **Dr Sarah Stewart-Brown**  
Director, Health Services Research Unit  
University of Oxford |
| **Professor Douglas Altman**  
Director, ICRF Medical Statistics Group  
University of Oxford  
| **Professor Martin Eccles**  
Professor of Clinical Effectiveness  
University of Newcastle-upon-Tyne  
| **Professor Gillian Parker**  
Nuffield Professor of Community Care  
University of Leicester  
| **Professor Ala Szczenura**  
Director, Centre for Health Services Studies  
University of Warwick |
| **Professor John Bond**  
Director, Centre for Health Services Research  
University of Newcastle-upon-Tyne  
| **Dr Alastair Gray**  
Director, Health Economics Research Centre  
Institute of Health Sciences  
University of Oxford  
| **Professor Gillian Parker**  
Nuffield Professor of Community Care  
University of Leicester  
| **Dr Gillian Vivian**  
Consultant in Nuclear Medicine & Radiology  
Royal Cornwall Hospitals Trust Truro |
| **Dr Jeremy Wyatt**  
Senior Fellow Health Knowledge Management Centre  
University College London  
| **Professor Graham Watt**  
Department of General Practice  
University of Glasgow |

Current and past membership details of all HTA ‘committees’ are available from the HTA website (see inside front cover for details)
### Diagnostic Technologies & Screening Panel

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<tr>
<td><strong>Chair</strong></td>
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<tr>
<td>Dr Ron Zimmern</td>
</tr>
<tr>
<td>Director, Public Health Genetics Unit Strangeways Research Laboratories Cambridge</td>
</tr>
<tr>
<td>Dr Philip J Ayres</td>
</tr>
<tr>
<td>Consultant in Epidemiology &amp; Public Health The Leeds Teaching Hospitals NHS Trust</td>
</tr>
<tr>
<td>Mrs Stella Burnside</td>
</tr>
<tr>
<td>Chief Executive, Altnagelvin Hospitals Health &amp; Social Services Trust Londonderry Northern Ireland</td>
</tr>
<tr>
<td>Dr Paul O Collinson</td>
</tr>
<tr>
<td>Consultant Chemical Pathologist &amp; Senior Lecturer St George’s Hospital, London</td>
</tr>
<tr>
<td>Dr Barry Cookson</td>
</tr>
<tr>
<td>Director, Laboratory of Hospital Infection Public Health Laboratory Service, London</td>
</tr>
<tr>
<td>Professor Howard Cuckle</td>
</tr>
<tr>
<td>Professor of Reproductive Epidemiology University of Leeds</td>
</tr>
<tr>
<td>Dr Carol Dezateux</td>
</tr>
<tr>
<td>Senior Lecturer in Paediatric Epidemiology Institute of Child Health London</td>
</tr>
<tr>
<td>Professor Adrian K Dixon</td>
</tr>
<tr>
<td>Aldenbrooke’s Hospital Cambridge</td>
</tr>
<tr>
<td>Mrs Steve Ebdon-Jackson</td>
</tr>
<tr>
<td>Head, Diagnostic Imaging &amp; Radiation Protection Team Department of Health, London</td>
</tr>
<tr>
<td>Dr Tom Fahey</td>
</tr>
<tr>
<td>Senior Lecturer in General Practice University of Bristol</td>
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<tr>
<td>Dr Andrew Farmer</td>
</tr>
<tr>
<td>General Practitioner &amp; NHS Clinical Scientist Institute of Health Sciences University of Oxford</td>
</tr>
<tr>
<td>Mrs Gillian Fletcher</td>
</tr>
<tr>
<td>Antenatal Teacher &amp; Tutor National Childbirth Trust Reigate</td>
</tr>
<tr>
<td>Dr JA Muir Gray</td>
</tr>
<tr>
<td>Joint Director, National Screening Committee NHS Executive, Oxford</td>
</tr>
<tr>
<td>Dr Peter Howlett</td>
</tr>
<tr>
<td>Executive Director – Development Portsmouth Hospitals NHS Trust</td>
</tr>
<tr>
<td>Professor Alistair McGuire</td>
</tr>
<tr>
<td>Professor of Health Economics City University, London</td>
</tr>
<tr>
<td>Mrs Kathleen Slack</td>
</tr>
<tr>
<td>Professional Support Diagnostic Imaging &amp; Radiation Protection Team Department of Health London</td>
</tr>
<tr>
<td>Mr Tony Tester</td>
</tr>
<tr>
<td>Chief Officer, South Bedfordshire Community Health Council Luton</td>
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### Pharmaceuticals Panel

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<tr>
<td><strong>Chair</strong></td>
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<td>Dr John Reynolds</td>
</tr>
<tr>
<td>Clinical Director – Acute General Medicine SDU Oxford Radcliffe Hospital</td>
</tr>
<tr>
<td>Dr Felicity J Gabbay</td>
</tr>
<tr>
<td>Managing Director, Transcrip Ltd Milford-on-Sea, Hants</td>
</tr>
<tr>
<td>Mr Peter Golightly</td>
</tr>
<tr>
<td>Director, Trent Drug Information Services Leicester Royal Infirmary</td>
</tr>
<tr>
<td>Dr Alastair Gray</td>
</tr>
<tr>
<td>Director, Health Economics Research Centre Institute of Health Sciences University of Oxford</td>
</tr>
<tr>
<td>Mrs Jeannette Howe</td>
</tr>
<tr>
<td>Senior Principal Pharmacist Department of Health, London</td>
</tr>
<tr>
<td>Dr Andrew Mortimore</td>
</tr>
<tr>
<td>Consultant in Public Health Medicine Southampton &amp; South West Hants Health Authority</td>
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<tr>
<td>Prof Robert Peveler</td>
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<tr>
<td>Professor of Liaison Psychiatry Royal South Hants Hospital Southampton</td>
</tr>
<tr>
<td>Dr Ross Taylor</td>
</tr>
<tr>
<td>Senior Lecturer Department of General Practice &amp; Primary Care University of Aberdeen</td>
</tr>
<tr>
<td>Dr Frances Rothlat</td>
</tr>
<tr>
<td>Manager, Biotechnology Group Medicines Control Agency London</td>
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<tr>
<td>Mr Bill Sang</td>
</tr>
<tr>
<td>Chief Executive Salford Royal Hospitals NHS Trust</td>
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<tr>
<td>Dr Eamonn Sheridan</td>
</tr>
<tr>
<td>Consultant in Clinical Genetics St James’s University Hospital Leeds</td>
</tr>
<tr>
<td>Mrs Katrina Simister</td>
</tr>
<tr>
<td>New Products Manager National Prescribing Centre Liverpool</td>
</tr>
<tr>
<td>Dr Richard Tiner</td>
</tr>
<tr>
<td>Medical Director Association of the British Pharmaceutical Industry London</td>
</tr>
<tr>
<td>Professor Jennifer Wilson-Barnett</td>
</tr>
<tr>
<td>Head, Florence Nightingale Division of Nursing &amp; Midwifery King’s College, London</td>
</tr>
<tr>
<td>Mr David J Wright</td>
</tr>
<tr>
<td>Chief Executive International Glaucoma Association, London</td>
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Current and past membership details of all HTA ‘committees’ are available from the HTA website (see inside front cover for details)
# Therapeutic Procedures Panel

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<tbody>
<tr>
<td><strong>Chair</strong></td>
<td><strong>Professor Bruce Campbell</strong></td>
</tr>
<tr>
<td>Consultant General Surgeon</td>
<td>Royal Devon &amp; Exeter Hospital</td>
</tr>
<tr>
<td><strong>Professor John Bond</strong></td>
<td>Professor of Health Services Research</td>
</tr>
<tr>
<td>University of Newcastle-upon-Tyne</td>
<td></td>
</tr>
<tr>
<td><strong>Ms Judith Brodie</strong></td>
<td>Head of Cancer Support Service</td>
</tr>
<tr>
<td>Cancer BACUP, London</td>
<td></td>
</tr>
<tr>
<td><strong>Ms Tracy Bury</strong></td>
<td>Head of Research &amp; Development</td>
</tr>
<tr>
<td>Chartered Society of Physiotherapy, London</td>
<td></td>
</tr>
<tr>
<td><strong>Mr Michael Clancy</strong></td>
<td>Consultant in A&amp;E Medicine</td>
</tr>
<tr>
<td>Southampton General Hospital</td>
<td></td>
</tr>
<tr>
<td><strong>Professor Collette Clifford</strong></td>
<td>Professor of Nursing</td>
</tr>
<tr>
<td>University of Birmingham</td>
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</tr>
<tr>
<td>Dr Katherine Darton</td>
<td>Information Unit</td>
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<tr>
<td>MIND – The Mental Health Charity, London</td>
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<tr>
<td><strong>Mr John Dunning</strong></td>
<td>Consultant Cardiothoracic Surgeon</td>
</tr>
<tr>
<td>Papworth Hospital NHS Trust</td>
<td>Cambridge</td>
</tr>
<tr>
<td><strong>Mr Jonathan Earnshaw</strong></td>
<td>Consultant Vascular Surgeon</td>
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<tr>
<td>Gloucestershire Royal Hospital</td>
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<tr>
<td><strong>Professor David Field</strong></td>
<td>Professor of Neonatal Medicine</td>
</tr>
<tr>
<td>The Leicester Royal Infirmary</td>
<td>NHS Trust</td>
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<tr>
<td><strong>Professor FD Richard Hobbs</strong></td>
<td>Professor of Primary Care &amp; General Practice</td>
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<tr>
<td>University of Birmingham</td>
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<tr>
<td><strong>Mr Richard Johanson</strong></td>
<td>Consultant &amp; Senior Lecturer</td>
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<tr>
<td>North Staffordshire Infirmary</td>
<td>NHS Trust, Stoke-on-Trent</td>
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<tr>
<td><strong>Dr Duncan Keeley</strong></td>
<td>General Practitioner</td>
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<td>Thame, Oxon</td>
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<tr>
<td><strong>Dr Phillip Leech</strong></td>
<td>Principal Medical Officer</td>
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<tr>
<td>Department of Health, London</td>
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<tr>
<td><strong>Professor James Lindesay</strong></td>
<td>Professor of Psychiatry for the Elderly</td>
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<tr>
<td>University of Leicester</td>
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<tr>
<td><strong>Professor Rajan Madhok</strong></td>
<td>Director of Health Policy &amp; Public Health</td>
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<tr>
<td>East Riding &amp; Hull</td>
<td>Health Authority</td>
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<tr>
<td><strong>Dr Mike McGovern</strong></td>
<td>Branch Head</td>
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<tr>
<td>Department of Health</td>
<td>London</td>
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<tr>
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# Expert Advisory Network

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Current and past membership details of all HTA ‘committees’ are available from the HTA website (see inside front cover for details)
Feedback

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

The Correspondence Page on the HTA website (http://www.ncchta.org) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.