



**Considering the evidence: What counts as the
best evidence for the Post Harvest
Management of Split Thickness Skin Graft
Donor Sites?**

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Abstract

This program of research comprises two studies conducted as the research component of the Doctor of Nursing degree. The first study involved the systematic review of evidence in relation to the post harvest management of split thickness skin graft (STSG) donor sites. This review was in relation to evidence of clinical effectiveness. The results of the review indicate that traditional paraffin gauze dressings, still in use in some practice settings, should be abandoned in favour of moist wound healing dressing products. The review failed to demonstrate a significant difference in the effectiveness of specific moist wound products. The second study in the series examined the cost effectiveness of a range of alternative dressing products and strategies. The results indicate that potential savings could be made by avoiding the routine removal of dressings for inspection early in the healing process without any clinical indication to do so. The clinical effectiveness of this strategy has yet to be rigorously tested in comparative clinical trials.

In addition to the results of the individual projects a range of issues in relation to emerging trends in evidence based practice were explored.

Statement

This work contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text.

I give consent to this copy of my thesis, when deposited in the University Library, being available for loan and photocopying.

Signature of Candidate

... Date

21/04

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Part 1: Portfolio Overview

Chapter 1. Portfolio Introduction

The report that is presented here completes the requirements for the award of Doctor of Nursing. The award comprised course work and research. This report in the form of a portfolio documents the research activities conducted by the candidate.

Portfolio aim

The fundamental aim of the Doctor of Nursing program is to provide nurses with the opportunity to develop skills that will enhance their role as leaders in the practice of nursing. These skills include, knowledge translation through the conduct of systematic review, knowledge generation through the conduct of primary research and knowledge dissemination through publication and presentation of the research in a variety of forums.

Portfolio theme

The program of research focussed on a specific area of clinical nursing. The candidate has spent a good deal of his practice working in the area of wound management. Although a multi-disciplinary field, nurses have considerable responsibilities in this area of health care. The intervention at the core of this program of research is the post harvest management of STSG donor sites. The topic was chosen primarily as it is an area that has considerable practice variability. The program commenced with a systematic review of the literature followed by an economic evaluation.

Portfolio structure

Unlike a doctoral thesis arising from a single study the portfolio report comprises the results of multiple studies. It is however more than a presentation of the individual studies. The studies conducted are part of a cohesive program of research around a specific theme. The studies are linked both in terms of the area of clinical practice in which the studies were conducted but also because of the complementary nature of the studies outcomes. This presents a challenge in terms of reporting the overall program and the individual studies within it. The approach taken has been to treat the portfolio as the report for the overall program of research. The individual studies therefore have been presented here as the results of the program. The studies themselves are presented intact as two results chapters, each with its background, methodology, study description, results and conclusions. Part of the reason for this is

that although the two studies are complementary they are quite different in terms of the style in which they are conventionally reported. Also the studies were conducted consecutively. The first, a systematic review has been published both as a review report (Wiechula, 2001) and abstracted in various forms in diverse publications (Joanna Briggs Institute, 2002; Joanna Briggs Institute, 2004a; Wiechula, 2003; World of Irish Nursing, 2003). It is presented here as it was first published with the content intact although some minor formatting has been necessary for incorporation into the portfolio. The second study is an economic evaluation and is presented in a conventional style. Presenting the studies in this way allows the reader to view each discreetly and to judge the studies on their own merits. However because the studies are so closely related this does result in some repetition particularly in relation to the clinical background to the studies. The overall results of the program integrating the two studies are presented in the discussion chapter. Finally the dissemination of the results of the studies by way of publications and presentations are detailed in the appendices.

Chapter 2. Portfolio Background

In planning this program of research the decisions made about the conduct of the program were subject to a variety of influences. Exploring these influences provides an opportunity to demonstrate both the motivation and justification for conducting the research. Some of these influences relate directly to the professional experience of the candidate such as previous clinical experience and current professional activities. Other influences relate to what was and is occurring in health care in a more general sense, particularly in relation to the evidence based practice movement.

Firstly, the clinical focus of the program, was naturally drawn from the candidate's previous clinical and professional experience. The candidate has worked for many years as a plastic surgical nurse caring for those with wounds. Not only has the candidate held senior clinical positions, but this interest in wound management has also led to participation in many representative bodies such as the Australian Wound Management Association. It is logical therefore that the theme for the program of research would be drawn from the area of wound management. In focussing the portfolio theme more specifically toward STSG donor site management the candidate has drawn not only on his professional experience but also on the extant literature that demonstrates this is an area of practice that despite considerable high quality research remains characterised by considerable practice variability. The moist wound healing approach has increased in popularity over the last three or more decades. The seminal work of Winter (1962) was the touchstone that demonstrated the potential of moist wound healing. Since then its adoption has been strongly advocated. The advantages of dressings using this approach are well documented. They prevent desiccation and the deepening of wounds, reduce the risk of mechanical damage of healing tissue at removal and provide an environment that results in more rapid healing (Hermans, 1995). Considering the advantages of using this approach it is surprising that there is still some hesitancy in adopting this approach to wound management (MacLellan, 1993). Also surprising is that in managing STSG donor sites, non-moist wound healing methods are still advocated as an alternative (Ablove & Howell, 1997; Fowler & Dempsey, 1998; McCain & Sutherland, 1998). The justification for focusing on this area of practice was deemed obvious and logical.

At the time of the commencement of the Doctor of Nursing program the candidate was (and still is) working with the Joanna Briggs Institute. This has proved a strong

influence on the conduct of the research program in a number of ways. The candidate's work has naturally exposed him to what has been occurring in the evidence based practice movement. Evidence-based health care (EBHC) has been promoted as an approach that organisations and professionals may use to inform decisions about the way in which health care is delivered. All health care organisations are faced with alternative interventions and strategies that have different implications for the organisation and the individuals that health care is provided for. In deciding which alternatives are used, the best available evidence must be sought to increase confidence in the decisions to be made. But what type of evidence is required?

Until now the output from evidence-based researchers has been focussed on clinical effectiveness derived from research trials (Hamer & Collinson, 1999). Certainly it is important to ascertain whether an intervention is clinically effective or more effective than an alternative. It is also important to determine the implications of utilising that intervention (Øvretveit, 1998). There will certainly be implications for the patient. A positive health outcome may be counter-balanced by pain, or unpleasantness, in delivering the intervention. There may be social implications that are not seen in the artificial confines of a randomised controlled trial. Health care organisations also have to resource the intervention which although effective clinically, may have significant resource implications for the health care provider.

In February of 2000 Pearson addressed the 2nd Australasian Colloquium on Evidence-Based Nursing in which these issues were raised. He spoke of the EBHC approach incorporating evidence of effectiveness balanced with the evidence of appropriateness and feasibility. This is a departure from the predominant view of EBHC that has largely ignored research that examines the 'experience' of being the recipient of health care. Interpretive research provides evidence that increases our understanding of the context in which the patient is situated. Evidence of feasibility addresses the structural and organisational issues relating to an intervention. Pearson suggested action research might provide evidence of how the feasibility of an intervention might be studied. Additionally economic evaluation may be useful in determining the financial feasibility of utilising a specific strategy or intervention. The objective would be to combine these types of evidence in a meaningful way without lending undue weight to one form of evidence. This pluralistic approach to evidence has resulted in a number of innovations being developed by Pearson and his

associates. In particular the FAME scale addresses the issue of the need to consider multiple types of evidence in making clinical decisions. The FAME scale arose from a project to develop a methodology and associated tools to review evidence from interpretive and critical research. Under the leadership of Pearson the Qualitative Assessment and Review Instrument (QARI) development group developed a scale that was intended to define levels of evidence for practice including evidence of feasibility, appropriateness, meaningfulness and effectiveness (Pearson, 2004). This work continues and recently the Joanna Briggs Institute has proposed both a hierarchy of evidence and grading of recommendations based on the FAME scale (Joanna Briggs Institute, 2004).

Working within this environment it was logical that the candidate would consider a program of research that involves not only a systematic review of the evidence of effectiveness but also the exploration of other forms of evidence in relation to STSG donor sites. To this end the economic evaluation was also conducted.

Chapter 3. Portfolio Objectives and Methods

Objectives

As with any research degree studies the purpose in conducting doctoral research is multifaceted. On one level it is about gaining the knowledge and experience in conducting research. In this instance the aim was to develop skills and abilities in conducting research using different designs. At the doctoral level there is of course another imperative, the research must result in generating new knowledge. The University of Adelaide doctoral program also stresses that the research must be applied and achieve a result that informs clinical practice. To this end the output from the studies is required to be published and disseminated. Appendix 1 documents the publications arising from the research conducted and appendix 2 the presentations given in relation to the portfolio program.

The overall aim of the program was to explore issues relating to the integration of the varying types of evidence required to make clinical decisions within a framework of evidence based health care. The systematic review established the best available evidence of clinical effectiveness in relation to the post harvest management of STSG donor sites. The economic evaluation was a primary research exercise that developed new evidence of economic effectiveness in relation to donor sites. Although they stand as individual works the results are combined to inform practice.

Methods

A brief overview of the methods used in conducting this research program is of use in introducing the portfolio. For a detailed description of the methods used for the individual projects please refer to the specific project reports.

Project 1 Systematic review

The first component of the research program was a systematic review. This review was conducted as an orthodox review of the evidence of clinical effectiveness. The candidate received training and was co-supervised by staff of the Joanna Briggs Institute. Although the candidate was working within the Joanna Briggs Institute his role did not involve the conduct of systematic reviews. In conducting a review as a student the candidate was precluded from using a secondary reviewer for critical appraisal and data extraction of identified studies. This was not because of any

restriction placed on the review in relation to the rules of the award but due to the lack of availability of a volunteer second reviewer.

The systematic review was then submitted and accepted for publication as a full report by the Joanna Briggs Institute (Wiechula, 2001). Fortunately the review identified a large number of studies across many different interventions. The review was then further abstracted and published as a supplement in the International Journal of Nursing Practice (Wiechula, 2003) and as a Best Practice Information Sheet (Joanna Briggs Institute, 2002). This publication has been additionally translated into Italian (Joanna Briggs Institute, 2004a) and also abstracted in the World of Irish Nursing (World of Irish Nursing, 2003). These additional publications are provided in appendix 1. The review has also been listed and critiqued in the DARE database. The results of the review have been presented in a range of forums and these are listed in appendix 2.

Project 2 Economic evaluation

The second project was an economic evaluation. Although there was the option available to conduct a primary clinical research project identified from gaps in the research following the systematic review this option was not taken. Certainly there were gaps in the clinical effectiveness evidence identified by the systematic review. In particular it was highlighted that there was very little evidence in relation to comparisons between moist wound healing products. The decision to conduct an economic evaluation arose principally from the notion that clinical decision making should take into account a broad range of evidence and not be restricted to clinical effectiveness. In conducting the review the issue of cost was raised in a number of publications. A search of the literature found no suitable economic evaluations in relation to STSG donor management. At the time of making the decision about the second project there was some growing interest within the evidence based movement about what place economic evaluation may have in evidence review. In particular there was some debate about the use of clinical data from met-analysis being used for economic modelling. These issues are explored in detail in the background of the economic evaluation report. The decision was then made to conduct an economic evaluation using the data extracted and synthesised from the systematic review. Again at the time the candidate had limited experience in this type of research. A range of strategies were undertaken to equip the candidate with

the necessary guidance to conduct such a study. In the first instance a short course in economic evaluation was undertaken at the University of Western Australia. This was followed by accessing a number of health economists at the Department of Human Services, South Australia. Fortunately the scope of the study, basically a micro-economic evaluation, was at the level that did not require formal training in health economics.

Program integration

The final step in the program was to integrate the results of the two studies. This was done by considering the combined results of the studies using the framework of the FAME scale (Joanna Briggs Institute, 2004b).

**Part 2: Post Harvest Management of Split Thickness
Skin Graft Donor Sites: A Systematic Review**

Chapter 4. Systematic Review Executive Summary

The use of the split skin graft as reconstructive technique is commonplace. This process involves the creation of a superficial wound that is the donor site.

The focus of this review is the post harvest management of the Split Thickness Skin Graft (STSG) donor site. The aim of donor management is to maintain an environment that promotes optimal healing and prevents morbidity that may include, pain, infection and ultimately delayed healing.

The focus of research in this area relates mainly to the type of dressings used.

The recent developments in dressing technology, the continued variability in practice and persistent recommendations to use non-moist wound healing methods as an alternative demonstrate the need for a systematic review in this area of care.

Objectives

To conduct a systematic review to determine the best available evidence related to the post harvest management of STSG donor sites. Specific review questions addressed; interventions/dressings used in the management of the STSG donor site, interventions/dressings used in managing infected STSG donor sites, and interventions managing the healed split skin donor site.

Criteria for considering studies in this review

This review considered all studies that included patients of any age and that related to the objectives of the review. Outcomes included measures of healing, infection rate, and pain scores.

The review primarily considered any intra-individual trials (IITs) and prospective randomised controlled trials (RCTs) relating to the management of STSG donors but also considered other studies when RCTs and IITs were not identified.

Search strategy for identification of studies

The search sought to find published and unpublished studies. The databases searched included; CINAHL, Medline, Pre-Medline, Cochrane Library, Current Contents, Healthstar, Embase, Expanded Academic Index, and Dissertation Abstracts International. Studies were additionally identified from reference list of all studies retrieved.

Assessment and data extraction

All studies were checked for methodological quality, and data extracted using a data extraction tool.

Results

Interventions relating to the post harvest management of STSG donor sites.

The objectives in managing a STSG donor site are, to achieve healing as rapidly as possible, without complication, maximising patient comfort and at a cost effective price. Treatment regimes vary considerably in terms of their ability to achieve these objectives and cost in particular can be a significant factor. The circumstances of the patient will dictate which of these objectives have priority.

Moist verses non-moist wound healing products

The analyses for this comparison revealed with a strong degree of confidence based on many acceptable RCT/IITs that moist wound healing products are significantly superior to non-moist products in terms of healing, infection rates and pain/comfort.

Calcium alginates

There were insufficient studies of sufficient quality to make any judgement between the performance of calcium alginates and other moist wound healing products or between specific products within the calcium alginate group. Well designed clinical trials should be conducted to compare calcium alginates with other moist wound healing products.

Hydrocolloids

Hydrocolloids were found to be superior to non-moist wound products in relation to healing, pain, and infection. The studies comparing hydrocolloids with other non-moist products in relation to healing are insufficient to indicate that they are superior to other moist wound healing products. The results for the outcomes of pain and rates of infection suggest that hydrocolloids are not superior to other moist products.

The overall cost of any of the treatments used in wound management is affected by frequency of dressing changes. It has been suggested that when hydrocolloids leak that reinforcement rather than changing the dressing outright is appropriate and has

no greater risk of morbidity. Further research is required to determine if hydrocolloids have any clinical advantage over other moist wound products.

Polyurethane semipermeable transparent films

The results for polyurethane films relating to healing in comparison to non-moist products are mixed. Polyurethane films fared better with regard to pain and infection suggesting they are superior to non-moist products. When compared to other moist wound products on balance there is no strong evidence to suggest one group is superior to another for any of the outcome categories. Polyurethane films can be recommended for use in the management of STSG donors and it can be suggested that polyurethane films are more suited to wounds with light to moderate amounts of exudate.

Polyurethane foams

Whilst no recommendations can be made with regard to polyurethane foams and the management of STSG donors it is recommended that these products be subjected to further clinical trials in comparison to other moist wound products.

Hydrogels

As these products are designed for wounds with only a low level of exudate these products would not be recommended for use in the management of STSG donors when alternative moist products are available.

Scarlet Red

This particular product was analysed separately to other non-moist wound products. Of all the non-moist products analysed the results relating to Scarlet Red, although not convincing, did hold some promise. Further clinical studies may clarify the potential of this product and this should be considered in light of its level of use.

Porcine or bovine derived dressings

These products are not recommended for use in the management of STSG donors.

Growth factors

Results suggest that rHGH is most promising in relation to improving healing times for STSG donors, however as an emerging technology the cost/benefit of these products is a major concern and should be further investigated.

Cultured epidermal allografts

These technologies are not being suggested for routine use but in cases where conventional therapy is inadequate. In these circumstances there may be a valid argument for their use despite their cost. Cost utility analysis should be conducted to more accurately determine the overall effectiveness of these products.

Biobrane

In view of the fact that more cost effective alternatives exist it would be difficult to recommend their use above moist wound healing products.

Meshed split skin graft, retention tape dressings, beeswax, Phenytoin, Asiaticoside, amniotic membrane, live yeast cell derivative, and Nobecutane spray.

Due to the lack of evidence relating to these treatments no recommendations can be made.

Interventions relating to the management of the infected STSG donor site

Extrapolating the evidence relating to antimicrobials and their use in managing infected superficial burns it can be recommended that certain topical antimicrobials may be used when clinical infection is confirmed. Silversulphadiazine and Iodine based treatments are recommended with suitable precautions.

Interventions relating to the management of the STSG donor site following epithelial cover

Patient education and specific interventions should include the use of moisturisers applied frequently, the avoidance of UV exposure and the use of strong sunscreens. This seems not to be a priority for research but considering the cost of many of these products and their extensive use clinical trials should be attempted.

Conclusions

Moist wound healing products have a distinct clinical advantage over non-moist products in the management of STSG donors. There is a strong case for head to head studies comparing products within the moist wound care group. Wounds with light to moderate exudate may best be managed with polyurethane films, wounds with moderate exudate with hydrocolloids, and heavily exuding wounds with calcium alginates. This has yet to be tested rigorously but should be considered.

Chapter 5. Systematic Review Introduction

The use of the split skin graft as reconstructive technique is commonplace. It involves the harvesting of a sheet of skin comprising epidermis and varying thickness of dermis. Naturally this process involves the creation of a superficial wound that is the donor site (Fowler & Dempsey, 1998).

The technique was used by the ancient Egyptians and was seen in India up to 3000 years ago. Skin grafting prior to this century was unsophisticated and was used often as a last resort. During the last 70 years improvements in technique have seen the procedure become precise and widely accepted (Ablove & Howell, 1997).

Considered one of the basic tools of plastic surgery the method is now being widely used by other surgical specialties. Although it is a surgical technique nursing involvement in the process is considerable. The nurse has a pre-operative role including physical preparation of donor and recipient sites, and also education/psychological support. Post operatively the nurse manages the patient to ensure 'take' of the graft at the recipient site and prevention of morbidity of the donor site.

The focus of this review is the post harvest management of the Split Thickness Skin Graft (STSG) donor site. The resultant wound is essentially a superficial to partial thickness wound depending on the depth of the graft. The donor heals by a process of re-epithelialisation. Epithelial cells migrate across the wound surface from the rim of the wound and the edges of various structures in the dermal layer, such as sebaceous glands and hair follicles. This process results in an epithelial cover usually within 7-14 days (McCain & Sutherland, 1998). The rate of healing is quite variable and is affected by factors such as depth, site, size and the age of the patient (Fowler & Dempsey, 1998). The aim of donor management is to maintain an environment that promotes optimal healing and prevents morbidity that may include, pain and infection and ultimately delayed healing.

In considering wound management generally, there has been a revolution in approaches to treatment particularly in terms of dressing selection. These developments have revolved around the introduction of many new dressing alternatives with the emphasis shifting to products that promote moist wound healing (Flanagan, 1992). The seminal work of Winter (1962) demonstrated the potential of the moist wound healing approach. Since then there has been the gradual

introduction into practice of many types of dressings that promote moist wound healing. The advantages of these dressings are well documented. They prevent desiccation and the deepening of wounds, reduce the risk of mechanical damage of healing tissue at removal and provide an environment that results in more rapid healing (Hermans, 1995). Considering the advantages of using this approach it is surprising that there is still some hesitancy in adopting this approach to wound management (MacLellan, 1993).

Also surprising is that in managing STSG donor sites, non-moist wound healing methods are still advocated as an alternative (Ablove & Howell, 1997; Fowler & Dempsey, 1998; McCain & Sutherland, 1998). STSG donor management is aimed at promoting optimal healing and preventing morbidity. The focus of research in this area relates mainly to the type of dressings used.

The dressings commonly used in the management of STSGs fall into a number of generic categories. The major categories are listed below.

Mesh Gauze

There are a number of products in this category that are impregnated with various substances such as paraffin, lanolin, Scarlet Red, petroleum jelly, etc. (McCain & Sutherland, 1998). These dressings are then covered with layers of absorbent dressings. The airflow through the dressings allows the exudate to dry and the dressings usually form a hard crust. Removal of the dressing often results in considerable pain and damage to new epithelium (Hermans, 1995).

Biological/biocomposite dressings

This group includes, Biobrane, a composite of silicone, nylon and porcine collagen peptides, and xenografts of porcine or bovine origin (Ablove & Howell, 1997).

Polyurethane Semipermeable Transparent Films

These products are self adhesive vapour permeable polyurethane sheets. This type of dressing has gained considerable clinical acceptance and utilises the principles of moist wound healing (Thomas, 1997).

Hydrocolloids

Also utilising the principles of moist wound healing these products are occlusive sheets of hydrocolloid polymer on a layer of polyurethane foam that form a gel like layer at the wound surface (Tan, Roberts, & Sinclair, 1993).

Fibre dressings

Calcium alginate dressings represent the majority of products in this category although there are now other fibre dressings coming on to the market as well as composite dressings, which include alginates. These are highly absorbent and like hydrocolloids form a gel surface when in contact with a moist wound (Steenfos & Agren, 1998; Thomas, 1997; Vanstraelen, 1992). Many of these dressings have haemostatic properties useful in the management of donor sites (Hollinworth, 1992).

This is not an exhaustive list and a number of additional dressings have been used in the management of STSG donor sites. A summary table of all dressings/products examined in this review are presented in appendix 3.

Rakel et al., (1998) have conducted a quantitative synthesis of the research relating these dressing methods. They point out that all methods have both advantages and drawbacks. They examined these dressing groups in terms of healing rates, quality of healing, infection rates, pain, and cost. They concluded that moist wound healing products are superior to non-moist wound healing products in the management of STSG donor sites and that transparent films demonstrated advantages over hydrocolloids and alginates particularly in relation to cost and healing quality. Whilst this is a useful and comprehensive review the authors acknowledge that they searched only Medline and CINAHL data bases up until 1996 with an additional search of reference lists of the retrieved articles. Few of the individual dressing products had studies that were replicated and standard deviation measures were unable to be used in their analysis. Outcome measures were quite variable and many measures such as healing quality were largely subjective. Since 1996 there has been considerable development in moist wound healing products but particularly the category of products now known as fibre dressings suggesting that a further review is timely (Steenfos & Agren, 1998; Young & Fowler, 1998). The Rakel et al., (1998) review examined infection rates of various dressing types but did not address the management of the infected donor site. The management of the donor following re-epithelialisation including protection and moisturisation has also not been dealt with.

The recent developments in dressing technology, the continued variability in practice and persistent recommendations to use non-moist wound healing methods demonstrate the need for a systematic review in this area of care.

Chapter 6. Systematic Review Objectives

To conduct a systematic review to determine the best available evidence related to the post harvest management of STSG donor sites. The specific review questions addressed were:

What interventions/dressings used in the management of the STSG donor site are most effective;

- in reducing time to healing,
- in reducing rates of infection, and
- in reducing pain levels and promoting comfort?

What interventions/dressings are most effective in managing delayed healing/infection in the split skin graft donor site?

What interventions are most effective in managing the healed split skin donor site?

Chapter 7. Systematic Review Methods

Criteria for considering studies in this review

Types of participants

This review considered all studies that included patients of any age with split thickness skin graft donor sites.

Types of interventions

Interventions of interest related to the post harvest management of the STSG donor sites included:

- Primary wound dressings of any type
- Secondary dressings and compression therapy
- Dressing regimens
- Non dressing topical applications

Interventions of interest related to the management of the delayed healing/infected STSG donor site included:

- Wound dressings of any type
- Non dressing topical applications including antibiotics and antiseptics

Interventions of interest related to the management of the healed split skin graft donor site included:

- Types of moisturisers
- Cleansing and moisturising regimens
- Strategies to protect the donor site from UV radiation

Types of outcome measures

Primary outcomes: objective measures of healing such as; the proportion of donors healed within the study period, time to complete healing, rate of infection, rate of breakdown following complete healing and pain scores.

Types of studies

The review primarily considered any intra-individual trials (IITs) and prospective randomised controlled trials (RCTs) that evaluated the effectiveness of interventions/strategies relating to the management of the STSG donor site. In the absence of RCTs/IITs other study designs such as controlled clinical trials (CCTs) were considered for inclusion. In the absence of studies that provided objective measures of healing and morbidity of STSG donor sites other studies were considered for the purpose of a narrative summary of current approaches.

Search strategy for identification of studies

The search sought to establish what published and unpublished studies were available relating to the review questions. The search strategy involved three phases:

- Phase 1: An initial search of Medline and CINAHL databases was undertaken to identify key words contained in the title or abstract, and index terms used to describe relevant articles.
- Phase 2: An extensive search of a number of databases, as listed below, was conducted using all identified key words and index terms. Unpublished and additional published papers were sought from a number of appropriate, educational and clinical units.
- Phase 3: Reference lists and bibliographies of all retrieved articles were searched for additional studies.

Initial search terms included:

- skin
- graft
- donor

The databases searched included:

- CINAHL
- Medline
- Pre-Medline
- Cochrane Library

- Current Contents
- Healthstar
- Embase
- Expanded Academic Index

The search for unpublished studies included:

- Dissertation Abstracts International

Searching of the databases commenced in May 1999 and was repeated at 4 months.

All studies identified during the database search were assessed for relevance to the review based on the information provided in the title, abstract, and descriptor/MeSH terms. A full report was retrieved for all studies that meet the inclusion criteria (see appendix 4). Studies identified from reference list searches were assessed for relevance based on the study title.

Assessment of methodological quality

Methodological quality was assessed using a checklist developed by the reviewer based on the work of the Cochrane Collaboration and Centre for Reviews and Dissemination and further refined by the staff of Joanna Briggs Institute for Evidence Based Nursing and Midwifery (see appendix 5). In the absence of RCTs/IITs other study designs such as controlled clinical trials (CCTs) were considered for inclusion. In the absence of studies that provided objective measures of healing and morbidity of split skin graft donor sites other studies were considered for the purpose of a narrative summary of current approaches. Due to the large number of studies and limited resources only a small number of studies were able to be assessed by a second reviewer.

It should be considered that there are a number of alternative treatments for STSG donor sites. In general dressing products are managed in a similar fashion in that ideally the products are left in place until epithelial cover has been completed. This is not always possible as dressings may be changed for a variety of reasons but principally due to leakage of exudate. Studies where one or either dressing product was changed due to leakage as would normally occur in practice were still included in the analysis. Studies where products were removed prematurely for observation were also included but only if both treatment and control groups were treated in the same

manner. In these cases only outcomes data up until the first dressing change were included.

A list of studies excluded on methodological grounds and the reasons for the exclusion can be seen in appendix 6.

Data extraction

Data was extracted using a data extraction tool developed specifically for this review (see appendix 7).

Data analysis

Where possible study results were pooled in statistical meta-analysis using Review Manager software from the Cochrane Collaboration (Review Manager V 4.04). All results were double entered. Odds ratio (for categorical outcome data) and weighted mean differences (for continuous data) and their 95% confidence intervals were calculated for analysis. In cases where meta-analysis was used to combine studies of broader categories of dressings, such as *moist wound healing products compared to non moist*, a random effects model was used. Otherwise the fixed effects model was used. Heterogeneity was assessed using standard Chi-squared test with a significance level of $p < 0.01$. Where statistical pooling was not possible the findings are presented in narrative form.

Chapter 8. Systematic Review Results

Based on the search strategies used 111 papers were identified that reported on clinical trials comparing various treatments in the post harvest management of split thickness skin graft donor sites. A breakdown of these studies is provided below:

110 Clinical Trials

1 Integrative review

0 Meta-analyses

0 Systematic Reviews

Of the 110 studies reporting on clinical trials 23 were excluded, as they did not meet the inclusion criteria that they were an RCT or II trial.

Of the 83 RCTs and IITs that met the inclusion criteria 25 studies were excluded on methodological grounds.

58 RCTs and IITs remained that met the inclusion criteria and were accepted on methodological grounds. These studies were included in the analyses. Where there were comparisons of clinical significance and there were no included studies, some previously excluded studies were used in the narrative summary. These studies are clearly delineated in the text of the results.

Interventions relating to the post harvest management of STSG donor sites.

There are many alternative treatments for managing STSG donor sites. The vast majority of studies relate to the alternative dressings available as primary treatment for new donor sites. For the purpose of analysis the range of treatment alternatives have been grouped in ways that are clinically relevant. Some groupings are broad and respond to clinical concerns that are more general in nature such as the comparison between moist and non-moist wound healing products. Other comparisons are more focussed examining specific generic dressings products such as hydrocolloid dressings. Analysis was attempted for the general outcomes of healing, pain, and infection for all comparative groups. For each of these outcomes there were a variety of outcome measures used in the studies and not all comparisons were able to have all outcomes analysed.

The following groups of comparisons are provided:

1. Moist wound healing products compared to non-moist wound healing products.
2. Calcium alginates are compared with non-moist (non biological) wound healing products
3. Calcium alginates are compared with other moist wound healing products
4. Comparison between calcium alginates
5. Hydrocolloids compared with non-moist wound healing products
6. Hydrocolloids compared with other moist wound healing products
7. Comparison between hydrocolloids
8. Polyurethane film dressings compared to non-moist wound healing products
9. Polyurethane film dressings compared to other moist wound healing products
10. Comparison between polyurethane film dressings
11. Polyurethane foam dressings compared to non-moist wound healing products
12. Polyurethane foam dressings compared to other moist wound healing products
13. Comparison between polyurethane foam dressings
14. Hydrogels compared with non-moist wound healing products
15. Hydrogels compared with other moist wound healing products
16. Comparison between hydrogels
17. Scarlet Red compared with other non-moist wound healing products
18. Scarlet Red compared with moist wound healing products
19. Bovine or porcine based products compared with non-moist wound healing products
20. Bovine or porcine based products compared with other moist wound healing products
21. Comparison between bovine or porcine based products

22. Growth factors compared with Placebo control
23. Cultured epidermal allografts compared to non-biological dressings
24. Cultured allogeneic keratinocyte sheet compared with moist wound healing products
25. Biobrane compared with non-moist wound healing products
26. Biobrane compared with moist wound healing products
27. Antimicrobials compared to non-moist wound products
28. Retention tape dressings
29. Meshed skin compared to paraffin gauze
30. Beeswax compared with non-moist wound healing products
31. Phenytoin compared with Opsite and compared with Soframycin
32. Amniotic Membrane compared to Antibiotic Impregnated Gauze
33. Asiaticoside compared to placebo
34. Hyaluronic acid compared to 100% glycerin
35. Live yeast cell derivative compared with placebo control
36. Nobecutane spray
37. Calcium alginate compared with calcium alginate and Bipuvicaine

Interventions relating to the management of the infected STSG donor site

No studies dealt specifically with the alternative treatments of infected donor sites. A number of the studies included in the analysis examined anti-microbial products but these were used on new donors and not on infected wounds.

Interventions relating to the management of the STSG donor site following epithelial cover

There were only two studies found that examined moisturisers used when epithelial cover was achieved. The following comparison is provided:

38. Bepanthen compared to placebo

Meta-analysis was conducted where studies of treatments and outcomes could be pooled. For certain outcomes there were insufficient studies for meta-analysis and these single studies are presented graphically. Some studies provided inadequate data for analysis and these studies are presented in narrative form as additions.

Note, all studies unless otherwise specified were RCTs or IITs, some with additional randomisation.

Interventions relating to the post harvest management of STSG donor sites.

The selection of the appropriate dressing product or topical application represents only one facet in the successful management of STSG donor site. Other issues that must be considered in the treatment regime are; strategies to maintain haemostasis, additional interventions to maintain comfort; measures to prevent contamination, timing and methods to remove the dressing without trauma and discomfort and cost containment. Virtually all clinical trials in this study related to alternative wound products rather than other aspects of treatment regimes. This results chapter is therefore naturally focussed to product alternatives and this is where the highest ranking of evidence exists. There were a number of studies that reported on aspects of management although in general this evidence is of the level of expert opinion. Where available and appropriate these issues are dealt with in the summary sections of each comparison.

Comparison 1: Moist wound healing products compared to non-moist wound healing products in the management of STSG donor sites;

Note, biological products have not been included in this comparison, non-moist wound healing products, mainly gauze products (impregnated with ointment or without) of various types have been included. Biological products will be dealt with in specific comparisons later in the chapter. When a meta-analysis has been conducted the specific dressing products are listed in table form below the graphed results.

Outcome 1A: Healing

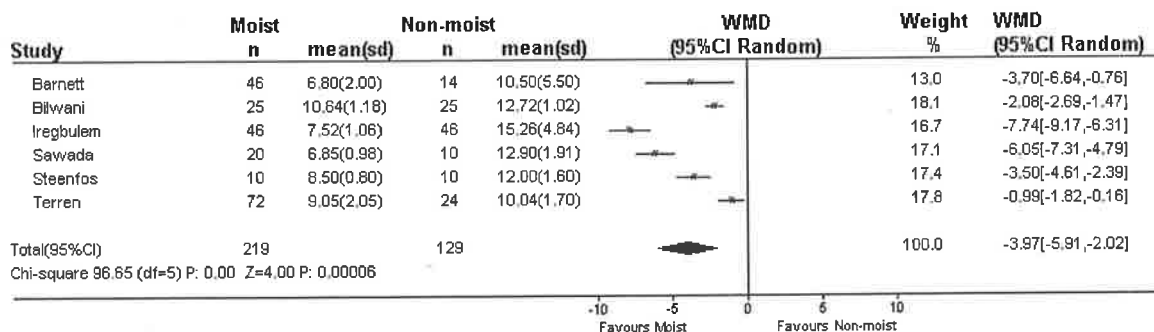
In comparing performance of moist and non-moist wound healing dressings in relation to healing times, varying criteria were used including; Days to complete healing, number of wounds not healed by day 7, 8, 9, 10, or 12. Results relating to each of these criteria are presented below.

Days to complete healing

Meta-analysis; 6 studies included

Donor sites were considered healed when dressings could be removed without trauma and pain. Six studies included in the meta-analysis significantly favoured moist wound healing products in relation to days to complete healing (figure 1).

**Figure 1. Comparison: Moist Vs non-moist wound dressings.
Outcome: Days to complete healing**



The combined result significantly favoured moist wound products (WMD -3.97 and 95% CI Random -5.91, -2.02). The specific dressings for included studies are listed in table 1.

Table 1: Moist compared to non-moist wound healing dressings for STSG donor sites: Days to complete healing, studies included in meta-analysis.

Study	Moist dressings	Non-moist dressings
Barnett, Berkowitz, Mills, & Vistnes (1983a)	Combined; Tegaderm, Opsite	Fine mesh gauze
Bilwani & Sheth (1988)	Lyof foam	Tulle Gras
Iregbulem (1983)	Opsite	Sofratulle
Sawada, Yotsuyanagi, & Sone (1990)	Silicone gel sheet with OFLX	Tulle Gras
Steenfos & Partoft (1997)	DuoDERM, Sureskin	Jelonet
Terren et al. (1993)	Eurothane, Comfeel Thin, Varihesive (DuoDERM)	Tulle Gras

Note; where more than one moist product is listed individual study results were combined.

Additional studies not included in meta-analysis for this category

In addition to the studies above there were a number of studies that could not be included in the meta-analysis due to incomplete data.

- Hickerson, Kealey et al. (1994) compared Wound Contact Layer(WCL) (moist) with Xeroform (non-moist). No standard deviations were provided however the results favoured the moist product. WCL, mean days to healing 7.9 (n=38) and Xeroform, 10.2 (n=38) (p<0.001).
- Feldman, Rogers et al. (1991) compared DuoDERM (moist), mean days to healing 15.3 (n=10), to Xeroform, mean days to healing 10.46 (n=13). No standard deviations were provided but Xeroform was stated as significantly better with regard to healing.
- Madden, Nolan et al. (1989) compared DuoDERM, mean days to healing 7.4 (n=15), with fine mesh gauze, mean days to healing 12.6 (n=15). Statistical significance was not provided and could not be derived from the data.
- Himel, Ratliff, Baruch, & Rodeheaver (1998) compared Ventex (moist) with Xeroform. The Ventex wounds were said to have all healed by day 10 (n=10), Xeroform wounds healed 10-14 days (n=10). No indication of statistical significance was given.
- Rives, Pannier et al. (1997) compared calcium alginate, mean days to healing 10 (n=34), with paraffin gauze, mean days to healing 11 (n=33). No standard deviations or level of significance were provided.
- Madden, Finkelstein, Hefton, & Yurt (1985) compared a hydrocolloid (moist dressing not specified), mean days to healing 7.4 (n=20), with fine mesh gauze, mean days to healing 12.6 (n=20). Only means were provided.
- Basse, Siim, & Lohmann (1992) compared Kaltostat (moist), mean days to healing 8.64 ± 1.83 (n=17), with Jelonet 9.94 ± 2.46 (n=17). Although the result favoured the moist product it was not significant. This study was excluded from meta-analysis as the dressings were soaked off at day 7.
- Mitra & Spears (1990) compared DuoDERM (moist), mean days to healing 8.6 (n=33), with Xeroform, mean days to healing 13.6 (n=33). No standard

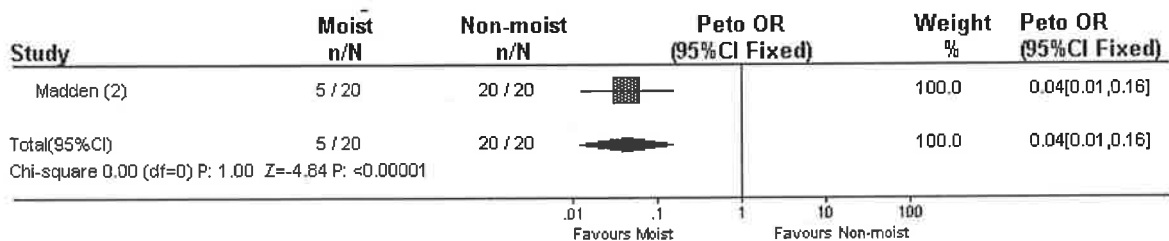
deviations were provided but DuoDERM was stated as significantly better with regard to healing.

- Foyatier (1992) compared DuoDERM (moist), mean days to healing 7.7 (n=34), with Tulle Gras, mean days to healing 13.0 (n=34). No standard deviations were provided but DuoDERM was stated as significantly better with regard to healing.

Donors not healed at Day 7

Meta-analysis not undertaken as only 1 study provided acceptable data (figure 2)

Figure 2. Comparison: Moist Vs non-moist dressings. Outcome: Not healed by day 7



Madden, Finkelstein et al. (1985) compared a hydrocolloid (moist) with fine mesh gauze (non-moist). Although this was only one small study, the result favoured the moist product significantly for healing at day 7.

Additional studies not included in meta-analysis for this category

- Cadier and Clarke (1996) compared Dermasorb (moist) with Jelonet (non-moist). Results presented were that Dermasorb (n=21) had significantly faster healing times than Jelonet (n=21). Data was only provided in graphic form, significance stated as (p<0.002).

Donors not healed at Day 8

Meta-analysis; 4 studies were combined for this category

The pooled result for donors not healed at day 8 favoured moist wound healing products (Odds Ratio 0.16, 95%CI Random 0.02, 1.51) (figure 3). The combined result was not statistically significant. It should also be noted the included studies showed statistically significant heterogeneity (p<0.01). Review of the articles revealed no clinical reason for this difference between studies.

Figure 3. Comparison: Moist Vs non-moist dressings. Outcome: Not healed at day 8

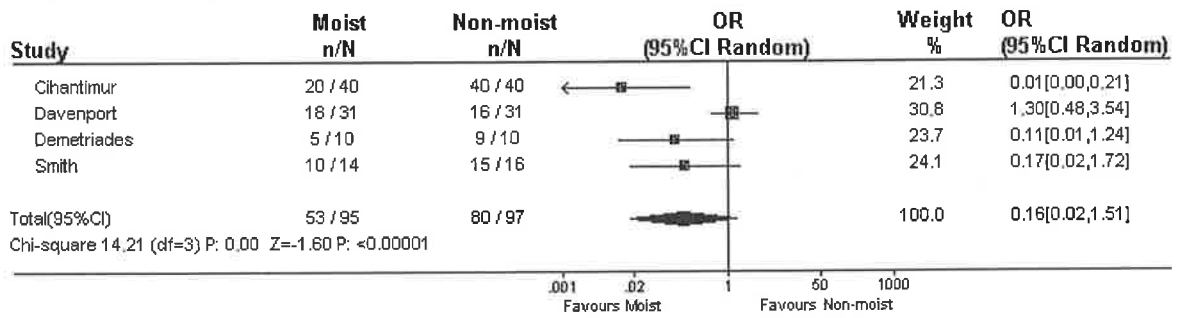


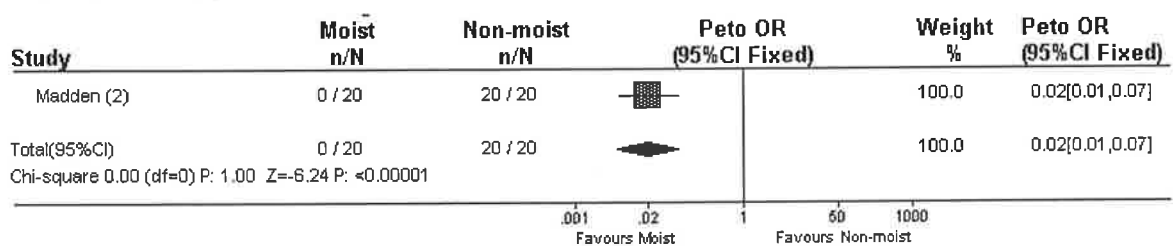
Table 2: Moist compared to non-moist wound healing dressings for STSG donor sites: Donor sites not healed at day 8, studies included in meta-analysis.

Study	Moist dressings	Non-moist dressings
Cihantimur, Kahveci, & Ozcan (1997)	Kaltostat	Jelonet
Davenport, Dhooghe, & Yiacoumettis (1977)	Lyof foam	Tulle Gras
Demetriades & Psaras (1992)	Granuflex	Tulle Gras
Smith, Thomson, Garner, & Rodriguez (1994)	Hydrocolloid	Xeroform

Donors not healed at removal of dressing on Day 9

Meta-analysis not undertaken as only 1 study provided acceptable data (figure 4)

Figure 4. Comparison: Moist Vs non-moist dressings. Outcome: Not healed at day 9



Madden, Finkelstein et al. (1985) compared a hydrocolloid (moist) with fine mesh gauze (non-moist). The result favoured the moist product significantly.

Donors not healed at removal of dressing on Day 10

Meta-analysis; 5 studies were included for this category

Three studies favoured non-moist dressings although not significantly. Pooled analysis favoured moist dressings overall however not significantly (Odds Ratio 0.7, 95%CI Random 0.22, 2.20) (figure 5).

Figure 5. Comparison: Moist Vs non-moist dressings. Outcome: Not healed at day10

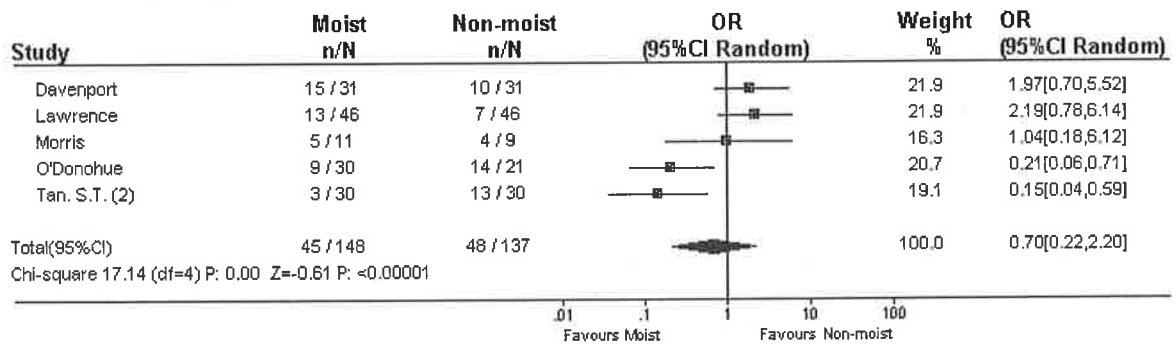


Table 3: Moist compared to non-moist wound healing dressings for STSG donor sites: Donor sites not healed at day 10, studies included in meta-analysis.

Study	Moist dressings	Non-moist dressings
Davenport et al. (1977)	Lyof foam	Tulle Gras
Lawrence & Blake (1991)	Kaltostat	Scarlet Red
Morris & Lamb (1990)	Opsite	Scarlet Red
O'Donoghue et al. (1997)	Kaltostat with .25% Bipuvicaine	Jelonet
Tan, Roberts, & Blake (1993)	DuoDERM	Scarlet Red

Additional studies not included in meta-analysis for this category

No additional studies were included for this outcome category.

Donors not healed at removal of dressing on Day 12

Meta-analysis; Two studies included

Only two small studies (figure 6) were included in this analysis however the result again significantly favoured moist wound healing products (Peto Odds Ratio 0.24, 95%CI 0.07, 0.76).

Figure 6. Comparison: Moist Vs non-moist dressings. Outcome: Not healed at day12

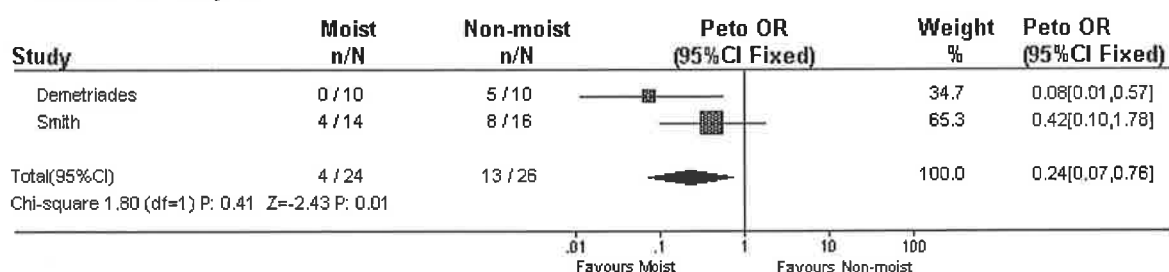


Table 4: Moist compared to non-moist wound healing dressings for STSG donor sites: Donor sites not healed at day 12, studies included in meta-analysis.

Study	Moist dressings	Non-moist dressings
Demetriades & Psaras (1992)	Granuflex	Tulle Gras
Smith et al. (1994)	Hydrocolloid	Xeroform

Additional studies not included in meta-analysis for this category

No additional studies were included for this outcome category.

Summary for the comparison of moist wound healing products and non-moist wound healing products in relation to healing.

In considering the performance of moist wound healing products compared to non-moist in the treatment of STSG donor sites it can be said with a strong degree of confidence that moist wound healing products are superior to non-moist wound healing products. In examining the meta-analyses, the two outcome measures, not healed by day 8, and not healed by day 10, did not show a significant result in favour of moist products. It should be considered that when using the outcome of 'donor not healed by a day x' that this represents an interim measure and that, days to

complete healing is a more accurate indicator of performance. It must also be stated that for the outcome days to complete healing, the studies included in meta-analyses lacked a high degree of homogeneity. The breadth of products used in the analysis would explain this and for this reason a random effects model was used for meta-analysis with the result still significantly favouring the moist wound products.

Outcome: 1B Pain

In comparing performance of moist and non-moist wound healing dressings in relation to pain, varying criteria were used including; Dressings rated more painful than alternate dressing, Overall pain rating using Visual Analogue Scales (VAS) of 1-5, 1-10, 1-100 and pain present at day 1. Results relating to each of these criteria are presented below.

Dressings rated more painful than alternate dressing

Note, only IITs have been included in this analysis.

Meta-analysis; 3 studies have been included in the analysis

The pooled result for, rating the dressing as more painful, was in favour of the moist products but not to statistical significance (Odds Ratio 0.80, 95%CI Random 0.01, 1.25) (figure 7). Chi-squared analysis revealed that the studies were not significantly heterogenous. Products used are listed in table 5.

Figure 7. Comparison: Moist Vs non-moist dressings. Outcome: Dressings rated as more painful

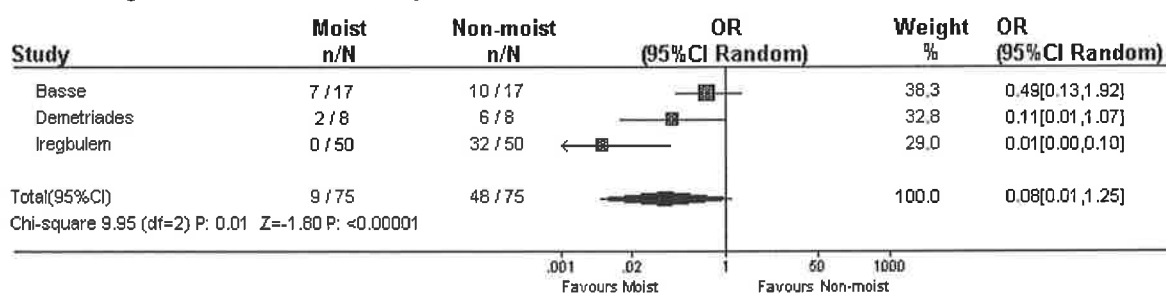


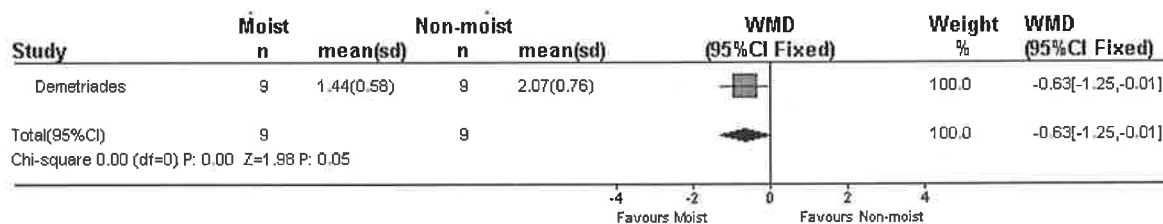
Table 5: Moist compared to non-moist wound healing dressings for STSG donor sites: Dressings rated more painful than alternate dressing, studies included in meta-analysis.

Study	Moist dressings	Non-moist dressings
Basse et al. (1992)	Kaltostat	Jelonet
Demetriades & Psaras (1992)	Granuflex	Tulle Gras
Iregbulem (1983)	Opsite	Sofratulle

Overall pain rating VAS 1-5, 5 is most painful.

Meta-analysis not undertaken, only 1 study with acceptable data (figure 8)

Figure 8. Comparison: Moist Vs non-moist dressings. Outcome: Overall pain rated 1-5,5 is most painful



Demetriades and Psaras (1992) compared Granuflex (moist) to Tulle Gras. The study results originally rated 5 as most comfortable. To maintain consistency for graphing the scale has been reversed, transposing 5 to most painful, so that the left side of the graph favours the treatment. The result favours the moist product significantly.

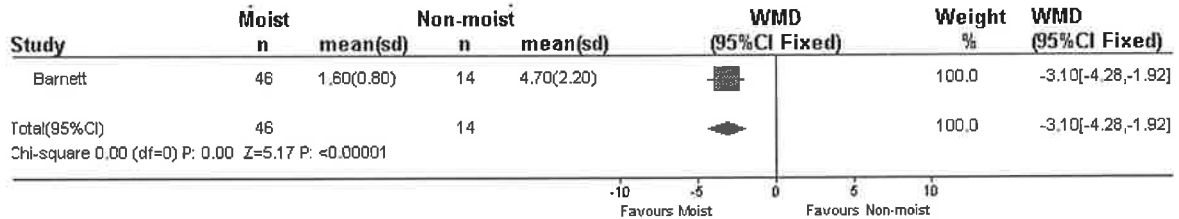
Additional studies not included in meta-analysis for this category

- Tan, Roberts & Blake (1993) compared DuoDERM to Scarlet Red and pain scores were stated as significantly worse for Scarlet Red (p<0.05).

Overall pain rating VAS 1-10, 10 is most painful.

Meta-analysis not undertaken as only 1 study provided acceptable data (figure 9).

Figure 9. Comparison: Moist Vs non-moist dressings. Outcome: Overall pain rated 1-10, 10 is most painful



Barnett, Berkowitz et al. (1983a) compared Tegaderm and Opsite, with the control, fine mesh gauze. For this study the individual results of the two moist wound products were combined. The result significantly favoured the moist wound healing products.

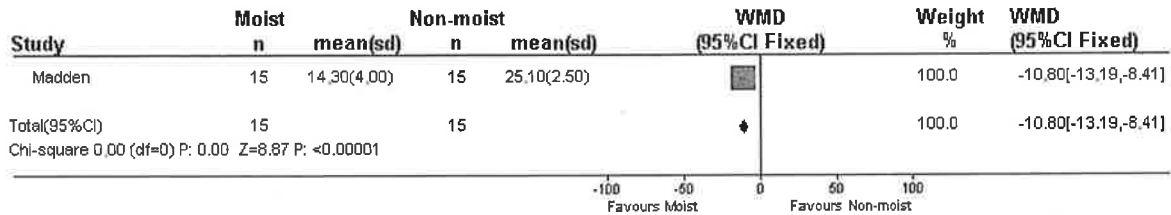
Additional studies not included in meta-analysis for this category

- Hickerson, Kealey et al. (1994) compared Wound Contact Layer, mean pain score 2.94 (n=38), with Xeroform, mean pain score 4.64, (n=38). No standard deviations were given however the result was stated as significantly favouring the moist product (p<0.001).
- Feldman, Rogers et al. (1991) compared DuoDERM, mean pain score 0.53 (n=10), with Xeroform, mean pain score 2.41 (n=13). No standard deviations were given however the result was stated as significantly favouring the moist product (p=0.01).

Overall pain rating VAS 1-100, 100 is most painful.

Meta-analysis was not undertaken, only 1 study with acceptable data (figure 10)

Figure 10. Comparison: Moist Vs non-moist dressings. Outcome: Overall pain rated 1-100, 100 is most painful



Madden, Nolan et al. (1989) compared DuoDERM with fine mesh gauze. Although the result significantly favours the moist product caution should be taken, as the sample was relatively small (n=15).

Overall pain rating VAS studies converted to the uniform scale of 1-10, 10 is most painful.

Meta-analysis: 3 studies included (figure 11)

For this meta-analysis the results of different visual analogue scales were converted to achieve a single uniform scale of 1-10. The pooled result favoured the moist products significantly, although there is still a lack of homogeneity for the combined VAS 1-10 scale outcome (WMD -1.75 and 95% CI Random -2.94, -0.56).

Figure 11. Comparison: Moist Vs non-moist dressings. Outcome: Overall pain rated 1-10, 10 is most painful (multiple ratings combined)

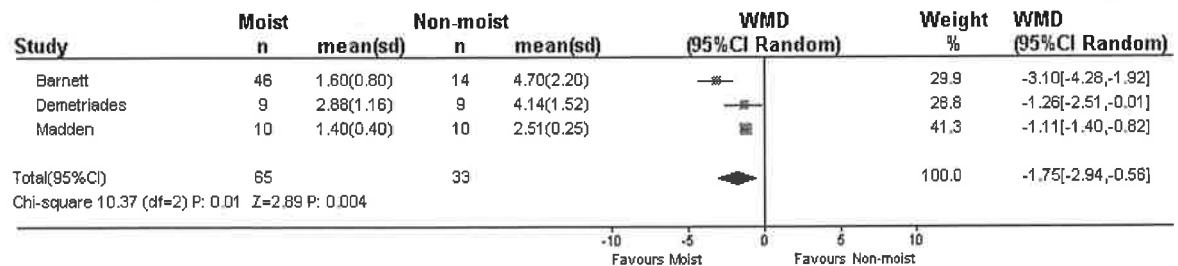


Table 6: Moist compared to non-moist wound healing dressings for STSG donor sites: Overall pain VAS rated 1-10, (multiple ratings combined) studies included in meta-analysis.

Study	Moist dressings	Non-moist dressings
Barnett et al. (1983a)	Tegaderm, Opsite	Fine mesh gauze
Demetriades & Psaras (1992)	Granuflex	Tulle Gras
Madden et al. (1989)	DuoDERM	Fine mesh gauze

Pain present at day 1

Meta-analysis: 2 studies included (figure 12)

The two studies have a high degree of homogeneity and the pooled result demonstrates a significant result in favour of the moist products in relation to pain present at day 1 (Odds Ratio 0.00, 95% CI 0.00, 0.04).

Figure 12. Comparison: Moist Vs non-moist dressings. Outcome: Pain present at day 1

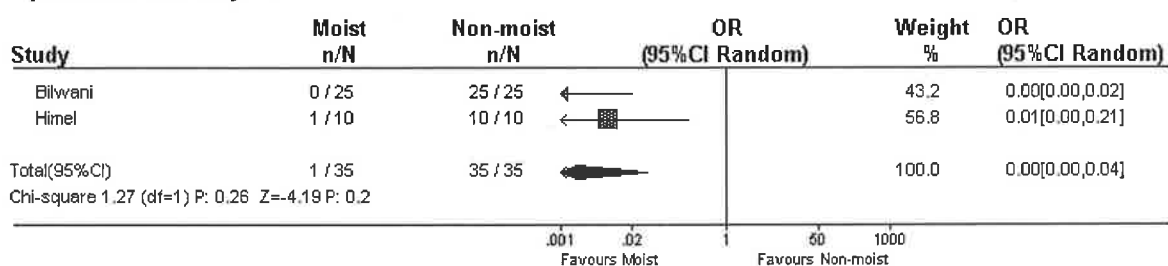


Table 7: Moist compared to non-moist wound healing dressings for STSG donor sites: Pain present at day 1, studies included in meta-analysis.

Study	Moist dressings	Non-moist dressings
Bilwani & Sheth (1988)	Lyfoam	Tulle Gras
Himel et al. (1998)	Ventex	Xeroform

Summary for the comparison of moist wound healing products and non-moist wound healing products in relation to pain.

Meta-analysis was able to be undertaken for the outcome measures of; 'Dressing rated as more painful', 'Overall pain using Visual Analogue Scales converted to a 1-10 scale, 10 being most painful', and 'Pain present at day 1'. For the comparison 'Dressing rated as more painful', the result was not statistically significant. In all other cases the pooled results significantly favoured the moist products. Additional studies, that were unable to be pooled for analysis, also supported that the moist products rated better in relation to pain. It may be argued that there is a lack of precision in the outcome measure, 'rating one dressing as more painful than another', in comparison to other outcomes for pain. The overall result remains convincing in favouring the moist products.

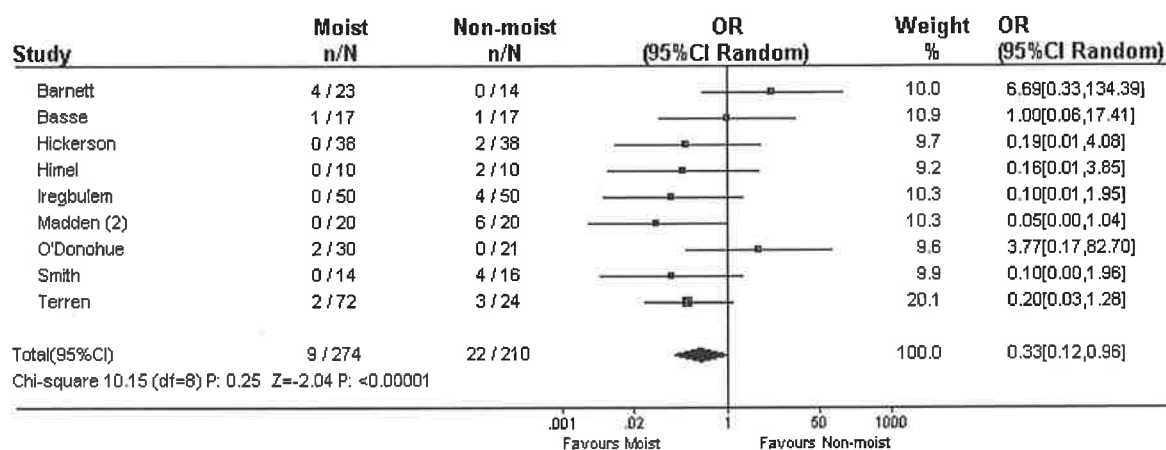
Outcome 1C: Infection

Wound showing positive signs of clinical infection

Meta-analysis: 9 studies included (figure 13)

There are many measures for determining if a wound is considered infected. In most studies examined a wound was classified as infected if there were obvious clinical signs of infection. It should be noted that not all studies uniformly used the same signs and indeed some studies were not specific about criteria for clinical infection.

Figure 13. Comparison: Moist Vs non-moist dressings. Outcome: Clinical Infection present



The pooled result for moist wound healing products in comparison with non-moist products significantly favoured the moist products (Odds Ratio 0.33, 95% CI 0.12, 0.96). The large combined sample size and the degree of homogeneity strengthen the result.

Table 8: Moist compared to non-moist wound healing dressings for STSG donor sites: Presence of clinical infection, studies included in meta-analysis.

Study	Moist dressings	Non-moist dressings
Barnett et al. (1983a)	Tegaderm, Opsite	Fine mesh gauze
Basse et al. (1992)	Kaltostat	Jelonet
Hickerson et al. (1994)	Wound Contact Layer	Xeroform
Himel et al. (1998)	Ventex	Xeroform
Iregbulem (1983)	Opsite	Sofratulle
Madden et al. (1985)	Hydrocolloid	Fine mesh gauze
O'Donoghue et al. (1997)	Kaltostat with .25% Bupivacaine	Jelonet
Smith et al. (1994)	Hydrocolloid	Xeroform
Terren et al. (1993)	Eurothane, Comfeel Thin, Varihesive (DuoDERM)	Tulle Gras

Note;, where more than one moist product is listed individual study results were combined.

Additional studies not included in meta-analysis for this category

In all the additional studies there were no cases of infection for any treatments and controls. These studies could not be used in the meta-analysis however the effect of inclusion would be to reduce significance overall with regard to infection.

- Cihantimur, Kahveci et al. (1997) compared Kaltostat (n=40) with Jelonet (n=40).
- Cadier and Clarke (1996) compared Dermasorb (n=21) with Jelonet (n=21).
- Tan, Roberts et al. (1993) compared DuoDERM (n=30) with Scarlet Red (n=30).
- Sawada, Yotsuyanagi et al. (1990) compared Silicone gel sheet with OFLX (n=20) with Tulle Gras (n=10).
- Madden, Nolan et al. (1989) compared DuoDERM (n=10) with fine mesh gauze (n=10).

- Steenfors and Partoft (1997) compared DuoDERM combined with Sureskin (n=20), with Jelonet (n=10).
- Bilwani and Sheth (1988) compared Lyofoam (n=25) with Paraffin Gauze (n=25).

Overall summary for moist wound healing products in comparison to non- moist wound healing products.

There were sufficient studies of adequate quality to conduct meta-analysis for all outcomes for this comparison. The moist category of products was found to be superior for the outcomes of healing time, pain, and infection rate. In general the studies lacked homogeneity but this could be expected when considering the variety of products included within this broad category. To compensate for this lack of homogeneity a random effects model was used in meta-analysis where a broad range of moist wound healing products were pooled. Therefore the results are quite convincing in suggesting that moist wound healing products are superior to traditional non-moist products.

The following group of comparisons examine studies in which various generic moist wound healing products are compared to other treatments. This provides a more specific view of the individual generic moist products than is the case when pooling all the moist products together.

Comparison 2: Calcium alginates are compared with non-moist (non-biological) wound healing products in the management of STSG donor sites;

Note, biological products have not been included in this comparison, non-moist wound healing products, mainly gauze products (impregnated with ointment or without) of various types have been included.

Outcome 2A: Healing

In comparing performance of calcium alginates and non-moist wound healing dressings in relation to healing times, varying criteria were used including; Days to complete healing, number of wounds healed by day 8, or 10. Results relating to each of these criteria are presented below.

Days to complete healing, all studies required complete epithelial cover with dressing able to be removed without trauma

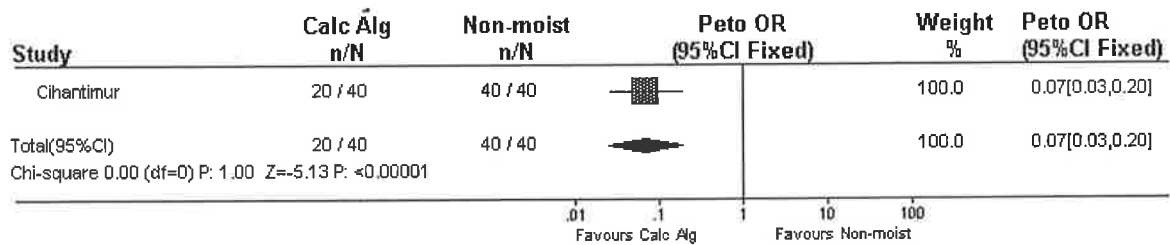
Meta-analysis not conducted due to insufficient studies and incomplete results

One study of acceptable design by Rives, Pannier et al. (1997) compared calcium alginate, mean days to healing 10 (n=34), with paraffin gauze, mean days to healing 11 (n=33). No standard deviations were provided and the author stated that healing times were 'comparable'. It was noted that the calcium alginate donors were able to be re-harvested earlier.

Donors not healed at removal of dressing on Day 8

Meta-analysis not conducted due to insufficient studies.

**Figure 14. Comparison: Calcium alginates Vs non-moist dressings.
Outcome: Not healed at day 8**



Cihantimur, Kahveci et al. (1997) compared Kaltostat (CA) with Jelonet and although only a single study the result was highly significant in favour of the calcium alginate.

Donors not healed at removal of dressing on Day 10

Meta-analysis 2 studies included (figure 15)

The studies used in the analysis were not homogenous and the result was not significant. Little can be drawn from this meta-analysis (Peto Odds Ratio 0.81, 95% CI 0.39, 1.68) (figure 15).

**Figure 15. Comparison: Calcium alginates Vs non-moist dressings.
Outcome: Not healed at day 10**

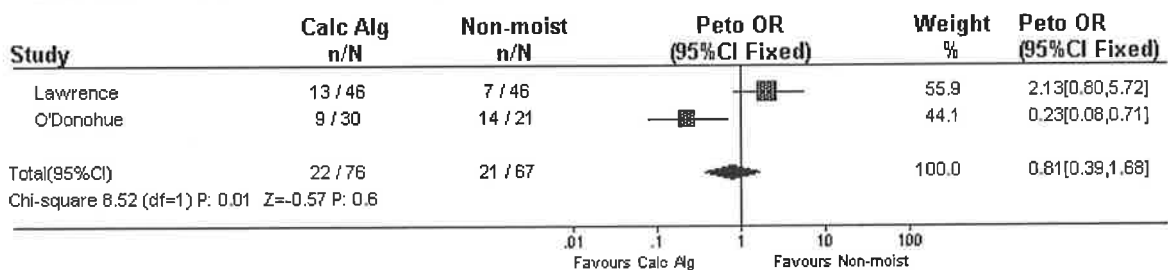


Table 9: Calcium alginate compared to other non-moist, non-biological dressings for STSG donor sites: Donor not healed at day 10, studies included in meta-analysis.

Study	Calcium alginates	Non-moist dressings
Lawrence & Blake (1991)	Kaltostat	Scarlet Red
O'Donoghue et al. (1997)	Kaltostat with .25% Bipuvicaine	Jelonet

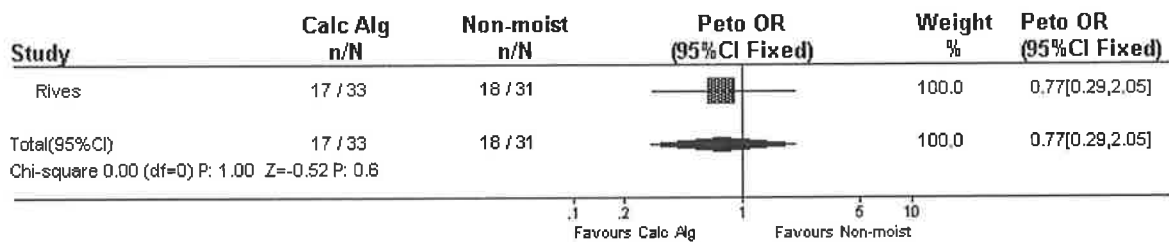
Outcome 2B: Pain

Patient requiring analgesia

Meta-analysis not conducted due to insufficient studies.

Figure 16. Comparison: Calcium alginates Vs non-moist dressings.

Outcome: Patient required analgesia



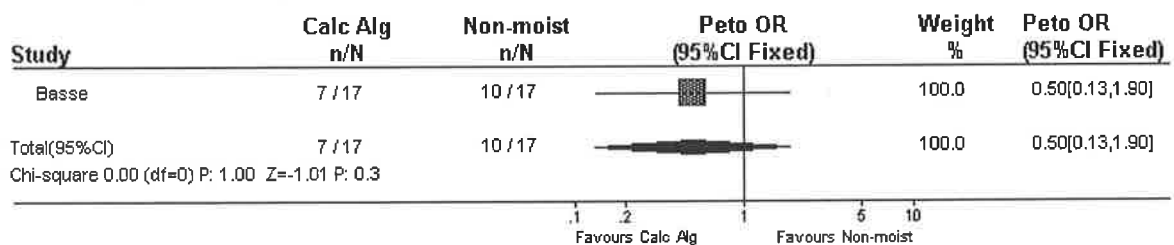
This single study by Rives, Pannier et al. (1997) showed no significant difference between the calcium alginate and the paraffin gauze dressings.

Dressings rated more painful than alternate dressing, only intra-individual studies included

Meta-analysis not conducted due to insufficient studies.

Figure 17. Comparison: Calcium alginates Vs non-moist dressings.

Outcome: Dressings rated as more painful



This single intra-individual study by Basse, Siim et al. (1992) whilst favouring the Kaltostat (CA) did not achieve a significant result compared with Jelonet.

Outcome 2C: Infection

Wound showing positive signs of clinical infection

Meta-analysis 2 studies included

Neither of the two studies demonstrated a significant difference of infection rates between treatments. The pooled analysis also failed to find a significant difference (Peto Odds Ratio 2.36, 95% CI 0.32, 17.45).

Figure 18. Comparison: Calcium alginates Vs non-moist dressings.
Outcome: Clinical infection present

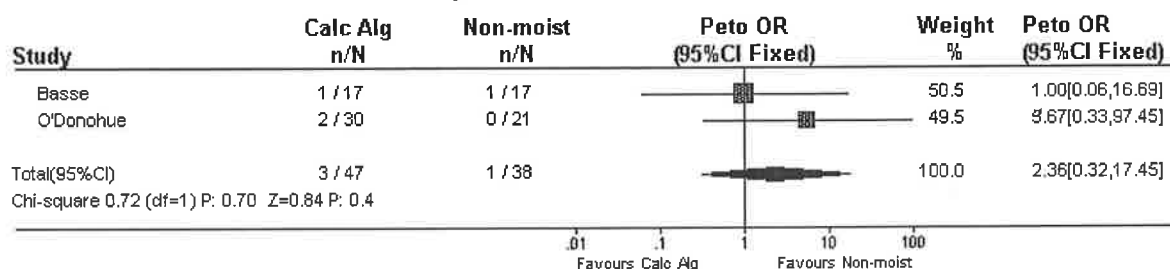


Table 10: Calcium Alginate compared to non-moist dressings for STSG donor sites: Clinical infection present, studies included in meta-analysis.

Study	Calcium alginates	Non-moist dressings
Basse et al. (1992)	Kaltostat	Jelonet
O'Donoghue et al. (1997)	Kaltostat with .25% Bipuvicaine	Jelonet

Additional studies not included in meta-analysis for this category

- An additional study by Cihantimur, Kahveci et al. (1997) compared infection rates between Kaltostat and Jelonet but was not able to be included in the meta-analysis as neither treatment nor control had any infections.

Overall summary for calcium alginates in comparison to non-moist wound healing products.

In comparing calcium alginates with non-moist wound healing products there were very few studies of adequate quality for any of the outcome categories. In considering healing there was only one outcome, healing at day 8, that demonstrated a statistical significance between treatment and control groups and this was the

result of only one study. In considering the outcomes of pain and infection no conclusions can be drawn, as there are insufficient studies to make a judgement.

Comparison 3: Calcium alginates compared with other moist wound healing products in the management of STSG donor sites;

Note; there were no studies comparing calcium alginates with other moist wound healing products that contained sufficient data for analysis.

One study by Porter (1991) did compare a calcium alginate (Kaltostat), with another moist wound healing product, a hydrocolloid (Granuflex E). Although the result favoured the hydrocolloid with mean days to healing of 10.0 compared with the calcium alginate 15.5 days. The results were unable to be used in analysis as part of the calcium alginate group was also dressed with Tulle Gras after the first dressing change. In addition some of the patients were also autografted and it is not clear if these patients were also included in the results.

Comparison 4: Comparison between calcium alginates in the management of STSG donor sites;

Note; there were no studies of comparisons between calcium alginates that contained sufficient data for analysis.

An additional attraction in using calcium alginates is the reported haemostatic qualities. Although none of the studies investigating the use of these products with STSG donors specifically measured outcomes of haemostasis many authors support this view (Cihantimur et al., 1997; Porter, 1991; Williams, 1994).

Comparison 5: Hydrocolloids compared with non-moist wound healing products in the management of STSG donor sites;

Outcome 5A: Healing

In comparing performance of hydrocolloids and non-moist wound healing dressings in relation to healing times, varying criteria were used including; Days to complete healing, number of wounds healed by day 7, 8, 9, 10, or 12. Results relating to each of these criteria are presented below.

Days to healing, all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis: 2 studies were included (figure 19)

The pooled result for days to complete healing significantly favoured the hydrocolloids (WMD -2.19 and 95% CI -2.89, -1.49) although it should be noted only two studies were included and they lacked homogeneity.

**Figure 19. Comparison: Hydrocolloids Vs non-moist dressings.
Outcome: days to complete healing**

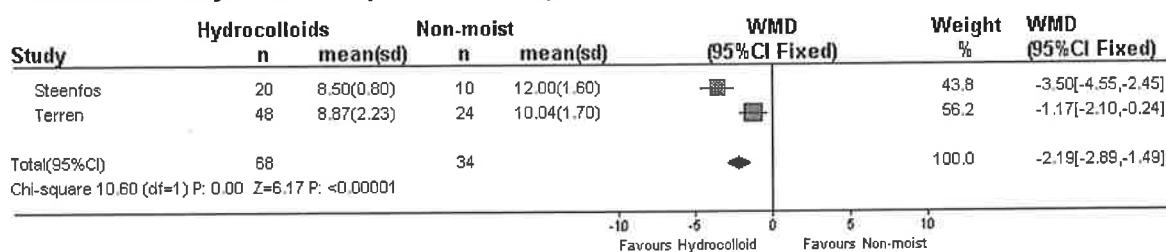


Table 11: Hydrocolloids compared to non-moist dressings for STSG donor sites: Days to complete healing, studies included in meta-analysis.

Study	Hydrocolloids	Non-moist dressings
Steenfos & Partoft (1997)	DuoDERM, Sureskin	Jelonet
Terren et al. (1993)	Comfeel Thin, Varihesive	Tulle Gras

Note;, where more than one moist product is listed individual study results were combined.

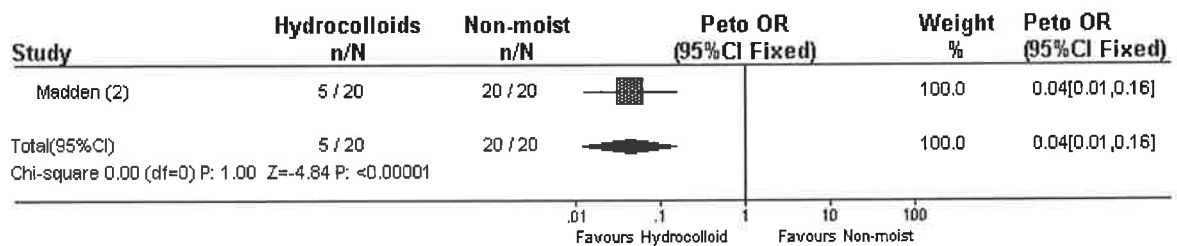
Additional studies not included in meta-analysis for this category

- Hickerson, Kealey et al. (1994) compared Wound Contact Layer (hydrocolloid), mean days to healing 7.9 (n=38), with Xeroform (non-moist), mean days to healing 10.2 (n=38). No standard deviations were provided however the results favoured the moist product (p<0.001).
- Cadier and Clarke (1996) compared Dermasorb (hydrocolloid) (n=21), with Jelonet (n=21) and healing times were noted to be shorter for the Dermasorb sites (p=0.0028).
- Feldman, Rogers et al. (1991) compared DuoDERM (hydrocolloid), mean days to healing 15.3 (n=10), to Xeroform, mean days to healing 10.46 (n=13). No standard deviations were provided but Xeroform was stated as significantly better with regard to healing.
- Mitra and Spears (1990) compared DuoDERM (hydrocolloid), mean days to healing 8.6 (n=33), to Xeroform, mean days to healing 13.6 (n=33). No standard deviations were provided but DuoDERM was stated as significantly better with regard to healing.
- Foyatier (1992) compared DuoDERM (hydrocolloid), mean days to healing 7.7 (n=34), to Tulle Gras, mean days to healing 13.0 (n=34). No standard deviations were provided but DuoDERM was stated as significantly better with regard to healing.

Donors not healed at Day 7

Meta-analysis not conducted due to insufficient studies.

**Figure 20. Comparison: Hydrocolloids Vs non-moist dressings.
Outcome: Not healed at day 7**



Madden, Finkelstein et al. (1985) compared a non-specified hydrocolloid with fine mesh gauze demonstrating a significant difference in donors healed at day 7 favouring the hydrocolloid.

Donors not healed at Day 8

Meta-analysis 2 studies included

Although neither study included in the meta-analysis provided a significant result both favoured the hydrocolloid. The combined result however did achieve a significant result in favour of the hydrocolloids (Peto Odds Ratio 0.19, 95% CI 0.05, 0.70) (figure 21).

**Figure 21. Comparison: Hydrocolloids Vs non-moist dressings.
Outcome: Not healed at day 8**

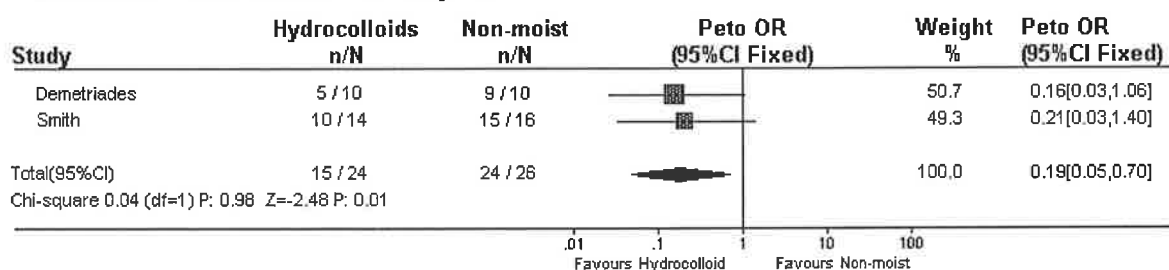


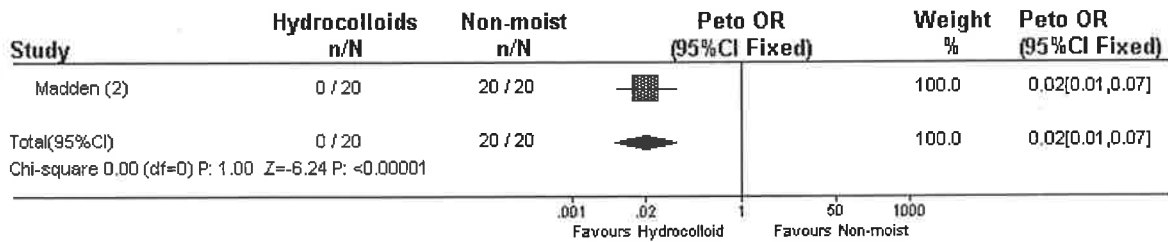
Table 12: Hydrocolloids compared to non-moist dressings for STSG donor sites: Donor not healed at day 8, studies included in meta-analysis.

Study	Hydrocolloids	Non-moist dressings
Demetriades & Psaras (1992)	Granuflex	Tulle Gras
Smith et al. (1994)	Hydrocolloid	Xeroform

Donors not healed at Day 9

Meta-analysis not conducted due to insufficient studies.

Figure 22. Comparison: Hydrocolloids Vs non-moist dressings.
Outcome: Not healed at day 9

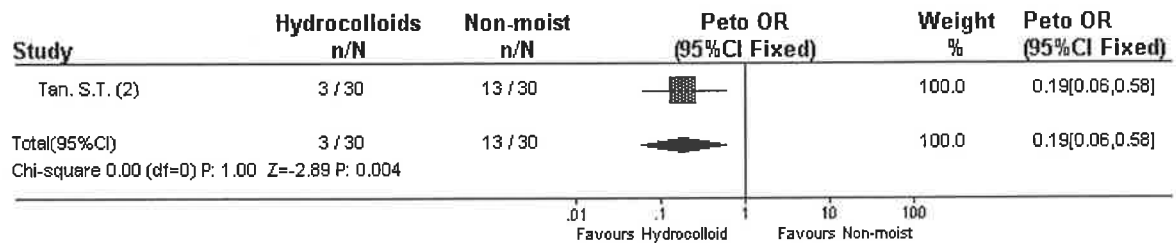


Madden, Finkelstein et al. (1985) compared a non-specified hydrocolloid with fine mesh gauze demonstrating a significant difference in donors healed at day 9 favouring the hydrocolloid.

Donors not healed at Day 10

Meta-analysis not conducted due to insufficient studies.

Figure 23. Comparison: Hydrocolloids Vs non-moist dressings.
Outcome: Not healed at day 10



Tan, Roberts et al. (1993) compared a DuoDERM (hydrocolloid) with Scarlet Red demonstrating a significant difference in donors healed at day 10 favouring the hydrocolloid.

Donors not healed at Day 12

Meta-analysis 2 studies included

The meta-analysis favoured the hydrocolloids (Peto Odds Ratio 0.24, 95% CI 0.07, 0.76). The result should be viewed with some caution, as the combined sample size is still small.

Figure 24. Comparison: Hydrocolloids Vs non-moist dressings.
Outcome: Not healed at day 12

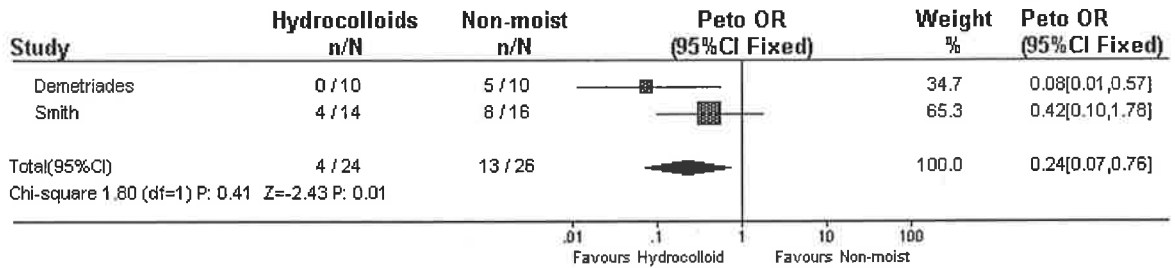


Table 13: Hydrocolloids compared to non-moist dressings for STSG donor sites: Donor not healed at day 12, studies included in meta-analysis.

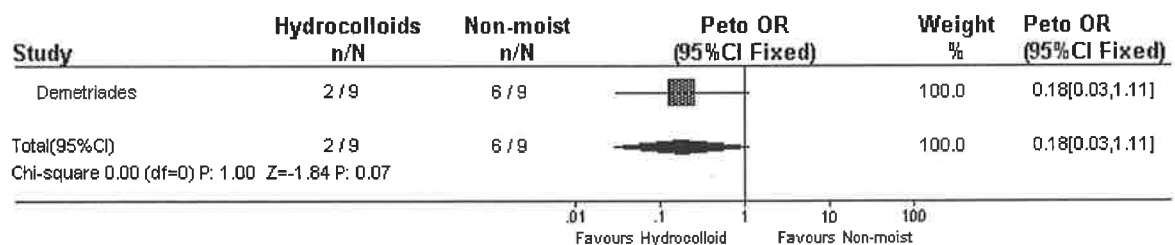
Study	Hydrocolloids	Non-moist dressings
Demetriades & Psaras (1992)	Granuflex	Tulle Gras
Smith et al. (1994)	Hydrocolloid	Xeroform

Outcome 5B: Pain

Dressing rated as more painful

Meta-analysis not conducted due to insufficient studies.

Figure 25. Comparison: Hydrocolloids Vs non-moist dressings.
Outcome: Dressing rated as more painful

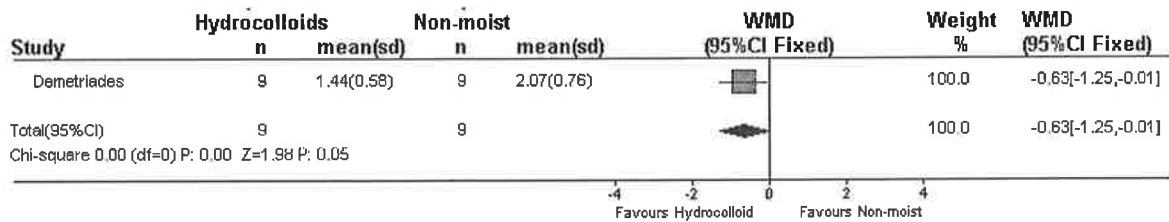


Demetriades and Psaras (1992) compared a Granuflex (hydrocolloid) with Tulle Gras demonstrating a significant difference in, dressing rated as more painful, favouring the hydrocolloid. Please note, in this study one patient rated both dressings as equal.

Overall pain rated 1-5, 5 is most painful

Meta-analysis not conducted due to insufficient studies.

Figure 26. Comparison: Hydrocolloids Vs non-moist dressings.
Outcome: Overall pain rated 1-5, 5 is most painful



In the same study as the previous comparison when the 1-5 overall pain scale was used in comparing Granuflex (hydrocolloid) and Tulle Gras the result significantly favoured the hydrocolloid however this single study had only a small sample (n=9) (Demetriades & Psaras, 1992).

Overall pain rating VAS 1-100, 100 is most painful.

Meta-analysis was not undertaken, only 1 study with acceptable data (figure 10)

Madden, Nolan et al. (1989) compared DuoDERM with fine mesh gauze. Although the result significantly favours the moist product caution should be taken, as the sample was quite small (n=15).

Additional studies not included in meta-analysis for the outcome pain

- Hickerson, Kealey et al. (1994) using a VAS of 1-10 with 10 most painful, compared Wound Contact Layer (hydrocolloid), mean pain score 2.94 (n=38), with Xeroform (non-moist), mean pain score 4.64 (n=38). No standard deviations were provided however the results favoured the hydrocolloid (p<0.001).
- Tan, Roberts et al. (1993) compared DuoDERM to Scarlet Red and pain scores were stated as significantly worse for Scarlet Red (p<0.05).
- Feldman, Rogers et al. (1991) compared DuoDERM, mean pain score 0.53 (n=10), to Xeroform, mean pain score 2.41 (n=13) No standard deviations were given however the result was stated as significantly favouring the hydrocolloid (p=0.01).

Outcome 5C: Infection

Wound showing positive signs of clinical infection

Meta-analysis 4 studies included

Although 3 of the 4 studies included did not achieve a significant result the combined result favoured the hydrocolloids significantly (Peto Odds Ratio 0.21, 95% CI 0.07, 0.65) with a considerable degree of homogeneity.

Figure 27. Comparison: Hydrocolloids Vs non-moist dressings.
Outcome: Clinical infection present

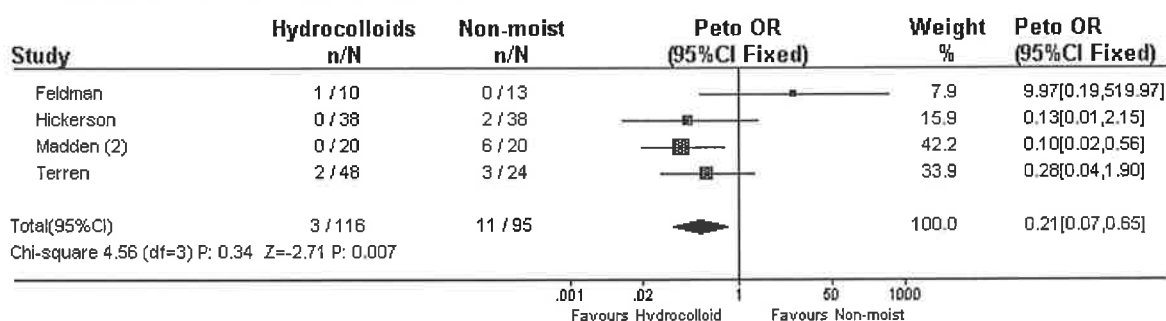


Table 14: Hydrocolloids compared to non-moist dressings for STSG donor sites: Clinical infection present, studies included in meta-analysis.

Study	Hydrocolloids	Non-moist dressings
Feldman et al. (1991)	DuoDERM	Xeroform
Hickerson et al. (1994)	Wound Contact Layer	Xeroform
Madden et al. (1985)	DuoDERM	Fine Mesh Gauze
Terren et al. (1993)	Comfeel Thin, Varihesive	Tulle Gras

Note;, where more than one moist product is listed individual study results were combined.

Additional studies not included in meta-analysis for this category

One additional study was unable to be included in the meta-analysis. For this study there were no reported infections.

- Steenfos and Partoft (1997) compared DuoDERM combined with Sureskin (n=20), with Jelonet (n=10).

Overall summary for hydrocolloids in comparison to non-moist wound healing products.

In considering healing there were three outcome categories; days to healing, healed at day 8, and healed at day 12 where meta-analysis was possible, although in each case only 2 studies were combined. The outcome categories of healed at day 7, 9, and 10 each had only one study of adequate quality. A statistically significant result was demonstrated for all of the healing categories where meta-analysis was possible. Only one study produced a result that significantly favoured the non-moist product (Feldman et al., 1991). Despite the relatively small number of studies this indicates with considerable confidence that hydrocolloids are superior to non-moist wound healing products in relation to healing. In considering the outcomes of pain it was not possible to combine any studies for meta-analysis however a number of single studies did significantly favour the hydrocolloids. Although the number of studies is small it can be stated with some confidence that hydrocolloids out-perform non-moist products in relation to pain. In relation to infection the meta-analysis significantly favoured the hydrocolloids.

Comparison 6: Hydrocolloids compared with other moist wound healing products in the management of STSG donor sites;

Outcome 6A: Healing

In comparing performance of hydrocolloids and other moist wound healing dressings in relation to healing times, the following criteria were used; Days to complete healing and number of wounds healed by day 10. Results relating to these criteria are presented below.

Days to complete healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis: 2 studies included

The pooled result in comparing healing of hydrocolloid treated donors and those with other moist wound healing products significantly favoured the hydrocolloids (WMD - 1.45 and 95% CI -2.17, -0.74) although it should be noted only two studies were included (figure 28).

Figure 28. Comparison: Hydrocolloids Vs other moist dressings.
Outcome: Days to complete healing

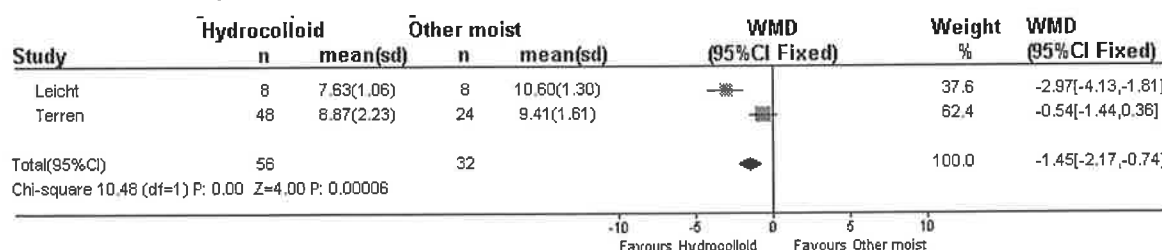


Table 15: Hydrocolloids compared to other moist dressings for STSG donor sites: Days to complete healing, studies included in meta-analysis.

Study	Hydrocolloids	Other moist dressings
Leicht, Siim, & Sorensen (1989)	DuoDERM	Omiderm
Terren et al. (1993)	Comfeel Thin, Varihesive	Eurothane

Note;, where more than one moist product is listed individual study results were combined.

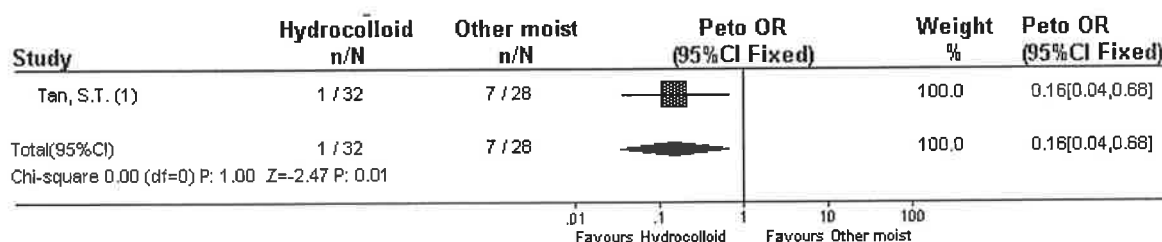
Additional study not included in meta-analysis for this category

- Rohrich and Pittman (1991) also compared DuoDERM, mean days to complete healing 11.78 (n=9), with Opsite, mean days to complete healing 8.23 (n=10).

Donors not healed at Day 10

Meta-analysis not conducted due to insufficient studies.

Figure 29. Comparison: Hydrocolloids Vs other moist dressings.
Outcome: Donors sites not healed by day 10



Tan, Roberts et al. (1993) compared DuoDERM with Zenoderm (hydrogel), the result significantly favouring the hydrocolloid. The results based on only one study must be viewed with caution.

Outcome 6B: Pain

No studies could be pooled for meta-analysis in comparing hydrocolloids with other moist wound healing products. The results of 3 individual studies are provided.

- Tan, Roberts et al. (1993) compared DuoDERM (n=32) with Zenoderm (hydrogel) (n=28) and the authors stated that intensity and duration of pain were similar for both treatments.
- Rohrich and Pittman (1991) compared DuoDERM (n=9) with Opsite (n=10) and it was noted that in using a VAS scale of 0-10, 10 being most painful, the result significantly favoured the hydrocolloid (< 0.001).
- Leicht, Siim et al. (1989) compared DuoDERM (n = 8) with Omiderm (n=8) and it was stated that the hydrocolloid was more comfortable after 1-2 days. No further detail was given.

Outcome 6C: Infection

Wound showing positive signs of clinical infection

Meta-analysis 2 studies included

The result of the meta-analysis shows no significant difference between the hydrocolloids and the other moist wound healing products in relation to infection (Peto Odds Ratio 0.67, 95% CI 0.09, 5.15).

Figure 30. Comparison: Hydrocolloids Vs other moist dressings.
Outcome: Clinical infection present

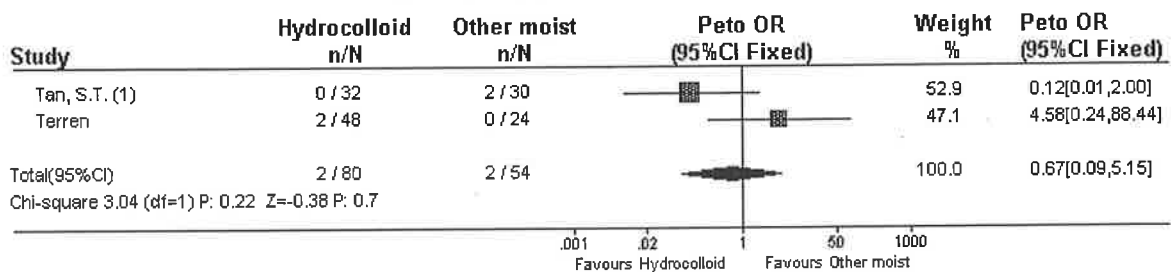


Table 16: Hydrocolloids compared to other moist dressings for STSG donor sites: Clinical infection present, studies included in meta-analysis.

Study	Hydrocolloids	Other moist dressings
Tan, Roberts, & Sinclair (1993)	DuoDERM	Zenoderm
Terren et al. (1993)	Comfeel Thin, Varihesive	Eurothane

Note;, where more than one moist product is listed individual study results were combined.

Additional studies not included in meta-analysis for this category

Two additional studies were unable to be included in the meta-analysis, as both studies reported no infections.

- Rohrich and Pittman (1991) compared DuoDERM (n=9) with Opsite (n=10).
- Leicht, Siim et al. (1989) compared DuoDERM (n=8) with Omiderm (n=8).

Overall summary for hydrocolloids in comparison to other moist wound healing products

The meta-analysis for days to healing included two studies that compared hydrocolloids with other moist products. In both studies the other products were polyurethane film sheets. The result significantly favoured the hydrocolloids although this result must be viewed with some caution. Only one study was examined for the category of 'numbers of donors healed by day 10' and this study significantly favoured the hydrocolloid over a hydrogel product. Although these results suggest that hydrocolloids are superior to polyurethane films and hydrogels in terms of healing this must be balanced against the limited number of studies available.

In considering the outcomes of pain and infection there is no evidence to suggest that hydrocolloids perform any better than other moist products.

Comparison 7: Comparison between different hydrocolloids in the management of STSG donor sites;

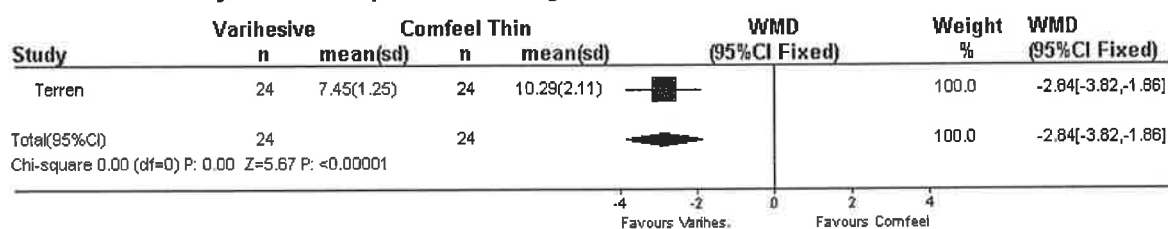
Outcome 7A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Varihesive compared to Comfeel Thin

Meta-analysis not conducted due to insufficient studies.

Figure 31. Comparison: Varihesive/DuoDERM Vs Comfeel Thin.
Outcome: Days to complete healing

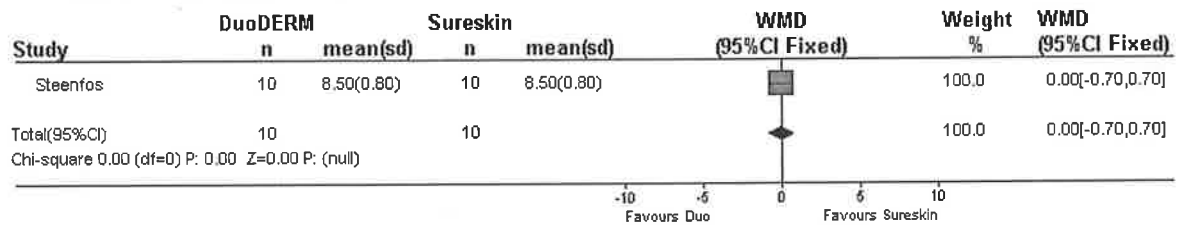


This study by Terren, Serna et al. (1993) compared Varihesive (DuoDERM) with Comfeel Thin. The result significantly favoured Varihesive however the sample size was quite small.

DuoDERM compared to Sureskin

Meta-analysis not conducted due to insufficient studies.

Figure 32. Comparison: DuoDERM Vs Sureskin. Outcome: Days to complete healing



This study by Steenfos and Partoft (1997) compared the two hydrocolloids, DuoDERM, and Sureskin. The results show no significant difference in healing between the two products.

Outcome 7B: Pain

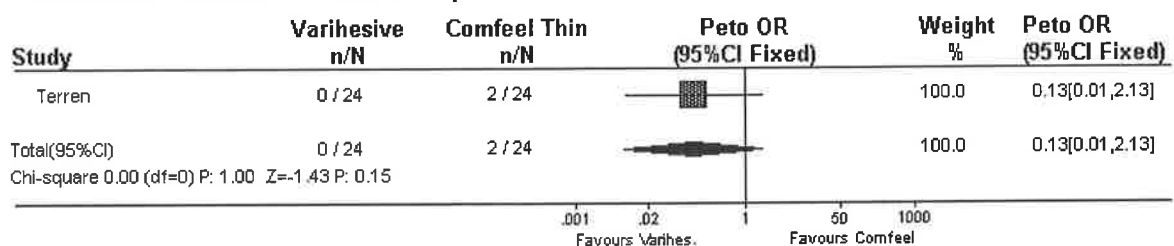
No studies were found that dealt specifically with the outcome of pain in relation to comparisons between hydrocolloids

Outcome 7C: Infection

Wound showing positive signs of clinical infection

Meta-analysis not conducted due to insufficient studies.

Figure 33. Comparison: Varihesive/DuoDERM Vs Comfeel Thin. Outcome: Clinical infection present



This study by Terren, Serna et al. (1993) comparing Varihesive (DuoDERM) with Comfeel Thin showed no significant difference between the two products in relation to infection.

Overall summary of comparisons between different hydrocolloid products.

There are a very limited number of studies comparing different hydrocolloids. Although one study revealed a significant result favouring Varihesive (DuoDERM) in terms of healing, no firm conclusions can be made about this comparison. Therefore there is little evidence to indicate that one hydrocolloid product is superior to another.

In considering the use of hydrocolloids a number of authors indicated that leakage and the need for additional dressings was a problem that would impact on treatment choice (Doherty, Lynch, & Noble, 1986; Rakel et al., 1998; Tan, Roberts, & Blake, 1993; Tan, Roberts, & Sinclair, 1993). In response to this problem several authors have indicated that they took the strategy of avoiding changing the hydrocolloids and reinforced them until healing resulting in use of only the one primary dressing (Foyatier, 1992; Madden et al., 1985; Madden et al., 1989).

Comparison 8: Polyurethane films compared to non-moist products in the management of STSG donor sites;

Outcome 8A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis 3 studies included

The three studies in this group lacked homogeneity although the combined result did significantly favour the polyurethane films (WMD -2.82 and 95% CI -3.58, -2.07).

Figure 34. Comparison: Polyurethane films Vs non-moist dressings. Outcome: Days to complete healing

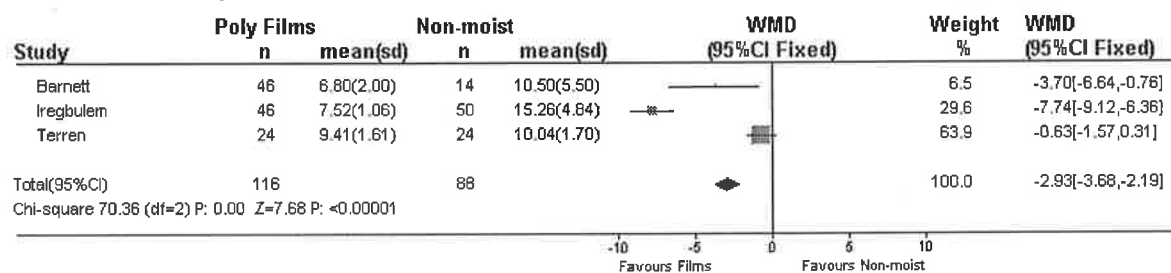


Table 17: Polyurethane films compared to non-moist dressings for STSG donor sites: Days to complete healing, studies included in meta-analysis.

Study	Polyurethane films	Non-moist dressings
Barnett et al. (1983a)	Tegaderm, Opsite	Fine Mesh Gauze
Iregbulem (1983)	Opsite	Sofratulle
Terren et al. (1993)	Eurothane	Tulle Gras

Note;, where more than one moist product is listed individual study results were combined.

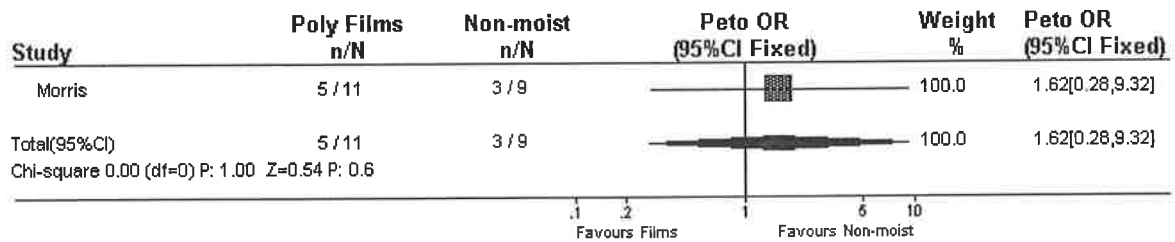
Additional studies not included in meta-analysis for this category

- Himel, Ratliff et al. (1998) compared Ventex (polyurethane film) with Xeroform. The Ventex treated wounds were said to have all healed by day 10 (n=10) and Xeroform wounds healed 10-14 days (n=10). No indication of statistical significance was given.

Donors not healed at Day 10

Meta-analysis not conducted due to insufficient studies.

Figure 35. Comparison: Polyurethane films Vs non-moist dressings.
Outcome: Donor sites not healed at day 10



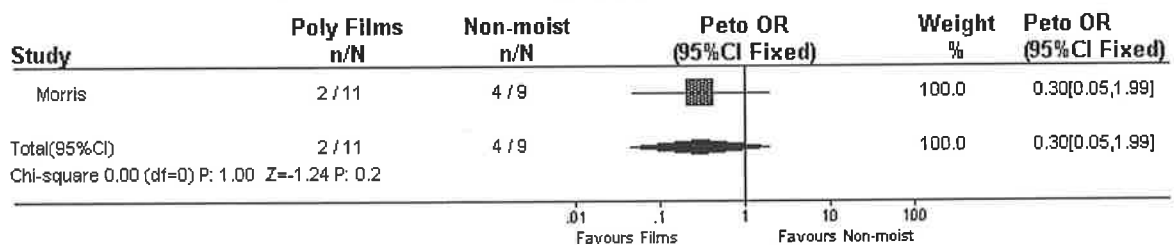
In relation to healing, Morris and Lamb (1990) compared Opsite to Scarlet Red and found no significant difference between dressings.

Outcome 8B: Pain

Dressing rated as more painful

Meta-analysis not conducted due to insufficient studies.

Figure 36. Comparison: Polyurethane films Vs non-moist dressings.
Outcome: Dressing rated as more painful

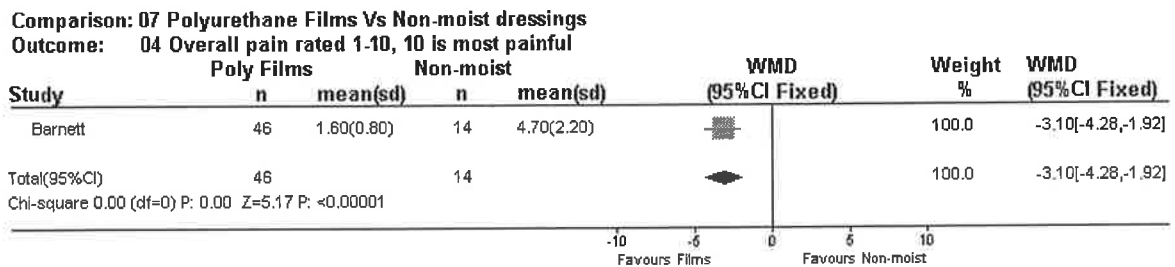


Morris and Lamb (1990) also compared Opsite to Scarlet Red in relation to pain. No significant difference was found.

Overall pain rated 1-10, 10 is most painful

Meta-analysis not conducted due to insufficient studies.

Figure 37. Comparison: Polyurethane films Vs non-moist dressings.
Outcome: Days to complete healing



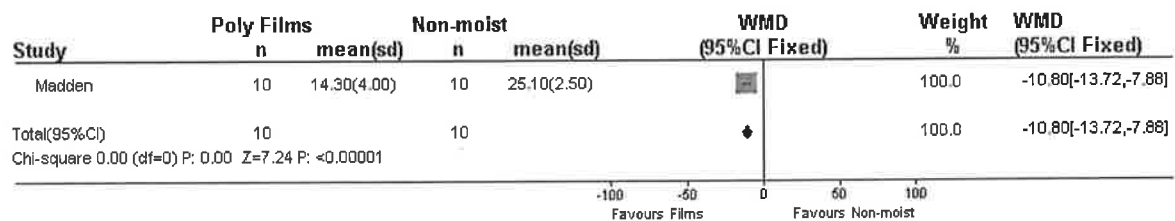
Barnett, Berkowitz et al. (1983a) compared two polyurethane films, Tegaderm and Opsite, with fine mesh gauze achieving a significant result in favour of the film dressings.

Overall pain rated 1-100, 100 is most painful

Meta-analysis not conducted due to insufficient studies.

Madden, Nolan et al. (1989) compared Opsite with fine mesh gauze achieving a significant result in favour of the film dressing (figure 38).

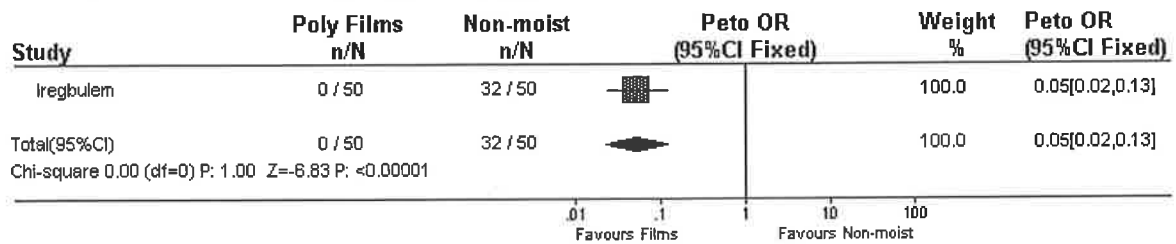
Figure 38. Comparison: Polyurethane films Vs non-moist dressings.
Outcome: Overall pain rated 1-100,100 is most painful



Patient requiring analgesia

Meta-analysis not conducted due to insufficient studies.

Figure 39. Comparison: Polyurethane films Vs non-moist dressings.
Outcome: Patient requiring analgesia

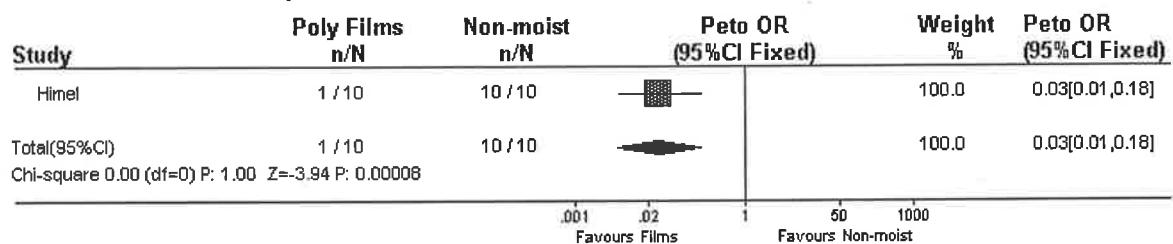


This study by Iregbulem (1983) compared Opsite with Sofratulle, achieving a significant result in favour of the film dressing.

Pain reported at 24hs

Meta-analysis not conducted due to insufficient studies.

Figure 40. Comparison: Polyurethane films Vs non-moist dressings.
Outcome: Pain reported at 24hrs



This study by Himel, Ratliff et al. (1998) compared Ventex (polyurethane film) with Xeroform, achieving a significant result in favour of the film dressing.

Outcome 8C: Infection

Wound showing positive signs of clinical infection

Meta-analysis: 4 studies included

The meta-analysis combined the results of four studies and demonstrated a significant result in favour of polyurethane films (Peto Odds Ratio 0.28, 95% CI 0.09, 0.91). The studies lacked strong homogeneity, however examining the individual studies gave no indication as to why this would be the case. The confidence intervals for the pooled result were narrow and the combined sample size large.

Figure 41. Comparison: Polyurethane films Vs non-moist dressings. Outcome: Clinical Infection present

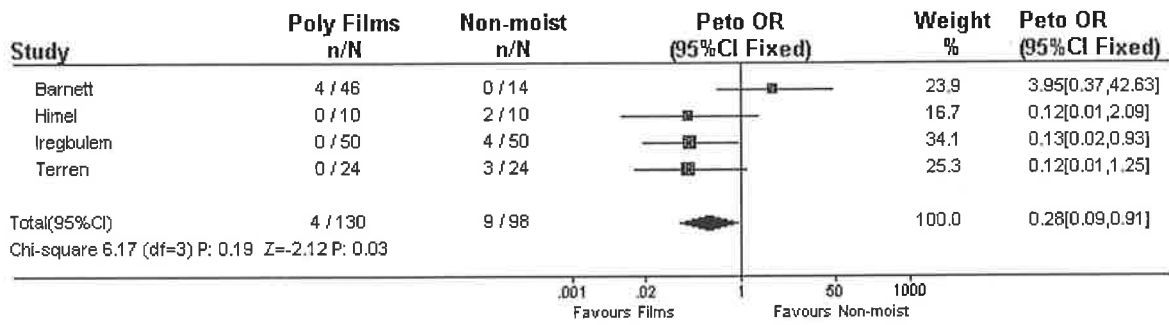


Table 18: Polyurethane films compared to non-moist dressings for STSG donor sites: Clinical infection present, studies included in meta-analysis.

Study	Polyurethane films	Non-moist dressings
Barnett et al. (1983a)	Tegaderm, Opsite	Fine Mesh Gauze
Himel et al. (1998)	Ventex	Xeroform
Iregbulem (1983)	Opsite	Sofratulle
Terren et al. (1993)	Eurothane	Tulle Gras

Note;, where more than one moist product is listed individual study results were combined.

Overall summary of comparisons between polyurethane films and non-moist wound healing products.

Meta-analysis was possible for the outcome categories of days to complete healing and clinical infection present. In both cases the result significantly favoured the polyurethane films. The studies in the meta-analysis for days to healing lacked homogeneity although additional individual studies supported the view that polyurethane films are superior to non-moist wound products with regard to healing. Of the four single studies that used outcomes related to pain three were significantly in favour of the polyurethane films, the other did not achieve a significant result. The samples for these studies are small and different criteria used to measure pain. It is difficult to draw any strong conclusions from these results.

Comparison 9: Polyurethane films compared to other moist products in the management of STSG donor sites;

Outcome 9A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis 2 studies included

The studies in this meta-analysis lacked homogeneity although no clear reason can be derived from the study reports. The pooled result did favour the other moist wound products (WMD 1.453 and 95% CI 0.740, 2.165).

Figure 42. Comparison: Polyurethane films Vs other moist dressings. Outcome: Days to complete healing

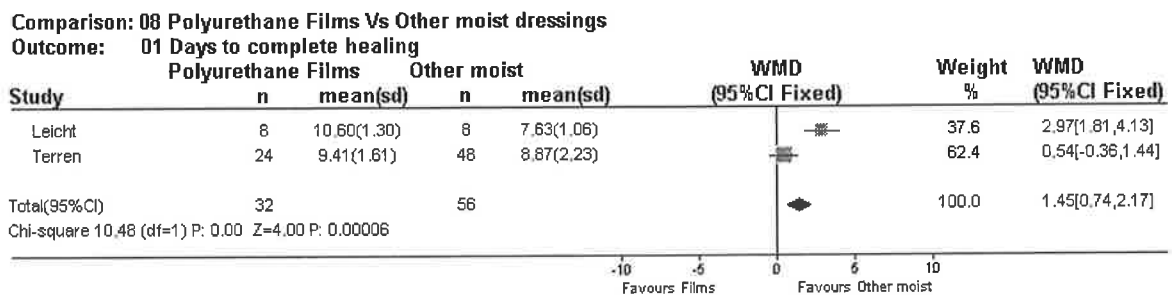


Table 19: Polyurethane films compared to other moist dressings for STSG donor sites: Days to complete healing, studies included in meta-analysis.

Study	Polyurethane films	Other moist dressings
Leicht et al. (1989)	Omiderm	DuoDERM
Terren et al. (1993)	Eurothane	Varihesive, Comfeel Thin

Note; where more than one moist product is listed individual study results were combined.

Additional study not included in meta-analysis for this category

- This study by Rohrich and Pittman (1991) also compared Opsite, mean days to complete healing 8.23 (n = 10), with DuoDERM, mean days to complete healing 11.78 (n = 9).

Outcome 9B: Pain

Two individual studies compared polyurethane films against other moist wound healing products. Insufficient data was presented to combine these studies.

- Rohrich and Pittman (1991) compared Opsite (film) (n=10) with DuoDERM (n=9) and it was noted that in using a VAS scale of 0-10, 10 being most painful, the result significantly favoured the other moist product (< 0.001).
- Leicht, Siim et al. (1989) compared Omiderm (n=8) with DuoDERM (n=8) and it was stated that the other moist product (DuoDERM) was more comfortable after 1-2 days. No further detail is given.

Outcome 9C: Infection

Two individual studies compared polyurethane films against other moist wound healing products. In both studies there were no cases of infection.

- Rohrich and Pittman (1991) compared Opsite (n=10) with DuoDERM (n=9).
- Leicht, Siim et al. (1989) compared Omiderm (n=8) with DuoDERM (n=8).

Overall summary of comparisons between polyurethane films and other moist wound healing products.

Meta-analysis was only possible for the outcome category of days to complete healing, the result significantly favouring other moist products. It should be noted that only two studies were included in the meta-analysis and additional studies did not strongly support the case for or against polyurethane films. As a result it is difficult to make any conclusions with regard to healing. No meta-analysis was possible for the outcomes of pain and infection. The single studies examined have small samples and it is difficult to draw any conclusions from these results.

Comparison 10: Comparisons between different polyurethane films in the management of STSG donor sites;

Outcome 10A: Healing

Meta-analysis not conducted due to insufficient studies.

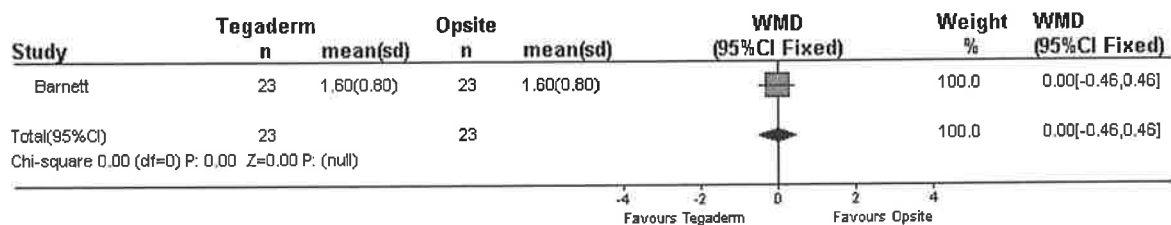
- One study by Barnett, Berkowitz et al. (1983a) compared two different polyurethane films, Tegaderm, mean days to complete healing 6.7 (n=23), and Opsite, mean days to complete healing 6.9 (n=23). No standard deviations were given and no comment was made with regard to significance.

Outcome 10B: Pain

Overall pain rated 1-10, 10 is most painful

Meta-analysis not conducted due to insufficient studies.

Figure 43. Comparison: Tegaderm Vs Opsite. Outcome: Overall pain rated 1-10, 10 is most painful



Barnett, Berkowitz et al. (1983a) compared Tegaderm (n = 23) to Opsite (n = 23). Scores for the two products of this small trial were identical.

Outcome 10C: Infection

Meta-analysis not conducted due to insufficient studies.

In the study by Barnett, Berkowitz et al. (1983a), Tegaderm (n = 23) was compared to Opsite (n = 23). There were two cases of reported infection in both groups.

Overall summary of comparisons between different polyurethane films.

Only one study was found of sufficient quality that compared two polyurethane films. This small study found no significant difference between the products with regard to healing, pain, or infection.

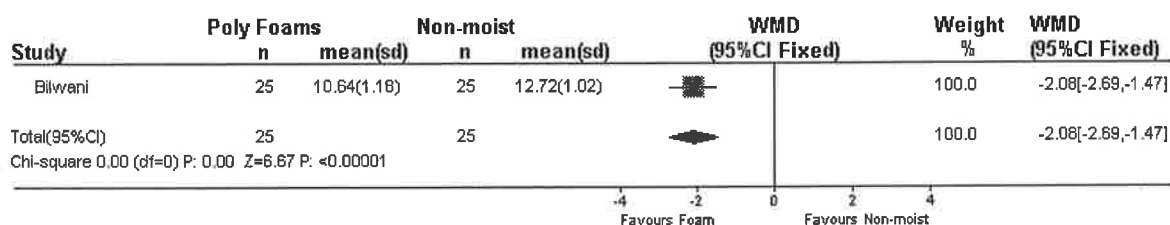
Comparison 11: Polyurethane foams compared to non-moist wound healing products in the management of STSG donor sites;

Outcome 11A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis not conducted due to insufficient studies.

Figure 44. Comparison: Polyurethane foams Vs non-moist dressings.
Outcome: Days to complete healing

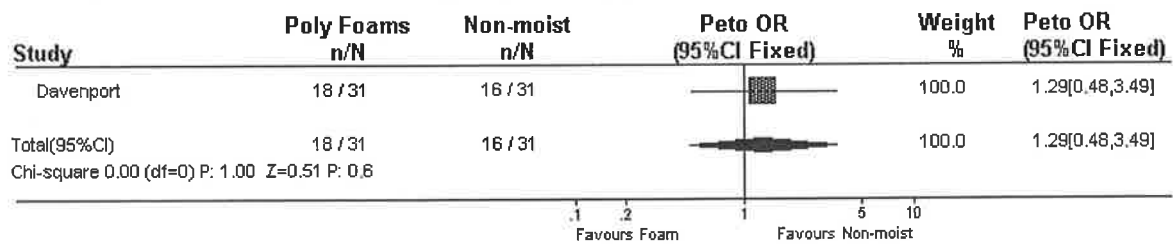


This study by Bilwani and Sheth (1988) compares Lyofoam (polyurethane foam) with paraffin gauze, the result significantly favouring the foam dressing with regard to healing.

Donors not healed at Day 8

Meta-analysis not conducted due to insufficient studies.

Figure 45. Comparison: Polyurethane foams Vs non-moist dressings.
Outcome: Donor sites not healed at day 8

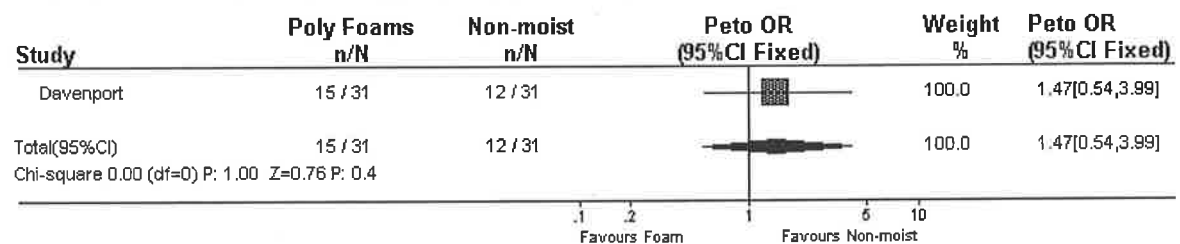


This study by Davenport, Dhooghe et al. (1977) compared Lyofoam with Tulle Gras showing no significant difference in healing at day 8.

Donors not healed at Day 10

Meta-analysis not conducted due to insufficient studies.

Figure 46. Comparison: Polyurethane foams Vs non-moist dressings.
Outcome: Donor sites not healed at day 10



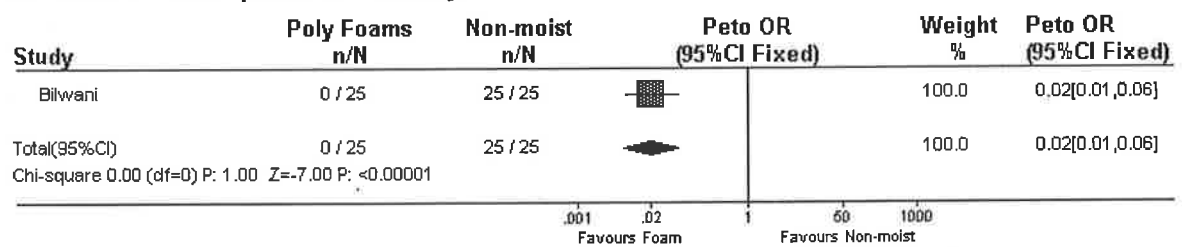
The study detailed in the previous comparison also compared healing rates at day 10 showing no significant difference between Lyofoam and Tulle Gras (Davenport et al., 1977).

Outcome 11B: Pain

Pain present initially

Meta-analysis not conducted due to insufficient studies.

Figure 47. Comparison: Polyurethane foams Vs non-moist dressings.
Outcome: Pain present initially

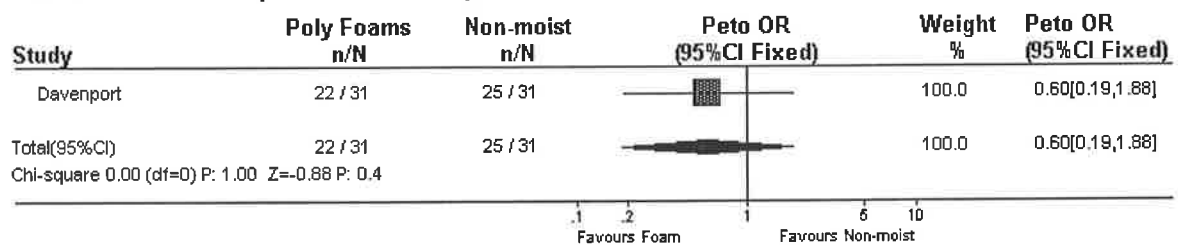


This study by Bilwani and Sheth (1988) compared Lyofoam with paraffin gauze, the result significantly favouring the foam dressing with regard to pain.

Pain present at day 8

Meta-analysis not conducted due to insufficient studies.

Figure 48. Comparison: Polyurethane foams Vs non-moist dressings.
Outcome: Pain present at day 8

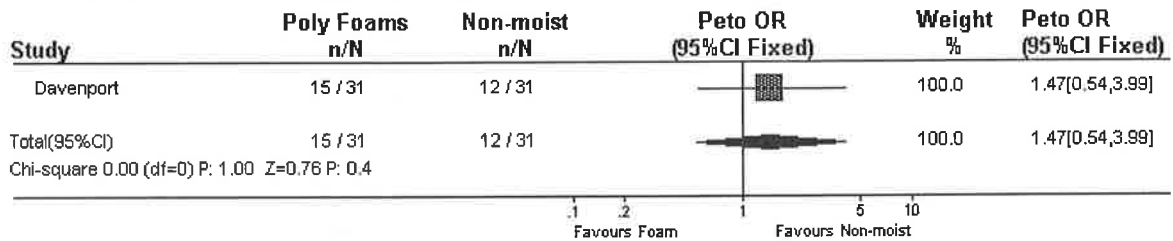


Davenport, Dhooghe et al. (1977) compared Lyofoam with Tulle Gras showing no significant difference in pain at day 8.

Pain present at day 10

Meta-analysis not conducted due to insufficient studies.

Figure 49. Comparison: Polyurethane foams Vs non-moist dressings.
Outcome: Pain present at day 10



The study by Davenport, Dhooghe et al. (1977) comparing Lyofoam with Tulle Gras also showed no significant difference in pain at day 10.

Outcome 11C: Infection

Meta-analysis not conducted due to insufficient studies.

Bilwani and Sheth (1988) compared Lyofoam (n=25) with Paraffin Gauze (n=25). There were no cases of reported infection in either group.

Overall summary of comparisons between polyurethane foams and non-moist wound healing products.

Only two studies were found of sufficient quality that compared two polyurethane foams and non-moist wound healing products. No meta-analyses were able to be performed for this comparison and the small number of studies and sample sizes prevent any strong conclusions, however there is an indication that in terms of days to complete healing and with regard to initial pain the foam dressings are favoured.

Comparison 12: Polyurethane foam dressings compared to other moist wound products in the management of STSG donor sites;

No studies of sufficient quality were found comparing polyurethane foam dressings with other moist products.

Comparison 13: Comparison between different polyurethane foam dressings in the management of STSG donor sites;

No studies were found comparing different polyurethane foam dressings in the management of split skin graft donor sites.

Comparison 14: Hydrogel sheet dressings compared to non-moist wound products in the management of STSG donor sites;

No studies of sufficient quality were found comparing hydrogel sheet dressings with non-moist wound products.

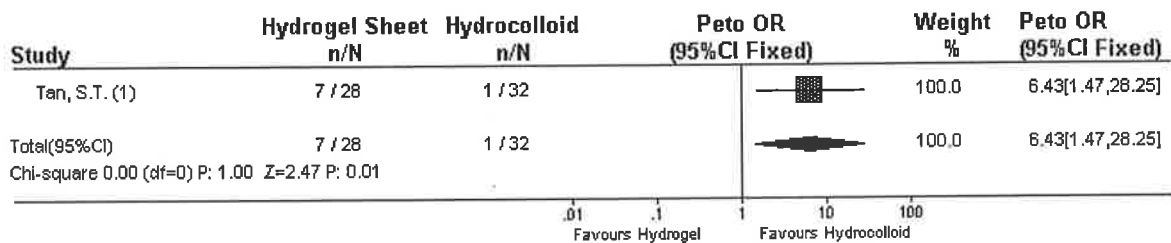
Comparison 15: Hydrogel sheet dressings compared to other moist wound products in the management of STSG donor sites;

Outcome 15A: Healing

Donors not healed at Day 10

Meta-analysis not conducted due to insufficient studies.

**Figure 50. Comparison: Hydrogel sheet dressing Vs hydrocolloid.
Outcome: Not healed at day 10**



Only one study involving hydrogel sheets was found. This study by Tan, Roberts et al. (1993) compared Zenoderm (hydrogel) and DuoDERM (other moist). In relation to healing of split skin donors at day 10 the result significantly favoured the other moist product.

The study did not provide sufficient data to make a comparison relating to pain or infection.

Comparison 16: Comparison between different hydrogel dressings in the management of STSG donor sites;

There were no studies found comparing different hydrogel products in the treatment of split skin graft donor sites

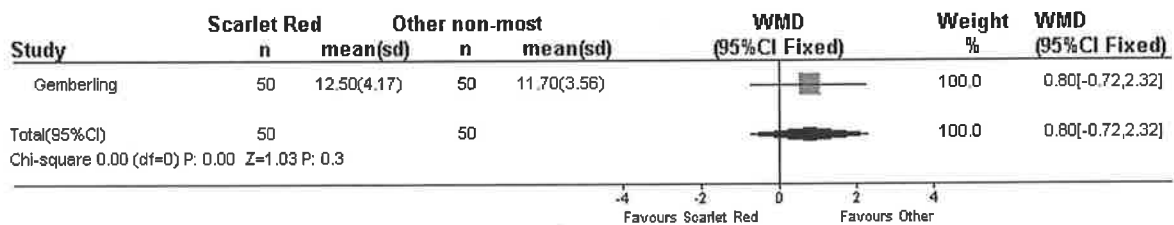
Comparison 17: Scarlet Red compared to other non-moist dressing products;

Outcome 17A: Healing

Days to healing, all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis not conducted due to insufficient studies.

**Figure 51. Comparison: Scarlet Red Vs other non-moist dressings.
Outcome: Days to complete healing**



The study by Gemberling, Miller, Caffee, & Zawacki (1976) compared Scarlet Red and Xeroform. There was no significant difference in healing rates between the two groups.

Additional studies not included in meta-analysis for this category

- One other study by Hirshowitz, Moscona, Dvir, Blank, & Mazor (1979) compared Scarlet Red (n=33), mean days to healing was 9.3 days, with Iodoplex (n=33), a slow release povidone based product, mean days to healing was 9.6 days. No standard deviations were provided although the authors indicated there was no statistical difference between groups.

Comparison 18: Scarlet Red compared to moist wound healing products;

Outcome 18A: Healing

Donors not healed at Day 10

Meta-analysis: 3 studies included.

The pooled result for the three studies concluded no significant difference between Scarlet Red and the moist products. The studies lacked homogeneity and it should be considered that no studies provided the outcome of days to complete healing which is a stronger indicator of performance.

Figure 52. Comparison: Scarlet Red Vs moist dressings. Outcome: Not healed at day 10

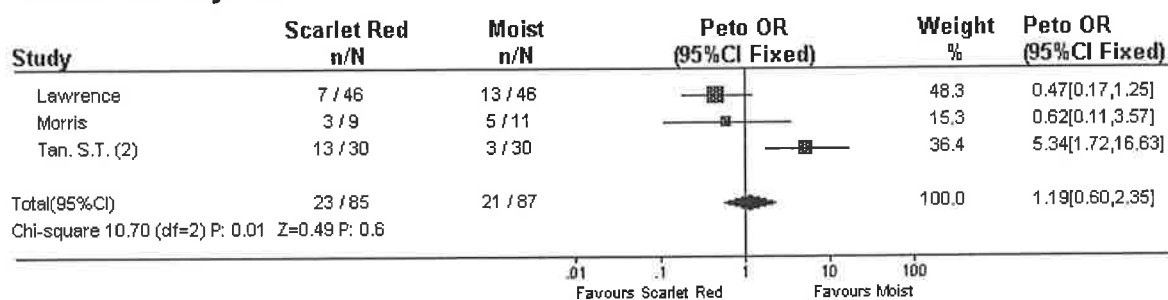


Table 20: Scarlet Red compared to moist wound dressings for STSG donor sites: Donor not healed at 10 days, studies included in meta-analysis.

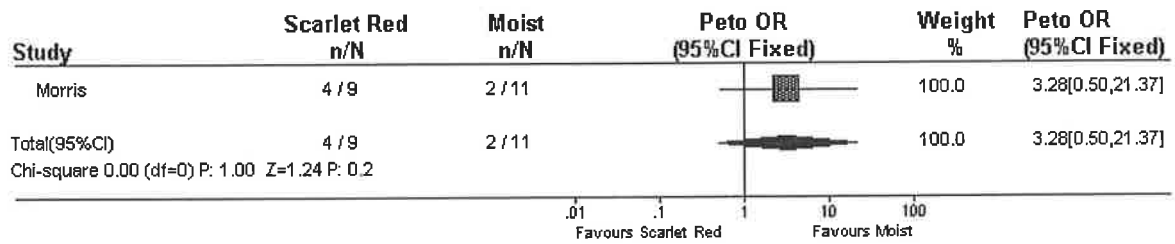
Study	Scarlet Red	Moist dressings
Lawrence & Blake (1991)	Scarlet Red	Kaltostat
Morris & Lamb (1990)	Scarlet Red	Opsite
Tan, Roberts, & Blake (1993)	Scarlet Red	DuoDERM

Outcome 18B: Pain

Dressing rated as more painful

Meta-analysis not conducted due to insufficient studies.

Figure 53. Comparison: Scarlet Red Vs moist dressings. Outcome: Dressing rated as more painful



This very small study by Morris and Lamb (1990) compared Scarlet Red with Opsite, the result showing no significant difference between the treatment and control groups.

Overall summary of comparisons between Scarlet Red, compared to other wound dressings.

Due to the small number of studies all with quite small samples it is difficult to draw any firm conclusions about the comparison between Scarlet Red and non-moist or moist wound healing products.

Comparison 19: Bovine or Porcine based dressings compared to non-moist wound healing products in the management of STSG donor sites;

Outcome 19A: Healing

Days to healing, all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis 2 studies included.

The two studies included in this meta-analysis had a high degree of homogeneity. The pooled result shows a statistically significant difference between the two groups favouring the porcine/bovine products (WMD -4.08 and 95% CI -4.75, -3.42) (figure 54).

Figure 54. Comparison: Porcine/bovine dressings Vs non-moist dressings. Outcome: Days to complete healing

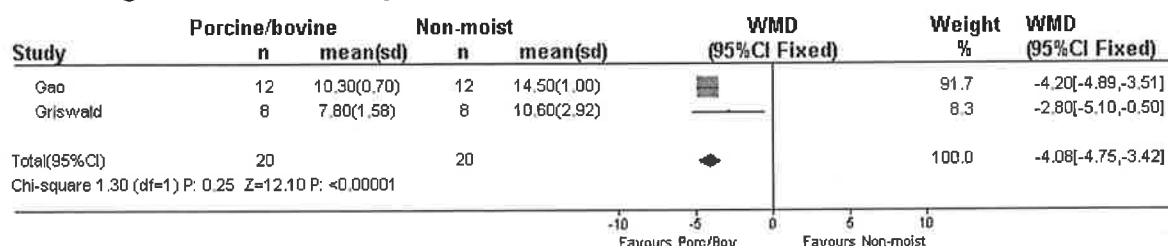


Table 21: Porcine or bovine dressings compared to non-moist dressings for STSG donor sites: Days to complete healing, studies included in meta-analysis.

Study	Porcine/ Bovine dressings	Non-moist dressings
Gao, Hao, Li, Im, & Spence (1992)	Porcine collagen sheet	Jelonet
Griswold et al. (1995)	SkinTemp (bovine)	Xeroform

Additional studies not included in meta-analysis for this category

- Sagi, Walter et al. (1986) compared Dermodress (bovine collagen sheet), healed between 15 and 20 days (n=10), with Furacin Gauze healed between 10 and 15 days (n=10). Statistical significance was not provided.

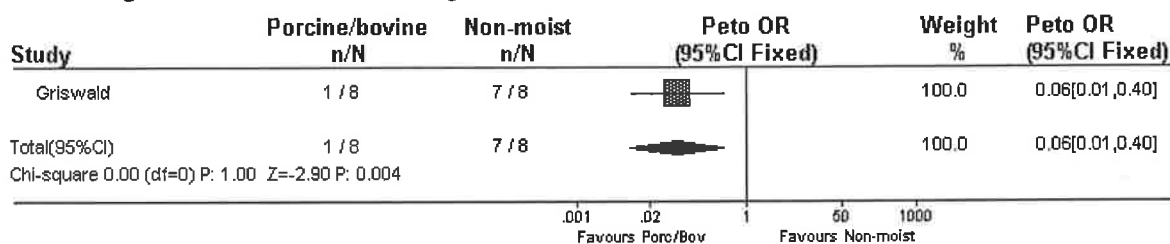
- Breach, Davies, & Yiacomettis (1979) compared lyophilised porcine epidermis (Corethium), and lyophilised bovine dermis with a control of Tulle Gras. No significant difference in healing was detected.
- Salisbury, Wilmore, Silverstein, & Pruitt (1973) compared porcine xenograft to fine mesh gauze and exposure. No significant difference in healing was detected.

Outcome 19B: Pain

Dressing rated as more painful

Meta-analysis not conducted due to insufficient studies.

Figure 55. Comparison: Porcine/bovine dressings Vs non-moist dressings. Outcome: Dressing rated as more painful



This study by Griswold, Cepica et al. (1995) compared SkinTemp (bovine dressing) with Xeroform, the result significantly favouring SkinTemp.

Additional studies not included in meta-analysis for this category

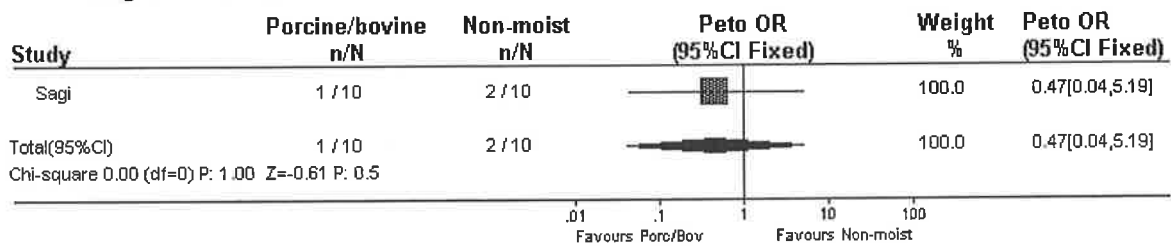
- Lyophilised porcine epidermis (Corethium), and lyophilised bovine dermis were compared with Tulle Gras in the study by Breach, Davies et al. (1979). Nine out of twenty patients complained of severe irritation under the bovine dressings and in some cases this irritation persisted for 8 weeks.

Outcome 19C: Infection

Wound showing positive signs of clinical infection

Meta-analysis not conducted due to insufficient studies.

Figure 56. Comparison: Porcine/bovine dressings Vs non-moist dressings. Outcome: Clinical infection present



This study by Sagi, Walter et al. (1986) compared Dermodress (bovine dressing) with Furacin Gauze, the result showed no significant difference between products.

Additional studies not included in meta-analysis for this category

- Gao, Hao et al. (1992) compared porcine collagen sheet (n=12) and Jelonet (n=12) with no infection in either group.
- The study by Griswold, Cepica et al. (1995) compared SkinTemp (bovine) (n=8) and Xeroform (n=8) with no infection in either group.

Overall summary of comparisons between porcine or bovine dressings compared to non-moist dressings.

Two studies combined in meta-analysis did demonstrate superior performance related to healing in comparison with non-moist products. This was in part balanced by a number of individual studies that showed no significant difference between the product groups. In one study there were a considerable number of patients had severe and persistent irritation where a bovine product was used. Another small study indicated bovine dressings are less painful than non-moist dressings.

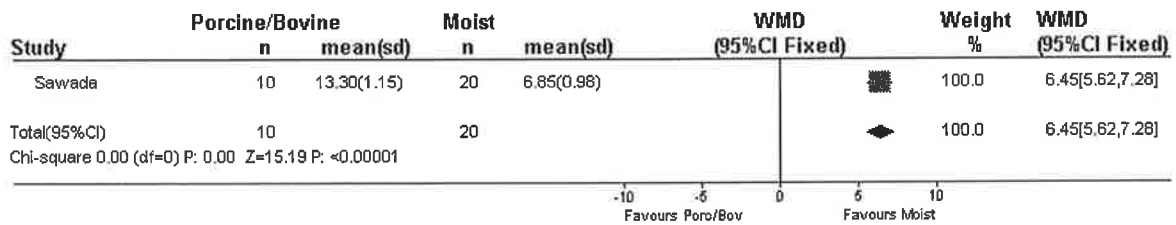
Comparison 20: Bovine or porcine based dressings compared to moist wound healing products in the management of STSG donor sites;

Outcome 20A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis not conducted due to insufficient studies.

Figure 57. Comparison: Porcine/bovine dressings Vs moist dressings. Outcome: Days to complete healing

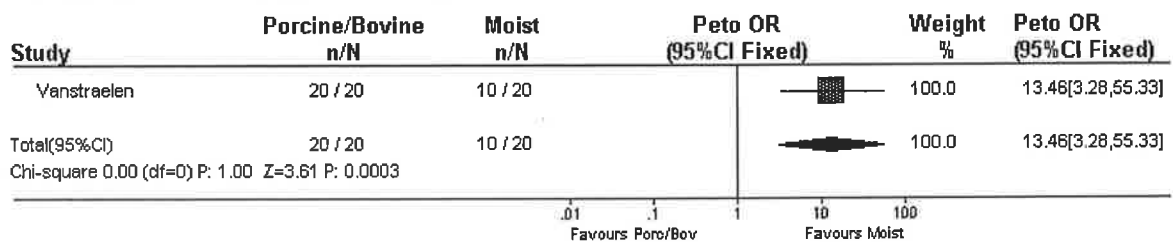


This study by Sawada, Yotsuyanagi et al. (1990) compared collagen sheet (unspecified) with a Silicone Gel Sheet with OFLX (Orfloxacin). Although only one small study the result significantly favoured the moist wound dressing.

Donors not healed at Day 7

Meta-analysis not conducted due to insufficient studies.

Figure 58. Comparison: Porcine/bovine dressings Vs moist dressings. Outcome: Not healed at day 7



This single study by Vanstraelen (1992) compared EZ Derm porcine xenograft with a calcium alginate, Kaltostat (moist). Although only one small study the result significantly favoured the moist wound dressing.

Outcome 20B: Pain

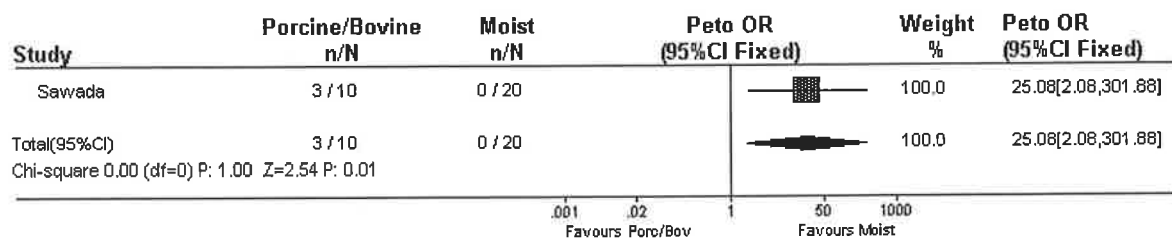
Neither of the two studies in this comparison addressed the issue of pain.

Outcome 20C: Infection

Wound showing positive signs of clinical infection

Meta-analysis not conducted due to insufficient studies.

Figure 59. Comparison: Porcine/bovine dressings Vs moist dressings.
Outcome: Clinical infection present



A collagen sheet (unspecified) was compared to a Silicone Gel Sheet with OFLX in a study by Sawada, Yotsuyanagi et al. (1990). The result was significant however, the confidence intervals were wide and the sample small.

Overall summary of comparisons between porcine or bovine dressings compared to moist wound dressings.

No meta-analysis was possible for this comparison. Only single studies were found that provided data to compare the two groups in relation to healing and infection. The only significant result favoured moist dressings for healing.

Comparison 21: Comparison between different bovine or porcine based products in the management of STSG donor sites;

Outcome 21A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis not conducted due to insufficient studies.

- The only study found of sufficient quality compared lyophilised porcine epidermis (Corethium) and lyophilised bovine dermis. The study by Breach, Davies et al. (1979) showed no significant difference in healing. No other details were provided.

Comparison 22: Growth factors compared to placebo in the management of STSG donor sites;

Outcome 22A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Recombinant human growth hormone rHGH 0.2mg/kg/day compared to placebo

Meta-analysis two studies included

Three almost identical studies comparing rHGH with placebo were pooled in this meta-analysis to demonstrate a significantly better healing rate for the growth factor group (WMD -1.847 and 95% CI -2.520, 1.174) (figure 60).

Figure 60. Comparison: rHGH 0.2mg/kg/day Vs placebo. Outcome: Days to complete healing

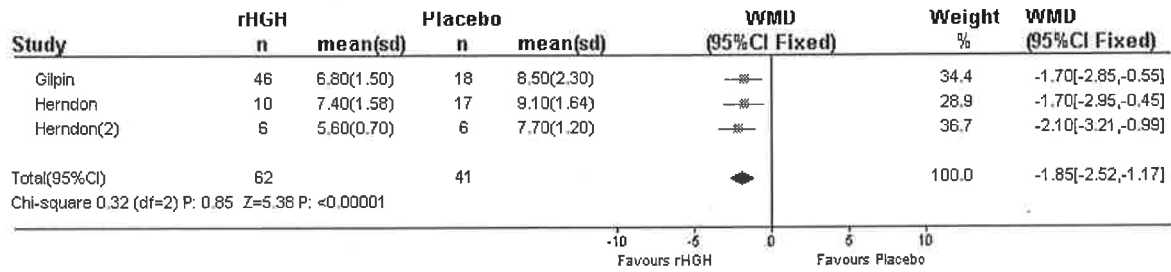


Table 22: Growth factor compared to control for STSG donor sites: Days to complete healing, studies included in meta-analysis.

Study	Growth Factor	Control
Gilpin, Barrow, Rutan, Broemeling, & Herndon (1994)	rHGH 0.2mg/kg/day with Scarlet Red dressing	Placebo with Scarlet Red
Herndon, Barrow, Kunkel, Broemeling, & Rutan (1990)	rHGH 0.2mg/kg/day with Scarlet Red dressing	Placebo with Scarlet Red
Herndon et al. (1995)	rHGH 0.2mg/kg/day with Scarlet Red dressing	Placebo with Scarlet Red

rHGH 10 mg SC/day compared to Placebo

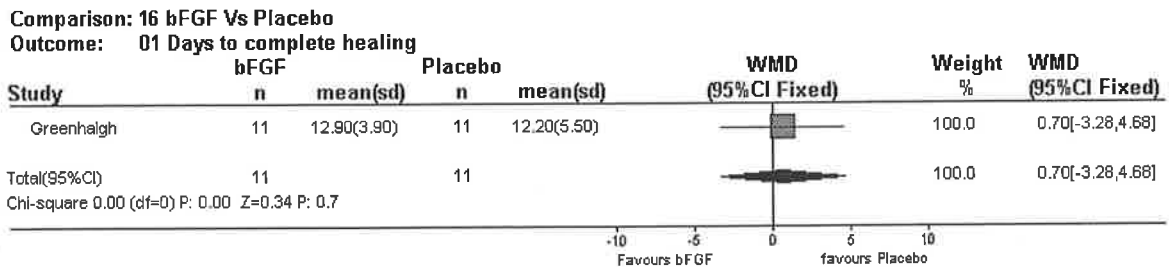
Meta-analysis not conducted due to insufficient studies.

In the 1989 study by Shernan, Demling et al. (1989) rHGH was administered daily to the treatment group, with a mean time to healing of 8±2.82 days (n=8), compared to placebo, mean time to healing of 10±0.0 days (n=9). This was a significantly better healing rate in favour of the growth hormone with p < 0.01.

Basic Fibroblast Growth Factor (bFGF) compared to Placebo

Meta-analysis not conducted due to insufficient studies.

Figure 61. Comparison: bFGF Vs placebo. Outcome: Days to complete healing



In a study by Greenhalgh and Rieman (1994) bFGF applied daily was compared to placebo with no significant difference between the two groups.

Recombinant human Epidermal Growth Factor (rEGF) compared to Placebo

Meta-analysis not conducted due to insufficient studies.

One study by Brown, Nanney et al. (1989) compared healing rates of rEGF applied daily in a vehicle of Silversulphadiazine with the control group receiving Silversulphadiazine only. The growth factor decreased healing time by 1.5 days compared to control ($p < 0.02$).

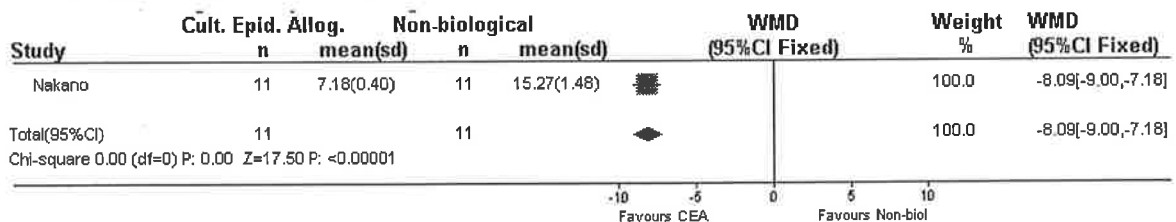
Comparison 23: Cultured epidermal allografts compared to non-biological dressings in the management of STSG donor sites;

Outcome 23A: Healing

Days to healing all studies required complete epithelial cover

Meta-analysis not conducted due to insufficient studies.

Figure 62. Comparison: Cultured epidermal allografts vs non-biological dressing. Outcome: Days to complete healing



This single study by Nakano (1990) compared cultured epidermal allografts with an unspecified ointment dressing with a very significant result favouring the allografts.

Additional studies not included in meta-analysis for this category

- This study by Teepe, Koch, & Haeseker (1993) compared cultured epidermal allografts, mean days to complete healing 6.2 (n=5), with Tulle Gras, mean days to complete healing 9.6 (n=5). Healing was said to be significantly faster for the allograft group (p=0.035), although no standard deviations were given.
- Phillips, Provan, Colbert, & Easley (1993) compared cultured epidermal allografts, mean days to complete healing 8.4 (n=10), with N-terface dressing (non-moist), mean days to complete healing 15.3 (n=10). Healing was said to be significantly faster for the allograft group (p<0.01) although no SDs were given.

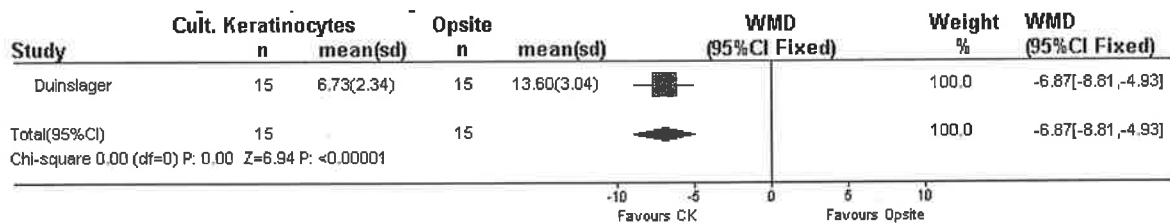
Comparison 24: Cultured allogeneic keratinocyte sheet compared to Opsite;

Outcome 24A: Healing

Days to healing all studies required complete epithelial cover.

Meta-analysis not conducted due to insufficient studies.

Figure 63. Comparison: Cultured allogeneic keratinocyte Vs Opsite. Outcome: Days to complete healing



This single study by Duinslaeger, Verbeken, Vanhalle, & Vanderkelen (1997) compared cultured allogeneic keratinocyte sheets with Opsite, with a very significant result favouring the keratinocyte sheets.

Comparison 25: Biobrane compared to non-moist wound dressings;

Outcome 25A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis: 2 studies included.

The two studies used in the meta-analysis are obviously not homogenous. The subjects in both studies were similar and the treatments administered in similar fashion. It is difficult from the study reports to explain the disparity between the two studies and so despite the strong result in favour of the Biobrane dressing this must be viewed with caution (figure 64).

Figure 64. Comparison: Biobrane Vs Scarlet Red. Outcome: Days to complete healing

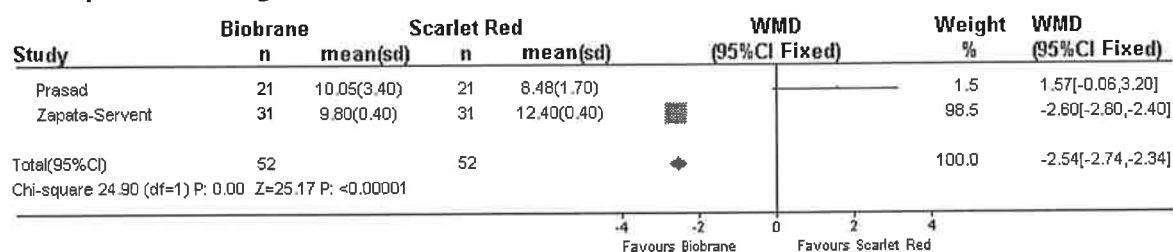


Table 23: Biobrane compared to Scarlet Red for STSG donor sites: Days to complete healing, studies included in meta-analysis.

Study	Biobrane	Non-moist
Prasad, Feller, & Thomson (1987)	Biobrane	Scarlet Red
Zapata Sirvent, Hansbrough, Carroll, Johnson, & Wakimoto (1985)	Biobrane	Scarlet Red

Additional study not included in meta-analysis for this category

- The study by Feldman, Rogers et al. (1991) compared Biobrane, mean days to complete healing 19 (n=7), with Xeroform, mean days to complete healing 10.46 (n=13). Healing was said to be significantly faster for the Xeroform group (p=0.023) although no SDs were given.

Outcome 25B: Pain

Meta-analysis not conducted due to insufficient studies.

Additional studies not included in meta-analysis for this category

- In the study by Prasad, Feller et al. (1987) comparing Biobrane and Scarlet Red, 11/21 patients stated that Biobrane was the preferred dressing with regard to pain, 5/21 patients preferred the Scarlet Red dressing and 5/21 were undecided.
- Although specific rates of pain are not provided, the study by Zapata Sirvent, Hansbrough et al. (1985) indicated that the Biobrane dressing (n=31) was significantly more comfortable than the Scarlet Red control (n=31) (p<0.05).
- The study by Feldman, Rogers et al. (1991) compared Biobrane, mean pain score 1.44 (VAS 1-10, 10 most painful, n=7) with Xeroform, mean pain score 2.41 (n=13), although no standard deviations or indications of significance levels were given.

Outcome 25C: Infection

Meta-analysis not conducted due to insufficient studies.

Additional studies not included in meta-analysis for this category

- The study by Feldman, Rogers et al. (1991) compared Biobrane, with an infection rate of 2/7 (n=7), with no infection in the Xeroform group (n=13). No indication of significance was given.

Overall summary of comparisons between Biobrane compared to non-moist wound dressings.

Due to the small number of studies all with quite small samples it is difficult to draw any firm conclusions about the comparison between Biobrane and non-moist products. There is a suggestion that Biobrane is superior in relation to pain although no meta-analysis was possible.

Comparison 26: Biobrane compared to moist wound dressings;

Outcome 26A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis not conducted due to insufficient studies.

Additional studies not included in meta-analysis for this category

- The study by Feldman, Rogers et al. (1991) compared Biobrane, mean days to complete healing 19 (n=7), with DuoDERM, mean days to complete healing 15.3 (n=10). No SDs were given and there was no indication the result was significant.

Outcome 26B: Pain

Meta-analysis not conducted due to insufficient studies.

Additional studies not included in meta-analysis for this category

- The study by Feldman, Rogers et al. (1991) compared Biobrane, mean pain score 1.44, VAS 1-10, 10 most painful (n=7), with DuoDERM, mean pain score 0.53 (n=10), although no SD or indications of significance levels were given.

Outcome 26C: Infection

Meta-analysis not conducted due to insufficient studies.

Additional studies not included in meta-analysis for this category

- The study by Feldman, Rogers et al. (1991) compared Biobrane, infection rate of 2/7, with DuoDERM infection rate of 1/10, no indication of significance was given.

Overall summary of comparisons between Biobrane compared to moist wound dressings.

Due to the inclusion of only one small study it is difficult to draw any firm conclusions about the comparison between Biobrane and moist products.

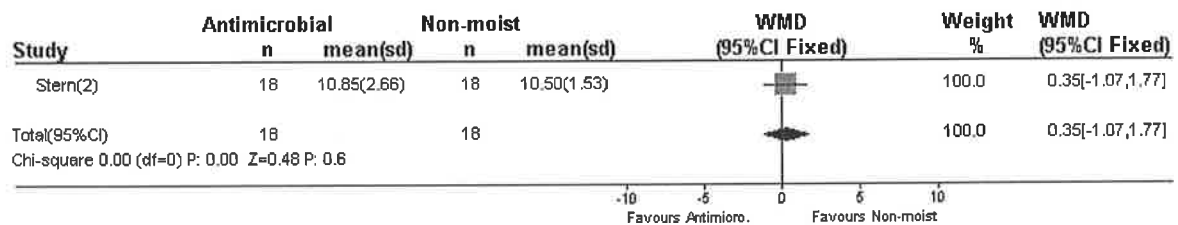
Comparison 27: Antimicrobials compared to non-moist wound healing products;

Outcome 27A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis not conducted due to insufficient studies.

Figure 65. Comparison: Antimicrobials Vs non-moist dressings.
Outcome: Days to complete healing



Stern (1989) compared Silversulphadiazine to Tulle Gras with no significant difference in healing between treatment and control.

Additional studies not included in meta-analysis for this category

- This study by Johansen and Sorensen (1972) compared Fucidin Gauze (Fucidin Sodium 2% impregnated gauze), n=93, mean days to healing was 10.6 days, with a range of non-moist wound products including;

Trex (silicone treated gauze, n=15, mean days to healing was 12.7 days), Haemodan (Andrenone impregnated gauze, n=16, mean days to healing was 12.9 days), Carbonet (polyethylene glycole impregnated gauze, n=21, mean days to healing was 13.2 days), Jelonet (n=18, mean days to healing was 10.1 days), Furazin Gauze (Nitrofurazon 0.2% impregnated gauze, n=11, mean days to healing was 12.6 days), and exposure without dressing (n=12, mean days to healing was 12.3 days).

The result was that there was no significant difference in healing between Fucidin and Jelonet.

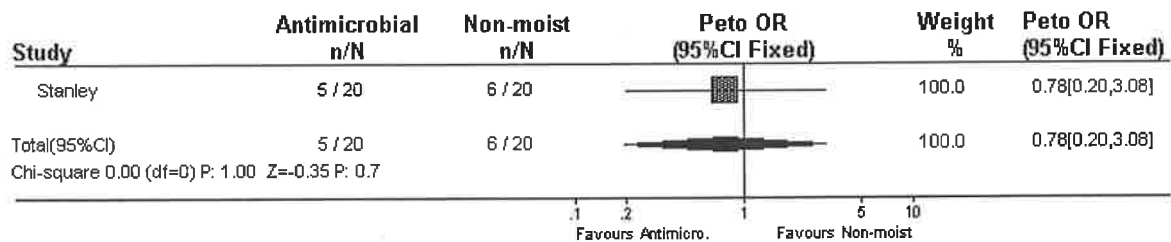
- One other study by Hirshowitz, et al. (1979) compared Iodoplex (n=33), a slow release povidine based product, mean days to healing was 9.6 days, with Scarlet Red (n=33), mean days to healing was 9.3 days. No standard deviations were

provided although the authors indicated there was no statistical difference between groups.

Donors not healed at Day 10

Meta-analysis not conducted due to insufficient studies.

Figure 66. Comparison: Antimicrobials Vs non-moist dressings.
Outcome: Not healed at day 10



The study by Stanley, Emerson, & Daley (1988) compared Jelonet and Whitehead's Varnish (compound iodoform paint) with plain Jelonet. There was no significant difference between treatment and control.

Comparison 28: Retention Tape Dressings;

Meta-analysis not conducted due to insufficient studies.

Only one paper was found that provided specific information regarding the use of retention tape dressings such as Mefix, Fixomull, and Hypafix in the management of STSG donors. No trial was reported but Giele (1997) indicated that they found retention tape dressings to be inexpensive and satisfactory in terms of comfort. No information about healing times was provided.

Comparison 29: Meshed split skin graft compared to paraffin gauze;

Outcome 29A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis not conducted due to insufficient studies.

One study by Fatah and Ward (1984) compared healing of donors in 20 patients where one half of the donor was grafted with meshed skin and the other treated with paraffin impregnated gauze. All grafted areas were healed by day 10 whilst the control areas experienced significant delays in healing.

Comparison 30: Beeswax compared to non-moist wound healing products;

Outcome 30A: Healing

Days to complete healing

Meta-analysis not conducted due to insufficient studies.

This single study by Robinson, Cawthorne et al. (1983), that was excluded on methodological grounds, divided a group of 50 patients to receive either a paraffin gauze (n=25) donor dressing or a dressing of 15% beeswax/85% liquid paraffin dressing (n=25). There was no indication that any randomisation was used and there was no intra-individual control. No difference was found in healing rates.

Comparison 31: Phenytoin compared with Opsite and compared with Soframycin;

Outcome 31A: Healing

Days to complete healing

Meta-analysis not conducted due to insufficient studies.

This single study by Yadav, Singhvi, Kumar, & Garg (1993), that was excluded on methodological grounds, of 60 patients, divided the sample into three groups based on 'matching wound size and age'. No other information was provided with regard to assignment. One group was treated with topical Phenytoin and dressed with paraffin gauze (n=30), with no indication of dosage given. The two other groups had either Opsite (n=15) or Soframycin (n=15). The Phenytoin group had a mean time to healing of 6.2 ± 1.6 , the Opsite group, 8.6 ± 2.2 , and the Soframycin group 12.6 ± 3.4 . The result was stated as significantly favouring the Phenytoin group $p < 0.001$.

Comparison 32: Amniotic membrane compared with antibiotic impregnated gauze;

Outcome 32A: Healing

Meta-analysis not conducted due to insufficient studies.

This study by Waikakul, Chumniprasas, Setasubun, & Vajaradul (1990), excluded on methodological grounds, compared freeze-dried amniotic membrane (n=65), with an unspecified antibiotic impregnated gauze (n=65). The author stated there was no significant difference between the products in relation to healing, $p > 0.2$.

Comparison 33: Asiaticoside compared with placebo;

Outcome 33A: Healing

Meta-analysis not conducted due to insufficient studies.

A single study by O'Keeffe (1974), excluded on methodological grounds, compared 2% Asiaticoside powder (n=26) with a placebo powder of magnesium stearate and talc (n=26). The rate of healing in both groups was said to be identical.

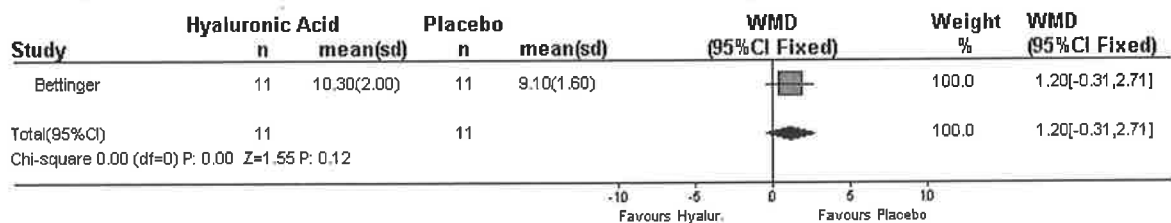
Comparison 34: Hyaluronic acid compared with 100% glycerin;

Outcome 34A: Healing

Days to 95% healing

Meta-analysis not conducted due to insufficient studies.

Figure 67. Comparison: Hyaluronic acid Vs placebo. Outcome: Days to complete healing



Bettinger, Mast, & Gore (1996) compared the topical application of 0.5ml of 1.5% hyaluronic acid covered with Tegaderm (n=11), and 100% Glycerin and Tegaderm (n=11) as placebo. The authors stated that hyaluronic acid significantly impeded healing compared to the control.

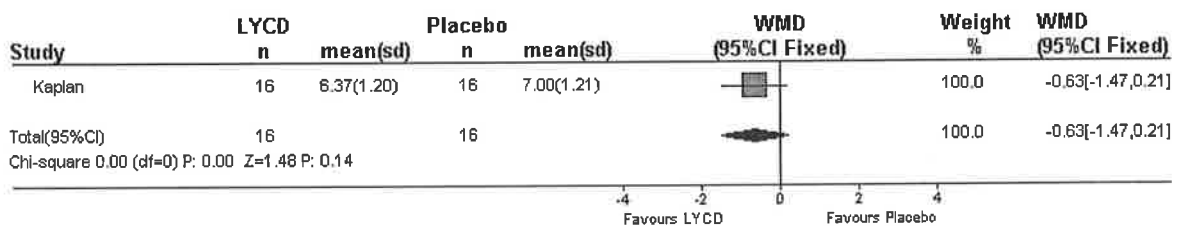
Comparison 35: Live yeast cell derivative compared to placebo;

Outcome 35A: Healing

Days to healing all studies required complete epithelial cover with dressing able to be removed without trauma

Meta-analysis not conducted due to insufficient studies.

Figure 68. Comparison: Live yeast cell derivative Vs placebo.
Outcome: Days to complete healing



Only one study was found for this comparison and it did not find a significant difference between the treatment and control group (Kaplan, 1984).

Comparison 36: Nobecutane spray;

Outcome 36A: Healing

Meta-analysis not conducted due to insufficient studies.

The study by Brodovsky, Dagan, & Bassatt (1986), that was excluded as it did not meet the inclusion criteria, was conducted on 50 patients without comparison. Nobecutane spray (containing an acrylic resin in an organic solvent) was applied to the donors forming an elastic film. The authors stated that healing was achieved in 7-10 days without complication.

Comparison 37: Calcium alginate compared with calcium alginate and Bupivacaine;

Outcome 37A: Pain

Pain at day 1, 2, and 3

Meta-analysis not conducted due to insufficient studies.

A single study by Butler, Eadie, Lawlor, Edwards, & McHugh (1993) compared calcium alginate (n=15), with calcium alginate soaked in Bupivacaine 0.5% (n=13). Using a pain scale of 0-10 with 10 the most painful, pain was said to be significantly lower at days 1 and 2 for the Bupivacaine group, $p < 0.04$. At day three there was no significant difference in pain levels.

Interventions relating to the management of the infected STSG donor site

No studies of clinical trials that dealt specifically with the alternative treatments of infected donor sites were found. A number of the studies included in the analysis examined anti-microbial products but these were used on new donors and not on infected wounds.

A wider search revealed a number of papers dealing with the use of antimicrobials and burns. It is logical that the evidence relating to antimicrobials and their use in managing infected superficial burns has been extrapolated to donor sites. No formal analysis has been done of these results as this was beyond the objectives of this review, however the following brief summary is provided as background information.

Many antimicrobials have been used in the management of burns and infected donors, examples include Silver Nitrate, acetic acid, Sulfamylon, Betadine, Gentamycin, Furacin, and Silversulphadiazine (Fox, 1977; Hollinworth, 1997; Sinha, Agarwal, & Agarwal, 1997; Steen, 1993). Although the management of clinical infection should be based on accurate diagnosis and consideration of the individual needs of the patient, Silversulphadiazine is often the treatment of choice with the ability to reduce bacterial load, particularly in the case of *Pseudomonas aeruginosa* (Ballin, 1974; Clarke, 1975; Fox, 1977; Hermans, 1984; Hollinworth, 1997; Koo, Zhen, Zhen, Shi, & Xiang, 1989).

Interventions relating to the management of the STSG donor site following epithelial cover

Very few articles were found that dealt with the management of the STSG donor site post healing. Management is directed at protecting the new epithelium from dehydration, physical trauma and UV damage. Patient education generally includes the use of moisturisers applied frequently, the avoidance of UV exposure and the use of strong sunscreens (Coull, 1991; Fowler & Dempsey, 1998). There were only two studies found that examined moisturisers used when epithelial cover was achieved. No trial reports were found that related to any other aspects of management and the evidence provided is at the level of expert opinion. The following comparison is provided:

Comparison 38: Bepanthen compared to placebo;

Outcome 38A: Healing

Two studies were reported comparing Bepanthen on newly epithelialised split skin donor sites with its vehicle. Both studies were double-blinded intra-individual designs with an area of unaffected skin providing control measures. The first study by Girard, Goujon, Violin, & Foyatier (1997) (n=5), used subjective measures of surgeons clinical assessment and patient satisfaction supported by objective measures of cutaneous micro-circulation and temperature as indicators of healing activity at day 14. All measures were said to favour the treatment group although the authors cautioned that a larger study was required.

The follow up study by Girard, Beraud et al. (1998) used a similar design (n=33) with measures taken at day 7 and day 14. Outcomes included; hydration of the skin microcirculation and temperature, suppleness, roughness, rigidity, thickness, pruritus and tonicity. At day 7 the treatment wounds were significantly more hydrated and whilst most other measures favoured this group these results were not significant. At day 14 there appeared to be no significant difference between the two groups.

Chapter 9. Systematic Review Discussion and Recommendations

Levels of evidence

Throughout this section the evidence referred to is ranked from I to IV. The classification system for these levels can be found in appendix 8.

Interventions relating to the post harvest management of STSG donor sites.

The objectives in managing a STSG donor site are, to achieve healing as rapidly as possible, without complication, maximising patient comfort and at a cost effective price. Treatment regimes vary considerably in terms of their ability to achieve these objectives and cost in particular can be a significant factor. The circumstances of the patient will dictate which of these objectives have priority. Rapid healing and the ability to re-crop from existing donor sites may be a high priority in the patient with extensive thermal injuries. High cost alternatives to achieve a more rapid healing rate may be a viable alternative. In the case of a single grafting event such as the repair of minor trauma or reconstruction following excision of lesion, comfort and cost may take a greater consideration.

Outcome category healing

The majority of studies defined healing as achieving complete epithelial cover. For many dressings this can be problematic. It can be argued that under adherent dressings the donor may be healed but the removal of dressings may damage the fragile epithelium. Most studies therefore judged the donor site to be healed when the dressings were able to be removed without trauma and undue discomfort. These studies provided data that allowed the outcome measure of 'days to complete healing'. This measure whilst being the most clinically relevant did rely on the skill of the clinician in removing the dressing thus introducing the possibility of operator error and bias. The alternative approach was to remove the dressings at regular intervals resulting in the outcome measure of 'donors not healed by day X'. This would more

accurately map the progress of healing over time but would also artificially interrupt the normal healing process. There is greater accuracy in this method of outcome measure but it is clinically less relevant.

Moist verses non-moist wound healing products

The first major comparison provided in the results compares the performance of moist wound healing products collectively against so called non-moist products. This is an important clinical comparison as the adoption of moist wound healing products has dominated wound management literature since the 1960s. This not only relates to STSG donor sites but also has implications for wound management generally. In the early 90s MacLellan (1993) noted with some dismay the delays in adopting moist wound healing approaches. A recent survey suggests that in relation to STSG donors there is still a problem in accepting moist wound healing methods (Lyll & Sinclair, 1999). There is some irony here in that the work by Winter (1962) most often cited as seminal in promoting this approach, used an experimental model most closely resembling the STSG donor.

The analyses for this comparison revealed with a strong degree of confidence based on many acceptable RCT/IITs that moist wound healing products are significantly superior to non-moist products in terms of healing, infection rates and pain/comfort. This information was based on level II evidence.

Naturally this result is tempered by the fact that not all moist wound products perform to the same level and there is variation in the performance of the non-moist products also. This is a possible explanation for the lack of homogeneity in the studies included in this category. For this reason, where possible, further analyses were conducted to examine individual generic groups of products within these broad categories.

Calcium alginates

The next group of comparisons examined calcium alginates. Considering the widespread adoption of these products particularly in Australia (Lyll & Sinclair, 1999) it was surprising to have so few studies of acceptable quality that were able to be used for analysis.

In comparison to non-moist wound products only one study of moderate size provided a significant result for the outcome category of 'donor not healed at day 8' representing level II evidence. In relation to pain and infection rate the limited studies provided indicate no significant difference between calcium alginates and non-moist products, representing level II evidence.

There were insufficient studies of sufficient quality to make any judgement between the performance of calcium alginates and other moist wound healing products or between specific products within the calcium alginate group.

Considering the level of acceptance of these products it would be highly recommended that well designed clinical trials are conducted to compare calcium alginates with other moist wound healing products and in particular with hydrocolloids.

Hydrocolloids

Of all the generic products within the moist wound healing category hydrocolloids were the most widely studied. The hydrocolloids were found to be superior to non-moist wound products in relation to healing, pain, and infection, level of evidence II for all outcomes.

The picture is less clear in comparing hydrocolloids with other moist wound products. The studies comparing hydrocolloids with other non-moist products included polyurethane films in all but one study that made the comparison with a hydrogel. The results relating to healing are insufficient to indicate with any confidence that hydrocolloids are superior to other moist wound healing products. The results for the outcomes of pain and rates of infection suggest that hydrocolloids are not superior to other moist products, level of evidence II.

The hydrocolloids; DuoDERM/Varihesive, Sureskin, and Comfeel Thin were included in this comparison. The only result that showed a significant difference between products was a single study that showed Varihesive (DuoDERM) to be superior in terms of healing when compared with Comfeel Thin, level of evidence II. This result is not too surprising. Comfeel Thin, as the name suggests, is a thinner version of the standard Comfeel and is not designed to have the fluid handling capacity of Comfeel regular or DuoDERM.

One aspect about the management of donors using hydrocolloids mentioned in a number of papers is the number of dressing changes required due to leakage of excess exudate. The overall cost of any of the treatments used in wound management is greatly affected by frequency of dressing changes. It has been suggested that when hydrocolloids leak that reinforcement, rather than changing the dressing outright is appropriate and has no greater risk of morbidity, level of evidence IV. There have been no RCTs or IITs that have specifically addressed this issue.

The evidence suggests that hydrocolloids are to be recommended for use in the management of STSG donors particularly above non-moist products. Further research is required to determine if hydrocolloids have any clinical advantage over other moist wound products. Clinical trials should also be conducted to determine the clinical effectiveness of reinforcing hydrocolloids as compared to changing dressings throughout the healing episode. This will have considerable cost implications and so these studies should incorporate a cost effectiveness component.

Polyurethane semipermeable transparent films

The results for polyurethane films relating to healing in comparison to non-moist products are mixed. For the outcome 'days to complete healing' the result significantly favoured the film dressings however the studies lacked homogeneity. The result then must be viewed with caution. Polyurethane films fared better with regard to pain and infection rates with level II evidence suggesting they are superior to non-moist products.

When compared to other moist wound products on balance there is no strong evidence to suggest one group is superior to another for any of the outcome categories.

Only one study allowed a comparison between different polyurethane films and for all outcomes there was no significant difference between the products Opsite and Tegaderm, level of evidence II.

Based on these results polyurethane films can be recommended for use in the management of STSG donors in preference to non-moist products. Concerns have been expressed about films in managing heavily exuding wounds (Rakel et al., 1998). It can be suggested that polyurethane films are more suited to wounds with light to moderate amounts of exudate, level of evidence IV.

Polyurethane foams

Only two studies of sufficient quality were found that dealt with polyurethane foams in the management of STSG donors. Both studies compared the same product Lyofoam with paraffin impregnated gauze. While one study favoured the foam product the other showed no significant difference between Lyofoam and the paraffin gauze product. These studies differed in that one used the outcome of 'days to complete healing' and the other 'healed at day 10'. The first outcome is more clinically relevant and this therefore suggests the foam dressing is in fact superior to the non-moist product, level of evidence II.

Whilst no strong recommendations can be made with regard to polyurethane foams and the management of STSG donors it is recommended that these products be subjected to further clinical trials in comparison to other moist wound products.

Hydrogels

Only one study was found of sufficient quality relating to the use of hydrogels and this compared the hydrogel, Zenoderm with the hydrocolloid, DuoDERM. The result significantly favoured DuoDERM, level of evidence II. As these products are designed for wounds with only a low level of exudate (Thomas, 1997), these products would not be recommended for use in the management of STSG donors when alternative moist products are available.

Scarlet Red

This particular product was analysed separately to other non-moist wound products. This was as a result of the Australian and New Zealand survey of Plastic Surgeons that revealed the popularity of Scarlet Red in New Zealand (Lyll & Sinclair, 1999). In comparing Scarlet Red with other non-moist products there were insufficient studies of appropriate quality to perform a meta-analysis however the results of one moderately sized study did find there was no significant difference between Scarlet Red and a Xeroform, level of evidence II. The comparison of Scarlet Red and moist wound products is less clear as the outcome measure of donors not healed at day 10 was the only indicator of performance with regard to healing. The studies lacked homogeneity and the result was not significant when pooled. Of all the non-moist products analysed the results relating to Scarlet Red, although not convincing, did

hold some promise. Further clinical studies may clarify the potential of this product and this should be considered in light of its level of use.

Porcine or bovine derived dressings

Only one study showed a significant result in favour of porcine or bovine dressings in relation to pain when comparing these products against non-moist products. This result was balanced against another study that reported severe irritation for 9 out of 20 patients with a bovine product used. Overall the evidence rated level II suggests no significant difference between these products and non-moist products.

When comparing this group to moist wound products the porcine/bovine dressings were found to be inferior in relation to healing and infection, level of evidence II.

These products should not be recommended for use in the management of STSG donors.

Growth Factors

Meta-analysis was conducted on three homogenous studies that compared recombinant Human Growth Hormone 0.2mg/kg/day and placebo. Results significantly favoured the treatment groups, level of evidence II. In addition a study comparing rHGH at 10mg/day to placebo also significantly favoured the treatment. The dressing used with the controls and treatment groups was Scarlet Red. As the carrier for the rHGH may have had some additional effect on healing no conclusions can be drawn about how the treatment might compare to non-moist wound products. No comparisons have been performed to compare rHGH with moist wound healing products.

Another study comparing basic Fibroblast Growth Factor to placebo showed no significant difference in healing between groups, level of evidence II.

From these results it is suggested that rHGH is most promising in relation to improving healing times for STSG donors, however as an emerging technology the cost/benefit of these products is a major concern and should be further investigated.

Cultured epidermal allografts

The three studies that compared cultured epidermal allografts with a range of non-moist products significantly favoured the treatment groups, level of evidence II. Like the previous group of comparisons this technology is relatively expensive. It should

be considered however that these new technologies are not being suggested for routine use but in cases where conventional therapy would provide insufficient skin within the required time frame and result in grave risk to the patient. In these circumstances there may be a valid argument for their use despite their cost. Cost utility analysis should be conducted to more accurately determine the overall effectiveness of these products.

Biobrane

This product, although used considerably in the management of burns, had very few studies of sufficient quality relating to the management of STSG donors. Those studies of acceptable quality provided only ambiguous and conflicting results.

In view of the fact that more cost-effective alternatives exist it would be difficult to recommend their use above moist wound healing products.

Meshed split skin graft, retention tape dressings, beeswax, Phenytoin, Asiaticoside, amniotic membrane, live yeast cell derivative, and Nobecutane spray.

Due to the lack of evidence relating to these treatments no recommendations can be made.

Interventions relating to the management of the infected STSG donor site

As no studies of clinical trials that dealt specifically with the alternative treatments of infected donor sites were found it is difficult to make confident recommendations about treatment. Extrapolating the evidence relating to antimicrobials and their use in managing infected superficial burns it can be recommended that certain topical antimicrobials may be used when clinical infection is confirmed. Silversulphadiazine and Iodine based treatments are recommended with suitable precautions, level of evidence IV. Although some clinical studies were of adequate quality and type this

level of evidence rating was allocated as the studies did not directly relate to STSG donors.

Interventions relating to the management of the STSG donor site following epithelial cover

Patient education and specific interventions should include the use of moisturisers applied frequently, the avoidance of UV exposure and the use of strong sun screens, level of evidence IV. As no head to head trials of moisturisers were found, no recommendations about specific moisturisers could be made.

This area seems not to be a priority for research, but considering the cost of many of these products and their extensive use, clinical trials should be attempted.

Summary

Clearly moist wound healing products have a distinct clinical advantage over non-moist products in the management of STSG donors. This advantage relates to healing, pain/comfort and infection rates. In differentiating between moist products there is a strong case for head to head studies comparing products within this group. In designing these studies it should be considered that products within the moist group best manage wounds with differing levels of exudate. It is logical that wounds with light to moderate exudate may best be managed with polyurethane films, wounds with moderate exudate with hydrocolloids, and heavily exuding wounds with calcium alginates. This has yet to be tested rigorously but should be considered. Alternatively existing or new moist products may be developed to deal with wounds over a wider exudate range as the prediction of the amount of exudate from STSG is often difficult.

It should also be noted that this review specifically looked at post harvest management of the STSG donor site. The candidate recognises that there are a number of interventions such as the use of haemostatics and topical analgesics that will impact on the post harvest care of the skin graft donor. The scope of this review prevented the candidate from examining these interventions also.

**Part 3: An Economic Evaluation of Alternate
Interventions for the Post Harvest Management of
Split Thickness Skin Graft Donor Sites.**

Chapter 10. Economic Evaluation Abstract

The purpose of this study was to examine the economic effectiveness of a range of alternative products and strategies for the post harvest management of split thickness skin graft donor sites.

This area of practice has long been subject to considerable practice variation. Traditionally paraffin gauze covered with bulky absorbent dressings was used to manage these wounds but in the last thirty years there has been a shift toward moist wound healing products. The shift is not complete and there are still those using the traditional paraffin gauze. The number of moist wound healing alternatives also being used further compounds practice variability.

In an attempt to determine what is best practice in this area two studies have been conducted. Previously a systematic review was undertaken to determine clinical effectiveness in this area and this economic evaluation builds on this initial work in an attempt to identify evidence of cost effectiveness.

The source of the clinical effectiveness data for the economic evaluation was meta-analyses in the systematic review. This resulted in two comparisons that were subjected to economic modelling. The first was a comparison between traditional paraffin gauze dressings and hydrocolloid sheet dressings. Due mainly to the impact of a differential infection rate the hydrocolloid dressings were determined to be more cost effective. The second comparison examined a number of moist wound dressing product alternatives and a variety of strategies. The result was that no product and/or strategy could be deemed as being more cost effective than another. This was due to the lack of specific clinical effectiveness data particularly in relation to mandatory changing of dressings early in the healing process. This raises some important issues about the use of data from meta-analysis in economic modelling. While the orthodox approach would be to establish the clinical effectiveness of alternative interventions first and use this for economic modelling this study suggests that economic modelling may drive further clinical effectiveness research where potential cost savings exist.

Chapter 11. Economic Evaluation Introduction

The information that is required to make decisions in health care includes objective evidence such as the clinical efficacy of alternative interventions and subjective or contextual information such as the specific characteristics of an individual or group that receive the care. The evidence based approach dictates that this information (evidence) from a variety of sources should be considered within a framework that balances these often competing sources.

This study is the second of the portfolio of studies undertaken as part of the requirements for the of the Doctor of Nursing. The portfolio is aimed at exploring the integration of various types of evidence required to make decisions about the post harvest management of split thickness skin graft (STSG) donor sites within a framework of evidence-based health care (EBHC). To do this, the studies within the portfolio firstly determined what objective evidence exists to inform the decision making process. In addition the portfolio examines how the objective evidence may be combined with contextual evidence to decide how patients with STSG donor sites may be managed.

The first study of the doctoral portfolio was a systematic review that examined the clinical effectiveness of interventions used in the post harvest management of STSG donor sites (Wiechula, 2001). This second study is an economic evaluation that incorporates and builds on results of the systematic review.

Study aims

There are a number aims in conducting this study, some broad and some specific to a particular area of practice. The primary objective of this economic evaluation is to determine the economic effectiveness of a range of alternative interventions relating to the management of the STSG donor site. In itself this outcome may have considerable value to those who care for such patients. The study also provides an additional opportunity in investigating the way in which this type of evaluation be conducted. The other major objectives of this study are therefore to consider the process of developing an economic model that may be adapted to other areas of similar practice and specifically to consider the use of clinical effectiveness data derived from systematic review and meta-analysis as the clinical outcome measures in this model.

Decision making in healthcare

Arguably there has never been a time when health professionals have been so pressured to consider how they conduct their practice. The evidence based movement has provided methods to establish the evidence that supports decision making to achieve best practice. Some of the criticisms of the movement are that the focus has been on establishing the evidence and not on supporting health professionals to incorporate the evidence into practice. More specifically there has been criticism that the focus of the evidence has been mainly on clinical effectiveness, ignoring other important elements that must be considered in clinical decision making. There has therefore been an increasing demand from health professionals for evidence that is more inclusive. Although there has been some recognition from evidence based researchers that this is a reasonable demand the delivery of this evidence is problematic. It must be considered that within the evidence based movement the focus on clinical effectiveness has meant that the methods used to identify, appraise and synthesise that particular type of evidence are highly developed. This is not the case for other forms of evidence. The methods used in the examination of interpretive and critical research are in their infancy however, the work of a number of groups such as the Joanna Briggs Institute, the Cochrane Qualitative Methods Group and the Campbell Collaboration are beginning to address this (Popay & Roen, 2003). Likewise there has been some considerable development in the EB review methods relating to economic effectiveness data but this work is characterised by debate on the broad approaches to be used rather than refinement of established processes. The number of systematic reviews that have been conducted on economic effectiveness data is understandably small and of questionable quality (Jefferson, Demicheli, & Vale, 2002). There is some argument to suggest that systematic reviews of this type are inappropriate due to the highly contextual nature of economic evaluation. The question must therefore be asked, 'If systematic reviews of economic effectiveness are not readily available what can the evidence based movement provide to clinicians to assist them in decision making?'

Economic evaluation of healthcare interventions

In the current climate of increasing demands on healthcare systems and scarce resources to provide this care the pressure to consider the costs involved is inescapable. It is also apparent that healthcare systems are complex and that in

examining the costs of healthcare the methods used must reflect this complexity and be both valid in the approach used and rigorous in their execution.

Economic evaluation is a broad term that encompasses a variety of methods used to establish the cost and cost effectiveness of health care interventions. The methods used are often limited by the data available to the investigator. For an intervention where the clinical outcome is not known or cannot be accurately measured only a simple costing exercise is possible. When clinical outcomes are known and alternative interventions can be compared, a more complex economic evaluation can be undertaken. Conducting an economic evaluation of any type requires drawing data from a variety of sources. In the past clinical outcomes data for economic evaluations were often derived from prospective clinical studies by the investigators or retrospectively from previously published clinical trials. The thrust of evidence-based practice has been in developing systematic reviews of clinical effectiveness that report the clinical outcomes relating to alternative treatments. Utilising systematic reviews enables economic evaluation to be conducted with the clinical efficacy already determined. In addition, when available, meta-analysis provides estimates of treatment effect with greater precision and confidence than single trials alone (Pang, Drummond, & Song, 1999). There is now a significant body of clinical outcomes data available in a number of published systematic reviews. The output from evidence-based researchers conducting systematic reviews of clinical effectiveness provides a potentially rich and readily available source of clinical outcomes data for input into economic evaluation. This approach has been used for this study but as the following chapter illustrates, the use of this method is not without its critics.

Evidence in relation to STSG donor site management

Although an important aspect of this study is to examine the issues in relation to the use of clinical effectiveness data from systematic review in economic modelling, the primary objective of the study is to provide health professionals with evidence to assist in clinical decision making. A fundamental principal of the evidence based approach to practice is to reduce practice variability and improve patient outcomes. This was the rationale for conducting the initial systematic review of the evidence of clinical effectiveness in relation to the management of STSG donor sites. It is an area of practice that is characterised by a large number of alternate therapies, some of which have the potential for significant adverse outcomes for the patients involved

(Wiechula, 2001). Although it was always intended that economic effectiveness evidence would be identified in relation to this area of practice the results of the systematic review reinforced the necessity to make this evidence available to clinicians. A literature search did not identify any primary economic effectiveness studies so a systematic review was not possible and this supported the need for a primary economic evaluation to be conducted.

Despite the debate about the method used in this study, the results of the previously conducted systematic review do provide clinical effectiveness data on a variety of alternative approaches available to manage the split thickness skin graft (STSG) donor site. It is, however, not the purpose of this study to determine what is the 'best' method to be used in managing STSG donor sites. It should be clear from the outset that the results of this study alone do not provide sufficient evidence to determine which alternative approach or intervention should be used in practice. This is but one piece of the jigsaw. This piece relates to the economic aspects of managing STSG donor sites and although in the current economic climate many might suggest this factor is of the highest importance, the results must be considered along with other objective evidence available and the context in which the care of these patients will be provided.

In summary this report provides evidence of the economic effectiveness in relation to the management of STSG donor sites. In doing so it also provides a model that may be adapted to other similar interventions and/or contexts. Finally it also explores issues around the use of data derived from systematic reviews of clinical effectiveness as inputs to primary economic effectiveness studies.

In reviewing the literature relating to this study the purpose is not only to provide a background that informs the reader about the context of the study but also to justify the decisions in relation to the conduct of the study. This is particularly important in an area of research that is subject to considerable debate. The examination of the literature has therefore been divided into two chapters. The following chapter deals with a number of issues both broad and specific. The refocus of the evidence based movement and in particular the increasing interest in economic effectiveness will be detailed. The issues around how this evidence should be used in clinical decision making will be explored. Finally the decision to examine the evidence in relation to STSG donor sites will be justified. Chapter thirteen deals quite specifically with the issues around the methods and overall approach used in conducting this study. The

chapter is titled 'Methodology' and although this may seem somewhat inappropriate it is quite deliberate. In conducting this economic evaluation the methods used are subject to some considerable debate particularly in relation to the use of systematic review output. While much of the debate is technical in nature there are also elements that are philosophical. This debate will be examined.

Chapter fourteen describes in detail the methods used in this study. An economic model by its very nature combines objective data within a specific context. In constructing the model many decisions are made about the contextual elements that were included in the study. These are detailed in this chapter.

The results chapter follows and details the outcomes of the two comparisons conducted in the study including the results of the sensitivity analysis.

The final chapters discuss the findings of the study and detail the implications for practice and research in relation to the management of STSG donor sites.

Chapter 12. Economic Evaluation Background

In the introductory chapter it was stated that the study intended to examine the cost effectiveness of alternatives for the post harvest management of STSG donor sites. Although this area of practice is quite specialised it provides a useful vehicle to address some broader issues about EBHC and the use of economic evaluation within this approach. This chapter therefore examines the available literature in relation to a range of issues on the EB approach to clinical decision making including the pluralistic approach to evidence. This includes the current role of economic evaluation in EBHC and potential methods that are the subject of some debate. In addition the chapter will detail the specific literature available in terms of STSG including issues of concern in relation to decision making and what evidence of clinical and economic effectiveness are available. The intention here is to demonstrate both the need to identify specific information to be used in the management of STSG donor sites and to validate the approach taken by the investigator to obtain this information.

Evidence-based health care

Evidence-based health care (EBHC) has been promoted as an approach that organisations and professionals may use to inform decisions about the way in which health care will be conducted. Every health care organisation is faced with alternative interventions and strategies that will have different implications for the organisation and the individual that health care is provided for. In deciding which alternatives will be used, the best available evidence must be sought to increase confidence in the decisions to be made.

Systematic reviews are produced and disseminated by an increasing number of organisations such as the Cochrane Collaboration, the Centre for Reviews and Dissemination in the UK and the Joanna Briggs Institute. Although there is a recent trend to broaden the focus of these reviews the output from evidence-based researchers has been largely focussed on clinical effectiveness derived from clinical trials research (Hamer & Collinson, 1999). The first study in this portfolio is such a review (Wiechula, 2001). Despite this apparent focus of EBHC on clinical effectiveness, it was always intended that other forms of evidence would be an integral part of the approach. Sackett and Rosenberg (1995) suggested that clinical and other health care decisions should be based on the best patient population and

laboratory based evidence and should involve the application of epidemiological, economic and biostatistical principles.

Certainly it is important to ascertain whether an intervention is clinically effective or more effective than an alternative. It is also important to determine the broader implications of utilising a particular intervention. In considering the implications for the patient, a positive health outcome may be counter-balanced by pain, or unpleasantness, in delivering the intervention. There may be social implications that are not readily seen in the artificial confines of a randomised controlled trial. The organisation will also have to resource the intervention which although effective clinically, may have significant resource implications for the health care provider. The cost effectiveness of alternative interventions has become increasingly important in an era of cost containment and reducing resources in the health sector (Øvretveit, 1998).

The current role of economic evaluations in EBHC

The notion of using economic evaluation to inform practice using an EB approach is not new. The link between EBHC and Health Technology Assessment (HTA) also supports the importance of economic evaluation. Health Technology Assessment is a broad examination of the safety, efficacy and feasibility of implementing particular health technologies, including cost-effectiveness, and grew out of the concern for emerging technologies and the corresponding expansion of expenditure in health. The principle here is that clinical effectiveness evidence must be placed within a context and other forms of evidence construct that context. The Australian Health Technology Advisory Committee (AHTAC), a subcommittee of the National Health and Medical Research Council (NHMRC), was formed to provide advice on emerging technologies because of these concerns. It should be noted that to assist AHTAC the Australasian Cochrane Centre was established by NHMRC. The intention was to bring together evidence of effectiveness and other relevant evidence including economic data to determine the overall value of a proposed health technology (Kearney & Willis, 1997).

There have been efforts by evidence-based research groups to make economic evidence available. The Department of Health in the UK commissioned the NHS Centre for Reviews and Dissemination to establish and maintain a database of critical abstracts of economic evaluations. The NHS Economic Evaluation Database (NHS

EED) is designed to compliment the Database of Abstracts of Reviews of Effectiveness (DARE) and can be accessed at the URL: <http://agatha.york.ac.uk/nhsdhp.html>. As with DARE, the NHS EED contains reports subjected to a process of determining suitability for abstraction and critique of quality (Vanoli, Drummond, & Sheldon, 1996). Other similar databases include Health Economic Evaluations Database (HEED) a subscriber service available at URL: <http://www.ohe-heed.com> and CDC-WONDER produced by the Center for Disease Control in the US at URL: <http://wonder.cdc.gov/>.

To have these databases available is a vital step in incorporating economic evidence into practice. How widely these resources are used and how useful they may be remains to be seen. CRD have committed to undertake impact evaluations of the NHS EED, to first determine the potential use of the information provided for decision making and to investigate the usefulness of the information in practice (Vanoli et al., 1996).

Potential methods of incorporating economic evaluation into EBHC

Given that to this point, economic aspects of EBHC have not been given due consideration (Hamer & Collinson, 1999), there is considerable potential to incorporate this type of evidence into the EBHC approach. There are a number of ways in which economic evaluations may be used although each has certain methodological and practical considerations that should be addressed.

Using economic evaluation to prioritise EBHC activities

As mentioned previously, as health care costs rise and technological advances lead to higher capital expenditure for health care providers, such providers need to make informed decisions about how best to spend their limited resources. Economic evaluation has always been an important feature of priority setting in health care if not always universally used. The process of improving practice itself is not without cost. To undertake a systematic review or any other EBHC activity is usually a resource intensive exercise. It should be noted that in this discussion the reference to EBHC relates not just to evidence review but the chain of processes including knowledge translation (review of the evidence), knowledge transfer (dissemination of

the evidence) and knowledge utilisation (real and sustained change in practice). As a general principle the target areas for practice improvement should be activities and interventions that involve high volume and/or known poor levels of performance and in the current economic environment those of high cost (Gates, 1995). This principle may be applied by organisations that are deciding which clinical interventions should be reviewed using evidence-based data sources, or by evidence-based researchers in determining the subject and scope of systematic review programs. The type and depth of economic evaluation will vary considerably and care should be taken to ensure the evaluation is valid and applicable. The health economics literature refers to a number of types of economic evaluations.

Needs analysis

A common type of economic evaluation that can be used in priority setting is a needs analysis. This type of assessment can be conducted in two ways. Firstly the assessment can be based on illness where the 'amount' of illness within a given population is calculated as incidence or prevalence (Mooney, 1994). This approach is reliant on the ability to accurately measure patient outcomes. To use an example, consider an initiative to introduce evidenced-based information on pressure ulcer prevention and treatment. A recent Australian study was conducted using a before and after design measuring the change in pressure ulcer prevalence at three different sites following the introduction of evidence based information. The study did not see a significant reduction in prevalence at any of the sites involved. The overall prevalence rate was 4.7% for the first survey and 4.6% on the second survey ($p > 0.05$) (Pearson, Wiechula, Nay, Mitchell, & Hodgkinson, 2000). Whilst no statistically significant change occurred it might be argued that the initial prevalence rate was satisfactory and therefore another focus area should have taken priority. For this to occur there would have to have been data available to determine the existing prevalence rate. This data was not available prior to commencement of the project.

The other approach to needs analysis is to consider the 'capacity to benefit'. Some assessment is made of the potential for current technology to cure or reduce the impact of the disease or condition. It may well be that for a disease or condition with a high prevalence, current technology may not provide an intervention to deal with it. This effectively reduces the priority for dealing with this disease over others that can be more easily managed with existing technology (Mooney, 1994). Both of these

approaches as described, provide only the most rudimentary assessment and alone are insufficient to rank a range of focus areas.

A more common approach in setting priorities is the use of cost of illness studies. These are used frequently and would be familiar to most readers. Studies normally would include the cost of treating the illness plus costs arising as a result of the illness (Mooney, 1994). The scope may range from a community level through to a national or global level. Too often only the cost of treating the illness or condition is provided. For example, a 1982 study in the UK reported that nationally the cost of treating patients with pressure ulcers was £150,000,000 annually (Scales, 1982). Figures from the US are even more impressive in the order of billions of dollars annually (Bergstrom, Bennett, Carlson, & al., 1994). These figures attract the attention of the reader and indicate to some degree the gravity of the problem, that is their purpose, however they do not provide sufficient information to determine priority. Mooney argues that this approach ignores the cost of illness in a broader sense, which may be considerable and not readily measured in dollar terms (Mooney, 1994). This approach also frequently disregards the cost of alternatives including methods of prevention. In some cases the cost of preventing an illness may be as significant as the treatment for it (Pieper, Sugrue, Weiland, Sprague, & Heimann, 1997). If economic evaluations are to be considered when prioritising evidence-based activities then ideally they should be at a level of complexity above that which is often undertaken at present. Unfortunately this would entail resources and a level of expertise that may not be readily available. More realistically, priority setting using economic evaluation should in the least consider the limitations of the current approaches taken.

Using economic evaluation in clinical decision making

In order to illustrate some of these issues about EBHC and the use of economic evaluation it is worth exploring these issues in relation to a specific area of practice, the post harvest management of STSG donor sites. The following discussion serves the dual purposes of considering broadly the use of economic evaluation in informing clinical decision making but also justifies the conduct of this study which is about an area where despite good clinical effectiveness evidence there still exists considerable variation in practice.

STSG donor sites

The use of the split skin graft as reconstructive technique is commonplace. This process involves the harvesting of skin resulting in the creation of a superficial to partial thickness wound that is the donor site (Fowler & Dempsey, 1998). The donor site wound heals by a process of re-epithelialisation. This process results in an epithelial cover usually within 7-14 days (McCain & Sutherland, 1998). The aim of donor management is to maintain an environment that promotes optimal healing and prevents morbidity that may include, pain and infection and ultimately delayed healing.

In considering wound management generally, there has been a revolution in approaches to treatment particularly in terms of dressing selection. The seminal work of Winter (1962) demonstrated the potential of the moist wound healing approach. Since then there has been the gradual introduction into practice of many types of dressings that promote moist wound healing. The advantages of these dressings are well documented. They prevent desiccation and the deepening of wounds, reduce the risk of mechanical damage of healing tissue at removal and provide an environment that results in more rapid healing (Hermans, 1995). Considering the advantages of using this approach it is surprising that there is still some hesitancy in adopting this approach to wound management (MacLellan, 1993). Also surprising is that in managing STSG donor sites, non moist wound healing methods are still advocated as an alternative (Ablove & Howell, 1997; Fowler & Dempsey, 1998; McCain & Sutherland, 1998). As a result the investigator conducted a systematic review, which forms part of this doctoral portfolio into the effectiveness of various alternative dressings for the management of STSG donor sites (Wiechula, 2001).

The results of the systematic review indicate the clinical effectiveness of various wound management products. Moist wound healing products were found to be superior to traditional products in terms of clinical effectiveness. There is however little evidence to suggest that one moist wound healing product is more clinically effective than another in the management of STSG donor sites (Wiechula, 2001). In considering what products should therefore be recommended for the management of STSG donor sites further information is required. In particular any evidence relating to cost should be taken into account. Incidental findings from this review suggested there are potentially significant cost differentials between moist wound healing products and various protocols that may be used for each product.

The investigator conducted an extensive literature search and no cost effectiveness studies specific to this area of practice were identified. It is timely then to explore the cost effectiveness of this particular area of wound management as this information would be valuable in determining decisions about alternative therapies for STSG donor site management.

Summary

This chapter has briefly explored the necessity to incorporate evidence of economic effectiveness in clinical decision making and practice improvement. In relation to this particular study it supports the case for determining the cost effectiveness of a range of possible alternative interventions for the post harvest management of STSG donor sites. Although this would be a useful outcome in itself, the study has much greater potential. As indicated previously the incorporation of economic evaluation in EBHC is at a stage of development where not only the methods used are the subject of considerable debate but also how the results of economic evaluation articulate with other forms of evidence is also being considered. The debate is multi faceted and is on the one hand mechanistic in terms of what methods are currently or potentially possible, on the other hand it is philosophical, particularly in relation to the emerging pluralistic approach to what counts as evidence to inform practice. In conducting the study a particular approach has been taken. The results of the study and the ensuing discussion I believe contribute to this debate from both a mechanistic and philosophical perspective. It is therefore important to provide an overview of these issues. The following chapter is titled methodology in that it not only supports the reasons for the methods used within the study but also examines the broader debate that is occurring in the EBHC movement about different types of evidence and how they can be incorporated into practice.

Chapter 13. Economic Evaluation Methodology

Many organisations have made, or claim to have made, some commitment to undertake practice based on the principles of EBHC. There are many reasons why an organisation might make the decision to take this approach, but in a time of limited resources organisations need to feel confident that interventions being used are not only clinically effective, but cost effective also.

This chapter examines specific issues relating to the use of economic evaluation in an evidence-based approach to health care. Economic evaluation will be defined in relation to health care and the varying types of evaluations will be briefly described. The various ways in which the use of economic evaluation may be expanded within an EBHC framework will be discussed in light of some of the methodological issues currently being debated. In particular the use of clinical effectiveness data derived from existing systematic reviews will be examined.

Economic evaluation in health care

The purpose of an economic evaluation is to determine the value of an intervention, strategy or program. To achieve this a comparison must be made between alternatives, considering not only the costs, but also importantly, the consequences. Economic evaluations can be conducted in a number of ways, differing in how they assess costs and the consequences of care, and what aspects of these are included or excluded from analysis (Øvretveit, 1998). The following are common types of evaluations used in health care.

Cost description evaluations: This is the simplest form of economic evaluation and can be the measurement of only the cost of an intervention. This is considered a partial evaluation and becomes a full evaluation when the cost of one intervention is compared to another (Bowling, 1997).

Cost minimisation evaluations: Similar to cost description evaluations, the purpose of the analysis is to compare costs between alternatives to determine which has the lower cost. This is based on the assumption that the outcome of both interventions is not significantly different (Øvretveit, 1998).

Cost effectiveness evaluations: These evaluations compare the cost of an intervention with a specific measure of clinical outcome. Alternate interventions

can be compared where the outcomes are assumed to be the same (Udvarhelyi, Colditz, Rai, & Epstein, 1992).

Cost-utility evaluations: More complex than cost effectiveness evaluations, the end result of the intervention is quantified and compared to the cost. QALYs (quality adjusted life years) is a common measure used (Øvretveit, 1998).

Cost-benefit evaluations: As with cost effectiveness studies the objective is to compare the cost against the outcome. The outcome however is also converted to monetary terms resulting in an overall monetary value for the intervention (Udvarhelyi et al., 1992).

The type of economic evaluation undertaken is determined by a number of factors. Primarily the decision relates to the availability of outcomes data and the degree of confidence in that data. For instance, cost minimisation studies rely on the assumption that the outcomes from alternative interventions are the same. Unless there is a high level of confidence that this is the case then cost minimisation studies should not be undertaken (Bowling, 1997). The level of confidence in outcomes data is important in considering how economic evaluations fit with EBHC. Systematic reviews, the cornerstone of evidence-based research, are concerned with determining the efficacy of clinical interventions based on a given level of confidence.

Using appropriate clinical data for economic evaluation

Economic evaluations differ from simple costing exercises in that they take into account the outcomes of alternative practices. The thrust of evidence-based practice has been in developing databases of clinical effectiveness that report the clinical outcomes relating to alternative treatments. If economic evaluation is to be included as part of the evidence to support decisions about alternative health care practices then how this economic evidence relates to evidence of clinical effectiveness should be considered.

The principles of evidence-based practice dictate that the evidence used should be of sufficient rigour and this should be determined by critical analysis. In the same way that criteria have been developed and used to conduct systematic reviews of clinical studies a similar set of criteria exist to judge economic evaluations. It is worth

examining these criteria as they provide valuable clues as to the part clinical effectiveness data may play in economic evaluation .

The ten point checklist developed by Drummond, O'Brien, Stoddart, & Torrance, (1997) p28 to critically assess economic evaluations includes the following criteria:

1. Was a well defined question posed in answerable form?
2. Was a comprehensive description of competing alternatives given?
3. Was the effectiveness of the alternatives established?
4. Were all the important and relevant costs and consequences for each alternative identified?
5. Were the costs and consequences measured accurately in appropriate physical units?
6. Were costs and consequences valued credibly?
7. Were costs and consequences adjusted for differential timing?
8. Was an incremental analysis of costs and consequences of alternatives performed?
9. Was allowance made for uncertainty in the estimates of costs and consequences?
10. Did the presentation of results include all issues of concern to users?

In a number of the criteria listed aspects of the consequences (outcomes) of the program/intervention are considered. In particular criteria no. 3 specifically examines evidence of effectiveness determined by clinical outcomes. This seems to suggest that clinical trials would provide an obvious source of outcomes data for economic evaluation. The alternative would be to use real time data from actual practice.

Clinical outcomes data from primary clinical research studies of experimental design

There are a number of ways clinical research data may be used in economic evaluation. In the first instance it has been suggested that clinical trials include economic analysis as part of the primary data collection. The advantage of this is that economic and clinical data are collected under identical environmental conditions with the same population sample resulting in a stronger relationship between the two

sets of data (Adams, McCall, Gray, Orza, & Chalmers, 1992). The counter argument is that collecting additional economic data significantly increases both the cost and complexity of clinical trials. If clinical efficacy is established first this would then justify the additional use of resources for economic evaluation (O'Brien, Drummond, Labelle, & Willan, 1994).

Clinical outcomes data from systematic reviews and meta-analysis

Another method of utilising clinical trials data is to aggregate results of clinical trials from systematic reviews that have already established the efficacy of alternatives. Not only would economic evaluation be conducted with the efficacy already determined but meta-analysis would provide estimates of treatment effect with greater precision and confidence than single trials alone (Pang et al., 1999). Where the result of the systematic review identified no significant difference in outcomes between alternative interventions, and the cost of the outcome can be accurately determined, then a cost effectiveness analysis can be conducted. If the cost of the outcome can not be determined then a cost minimisation analysis could still be conducted (Udvarhelyi et al., 1992). The advantage in using this method is that there is now a significant body of clinical outcomes data available in a number of systematic review databases. The databases are readily accessible and relatively inexpensive to use. There are however, a number of criticisms to this approach that must be considered. It has been argued that the strict conditions under which some clinical trials, and in particular randomised controlled trials, are conducted give rise to questions of external validity and generalisability, as these conditions are not likely to be found in the natural setting where practice actually occurs (Adams et al., 1992). The RCT design is used to eliminate or neutralise the effect of variables other than the interventions being investigated. As a result it allows prediction with some certainty as to how the intervention will impact on a patient within a given set of circumstances (Bowling, 1997). These circumstances (confounding variables), often have considerable social and economic impact that must be determined by other research designs (Bowling, 1997). As a result economists may feel that clinical trials of non-RCT data may be more realistic for use in economic evaluation. When primary studies are aggregated in a systematic review there are concerns that the resulting data is retrospective and so has a greater potential for bias (Pang et al., 1999). The

quality of the systematic review itself must also be carefully considered. In the same way that individual studies are assessed for quality, systematic reviews must also have their quality assessed critically. Although the DARE is a reliable source of evidence evaluating systematic reviews, not all published systematic reviews are listed in the database and many listed are still awaiting review. Where this is the case, those using systematic reviews for economic evaluation must have the knowledge and skill to make their own judgments about the quality of the reviews.

Caution also needs to be taken to ensure that the review based on a particular clinical focus has not excluded studies or outcomes data that would be important from the perspective of the economic evaluation (Pang et al., 1999). The candidate recently completed a systematic review on split skin graft donor sites (Wiechula, 2001). The outcome measures extracted from the studies reviewed were, healing times, pain and infection. All of these outcomes have both clinical and economic implications. Data relating to the frequency of dressing changes was not extracted from studies for the review. This data was only available for a small number of studies and it did not fit with the specific clinical objectives of the review, which related to clinical efficacy. This data, if extracted, would have had considerable implications from an economic perspective.

Recognising the limitations of using meta-analysis of RCTs in economic evaluation, a possible solution is to incorporate this data with that of other experimental designs providing a fuller picture of how an intervention may behave in the natural setting. This development in meta-analysis is called cross-design synthesis. It is in the early stages of development but may prove to be more useful and palatable for the health economist (Pang et al., 1999).

Approaches to combining results of economic evaluation studies

The other development where the EBHC research methods may assist economic evaluation is in the use of systematic review and application of meta-analysis to existing economic evaluations. Economic evaluations like any research are costly, may be time consuming and require a level of expertise. If suitable economic evaluations exist for a specific clinical intervention or program then the systematic review methodology would assist in accessing these, preventing repetition. Additionally, if a number of economic evaluations with sufficient homogeneity could be combined with

meta-analysis, this would increase the confidence in decisions made arising from the evaluations (Pang et al., 1999). This may also address the concerns of economists about the cross-national differences in economic evaluations where combining studies from a wide variety of settings increases generalisability (Drummond et al., 1992). Pang et al. point out this type of meta-analysis is in the very early stages of development and many that have been conducted have had serious methodological deficiencies (Pang et al., 1999). Significantly, Vanoli et al. (1996) in reviewing the NHS EED stated that although many studies had been assessed for quality no quality scoring method had been validated.

The lack of expertise and resources for conducting economic evaluation means that many organisations would benefit from being able to access this evidence, as they do with evidence of clinical effectiveness. Unfortunately it appears that the lack of expertise and resources is restricting the development of economic evaluation as part of the EBHC approach. This does not preclude the use of the resources that are currently available, but due caution should be exercised.

Chapter 14. Economic Evaluation Methods

Study overview

This study was essentially a micro-economic evaluation of a range of alternatives for the post harvest management of STSG donor sites. Due to the clinical data available two methods of economic evaluation were utilised. In the comparison between the hydrocolloids and the traditional paraffin gauze style dressings, a cost effectiveness evaluation was used. This was possible as the two interventions have different infection rates as determined by the candidate's previously conducted systematic review (Wiechula, 2001). The second comparison used a cost minimisation evaluation. This was conducted on the comparison between interventions using a range of moist wound healing products including hydrocolloids, calcium alginates and retention tape dressings. This chapter will outline the processes used to conduct the evaluations and detail the rationale for the decisions made about the methods used and the inputs for the study.

Study perspective

In the complexity of the modern health care system even the simplest of clinical interventions will have a broad range of cost and benefit implications for all those involved. The first decision to be made in conducting this type of study is to determine from whose perspective the study is conducted. For the purpose of this study the evaluation was conducted from the perspective of the health service and the health professionals providing the interventions used to manage donor sites. This is not intended to diminish the significant potential costs and benefits to patients and their families. In terms of the traditional paraffin gauze donors the clinical evidence alone indicates considerable costs to the patient in terms of pain and discomfort and this cannot not be ignored. The perspective chosen was deemed to be appropriate as the overall study program aims are related to exploring the decision making process employed by health professionals.

Data collection and preliminary analysis

In terms of wound management the STSG donor site is a relatively simple wound. It is created in a controlled environment in a consistent manner. The modern dermatome is very accurate and although there are patient specific characteristics that may

influence management, in general these wounds are able to be created and managed in a uniform manner. Despite this there is considerable variation in practice. The systematic review previously conducted by the candidate supports this and indicates that consequently there is also variation in the outcomes of these interventions (Wiechula, 2001). This adds a complexity to the economic evaluation that necessitates a stepped process of initial data collection and analysis to allow decisions to be made in proceeding to further data collection and analysis. In determining what interventions would be compared consideration was given to what clinical effectiveness data was available, what data could be collected from the sites available to the investigator and what would be of interest to clinicians who manage these wounds, not only locally, but as widely as possible. As a result the evaluation occurred in a stepwise fashion with each phase determining the subsequent direction in data collection and analysis. The following is a detailed description of each consecutive phase of the economic evaluation.

Phase 1: Decision analysis and preparation for phase 2

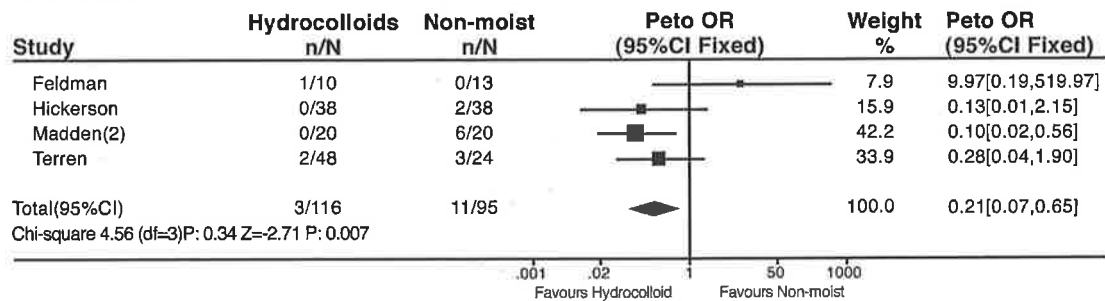
The first task undertaken was to determine which alternative interventions for the post harvest management of STSG donor sites were to be used for the evaluation. This was done by considering the results of the previously completed systematic review (Wiechula, 2001). Specifically, the process sought to determine which interventions were commonly used and what evidence existed in relation to the clinical effectiveness of these alternatives. Outcomes were examined to identify which were likely to have an economic impact and to what degree this would differ between alternate interventions. Outcomes of interest that were considered initially included healing and infection rates. Both had the potential to impact on length of stay, incurring additional treatment costs.

The systematic review identified clinical trials relating to an extremely large number of interventions (Wiechula, 2001). Many of these, such as live yeast cell derivative and asiaticoside, a plant extract, are clearly not commonly used and were not considered for economic evaluation. Many of these interventions and others were likewise excluded, as there was little evidence of their clinical effectiveness. This was either due to a lack of suitable studies or, where studies were identified, there was

inadequate reporting of results. Using the criteria that the interventions were currently in use and there was evidence of their clinical effectiveness, the following interventions were chosen for evaluation.

The comparison of hydrocolloids against traditional paraffin gauze was selected because the evidence from meta-analysis indicated that infection rates were higher for the traditional dressings and because paraffin gauze dressings are still being used in some areas (fig. 69).

Figure 69. Meta-view graph; Comparison: Hydrocolloids Vs Non-moist dressings, Outcome: Clinical infection present.



It may be argued that the promotion of moist wound healing principles has largely removed this method from practice, however incidental findings from the review suggest sadly this is not the case (Wiechula, 2001).

The next group of interventions that were chosen, employ moist wound healing methods. The clinical effectiveness evidence indicates that these dressings, when used appropriately, achieve similar outcomes particularly in terms of infection (Wiechula, 2001). Calcium alginates represent an interesting case. The review identified that most of the trials of calcium alginates specific to donor sites used traditional paraffin gauze dressings as controls. There were only a small number of trials where calcium alginates were compared head to head against other moist wound healing products in the management of donor sites. The decision to include calcium alginates related specifically to their wide use, particularly in Australia, where the evaluation was conducted. Hydrocolloids were included for their common usage and evidence of their clinical effectiveness. Polyurethane semi-permeable films were initially considered but withdrawn from the study due to the lack of additional clinical information, as they were no longer used on any of the sites where data was collected. The final major dressing type to be included for evaluation was the retention tape dressings. At the time of the systematic review there were few comparative clinical trials identified that examined these dressings. Despite this they

have been included for a number of reasons. Ironically a well run clinical trial evaluating retention tape dressings was reported at the World Wound Congress in 2000 in Melbourne in the session immediately following the presentation of the donor site review. The article reporting this study has only recently been published (Hornbrey, Pandya, & Giele, 2003). Coincidentally this study was presented at the same session in which the candidate's systematic review was reported. In addition the candidate is aware of a number of plastic and burn surgery units around Australia where these dressings are commonly used. One of the sites used to collect additional clinical data for this study had recently adopted retention tape dressings as their primary approach to STSG donor management.

Phase 2: Data collection: additional clinical information

The clinical information derived from the systematic review was drawn principally from randomised controlled and intra-individual trials. The information from the trials included types of interventions, descriptions of the interventions and most importantly comparisons of the clinical outcomes from the various alternatives. Although the interventions within the trials were well described, they did not include all the required clinical information to determine the economic effectiveness of the alternatives. Additional clinical data was required to determine specific aspects of the alternative interventions for the purposes of comparative costing. After deciding on the alternative dressings to be compared it was necessary to find sufficient sites that employed the various alternatives. There were ultimately three hospitals involved in the study, all within the public health system. Each had plastic and reconstructive surgical wards/units that performed STSG for a variety of purposes. The hospitals chosen were a purposive sample. These sites were chosen, as they are known to the investigator to have units that performed STSG in sufficient numbers to allow for adequate data collection in the time required. Some of these hospitals had dedicated plastic surgery units others had wards with composite units that included plastics and other clinical specialist units such as orthopaedics. The number of hospitals and units within these hospitals that are observed was not a critical issue. The purpose of the data collection was not to quantify the variation in practice but to document a sufficiently broad range of alternate interventions. Initially it was intended to access sites in both the public and private health sectors and if possible include both adult

and paediatric settings. For a variety of reasons this was not feasible and ultimately only public hospitals with adult patients were used. Recruitment of sites for this study in many cases was difficult. The collection of some data involved material that was classified as 'commercial in confidence' and although guarantees were given that sites would remain anonymous and confidential information would be managed in a secure manner, clearly this was a cause of concern for some sites. In addition all sites required approval from their local research and ethics committees. The protocol proformas and the processes of the individual committees varied considerably between sites. Even though a number of sites had a common uniform proforma the interpretation of the stated requirements differed considerably. In one case approval was achieved for the study within two weeks of submission. At a number of sites it took 10 months of submission and resubmission. At some sites the attempt to get ethics approval was abandoned due to time, resources or sheer frustration. Ultimately this has not greatly impacted on the results of the study as there was sufficient variation in practice at the recruited sites to provide a broad range of interventions that were modelled.

To determine how the interventions were conducted and what resources were used data was collected from a variety of sources. Where they existed, any protocols prescribing donor site management were collected. Discussions with nursing and medical staff were conducted to verify the accuracy and currency of these protocols. In addition patient documentation, including operation records and progress records were examined. Where possible actual care was observed. When data collection involved clinical observation, no patient specific data was collected, as it was not required for the study. Informed written consent, however, was obtained from each patient prior to observation of any intervention and/or accessing of patient records. The involvement of patients and staff was voluntary and participation could be withdrawn without consequence at any time during the study.

Data collected included details of resources used in the post harvest management of STSG donor sites that impacted on direct and overhead costs of specific interventions and induced costs particularly where negative outcomes occurred. Data collected included the type and number of consumables used such as dressings, tapes and cleansing solutions. Data on staff time and level of staff typically used for the specific procedures was also collected by direct observation with validation from discussion with staff.

Phase 3: Data collection: costing information

In determining the costs involved in the post harvest management of the STSG donor sites a number of issues must be highlighted. Firstly the primary procedure and the major focus of care in such circumstances is the wound that receives the grafted skin, not the donor site. The progress of the grafted wound determines the length of stay and is not usually effected by the healing of the STSG donor site. It is possible that complications arising from the donor site can impact on length of stay but staff at all sites indicated this was very rare. For this reason hospitality costs and other overheads were not included in the analysis as they would have been equivalent for each of the alternative therapies.

During the period of observation it became obvious that many of the consumables, particularly the primary dressings came in a range of sizes and that as expected different size dressings would be used for different size wounds. It was decided that all analysis would be conducted on two donor wound models, a 7.5 x 7.5 cm and a 15 x 15 cm donor model. The majority of the dressing products were available in a 10 x 10 cm (± 1 cm) size, which was mostly the minimum size used. A single primary dressing would accommodate a wound of 7.5 x 7.5 cm. For the larger donor model not all types of dressings had a size that would cover the wound with one dressing and this had a significant impact on the overall evaluation.

Costing data was collected on all resources used for alternative interventions of STSG donor management from sources including the materials management departments, pharmacy supply departments and central sterilising services of the participating hospitals. All costs were in Australian dollars and collected during the period of July to September 2002. The cost of some resources such as staff time was uniform across all sites. All hospitals were in the public sector and permanent nursing staff were employed under the same award. Transient staff, such as agency nurses, were not considered in the analysis. When it came to the cost of consumables there was some variation for the same product between sites. For this reason it was decided to obtain costs on all consumables at each of the sites. Where significant variations existed (greater than 20%) the costs were verified again with the materials management staff. In some cases the products were costed by the box or carton that would contain multiple units. Particular care was taken to ensure the unit cost was accurate. For certain products there was a significant cost variation but this was

usually due to discounts provided because of larger volumes being purchased. Only the mean costs of the consumables are provided in this report. This accommodates the price variation and protects the confidentiality of the organisations involved. Details of the alternative interventions and the corresponding costing tables are provided in appendix 9.

As the economic evaluation was taken from the perspective of the organisation providing care it was decided to determine the number of patients who for a given period would have a STSG donor site requiring care. Within these organisations there are a number of databases that could potentially provide this information. At each site nurses used a computerised care plan system called Excelcare. The system had components known as a 'Units of Care' (UoC) that indicated what interventions were performed for the individual patient. Although each site had a UoC for STSG donor sites at one site the UoC was inactive and staff were instructed not to use this particular UoC. Staff at all sites questioned the accuracy of this system in documenting care. The next attempt at extracting the data required was to access theatre utilisation systems. These systems were not uniform across sites and did not include procedures performed in outpatient departments or on wards where small grafts may be harvested. Finally it was decided that the data would be retrieved from case mix data, which was collected uniformly at all sites. This was particularly useful as the reports for all sites could be generated centrally. The report was based on the following ICD10 codes (table 24).

Table 24: Summary of ICD10 Codes relating to the excision of STSG

ICD10 Code numbers	Intervention/procedure description
45400-01, 45403-01	SSG to granulating burn site
45400-00, 45403-00	SSG to other granulating area
45421-00 to 45421-08	SSG to burn
45406-00, 45409-00, 45412-00, 45415-00, 45418-00	SSG to burn
45448-00 to 45448-08, 45439-00	SSG, small
45442-00	SSG, extensive
45445-00	SSG, inlay
*All the above codes are inclusive of 'excision of skin for graft'.	
90669-00	Harvesting of skin, grafting separate episode

* It should be noted, that in the majority of cases donor skin would be harvested (excised) and laid on the primary wound at the same time. Although this would essentially be two procedures, they achieve one code. These codes are those in the left part of table 26. In some cases skin may be harvested to be laid at another time, which is why the final code in the table was also included. Please note that the full descriptions of the ICD10 codes and the details of the number of patients corresponding to these codes for the participating sites during the study period are provided in appendix 10 (table 57).

Phase 4: Cost effectiveness analysis

The results of the investigators previous systematic review and additional analysis from phase one provided the necessary clinical effectiveness data. Phases two and three provided costing data and detailed protocols of alternate interventions for managing STSG donors. The available data was used for two types of analysis. The comparison of hydrocolloids and the traditional paraffin gauze dressings was a 'cost effectiveness' evaluation. The systematic review previously conducted provided a differential infection rate between the two interventions. A decision tree was built based on the available data. This incorporated both large and small STSG donor sites. The proportion of large to small donor sites was estimated from the ICD-10 reports for the three participating sites for the year 2001-2002 (appendix 10). The second type of analysis conducted was a 'cost minimisation' evaluation comparing a wide range of interventions involving the use of moist wound healing products. In both

cases the analysis was conducted from the perspective of the health care provider to determine which of the alternative interventions is most cost effective. All costing data was incorporated into costing tables in Excel 2000 for Macintosh. Mean costs were used for all consumables and staffing time was based on an RN level 1, year 3, South Australian Public Service Nursing Award rates at July 2002.

The post harvest management of STSG donor sites is episodic and typically occurs at intervals dictated by both prevailing clinical factors and personal preference. These episodes of care are easily documented in table form the descriptions of the alternative interventions are therefore presented in this manner in appendix 9.

Chapter 15. Economic Evaluation Results

As stated previously, this study includes two types of economic evaluation. In comparing the use of hydrocolloid dressings (moist wound healing) and the traditional paraffin gauze dressings (non-moist wound healing) a cost effectiveness analysis was possible because the clinical data available indicated a difference between the two approaches in relation to infection rates. When comparing dressings within the moist wound healing category there was no clinical data available that demonstrated different clinical outcomes so a cost minimisation analysis was conducted.

The chapter is therefore divided into two broad sections dealing with the two evaluations separately. The chapter begins with some data that is common to both evaluations particularly with respect to the number of patients within the study settings for the previous financial year who were subject to the harvest of a STSG.

Scope of condition at study sites

Determining how many patients have a STSG donor site for a given period at a number of locations serves two major purposes. In the first instance it provides information about the significance of the issue under examination and addresses the question, 'Is the scope of the issue sufficient to support the resources required to investigate it and if required institute a change process to modify current practice?' Next the scoping exercise provides real world examples that may provide useful comparisons with similar organisations. Using the ICD10 codes provided a uniform and accurate method of determining a number of factors from the participating sites.

Number of episodes of STSG donor sites.

The ICD10 code report (appendix 10, table 60) was conducted for the 12 month period from July 2001 to June 2002. Overall for three participating sites there were 737 episodes in which patients had a STSG donor site created. At hospital 1 this figure was 161, at hospital 2 there were 185 episodes and at hospital 3, 391 episodes were recorded. It should be noted this does not represent the number of patients involved. Although the vast majority of these patients will only have a single donor site, some patients would have had multiple procedures. It does however, represent the number of instances in which a donor site is created and this is the appropriate figure for analysis.

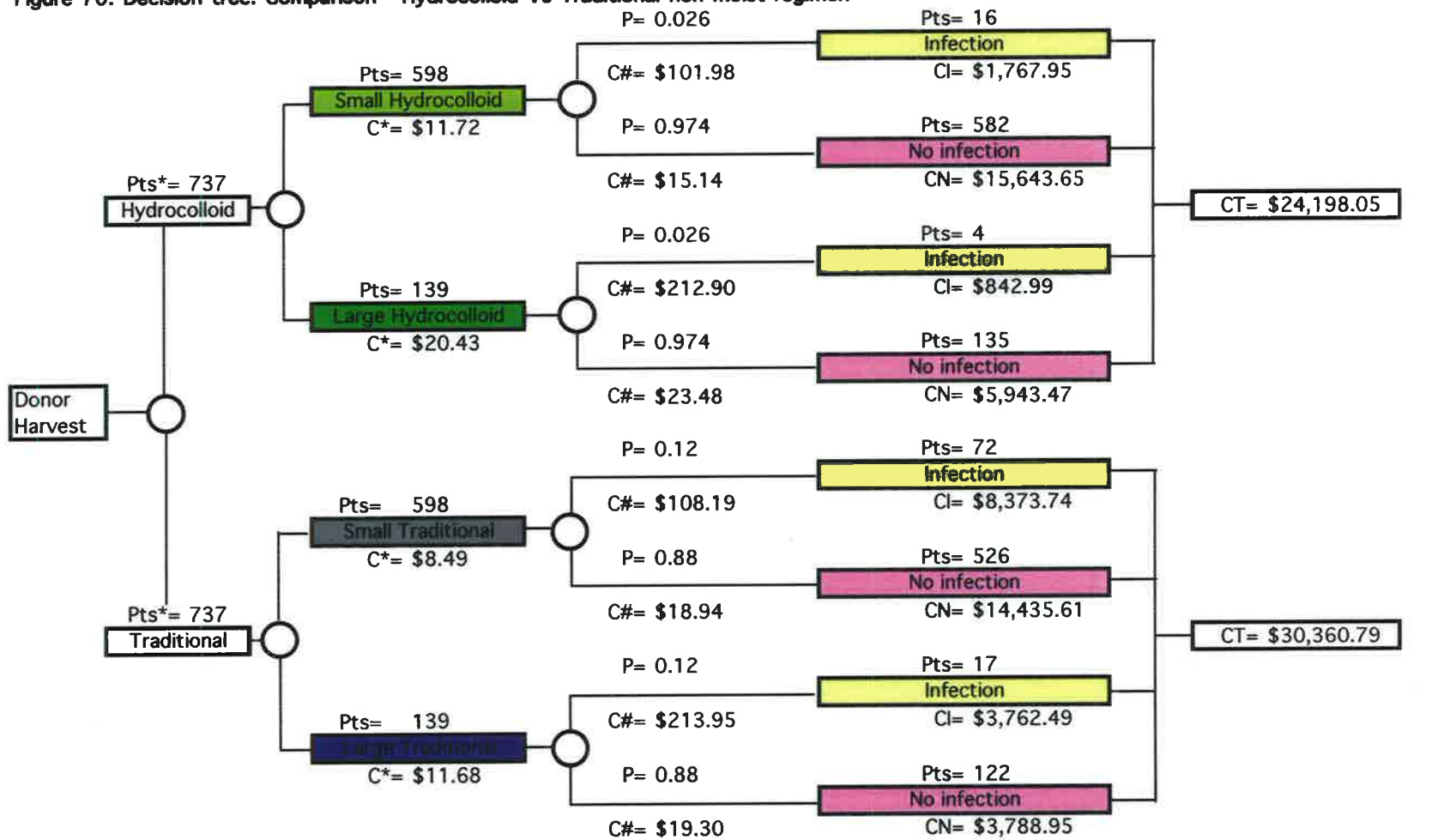
Size of donor sites

As the initial stages of the investigation developed it became increasingly obvious that it was important to determine, if possible, the size of the donor sites being harvested. Fortunately the ICD10 codes do provide some detail about the size of the grafted area thus providing an estimate of the size of the donor site required to cover this area. The table in appendix 10 has been structured to present the data categorised as either small or larger donor sites. From this report it was determined that overall 81.15% of donor sites would be classed as small and for this analysis would be considered for the 7.5cm x 7.5cm model. There was one code for excision of skin graft that was not size specific and these episodes were divided proportionally using the percentages for the other categories. As a result it was determined that 598 episodes would be classed as requiring the 7.5cm x 7.5cm model of intervention and 139 episodes requiring the larger model of intervention. These resultant figures were then used as a basis to provide an estimated of the comparative costs of a range of interventions to manage STSG donor sites at the participating sites for the 12 month period.

Comparison 1: Hydrocolloid dressings vs Paraffin gauze dressings: A cost effectiveness analysis

As previously discussed, the clinical effectiveness data derived from the systematic review indicated there was a significant difference between the infection rates of donor sites in which hydrocolloids were used as compared to the traditional paraffin gauze dressings. As a result it could be assumed that a given proportion of patients for each intervention will sustain a donor site infection. These patients would then be managed differently incurring induced costs to treat the infected donor site. Fig. 70 details a decision tree that models what would occur given the two alternative interventions based, on the 2001-2002 figures for the total number of episodes for the three participating sites.

Figure 70. Decision tree: Comparison - Hydrocolloid Vs Traditional non moist regimen



Proportion small donors 81.15%
 Proportion large donors 18.85%

Pts* Pts with donors for 2001-2002 at study sites
 C* = Additional cost at initial dressing
 C# = Additional cost to healing/pt

CI = Total additional cost for infected pts
 CN = Total additional cost for non-infected pts
 CT = Total additional cost for all pts

Description of alternative interventions

The following description gives an overview of the alternative interventions based on the decision to use either hydrocolloids or the traditional paraffin gauze dressings in the management of STSG donor sites.

Hydrocolloids

As detailed in fig. 70, when 737 cases are allocated to have hydrocolloids as the therapy of choice, 598 cases (81.15%) would have a small dressing applied and 139 (18.85%) would have the larger dressing applied. In determining costs for this episode of care materials included the primary dressing, secondary dressings and the tapes used to secure these items. Staff time to conduct the intervention was also calculated. It should be noted that overheads and the cost of the primary procedure, that of skin grafting the primary wound, was not calculated as this cost would have been equal regardless of which alternative was used in the management of the donor site. The details of the costings for this component of the intervention are found in appendix 9, table 30 for the smaller dressing model, and table 31 for the larger dressing model. The cost for the smaller dressing model was \$11.72 per episode and \$20.43 for the larger dressing model. The primary dressing (hydrocolloid) closest to the skin is self-adhesive and would not necessarily require any additional fixation. At the sites used to collect additional clinical information however, the primary dressing was additionally secured with a border of fabric retention tape. For this reason this item was also included in the costing. The primary dressing would then routinely be covered by a secondary dressing of combine and crepe bandage to manage any unforeseen leakage from the primary dressing. From the systematic review previously conducted it can be assumed that for those cases with the hydrocolloid dressing regimen 97.4% would not get infected.

Non-infected cases

For the purpose of this analysis it has been assumed that for the non-infected group there would be a dressing change at day 3, post excision. At the study sites using hydrocolloids this occurred frequently as a result of leakage and or for inspection. The costing details for this component are detailed in appendix 9, table 32 for the small donor model and table 33 for the larger model. The next component of the

intervention would be the removal of the dressing at time of complete healing. Details of this final component are provided in appendix 9, table 34 for the small donor model for the larger model. The cost of the removal of the small and large dressings were determined to be the same as the size difference made no appreciable difference in the time taken to remove the dressings the healed donor was not redressed after complete healing had occurred.

Infected cases

In the model used for this analysis it was determined that if all cases used the hydrocolloids 2.6% of cases (16 small donors and 4 large donors) would become infected. At the participating sites the management of infected donors was quite uniform. Infected donors were treated with silversulphadiazine cream. For the purpose of analysis the model assumes that treatment was daily for three days. The details of the costs are provided in appendix 9, table 35 for the small donor model and table 36 for the larger model. The application of silversulphadiazine cream was facilitated by impregnating thin porous cloth sheets by hand and applying these sheets directly to the infected donor site. This was then covered with combine dressing and crepe bandage and secured with elastic tape. Following successful treatment of the infection the donor site would be redressed with the hydrocolloid dressing (appendix 9, table 37 for the small donor model and table 38 for the larger). The final component of the intervention is identical to the non-infected donors as detailed in table 34.

Based on 737 cases that represents the situation for the 3 participating sites for a 12 month period, the additional costs of managing the STSG donor sites with hydrocolloids is \$24,198. This includes both small and large donors and those infected and without infection.

Paraffin gauze

In fig. 70, in the lower half of the decision tree, when 737 cases are allocated to use the traditional paraffin gauze dressings as the therapy of choice, 598 cases (81.15%) would have a small dressing applied and 139 (18.85%) would have the larger dressing applied. In determining costs for this episode of care materials included the primary dressing, secondary dressings and the tapes used to secure these items. Staff time to conduct the intervention was also calculated. As with the hydrocolloid regimen overheads and the cost of the primary procedure, that of skin

grafting the primary wound, were not calculated as this cost would have been equal regardless of which alternative was used in the management of the donor site. The details of the costings for this component of the intervention are found in appendix 9, table 39 for the smaller dressing model, and table 40 for the larger dressing model. The cost for the smaller dressing model was \$8.49 per episode and \$11.68 for the larger dressing model. At this point the cost comparison, prior to any infection, is considerably less for the paraffin gauze regimen. However, when the infection rate derived from the meta-analysis of the systematic review (Wiechula, 2001) is applied it can be assumed that 89 cases (12%) would become infected.

Non-infected cases

For the purpose of this analysis it has been assumed that for the non-infected group there would be a dressing change at day 3, post excision. This would not involve the complete removal of dressings but would entail the removal of tapes and outer dressings that would then be replaced. The traditional STSG donor site dressing was/is multi-layered, consisting of paraffin gauze, closest to the wound, covered then with a thick layer of cotton gauze, combine dressing and crepe bandage. The bulky dressing was designed to absorb and draw away from the wound the large amounts of haemoserous exudate so as to dry the wound out. The dressings were then secured with a binding of tape to secure the dressings even when the patient was able to ambulate. The traditional donor site dressings is no longer used at any of the study sites however many senior staff were able to describe the regimen in elaborate detail. They indicated that at some point usually within the first three days post excision the amount of exudate would strike through the outer dressings and would facilitate the need to change the outer dressings of combine and crepe. The costing details for this component are detailed in appendix 9, table 41 for the small donor model and table 42 for the larger donor.

For the non-infected cases the next component of the intervention would be the removal of the dressing at time of complete healing. Details of this final component are provided in appendix 9, table 43 for the small donor model for the larger model. As with the hydrocolloid regimen the cost of the removal of the small and large dressings were determined to be the same as the size difference made no appreciable difference in the time taken to remove the dressings the healed donor was not redressed after complete healing had occurred.

Infected cases

In the model used for this analysis it was determined that if all cases were managed with the paraffin gauze regimen 12% of cases (72 small donors and 17 large donors) would become infected. At the participating sites the management of infected donors was quite uniform and in fact was the same as for the hydrocolloid example. Infected donors were treated with silversulphadiazine cream. For the purpose of analysis the model assumes that treatment was daily for three days. The details of the costs are provided in appendix 9, table 44 for the small donor model and table 45 for the larger model. Following successful treatment of the infection the donor site would be redressed with the paraffin gauze dressing (appendix 9, table 46 for the small donor model and table 47 for the larger model). The final component of the intervention is identical to the non-infected donors as detailed in table 43.

Based on 737 cases that represents the situation for the 3 participating sites for a 12 month period, the additional costs of managing the STSG donor sites with the traditional paraffin gauze regimen is \$30,360. This includes both small and large donors and those infected and without infection.

Sensitivity analysis

One of the difficulties in determining the infection rate using data from the meta-analysis in the systematic review is that is that the rate did not account for the weighting of the studies combined in the meta-analysis. It may be argued that this would then have the potential to inflate the infection rate of the paraffin gauze regimen. It was therefore decided to conduct a sensitivity analysis to determine what the result of the analysis would be if it were assumed that the infection rate for cases managed with paraffin gauze was reduced. Assuming an infection rate of only 6% (paraffin gauze regimen) and not the 12% as previously described would still result in the hydrocolloid being more cost effective with albeit a small potential saving of \$1,337. At the point where the infection rates were assumed to be equivalent for the two alternative regimens the analysis would indicate the traditional regimen to be most cost effective but only by \$1,397. This would only represent a saving of effectively less than \$2.00 per patient.

Summary of findings

In considering the two alternative interventions of, hydrocolloid regimen and the traditional paraffin gauze regimen for the management of STSG donor sites, the cost effectiveness analysis establishes that the hydrocolloid regimen is the most cost effective. In the model described in fig. 70, should the three study sites have chosen to use the hydrocolloid regimen for all the 737 cases the cost of managing these cases would have been \$24,198. The cost of choosing the paraffin gauze alternative would have been \$30,360. Utilising the hydrocolloids provides a potential saving of \$6,162.

Comparison 2: Hydrocolloid, calcium alginate and retention dressing regimens: A cost minimisation analysis

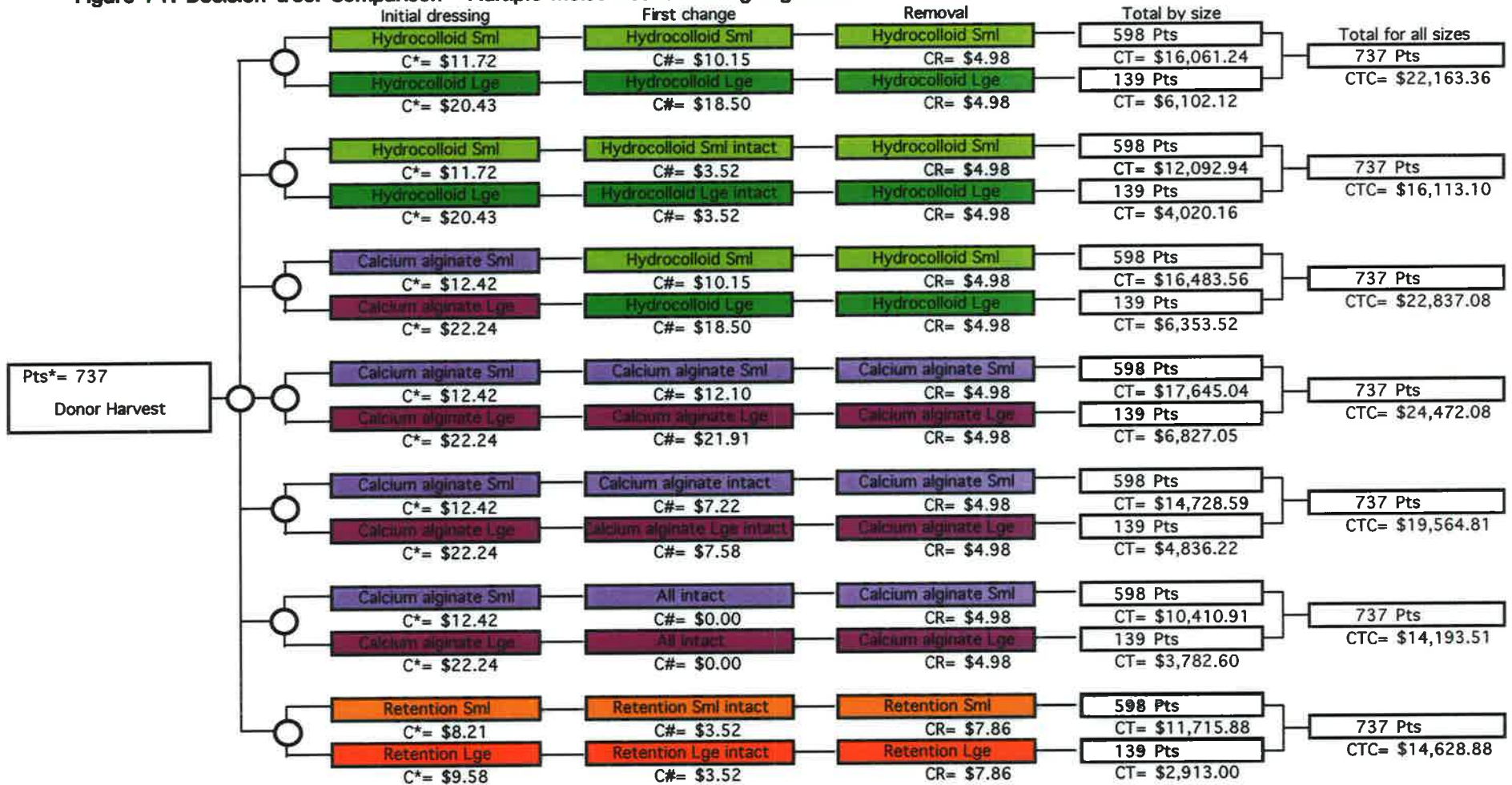
As with the previous cost effectiveness analysis the intention is not to describe every possible alternative dressing regimen but to cover a range of alternatives that were commonly seen in the study units. The three generic dressings that are considered are hydrocolloids, calcium alginates and fabric retention dressings. The main assumption used in the analysis is that the clinical outcome in terms of healing and infection were equal for all regimens described.

Descriptions of alternative interventions

The following descriptions give an overview of the alternative interventions based on the decision to use a particular moist wound healing dressing as the primary dressing in the management of STSG donor sites. The details of the analysis are depicted graphically in fig. 71, in the section following. As with the previous analysis the model describes the number of cases that occurred over a 12 month period with cases divided proportionally between small and large STSG donor sites. It should also be noted that the analysis deals with the issue of an early dressing change/inspection. Moist wound healing dressings are designed to remain intact until healing is complete. In the case of STSG donor sites this is the ideal circumstance and is frequently achieved. There are however, a number of reasons why a dressing may be removed prior to healing. These dressings have a potential to absorb a certain amount of fluid. When this potential is exceeded then the dressing will leak this excess fluid, requiring in the least a change of the secondary dressings and most often a primary dressing change. In addition, as routine there were a number of plastic surgeons that required

dressings to be removed prior to healing, as their preference was to conduct a visual inspection of the wound. For one of the regimens described, the primary dressing is changed to an alternative at this inspection stage.

Figure 71. Decision tree: Comparison - Multiple moist wound healing regimens



Proportion small donors 81.15%
Proportion large donors 18.85%

Pts* Pts with donors for 2001-2003 at study sites
C* = Additional cost at initial dressing
C# = Additional cost at first change of dressing
CR = Additional cost at removal of dressing
CT = Total additional cost including removal
CTC = Total additional cost including removal combined (S+L)

Hydrocolloids

For this group of regimens hydrocolloid dressings are the primary dressings used throughout. For each regimen the care is described for both small and large donors. The regimen is illustrated by using the number of cases that had occurred during the 12 month period at the three participating sites. It should be stressed that this is a model of what would have occurred if a particular regimen were used for all these cases. It is not a record of what actually occurred.

In fig. 71, when 737 cases are allocated to have hydrocolloids as the therapy of choice, 598 cases (81.15%) would have a small dressing applied and 139 (18.85%) would have the larger dressing applied. In determining costs for this episode of care materials included the primary dressing, secondary dressings and the tapes used to secure these items. Staff time to conduct the intervention was also calculated. It should be noted that overheads and the cost of the primary procedure, that of skin grafting the primary wound, was not calculated as this cost would have been equal regardless of which alternative was used in the management of the donor site. As the care for this regimen is identical to that described in the previous cost effectiveness analysis the details of the costings for this component of the intervention are found in appendix 9, table 30 for the smaller dressing model, and table 31 for the larger dressing model.

Primary dressing changed once prior to final removal

For this group the analysis assumes a change of dressing at day 3 post excision. The timing of this dressing change is not critical and does not effectively impact on the cost. The costing details for this component are identical to the hydrocolloid regimen used in the cost effectiveness analysis and are therefore detailed in appendix 9, table 32 for the small donor model and table 33 for the larger model. The next component of the intervention would be the removal of the dressing at time of complete healing. Details of this final component are provided in appendix 9, table 34 for the small donor model and for the larger model.

Primary dressing intact until final removal

The variation for the hydrocolloid regimen involves inspection of the dressings but with leaving the primary dressing intact. The cost of the initial dressings remains the same but there is a cost reduction if at inspection the primary dressing remains

intact. The costing details of this component of the regimen are presented in table 48. The cost of removal of the dressing once healed is the same for all hydrocolloid examples (see table 34).

Summary for the hydrocolloid regimens

The analysis indicates that if there were 737 cases and all cases used a hydrocolloid regimen that included a change of primary dressing prior to healing the total additional cost would be \$22,163 (see fig. 71). This does not take into account infected donor sites as the model assumes no difference in infection rates between the moist wound healing regimens. If all cases (737) were subjected to a hydrocolloid regimen that had the primary dressing remain intact the total additional cost would be \$16,113 (see fig. 71).

Calcium alginates

For this group of regimens calcium alginates are the primary dressings used throughout the intervention until the donor is healed.

In determining costs for this episode of care materials included the primary dressing, secondary dressings and the tapes used to secure these items. Staff time to conduct the intervention was also calculated. As with the hydrocolloids two regimens are described one with the primary dressing removed and redressed and alternatively with the primary dressing remaining intact throughout the management of the STSG donor site. Calcium alginates are highly absorbent dressings that can manage wounds with high exudate levels. The calcium alginate is applied directly to the wound and reinforced with further absorbent layers of gauze, combine dressings crepe bandage and elastic tape. The details of the additional cost for the initial calcium alginate donor site dressings are provided in the costing tables; table 49 (small donors) and table 50 (large donors).

Primary dressing changed once prior to final removal

For this group the analysis assumes a change of dressing at day 3 post excision. The costing details for this component are detailed in appendix 9, table 51 for the small donor model and table 52 for the larger model. The next component of the intervention would be the removal of the dressing at time of complete healing. Details of this final component are provided in appendix 9, table 53 for the small donor model and for the larger model.

Primary dressing intact until final removal

The variation for the calcium alginate regimen involves inspection of the dressings but with leaving the primary dressing intact. The cost of the initial dressings remains the same but there is a cost reduction if at inspection the primary dressing remains intact. The costing details of this component of the regimen are presented in table 54 for small donor sites and table 55 for large donor sites. The cost of removal of the dressing once healed is the same for all calcium alginate examples (see table 53).

Primary and secondary dressings intact until final removal

A further variation for the calcium alginate regimen involves leaving both the primary and secondary dressings intact. No additional costs are incurred in the interim period.

Summary for the calcium alginate regimens

The analysis indicates that if there were 737 cases and all cases used a calcium alginate dressing regimen that included a change of primary dressing prior to healing the total additional cost would be \$24,472 (see fig. 71). This again does not take into account infected donor sites as the model assumes no difference in infection rates between all the moist wound healing regimens. If all cases (737) were subjected to a calcium alginate regimen that had the primary dressing remain intact the total additional cost would be \$19,565 (see fig. 71). For the third variation where all dressings remain intact until healing is achieved the total additional costs would be \$14,194 (see fig. 71).

Calcium alginate/hydrocolloid combination

At two of the study sites a regimen was regularly used in which the primary dressing was changed at the early inspection stage from a calcium alginate to a hydrocolloid dressing. The staff involved provided the rationale that, when the donor site was newly excised the calcium alginate provided the additional absorption required. When the donor had stabilised and was exuding only small to moderate amounts of fluid the hydrocolloid provided adequate absorption and was flexible enough to increase comfort when ambulating. This explanation was anecdotal and was not specifically tested by this study. The costing tables previously used for calcium alginates (initial dressings) and hydrocolloids (inspection/first change and removal) were used for this regimen. The result was that for the example of 737 cases the total additional costs for donor site management were \$22,837 (see fig. 71).

Retention tape dressings

The final group of dressing regimens concerns those with the primary dressing of fabric retention tape. This dressing is gaining some popularity and was used almost exclusively at one of the units at a participating site. The method involves applying the adhesive tape directly to the wound. There are a number of brands available in a variety of widths so that most wounds can be totally covered with an adequate margin. The tape is porous and exudate escapes into the absorbent secondary dressings. Once haemostasis has been achieved the outer dressings are removed and the primary dressing can be wet and dried again allowing patients who are capable, to shower. Due to the conformability of the dressing patient can ambulate with comfort. Again it should be noted that this is was beyond the resources of this study to quantifiably demonstrate these attributes of the retention dressings.

The costing tables that describe the initial dressings for both wound sizes for retention dressings are presented in tables 56 (small) and 57 (large) respectively. The costings for the inspection with secondary dressings only removed are presented in table 58 (both small and large donor sizes). The removal of the retention tape dressings, are costed in table 59. The total additional costs, if all 737 cases were to have the retention tape dressings, is \$14,628.

Summary for the comparison of all moist wound healing regimens

A wide range of alternative moist wound healing dressing interventions were analysed to determine which regimen produced the minimal costs. Based on a 737 cases, 598 cases would represent wounds of approximately 7.5 x 7.5 cm or less and 139 cases of larger donors up to approximately 15 x 15cm. The analysis detailed in fig. 71 indicates the total additional costs if all cases were to follow one particular regimen. As these regimens essentially are a secondary procedure overhead costs such as hospitality costs are not included in the analysis. The regimen with the least additional costs is that where calcium alginates are used and all dressings are left intact until complete healing has occurred (\$14,192). The regimen that incurs the greatest additional cost is also a calcium alginate regimen in which there is replacement of the primary dressing during the period of healing (\$24,472). The difference between these two strategies is over \$10,000 or a mean of \$13.94 per

case. The example using retention tape dressings (\$14,628) is almost equivalent to calcium alginate regime with all dressings intact. In general for the regimens where the primary dressing remains intact the cost difference is negligible. Further fine-tuning would involve mixing regimens based on size of donor wound. Using the number of cases previously specified if all patients with the smaller donor sites were managed with calcium alginates and the cases with larger donors managed with retention tape dressings the total additional costs would be \$13,324.

Chapter 16. Economic Evaluation Discussion

In regarding the results of this study the reader is reminded that the intention is to compare the cost effectiveness of a range of interventions used in the post harvest management of STSG donor sites. The analysis uses a number of regimens that describe, in as much detail as possible, what would occur in actual practice. In describing these regimens there are two major inter-related issues that the reader must consider. In the first instance, as with any area of practice, there is the potential for variability in practice. The regimens describe a range of interventions that differ in the type of materials and the manner in which they are used. For instance, in some cases one primary dressing is used and maintained until the intervention is completed, in other circumstances the dressings are removed prior to healing and the donor site redressed with either the same primary dressing or even another type of primary dressing. Throughout the period of data collection in the clinical area a great deal of variation in practice was observed. This variation was evident both between sites and between individuals at the same sites. In some cases variation was due to personal preference of the clinicians. In other cases, as expected, it was due to the specific circumstances of the individuals that were the subject of the intervention. There was no intention to present all observed regimens but to represent a reasonable cross-section to provide the reader with a range of alternatives to consider.

The second issue that should be considered is that within the confines of the study not all variables could be observed directly. In the case of the traditional paraffin gauze dressings, none of the sites reported using this dressing method although all sites had previously done so. Clinicians were able to describe in detail this intervention and 'mock' dressings were conducted to achieve reasonably accurate timings.

Limitations

As with any research exercise this study was compromised in a number of ways that ultimately limit the strength of the results. In particular, economic evaluation is criticised because it often includes assumptive elements in modelling that may be judged as unrealistic or inaccurate. There have been assumptions made in conducting this study that if adequate resources were available may have been more accurately verified. The following sections deal with the limitations of the study and detail why

certain assumptions were made and in what way this may have impacted on the strength of the results.

Accuracy of costings

As detailed in the methods chapter, the cost of various items used in the analysis were provided by materials management and other relevant departments at the three participating sites. In terms of staffing costs this was calculated at the rate for a base level registered nurse at three years post registration. For the participating sites the hourly rate for this level of staff would have been uniform as all sites were public hospitals and subject to the same industrial award. It may be argued that a more junior staff member could have conducted the interventions. If a junior staff member was used in the modelling this would have some impact on the comparative cost of the alternative regimens however the impact of time on overall costs was minimal and this was not likely to alter the overall results.

The cost of the dressings and consumables did alter between sites and this occurred for a variety of reasons. In discussion with materials management staff, prices varied in the first instance due to the volume purchased. This is particularly important for wound products where there are not only viable alternatives between generic types of dressings but also within generic dressing groups. These wound products are not only used for donor sites but many other wound types also. Consequently depending on the types of wounds (including donors) and the volumes to be treated, a particular site may achieve a significant discount price for their dressing purchase. It was also apparent that companies who supplied a range of dressing types provided discounts for 'bundled' purchases. For example, if a site required four or five different dressing types, and these could all be supplied from the same company, a discount would be offered to have the products supplied from the one source. There was no way to determine what discounts might be applied for particular dressing products if the volumes used in the analysis were applied. This would only represent a proportion of the total product purchased. Given these limitations it was decided that averaging the unit prices between sites was the only viable approach. The other issue that must be addressed in relation to the cost of dressings is that within generic dressing groups there may be several suppliers with dressings that are identical or have some minor variation. In what is a very competitive market there was often variation in cost between products that clinicians would otherwise consider identical. Again, it was

decided that where two alternatives of the same dressing type were available an average would be used in the analysis. These costs are detailed in the costing tables in appendix 9. The specific costs of products provided by the individual sites are not detailed in this report on instruction from the participating sites.

The use of clinical effectiveness data from systematic review

A crucial element in any economic evaluation of practice is the integrity or robustness of the clinical effectiveness data used in the analysis. As previously indicated there are a number of alternative approaches to deriving this data. The clinical effectiveness data used in this study were derived using meta-analysis of previously conducted clinical trials. Using this approach means the study is to a degree constrained by the data that is available. This constraint is twofold. In the first instance there is the level of confidence in the accuracy of the effectiveness measures used in the analysis. In the case of the infection rates for the comparison between hydrocolloids and the traditional paraffin gauze dressings results were determined from the meta-analysis of only a small number of studies with modest sample sizes. The sensitivity analysis compensates for this limitation to a degree.

The other constraint that must be considered is the availability of head to head trials. The retention tape dressings were included in the comparison because of the growing interest in this approach to donor site management but clearly there are very few well designed RCTs or IITs to substantiate their clinical effectiveness. These issues will be specifically explored in the discussion that follows in relation to the results of the two comparisons.

Comparison 1: Hydrocolloids versus paraffin gauze dressings

The decision tree (fig. 70) illustrates both the probable clinical outcomes for our study population and the associated costs (excluding common costs) of the alternative interventions. As a result of the increased infection rate for the traditional paraffin dressings the hydrocolloid is determined to be the most cost effective of the two alternatives. The result however is not absolute and the following questions should be addressed. Firstly how confident are we in this outcome and then to what degree is the result generalisable?

Addressing the first part of this question there are a range of issues that should be considered. As previously discussed the clinical effectiveness data used in this analysis is retrospective and derived from the meta-analysis of four studies. When pooled the total number of subjects was only 211 patients (Wiechula, 2001). Although the result was statistically significant in favour of the hydrocolloids with regard to infection rate this represents a modest sample size. This is somewhat balanced by fact that the studies used were of high quality using the gold standard of RCT/IIT design. In addition the sensitivity analysis demonstrated that after the infection rate for the traditional donor dressings was reduced by 50%, the hydrocolloid was still more cost effective. In determining the costs of the alternate interventions it should also be considered that only the hydrocolloid intervention was observed in actual practice. As the traditional paraffin dressing was no longer used at any of the study sites a mock dressing was performed to establish both the consumables that would be used and the time to undertake the intervention. At all sites there were clinicians that had previously performed this intervention and were able to verify what consumables would be used for the dressing. The less reliable element in the modelling was the time taken and thus the labour costs of the intervention. The most accurate method of determining the time taken for the procedure would have been to observe this care being undertaken on actual patients in the clinical setting but this was simply not possible. Given these considerations it can be argued that there is still a strong degree of confidence in the results of the analysis.

The analysis was conducted within a given context; three large teaching hospitals in one city in Australia, at a given time, 2001, with a particular population using dressings that were managed in a specified manner. The purpose of conducting the analysis was to inform clinicians not only in the study settings but also more broadly. In determining the generalisability of the findings, the following should be considered. Using the output from meta-analysis has an advantage over prospective data from a single study as the pooling of multiple study results increases their generalisability (Pang et al., 1999). In this case the studies used were from a variety of settings and demographic types (Wiechula, 2001). The fact that the study sites for the additional clinical data and cost data were large teaching hospitals should be considered. In terms of the feasibility of using hydrocolloids for STSG donor management in other settings it should be noted that the intervention is not reliant on any specific

infrastructure and the post harvest care using hydrocolloids could easily be managed in a variety of settings. The availability of hydrocolloids may be an issue, however as evidenced from the systematic review, clinical studies were conducted in a number of countries and this suggests they are widely available.

In summary comparing the two interventions, the traditional paraffin tulle donor dressing regimen and the hydrocolloid regimen, without the confounding impact of complications, the hydrocolloid is more costly. However, when the impact of infection is taken into account, clearly the hydrocolloid regimen is more cost effective. These results are sufficiently robust that from an economic perspective it is difficult to support the continued use of the paraffin tulle regimen. Clinical decision making however must consider issues other than cost. The results of the analysis should be considered in conjunction with subjective evidence particular to the individual and the setting in which the clinical decision is made, but there is also some objective evidence that should also be considered. The results of the systematic review indicate that in addition to infection rates the hydrocolloid is superior in terms of healing time and pain further supporting the case for the use of hydrocolloids (Wiechula, 2001).

Comparison 2: Multiple moist wound healing products/strategies compared

The major issue to address when considering the results of the cost minimisation analysis of the range of moist wound healing dressings/regimens is the assumption that all the alternatives perform equally well in terms of clinical effectiveness. It is assumed that rates of infection, healing and pain levels will be the same for all regimens. It is important to note that this assumption is made not because we have objective evidence that this is the case but because there is no strong evidence to dispute this. As previously discussed, there are few head to head trials comparing the clinical effectiveness of hydrocolloids and calcium alginates. There is even less objective evidence with regard to retention tape dressing regimens (Wiechula, 2001). In most cases where moist wound healing products have been subjected to comparative trial the control/comparator was the traditional paraffin gauze regimen. Arguably, in the past this choice of control was appropriate, however with an apparent shift in interest to moist wound healing regimens it is odd that more recent studies are still being conducted with the traditional comparator. There is an

argument that suggests that without strong clinical effectiveness evidence the cost minimisation analysis should not be conducted (Drummond et al., 1997). The decision to conduct the analysis was based on the concern that despite the lack of clinical trials these products are being used in practice. This does not supersede the need to conduct head to head trials, in fact it further supports that their conduct is imperative. The reader should then consider the results of the analysis knowing that the head to head clinical effectiveness data is deficient and treat the results with due caution.

In the first comparison for this study only two alternate dressing regimens were compared. In the second comparison a wider variety of regimens were considered. Importantly the variation in the regimens is not only in the type of primary dressing used but also in how the dressings are managed. The major variations in management relate to the inspection and or replacement of the primary dressing. As stated in the results chapter when the primary dressings are left intact the difference in cost between the regimens is minimal. For instance the average cost per patient (total excluding common costs) for the hydrocolloid regimen with the primary dressing intact at the inspection stage is AUD\$21.85. For the calcium alginate regimen, when all dressings are intact until complete healing, the average cost is AUD\$19.25. Naturally, as indicated in fig. 71, when the primary dressings are inspected and changed the cost per patient increases considerably. This is a crucial consideration. When the additional clinical data was being collected a variety of justifications were given for both leaving the primary dressing intact or alternatively replacing it. Some clinicians indicated that their preference was to remove the primary dressing, usually at day three post operatively to definitively assess the wound. Others indicated that they felt they could adequately assess the wound with the primary dressing intact and that removing the primary dressing increased the risk of contamination. The problem is that these clinical opinions are anecdotal. One of the objectives of the systematic review of clinical effectiveness was to identify studies where, for the same primary dressing there was comparison of different management methods. No studies examining the issue of leaving the primary dressing intact versus changing it were identified (Wiechula, 2001). Again we have the situation where variation in practice is occurring but has not been tested objectively with high quality clinical comparative trials.

Combining clinical and cost effectiveness results

One of the aims of this study was to compare the cost effectiveness of a range of regimens for the post harvest management of STSG donor sites. Due largely to the available clinical effectiveness data two comparisons using different techniques were conducted. The first comparison between the traditional paraffin gauze dressings and the more contemporary hydrocolloid dressings favours the hydrocolloids, that is the hydrocolloid is the more cost effective treatment option. This result is given with a strong level of confidence and is relatively generalisable. Combined with the available clinical effectiveness data from the systematic review in relation to patient pain/comfort levels and healing rates, the objective evidence suggests that paraffin gauze dressings should not be used. The evidence does indicate that hydrocolloids should be used but only as an alternative to the traditional style of dressings. This is also in keeping with the principles of moist wound healing. The difficulty is that there are many other options for the management of STSG donor sites, which the second comparison attempts to address. The analysis for this comparison is based on the assumption that all regimens are equally clinically effective. The major differences in the regimens are the primary dressing product used and the necessity to visually inspect the wound early in the intervention. This assumption is not based on objective evidence but rather the absence of evidence to dispute this. If the assumptions about the product used and visual inspection are tested in rigorous clinical trial the outcomes may impact on our analysis and subsequent recommendation in a number of ways.

If the assumption that there is no greater risk in leaving the dressings intact is supported by clinical trial, regardless of the primary dressing products used, then the clinical and economic evidence supports the case that unless otherwise clinically indicated dressings should be left intact and the type of primary dressing used will not significantly impact on cost.

If by way of rigorous clinical trial it can be shown that mandatory early inspection, regardless of dressing type, will result in significantly reduced infection rates then the focus shifts to the type of primary dressing used. This is because the analysis indicates that the additional cost of changing the primary dressings varies depending on the dressing type used.

If it can be demonstrated that depending on the type of primary dressing used different clinical outcomes occur (particularly in relation to infection rates) then the current analysis is redundant and no conclusions can be drawn from it.

Another element that has not been considered in either of the two comparisons presented in the study is the cost of changing practice. Clearly from the data collection at the three sites there is quite a deal of variation both in the primary dressing product and the manner in which that product is used. In the least there would be some costs incurred for staff training when altering practice.

Summary of discussion

Due to the uniform nature of the creation of the STSG donor site it is reasonable to assume that there is considerable opportunity for consistency in the management of these wounds. Despite this we know that there is considerable practice variability both in terms of products used and the manner in which they are used. The analysis conducted in this study provides us with cost effectiveness results that when combined with clinical effectiveness data provide evidence that supports a reduction in this variability. The strength of this evidence is however variable largely due to the confidence in the assumptions made in the economic modelling used in the analysis. In the case of the traditional paraffin gauze dressings there is strong evidence that this intervention is not cost effective and considering adverse clinical outcomes should be abandoned. The analysis does not however provide us with a single definitive product and regimen that can be considered best practice. The evidence suggests that hydrocolloids are a more cost and clinically effective alternative, but there is lack of evidence to indicate that they are superior to other moist wound healing alternatives. There is some evidence to suggest that calcium alginates or retention tape dressings may be more cost effective but this is based on clinical assumptions that are yet to be rigorously tested.

Although the results of this study may be seen as somewhat disappointing in that the evidence is variable in strength and therefore limited in its ability to support and direct a reduction in practice variability a number of recommendations for practice and future research can be made. The final chapter will summarise these recommendations.

Chapter 17. Economic Evaluation Conclusions

An inherent characteristic of clinical wound management is that in all cases the focus of the care, the wound and off course the wounded, is variable. No two wounds are identical. In the case of traumatic and chronic wounds the number of intrinsic and extrinsic factors that can impact on the wound and on the subsequent management are considerable. There is at least one example that is an exception. In the case of STSG donor using modern harvesting methods wounds can be created relatively uniformly. This is not to say that all donor sites are identical and that the individuals with these wounds are also identical but compared with many other wound types there is a high degree of uniformity in the wound itself. It is this level of uniformity that allowed Winter (1962) to conduct his seminal research comparing dry and moist wound healing techniques on domestic pigs. It is this uniformity that provides a reasonable potential to reduce variability in the management of these wounds.

Despite this potential it is obvious there is practice variability both in the products and strategies used in the management of STSG donor sites. To reduce this variability will require individuals to change their practice. Inducing clinicians to change practice is a complex issue that is the subject of considerable study and debate. The major contribution of the evidence based movement to practice change is in providing objective evidence to support which practice alternative should be considered best practice. In the case of STSG donor sites this study and the preceding systematic review provide objective evidence of clinical and economic effectiveness. The task is to consider what implications this evidence has for practice recommendations.

Recommendations for practice

From the outset it must be stated that the clinical and economic effectiveness evidence does not provide us with a single unequivocal regimen that could be considered best practice. The evidence does allow some recommendations about practice to be made.

If we consider the vast array of alternatives available for the post harvest management of STSG donor sites our strongest evidence directs us against the use of the traditional paraffin gauze type regimens. They should simply not be used in practice. The use of hydrocolloid sheet dressings is considered to be superior. However, there are a large number of moist wound healing alternatives to

hydrocolloids. Unfortunately there is no strong objective evidence to indicate which of these alternatives are superior and should be considered best practice. Further there are variations in the manner in which these dressings can be used. The cost effectiveness analysis indicates that mandatory change of dressings can be a significant factor when deciding on a particular dressing type but critically there is a gap in the clinical effectiveness evidence to direct us with this recommendation.

Recommendations for research

It is often the case with evidence based researchers that when evidence synthesis fails to provide definitive recommendations for practice then somewhat ironically it leaves us with strong and definitive recommendations for research. This study is no exception. In terms of clinical trials the primary recommendation would be to cease using the control/comparator of the traditional paraffin gauze dressing. Instead it is strongly recommended that head to head trials comparing alternative moist wound healing products should be conducted and the focus should be on those most widely used in the first instance. Perhaps the most important finding and subsequent recommendation to come from this study relates to the issue of mandatory dressing changes. This has previously not been explored in clinical trials. It certainly has potential cost implications but also may have considerable impact on patient comfort and therefore should be investigated in future trials. This is a fundamental issue and one that is wider than STSG donor management. The basis of moist wound healing is that the dressings are able to maintain an optimum environment to best facilitate healing. Unnecessary dressing changes have the potential to disrupt this environment and retard wound healing. The STSG donor site does provide a relatively unique opportunity where clinical trials can be conducted with a high level of control and uniformity to explore this issue.

Part 4: Portfolio Integrating the Findings

Chapter 18. Portfolio Discussion and Conclusions

As stated previously the value of undertaking doctoral research is not isolated to the study findings. In being instructed and supported through a research project the doctoral candidate develops skills that can then be used to conduct further research. Since completing the systematic review as part of this program the candidate has completed further reviews and is currently involved in teaching the review process to others. In the case of the Doctor of Nursing the candidate develops skills within a number of research designs. This is particularly important for nursing, although arguably the same can be said for healthcare generally, where the complexity of practice demands that research be an integrated process using a variety of study designs. This is perhaps the major appeal of the Doctor of Nursing where a program of research is completed rather than a single study. This also fits well with what is emerging in the evidence based practice movement. The recent and growing impetus to review and incorporate evidence beyond the RCT into practice recommendations (Pearson, 2004; Popay & Roen, 2003) is recognition that a pluralistic approach to evidence is necessary. The structure of the Doctor of Nursing is also demonstrative of the symbiosis of knowledge translation and knowledge generation. Nursing in particular has been criticised for conducting small, isolated and often unnecessarily duplicated clinical studies. It is therefore logical to conduct a systematic review to confirm with confidence the justification for conducting further primary research.

Perhaps the most significant limitation of this particular Doctoral portfolio is that it was undertaken at a time when the methods of reviewing evidence other than clinical effectiveness were only just emerging. The Cochrane Qualitative Methods Group, the Campbell Collaboration and the Joanna Briggs Institute among others have been examining the review of qualitative research (Popay & Roen, 2003). Pearson (Pearson, 2004) is taking this a step further with the development of the SUMARI software suite that will allow the conduct of the Comprehensive Systematic Review. This involves conducting an integrated review of multiple evidence types.

Integration of studies

In addition to providing the candidate with research skills the studies have also provided evidence that informs practice. The results of the studies as detailed in the individual reports are of value even when viewed in isolation however in keeping with

the notion of integrating evidence the following discussion will consider the results of the two studies and how they may be combined to inform practice.

There is always the hope that in reviewing the evidence that, simple and direct recommendations, without equivocation can be made. In the review of the evidence of clinical effectiveness no one intervention stood out as best practice. The review established, with a great degree of confidence, that moist wound healing methods of dressing STSG donor sites are superior to the traditional 'dry' methods in terms of healing, infection and patient comfort. These traditional methods are still being used in some practices and should be abandoned. When considering the range of moist wound healing dressings the picture is less clear. The lack of head to head research comparing moist wound healing dressings of different types means that no particular generic group can be held above another. These dressings all function by attempting to maintain a moist wound environment but they do not do this uniformly. Dressings within one generic group such as semi-permeable films are designed to manage wounds with a low level of exudate. At the other end of the spectrum calcium alginates are able to manage wounds with high levels of exudate. This suggests that clinicians have available to them a range of dressing products that can be tailored to the individual circumstances that they may be presented with in the practice setting. There was however no evidence identified that would confirm this conclusively, leading to the recommendation that this research be conducted.

Based on the premise that evidence of clinical effectiveness is only one factor in considering how to manage a STSG donor site other evidence that might additionally direct practice was sought. The second project of the portfolio was the economic evaluation. The purpose of conducting the economic evaluation was not only to generate evidence of economic effectiveness in relation to the management of STSG donor sites but to demonstrate how the clinical effectiveness data from meta-analysis may be incorporated into this type of study. In this way not only can the results of the two studies be integrated but the conduct of the second study is linked to the results of the review. The economic evaluation concluded that the traditional dry methods of dressing STSG donor sites was less cost effective than using hydrocolloids. This was due mainly to the increase in infection rate for the traditional donor dressing as identified in the systematic review. When comparing a variety of moist wound dressings the results were more complex and related to the

size of the wound and the frequency of dressing changes. It is possible to consider the results of the systematic review and the economic evaluation within a framework.

The tables (25 and 26) below are a further refinement by the JBI of the work done by Pearson and the QARI development group on the FAME scale (Joanna Briggs Institute, 2004b).

Table 25: Joanna Briggs Institute Levels of Evidence Hierarchy

Level of Evidence	Feasibility F(1-4)	Appropriateness A(1-4)	Meaningfulness M(1-4)	Effectiveness E(1-4)	Economic Evidence EE (1-4)
1	SR of research with unequivocal synthesised findings	SR of research with unequivocal synthesised findings	SR of research with unequivocal synthesised findings	SR (with homogeneity) of Experimental studies (eg. RCT with concealed allocation) Or 1 or more large experimental studies with narrow confidence intervals	SR (with homogeneity) of evaluations of important alternative interventions comparing all clinically relevant outcomes against appropriate cost measurement, and including a clinically sensible sensitivity analysis
2	SR of research with credible synthesised findings	SR of research with credible synthesised findings	SR of research with credible synthesised findings	Quasi-experimental studies (eg. without randomisation)	Evaluation of important alternative interventions comparing all clinically relevant outcomes against appropriate cost measurement, and including a clinically sensible sensitivity analysis
3	SR of text/opinion with credible synthesised findings	SR of text/opinion with credible synthesised findings	SR of text/opinion with credible synthesised findings	3a. Cohort studies (with control group) 3b. Case-controlled 3c. Observational studies without control groups	Evaluation of important alternative interventions comparing a limited number of outcomes against appropriate cost measurement, without a clinically sensible sensitivity analysis
4	Expert opinion without explicit critical appraisal	Expert opinion without explicit critical appraisal	Expert opinion without explicit critical appraisal	Expert opinion without explicit critical appraisal, or based on physiology, bench research or consensus	Expert opinion without explicit critical appraisal, or based on economic theory

Table 25 is an evidence hierarchy table that accommodates the ranking of different types of evidence. It is intended that this table will undergo further refinement. Evidence tables/hierarchies are the source of considerable debate. Many alternative hierarchies exist and there is no consensus about which is most appropriate. Fundamentally this table addresses the issue that for a given area of practice clinicians can and should consider a range of evidence types and that these different types of evidence can be considered in an integrated fashion.

Table 26 is a hierarchy of grades of recommendation. Again it is distinct in that it attempts to accommodate the principle that recommendations can arise from a variety of evidence types and that each can inform practice in a different way.

Table 26: Joanna Briggs Institute Grade of Recommendation Hierarchy

Grade of Recommendation	Feasibility	Appropriateness	Meaningfulness	Effectiveness
A	Immediately practicable	Ethically acceptable and justifiable	Provides a strong rationale for practice change	Effectiveness established to a degree that merits application
B	Practicable with limited training and/or modest additional resources	Ethical acceptance is unclear	Provides a moderate rationale for practice change	Effectiveness established to a degree that suggests application
C	Practicable with significant additional training and/or resources	Conflicts to some extent with ethical principals	Provides limited rationale for practice change	Effectiveness established to a degree that warrants consideration of applying the findings
D	Practicable with extensive additional training and/or resources	Conflicts considerably with ethical principals	Provides minimal rationale for advocating change	Effectiveness established to a limited degree
E	Impracticable	Ethically unacceptable	There is no rationale to support practice change	Effectiveness not established

To illustrate how these hierarchies may be used the results of the two projects will be considered.

In comparing the traditional paraffin gauze dressings with the hydrocolloids the systematic review provided evidence rated at E1 that the hydrocolloids were superior in terms of clinical effectiveness. Assuming the economic evaluation is of sufficient quality the results indicate that there is evidence rated at EE2 that hydrocolloids are more cost effective than the traditional donor dressings. In both cases these are high rankings without conflict. In recommending hydrocolloids the grade of recommendation would be the highest A in terms of effectiveness. The review did not examine evidence of meaningfulness, appropriateness or feasibility although the results of the economic evaluation indicate that hydrocolloids do not require any additional resources and would receive an A rating for feasibility.

Comparing the different moist wound healing alternatives is quite a different matter. The evidence of clinical effectiveness from the systematic review established that hydrocolloids and calcium alginates are a better option than the traditional donor

dressing. The review failed to establish a clear leader in terms of the moist dressings. A third classification of dressing was included in the economic evaluation, the retention tape dressing. This was included in the evaluation as it is being used in a number of practice settings. This is despite the fact that at the time of the systematic review there were no clinical trials identified that assessed the effectiveness of this dressing type. Taking the case of the retention tape dressing in particular the level of evidence of clinical effectiveness is the lowest level, E4. The level of economic effectiveness with regard this dressing was EE2. Further the evidence from the economic evaluation indicated that although dressing type did have some impact on cost it was the frequency of dressing change that was one of the most important factors. The evidence regarding frequency of dressing change was therefore rated EE2 but only rated E4 as the clinical effectiveness of this strategy has not been determined in clinical trial. The recommendation that dressing changes for routine inspection early in the healing phase of a donor not occur, would have a grade of recommendation of A for feasibility and E for effectiveness.

Table 27: Example levels of evidence and grades of recommendation

Intervention/ Comparison	Level of Evidence					Recommendation	Grade of Recommendation					
		F	A	M	E		EE		F	A	M	E
Hydrocolloid Vs paraffin gauze for STSG donor sites	1						The use of paraffin gauze should be abandoned	A				
	2							B				
	3							C				
	4							D				
								E				
Retention tape Vs other moist for STSG donor sites	1						Retention tape may be used	A				
	2							B				
	3							C				
	4							D				
								E				
Routine early inspection of STSG donor sites	1						Routine early inspection of donor sites should be avoided	A				
	2							B				
	3							C				
	4							D				
								E				

A number of issues arise from this classification process. Firstly although it would be preferable to provide clinicians with direct and unequivocal recommendations for practice this is not always going to be the case. In considering the traditional paraffin gauze dressings the evidence and subsequent recommendation is clear. Regarding the moist wound healing alternatives, recommendations for practice are hampered by

not only by a lack of evidence but conflicting directions from different types of evidence. This approach will naturally be the subject of considerable debate and is highly likely to undergo many further refinements, however its value is in attempting to provide a frame work that considers different types of evidence that inform an area of practice and to consider the distinction between the resultant levels of evidence and grades of recommendation.

Conclusions

This program of research was intended to achieve a number of aims. In the first instance it was an attempt to translate existing research and generate new research to inform practice and this has certainly been the case. The evidence available to inform practice varied for a variety of reasons not the least of which was the amount and quality of evidence already in existence. Despite this some significant recommendations for practice have been identified. The program additionally encouraged the dissemination of the evidence for practice. The subsequent publications and presentations of the studies conducted testify to the success of that aim. The program also provided an opportunity to examine of a number of trends emerging from the evidence based practice movement including the recognition that multiple forms of evidence from a variety of research designs are appropriate to inform practice and that these require a framework that can be used to consider each with due weight.

The program of research also raised for the candidate a number of questions that have prompted ongoing research. One of the fundamental issues that confronts anyone researching healthcare, either by conducting primary research or through the synthesis of research via systematic review, is that different types of evidence are not uniformly valued. It is clear that until recently many involved in the evidence review held evidence of clinical effectiveness as having greater value than that of other evidence. We can speculate as to why this is now changing. Clearly there are now health professionals conducting systematic reviews that have come from research traditions not dominated by quantitative research. Logically this has and will continue to result in the dominant position of clinical effectiveness being challenged. It is also reasonable to speculate that those who use the output from systematic reviews might also exert some influence on the emerging approach to evidence

review. With this in mind the candidate has commenced an ethnographic study to examine some of these issues. If as researchers we wish to provide evidence that informs practice and leads to practice change then we must consider what value the end users will place on the evidence. The study is examining a number of similar practice settings where all had previously used the traditional paraffin dressing routinely to manage STSG donor sites. All have abandoned the traditional dressings but subsequently there is no consistency between units as to the dressings and strategies used to manage donors. The question to be answered is what evidence was used to change practice? How was this evidence processed? What value was given to the different types of evidence? This research is due for completion in late 2004.

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**Appendix 1 - Publications Arising from Research
Projects**

1.1 Systematic Review Report

Wiechula, R. (2001). *Post harvest management of split thickness skin graft donor sites*. Adelaide: Joanna Briggs Institute for Evidence-Based Nursing and Midwifery.

NOTE:

This publication is included in the print copy
of the thesis held in the University of Adelaide Library.

1.2 Peer Reviewed Article from the Systematic Review

Wiechula, R. (2003). The use of moist wound-healing dressings in the management of split-thickness skin graft donor sites: a systematic review. *International journal of nursing practice*, 9(2), S9-S17.

NOTE:

This publication is included in the print copy of the thesis held in the University of Adelaide Library.

It is also available online to authorised users at:

<https://doi.org/10.1046/j.1322-7114.2003.00417.x>

**1.3 Joanna Briggs Institute Best Practice Information Sheet
(English and Italian Versions)**

Wiechula, R. J. (2002). Split thickness skin graft donor sites: post harvest management. *Best Practice*, 6(2), 1-6.

Also the same article translated into Italian.

NOTE:

This publication is included in the print copy
of the thesis held in the University of Adelaide Library.

1.4 Abstraction of Best Practice Information Sheet

Wiechula, R. J. (2003). Management of skin graft donor sites. *The World of Irish Nursing*, [3p.].

NOTE:

This publication is included in the print copy
of the thesis held in the University of Adelaide Library.

Appendix 2 - List of Portfolio Related Presentations

Wiechula, R. 'Post Harvest Management of the Split Thickness Skin Graft Donor Site: A Systematic Review' at First World Wound Healing Congress, Melbourne, September 2000.

Wiechula, R. 'Post Harvest Management of the Split Thickness Skin Graft Donor Site: A Systematic Review' at Generating and Using Research Findings to Achieve Best Practice, Royal Adelaide Hospital, Adelaide, September 2001.

Wiechula, R. 'An economic evaluation of alternate interventions for the post-harvest management of split thickness skin graft donor sites.' 2nd Biennial International Conference on Nursing Best Practice Guidelines, Ontario. June 2003

Wiechula, R. 'The integration of evidence of clinical effectiveness, economic effectiveness and context to assist decision making in wound management.' 2nd Biennial International Conference on Nursing Best Practice Guidelines, Ontario (poster presentation). June 2003.

Appendix 3 - STSG Donor Site Products/Treatments used in this Review

Table 28: Categories of products treatments used in the review

General Category	Generic Group	Trade Names
Non-moist	Fine mesh gauze	Aquaphor
	Impregnated gauze (non medicated)	Jelonet Scarlet Red Tulle Graz Xeroform
	Impregnated gauze (medicated)	Aquaflo Carbonet Fucidin Furacin Haemodan Sofratulle Trex
Moist wound healing	Calcium alginate	Algiderm Kaltostat
	Hydrocolloid sheet	Comfeel Thin Dermasorb, (DuoDERM, Granuflex, Varihesive) Sureskin Wound Contact Layer
	Hydrogel sheet	Zenoderm
	Polyurethane foam	Lyof foam
	Polyurethane semi-permeable membrane	Eurothane Omiderm Opsite Tegaderm Ventex

General Category	Generic Group	Trade Names
Biological	Allograft (cultured epidermal)	
	Allograft (cultured keratinocyte)	
	Allograft meshed	
	Amniotic membrane	
	Collagen sheet (human)	Biobrane
	Collagen sheet (bovine)	Corethium Dermodress Skin Temp
	Collagen sheet (porcine)	Coethium EZDerm
	Growth factor (rHGH)	Nutropin, Protopin
	Growth factor (bFGF)	
	Growth factor (rEGF)	
Miscellaneous	Aerosol acrylic film	Nobecutane
	Anticonvulsant	Phenytoin
	Antimicrobial	Silversulphadiazine Betadine Iodoplex
	Beeswax	
	Herbal	Asiaticaside
	Hyaluronic acid	
	Live yeast cell derivative	
	Non-adherent sheet	N-terface
	Ointment	Bepanthen
	Retention tape dressing	Fixomull Hypafix Mefix
	Silicone sheet	(with Orfloxacin)

Appendix 4 - Inclusion Criteria: Split Skin Graft Donors

Inclusion Criteria: Split Skin Graft Donors

Author _____ Year _____ Record Number _____

Types of Participant

Patients with split skin graft donor sites



Types of Intervention

Intervention(s) relating to the management of SSG Donors



Types of Outcome Measure

Measures of healing of SSG Donors



and/or

Infection rates of SSG Donors



and/or

Pain scales



Types of Studies

Randomised controlled trial



Intra-Individual Controlled trial



Appendix 5 - RCT/II Critical Appraisal Form: Split Skin Graft Donors

RCT/II Critical Appraisal Form: Split Skin Graft Donors

Author _____ Year _____ Record Number _____

Questions 1-4 must be answered "yes" for study to be included in the meta-analysis.

1. Were the recipients randomised to study groups or where intra-individual controls used?

yes no not clear

2. Other than the research interventions were participants/sites in each group treated the same?

yes no not clear

3. Were the outcomes measured in the same manner for all participants?

yes no not clear

4. Were the groups comparable at entry?

yes no not clear

Studies that answer no to questions 5,6 or 7 will only be included in the systematic review if no other high quality studies are identified, however this must be noted in the report.

5. For RCT only studies was randomisation of participants blinded?

yes no not clear

6. Were those assessing outcome blinded to treatment allocation (if outcome was not objective such as survival or length of hospitalisation)?

yes no not clear

7. Was there adequate follow-up of participants?

yes no not clear

(Less than 80% followed up)

Appendix 6 - References Excluded from Analysis

The following are references that were accepted as fulfilling the criteria for study type but were unable to be used in analyses due to methodological issues.

Table 29: References excluded from analysis

Study	Comparison	Reason for exclusion
Attwood (1989)	Calcium alginate Vs Jelonet	Following phase I some treatment areas were changed to become control areas for phase II. Result were unable to be isolated for phase I
Barnett, Berkowitz, Mills, & Vistnes (1983b)	Fine mesh gauze Vs Opsite Vs Tegaderm	Some dressings were altered to Xeroform prior to healing
Bettinger, Gore, & Humphries (1995)	Calcium alginate Vs Scarlet Red	Some patients had CA dressings removed daily others were left for longer periods
Biltz, Kiessling, & Keyser (1985)	Hydrocolloid Vs saline gauze	Report did not indicate if groups were randomised
Birdsell, Hein, & Lindsay (1979)	Opsite Vs Owens Silk Vs Scarlet Red	No numerical results were provided
Blight, Fatah, Datubo Brown, Mountford, & Cheshire (1991)	"The treatment of donor sites with cultured epithelial grafts."	Patients with delayed healing excluded from analysis
Brady, Snelling, & Chow (1980)	Opsite, Vaseline Petroleum Gauze (fine), Jelonet (course), Scarlet Red, & exposure.	Randomisation process was invalidated by local conditions
Brotherston & Lawrence (1993)	Hydrocolloid Vs Tulle Gras	Treatment allocated on rotation
Cadier & Clarke (1996)	DuoDERM Vs Tulle-gras.	In the treatment group the method of dressing changes was altered during the study
Genecov et al. (1998)	A subatmospheric pressure dressing V.A.C. Vs Opsite	Over 30% 5/15 of the treatment group dropped out of the study
Harris, Filarski, & Hector (1973)	Silastic sheet Vs fine mesh gauze	No detailed results of the study were provided

Study	Comparison	Reason for exclusion
Horch & Stark (1998)	Collagen dressing Vs polyurethane dressing	No information provided re randomisation
Jonkman, Bruin, Pennings, Coenen, & Klasen (1989)	Poly(ether urethane) dressing Vs Tulle Gras	In the film group some dressings were removed and others left intact following trauma
Myczkowski (1975)	Perforated cellophane Vs Tulle Gras	No information provided re randomisation
Owen & Dye (1990)	Lignocaine gel Vs K-Y jelly	Allocation not randomised
Perrot, Carsin, & Gilbaud (1986)	DuoDERM Vs Tulle Gras	The management of the DuoDERM group in terms of dressing changes was altered throughout the study
Porter (1991)	Hydrocolloid Vs calcium alginate	A number of patients had donor sites grafted if delayed healing was expected these patients were included in the results for both groups but could not be distinguished
Reig, Tejerina, Codina, Hidalgo, & Mirabet (1991)	Varihesive Vs Opsite	Only half of the subjects were treated with control and treatment. These patients are unable to be distinguished in the results
Roberts, McManus, Mason, & Pruitt (1985)	DuoDERM Vs fine mesh gauze	Prior to dressing application the FMG group were treated with 'hot' saline pads while the DuoDERM group received thrombin soaked pads.
Robinson et al. (1983)	Beeswax Vs paraffin gauze	No details of allocation method
Shelanski (1992)	DuoDERM Vs Tegaderm Vs Alldress + NormlGel Vs Opsite + Intrasite	The Opsite + Intrasite group was discontinued part way through the study
Steenfos & Agren (1998)	Calcium alginate Vs Jelonet	Not all patient in the Alginate group were treated the same
Waymack et al. (1986)	Aquaphor Gauze Vs fine mesh gauze	Criteria only applies to Phase I which was abandoned after three cases
Weber et al. (1995)	Polyurethane Foam Vs Paraffin Gauze	Some patients given ABs. Some patients did self assessment
Yadav et al. (1993)	Topical Phenytoin Vs Opsite Vs Soframycin	No evidence of randomisation

Appendix 7 - Data Extraction Form: Split Skin Graft Donors

Data Extraction Form: Split Skin Graft Donors

Author Record Number

Journal

Year

Reviewer

Method

Setting

Participants
(male or female)

Number of Participants

Group A Group B Group C

Interventions

Intervention A

Intervention B

Intervention C

Outcome Measures

Definition of donor healing

Other Outcome Measures

Outcome Description	Scale/measure

Results

Dichotomous Data

Outcome	Treatment Group number/total number	Control Group number/total number

Continuous Data

Outcome	Treatment Group mean & SD (number)	Control Group mean & SD (number)

Authors Conclusions

Comments

Appendix 8 - Level of Evidence Ratings for the Systematic Review

Level of Evidence Ratings

Studies were categorised according to the strength of evidence based on the following classification system.

Level I Evidence obtained from a systematic review of all relevant randomised controlled trials

Level II Evidence obtained from at least one properly designed randomised controlled trial

Level III.1 Evidence obtained from at least one well designed controlled trial without randomisation

Level III.2 Evidence obtained from well designed cohort or case control analytic studies preferably from more than one centre or research group

Level III.3 Evidence obtained from multiple time series with or without intervention. Dramatic results in uncontrolled experiments

Level IV Opinion of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Appendix 9 - Costing Tables for Interventions

Comparison 1 Hydrocolloid dressing regimen verses paraffin gauze regimen

Table 30: Costing table, hydrocolloid dressing intervention, initial dressing at excision, day 0 post-op, small donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	hydrocolloid sheet	9.5 x 9.7 cm	1	\$3.80	\$3.80
	retention tape	2.5 cm x 10 m	0.06	\$6.18	\$0.37
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	10 cm x 1.5 m	1	\$0.92	\$0.92
	Elastoplast tape	2.5 cm x 3m	0.5	\$3.12	\$1.56
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$11.72

Table 31: Costing table, hydrocolloid dressing intervention, initial dressing at excision, day 0 post-excision, large donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	hydrocolloid sheet	18.9 x 19.5 cm	1	\$11.90	\$11.90
	retention tape	2.5 cm x 10 m	0.1	\$6.18	\$0.62
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	15 cm x 1.5 m	1	\$1.29	\$1.29
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$20.43

Table 32: Costing table, hydrocolloid dressing intervention, inspection/redress, day 3 post-excision, small donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	hydrocolloid sheet	9.5 x 9.7 cm	1	\$3.80	\$3.80
	retention tape	2.5 cm x 10 m	0.06	\$6.18	\$0.37
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$10.15

Table 33: Costing table, hydrocolloid dressing intervention, inspection/redress, day 3 post-excision, large donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	hydrocolloid	18.9 x 19.5 cm	1	\$11.90	\$11.90
	retention tape	2.5 cm x 10 m	0.1	\$6.18	\$0.62
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$18.50

Table 34: Costing table, hydrocolloid dressing intervention, removal of dressings, at complete healing, small and large donor sites.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	dressing pack	1	1	\$1.19	\$1.19
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$4.98

Table 35: Costing table, hydrocolloid dressing intervention, treatment day 3, 4 and 5 post-excision, small infected donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	Silversulphadiazine	100 gm	1	\$10.77	\$10.77
	Daylee towels	34 x 60 cm x 2	1	\$0.87	\$0.87
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	10 cm x 1.5 m	1	\$0.92	\$0.92
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves sterile size 8	1 pair	1	\$0.70	\$0.70
	gown sterile	1	1	\$2.00	\$2.00
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	Staffing RN1 yr3	minutes	10	\$0.45	\$4.49
Sub Total					\$27.78
Total	Treatment for 3 days				\$83.34

Table 36: Costing table, hydrocolloid dressing intervention, treatment day 3, 4 and 5 post-excision, large infected donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	Silversulphadiazine	500 gm	1	\$42.95	\$42.95
	Daylee towels	34 x 60 cm x 2	1	\$0.87	\$0.87
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	15 cm x 1.5 m	1	\$1.29	\$1.29
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves sterile size 8	1 pair	1	\$0.70	\$0.70
	gown sterile	1	1	\$2.00	\$2.00
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	Staffing RN1 yr3	minutes	13	\$0.45	\$5.84
Sub Total					\$61.67
Total	Treatment for 3 days				\$185.01

Table 37: Costing table, hydrocolloid dressing intervention, infected donor site, redress following treatment for infection, small infected donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	hydrocolloid sheet	9.5 x 9.7 cm	1	\$3.80	\$3.80
	retention tape	2.5 cm x 10 m	0.06	\$6.18	\$0.37
	dressing pack	1	1	\$1.19	\$1.19
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	drape cloth sterile	1	1	\$1.00	\$1.00
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	7	\$0.45	\$3.14
Total					\$13.65

Table 38: Costing table, hydrocolloid dressing intervention, infected donor site, redress following treatment for infection, large infected donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	hydrocolloid sheet	18.9 x 19.5 cm	1	\$11.90	\$11.90
	retention tape	2.5 cm x 10 m	0.1	\$6.18	\$0.62
	dressing pack	1	1	\$1.19	\$1.19
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	drape cloth sterile	1	1	\$1.00	\$1.00
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	9	\$0.45	\$4.04
Total					\$22.90

Table 39: Costing table, paraffin gauze dressing intervention, initial dressing at excision, day 0 post-op, small donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	paraffin gauze	10 x10 cm	2	\$0.47	\$0.94
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	10 cm x 1.5 m	1	\$0.92	\$0.92
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$8.49

Table 40: Costing table, paraffin gauze dressing intervention, initial dressing at excision, day 0 post-excision, large donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	paraffin gauze	10 x10 cm	8	\$0.47	\$3.77
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	15 cm x 1.5 m	1	\$1.29	\$1.29
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$11.68

Table 41: Costing table, paraffin gauze dressing intervention, inspection/redress, day 3 post-excision, small donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	10 cm x 1.5 m	1	\$0.92	\$0.92
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$7.22

Table 42: Costing table, paraffin gauze dressing intervention, inspection/redress, day 3 post-excision, large donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	15 cm x 1.5 m	1	\$1.29	\$1.29
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$7.58

Table 43: Costing table, paraffin gauze dressing intervention, removal of dressings, at complete healing, small and large donor sites.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	dressing pack	1	1	\$1.19	\$1.19
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	n/saline	1 Litre	1	\$1.47	\$1.47
	Staffing RN1 yr3	minutes	20	\$0.45	\$8.98
Total					\$11.72

Table 44: Costing table, paraffin gauze dressing intervention, treatment day 3, 4 and 5 post-excision, small infected donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	Silversulphadiazine	100 gm	1	\$10.77	\$10.77
	Daylee towels	34 x60 cm x 2	1	\$0.87	\$0.87
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	10 cm x 1.5 m	1	\$0.92	\$0.92
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves sterile size 8	1 pair	1	\$0.70	\$0.70
	gown sterile	1	1	\$2.00	\$2.00
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	Staffing RN1 yr3	minutes	10	\$0.45	\$4.49
Sub Total					\$27.78
Total Treatment for 3 days					\$83.34

Table 45: Costing table, paraffin gauze dressing intervention, treatment day 3, 4 and 5 post-excision, large infected donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	Silversulphadiazine	500 gm	1	\$42.95	\$42.95
	Daylee towels	34 x60 cm x 2	1	\$0.87	\$0.87
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	15 cm x 1.5 m	1	\$1.29	\$1.29
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves sterile size 8	1 pair	1	\$0.70	\$0.70
	gown sterile	1	1	\$2.00	\$2.00
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	Staffing RN1 yr3	minutes	13	\$0.45	\$5.84
Sub Total					\$61.67
Total Treatment for 3 days					\$185.01

Table 46: Costing table, paraffin gauze dressing intervention, infected donor site, redress following treatment for infection, small infected donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	paraffin gauze	10 x 10 cm	2	\$0.47	\$0.94
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	10 cm x 1.5 m	1	\$0.92	\$0.92
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	7	\$0.45	\$3.14
Total					\$13.13

Table 47: Costing table, paraffin gauze dressing intervention, infected donor site, redress following treatment for infection, large infected donor site.

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	paraffin gauze	10 x 10 cm	8	\$0.47	\$3.77
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	15 cm x 1.5 m	1	\$1.29	\$1.29
	Elastoplast tape	2.5 cm x 3m	0.5	\$3.12	\$1.56
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	n/saline	1 Litre	1	\$1.47	\$1.47
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	9	\$0.45	\$4.04
Total					\$17.22

Comparison 2: Hydrocolloid, calcium alginate and retention dressing regimens

Table 48: Costing table, hydrocolloid dressing intervention, inspection, primary dressing remains intact, small and large donor sites

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	dressing pack	1	1	\$1.19	\$1.19
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$3.52

Table 49: Costing table, calcium alginate dressing intervention, initial dressing at excision, day 0 post-op, small donor site

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	calcium alginate sheet	10 x10 cm	1	\$4.88	\$4.88
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	10 cm x 1.5 m	1	\$0.92	\$0.92
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$12.42

Table 50: Costing table, calcium alginate dressing intervention, initial dressing at excision, day 0 post-op, large donor site

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	calcium alginate sheet	10 x20 cm	2	\$7.16	\$14.33
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressings	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	15 cm x 1.5 m	1	\$1.29	\$1.29
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$22.24

Table 51: Costing table, calcium alginate dressing intervention, inspection/redress, day 3 post-excision, small donor site

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	calcium alginate sheet	10 x10 cm	1	\$4.88	\$4.88
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	10 cm x 1.5 m	1	\$0.92	\$0.92
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$12.10

Table 52: Costing table, calcium alginate dressing intervention, inspection/redress, day 3 post-excision, large donor site

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	calcium alginate sheet	10 x20 cm	2	\$7.16	\$14.33
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	15 cm x 1.5 m	1	\$1.29	\$1.29
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	gloves non-sterile med	1	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$21.91

Table 53: Costing table, calcium alginate dressing intervention, removal of dressings, at complete healing, small and large donor sites

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	dressing pack	1	1	\$1.19	\$1.19
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	n/saline	1 Litre	1	\$1.47	\$1.47
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$4.98

Table 54: Costing table, calcium alginate dressing intervention, inspection, primary dressing remains intact, small donor sites

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	10 cm x 1.5 m	1	\$0.92	\$0.92
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$7.22

Table 55: Costing table, calcium alginate dressing intervention, inspection, primary dressing remains intact, large donor sites

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	15 cm x 1.5 m	1	\$1.29	\$1.29
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	dressing pack	1	1	\$1.19	\$1.19
	drape cloth sterile	1	1	\$1.00	\$1.00
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$7.58

Table 56: Costing table, retention tape dressing intervention, initial dressing at excision, day 0 post-op, small donor site

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	retention tape	10 x 10 cm	1	\$0.66	\$0.66
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	10 cm x 1.5 m	1	\$0.92	\$0.92
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$8.21

Table 57: Costing table, retention tape dressing intervention, initial dressing at excision, day 0 post-op, large donor site

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	retention tape	15 x 40 cm	1	\$1.67	\$1.67
	gauze squares	10 x 80 cm x 4	1	\$2.60	\$2.60
	combine dressing	20 x 20 cm	1	\$0.21	\$0.21
	crepe bandage	15 cm x 1.5 m	1	\$1.29	\$1.29
	Elastoplast tape	2.5 cm x 3 m	0.5	\$3.12	\$1.56
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$9.58

Table 58: Costing table, retention tape dressing intervention, inspection, primary dressing remains intact, small and large donor sites

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	dressing pack	1	1	\$1.19	\$1.19
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$3.52

Table 59: Costing table, retention tape dressing intervention, removal of dressings, at complete healing, small and large donor sites

Direct costs	Materials	Unit measure	Quantity	Unit cost	Total cost
	dressing pack	1	1	\$1.19	\$1.19
	gloves non-sterile med	1 pair	1	\$0.08	\$0.08
	Zoff adhesive remover	250mL	0.5	\$5.76	\$2.88
	n/saline	1 Litre	1	\$1.47	\$1.47
	Staffing RN1 yr3	minutes	5	\$0.45	\$2.25
Total					\$7.86

Appendix 10 - ICD10 Codes Report

Table 60: Complete episodes recorded for the period July 2001 To June 2002

ICD10 code	Descriptor	Hosp 1	Hosp 2	Hosp 3	Totals
45400-00	Split skin graft of small granulating area	1	2	2	5
45400-01	SSG small granulating burn site <3% BSA	0	1	1	2
45406-00	SSG to burn of other sites inv <3% BSA	5	1	64	70
45421-08	Split skin graft to burn of genitals	0	0	2	2
45439-00	Small split skin graft of other site	111	156	220	487
45445-00	Split skin graft as an inlay graft	1	0	0	1
45448-00	Small split skin graft of eyelid	1	4	8	13
45448-08	Small split skin graft of genitals	0	0	1	1
Sub-total		119	164	298	581
45403-00	SSG of extensive granulating area	7	3	3	13
45403-01	SSG extensive granulating burn site >=3% BSA	0	0	2	2
45409-00	SSG burn other sites inv >=3% & <6% BSA	4	1	10	15
45412-00	SSG burn other sites inv >=6% & <9% BSA	1	1	8	10
45415-00	SSG burn other sites inv >=9% & <12% BSA	1	0	4	5
45418-00	SSG to burn other sites inv >=12% BSA	1	0	13	14
45442-00	Extensive split skin graft of any site	26	16	34	76
Sub-total		40	21	74	135
90669-00	Excision of skin for graft	2	0	19	21
TOTAL	All categories	161	185	391	737

Note; the pink area relates to donor sites in the smaller range, the grey area is of donor sites in the larger range.