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WORKING PAPER 104

Moist Wound Dressings and Pressure Relieving Surfaces

Mechanisms, Materials and a Review of Some Cost-Effectiveness Findings

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ACKNOWLEDGMENTS

The Health Economics Unit of the CHPE is supported by Monash University.

The Program Evaluation Unit of the CHPE is supported by The University of Melbourne.

Both units obtain supplementary funding through national competitive grants and contract research.

The research described in this paper is made possible through the support of these bodies.

AUTHOR ACKNOWLEDGMENTS

This paper reports findings from an appraisal of cost-effectiveness analyses commissioned by the Wound Care Industry Council (WCIC) of the Medical Industry Association of Australia (MIAA). The views expressed are not necessarily those held by the Wound Care Industry Council or by the Medical Industry Association of Australia.

Many thanks to Dr Graeme Hawthorne for his various helpful comments relating to certain aspects of this paper.

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Abstract

This paper is intended to provide background to guide future work in establishing the cost-effectiveness of modern wound care practices. An outline of the rationale, indications and effectiveness is given for two aspects of the total wound care protocol: pressure relief and moist wound dressings. Against this background of mechanisms and materials for wound healing, methodology employed in reported cost-effectiveness studies is appraised with a view to identifying a set of rigorous studies that might accurately reflect the value of adopting alternative wound care methods as part of a standard treatment protocol.

Several methodological shortcomings were identified in the studies reviewed. Moreover, these studies generally fell well short of the rigorous application of CEA methods necessary to inform questions of resource allocation at the societal level. Nonetheless, reviewed findings provide a guide to the magnitude of key factors influencing the cost-effectiveness of pressure relieving surfaces and moist wound healing. Further, modelling cost-effectiveness around reviewed findings could well produce robust estimates of C/E suitable to guide resource allocation.

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A An Overview of Wound Healing

1 Introduction

A greater understanding of the broad range of factors in effective wound care has evolved in tandem with the success of a multi-disciplinary approach to total wound care (Ameis *et al*, 1980; Van Ness, 1989). Wound care protocols may vary as to management of underlying disease processes, method of debridement, method of wound cleansing, choice of dressing, topical medication, nutrition and pressure relief. Clearly, interactive effects are likely between particular permutations of treatment parameters and the evaluation of wound healing becomes increasingly complicated as additional effects are taken into account. Nonetheless, advances in knowledge as to prevention strategies and optimal healing environments demand particular attention to two aspects of the total wound care protocol: pressure reduction and moist wound healing.

The ambition of Part A of this paper is to provide an outline of the rationale, indications and effectiveness of pressure reduction and moist wound healing. In addition, competing product classes for moist wound healing and for pressure reduction will be described and their specific indications and effectiveness noted. A good deal of medical terminology is used throughout this review and the reader is referred to the glossary (Appendix 1) for clarification of terms.

2 Aetiology and treatment considerations

Wound care encompasses a number of disparate interventions tailored to a broad range of underlying causes and mechanisms for initial injury. Consequently, this review must narrow its focus for some topics and provide a more general outline of others. Due to the large number of elderly people affected and the significant cost of illness, pressure ulcers will be taken as the proto-typical case. A more general outline of relevant considerations will be provided for venous ulcers, donor site repair, burns and for acute and traumatic wounds.

2.1 Pressure Ulcers

Pressure ulcers generally occur due to the application of external forces such as pressure, friction and shear. Remsburg and Bennett (1997) identify pressure as the main cause of pressure ulcers and outline the mechanism for tissue damage;

'Pressure can lead to tissue damage through a cascade of events beginning with hypoperfusion. Compromised blood flow can lead to tissue hypoxia, acidosis, haemorrhage into the interstitium and accumulation of toxic cellular wastes resulting in cell death. Initial microscopic necrosis elicits an inflammatory response, inflammation causes further damage' (Remsburg and Bennett, 1997 p. 516).

A threshold pressure of 32 mm Hg is generally regarded as sufficient to result in tissue damage (Remsburg and Bennett, 1997), with 'the amount of damage proportional to the extent of the pressure and the time it is applied' (Leigh and Bennett, 1994 p. 28s). However, relatively short periods of pressure-relief have been found to significantly reduce the risk of tissue damage (Bader, 1993; Kosiak, 1961). Shear and friction forces act to weaken the resilience of affected sites, tissue damage then becomes likely at increasingly lower pressures and with increasingly brief exposure. Pressure ulcers usually occur at sites over bony prominences such as the sacrum, ischial tuberosities, greater trochanter and heel (Leigh and Bennett, 1994) where pressure may be as high as 100 to 150 mm Hg (Houle, 1969; Lindan, 1961).

Several additional risk factors identified by Leigh and Bennett (1994) serve to moderate the mechanism for tissue damage outlined above;

- ***Immobility*:** short periods of pressure-relief afford a significant reduction in the risk of tissue damage. Goode and Allman (1989) cite a study by Exton-Smith and Sherwin (1961) in which 'no patient with more than 50 spontaneous nocturnal movements developed a pressure ulcer, 90% of patients with 20 or fewer spontaneous movements developed an ulcer' (p. 1513).

- ***Incontinence*:** skin contact with moisture acts to 'macerate tissue' (Remsburg and Bennett, 1997) and 'predisposes to damage of the deeper layers of the skin' (Goode and Allman, 1989; Remsburg and Bennett, 1997). Risk of pressure ulcer development in patients with urinary incontinence may be as high as 5.5 times that of continent patients (Lowthian, 1977).

- ***Sensory perception/Motor control:*** impaired pain sensation reduces the impetus for the patient to change position. Further, reduced awareness and loss of motor control impair mobility and diminish the patient's ability to relieve prolonged pressure. Finally, deterioration of motor control and fitting may result in increased shear forces and friction (Leigh and Bennett, 1994). Various diseases of the nervous system may act to reduce sensory perception and motor control. Further, management of disease symptoms becomes increasingly complicated given the likely elevated risk of pressure ulcers associated with sedation and pain relief.

- ***Reduced blood flow:*** pressure induced hypoperfusion is the precipitating factor in the cascade of events leading to tissue damage (Remsburg and Bennett, 1997). Factors which predispose to compromised blood flow, such as hypotensive medication, ischaemic heart disease, peripheral vascular disease or low blood pressure, therefore increase the risk of pressure ulcer formation (Leigh and Bennett, 1994).

- ***Age*****:** each of the risk factors discussed above are more prevalent in the elderly. In addition, 'increased skin permeability, decrease in subcutaneous and dermal tissue mass, and decline in the repair rate in elderly skin' (Goode and Allman, 1989 p. 1514) contribute to the higher risk of pressure ulcers in the aged.

- ***Nutrition*****:** increased risks of tissue damage and adverse effects on healing rates both arise due to loss of condition. Their severity may be reduced through avoidance of dehydration and increased intake of protein, vitamins and zinc (Leigh and Bennett, 1994).

- ***Pressure relief and reduction*****:** the deleterious effects of immobility may be reduced through strategies for turning and positioning and the avoidance of inappropriate support surfaces.

The individual and joint effects of these disparate risk factors determine the incidence and severity of pressure ulcers. Aspects of wound care will likely vary according to the severity of the treated wound. The U.S. National Pressure Ulcer Advisory Panel has developed a standardised classification of pressure ulcer severity to facilitate the clear specification of indications and contra-indications related to wound severity. Goode and Allman (1989) summarise this classification as follows:

> ***Stage 1:*** Non-blanchable erythema of intact skin
> ***Stage 2:*** Partial thickness skin loss involving the epidermis or dermis
> ***Stage 3:*** Full-thickness skin loss involving subcutaneous tissue that may extend to, but not through, the underlying fascia.
> ***Stage 4:*** Deeper, full-thickness lesions extending into muscle or bone (p. 1511).

It should be noted that progression through various stages of healing occurs for wounds at each severity level. This healing process and its stages are discussed in Part A Section 4.

2.2 Aspects of Wound Care by Aetiology

The underlying mechanisms for tissue damage dictate the range of relevant considerations in specifying a treatment protocol. However, certain concerns are common to all wounds and a general outline of the ideal healing environment is given in Part A Section 4.1 and 4.2.

Venous ulcers

Venous ulcers develop due to irregularity in venous blood flow. Burton (1994) outlines one of several possible mechanisms for tissue damage;

> 'Incompetent valves of the leg veins and the associated venous reflux and retrograde flow result in high venous pressure. …raises microcirculatory pressure, with an enhanced permeability of large molecules into the skin. One of these molecules polymerises as fibrin in the perivascular space. …..fibrin cuffs impede oxygen diffusion and nutrient/waste exchange' (p. 38s).

The outline of risk factors for pressure ulcers identified pressure relief as an important aspect of the treatment protocol. Similarly, treatment of the underlying mechanisms for tissue damage must accompany local wound care for venous ulcers. Local wound care entails selection of dressings to maximise fibrinolysis whilst management of the underlying disease requires control of venous pressure to prevent further tissue damage. 'Compression bandaging counteracts the harmful effects of ambulatory venous hypertension while avoiding the need for bed rest' (Burton, 1994 p. 39s).

Acute and traumatic wounds

The absence of a persisting, underlying disease greatly simplifies the treatment protocol for traumatic and acute wounds. However, the underlying causes of injury may still influence the appropriate local treatment. 'The ability of a wound to resist infection has a direct relationship to the mechanism and cause of injury' (Wijetunge, 1994 p. 57s). For example, impact wounds are substantially more susceptible to infection than wounds secondary to shearing forces or surgery (Wijetunge, 1994). Additional concerns stem from the relative importance of scarring and pain as dimensions of effectiveness in treating acute and traumatic wounds.

Burns

Treatment concerns specific to burns stem from the functional and cosmetic effects of hypertrophic/keloid scarring. 'The majority of burns are superficial partial skin thickness injuries njunction with relief from pain and prevention of infection is as important as rapid wound closure' (Smith et al, 1994a p. 46s). Local wound care might therefore consist of compression with silicone gels which has been shown to be effective in several studies cited by Reiter (1994) in reducing the colour, texture and thickness of hypertrophic and keloid scars (Quinn, 1987; Ahn et al, 1989; 1991; Mercer, 1989).

Donor sites

Accelerated healing may have particular advantages for skin graft donor sites. Faster healing rates reduce the interval required between harvest and re-harvest (Smith et al, 1994b). Additional concerns stem from the possible deterioration of partial skin thickness donor sites to full skin thickness wounds due to secondary infection.

3 Prevention and pressure relieving surfaces

Pressure reduction/relief was identified from the aetiology of pressure ulcers as an important aspect of treatment. A reduction in tissue interface pressure below the threshold of 32 mm Hg and/or regular periods of pressure relief prevent hypoperfusion and hence reduce the risk of eventual tissue damage. Traditional treatment strategies focused on regular turning to relieve prolonged pressure and positioning to minimise pressure over bony prominences. More recently, a focus on cost containment through prevention has seen increasing use of pressure relieving devices in the treatment and prevention of pressure ulcers. Pressure relieving surfaces conform 'to the contours of the body so that pressure is distributed over a larger surface area rather than concentrated on a more circumscribed location' (Remsburg and Bennett, 1997 p. 518). Goode and Allman (1989) advise the use of pressure relieving surfaces as a preventative measure in high risk populations and in any patient diagnosed with a pressure ulcer at a stage 1 or greater level of severity (p. 1517).

A broad range of strategies and products for pressure relief/reduction are currently in use, with the adoption of particular approaches primarily dependent on the biases of treating physicians rather than on the basis of established clinical effect. The US Agency for Health Care Policy and Research (AHCPR) has recommended the use of various pressure relieving surfaces for the treatment and prevention of pressure sores despite 'a paucity of evidence to support their effectiveness' (Remsburg and Bennett, 1997 p. 513). Findings of reduced tissue interface pressures or increased capillary blood flow are often *presumed* to translate into lower pressure ulcer incidence. However, two recent prospective descriptive studies cited by Remsburg and Bennett (1997) reported that pressure ulcer incidence was not associated with the use of pressure-relieving surfaces (Allman *et al*, 1995; Pase, 1994). Despite these findings, the majority of clinical studies reviewed by the AHCPR lend support to the preventive and treatment effects of pressure relief (Anderson *et al*, 1983; Bliss, McLaren and Exton-Smith, 1967; Hofman *et al*, 1994; Inman *et al*, 1993). This overview seeks to provide a description of the various strategies for pressure relief/reduction and a brief review of some of the key effectiveness findings. A full review of cost-effectiveness findings is given in Part B Section 2.

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[1] relieves pressure on all 5 classic ulcer sites – over the sacrum, greater trochanters, ischial tuberosities, lateral malleoli and heels (Seiler and Stahelin, 1986)' (Goode and Allman, 1989 p. 1516). Other positions such as the supine and 90-degree lateral positions exert pressure over high prevalence sites and frequent re-positioning is advisable to minimise time in these positions. Prone positioning carries an associated risk of suffocation in immobile and sedated patients. Given the limited range of positions for pressure relief and the increasing threat of litigation, use of pressure-relieving surfaces generally supplements schedules of re-positioning. For example, Seiler and Stahelin (1986) specify use of a 'super-soft' mattress in conjunction with a schedule of turning from supine to right and left 30-degree lateral positions (Goode and Allman, 1989). Clearly, the extent to which turning and positioning are necessary will depend upon the particular coincidence of risk factors in each individual patient. It is generally accepted that immobile, bed-bound patients should be re-positioned at least every 2 hours (Goode and Allman, 1989; Remsburg and Bennett, 1997). However, some patients may develop erythema and more advanced tissue damage despite adherence to schedules of turning and positioning. In such circumstances, the patient should be afforded additional pressure relief and the treatment of *all* predisposing factors should be revised (Goode and Allman, 1989).

The few studies reported in the literature give conflicting findings. Norton, McLaren and Exton-Smith (1975) found that, compared to historical levels of incidence, a 75% reduction in the incidence of pressure ulcers could be achieved through implementation of simple turning schedules. In contrast, Allman and colleagues (1995) found no association between the use of pressure relieving strategies such as turning and positioning and the development of pressure ulcers. Further, 'reports of infrequent re-positioning and failure to use other preventive interventions were not associated with higher rates of sore development' (Remsburg and Bennett, 1997 p. 518). Each of these studies potentially suffers confounding. In particular, heterogeneity in the risk of pressure sore development could easily account for the lack of association found by Allman and colleagues.

[1] Wherein the patient is positioned with their back at 30 degrees to the support surface (Goode & Allman, 1989).

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Foam devices

[Geo-Matt, Iris 10,000] (Conwill, 1992).

A broad range of foam products is available and not all are suitable for effective pressure relief. Adequate reduction in tissue interface pressure is more likely for products with certain ideal properties outlined by Remsburg and Bennett (1997);

- ***Thickness:*** adequate thickness of 3 to 4 inches;
- ***Load deflection:*** 25% indentation load deflection with 30 lb of load;
- ***Density:*** foam density between 1.3 to 2.5 lb per cu ft (p. 519).

The effectiveness of foam support surfaces has not yet been established in clinical trials. Risk reduction may be limited by a tendency for devices to retain moisture and due to the deterioration of their pressure relieving properties (Remsburg and Bennett, 1997). The perceived advantages of relatively low cost and ease of use have resulted in the widespread application of foam support surfaces. However, cleaning or replacement of devices in incontinent populations may significantly increase costs (Remsburg and Bennett, 1997).

Air-filled devices

Static air mattresses (eg. Sof-Care) allow an equalisation of tissue interface pressure for each point of interface with the support surface (Remsburg and Bennett, 1997). Inter-connecting air cells allow air to move between cells in response to the pressure exerted upon each cell. 'Some devices are reportedly capable of decreasing skin pressures to below capillary filling pressure under most bony prominences' (Goode and Allman, 1989 p. 1518).

Dynamic air mattresses [eg. Lapidus air float system, Grant PCA, Betabed] seek to achieve an improvement on the pressure equalisation afforded by static mattresses. Dynamic air mattresses, variously referred to as alternating pressure pads, air-suspension mattresses or air-suspension beds (Remsburg and Bennett, 1997), actively vary interface pressure at each point of contact with the support surface. Alternating inflation and deflation of separate air cells allows frequent redistribution of body weight and the variation in pressure gradients is claimed to enhance capillary blood flow (Remsburg and Bennett, 1997).

A randomised control trial conducted by Andersen and colleagues (1982) 'demonstrated a greater than 50% decrease in the incidence of pressure ulcers using alternating air mattresses or water mattresses compared with the use of conventional hospital mattresses'(Goode and Allman, 1989 p. 1517). The evidence is more equivocal for static air-filled devices. Further, care should be taken to ensure adequate inflation to prevent excessive interface pressures, particularly at the sacrum (Goode and Allman, 1989). Use of air filled devices is common despite staffing costs incurred in set-up, and in ongoing maintenance and assessment (Remsburg and Bennett, 1997).

Water and gel filled devices

Water and gel filled devices conform to the contours of the body as water is displaced in response to the pressure exerted by contact with the support surface (Remsburg and Bennett, 1997). The patient effectively floats on the support surface, decreasing interface pressure and reducing the potential for shearing stress during turning. Andersen and colleagues' (1982) findings, cited above, provide a degree of support for the clinical effectiveness of water mattresses in reducing the incidence of pressure ulcers (Goode and Allman, 1989). Use of water and gel filled devices has been limited by costs incurred in set-up and by the need for ongoing monitoring for leaks and adequate fluid level (Remsburg and Bennett, 1997). Moreover, the devices are exceptionally heavy and, consequently, difficult to move (Goode and Allman, 1989).

Low-air loss beds and mattresses

[Flexicair and KinAir] (Remsburg and Bennett, 1997).

The disadvantages of foam devices and air/fluid filled mattresses have resulted in development of various more complex products for pressure relief. Low air loss mattresses afford pressure relief in much the same manner as for static air mattresses and may additionally reduce some of the risks due to deflation and moisture. These devices are constantly inflated to compensate for the slow loss of pressure through the semi-permeable fabric of the mattress (Remsburg and Bennett, 1997). 'The escaping flow of warm air may facilitate evaporation of skin moisture but whether it reduces the risk for patients developing a pressure ulcer is unknown' (Remsburg and Bennett, 1997 p. 520). Low air loss beds have a conventional hospital bed frame such that raising and lowering of the entire bed and of the head and feet remains possible with these devices (Goode and Allman, 1989).

Remsburg and Bennett (1997) report conflicting evidence regarding the effectiveness of low air loss devices. Inman and colleagues (1993) found superior healing rates in a randomised prospective trial of low air-loss beds and conventional hospital mattresses. However, these improved healing rates are relative to healing rates using a conventional hospital bed. Consequently, this study indicates only that some form of pressure relief is beneficial and cannot specifically recommend the use of low air loss beds. Mulder and colleagues (1994) found no significant additional effect in comparison with conventional treatment. Finally, Ferrell and colleagues (1993) found a 'three-fold improvement in the median rate of healing for low air loss beds compared with foam mattresses' (p. 494). It should be noted that the adoption of an expensive and complex intervention requires demonstration of a significant *clinical* effect. More generally, intermediate outcomes must translate into real gains in quality or quantity of life. This issue will be discussed more fully in Part B. Assessment of cost-effectiveness alongside randomised control trials is required to determine whether the reported cost of $40 to more than $100 per day (Remsburg and Bennett, 1997) is justified.

Air-fluidised beds

[Clinitron and Fluidair] (Remsburg and Bennett, 1997).

Air fluidised beds are probably the most complex of pressure relief devices. The devices consist of micro-spheric ceramic glass beads about the size of a grain of sand, trapped under an air-permeable filter sheet (Goode and Allman, 1989). The glass beads are suspended on a constant stream of warm air, simulating the characteristics of a fluid (Goode and Allman, 1989). The patient effectively floats on the support surface as it conforms to body contours, distributing pressure over a larger surface area (Remsburg and Bennett, 1997). Evaporation of skin moisture is accelerated by the flow of warm air through the filter sheet. However, the volume of escaping air is considerably greater than for low-air loss beds and consequently, air fluidised therapy carries an associated risk of dehydration and hypo/hyper-thermia (Remsburg and Bennett, 1997). Despite the likely reduction in skin moisture, 'patients with urinary incontinence typically must have an indwelling catheter because the beads clump when wet and waste removal is not simple' (Remsburg and Bennett, 1997 p. 520). Elevation of the head and foot of the bed is not possible when using these devices.

Few studies have evaluated the effectiveness of air fluidised therapy. Allman and colleagues (1987) compared healing rates for air-fluidised therapy plus re-positioning every 4 hours with healing rates for a conventional therapy comprising alternating air mattresses covered with a foam pad plus re-positioning every 2 hours. 'The estimated relative odds of improvement with air-fluidised beds were 5.6-fold greater than with the conventional therapy' (Allman *et al*, 1987 p. 641). Despite the statistical significance of this result, the median change in wound surface area of –1.2 cm^2 for air fluidised therapy and .5 cm^2 for conventional therapy represents only a marginal difference in clinical effects (Allman *et al*, 1987). Bennett and colleagues (1989) confirm the relatively unspectacular effects of air- fluidised therapy. Only 14% of treated wounds healed completely and the median time to healing for these wounds was 119 days (Goode and Allman, 1989). As aforementioned, it should be noted that the adoption of an expensive and complex intervention requires demonstration of a significant *clinical* effect. Assessment of cost-effectiveness alongside randomised control trials is required to determine whether the reported cost per day of $50 to more than $100 per day plus ongoing maintenance (Goode and Allman, 1989) is justified.

Other devices for pressure relief

Several simpler devices for pressure relief are available, ranging from seat cushions to foam boots to doughnut cushions. These devices are commonly tailored for use in specific postures or pressure relief at high-risk sites. Consequently, the potential for pressure distribution over a wide surface area and away from bony prominences is greatly reduced. Seat cushions are constructed in just the same manner as the foam, air and fluid mattresses/overlays already discussed (Remsburg and Bennett, 1997). Pressure relief at isolated sites allows an alternative strategy of pressure elimination through use of mattresses with removable sections and doughnut cushions.

The AHCPR guidelines caution against the use of doughnut cushions due to the risk of ischaemia in the centre of the doughnut or damage to surrounding tissue (Goode and Allman, 1989; Remsburg and Bennett, 1997). Pressure elimination strategies allow pressure relief at a given circumscribed location but greatly increase the interface pressure at other sites.

4 Dressings

The selection of dressings for wound healing has become increasingly tailored to optimal healing environments. Optimal healing environments vary dependent upon the characteristics of the treated wound and according to the extent of progression towards tissue repair as a final outcome. Tissue repair conforms to a three-stage process following a progression from inflammation, to proliferation and finally to maturation (Choate, 1994; Barr and Cuzzell, 1996). 'During each phase of healing, a predominant cell type is present within the wound. A dressing acts to provide the necessary environment for each of these cell types to thrive' (Choate, 1994 p. 463). However, specification of a treatment protocol requires a more precise characterisation of wound attributes and of treatment action required for specific wound types. The following classification of wound attributes is adapted from Westmead Hospital (199X):

- ***Necrotic:*** characterised by areas of dead tissue and identified by visible black eschar. Debridement is necessary if effective healing is to occur.

- ***Sloughy:*** exuding wound, characterised by the formation of fibrin cuffs and accumulation of dead cells. Identified by yellow to white slough. Effective healing requires absorption of exudate, fibrinolysis and removal of slough.

- ***Granulating*****:** characterised by red granulation tissue and production of serous/bloody exudate. Care should be taken not to disrupt new granulation tissue.

- ***Epithelialising:*** pink, partially open wound, possibly producing a serous/bloody exudate and characterised by migration and proliferation of epithelial cells. Epithelium requires thermal insulation and protection from external forces.

- ***Reddened*****:** erythema that requires protection from external forces.

Wound care products have proliferated to meet the specific requirements for optimal healing at each stage of healing. This proliferation has, in turn, resulted in an increasing level of specificity in clinical treatment protocols. The appropriate treatment will vary according to several dimensions: wound aetiology, severity of wound, stage of tissue repair, presence of infection, and the presence of causative co-morbid illnesses such as diabetes mellitis and immune compromising disorders. 'There is no ideal dressing for all wound types' (Hansson, 1997 p. 271). An outline of the rationale of various treatments and a brief review of efficacy and effectiveness findings may provide a useful background in understanding the remainder of this review. A full review of cost-effectiveness findings is given at Part B Section 3.

4.1 Dressings for Optimal Healing Environments

Several authors (Choate, 1994; Hansson, 1997; Pruitt and Levine, 1984; Wijetunge, 1994) have proposed certain ideal characteristics of dressings and the wound environment. A summary of the characteristics identified in the literature reviewed is provided in Table 1.

Table 1: Attributes of an ideal dressing

Healing	Dressings should facilitate haemostasis, debridement and healing through the maintenance of a moist wound/dressing interface.
Protection	Dressings should provide thermal insulation and protection from external forces.
Infection	Risk of secondary infection should be minimised. Dressings should provide an effective barrier against micro-organisms and 'prevent bacterial multiplication by assisting the body's natural defences' (Wijetunge, 1994 p. 60s).
Absorption	Dressings should facilitate the removal or absorption of exudate and substances toxic to cells.
Comfort	Dressings should minimise pain and discomfort to the patient during removal, application and use. Dressings should be hypo-allergenic and bio-degradable.
Use	Dressings should be easy to use and should facilitate monitoring of the wound. Dressing changes should be quick and relatively infrequent. Dressings should be conformable to irregular wound surfaces and body contours and should not restrict activities of daily living.
Value	Dressings should minimise cost per unit of health gain.

Adapted from Choate (1994 p. 464), Hansson (1997 p. 272), Smith (1995 p. 317), Wijetunge (1994 p.60s).

These attributes may be interpreted as providing a framework for the evaluation of dressings. However, it should be noted that the importance of each attribute will vary according to the specific type of wound and patient treated. That is, there will always be a trade-off in weighing the attributes of particular dressing choices. It should again be emphasised that 'there is no ideal dressing for all wound types' (Hansson, 1997 p. 271). The specification of cost-effectiveness as one of these attributes is, in some respects, the overarching goal in wound care. However, in the absence of multi-attribute outcome measures, several attributes of health gain will, of necessity, be excluded in estimating cost-effectiveness. Evaluation of wound care treatments against the criteria of cost-effectiveness must therefore be tempered by reference to those attributes excluded from the analysis.

4.2 Moist Wound Healing

In general, healing occurs more quickly under moist rather than dry conditions. This effect has been demonstrated through direct comparison of moist wound environments and dry, air-exposed conditions (Winter, 1962; Winter and Scales, 1963; Hinman and Maibach, 1963; Vogt *et al*, 1995). However, an understanding of the mechanisms of moist wound healing will be useful in later explanation of the differences between the various types of dressings.

The specification of a moist wound/dressing interface for optimal healing stems from the effectiveness of moist wound conditions in achieving a number of beneficial effects. A full review of the mechanisms and effectiveness of moist wound healing is beyond the scope of this report. The interested reader is referred to Field and Kerstein (1994) for an excellent review of relevant findings. However, Hansson (1997 p. 273) cites several studies (Vargese *et al*, 1986; Dyson *et al.*, 1988; Katz *et al.*, 1991; Kannon and Garrett, 1995) in providing a more basic outline of some of the beneficial effects precipitated by moist local wound conditions;

- ***Debridement of necrotic tissue*:** Moist wound conditions facilitate 'autolytic debridement because they retain the enzymes and water required to help dissolve dead tissues (Bolton *et al*, 1990; Constantine and Bolton, 1986)' (Field *et al*, 1994 p. 3s). Further, some findings indicate that dressings that maintain moist wound conditions may promote fibrinolysis (Field *et al*, 1994).

- ***Proliferation and release of growth factors*:** Several effects may act to stimulate the production and release of growth factors. Firstly, fibrinolysis may have benefits beyond its function in debridement. 'Fibrin degradation products may exert a chemotactic effect on macrophages and the subsequent secretion of many of the macrophage derived growth factors (Lydon *et al*, 1989)' (Field *et al*, 1994 p. 3s). Secondly, Field and colleagues (1994) cite findings from a study by Knighton, Silver and Hunt (1981) which imply that macrophages may be activated to release growth factors by the relatively hypoxic wound environment created by moisture retentive dressings. Further, several beneficial effects have been demonstrated on specific growth factors such as platelet driven growth factor and transforming growth factor beta (see Field *et al*, 1994 p. 4s for a review).

- ***Stimulation of cell growth*:** Cells remain viable under moist wound conditions (Field *et al*, 1994) and hypoxia may stimulate growth of fibroblasts (Varghese *et al*, 1986; Horikoshi *et al*, 1984; 1986), and endothelial and epidermal cell proliferation (Hansson, 1997).

- ***Acceleration of angiogenesis*:** The relatively hypoxic environment created under moisture retentive dressings has been shown to enhance capillary proliferation and ingrowth (Knighton, Silver and Hunt, 1981). 'Studies using microangiography have established that angiogenesis occurs more rapidly under moist conditions versus dry conditions (Dyson *et al*, 1992)' (Choate, 1994 p. 464).

- ***Inhibition of clinical infection*:** Findings of an increased bacterial count under moisture retentive dressings have not translated into findings of higher rates of clinical infection (Friedman and Su, 1984; Hutchinson, 1989). Wound hypoxia results in a relatively acid environment that may inhibit bacterial proliferation (Varghese *et al*, 1986). 'Hutchinson and McGuckin (1990) reviewed 75 studies investigating the incidence of infection under occlusive dressings and 36 studies comparing infection rates under occlusive dressings using conventional gauze or impregnated gauze dressings as controls. Overall infection rates were 2.6% for occlusive dressings and 7.1% for nonocclusive dressings' (Field *et al*, 1994 p. 5s).

More generally, moisture retentive dressings result in faster healing rates than conventional gauze dressings. Field and colleagues (1994) estimated a 3-4 day average increase in healing rates for acute, partial-thickness wounds from their survey of several comparative studies (Madden *et al*, 1989; Wyatt *et al*, 1990; Hermans and Hermans, 1986; Perrot *et al*, 1986; Roberts *et al*, 1985). This provides some indication that these beneficial micro healing mechanisms translate into better intermediate and final patient outcomes.

4.3 Moist Wound Dressings

Occlusive dressings maintain moist wound conditions through a reduction in moisture transmission through the dressing from the wound surface. Reiter (1994) defines an occlusive dressing as 'impermeable to the passage of moisture and other substances' (p. 553). Whereas a semi-occlusive dressing remains permeable 'to water vapour but not to bacteria or liquid' (p. 553). A more precise measure of the extent to which a particular dressing or class of dressings maintains a moist environment may be defined by the moisture vapour transmission rate (MVTR). Bolton and colleagues (1990; 1992) found 'that a MVTR of <35 g of water vapour transmitted per square meter of dressing per hour is low enough to maintain a moist wound surface' (Field *et al*, 1994 p. 4s). MVTRs vary significantly both between dressing classes *and* within the class of true occlusive dressings (Bolton *et al*, 1990; 1992). Bolton and colleagues demonstrated that neither open gauze (MVTR 68 g +/- 2) nor impregnated gauze (MVTR 57 g +/- 4) were able to maintain a moist wound surface (Bolton *et al*, 1990; 1992). In contrast, an occlusive dressing (DuoDERM CGF) tested by Bolton and colleagues allowed a MVTR of only 8 g (+/- .8); a figure significantly below the rate identified as necessary to maintain a moist environment (Field *et al*, 1994).

Occlusive dressings have an additional beneficial effect (beyond maintenance of a moist wound surface) that should be obvious from the above discussion. Recall from Table 1 that risk of secondary infection will be reduced where an effective barrier against micro-organisms is established. Both occlusive and semi-occlusive dressings are impermeable to bacteria, thereby serving 'to isolate the wound from external enemies' (Choate, 1994 p. 464).

It should be noted that alternative classifications of dressings are sometimes used in the literature. Hansson (1997) refers to 'passive', 'active' and 'interactive' dressings. 'An active dressing creates a favourable local environment for healing, with optimal moisture and temperature levels' (Hansson, 1997 p. 274). The class of moisture retentive dressings should therefore, at a minimum,

have the properties of an ‘active’ dressing. However, many of the beneficial effects of moist wound healing outlined in Part A Section 4.2 may occur due to an ‘interacti
and the dressing (Hansson, 1997). These interactive effects will be outlined for each class of dressing discussed below.

It should be noted that the outline for each class of occlusive dressings is intended as general background to latter stages of this paper rather than a comprehensive review of the literature.

Alginates

[Algosteril, Comfeel Seasorb, Kaltogel, Kaltostat, Sorbsan, Sorbsan Plus, and Tegagen] (Choate, 1994).

Alginates are the extracted alginic acids (sodium alginate) from the intercellular spaces of some species of brown seaweeds (Choate, 1994; Hansson, 1997). When combined with calcium ions in solution, fibres of calcium-sodium or calcium salts are formed (Seymour, 1997). These fibres provide the basis for calcium-sodium alginate or calcium alginate dressings. Alginate dressings interact with exudate to produce a biodegradable hydrophilic gel (Seymour, 1997), this gel absorbs exudate whilst maintaining a moist wound surface. Since the actual dressing gels, a secondary occlusive dressing is required to keep the gel in place and maintain a moist wound surface (Seymour, 1997).

At a general level, some studies have reported accelerated healing under alginate dressings. Thomas and Tucker (1989) found healing rates for leg ulcers dressed with calcium alginate were, on average, 4 times faster than for paraffin tulle (Hansson, 1997). In a prospective clinical trial, O’Donoghue and colleagues (1997) found 21 of 30 split skin graft donor sites dressed with calcium alginate had completely healed after 10 days. In contrast, 7 of 21 donor sites treated with paraffin gauze were completely healed after 10 days. Attwood (1989) found time to complete healing of donor sites of 7 days (+/- .71 days) for an alginate dressing and 10.75 days (+/- 1.6 days) for paraffin gauze. Similarly, Thomas (1985), Basse and colleagues (1992) and Sayag and colleagues (1996) have found increases in healing rates for alginate dressings. However, Lawrence and Blake (1991) found a lower proportion of split thickness donor sites treated with an alginate dressing (72%) had healed at 10 days after harvest as compared with sites treated with scarlet red (84%). Similarly, Bettinger and colleagues (1995) found no difference in healing rates in a comparison of calcium alginate and scarlet red dressings.

Several of the beneficial effects of moist wound healing outlined in Part A Section 4.2 have been observed for alginate dressings. Alginate dressings have been found to have haemostatic properties (Groves and Lawrence, 1986; Barnett and Varley, 1987; Placquadio and Nelson, 1992). This effect may be particularly beneficial in treating donor sites after surgery (Groves and Lawrence, 1986) and ‘in patients who are receiving anti-coagulants and in ulcers that are prone to bleeding and rich in granulation tissue (Placquadio and Nelson, 1992)’ (Hansson, 1997 p. 277). Animal studies have demonstrated enhanced re-epithelisation and granulation for alginates

covered with an occlusive dressing as compared with open treatment (Pirone *et al*, 1992). Similar findings regarding re-epithelisation and granulation are reported by Choate (1994) citing studies by Barnnett and Odugbesan (1988; 1989).

Aside from the healing effects already outlined, alginates, and occlusive dressings more generally, may have additional advantages over more conventional treatments. Comparison with proflavine (Gupta, Foster and Miller, 1988), with xenograft (Vanstraelen, 1992) and with scarlet red (Bettinger, Gore and Humphries, 1995) dressings has demonstrated significant pain reduction and higher patient preference for alginate dressings. Further, Vanstraelen (1992) found lower rates of hypertrophic scar formation for skin graft donor sites treated with alginate dressings.

Alginates are widely regarded as being non-toxic and non-allergenic, properties which may allow their use in patients who have reacted to less benign moist wound dressings (Hansson, 1997). Maceration of healthy tissue surrounding the wound is a risk if excess exudate/gel is allowed to spread beyond the wound edges. Tissue damage due to maceration should be prevented through careful trimming of dressings and protection of surrounding skin (Thomas, 1992). Alginate dressings are indicated for most types of heavily exuding wounds and are highly conformable to irregular cavities and wound surfaces. For this reason Choate (1994) contends they are indicated in deep wounds and fistulas where many occlusive dressings are not. In contrast, Hansson (1997) cites Sayag and colleagues (1996) in arguing that their use in narrow sinuses and fistulas is not appropriate. The beneficial gelling effects of alginates require interaction with exudate and alginates may cause irritation if they remain in contact with a dry wound bed. Alginates are therefore less likely to be a cost-effective option in dry, non-exuding wounds.

The gelling properties of the dressing and maintenance of a moist wound surface prevent adherence of the dressing to the wound surface. Consequently, dressing removal is quick and largely painless. Remnants of the dressing are easily flushed using sterile saline (Plaquadio and Nelson, 1992) and 'any trace material left behind need not be of concern because it will be broken down and metabolised by the body (Burrows and Welch, 1983)' (Choate, 1994 p. 466). Dressing changes should be timed to allow the beneficial effects of the gelling action to take full effect. Changes should occur when the dressing is 'completely soaked' (Hansson, 1997) or when 'exudate (Plaquadio and Nelson, 1992). During use with dry wounds alginate dressings may adhere to the wound surface. However, the risk of denuding new epithelium during removal may be avoided by prior soaking of the dressing with sterile saline (Seymour, 1997). A broad guideline of dressing change every 1 to 4 days is consistent with the various recommendations in the literature (Choate, 1994; Hansson, 1997; Plaquadio and Nelson, 1992; Seymour, 1997). At a minimum, dressings should be changed every 7 days (Plaquadio and Nelson, 1992; Hansson, 1997).

Hydrocolloids

[Comfeel, Cutinova Hydro, DuoDERM, DuoDERM E, Granuflex, Hydrapad, Intact, Intrasite, J and J Ulcer Dressing, Restore, and Tegasorb] (Choate, 1994).

Hydrocolloid dressings vary in composition and properties. The inner layer of these dressings consists of carboxymethylcellulose or other polysaccharides and proteins which react with exudate to form a hydrophilic gel and create a moist healing environment (Hansson, 1997; Barnes, 1993). An outer layer of foam or film effectively seals the wound site against external contamination (Lawrence and Lilly, 1987) and provides an occlusive or semi-occlusive barrier against moisture loss (Barnes, 1993; Reiter, 1994).

Improved healing outcomes have been reported for wounds treated with hydrocolloid dressings. Field and colleagues (1994) cite several controlled clinical trials (Gorse and Messner, 1987; Handfield-Jones *et al*, 1988; Cordts *et al*, 1992; Smith *et al*, 1993) which have demonstrated faster healing rates for treatment with hydrocolloids as compared with conventional gauze dressings. Further, increases in epidermal healing rates of between 30% and 36% (Alvarez, 1987; Madden *et al*, 1989; Leipziger *et al*, 1985) have been found in comparisons of hydrocolloids and conventional dressings (Choate, 1994).

Many of the mechanisms for moist wound healing outlined in Part A Section 4.2 were initially identified from comparative studies of hydrocolloids and conventional dressings. Decreased formation of pericapillary fibrin cuffs has been observed in venous ulcers treated with DuoDERM (Lydon *et al*, 1989; Mulder *et al*, 1993), indicating that hydrocolloids may act to increase fibrinolysis and to debride necrotic tissue and slough. Hydrocolloids may also act to accelerate re-epithelisation and collagen production (Varghese *et al.,* 1986; Kannon and Garrett, 1995). Clinical studies have shown that hydrocolloids maintain a hypoxic environment (Varghese *et al*, 1986) with consequent beneficial effects in stimulating angiogenesis (Cherry and Ryan, 1985; Lydon *et al*, 1989). Maintenance of low oxygen tension may also retard bacterial proliferation despite higher rates of bacterial colonisation under moist rather than dry conditions (Varghese *et al.,* 1986). More generally, compared to conventional treatment, reduced clinical infection rates have been found in donor sites treated with hydrocolloid dressings (Smith *et al*, 1993).

The pain relieving properties of hydrocolloids have been well documented (Friedman and Su, 1984; Roberts *et al*, 1985; Hermans and Hermans, 1986; Perrot *et al*, 1986; Handfield-Jones *et al*, 1988; Madden *et al*, 1989; Wyatt *et al*, 1990; Nemeth *et al*, 1991; Cordts *et al*, 1992). 'This added benefit has been attributed to the moist dressing/wound interface that protects nerve endings from drying and exposure' (Field *et al*, 1994 p. 5s). Further, the gelling action of the hydrocolloid layer prevents adherence of the dressing to the wound surface, reducing pain during dressing changes and preventing disruption of granulation tissue and epidermal cell growth (Reiter, 1994).

Some protection from shearing stress may be afforded by hydrocolloids (Barnes, 1993). However, they do not substantially reduce pressure to the wound area (Barnes, 1993) and should be viewed as but one component of a total treatment protocol; incorporating specific means of pressure reduction when used in the treatment of pressure ulcers.

The beneficial healing effects of hydrocolloid dressings depend upon the interaction between the dressing and exudate to create a moist healing environment. Use of hydrocolloids in dry wounds will not produce the healing effects outlined above and more cost-effective options are available in these circumstances. Further, the risk of denuding new epithelium is more difficult to reduce than for alginate dressings as the outer layer of hydrocolloids is resistant to soaking with sterile saline. Use of hydrocolloids is therefore indicated for most moderately exuding wounds. However, hydrocolloids are absorbent only to a certain extent. The dressings do not cope well with heavily exuding wounds and excessive exudate may tend to saturate the dressing. Under such circumstances, exudate may spread beyond the wound edges and lead to maceration of the surrounding skin (Hansson, 1997). It should also be noted that the interaction between the dressing and exudate creates a yellow, foul smelling and (occasionally) bloody discharge (Barnes, 1993; Choate, 1994). Saturation of dressings in heavily exuding wounds and leakage of this discharge may significantly reduce patient tolerance (Barnes, 1993).

As for all moist wound dressings, use of hydrocolloids is contraindicated for clinically infected wounds. However, the presence of an unpleasant exudate should not be confused with clinical infection (Choate, 1994). Hydrocolloid dressings are opaque and should be changed infrequently. Consequently, use is precluded in wounds with bone and tendon involvement due to the need for close monitoring of such wounds (Barnes, 1993). Use in diabetic patients (Apelqvist *et al*, 1990) and in patients with ischaemic ulcers is generally ill-advised (Kannon and Garrett, 1995).

Allergic reactions have been observed for specific products; sensitivity to a dressing may be due to the specific formulation of the inner layer of hydrocolloid material rather than to the class of dressings. Hydrocolloid dressings are highly conformable to irregular wound surfaces and are marketed as sheets, granules, pastes and powders (Choate, 1994). The outer layer of these dressings forms an effective barrier against water so that the patient may bathe normally and without additional restriction (Choate, 1994). Dressing changes should be limited to facilitate the beneficial effects of the moist wound environment and prevent undue disruption of granulation tissue and epidermal cell growth (Barnes, 1993). However, care should be taken to minimise the risk of maceration discussed above. At a minimum, dressing changes should occur once every 7 days but may be as frequent as every day for heavily exuding wounds (Choate, 1994; Reiter, 1994).

Hydrogels

[Aquasorb, Biolex Wound Gel, Carrasyn Gel, Carrasyn-V, Elasto-Gel, Hydron, Intrasite Gel, NU-Gel, Vigilon] (Choate, 1994).

The gelling compound active in hydrogels varies in composition, consisting mainly of starch polymers, pectin, propylene glycol and perhaps alginate in various ratios (Hansson, 1997). Complex lattices of this compound are either backed with a semi-occlusive film for sheet dressings or hydrated to an initially high viscosity to form an amorphous gel (Hansson, 1997). The active compound of a hydrogel progressively reduces viscosity as it absorbs exudate, whilst the outer film acts to maintain a moist environment in much the same manner as hydrocolloids. However, whilst hydrocolloids require the prior debridement of dry, black eschar; hydrogels in amorphous form can hydrate and liquefy necrotic tissue, slough and fibrin (Hansson, 1997). Choate (1994) specifies 'shallow abrasions, blister and superficial wounds' (p. 464) as the relatively limited indications for the use of hydrogels. Dressing change should occur every 1 to 3 days depending upon the extent of exudate and the particular form of hydrogel used (Choate, 1994).

Foams

[Allevyn, Allevyn Cavity, Cutinova Cavity, Epilock, LYOfoam, LYOfoam A, Mitraflex, Polymem, Silastic and Tielle] (Choate, 1994; Hansson, 1997).

Foam dressings consist of a hydrophilic inner layer of polyurethane/sodium acrylate foam and a hydrophobic backing of semi-occlusive film (Choate, 1994; Hansson, 1997). Relatively few studies of moist and dry wound environments have focused on foam dressings. Foams absorb exudate and maintain a moist wound environment beneath their semi-occlusive film backing. However, the gelling action of more interactive dressings is absent in foams and caution should be exercised in generalising effects from alginate and hydrocolloid studies. The class of foam dressings is less homogenous than other dressing classes discussed in this outline. Several of the newer products are impregnated with 'bacteriostatic, cleansing, and moisturising agents' (Choate, 1994) which may have additional effects that cannot be attributed to foam dressings in general.

As with many of the moist wound dressings, foams are limited in their ability to absorb exudate. However, Banks and colleagues (1997) report less leakage and greater absorption in comparison of a foam dressing with a hydrocolloid. Dressings should be changed when completely soaked or when exudate is visible on the outer surface of the dressing. More frequent changes or use in dry wounds may result in irritation and disruption of the wound bed (Choate, 1994). At a minimum, dressing changes should occur every 7 days.

Films

[ACU-Derm, Bioclusive, Opraflex, Opsite, Polyskin II, Tegaderm, Transite, Uni-flex] (Choate, 1994).

Films form the outer layer or act as a secondary dressing for several of the dressing classes already discussed. However, they may also be used as a primary dressing that has been likened to a skin substitute. Film dressings are thin, elastic, 'transparent, adhesive backed plastic membranes usually composed of microporous polyurethane' (Fowler, Cuzzell and Papen, 1991). Most are semi-occlusive, allowing the maintenance of a moist wound environment and providing an effective barrier against external contamination. However, they are not absorbent or hydrating and do not interact with the wound surface in the manner of hydrocolloids or alginates.

The non-absorbent properties of films have certain advantages in wounds with lower levels of exudate. Autolytic debridement is facilitated by the maintenance of a moist environment. Films act as a blister or skin substitute, retaining moisture at the wound surface. These blister like conditions will help liquefy necrotic tissue and promote many of the beneficial effects on growth factors and cell growth discussed in Part A Section 4.2 (Barnes, 1993). Such healing effects have been demonstrated in several studies focused on the evaluation of thin film dressings (Leiziger *et al*, 1985; Lydon *et al*, 1989; Pirone, 1990; Rubio, 1991). Additionally, film dressings reduce shearing stress across the wound surface at least as well as hydrocolloids but at a comparatively lower cost (Fowler, Cuzzell and Papen, 1991).

Indications for use vary according to the properties of individual dressings but are generally suitable for donor sites, skin tears, shallow abrasions, burns, post-operative wounds and stage 2 pressure ulcers (Fowler, Cuzzell and Papen, 1991; Hansson, 1997). Use is limited by the non-absorbent properties of the dressings. Excessive exudate may cause channels to develop under the adhesive contact with wound edges. Under such circumstances, films no longer form an effective barrier against bacterial contamination (Dyson *et al*, 1992) and leakage of exudate will increase the risk of maceration and further pressure injury (Choate, 1994 p. 465). Fowler, Cuzzell and Papen (1991) detail the specific contraindications of use;

> 'heavily exuding wounds, clinically infected wounds, full thickness wounds with crater formation (such as stage 4 pressure ulcers), ulcers caused by cutaneous fungal or viral infections, or primarily closed incisions if the wound was contaminated prior to closure. Use only with close supervision on wounds in patients with inadequate immune response, diabetic foot ulcers, arterial ulcers and extensive burns' (p. 38).

Some difficulty in application and removal has been detailed in the literature. Films are highly adhesive and will adhere to the wound surface. Damage during dressing change to the wound surface and surrounding skin is therefore a significant risk for film dressings and they are 'best

avoided in the elderly' for whom this risk is yet greater (Hansson, 1997 p. 280). They are highly conformable, do not additionally restrict activities of daily living and allow inspection of the wound site.

As with all of the occlusive dressings, the ability of the dressing to cope with exudate dictates the frequency of change. At a minimum, dressing changes should occur every 7 days but will generally be more frequent due to the non-absorbent properties of film dressings. Dressings used to debride necrotic tissue should be changed every 12 to 24 hours but every 2 to 3 days once granulation tissue is visible (Fowler, Cuzzell and Papen, 1991; Choate, 1994). Excessive exudate may cause leakage and necessitates dressing change. Some authors recommend using a needle to draw excessive exudate through the dressing, with puncture repair to reseal the 'blister' (Choate, 1994). Fowler, Cuzzell and Papen (1991) reject this procedure and favour use of an absorbent dressing to cope with heavily exuding wounds.

3.4 Conventional Dressings

[Open Gauze (Adaptic and others), Paraffin gauze (Jelonet and others), Paraffin Tulle, Xeroform gauze, Scarlet Red].

Prior to Winter's (1962) findings which identified some of the beneficial effects of moist wound healing, wet-to-dry saline dressings were widely regarded as ideal in most situations (Choate, 1994). Wet-to-dry gauze is extremely effective in debriding necrotic tissue. The gauze is soaked with saline and allowed to adhere to the wound as the saline evaporates. Removal of the dressing results in mechanical debridement of necrotic tissue with an associated high risk of damage to new granulation tissue. Conventional open and semi-open dressings allow MVTRs significantly above those necessary for the maintenance of a moist wound environment. This moisture loss allows scab formation, preventing 'epidermal migration across the wound surface' (Hansson, 1997 p. 273) and impairing the various healing mechanisms outlined in Part A Section 4.2. Frequent dressing changes are necessary for most types of conventional dressing and changes may be quite painful due to the tendency for these dressings to adhere to the wound bed. Use with heavily exuding ulcers may cause maceration of wound edges and surrounding skin due to a tendency for dressings to soak relatively quickly.

Despite the observed problems with more conventional dressings, they remain the gold standard in certain situations. Wet-to-dry saline gauze may useful in treating wounds with bone and tendon involvement. Scarlet red has shown good healing effects in donor site repair (eg. Lawrence and Blake, 1991). Further, several of the advantages of occlusive dressings are observed in certain more 'conventional' dressings. Biobrane has pain-reducing properties, copes well with external wetting, absorbs exudate and may be changed relatively infrequently (Smith *et al*, 1995).

B A Review of Some Cost - Effectiveness Findings

1 Introduction

Against the background of mechanisms and materials for wound healing outlined above, a review of reported cost-effectiveness findings was undertaken with a view to identifying a set of rigorous studies that might accurately reflect the value of adopting alternative wound care methods as part of a standard treatment protocol. An extensive literature search was conducted using the methods outlined in Appendix 2. Studies for inclusion in the review were selected on the basis of an assessment of content against a sub-set of the criteria specified by Drummond and Stoddart (1985) in their checklist for the critical assessment of economic evaluations. Specifically,

- Studies should involve a comparison of alternatives;
- Studies should involve an assessment of both costs and consequences of each alternative;
- Studies should adequately establish effectiveness[2].

Studies selected for review have been critically evaluated against Drummond and Stoddart's (1985) checklist for the economic evaluation of health programs[3] to determine the usefulness and limitations of reported cost-effectiveness findings.

2 Cost-Effectiveness of Pressure Relieving Surfaces – Assessing the Evidence

An initial reading of abstracts and/or full-text of references identified only five studies of pressure-relieving devices meeting the criteria outlined above in Section 1. A summary of the author's appraisal of each study is given in Tables 2.1 to 2.5 and issues of particular note are highlighted in the comments following each table. General concerns relevant to methodology and policy application are outlined at the end of this section.

[2] In practice, we deemed effectiveness to have been established only where the findings as to effectiveness were sourced from randomised control trials.

[3] A more detailed discussion on the appropriate methodology for cost-effectiveness analysis may be found in the various guidelines on the subject (Drummond and Stoddard, 1985; Evans *et al*, 1990; PBAC Guidelines, 1995; Gold *et al*, 1996; CCOHTA Guidelines, 1997).

Table 2.1: Critical appraisal of Conine and colleagues (1990) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Conine, Daechsel *et al.* (1990)	One hundred and eighty seven 'high-risk' patients resident in an extended care facility. Patients were between 18 and 55 yrs old and all had chronic neurological conditions.	Alternating air (AA) mattress overlay (Pillo-pad: Gaymar Ind., US) for the prevention of pressure sores over 3 months.	Silicore (S) mattress overlay (Spenco: Spenco Medical Corp., US) for the prevention of pressure sores over 3 months.	Patients were randomised to treatment and control groups, in sets of 30 patients, by an unspecified method.	54% of AA patients and 59% of S patients developed pressure sores during the study period. The authors concluded: 'we found no statistically significant differences between groups in the incidence, location, severity or healing duration of pressure sores' (Conine *et al.*, 1990 p. 134).	Possibility of confounding cannot be discounted.

Table 2.1 (cont.): Critical appraisal of Conine and colleagues (1990) – Summary

Author/Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Conine, Daechsel *et al.* (1990)	Costs were limited to the direct costs associated with each device (depreciation, operation, maintenance and cleaning, and repair). The AA overlay required 'more personnel in assisting patients' (p. 136) but nursing time was excluded from incremental costs. Costs were assessed from the perspective of the care facility.	Direct costs assessed for 148 patients completing the trial. *Total initial costs:* 15 AA overlays + one spare pump and 3 spare pads per 15 patients. 16 S overlays per 15 patients. *Depreciation:* AA - useful life of 4 yrs. S - useful life of 1 year. *Cleaning:* S - Average of 7 cleans per year per pad. *Maintenance:* AA - Staff monitoring costs. *Repair:* AA – puncture and pump repair.	Unit costs or costs per year calculated from internal records.	All costs are $Canadian values. Costs and effects do not appear to have been adjusted for differential timing nor deflated to a base year despite assessment of costs over a 2 year period.	$271 total additional cost per patient per year [$771 (AA) - $500 (S)]. The additional cost was largely due to excessive operation, maintenance and repair costs for the AA overlay.	No adjustment was made for uncertainty in incremental costs.

Comment: Where a treatment and its comparator have been shown to have identical intermediate or final outcomes, economic efficiency requires the listing of the less costly intervention. Unfortunately, the methodology employed by Conine and colleagues (1990) suffers several flaws that preclude recommendation of either the alternating air or silicore overlay on the basis of reported findings.

- Due to the narrow range of costs identified, the cost-analysis fails to account for actual incremental costs to the care facility.
- The logic of cost-effectiveness analysis depends on a comparison between an evaluated intervention and an 'existing practice compa generally, in allocating the budget for pressure ulcer care, all policy relevant alternative interventions should be considered. Effectiveness and acceptability findings reported by Conine and colleagues (1990) suggest that neither treatment is particularly satisfactory and that some unspecified alternative device for pressure-relief may be more cost-effective than the alternating air and silicore overlays evaluated in this study.

Table 2.2: Critical appraisal of Ferrell and colleagues (1995) – Summary

Author /Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Ferrell, Keeler, *et al.* (1995)	Eighty-four nursing home patients with trunk/trochanter pressure sores (Shea Stage II or greater)	KinAir (Kinetic Concepts, US) low-air-loss bed.	Conventional pressure reduction using a 4-inch corrugated foam mattress over a conventional hospital mattress.	Patients were randomised to treatment (n = 43) and control groups (n = 41) by an unspecified method. Between group differences in age, sex, race, initial wound stage and diameter, and risk factors for pressure sore development were not significant at the .05 level. Local wound care was not significantly different for treatment and control patients.	Clinical effect was assessed as each patient's average reduction in wound diameter over the period of care (mm/day). Healing rates were modelled to separate effects due to risk factors, initial wound severity and characteristics, and type of pressure-relief. After controlling for a range of factors in wound healing, use of the low-air-loss bed increased healing rates by an average of 0.42 mm/day for patients with urinary and/or faecal incontinence. Use of the low-air-loss bed had no effect for continent patients. The healing model was used to estimate the expected number of days until cure for treatment (75 days) and control group (172 days) patients. Assuming a death rate of 40%, an estimate of incremental effectiveness is given as additional days per year free of ulcers.	Treatment group patients had significantly higher Sessing[4] scores (p = .02) than control group patients. However, initial Sessing score was included in the regression model to control for bias due to group differences in wound characteristics.

[4] 'The Sessing scale is a 7-point scale describing wound characteristics such as the presence of eschar, drainage, granulating tissue, erythema, and infection' (Ferrell, Keeler, *et al.*, 1995 p. M142).

Table 2.2 (cont.): Critical appraisal of Ferrell and colleagues (1995) – Summary

Author /Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Ferrell, Keeler, *et al.* (1995)	Costs were limited to those incurred by nursing home administrators. Nursing time for pressure ulcer care, average other treatment costs, and costs for the low-air-loss bed were included. Insufficient detail is reported to determine the extent to which the cost-analysis accounts for actual incremental costs to hospital administrators.	Costs of treatment calculated as [days of care] x [treatment cost per day]. Where days of care per year are estimated as days until cure from the regression model outlined above.	Treatment costs per day were estimated from: ▪ Published findings as to nursing labour costs per day and average cost of pressure ulcer care per day. ▪ Subjective estimation of average other treatment costs. ▪ Minimum observed price per day for low-air-loss bed lease.	1987/1988 cost per day was inflated using the medical CPI. Presumably, costs are given in 1995 $US. No adjustment was made for timing in accordance with projection of results to a 52-week period.	*Standard case:* $26 per additional day without pressure ulcers in one year.	A range of plausible values was assumed for effectiveness (0.22 – 0.42 mm/day), death rate (20 – 40%), costs of care ($5 - $20 per day), costs of the low-air-loss bed ($20 - $70 per day), and time-frame (1 – 2 years). C/E varied from a $5 saving to a $153 cost per additional day without pressure ulcers. Healing rate and the cost of the low-air-loss bed produced the most pronounced variation from the standard case C/E. Similarly, C/E varied according to clinical characteristics and due to an interaction between clinical characteristics and mortality rate. The low-air-loss bed is rather less C/E for patients with faecal incontinence, contractures, recent pneumonia, severe ulcers, and a high risk of mortality.

Comment: It should be noted that these C/E findings are based on projections beyond the study period as to days free of ulcers and days to cure. The usual caveats apply in interpreting forecasts. Moreover, projections seem to be based on the assumption that patients have a zero risk of developing pressure ulcers, and hence of re-entering the disease-state, once complete healing has been achieved. Assuming a positive risk of re-entering the disease state would have the likely effect of increasing between group differences in days free of pressure ulcers and in days to complete healing.

Additional concerns stem from the use of estimates of per day cost of care based on subjective estimates or on findings of unknown validity. In recognition of these concerns, a broad range of values for uncertain variables is included in the sensitivity analysis. Unfortunately, the wide interval of plausible C/E values ($5 saving to a $153 cost per additional day without pressure ulcers) implies only that low-air-loss beds may or may not be relatively more cost-effective for the treatment of pressure sores in a nursing home setting.

Table 2.3: Critical appraisal of Gebhardt and colleagues (1996) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Assignment	Effectiveness	Threats
Gebhardt, Bliss *et al.* (1996)	Fifty-two ICU patients at medium or high risk of developing pressure ulcers.	Low, medium or high cost-band alternating pressure air mattress (several types in each band). Patients were moved to a higher cost-band device if pressure areas deteriorated.	Low, medium or high cost-band constant low-pressure mattress (several types in each band). Patients were moved to a higher cost-band device if pressure areas deteriorated.	Patients were systematically allocated to treatment and control groups 'according to the last digit of their hospital number' (p. 117) (quasi-random). Patients were randomly allocated to one of the several mattresses scheduled for use in each group and cost-band. After excluding drop-outs and subjects used in piloting treatment protocols, 23 treatment and 20 control patients were available for study. Between group differences in age, sex, build, diagnostic categories, consciousness, severity of illness, sedation, mortality, nursing care, and re-positioning were not significant at the 0.05 level.	Four percent of treatment group patients (1/23) and 55% of control groups patients (11/20) were moved to a higher cost-band device following the appearance of persistent erythema or sores. 'The 95%CI on this 51% difference is 27% to 74%' (p. 120).	Between group differences in risk of pressure sore development with 5 treatment group patients and 1 control group patient classified as medium risk (Norton 13-9). Eighteen treatment group and 19 control group patients were classified as high risk (Norton 8-5). Patients developing erythema or pressure sores were all classified as 'high-risk'. Between group differences in cancer, breathlessness, use of certain drugs and use of infusion pumps.

Table 2.3 (cont.): Critical appraisal of Gebhardt and colleagues (1996) – Summary

Author/Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Gebhardt, Bliss *et al.* (1996)	Costs appear to be limited to the direct cost of the pressure relief device and maintenance to the ICU unit. 'The cost calculations do not include any effect that the development of sores might have had on length of stay or treatment' (p. 118).	Average time in the trial per patient 11.5 days (range 4 – 31/32 days). No indication given as to the period of time spent on each device. Maintenance costs appear to have been based on a nominal charge per patient rather than actual resource use.	The cost of the device given by depreciating the purchase price over the useful life of the device or by rental prices (in the case of high cost-band devices). Cleaning and servicing charges, cost of replacement covers, and laundry costs were added to the cost of some devices.	All values are in 1993 UK pounds. Costs and effects have not been adjusted for differential timing.	*Incremental cost:* £41.70 saved per patient (£44.50 - £86.20). *Incremental effect:* Between 27 and 74 (mean = 51) cases of persistent erythema/pressure sores avoided per 100 at-risk patients.	Uncertainty in clinical effect reflected in 95%CI. No adjustment for uncertainty in incremental cost or in C/E.

Comment: Aside from the narrow perspective adopted by Gebhardt and colleagues (1996), several aspects of the study methodology should be noted in interpreting findings:

- Due to the narrow range of costs identified, the cost-analysis may not account for actual incremental costs to the ICU.
- Costs appear to be based on notional estimates of costs per patient rather than on actual resource use.
- Between group differences in risk of pressure sore development and variation in pressure sore development according to risk-level imply that the observed difference in clinical effect is at least partially due to the relatively adverse risk-profile of controls.

Table 2.4: Critical appraisal of Inman and colleagues (1993) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Inman, Sibbald *et al*. (1993)	One hundred consecutively admitted, 'at-risk' patients.	KinAir (Kinetic Concepts, US) low-air-loss bed.	Two-hourly turning schedule and standard ICU bed.	Patients were randomised to treatment (n = 50) and control groups (n = 50) by an unspecified method. Between group differences in selected patient characteristics were not significant at the .05 level.	Clinically significant difference in the rate of pressure sore development: 39 pressure sores detected in the control group and 8 in the treatment group. Pressure sores were detected in 6 treatment group patients and 25 control group patients. Treatment group patients were 18% (95%CI = 8% – 41%) as likely as control group patients to develop a single pressure ulcer, 11% (95%CI = 2% - 54%) as likely to develop multiple pressure ulcers, and 16% (95%CI = 6% - 44%) as likely to develop severe pressure ulcers.	Tests for confounding did not include assessment of between group differences in incontinence, sensory perception/motor control, mobility and several other risk factors for pressure sore development.

Table 2.4 (cont.): Critical appraisal of Inman and colleagues (1993) – Summary

Author /Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Inman, Sibbald *et al*. (1993)	Costs were limited to those incurred by third-party payers. Prophylactic, diagnostic and treatment costs were included but insufficient detail was given to allow an assessment of the extent to which the cost-analysis accounts for actual incremental costs to third-party payers.	The authors reported only gross cost-category aggregates, with no indication as to physical units of resource use. As a result, assessment of the validity of resource measurement is not possible.	Failure to report unit costs (except for per day leasing rates for the low-air-loss bed) precludes an appraisal of methods for resource valuation. Cost estimates are given in Canadian and US dollars, the divergence presumably due to unit cost differences and application of purchasing power parity. Cost aggregates reported by Inman and colleagues in Table 1 and Table 6 appear to be inconsistent.	All costs are 1988 values, price indices used in deflating costs to 1988 values are not reported. Costs and consequences have not been adjusted for differential timing in accordance with the short study period.	*US:* $1158.71 saved per pressure sore prevented *Canada:* $98.48 saved per pressure sore prevented	Sensitivity analysis was conducted at the level of broad cost aggregates. Cost category sub-totals were 'varied by 25% increments from 75% to 200% of original estimates' (p. 1140). The low-air-loss bed remained cheaper and more effective for all but two situations. However, the sensitivity analysis ignores possible between-group variation in costs and would be more appropriately undertaken at the level of uncertain variables. No adjustment was made for uncertainty in estimates of clinical effect despite wide confidence intervals surrounding odds ratios.

Comment: Where a 'new technology is less costly and at least as effective as the current standard' (Inman et al., 1993 p. 1142), then the new technology should be adopted as the new standard for treatment. Inman and colleagues (1993) contend that the low-air-loss bed meets this criterion and should be applied in the treatment of critically ill patients at risk of pressure sore development. However, it should be emphasised that the status of 'ICU bed plus turning' as the 'current standard' treatment would seem less than secure. More specifically, it would seem likely that the use of foam mattresses or static air mattresses or some other form of basic pressure relief device would form part of the current standard. Despite the reported findings of cost-effectiveness, competing interventions such as a foam mattress or dynamic air mattress may be just as effective and less costly than

the low-air-loss bed evaluated in this study. That is, the ICU bed plus turning does not provide a fair standard for comparison and the full range of policy relevant alternatives for prevention and treatment have not been assessed.

Table 2.5: Critical appraisal of Strauss and colleagues (1991) – Summary

Author /Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Strauss, Gong, *et al.* (1991)	One hundred and twelve patients with 3rd or 4th (Shea) stage pressure ulcers and meeting patient selection criteria regarding age, support, likely compliance and mobility (see Strauss *et al*, 1991 p. 53).	36-weeks of home air-fluidised bed therapy (AFBT) on a CLINITRON therapy unit (Support Systems Int., US) and regular visits by a home care nursing specialist (HCC) whenever the patient had 3rd or 4th stage pressure sores. Either moist or wet-to-dry dressings.	36-weeks of patient-specific conventional therapy. Pressure support using a range of devices: alternating pressure pads, air support mattresses, water mattresses, high-density foam pads. Either moist or wet-to-dry dressings.	Patients randomised to treatment (n = 58) and control groups (n = 54) by either the HCC or the study physician using random number tables. Between group differences in age, sex, education, principal payer, type of home support, reasons for immobility, and incontinence were not statistically significant.	Patients were categorised according to clinical improvement in pressure sores by two independent nurse reviewers. After excluding patients dropped from the study, patients who died during the study and patients with missing or uninterpretable records, only 22 treatment group patients and 13 control group patients remained for comparison of effectiveness. Reviewer 1- Treatment group: 91% of patients 'improved', 9% 'no change'. Control group: 62% of patients 'improved', 38% 'no change'. Reviewer 2 - Treatment group: 82% 'improved' 18% 'no change'. Control group: 77% 'improved', 23% 'no change'. Between group differences in proportion 'improved' were not significant. Between reviewer differences in proportion 'improved' not tested.	Clinical effect assessed subjectively and outcomes are intermediate. High proportion of patients excluded from the effectiveness trial resulting in inadequate sample size to generalise results. Between group differences in patient exclusion rates may indicate that the treatment group had lower disease severity than controls: partial or complete drop-out (26% treatment group, 9% control group), death during study (24% treatment group, 35% control group), patient record problems (12% treatment group, 31% control group).

Table 2.5 (cont.): Critical appraisal of Strauss and colleagues (1991) – Summary

Author /Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	**Measurement**	**Valuation**			
Strauss, Gong, *et al.* (1991)	Costs were evaluated as costs to the patient + private insurer (private insurance model) and cost to the US Medicare fund. Average total cost was derived from the sum of inpatient (pressure sore related and not pressure sore related) and outpatient (home health aide, visiting nurse, AFT and other) costs.	Control (n = 47) and treatment group (n = 50) resource use was assessed from patient report to the HCC, receipts, summary hospital bills and AFTB days. Control and treatment group patients spent roughly the same proportion of the 36-weeks in hospital, but treatment group patients had significantly fewer pressure sore related admissions and significantly lower average length of stay. Treatment group patients spent an average of 116 days on AFT. Note that costs and effects pertain to different patient samples.	Private insurance model valued resources at actual cost to patient/insurer + $70 per AFTB day. Medicare model valued resources at 80% of the prevailing charge + nursing home charges less patient co-payment + 80% of $70 per AFTB day.	Presumably, costs are given in 1991 $US. No adjustment is made for differential timing in accordance with the 36-week study period.	*Private ins. model:* $5731 average saving per patient ($p > .05$ due to SE). *Medicare:* $385 average saving per patient ($p > .05$ due to effect size and SE).	The authors have chosen to adjust for uncertainty around clinical effect and cost savings by assuming a zero effect for insignificant between group differences. However, the CI surrounding the ratio of two effects is not equal to the ratio of the CIs for each effect. Adjustment for uncertainty should evaluate the change in C/E under a range of plausible values for each uncertain parameter.

Comment: The rationale behind allocating funds to the most cost-effective interventions is to maximise health gain for a given use of resources, irrespective of who actually pays out the dollar cost of an intervention. The analysis given in this study of costs borne by patients, insurers or Medicare tells us more about the mechanism for funding health care in the US than it tells us about the efficient use of society's resources. The divergence in cost saved per patient under the two funding models is entirely due to the difference in the price paid in the private insurance model versus the price paid under Medicare. Treatment and control patients use the same amount of resources under each funding model. An approximation of per patient cost savings from the societal perspective is probably somewhere between the values given for the two models but somewhat closer to the costing given for the private insurance model.

Strauss and colleagues conclude:

> AFTB is a safe and effective treatment for pressure sores, significantly reduces the patient's need to be hospitalised, is no more costly than alternative treatments, and may save resources. Third-party payers should consider providing coverage for home AFTB for properly selected patients in order to reduce hospital and other health care costs (Strauss *et al*, 1991 p. 59).

However, the range of costs included in each model may not allow an accurate assessment of the financial impact on third party payers and conclusions regarding the relative cost of the two interventions are subject to the caveats outlined above.

DISCUSSION

The majority of these studies adopt an evaluation perspective that implies a limited policy application for study findings. If we want to know whether the government should allocate resources to a particular intervention, it is not necessarily very useful to know the relative C/E of competing interventions from the perspective of a hospital unit, nursing home, or hospital administration. Ideally, economic evaluation should assess costs and effects form the perspective of society (Evans et al, 1993; PBAC Guidelines, 1995; Gold et al, 1996; CCOHTA Guidelines, 1997). 'On the assumption that the role of government is to benefit society as a whole ….all costs and benefits are considered regardless of where they fall or who meets the cost' (Evans et al., 1993 p. 11). That is, the appropriate perspective is determined by policy considerations and should not be specified in an ad hoc manner. The societal analysis may then be transparently broken down to determine the impact upon the patient, the insurer or the health system.

The purpose of this review is to identify studies that might be useful in guiding the allocation of the overall health budget to maximise health gains (by identifying the best value-for-money pressure-relief devices). However, the narrow perspective adopted by Gebhardt and colleagues (1996) implies that their findings are applicable only to resource allocation decisions at the level of the ICU. More generally, findings from each of the studies reviewed should be interpreted with particular attention to the study perspective and range of costs included[5].

Due to serious methodological flaws outlined above, findings reported by Conine and colleagues (1990) and Gebhardt and colleagues (1996) are not considered suitable to inform questions of resource allocation. Findings reported by Inman and colleagues (1993) and Strauss and colleagues (1991) are subject to various caveats outlined above and should be interpreted with caution. Findings reported by Ferrell and colleagues (1995) are considered suitable to inform policy debate.

[5] Note the divergence in C/E, despite equivalent resource use for treatment and control groups under each model, under private insurance and Medicare models given in Strauss and colleagues (1991).

3 Cost-Effectiveness of Moist Wound Dressings – Assessing the Evidence

An initial reading of abstracts and/or full-text of references identified 12 studies of moist wound dressings meeting the criteria outlined in Part B Section 1 (although many included only superficial analysis of the relative cost of competing interventions). Studies comparing dressings within a particular class of moist wound dressings, such as studies comparing two hydrocolloid dressings, were excluded from the review. The 12 included studies have been critically evaluated against Drummond and Stoddart's (1985) checklist for the appraisal of economic evaluation to determine the usefulness and limitations of reported cost-effectiveness findings. A summary critical appraisal for each study is given in the following tables and issues of particular note are highlighted in the comments following each table. General concerns relevant to methodology and policy application are outlined at the end of this section.

3.1 Comparison Between Moist Wound Dressing Classes

Table 3.1.1: Critical appraisal of Bale and colleagues (1994) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Bale, Banks *et al.* (1994)	100 community-care patients with pressure sores, leg ulcers or other wounds of unspecified severity.	Allevyn hydro-cellular dressing (Smith and Nephew) for eight weeks or until complete healing achieved.	Improved formula hydrocolloid dressing (ConvaTec) for eight weeks or until complete healing achieved.	Patients randomised to treatment (n = 51) and control groups (n = 49) from wound-type strata by an unspecified method. Resulted in 'equivalent groups with respect to age and sex' (p. 58).	After excluding several patients due to inadequate data or protocol violation, 50 treatment and 46 control patients were available for analysis. 23 of 50 treatment group patients and 15 of 46 control group patients achieved complete healing within the study period. A subset (47 treatment, 46 control) of patients was assessed for reduction in wound area. Percentage reduction in wound area for this sub-set was generally greater for treatment group patients (mean = 52%, median = 96%) as compared with control group patients (mean = 40.8%, median = 64.4%).	No assessment of between group differences in: wound risk factors, initial severity of wounds, or aspects of treatment other than dressing choice. Between group differences in patient exclusion and withdrawal rates.

Table 3.1.1 (cont.): Critical appraisal of Bale and colleagues (1994) – Summary

Author /Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Bale, Banks *et al.* (1994)	Costs appear to be limited to the direct cost of *materials* to the Wound Healing Research Unit and patient (evaluation perspective not specified). The only reference to the identification of costs states that: 'not only do the materials being evaluated need to be costed but also all the other products' (p. 59). That is, nursing costs, cost of dressing disposal, cleaning costs, cost of home care-givers etc do not appear to have been included.	Actual use of wound care materials recorded by community-trained research nurses at periodic patient assessments. On average, dressing changes occurred every 3.6 days (SD = 1.6) for treatment group patients and every 4.1 days (SD = 1.6) for control group patients. Units of resource use were not reported.	All resources valued in June 1994 prices.	All costs in 1994 £UK. No adjustment for differential timing in accordance with the 8-week study period.	*Incremental cost:* £107.83 per 100 patients (£5960 - £5852.17). *Incremental effect:* 13 additional patients healed per 100 patients (46 – 33 patients healed). ∴ Additional cost of £8.29 per additional patient healed.	No adjustment was made for uncertainty in either costs or effectiveness.

Comment: Several aspects of the study methodology should be noted in interpreting findings:

- Due to the narrow range of costs identified, the cost-analysis fails to account for the incremental cost to the Wound Healing Research Unit and patient.
- The possibility of confounding due to between group differences in wound risk factors, initial severity of wounds, or aspects of treatment other than dressing choice cannot be discounted.
- The beneficial healing effects of hydrocolloid dressings depend upon the interaction between the dressing and exudate to create a moist healing environment. More generally, use of moist wound dressings in dry wounds will not produce the accelerated healing effects noted in the literature and more cost-effective options are available in these circumstances. Patients with 'superficial' pressure sores may therefore have been more appropriately treated with conventional dressings.

Table 3.1.2: Critical appraisal of Smith (1994) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Smith (1994)	Forty Dermatology Clinic patients with venous leg ulcers > 2.5 cm in diameter and without any condition that might affect healing.	Granuflex (ConvaTec) hydrocolloid dressing + compression bandage. Dressing change one to three times per week.	Alginate dressing and gauze secondary dressing + compression bandage. Dressing change one to two times per week.	Patients were randomised to treatment (n = 22) and control groups (n = 18) by an unspecified method. Six patients were withdrawn from each group, with a greater number withdrawn from the alginate group due to adverse events. After excluding withdrawn subjects, groups were similar with respect to age, gender, mobility, work, and smoking status.	'Ulcers healed completely in 6 of the 40 patients during the six weeks of trial treatment, 2 using the alginate and 4 using Granuflex. There was a 34.9% decrease in mean ulcer area after the alginate and a 57.1% decrease after Granuflex, but no statistically significant difference between groups' (p. 351).	'The mean ulcer area at enrolment was considerably larger in the Granuflex group (22.17 cm^2) than the alginate group (12.74 cm^2)' (p. 350). Between group differences in wound size may imply between group differences in wound exudate.

Table 3.1.2 (cont.): Critical appraisal of Smith (1994) – Summary

Author /Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Smith (1994)	Cost-analysis was limited to cost of materials. Excluded costs: nursing time, home carer time, dressing disposal, etc.	'A costing sheet was completed at each dressing change, listing all materials used, to allow approximate materials cost to be calculated' (p. 350).	Methods for estimating materials cost not specified. 'The mean total approx. cost of materials was £364.08 for the alginate and £431.73 for Granuflex' (p. 351).	Costs probably in current British pounds at the time of the study (not reported). No adjustment made for differential timing.	*Incremental cost:* average of £68 additional materials cost per treated patient per 6-week period. *Incremental effectiveness:* additional 8 completely healed patients per 100 treated patients per 6-week period.	Sensitivity of C/E to variation in uncertain variables not assessed.

Comment: Smith (1994) notes the likely confounding effect due to between group differences in wound size and hence in exudate:

> 'In this study the difference in the degree of pain experienced may also have been associated with the degree of wound hydration. The larger wounds in the Granuflex group may have been more heavily exuding and hence remained more moist than the smaller wounds in the alginate group' (p. 351).

> 'The better healing rate with Granuflex may have been partly due to ease of removal; since newly formed granulation tissue and capillary buds are not damaged. The difference between treatment groups in ease of removal could be explained by a difference in the amount of exudate in the two groups. The wounds in the alginate group may have become dehydrated, resulting in dressing adherence and a reduced healing rate' (p. 352).

More generally, the study may not provide a fair comparison between alginate and hydrocolloid dressings:

> 'The degree of hydration of the alginate dressing has been shown to affect the consequent healing rate. Porter (1991) suggests that alginates are particularly suited to dressing heavily exuding wounds, and Thomas (1990) states that alginates need to be occluded over lightly exuding wounds to enable complete hydration of the dressing' (p. 352).

Despite the fact that these findings were known to the author, the alginate dressing was not occluded and the dressings were trialed in light to moderate exuding wounds.

3.2 Comparison Between Moist Wound and Conventional Dressings

Table 3.2.1: Critical appraisal of Colwell and colleagues (1993) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Colwell, Foreman *et al.* (1993)	Seventy elderly, poorly nourished, and debilitated hospital patients with 97 pressure sores (Stage II or III).	DuoDERM CGF (ConvaTec) hydrocolloid dressing changed at least every 4 days + pressure-relief.	Saline moistened sterile gauze changed at least every 6 hours + pressure relief.	'Each patient's ulcers were randomly assigned to either moist gauze or hydrocolloid dressings' (p. 32) by an unspecified method. This resulted in 33 patients with 48 pressure sores in the treatment group and 37 patients with 49 pressure sores in the control group. The groups were broadly similar on a range of patient characteristics.	Between group differences in total surface area of pressure ulcers and in pre/post treatment change in length and width were not significant. Eleven treatment group pressure sores and 1 control group pressure sore completely healed within the study period.	Sample initially included 94 patients, 24 excluded patients with 12 dropped from each group. Possible differential exclusion of patients due to infection or deterioration in condition. 'Significantly more stage II pressure ulcers were randomised to the hydrocolloid dressing group (n = 33) than to the moist gauze dressing group (n = 21). Significantly, more stage III ulcers were randomised to moist gauze therapy (n = 28) than to hydrocolloid therapy (n = 15)' (p. 33).

Table 3.2.1 (cont.): Critical appraisal of Colwell and colleagues (1993) – Summary

Author /Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Colwell, Foreman *et al.* (1993)	Costs appear to be limited to direct costs to the hospital. Costs identified for inclusion: costs of dressing, costs of ancillary supplies, and labour incurred in the use of dressings. Excluded costs: costs of dressing disposal, cost of pressure-relief, cost of hospital stay. Therefore, fails to account for actual incremental costs to the hospital.	Labour time assessed by observation of dressing changes within an initial two-week period. Supplies assessed by observation during an initial two-week period and by nurse report for the first 50 treated pressure sores. Note that norm resource use rather than actual use measured.	Unit costs for supplies not reported. Unit costs for labour were 'an average hourly rate of pay per category of nursing personnel who performed the dressing change' (p. 30).	Presumably, costs are in 1989/1990 $US and have not been deflated to a base year. No adjustment has been made for differential timing due to relatively short study period.	*Incremental effectiveness:* 21 additional sores healed per 100 treated pressure sores. *Incremental cost:* Additional cost saving of $123.22 per case (HCD: $53.68, Gauze: $176.90). Note that cost per patient and effect per treated pressure sore are not directly comparable.	No adjustment was made for uncertainty in either costs or effectiveness.

Comment: Aside from the non-comparability of incremental effectiveness and incremental costs derived from this study, several aspects of the methodology employed in this study should be noted in interpreting findings:

- Due to the narrow range of costs identified, the cost-analysis fails to account for the incremental cost to the hospital.
- Between group differences pressure sore severity and failure to report the initial stage of healed ulcers imply that the observed difference in clinical effect and treatment costs may be at least partially due to the relatively lower pressure sore severity in the treatment group.
- 'If patients had been randomised instead of the ulcers being randomised, the wound healing findings may have been different' (p. 35).
- 'More than 80% of patients in this study lacked adequate blood levels of protein to support wound healing' (p. 35). The importance of fully specifying all aspects of care in comparing evaluated treatment protocols should be obvious given the potential for between group differences in nutrition. Moreover, the characteristics of the Australian target population for use of hydrocolloid dressings should be compared with the characteristics of the study population in assessing the extent to which findings may be generalised.

Table 3.2.2: Critical appraisal of Feldman and colleagues (1991) – Summary

Author /Date	Subjects	Comparison			Evidence of Effectiveness		
		Group A	Group B	Group C	Randomisation	Effectiveness	Threats
Feldman, Rogers *et al.* (1991)	Thirty split-thickness skin graft patients with 30 treated donor sites.	DuoDERM (ConvaTec) hydrocolloid dressing + antibiotics. Dressing change at least every 7 days.	Biobrane dressing (Winthrop) + antibiotics. Dressing change only if large blood clots observed.	Xeroform fine mesh gauze + antibiotics + heat lamp. Dressings only removed on complete re-epithelialization	Patients randomised to treatment groups as follows: 'Just prior to skin grafting, an envelope containing one of the three dressing assignments was opened' (p. 2). Either by design or random error, resulted in uneven groups (Duoderm n = 10; Biobrane n = 7; xeroform n = 13). The groups were of similar age and indications.	'Patients whose donor sites were dressed with xeroform healed[6] the fastest – an average of 10.46 days. This is significantly different from those dressed with Biobrane 19 days (p = 0.023) – or Duoderm – 15.3 days (p = 0.002)' (p. 3). Between group differences in infection (Biobrane: 2 cases, Duoderm: 1 case, xeroform: no cases) and pain (Duoderm: 0.53, Biobrane: 1.44, xerform: 2.41) reported.	Between group differences in nutrition, general condition, and other patient characteristics that may influence healing not tested. Healing time for Duoderm may be artificially high due to inspection at 7-day intervals. Insufficient sample size to attribute differences in incidence of infection to dressing type. Validity and interpersonal comparability of the rating scale pain index uncertain.

[6] 'The date of healing was recorded at the time no further dressings were needed, when 100 per cent re-epithelialization had occurred' (Feldman *et al*., 1991 p. 3).

Table 3.2.2 (cont.): Critical appraisal of Feldman and colleagues (1991) – Summary

Author /Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Feldman, Rogers *et al.* (1991)	Costs limited to the cost of dressings per patient. Excluded costs: cost of medication for wound pain, cost of ancillary supplies, costs of dressing disposal, cost of treating infection etc. Therefore, cost-analysis fails to account for actual incremental costs to the hospital.	Standard units of each dressing and average units per patient reported.	Cost per square inch derived from standard units of each dressing and cost per standard unit to the hospital. Costs are in $US.	Costs in 1988 $US. No adjustment made for differential timing due to relatively short study period.	*Incremental effectiveness:* xeroform *vs.* Duoderm: 10.46 – 15.3 = 4.84 additional days without donor site wound[7]. xeroform *vs.* Biobrane: 10.46 – 19 = 8.54 additional days without donor site wound. *Incremental cost:* xeroform *vs.* Duoderm: $1.16 – $54.88 = $53.72 additional saving in dressing costs per patient. xeroform *vs.* Biobrane: $1.16 – $102.57 = $101.41 additional savings in dressing costs per patient.	No adjustment was made for uncertainty in either costs or effectiveness.

Comment: Several aspects of the methodology employed in this study should be noted in interpreting findings:

- Due to the narrow range of costs identified, the cost-analysis fails to account for incremental costs to the hospital.
- Potential for confounding and bias in assessment of healing times for Duoderm may account for some of the observed difference in clinical effect and/or treatment costs.
- Relatively small sample size may limit the extent to which findings may be generalised to different settings.

Additionally, this study serves to emphasise the multi-dimensionality (healing, pain, infection) of dressing effectiveness. In the absence of multi-attribute outcome measures, several attributes of effectiveness will, of necessity, be excluded in estimating cost-effectiveness. Evaluation of wound care treatments against the criteria of cost-effectiveness must therefore be tempered by reference to those attributes excluded from the analysis.

[7] Note that this measure of incremental effect fails to specify a period in which gains accrue. Contrast this with Ferrell and colleagues (1995) (see Table 2.2) calculation of additional days without pressure ulcers in one year.

Table 3.2.3: Critical appraisal of Gates and Holloway (1992) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Assignment	Effectiveness	Threats
Gates and Holloway (1992)	Forty female OB/GYN patients with open abdominal incisions.	Moist wound environment comprising Intrasite hydrogel (Smith and Nephew), Allevyn foam wound cavity filler (Smith and Nephew), and Bioclusive transparent film (J and J Medical). Dressing change every Mon, Wed, Fri.	Normal saline wet-to-dry dressings (gauze sponge and gauze cover). Dressing change every 8 hours.	Selective and quasi-random assignment to groups. Patients with low transverse incisions were assigned to the control group. Remaining patients were 'assigned alternately' to treatment and control groups. 20 patients assigned to each group.	Treatment group patients generally healed faster as measured by days prior to secondary closure[8]. Treatment group patients were closed at an average of 5.1 days, as compared to control group patients at an average of 8.5 days. Fewer complaints of pain were noted for the treatment group as compared with the control group.	Selective/quasi-random assignment and between group differences in age distribution and wound position may account for some of the observed difference in clinical effect.

[8] 'Wounds were considered ready for secondary closure when they were free of slough, clots or obvious signs of infection' (Gates & Holloway, 1992 p. 36).

Table 3.2.3 (cont.): Critical appraisal of Gates and Holloway (1992) – Summary

Author /Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Gates and Holloway (1992)	Costs were limited to the cost of dressings plus nursing time for dressing changes, presumably assessed from the hospital perspective. Excluded costs: cost of dressing disposal, cost of hospital stay, cost of pain medication, etc. The authors note: 'the moist wound dressing group was able to be discharged sooner, on average three days after treatment began and three to four days earlier than the wet-to-dry patients' (p. 36). However, 'pain medications and extended hospital stay costs, could further magnify the benefits of the moist wound healing environment' (p. 36).	Fixed schedule of dressing changes so dressing change per patient determined by the period of treatment. On average, treatment group patients required 3 dressing changes as compared with 25 for controls. Assessment of nursing time per dressing change not specified.	Costs in $US. Unit costs for nursing time and dressings not specified. Average cost per dressing change (including nursing time) given as $38.30 for treatment group patients and $27.50 for controls.	Costs probably in 1992 $US. No adjustment made for differential timing due to relatively short study period.	*Incremental effectiveness:* 5.1 – 8.5 = 3.4 fewer days prior to secondary closure[9]. *Incremental cost:* $114.90 – $687.50 = $572.60 additional savings in dressing costs (including nursing time) per patient.	No adjustment was made for uncertainty in either costs or effectiveness.

Comment: It might be argued that a measure of incremental effect such as days of hospitalisation avoided would allow clearer presentation of study findings. In addition, certain aspects of study findings should be noted in interpreting findings:

- Due to the narrow range of costs identified, the cost-analysis fails to account for incremental costs of moist wound care over conventional wet-to-dry dressing to the hospital.
- Potential for confounding due to selective and quasi-random assignment and between group differences in age distribution and wound site may account for some of the observed difference in clinical effect.

[9] Note that this measure of incremental effect fails to specify a period in which gains accrue. Contrast this with Ferrell and colleagues (1995) (see Table 2.2) use of modelling to determine additional days without pressure ulcers in one year.

Table 3.2.4: Critical appraisal of Gorse and Messner (1987) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Assignment	Effectiveness	Threats
Gorse and Messner (1987)	Fifty-two male patients with 128 pressure sores (Stage II, III or IV) treated in an acute-care facility.	DuoDERM hydrocolloid dressing (ConvaTec) + pressure relief. Dressing change at least every 4 days.	Dakin's solution soaked wet-to-dry dressing (sterile mesh-gauze) + pressure-relief + whirlpool hydro-therapy. Dressing change every 8 hours.	Quasi-random assignment to groups determined by admission to a particular nursing ward. 'Each ward was assigned one or the other pressure sore treatment regimen, and wards were chosen such that each treatment arm included both medical and surgical patients' (p. 767). The groups were similar with respect to average age, mobility, incontinence, underlying disease, anatomical site of pressure sores, nutritional status, and initial wound severity.	Sixty-six of 76 (87%) of pressure sores in treatment group patients healed or were healing as compared with 36 of 52 (69%) pressure sores in control group patients (p = .026). 'Treatment regimes compared in this study were more likely to be effective in the treatment of uncomplicated (uninfected, stage II) pressure sores' (p. 769). Among pressure sores that worsened, a significantly higher rate of increase in surface area was noted in the hydrocolloid group compared with the wet-to-dry group' (p. 770).	'Despite our randomisation protocol, the two treatment groups were not totally comparable, but factors that may have favoured one regimen over the other were identified in both treatment groups' (p. 768). Between groups differences observed for pressure sores per patient, proportion of pressure sores in ambulatory patients, and proportion of infected sores amongst incontinent patients.

Table 3.2.4 (cont.): Critical appraisal of Gorse and Messner (1987) – Summary

Author/Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Gorse and Messner (1987)	Costs were limited to the cost of 'supplies' plus nursing time for dressing changes, presumably assessed from the perspective of the acute-care facility. The costs of hydrotherapy, pressure-relief, hospitalisation, dressing disposal, cleaning etc. were excluded.	Supplies and nursing time per week based on the protocol rather than on the actual number of dressing changes and actual materials used. Nursing time based on estimated time per dressing change rather than actual time.	Nursing costs only reported as nursing time per week or per dressing change. Supplies were probably costed at price paid by the acute care facility. However, unit costs for dressings and other supplies were not reported.	Costs probably in 1984/85 $US. No adjustment made for differential timing due to relatively short study period.	*Incremental effectiveness:* 18 additional healed or healing pressure sores per 100 patients. *Incremental cost:* $46.30 saving in supply costs per pressure sore per week of treatment + 6 hrs and 50 mins nursing time saved per pressure sore week of treatment.	No adjustment was made for uncertainty in either costs or effectiveness.

Comment: Various aspects of the methodology employed in this study severely limit the usefulness of study findings in assessing the relative cost-effectiveness of the evaluated interventions:

- A number of potential confounders were identified. In particular, it should be noted that 'the treatment regimes compared in this study were more likely to be effective in the treatment of uncomplicated pressure sores. Since a larger proportion of pressure sores treated in the wet-to-dry group were infected (and of a higher severity) compared with the hydrocolloid group, this could in part have contributed to the better overall response in the hydrocolloid group' (Gorse and Messner, 1987 p. 769).
- Due to the narrow range of costs identified, the cost-analysis fails to account for incremental costs of moist wound care over conventional wet-to-dry dressings.
- The reported between group differences in clinical effect would imply a relatively shorter period of treatment for patients treated with the hydrocolloid as compared to those treated with the wet-to-dry regimen. Consequently, the comparison of cost per week of treatment fails to provide a fair standard of comparison between the evaluated interventions.

Table 3.2.5: Critical appraisal of Kim and colleagues (1996) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Kim, Shin *et al.* (1996)	Forty-four hospital patients with stage I or II pressure ulcers.	DuoDERM hydro-colloid dressing (ConvaTec) + re-positioning. Dressing changed every 4 to 5 days.	Povidine soaked wet gauze covered with secondary dry gauze dressing + re-positioning. Dressing changed 3 times per day.	Patients were randomised to treatment (n = 26) and control groups (n = 18) by an unspecified method. Groups were similar with respect to age, gender, ulcer size, stage and site, presence of exudate, and presence of necrotic tissue. Between group differences in nutritional deficits and incontinence were not statistically significant.	Groups were similar with respect to proportion of patients achieving complete healing (treatment = 80.8%, control = 77.8%). Between group differences in treatment duration and healing speed were not statistically significant. Calculation of additional days free of pressure ulcers per year precluded by failure to report study period.	Between group differences in nutrition and incontinence may fail to reach significance due only to inadequate sample size.

Table 3.2.5 (cont.): Critical appraisal of Kim and colleagues (1996) – Summary

Author/Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Kim, Shin *et al.* (1996)	Costs were limited to materials and time for dressing change. Excluded costs: hospitalisation, dressing disposal, cleaning, re-positioning.	Methods for measurement of materials and time for dressing change not reported.	Materials for dressing change were valued in Korean won by an unspecified method. Time for dressing change not reported in monetary units.	Costs probably in current Korean won at the time of the study (not reported). No adjustment made for differential timing.	*Incremental cost:* average of 6367 won saved per patient. However, SD suggests a range from an additional cost of about 12,000 won per patient to a saving of about 25,000 won per patient.	Sensitivity of C/E to variation in uncertain variables not assessed.

Comment: Where a treatment and its comparator have been shown to have identical intermediate or final outcomes, economic efficiency requires the listing of the less costly intervention. Unfortunately, the methodology employed by Kim and colleagues (1996) suffers several flaws:

- Kim and colleagues (1996) state: 'we only considered the costs of dressing materials…, but the cost saved would be even more if the decrease in owever, due to the narrow range of costs identified (materials + nursing time for dressing changes), the cost-analysis fails to account for the actual incremental cost of moist wound treatment as compared to the wet-to-dry regimen.
- The wide interval of plausible values for incremental dressing materials costs implies only that the evaluated moist wound dressing may or may not be relatively less costly with respect to dressing materials.

Table 3.2.6: Critical appraisal of Kraft and colleagues (1993) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Kraft, Lawson *et al.* (1993)	Thirty-eight male veterans with Stage II (n = 22) or III (n = 16) pressure ulcers. Patients were drawn from geriatric and spinal cord injured (n = 33) populations and were treated in a tertiary care veteran's hospital.	Epi-Lock polyurethane foam dressing (Calgon Vestal).	Saline-moistened gauze dressings.	Patients were randomised to treatment (n = 24) and control groups (n = 14) by an unspecified method. There were 'no important differences between groups' in various patient characteristics including medication, cultures, age, smoking, nutritional depletion.	Ten of the 24 treatment group patients and 2 of the 14 control group patients had healed by week 12 of the study. At week 24 of the study, 10 of the 24 (42%) treatment group patients and 3 of the 14 (21%) control group patients had healed.	Between group differences in incontinence, sensory perception/motor control, mobility, initial severity of pressure sores, underlying disease, and modalities for pressure relief were not assessed.

Table 3.2.6 (cont.): Critical appraisal of Kraft and colleagues (1993) – Summary

Author/Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Kraft, Lawson *et al.* (1993)	Costs were limited to actual dressing/supplies costs plus estimated nursing time for dressing changes. Excluded costs: hospitalisation, dressing disposal, cleaning etc.	Nursing time costs based on dressing changes per week for treatment (2.5 average) and control (21 minimum) groups. It was assumed that dressing changes took 10 minutes for both groups. Dressing/supplies cost reportedly based on actual use.	Dressing/supplies use valued at facility rates. Nursing time valued at the mid-point of registered nurses' salaries ($19.90 per hour).	Costs probably in current $US at the time of the study (not reported). No adjustment made for differential timing due to relatively short study period.	*Incremental effectiveness:* 21 additional healed patients per 100 patients per 24 week period. *Incremental cost:* $54.49 saving in average nursing and dressing/supply costs per patient per week of treatment.	No adjustment was made for uncertainty in either costs or effectiveness.

Comment: The ICWM (1995) statement on cost analysis specifies a broad range of costs to be considered in evaluating wound care interventions. As with the majority of studies reviewed in this section, the cost-analysis failed to account for the actual incremental cost of the moist wound care regimen over the conventional wet-to-dry regimen. In addition, between group differences in a number of potential confounders were not assessed and may account for some variation in healing rates and/or treatment costs.

Table 3.2.7: Critical appraisal of Mulder (1995) – Summary

Author /Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Mulder (1995)	Seventeen nursing home patients with wounds at least 75% covered with dry adherent eschar. Patients were not candidates for surgical debridement.	Autolytic debridement using Hypergel (Scott Health Care) hyper-tonic hydrogel + polyurethane secondary dressing to provide a moist wound environment. Dressing change once per day.	Wet-to-dry method of debridement using saline moistened gauze (NUGauze, J and J Medical). Dressing change twice per day.	Patients were randomised to treatment (n = 9) and control groups (n = 8) by an unspecified method. The control group was latter reduced to 7 patients after one patient broke the treatment protocol. The groups were similar with respect to age, medical and nutritional status.	Assessment of clinical effect (and costs) focused on time to achieve transition (≥50% debridement of eschar). All treatment group patients achieved transition within the four-week study period. Treatment group patients averaged 10.9 days (SD = 5) to transition. Three of the 7 control group patients reached transition. Two of the control group patients were removed from the trial due to infection and 2 were treated for the full 4-week study period without reaching transition. Comparison between groups on the basis of average days to transition not possible with reported data.	Over-estimation of average wound size in the control group due to inclusion of the eighth control group patient in calculations of average wound size. Between group differences in wound dimensions and possible between group differences in other patient characteristics.

Table 3.2.7 (cont.): Critical appraisal of Mulder (1995) – Summary

Author/Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Mulder (1995)	Costs were limited to actual dressing/materials costs plus actual nursing time for dressing changes. Excluded costs: hospitalisation, dressing disposal, antibiotics etc.	Materials used and time required to change dressings were noted at each visit. Nursing time per patient 'calculated from the average number of dressing changes per patient' (p. 69).	'Cost of labour was based on the average salary of an RN in a nursing home setting. Costs of materials were based on the average charge from three distributors' (p. 69).	Costs probably in current $US at the time of the study (not reported). No adjustment made for differential timing due to relatively short study period.	Insufficient data to estimate incremental cost/effectiveness.	No adjustment was made for uncertainty in either costs or effectiveness.

Comment: This study suffers from the common problems of a narrow range of identified costs and potential confounding due to between group differences in patient characteristics. However, it should be noted that including the costs of treating infection and adjustment of findings for group differences in wound dimensions wound serve to reinforce the author's conclusion that 'the hydrogel is a more cost-effective means of debriding wounds than gauze' (Mulder, 1995 p. 70). It is worth noting that findings from this study indicate that the hydrogel may be both more effective and less costly than the conventional wet-to-dry method for debridement. However, a couple of aspects of the study methodology should be noted in interpreting study findings. Firstly, the treatment endpoint of debridement is an intermediate outcome and, whilst a link to final outcomes is demonstrated, there is no suggestion that variation in time to complete healing could be predicted from variation in time to debridement. Secondly, a focus on time to debridement as the treatment endpoint has resulted in an inadequate time horizon to account for all future costs/effects arising from treatment. Finally, due to insufficient data, it would not be possible to compare the relative cost-effectiveness of the hydrogel and the gauze with alternative methods for debridement not evaluated in this study.

Table 3.2.8: Critical appraisal of Ohlsson and colleagues (1994) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Ohlsson, Larsson *et al*. (1994)	Thirty consecutive primary care centre patients with leg ulcers of venous or mixed arterio-venous origin.	DuoDERM hydro-colloid dressing (ConvaTec) changed at least once per week + Comprilan low-stretch compression bandage (Beiersdorf AG).	Saline-soaked gauze dressing changed twice per day + Comprilan low-stretch compression bandage (Beiersdorf AG).	Patients were randomised to treatment (n = 15) and control groups (n = 15) by an unspecified method. After excluding drop-outs, 14 patients remained in each group. The groups were similar with respect to age, smoking, hypertension, general health, BMI, and various other patient characteristics.	'Seven patients healed (50%) and four improved in the HCD-group, while two healed (14%) and seven improved in the saline-gauze group' (p. 297). In the treatment group, reduction in wound area from an average of 1387 mm^2 to an average of 678 mm^2. In the control group, wound area decreased from an average of 857 mm^2 to an average of 696 mm^2. Average reduction in wound area of 51% for treatment group patients and 19% for control group patients ($p = 0.13$). Treatment group patients reported significantly less pain during dressing changes than control patients ($p < 0.003$).	Between group differences in proportion of diabetic patients and mobility.

Table 3.2.8 (cont.): Critical appraisal of Ohlsson and colleagues (1994) – Summary

Author/Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Ohlsson, Larsson *et al*. (1994)	The cost analysis included dressings/materials, nursing time, and nurse travel time. Inclusion of nurse travel time but not of patient travel time implies cost-analysis from the perspective of the primary care centre.	At each home/clinic visit information regarding distance, dressing/material cost, treatment time, and travel time was collected. Treatment group patients averaged 9 home visits (max 26) and 4 clinic visits (max 15). Control group patient averaged 59 home visits (max 86) and 16 clinic visits (max 55).	Unit costs for dressings/ supplies, nursing time, and travel time were not reported.	Costs probably in current Swedish Kroner (SEK) at the time of the study (not reported). No adjustment made for differential timing due to short study period.	*Incremental effectiveness:* 15 additional healed patients per 100 patients per 6-week period. *Incremental cost:* 2561 saving in average nursing, nurse travel time and dressing/supply costs per patient per 6-week period.	No adjustment was made for uncertainty in either costs or effectiveness.

Comment: Ohlsson and colleagues (1994) note that 'all patients were bandaged by a nurse on all occasions,….in an authentic clinical situation, it is likely that some patients would be able to perform some dressing changes by themselves' (p. 298). Between group variation in home/clinic visits accounted for a significant fraction of between group variation in total costs. It is possible that, with the larger number of total dressing changes in the saline gauze group, a move to dressing changes by patients would result in a greater reduction in the cost of treating patients with saline gauze than with the HCD. Additional concerns stem from the short study period of only 6-weeks, an inadequate time horizon to account for all future costs/effects arising from treatment.

Table 3.2.9: Critical appraisal of Sebern (1986) – Summary

Author/Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Sebern (1986)	Forty-eight very severely disabled home care patients with 77 stage II or III pressure ulcers.	TegaDerm transparent moisture vapour permeable (MVP) dressing + pressure relief. Dressings changed every 1 to 3 days.	Saline soaked gauze covered with dry gauze and ABD pad + pressure relief. Dressings changed every 24 hours.	An initial sample of 100 ulcers was randomly assigned to treatment (n = 50) and control (n=50) groups. After 23 drop-outs, 37 ulcers remained in the treatment group and 40 in the control group. The groups were similar in age, height, weight, and PULSES[10] score.	Between group differences in healing status, final grade, and median decrease in wound area were not significant for grade III ulcers. Of the 34 grade II ulcers, 22 were assigned to the treatment group and 12 to the control group. 14 of the 22 treatment group grade II ulcers healed within the eight-week trial period, compared with none of the 12 control group ulcers. Treatment group grade II ulcers achieved a significantly lower final grade than their control group counter-parts. Median reduction in wound area was significantly greater for treatment group grade II ulcers than for the control group.	Between group differences in initial wound size with grade II wounds smaller in the treatment group as compared with the control group and grade III wounds smaller in the control group as compared with the treatment group. Equivalence of treatment and control groups for grade II ulcers cannot be assumed from comparison of treatment and control groups for the pooled sample of grade II and III ulcers.

[10] Functional assessment profile covering physical condition, upper limb function, lower limb function, sensory, excretory, and support factors.

Table 3.2.9 (cont.): Critical appraisal of Sebern (1986) – Summary

Author/Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Sebern (1986)	The cost analysis included nursing visits for the trial period and treatment supplies. Excluded costs: pressure-relieving devices, home carer time, nurse travel time (?), dressing disposal etc.	Methods for measurement of materials and nursing visits dressing change not reported. Physical units of resource use not reported.	Methods for valuation of resources were not reported. Mean cost of nursing visits and supplies over the 8-week trial period was $845 for grade II treatment group ulcers and $1359 for grade II control group ulcers ($p < .05$). Cost of treatment was not significantly different between treatment ($1470) and control ($1412) groups for grade III ulcers.	Costs probably in current $US at the time of the study (not reported). No adjustment made for differential timing due to short study period.	*Incremental effectiveness:* 49 additional healed or improved ulcers per 100 grade II ulcers treated per 8-week period. *Incremental cost:* $514 mean cost saving for nursing visits and supplies per grade II ulcer treated per 8-week period. *C/E:* $1049 saved per additional healed or improved grade II ulcer per 8-week period.	Sensitivity of C/E to variation in uncertain variables not assessed.

Comment: The methodology employed by Sebern (1986) suffers several flaws:

- The ICWM statement on cost analysis specifies a broad range of costs to be considered in evaluating wound care interventions. As with the majority of studies reviewed in this section, the cost-analysis failed to account for the actual incremental cost of the moist wound care regimen over the conventional wet-to-dry regimen.
- Potential confounding due to between group differences in wound size. Moreover, results are separately reported for grade II and grade III ulcers but randomisation and tests for group equivalence are for the pooled sample of grade II/III ulcers.

Table 3.2.10: Critical appraisal of Xakellis and Chrischillis (1992) – Summary

Author /Date	Subjects	Comparison		Evidence of Effectiveness		
		Treatment	Control	Randomisation	Effectiveness	Threats
Xakellis and Chrischillis (1992)	Thirty-nine long-term care facility patients with stage II or III ulcers. One ulcer from each patient included, selected at random.	DuoDerm CGF (ConvaTec) + re-positioning and pressure-relief (Softcare, Gaymar Ind.). Dressings changed twice weekly or if non-occlusive.	Saline soaked non-sterile eight-ply gauze + dry gauze secondary dressing + re-positioning and pressure-relief (Softcare, Gaymar Ind.). Dressings re-moistened after 4 hours and changed after 8 hours.	Subjects were randomised to treatment (n = 18) and control (n = 21) groups by an unspecified method. The groups were similar with respect to age, sex, underlying condition, risk of pressure ulcer development, incontinence, nutritional status, and wound characteristics.	'Sixteen hydrocolloid subjects (89%) and 18 saline-gauze subjects (86%) had completed healing of their pressure sores. The median time to healing after randomisation was shorter for the hydrocolloid dressing group (nine days) than it was for the saline-gauze group (11 days), although the difference between the (Kaplan-Meier) curves did not reach statistical significance (p = .12). Seventy-five percent of subjects treated with hydrocolloid dressings had healed within 14 days; 75% of subjects treated with saline-gauze had healed within 26 days. After adjusting for exudate present at baseline, healing rates did not differ significantly for the two treatment groups, although a trend toward slower healing with saline-gauze dressings persisted' (p. 466).	'There may be a clinically important difference in efficacy between the two treatment groups that a larger sample would have demonstrated' (p. 468).

Table 3.2.10 (cont.): Critical appraisal of Xakellis and Chrischillis (1992) – Summary

Author/ Date	Cost Analysis			Timing	C/E ratio	Sensitivity analysis
	Identification	Measurement	Valuation			
Xakellis and Chrischillis (1992)	The cost analysis included the cost of dressing supplies and nursing time for dressing changes. Excluded costs: hospitalisation, nursing time for re-positioning, cost of devices for pressure relief, dressing disposal etc	Use of dressing supplies was logged by nursing staff. 'Nursing time required for dressing changes and re-moistening was measured using a random sample of ten subjects from each group' (p. 465). Estimated median times were then 'multiplied by the number of dressing changes and re-moistenings for each subject in the total sample to estimate the nursing time required to treat wounds to the study endpoint' (p. 465). LPNs completed about 60% of all dressing changes etc, RNs completed the remaining 40%.	'The cost of dressings was the 1990 wholesale price charged to long-term care facilities' (p. 465). Nursing time valued by 1990 local hourly wages for long-term care facilities (RN: $10, LPN: $8) and by appropriate national average hourly wages inflated to 1990 values (RN: $11.86, LPN: $8.86).	All costs in 1990 $US values. CPI for non-physician medical services used to inflate national average hourly wages from 1984 and 1988 values. No adjustment made for differential timing due to relatively short study period.	*Incremental costs:* median saving in materials and nursing time for dressing changes was $7.07 using local wages or $9.41 using national wages to treat patients to endpoint.	Sensitivity of C/E to variation in uncertain variables not assessed.

Comment: Where a treatment and its comparator have been shown to have identical intermediate or final outcomes, economic efficiency requires the listing of the less costly intervention. After controlling for the presence of exudate, healing rates were not significantly different for the competing interventions such that the study may be assumed to provide evidence for equivalence of outcomes and the decision rules of cost-minimisation adopted.

Xakellis and Chrischillis (1992) make several observations that seem critical in interpreting findings from the various studies reviewed in this section:

> 'Treating pressure ulcers in a long-term care setting was inexpensive. This was true for both treatments evaluated by this study. The costs were dramatically less than those previously reported for in-hospital pressure ulcer treatment, which were as high as several hundred dollars per patient per day or several thousand dollars for an entire course of treatment……This discrepancy may also be due to the fact that the in-hospital estimates of materials cost, nursing time, and nursing wages were higher than the corresponding long-term care values. In the hospital setting, the gauze dressing treatment was estimated to range upward from $2.50 per dressing, substantially higher than the $0.04 per dressing in this study. One possible explanation for this difference is that some of the in-hospital studies used sterile gauze; whereas we used non-sterile gauze. Likewise, nursing time for performing gauze dressing changes was estimated by previous authors to range from 17 minutes daily to 1½hours daily compared to less than 15 minutes in this study. Use of sterile technique may have contributed to this difference as well' (Xakellis and Chrischilles, 1992 p. 468).

The difference in cost between the two comparators has likely been underestimated due to the narrow range of costs identified and it is likely that the inclusion of a broader range of costs would dwarf the reported savings outlined above. However, the discrepancies in cost estimates highlighted by Xakellis and Chrischilles (1992) are of some considerable concern and may seriously limit the usefulness of the reviewed cost-effectiveness findings in informing policy debate.

DISCUSSION

The range of alternative dressings available implies that a two-way comparison may not be sufficient to provide much guidance in selecting a set of cost-effective products. Xakellis and Chrischilles (1992) provide the example of comparison of hydrocolloid dressings with sterile *vs.* non-sterile gauze. If sterile-gauze provides no clinically important gains in effectiveness over clean-gauze and substantially increases costs, the appropriateness of sterile-gauze as a fair comparator is called into question. That is, evidence that an evaluated hydrocolloid dressing provides greater benefits at less cost than sterile-gauze may overstate the relative cost-effectiveness of the hydrocolloid dressing by excluding policy relevant alternatives.

The majority of studies reviewed failed to report the perspective, methods and values upon which cost estimates are based. More generally, cost-analyses were frequently of poor quality and failed to include a range of factors likely to vary according to the assigned treatment. The effect of including such cost factors as hospitalisation, dressing disposal, home-carer time etc. may be predictable and a more inclusive cost-analysis may not alter qualitative findings of some studies.

However, the likely sensitivity of cost-effectiveness findings to variation in the range of included costs should be assessed in estimating the likely impact of adopting an evaluated intervention.

The majority of studies reviewed in this section are, at least potentially, subject to confounding. It should be noted that adequate controls or demonstration of group equivalence were included in very few studies (Xakellis and Chrischilles, 1992; and possibly Kim and colleagues, 1996). None of the studies reviewed assessed the sensitivity of cost-effectiveness findings due to variation in clinical effect.

The studies reviewed in this section generally adopt an evaluation perspective that implies a limited policy application for study findings. The discrepancies in cost estimates identified by Xakellis and Chrischilles (1992) may be partly due to funding arrangements or taxes/subsidies applicable to long-term care facilities but not to hospitals or outpatient clinics. It is not necessarily very useful, from a policy perspective, to know the relative cost-effectiveness of competing interventions *to the hospital or to the long-term care facility* (see Part A Section 2 for a fuller discussion of evaluation perspective).

Clearly, the studies reviewed in this section fall well short of rigorous application of the methodology of cost-effectiveness analysis. At best, it may be concluded that modelling the C/E of moist wound dressings, based on the reviewed findings, might produce more robust estimates of C/E suitable to inform questions of resource allocation.

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