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Department of **SCHOOL OF NURSING**

The University of British Columbia
Vancouver, Canada

Date **Sept. 23, 1990**
ABSTRACT

The purpose of this thesis was two-fold: first, to develop a Patient Satisfaction Questionnaire which reflects patient satisfaction with dressings used in the care of ulcerating metastatic skin lesions; and second, to evaluate patient satisfaction and patient preference with two types of dressings: Mesalt dressings and continuous wet saline dressings.

The Patient Satisfaction Questionnaire was developed to measure patient satisfaction with dressing performance. Patients with ulcerating metastatic skin lesions were asked to identify important characteristics for evaluating patient satisfaction with dressings. These questions were validated and reviewed for clarity by the patients. A visual analogue scale was used as the response scale. Testing for reliability was limited.

Mesalt dressings were compared to continuous wet saline dressings by evaluating patient satisfaction with pre-defined criteria. The criteria for evaluation included ease of application and removal, discomfort during and between dressing changes, control of odor, and patient preference. The study used a cross-over design in which each patient used one dressing for a month and the other dressing for the next month. Although 14 patients were involved in the study, only 10 were statistically analyzed. The remaining four patients were excluded because they were unable to complete a portion of each treatment.
Two major findings were identified. First, regarding the Patient Satisfaction Questionnaire, patients with ulcerating metastatic skin lesions had numerous ideas about what should be asked to evaluate patient satisfaction with dressings. They considered the questionnaire to be an appropriate format and the questions generated by the investigator to be both important and understandable.

Second, the findings of the study indicated that the Mesalt dressings received significantly more positive ratings when compared with continuous wet saline dressings for ease of application and odor control. Mesalt dressings were also significantly preferred to continuous wet saline dressings. The knowledge gained through this study is useful when helping patients decide which dressings to use in the care of ulcerating metastatic skin lesions. The Mesalt dressing appears to be a favorable choice, particularly when ease of application and odor control is important.
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CHAPTER 1
Introduction

Background of the Study

Living with cancer is a phenomenon that has become more significant as technological advances increase the life expectancy of cancer patients (Rosenbaum, 1982). In addition to developing new coping skills for living with cancer, some individuals and their families have the added stresses of ulcerating metastatic skin lesions. As these lesions may produce "gross deformities, unsightly sores, or intolerable odors, and may plague the patient with drainage and bleeding" (Billings, 1985, p. 103), they are among the most difficult manifestations of advanced cancer for the patient, family and health care providers. Compounding these difficulties are the needs to regularly cleanse the lesion and change the dressing. Although occurrence is uncommon, these lesions may be present for months or in some cases even years (Andreev, 1978). Consequently, attention needs to be paid to the types of dressings chosen and their affect on patient comfort.

Conceptual Framework

Satisfaction with health care is an important component of satisfaction with life or quality of life, especially in chronic, long-term care situations (McMillan, 1987). Satisfaction is a positive judgment of a product or service, compared to one's own expectations (McMillan). Because
patients are consumers of health care, consumer satisfaction will be referred to as patient satisfaction.

Efforts to evaluate patient satisfaction in health care are being emphasized as an important aspect of quality assurance programs (Black, 1985). Although quality of care and patient satisfaction are often related, the presence of quality care does not necessarily mean the patient is satisfied (Oberst, 1984). Therefore, evaluating health services using clinical and economic criteria is inadequate without input from the patient (Locker & Dunt, 1978).

Patient satisfaction has been gaining importance in recent years for a variety of reasons. Not only is it ethically important to satisfy the patient, but in some countries such as the United States, it is also a financial requirement for the institution's success (McMillan, 1987). Emphasizing the accountability of health care professionals to provide effective patient care also necessitates evaluating patient satisfaction (Black, 1985; McMillan). Concern about the effects of patient dissatisfaction on compliance with recommended health care regimens has also increased the importance of evaluating patient satisfaction (Larsen & Rootman, 1976).

The consumer movement has contributed to the significance of patient satisfaction. Canadians have declared the consumer's right to "participate in decision making affecting his health, with the health professionals and personnel involved in his direct health care" (Consumers' Association of
A study of cancer patients revealed that 51% to 87% preferred to participate in making decisions about their treatment (Cassileth, Zupkis, Sutton-Smith & March, 1980). The need for patient input is not only a goal; it is a certainty as proclaimed by the Honorable Jake Epp, Minister of National Health and Welfare (1986). Canada's health care system is changing to a system where consumers have a greater responsibility for participating and making decisions about their health care.

At the present time, knowledge about patients' expectations and satisfaction with dressings in the care of ulcerating metastatic skin lesions is limited to individual contacts with health care professionals. No specific information is available about patient satisfaction and preferences related to dressings.

**Statement of the Problem and Purpose**

The dressing care of ulcerating metastatic skin lesions is not well established (Ivetic & Lyne, 1990). The available literature is limited and the recommended care is based mainly on personal experiences. The evaluation of dressings is also limited. To date, no tools which evaluate dressings have been reported in the literature, nor have any been developed specifically to evaluate dressings in ulcerating metastatic skin lesions. Patient satisfaction in the evaluation of dressings also has not been considered. Most patient satisfaction tools evaluate satisfaction with care only from a
broad perspective.

No known studies have formally evaluated dressings used in the care of ulcerating metastatic skin lesions, or examined the patient’s perspectives on the comfort of the dressings. A British Columbia Cancer Agency (BCCA) survey of major cancer centers across Canada reveals that of the various dressings used, wet saline dressings were the most common (Chris Salton, personal communication, November 14, 1988). Continuous wet saline dressings can be uncomfortable and may cause bed linen and/or clothing to become wet. If the dressings do not maintain their moisture, they can cause problems with pain and bleeding. However, the frequent dressing changes required to maintain moistness are not always a feasible option, especially in the community setting where additional dressing changes require more frequent visits by the Home Care Nurses.

The Mesalt dressing is a dry, saline-impregnated gauze which is useful in the care of leg and decubitus ulcers (Gallant & Sibbald, 1986; Gross & Gerner, 1982; Ruth, 1979) and in open, infected lesions (Jagelman & Spencer, 1986). As dry dressings, Mesalt dressings are easy to apply and require fewer dressing changes. Mesalt dressings are removed when they are moist and therefore resist sticking to the wound. One anecdotal report found that Mesalt dressings considerably decreased the odor of an ulcerating metastatic skin lesion resulting from breast cancer (Spencer, 1988).

One purpose of this thesis, consequently, was to develop an evaluation tool which, based on patient input, measures the
patient’s satisfaction with dressings in the care of ulcerating metastatic skin lesions.

Another purpose was to evaluate the patient satisfaction and patient preference components of a larger study conducted by the BCCA in Vancouver, B.C. The study compared Mesalt dressings with continuous wet saline dressings in ulcerating metastatic skin lesions by evaluating patient satisfaction with dressing performance, patient and nurse preference, occurrence of infection, number of dressing changes, time spent for care of the lesion, and cost of dressing materials. Two pre-developed tools were used to measure patient satisfaction and patient preference. The Overall Evaluation Scale was used to evaluate patient satisfaction with dressing performance, including ease of application and removal of the dressings, discomfort during and between dressing changes, and control of odor. The Preference Scale was used to evaluate patient preference. It was hoped that the patient satisfaction tool developed for this thesis would also be used as part of the study. However, due both to low numbers of patients with ulcerating metastatic skin lesions and to time constraints, the tool was developed but not used.

Hypotheses

The hypotheses are:

1. Mesalt dressings will receive a more positive rating than continuous wet saline dressings with respect to patient satisfaction with dressing performance.
2. Mesalt dressings will be preferred by patients to continuous wet saline dressings.

Definition of Terms

For the purposes of this study, the terms "patient," "ulcerating metastatic skin lesion," "satisfaction" and "preference" are defined. "Satisfaction" and "preference" are operationally defined so as to more accurately reflect their use within the study.

Patient

The patient is an individual 18 years or older, with a confirmed diagnosis of cancer, registered with the BCCA, and requiring dressings for an ulcerating metastatic skin lesion.

Ulcerating metastatic skin lesion

An ulcerating metastatic skin lesion is an open and draining cancerous lesion within the dermis of the skin. This lesion may result from a metastasis to the skin from a local tumor or from a tumor in a distant site (Rosenberg, 1977).

Satisfaction

Satisfaction is the patient's judgment of a product or service, compared to his/her own expectations (McMillan, 1987). It is a subjective, evaluative rating on a continuum which cannot be directly observed by others. Satisfaction varies from a very negative judgment to a very positive judgment.

Measures of satisfaction were incorporated into the
Patient Satisfaction Questionnaire developed in this thesis. Patients identified factors which they expected to find in dressings, and the response scale allowed the patients to rate the dressings on a continuum.

Satisfaction was also measured using the Overall Evaluation Scale as part of the evaluation of Mesalt dressings and continuous wet saline dressings. The patients were asked to evaluate the dressings in terms of ease of application and removal, discomfort during and between dressing changes, and control of odor.

Preference

Preference is determined when the patient subjectively chooses a particular dressing which he/she favors over the other dressing (Avis, Drysdale, Gregg, Neufeldt, & Scargill, 1983). Preference is a general evaluation of satisfaction. Patients were asked to indicate a preference as part of the evaluation of Mesalt dressings and continuous wet saline dressings.

Assumptions and Limitations

Assumptions

There are three major assumptions in this study:

1. Patients receiving care for their ulcerating metastatic skin lesions have an interest in decision-making regarding the dressings being used.
2. Patients are able to evaluate the performance of
dressings and make decisions regarding preference.

3. Changes in the clinical wound condition during the study are primarily a result of the dressing being used.

Limitations

There are two major limitations in this study:

1. The Patient Satisfaction Questionnaire developed during the study has had limited testing for reliability and validity.

2. The Overall Evaluation Scale measures the patients' satisfaction with pre-determined criteria, thus limiting the evaluation to those particular criteria. The criteria were identified from previous contacts with patients caring for ulcerating metastatic skin lesions. However, this input was not formally obtained for the purposes of tool development.

Summary

In this chapter, the background of the study, including the conceptual framework, has been presented; and the problem and purpose of the study have been introduced. The hypotheses have been identified, terms defined, and assumptions and limitations recognized. The next chapter presents the literature relevant to the care of ulcerating metastatic skin lesions and the evaluation of patient satisfaction. Subsequent chapters include the methodology, presentation and discussion of findings, and conclusion and recommendations.
CHAPTER 2

Review of Relevant Literature

Introduction

Presented in this chapter are a review of the literature on the incidence, medical treatment, and care of ulcerating metastatic skin lesions. Continuous wet saline dressings and Mesalt dressings are discussed in more detail, and the conceptual framework of patient satisfaction is expanded.

Incidence of Ulcerating Metastatic Skin Lesions

The occurrence of skin metastases without ulceration is relatively uncommon. Little documentation to determine the exact frequency of this problem is available (Rosen, 1980). Even less documentation about the occurrence of ulcerated metastases exists. Andreev (1978) estimates that skin metastases account for approximately 2.7% of all metastatic lesions. It is generally agreed that skin metastases are most commonly associated with breast cancer and, according to Andreev, occur in 7.3 - 31.9% of all patients with breast cancer. Skin metastases can also occur in malignant lymphoma; or carcinoma of the stomach, lung, uterus, kidney, ovary, colon, bladder, head, or neck (Rosenberg, 1977; Watson, Sweeney, McGregor, & Sleigh, 1986). A malignant growth occurs from a local infiltration of a tumor, or a metastatic process of embolization through lymphatics and blood vessels (Rosenberg). Skin ulceration results when proliferating and
infiltrating malignant cancer cells destroy tissue (Andreev). The ulcerating metastatic skin lesion may take the form of a cavity, an open area on the surface of the skin, skin nodules, or a nodular growth extending from the surface of the skin (Andreev; Rosen, 1980).

The frequency of these lesions in patients was determined by the investigator through identification of patients by BCCA staff and chart reviews. During the period January 1988 - December 1989, 87 patients were identified with ulcerating metastatic skin lesions which did not respond easily to aggressive medical treatment. At the end of December 1989, 21 of the 87 lesions had eventually healed with medical treatment. The 66 remaining lesions either were still present at the end of December 1989, or were present at the time of the patient's death. Of the 66 lesions, the average duration of presence was 9.3 months, with a range of 1 week to 60.5 months. The median duration was 6.5 months.

Medical Treatment of Ulcerating Metastatic Skin Lesions

Medical treatment focuses on destroying or removing the malignant cells, or stabilizing their growth with the intention of healing the ulceration or at least controlling its complications (Billings, 1985; Borg, Rubin, & DeWys, 1983). Controversy exists, however, as to the degree to which the malignancy affects the healing potential of the lesion (Irvin, 1981). Medical treatments for localized
ulcerations may include radiation therapy, surgical
debridement, excision (Billings), or more recently in some
breast lesions, chemomastectomy (Goncalves, 1987). Systemic
treatments such as chemotherapy or hormonal therapy may be
involved in addition to, or instead of, local therapy
(Petrek, Glenn, & Cramer, 1983; Wood, 1980). Unfortunately,
when these modalities are inappropriate or no longer
effective, palliative care of the lesion focuses on minimizing
related problems.

**Care of Ulcerating Metastatic Skin Lesions**

The care of ulcerating metastatic skin lesions is not
well established, and few studies have systematically
investigated the efficacy of different treatments. Literature
relating to the wound care of ulcerating metastatic skin
lesions often includes information about cleansing the lesion,
controlling and preventing bleeding, preventing and managing
clinical infection, controlling and preventing odor,
containing drainage, and promoting healing where possible
(Foltz, 1980; Sims & Fitzgerald, 1987). The promotion of
patient comfort may be the primary objective where the lesion
has little or no potential for healing.

**Cleansing**

Traditionally, many solutions have been recommended in
the cleansing process: normal saline solution, hydrogen
peroxide, povidone iodine, and hexa-chlorophene (Foltz, 1980;
Sims & Fitzgerald, 1987). Recent studies, however, indicate
that the traditional use of antiseptics in wound care is no longer appropriate as they are detrimental to the wound and interfere with wound healing (Alvarez, Rozint, & Wiseman, 1988; Rodeheaver, 1988). Except for the normal saline solution and the solution "Shur Clens" (Rodeheaver), most other commonly used antiseptics have toxic effects on either the wound tissue or the cells that eliminate bacteria and/or orchestrate healing (Alvarez et al.; Rodeheaver). These antiseptics include sodium hypochlorite (Dakin’s solution), hydrogen peroxide, acetic acid, and povidone iodine (Brennan & Leaper, 1985; Lineaweaver et al., 1985; Van den Broek, Buys, & Van Furth, 1982). Povidone iodine in concentrations of 10% (full-strength) and 5% has been found not only to damage the wound, but also to increase the occurrence of infection (Becker, 1986; Viljanto, 1980). Further, there is speculation about the bactericidal effectiveness of antiseptics such as povidone iodine and hydrogen peroxide in diluted, non-toxic concentrations (Lineaweaver et al.; Rodeheaver et al., 1982).

The literature has also recommended debridement to maintain the cleanliness of the wound (Foltz, 1980). In general, debridement of dead tissue is considered vital in promoting wound healing (Stotts, 1990). Foltz suggests that debridement involve the use of wet-to-dry saline dressings, and/or enzymatic or oxidizing agents such as Dakin’s solution. Active debridement, however, may be questionable in wounds with little potential for healing since it may in fact exacerbate problems with bleeding and drainage. Wet-to-dry
saline dressings stick to the wound and often cause bleeding of the ulcerating metastatic skin lesion when removed. Also, a recent study discourages using wet-to-dry dressings because removing the dressing disturbs the crusts attached to the wound bed, thereby interfering in wound healing (Alvarez & Eaglstein, 1984). Although Dakin's solution has been used extensively, a recent study indicates that as there are no "safe" concentration levels, its use should be discontinued (Kozol, Gillies, Salwa, & Elgebaly, 1988). Dakin's solution also contains anticoagulant properties (American Medical Association, 1986) which may potentiate problems in a metastatic lesion already prone to bleeding. Products such as Elase, Travase, Mezinc, as well as papaya, have been used for debridement. No literature was found, however, regarding these agents' use in metastatic wounds. A less aggressive and more uncommon method of removing dead tissue in wounds involves the process of autolysis (Alvarez et al., 1988). This method causes the wound to debride itself through a slower but less harmful process. This may be achieved by using occlusive dressings such as DuoDerm (Friedman & Su, 1984) or Mezinc, all of which provide a moist, warm environment. Importantly, however, occlusive dressings should not be used in a clinically infected wound where the dressing completely occludes the wound (Alvarez et al.). A still acceptable method of removing sloughing tissue without causing great harm to the wound is through mechanical means; using continuous wet saline dressings.
Bleeding

Bleeding can be controlled by the application of a topical hemostatic product such as Kaltostat or an absorbable gelatin sponge such as Gelfoam (Foltz, 1980). Applied to focal bleeding points, these products are left in place until absorbed.

Dressings which stick to the wound not only promote irritation and bleeding, but also interfere in wound healing. Designed to prevent sticking are the following: non-adherent dry dressings (e.g. ETE dressing); impregnated gauze dressings between the wound and the absorbent dressing (e.g. Adaptic, or Jelonet); creams/ointments which act as barriers (e.g. silver sulfadiazine (Flamazine)); or dressings which promote moisture as a barrier (e.g. continuous wet saline dressings, or hydrocolloid dressings such as DuoDerm). Despite their non-adherent intentions, some dressings nevertheless do stick to the wound. There is a lack of information about factors which may cause a dressing to stick, such as the amount, consistency, or type of drainage. Dressings also delay wound healing if they prevent organisms which support healing from moving across the wound (Alvarez et al., 1988; May & Still, 1985). Little is known about the effects on the wound healing process of gauze dressings impregnated with paraffin or an oil emulsion. Dressings which completely occlude the wound, such as hydrocolloid dressings, are viewed as the safest dressings to prevent sticking to the wound and to promote wound healing.
Clinical Infection

A clinical infection may involve a local and/or systemic infection. A local wound infection includes signs such as purulent drainage, redness and swelling, and increased tenderness (Westaby & White, 1985). A systemic infection includes signs of a fever and a high white blood cell count (e.g. > 10,000). Managing either a local or a systemic infection requires involving a physician. Both local and systemic infections may require antibiotic therapy, with possible hospitalization for wound management and/or intravenous antibiotic therapy. The types of dressings used during a clinical infection are similar to those described in the upcoming section on odor.

Wound cultures taken from ulcerating metastatic skin lesions almost always demonstrate a colonization of bacteria. However, without the signs of a clinical infection, the wound is not considered to be infected and therefore does not require any further attention unless it is causing odor problems. Preventing clinical infection involves providing an environment which promotes cleanliness, thus decreasing the risk of wound contamination.

Odor

Ulcerating metastatic skin lesions are often malodorous, due mostly to the presence of anaerobes or as a result of the necrosis of tissue cells (Ashford, Plant, & Maher, 1984; Sparrow, Minton, Rubens, Simmons, & Aubrey, 1980).
Traditionally, bactericidal solutions have been used to
decrease bacteria (Ellerhorst-Ryan, 1987; Foltz, 1980).
However, both the injury to the wound bed and interference in
wound healing are causing reevaluation of this practice.
Gauze impregnated with antimicrobial agents considered to be
toxic to the wound may also have a detrimental effect on the
wound (Alvarez et al., 1988; Geronemus, Mertz, & Eaglstein,
1979; May & Still, 1985). Topical antimicrobial
creams/ointments may be used to treat a local infection as
well as to provide a barrier which prevents the absorbent
dressing from sticking. Research has shown that some
antimicrobial creams/ointments such as Flamazine, Polysporin,
and Neosporin are not only safe to use in wounds, but also
promote healing (Alvarez et al.; Geronemus et al., 1979). The
indications for using antimicrobial creams/ointments in
general wound care are not entirely clear as there is
controversy about their effectiveness and the development of
resistance.

Metronidazole (Flagyl) taken orally was found to be
effective in controlling both infection and odor in a variety
of ulcerating metastatic skin lesions (Ashford, et al., 1984;
Sparrow, et al., 1980). For odor control, traditional
deodorant products like Nilodor, Hexon, and Banish have been
applied to the outside of dressings and are still used
effectively (Foltz, 1980). Increasing the frequency of
dressing changes may also decrease the exposure to dressings
saturated with odorous drainage. Hydrocolloid dressings such
as DuoDerm may decrease the number of dressing changes necessary, thereby decreasing the patient's exposure to odor. Although charcoal dressings have also been used to control odor (Beckett, Coombs, Frost, McLeish, & Thompson, 1980), they are expensive and therefore difficult for patients to obtain and hospitals to justify.

Drainage

After cleansing the lesion and considering what is needed to manage bleeding, infection, and odor, the drainage needs to be contained. The inner dressings chosen are those which are in direct contact with the wound (e.g. Adaptic, Flamazine cream, or continuous wet saline dressings). The outer dressing, covering the inner dressing, is usually a dry dressing. The size of the outer dressing depends on the amount of drainage. If there is minimal drainage and no clinical infection, a hydrocolloid dressing such as DuoDerm may be used in place of an inner dressing. Hydrocolloid dressings require fewer dressing changes than do most of the other dressing types. However, they often cannot adapt to the many unusual shapes and sizes of the ulcerating metastatic skin lesions. In some cases where dry gauze dressings do not stick, they are all that is required. In cases where drainage is considerable, a wound drainage collector such as an ostomy pouch may be useful. Tape, netting or clothing may be used to secure the outer dressings.
Continuous Wet Saline Dressings

Wet saline dressings are dry gauze dressings soaked in an isotonic "normal saline" solution (0.9% sodium chloride in water) and are often recommended in the treatment of ulcerating metastatic skin lesions (Stair, 1986). Continuous wet saline dressings dilute viscous exudate and keep the wound constantly moist, thus preventing adherence to the lesion and decreasing problems with pain and bleeding (Cuszell, 1985). They provide an appropriate dressing for ulcerating metastatic skin lesions because adhesion to the lesion is not recommended (Greenberg, 1978).

Unfortunately, continuous wet saline dressings often require frequent dressing changes to keep the dressing moist, or to remove drainage that has saturated through. As mentioned previously, this increased frequency of dressing changes is economically undesirable in the Home Nursing care situation, as well as more bothersome for the patient changing his/her own dressings. A second consideration is that continuous wet dressings may result in maceration of viable tissue and may increase bacterial proliferation (Cuzzell, 1985). Third, continuous wet dressings can be uncomfortable, and may cause bed linen and/or clothing to become wet.

Mesalt Dressings

Mesalt dressings are made of bleached 100% cotton gauze impregnated with crystalline sodium chloride (Sancella,
pamphlet). They are frequently used in both community and hospital settings. When Mesalt dressings are applied, a hypertonic environment is created, stimulating wound cleansing and removing excess fluid, thus decreasing interstitial edema (Sancella, pamphlet). Applied dry, Mesalt dressings are left in place to become moistened by drainage. To be effective, Mesalt dressings must be in contact with a moist ulcer base which has a moderate to large amount of drainage. Mesalt dressings are removed when they are moist, thereby decreasing their potential for sticking to the wound. Also suggested is that the hypertonic environment decreases the potential for bacterial growth (Sancella, booklet). However, no research in the clinical setting substantiates this effect. As previously noted, Mesalt dressings considerably decreased odor in one case involving an ulcerating metastatic skin lesion resulting from breast cancer (Spencer, 1988). Additionally, since Mesalt dressings are dry, the problems of wet clothing/bed linen associated with wet dressings are minimized.

To date four studies, all of them dealing with non-cancerous skin lesions, have evaluated Mesalt dressings. All of these studies used a descriptive design with limited information about the specific methods of collecting data and the measurement tools used. Of the two studies published, however, only one has been translated into English.

The first study evaluated Mesalt dressings in 17 patients with arterial wounds, pressure wounds, an infected venous wound, and a large amputation wound (Ruth, 1979). Results
showed that Mesalt dressings, comparable to traditional wet saline dressings, were the most effective with decubitus ulcers. Mesalt dressings, though, were favored over wet saline dressings because they decreased the required frequency of dressing changes, were easier to handle and did not cause maceration at the wound edges.

The second study evaluated Mesalt dressings among 21 paraplegic patients with decubitus ulcers (Gross & Gerner, 1982, 1985). Mesalt dressings were beneficial in promoting cleanliness of the wound, granulation and healing. These dressings required fewer changes than did wet saline dressings. As well, Mesalt dressings were easy to apply, reducing dressing change time.

The third study evaluated Mesalt dressings with 16 patients having leg ulcers secondary to peripheral venous deficiency, three of them having lesions suitable for paired comparisons (Gallant & Sibbald, 1986). Of the paired comparisons, one of the ulcers was treated with Mesalt dressings, the other with benzoyl peroxide and/or Bard gel. Results indicated that 10 of the 14 ulcers treated only with Mesalt dressings, healed completely within 2 to 14 weeks. In the paired comparisons, two patients experienced improvement of both ulcers, and in the third patient there was a failure to show any significant response. The authors concluded that 1) the healing properties of Mesalt dressings were comparable to those of other established modalities and 2) that Mesalt dressings were significantly less expensive
than most other therapies used in their clinic. Nursing staff preferred Mesalt dressings to other dressings because they were simple and required less time to change.

The last study evaluated Mesalt dressings in 27 patients with open infected lesions (Jagelman & Spencer, 1986). Evaluation included the overall performance of Mesalt dressings for ease of application and removal, ability to cleanse and debride the lesion, and effect on the surrounding skin. All patients were part of a structured care plan including a variety of other treatment modalities. "Representative cases" were described with respect to treatment protocols, size of the lesion prior to and during the treatment, and frequency of Mesalt dressing changes. The authors concluded that Mesalt dressings appeared to hasten and stimulate wound healing, reduce wound edema, and increase the rate of granulation tissue formation, while not adversely affecting the surrounding skin. In addition, Mesalt dressings were convenient to apply, the patients appeared more comfortable during the dressing changes, and the frequency of dressing changes decreased. Thus, the cost related to material and nursing staff was minimized.

In general, these results indicate that the Mesalt dressing is a promising dressing which could be used in the care of ulcerating metastatic skin lesions. However, these conclusions must be considered with caution because of the methodological limitations of the studies, and in particular, the absence of a proper control group.
Patient Satisfaction

Patient satisfaction is infrequently or unclearly defined in the literature (Oberst, 1984). Often the results of a study are presented and analyzed without defining patient satisfaction or describing the criteria used to measure it. Satisfaction is a subjective rating on a continuum that includes an evaluative component which cannot be directly observed by others (Ware, 1981). Satisfaction can be viewed as the patient's judgment of the actual care received, compared to his/her own expectations or standards (McMillan, 1987; Oberst; Ware). Dissatisfaction occurs when the product or service is perceived to be lower in performance than expected (McMillan).

Numerous patient satisfaction studies have examined medical services such as those of the general practitioner, in-patient and out-patient hospital services, and the influence of various personal and institutional characteristics (Lemke, 1987; Locker & Dunt, 1978). Satisfaction with the delivery of nursing care has also been studied (Derdarian, 1990; Hinshaw & Atwood, 1982; Risser, 1975; Ventura, Fox, Corley, & Mercuro, 1982). Only a few studies have evaluated specific treatments or products. These studies include the evaluation of a treatment for impotence (Sidi, Reddy, & Chen, 1988) and the implantation of a dental bridge (Hoogstraten & Lamers, 1987).

Although there is no generally accepted method for measuring patient satisfaction (McMillan, 1987), the most
commonly used tool is the questionnaire (Ware, 1981). Most hospital studies either have developed their own questionnaire or have used a questionnaire previously developed (Abramowitz, Cote, & Berry, 1987). The questionnaire was either mailed out to discharged patients, delivered to the still-hospitalized patient, or used as format for an interview (Abramowitz et al.). As mailings often result in low return rates, direct contact with patients through interviews is preferred (French, 1981).

While most questionnaires use only structured questions, some combine structured and unstructured questions (Locker & Dunt, 1978). Generally, the questionnaire has two parts: 1) the items to be evaluated and 2) the response scales (Ware, 1981).

Numerous problems exist regarding the methodology used to evaluate patient satisfaction (French, 1981; Locker & Dunt, 1978; Oberst, 1984; Ware, Davies, & Stewart, 1978). Validity of the measurement tool is a major concern (Oberst; Ware et al., 1978). Many studies measure satisfaction from a broad perspective, sometimes as a single question. Patients may be asked how satisfied they are in general, and the results tend to be insensitive to differences in specific aspects of the care received (Locker & Dunt). Further, the results do not indicate how care may be changed to improve satisfaction (Locker & Dunt). Henley and Davis (1967) suggest that consumer satisfaction be evaluated using two tools: first, a satisfaction measure for each aspect of the individual's care;
Not clearly defining what is being measured is a major problem in evaluating patient satisfaction. Two aspects of this problem exist. First, some questionnaires have been developed for use in hospital environments with the intention of being more universally used. These include the Patient Satisfaction Questionnaire by Ware, Snyder, & Wright (Ware, 1981) and the Patient Satisfaction Instrument by Risser (1975). However, as both of these questionnaires measure only general care received, they are not sensitive to particular aspects of the care (Oberst, 1984). Second, there is a problem with the development of the questionnaire itself. Researchers often measure satisfaction based on pre-determined topics. The questions often relate to what the researchers want the patient to evaluate or what they assume is important for evaluating patient satisfaction (Oberst). Without patient involvement in tool development, the validity of the measurements obtained is questionable (Oberst). The lack of validity is a major concern because the majority of patient satisfaction studies do not indicate patient involvement in tool development.

Other problems involve the format of the questions, whether used in an interview or a questionnaire. Some are rendered useless as they are ambiguous, badly worded, or fail to identify or misrepresent patients' attitudes (French, 1981).

A common problem in measuring consumer satisfaction is
that satisfaction ratings are frequently high (Oberst, 1984). This may be a result of the insensitivity of the tool used to measure satisfaction. Oberst recommends using a visual analogue scale to increase the sensitivity of the responses.

A visual analogue scale (VAS) consists of a single horizontal line (conventionally 10 centimeters in length) with anchor words at each end of the line (Reading, 1980). Each of the words indicate polar opposites with respect to meaning (e.g. not uncomfortable at all, very uncomfortable). The respondent places a mark, a point on the line which corresponds to his/her feelings on the continuum relative to the two extremes (Oberst, 1984). The distance from the first anchor word to the mark is measured and a score in millimeters is obtained. The VAS is short, and easy to administer and score (Jensen, Karoly, & Braver, 1986). Used extensively in pain studies, it has been shown to be reliable and sensitive to variations (Seymour, 1982). In addition, VAS is a ratio scale (Price, McGrath, Rafii, & Buckingham, 1983). This important characteristic enables the quantitative expression on intensity levels. A potential limitation of this scale is that some subjects have difficulty understanding the task (Stewart, 1977). This may be overcome by ensuring that the patient clearly understands the task prior to using the scale.

The few studies that have evaluated a particular treatment do not appear to have involved the patient in developing the questionnaire, and the evaluations of patient
satisfaction vary from specific responses to an overall rating (Hoogstraten & Lamers, 1987; Sidi, Reddy, & Chen, 1988). No questionnaire is available to measure patient satisfaction with respect to the type of dressings used in the care of ulcerating metastatic skin lesions, nor is there one which includes the development principles Oberst suggested (1984).

**Summary**

In summary, the care of ulcerating metastatic skin lesions is neither well established in the literature nor researched. Though continuous wet saline dressings are commonly used, some inconveniences and patient discomfort do not make them ideal choices. Mesalt dressings may provide a good alternative. They are dry, and studies have shown them to be convenient and require fewer dressing changes; thus, they decrease the nurse’s workload and increase patient comfort.

Using patient satisfaction to specifically evaluate dressings is unique since most patient satisfaction tools have a broad focus. Most patient satisfaction tools seem to be developed without patient involvement. No evaluation tools have been developed for evaluating dressings, and specifically not for ulcerating metastatic skin lesions. The next chapter discusses the methods used to develop the Patient Satisfaction Questionnaire, and to compare Mesalt dressings with continuous wet saline dressings, using patient satisfaction as an indicator.
CHAPTER 3
Methodology

Introduction

The research for this thesis is part of a larger study conducted by the BCCA, comparing Mesalt dressings with continuous wet saline dressings in the care of ulcerating metastatic skin lesions. The larger study evaluated: patient satisfaction with dressing performance, patient and nurse preference, occurrence of infection, number of dressing changes, care of the lesion, and cost of dressing materials. This thesis focused on the part evaluating patient satisfaction with dressing performance and patient preference. The focus on the patient was considered to be important because many patients change their own dressings and often have the lesion for a considerable period of time. Therefore, the purposes of this thesis were two-fold: first, to develop a Patient Satisfaction Questionnaire which reflects patient satisfaction with dressings used in the care of ulcerating metastatic skin lesions; and second, to compare Mesalt dressings with continuous wet saline dressings. Unfortunately, due to time constraints and the low numbers of patients accrued to the study, the Patient Satisfaction Questionnaire was not used during the study. Instead patient satisfaction data were obtained using two pre-developed BCCA instruments. For clarity in discussing the methodology and
study findings, "study" will refer only to the thesis component of the larger BCCA study.

Two hypotheses were tested: first, Mesalt dressings will receive a more positive rating than continuous wet saline dressings with respect to patient satisfaction with dressing performance; and second, Mesalt dressings will be preferred by patients to continuous wet saline dressings. This chapter reviews the methodology and analysis used both for developing the tool and evaluating the dressings during the study.

Development of the Patient Satisfaction Questionnaire

The Patient Satisfaction Questionnaire was developed to measure satisfaction with dressing performance (Appendix A). The questionnaire has two parts: 1) the items to be evaluated and 2) the response scales. Items to be evaluated were developed from input by patients as well as support from the literature. The VAS was used as the response scale.

Sample for Patient Satisfaction Questionnaire

Patients with ulcerating metastatic skin lesions who were seen in the Ambulatory Care Unit of the BCCA Vancouver Clinic formed the majority of the sample used to develop the questionnaire. A few patients were seen as in-patients at the BCCA Vancouver Clinic. Subjects were required to understand, speak and read English. All those patients who fit the criteria were approached and those who consented were included in the sample.
Procedure for Questionnaire Development

The questionnaire was developed through a process of content identification, content validity verification, and reliability testing.

Content Identification. Content for the questionnaire was identified through a combination of patient interviews, review of the literature, and personal experiences. A total of eight patients with ulcerating metastatic skin lesions were interviewed by the investigator who used an interview guide (Appendix B) to determine those factors to be considered when evaluating patient satisfaction with dressings. The data obtained was used to develop the Preliminary Questionnaire (Appendix C). A letter of introduction was written to explain the purpose of the questionnaire and give an example question and response (Appendix D).

Content Validity Verification. Content validity is the extent to which the items included in the scale are relevant and complete (Nunnally, 1978). The investigator administered the preliminary questionnaire to eight patients (not previously involved in the first step) with ulcerating metastatic skin lesions to determine the relevance and completeness of the questionnaire, and the clarity and importance of each of the items identified. Only the responses of five patients were used to refine the questionnaire. The other three patients had to be eliminated from the study because they appeared slightly disoriented and
often were unable to complete the questionnaire without a
great deal of assistance. Comments about the wording and
meaning of the questions were considered and used for revising
the questionnaire. For each item, the average importance was
calculated. Items with an average rating of 50% or greater
were kept, while those with an average rating of less than 50%
were deleted. These results were used to develop the Pilot
Questionnaire (Appendix E).

Reliability Testing. The Pilot Questionnaire was
tested for reliability using the test/re-test method. The
questionnaire was administered to four patients with
ulcerating metastatic skin lesions (who were not previously
involved in the first two steps). One week later it was
re-administered to three of the four patients. However, one
patient was not feeling well enough to complete the second
part of the testing.

The average differences between the first test and the
second test were depicted in the form of a histogram. The
Pearson correlation coefficient was determined by the
investigator, recognizing the limitations of such a small
sample. The analysis involved correlating 1) the sum of the
average responses to each question of the first test, with 2)
the sum of the average responses to each question for the
second test. The results were further tested for internal
consistency. Homogeneity of the questions was assessed using
the split-half method: dividing the questions into two
groups by alternating questions. The two groups were then
re-tested using the Pearson correlation coefficient.

The final outcome of the tool development was the Patient Satisfaction Questionnaire which was made available for use in the study. Unfortunately, there was a lack of opportunity to administer this questionnaire with patients still in the study, due to time constraints and the low numbers of patients involved.

Study Methodology

Study Design

The study used a cross-over design to compare Mesalt dressings with continuous wet saline dressings. The cross-over design is a "within-patient" study in which each patient receives two treatments, one following another, with the order of treatments being decided randomly (Pocock, 1983). This type of design is appropriate for use in comparing individual patient preferences for two treatments (Pocock). It is best suited where a patient sample is relatively stable in terms of disease state, and the treatment is relatively short-term (Pocock). The duration of treatment in this study was 2 months for each subject: 1 month for the first arm of treatment and 1 month for the second. Patients were randomly assigned to their first treatment using a randomization table developed by the Division of Epidemiology, Biometry and Occupational Oncology, BCCA.


Study Group

Fourteen patients were accrued to the study during the time period covered by this thesis. They were selected from registered BCCA patients: outpatients, inpatients, and homecare patients. Patients were excluded if they were undergoing radiation or chemotherapy affecting the condition of the lesion. To be eligible for the study, patients had to satisfy the following criteria:

1. BCCA registered patient, 18 years or over, with no upper limit.
2. Resident of the Greater Vancouver Lower Mainland area.
3. Ulcerating metastatic skin lesion secondary to a confirmed cancer.
4. Ulcerating metastatic skin lesion with discharge requiring at least two dressing changes per 24 hours.
5. Free of clinical and microbiological evidence of infection.
6. Survival expectancy greater than 3 months.
7. Stable disease one month prior to study entry.
8. Competent to answer questions and willing to be compliant with the therapeutic protocol.
9. Consenting to participating in the study and having signed the consent form.

The sample used for this study was a sample of convenience. Many of the patients were not eligible for the study as they were from outside the Greater Vancouver Lower Mainland, were receiving chemotherapy or radiation therapy.
which was effecting their lesion, were in the terminal stages of their disease, or had too little drainage. In a number of instances, it was not feasible for the Home Care Nurses to increase their visits to accommodate study patients who were on the treatment arm using the continuous wet saline dressings. It was thus difficult to accrue patients who were completely dependent on the Home Nursing care program for their dressing changes. During the study period, five patients decided not to participate in the study, mostly due to the inconvenience of the visits and the need to follow a protocol.

Study Procedure

**Accrual.** Nurses and physicians at the BCCA, and nurses in the community, identified potential study patients and contacted the investigator to determine eligibility. If the patient was eligible, the nurse or physician briefly explained the study to them. If the patient was interested in participating in the study, the investigator was contacted to further explain the study to the patient in more detail. If the patient was not actively being seen at the BCCA, the patient's BCCA physician was asked to contact the patient regarding his or her participation in the study. Later in the study, all of the hospitals in the Greater Vancouver Lower Mainland were contacted in an attempt to promote accrual. However, this did not result in the accrual of any patients to the study.

**Procedure.** If the patient consented to the study,
the investigator took a medical history (Appendix F) prior to study. The family physicians of all the patients involved in the study were informed at the beginning and end of the study. Only one patient had clinical and microbiological evidence of infection, and entered the study after resolution of the infection.

The lesion was cared for according to a standard protocol (Appendix G). Most of the patients were independent in the care of their lesions, but in some cases Home Care Nurse in the community or the Staff Nurse in the hospital changed the dressings. Prior to entering the study, the investigator oriented the patient to the wound care protocol. The program of care was the same for both types of treatments. The investigator monitored the protocol compliance on a weekly basis.

The study took place primarily in the patients' homes. However, three patients were visited once or twice while at the BCCA to see a physician; four patients were visited once or more in a hospital setting while they were receiving treatment for complications not involving their wound. Home Care Nurses regularly visited seven of the study patients.

The Overall Evaluation Scale was administered at the end of the first treatment arm and the end of the second treatment arm. The Preference Scale was administered at the end of the second treatment arm.
Study assessments:

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<th>Beginning of Study</th>
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<th>End of first treatment arm</th>
<th>End of second treatment arm</th>
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<td>Medical History</td>
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<tr>
<td>Assessment of Compliance</td>
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<tr>
<td>Overall Evaluation Scale</td>
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<tr>
<td>Preference Scale</td>
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**Evaluation Tools**

The study used two measurement tools previously developed for the BCCA study. The first tool, the "Overall Evaluation Scale," used a questionnaire format (Appendix H). The patient was asked five questions, and each question was followed by a response scale in the visual analogue format. Each question identified was a result of previous contacts with patients who were using dressings in the care of their ulcerating metastatic skin lesion. However, the questions did not undergo any testing for validity or reliability prior to use in the study.

The second tool, the "Preference Scale," asked the patient to indicate a preference for the "first dressing", the "second dressing" or "no preference" (Appendix I). An open-ended question asked "Why?" As part of this thesis, a VAS was added to this tool to measure the degree of preference.
for a dressing. The question used was "If you did have a preference indicated above, how strong was your preference?" The two endpoints used were "Not very strong" and "Very strong." As a result of this question, the "Why?" question was expanded to "If you did have a preference (indicated above), why did you prefer the dressing?" The revised scale is in Appendix J.

**Statistical Analysis**

**Sample Size.** Previous studies using Mesalt dressings were mostly concerned with describing its healing properties, and consequently no data were available to calculate sample size. Therefore, the calculation of sample size for this study was based on the number needed to evaluate patient preference. A sample of 26 patients was required to determine a 75% preference for the Mesalt dressing compared to preference for neither dressing with \( \alpha = 0.05 \) and \( 1 - \beta = 0.80 \). The sample size was based on binomial probability (Fleiss, 1981) and was calculated by the BCCA Division of Epidemiology, Biometry, and Occupational Oncology.

Unfortunately, at the time that this thesis was completed, only fourteen patients had been accrued to the study. Therefore, the analysis of the results has some limitations.

**Statistical Procedures.**

1. **Overall Evaluation Scale**

The hypothesis tested was "Mesalt dressings
will receive a more positive rating than continuous wet saline dressings." The responses to each of the five questions were tested using the Wilcoxon signed-rank test using a one-tailed test with an $\alpha = .05$. (Neave & Worthington, 1988).

**Ho:** There is no difference in the average ratings (for each question) for Mesalt dressings and for continuous wet saline dressings.

**Hi:** Mesalt dressings will receive a more positive average rating (for each question) than continuous wet saline dressings.

Let "+" indicate a positive difference in favor of the Mesalt dressings and "−" indicate a negative difference in favor of the continuous wet saline dressings. If the Ho (null hypothesis) is true, the average (median) of differences will be zero. If the Hi (alternate hypothesis) is true, the true average difference will be positive. The difference was obtained by subtracting the score obtained with the continuous wet saline dressings from the score obtained with the Mesalt dressings. The differences were ranked, and the negative scores totalled. For this test, "T" was defined as the sum of ranks of negative differences, as T would be expected to be smaller if Hi were true.

**Decision rule:**

If $T \leq T$ critical, Hi is supported.
Using the statistical tables for this test (Neave & Worthington, 1988), the T critical was determined and a decision made.

2. Preference Scale

The hypothesis tested was "Mesalt dressings will be preferred by patients to continuous wet saline dressings." This hypothesis was tested using the sign test (one-tailed) with a critical level $\alpha = .05$ (Neave & Worthington, 1988).

$H_0$: Preference is equal between Mesalt dressings and continuous wet saline dressings.

$H_1$: Mesalt dressings are preferred more than continuous wet saline dressings.

Let "+" indicate the number of preferences for Mesalt dressings and "-" indicate the number of preferences for continuous wet saline dressings. If $H_0$ (null hypothesis) is true, the number of "+" and "-" signs would be roughly equal. Whereas, if $H_1$ (the alternate hypothesis) is true, there would be a relatively large number of "+" signs and correspondingly few number of "-" signs.

No preferences were omitted from the analysis. Since it was expected that there would be smaller numbers of the "-" signs, the test statistic "$S$" was defined as the number of "-" signs.

Decision rule:

Hi tenable if $S \leq S_{critical}$
Using the statistical tables for this test (Neave & Worthington, 1988), the S critical was determined and a decision made.

The open-ended question results were examined using a theme analysis approach. The VAS results from the revised Preference Scale reflecting strength of preference were also evaluated.

Withdrawals. Patients who did not complete at least one week of both study arms were omitted from the statistical analysis. The results of the remaining patients were analyzed by sub-groups depending on the length of time they were in the study.

Ethics. Patients were informed of the purpose and procedures of the study as well as the potential benefits and inconvenience that could occur during the study. Patients were also informed that their participation was voluntary and their refusal or withdrawal from the study would not compromise their treatment and care at the BCCA. Patients signed a consent form before entering the study (Appendix K).

A unique study number was assigned to each participant. No name was written on the data and coding forms, except for the consent form. All the forms used in the study were kept under secure conditions in the Division of Nursing, BCCA.

Summary

This chapter has presented the methodology and analysis used to develop the Patient Satisfaction Questionnaire as well
as to compare Mesalt dressings with continuous wet saline dressings as part of a larger study. The results are presented and discussed in the next chapter, followed by a chapter describing the conclusions and recommendations.
CHAPTER 4

Presentation and Discussion of Findings

Introduction

The findings are presented in two sections in this chapter. The development of the Patient Satisfaction Questionnaire is described in the first section. Findings related to the two study hypotheses are presented in the second section. Within each section, the characteristics of the sample are described. The findings are discussed at the end of each section.

Patient Satisfaction Questionnaire

The questionnaire development involved three steps: content identification, content validity verification, and reliability testing. The characteristics of the sample are described and the results given.

Content Identification

Eight patients were interviewed to identify content for the Preliminary Questionnaire. Additional content was identified through a review of the literature and personal experiences.

Characteristics of the Sample. Of the eight patients, six were females and two were males. Their ages ranged from 35 to 78 years, with an average 61.1 years, and a median of 63 years. The length of time that they had their
lesions ranged from 1 week to 33.5 months, with an average of 11.3 months and a median of 7 months. Seven lesions were a result of breast cancer and the eighth lesion was due to melanoma. The lesions involved the breast or chest wall in seven instances, and the leg in one instance.

Results of the Interviews. The first step in the questionnaire development was to interview eight patients with ulcerating metastatic skin lesions to determine factors to be considered when evaluating patient satisfaction. The interview guide was well received, although some patients had difficulty articulating their likes and dislikes about dressings. The patients who had used dressings for some time or had used a variety of dressings found the questions easier to answer than did those with limited experience with dressings. Also, those patients who changed their own dressings seemed to be more interested in the questions than those who had their dressings changed by another person such as the Home Care Nurse.

The first question asked was "What types of dressings have you used in the care of your open wound?" The responses included Telfa, Jelonet, Sofratulle, Unitulle, wet saline dressing, paraffin dressing, Mesalt dressing, Vaseline ointment and dry gauze, and a variety of plain dry gauze dressings.

The second question asked was "What did you like about each dressing?" Four patients responded that they liked the fact that the dressing did not stick. One patient clarified
that if it did not stick, then it did not cause bleeding. Another response was that the dressing dried the lesion faster, evidence to the patient that the lesion was healing. In addition, one patient considered it important that the dressing was easy to use.

The third question asked was "What did you dislike about each dressing?" Dressings that stuck to the wound were a major dislike. If the dressing stuck, it was uncomfortable to remove and could make the lesion bleed. Using a cleanser which did not sting was identified as being important. One dressing was found to be too sticky and "gummy," and caused a "strange" odor. Another dressing caused the wetness to go outside the dressing and was a "bother" at night. One patient disliked one of the dressings as it made the tumor wetter. She thought this would cause the tumor to break down and take longer to heal.

The fourth question asked was "What do you want the dressing to do?" or "What characteristics of the dressing would you consider important in choosing a dressing?" This was a difficult question for many of the patients. Some patients preferred to leave this question and answer the fifth question instead. Those who did respond thought a major characteristic should be that it did not stick. Other characteristics identified were that it should be easy to take off, absorbent, usable without tape, non-abrasive, and without lint. It should be also fitted so it does not slip, it should promote healing and it should not allow the drainage to pass.
The final question asked was "What factors would influence your satisfaction with the dressing?" or "Can you describe the 'perfect' dressing?" Like the fourth question, many patients had difficulty answering this question. Those who answered the fourth question usually did not answer this question. Those who did respond suggested dressings which would be soft, easy to apply and remove, not sticky, and absorbent but not bulky; and which would not adhere to the wound. Some of the suggestions focused on the shape of the bandage, the desirability of having it come in different sizes contoured to adapt to shape, and fitted such as a spray foam which peels off. One patient suggested having a dressing where you put on one thing - "just open it up and put it on like a Band-Aid."

Development of the Preliminary Questionnaire.
Considering the characteristics identified in the previous step (summarized in Appendix L), the Preliminary Questionnaire was developed (Appendix C). The wording and format of the questionnaire was influenced by the comments from a large number of non-health care workers and a few patients.

A total of 28 questions were identified. The response scale used for each item to be evaluated was the Visual Analogue Scale (VAS). This scale consisted of a single 10 cm horizontal line with anchor words at each end of the line. Each anchor word represented an extreme with respect to meaning (e.g. a great deal, not at all). The patients were
asked to "place a mark through the line, between the two extremes to indicate the degree of your response."

The second part of each of the questions asked about the importance of the question. It was worded "Is the subject of the question important to you?" Initially a VAS was considered for rating the importance of each question. However, the feedback received was that the VAS was somewhat difficult and time consuming, especially for the number of questions being asked. Since the initial question already used the VAS, the issue was compounded. As it was pre-determined that only questions which averaged greater than a 50% rating would be included, it was easier overall to use a "yes" or "no" type response.

The wording of the question regarding importance was difficult as it attempted to identify only those questions which were important to the patient by their own experience and omit questions which the patient perceived as "generally important." An introductory letter was developed (Appendix D) to describe the questionnaire's purpose, give an example, and reinforce that the question about importance related to their own personal experiences. The letter of introduction was also used to remind patients that the questions were related only to the dressing and not to tape or other devices used to hold the dressing in place.

Content Validity Verification

To determine the validity of the content, the Preliminary
Questionnaire was tested to determine if the questions were understandable and important, and if the questionnaire was easy to fill out.

The investigator administered the questionnaire to eight patients, remaining in attendance while the patients filled them out. Unfortunately, three of the eight patients were unable to complete the questionnaire as they were not feeling well enough. For these three the questionnaire was filled out mostly by the investigator, using their verbal responses. During the discussions with the investigator, the three patients often responded vaguely and somewhat inappropriately to questions unrelated to the questionnaire, and their attention span was poor. Therefore, only five of the patients were used as the sample. Some of the comments from the three patients excluded from the sample were useful and were incorporated into the revisions.

Characteristics of the Sample. The five patients included four females and one male. Their ages ranged from 64 to 73 years, with an average of 68.6 years, and a median of 63 years. The length of time that they had their lesions ranged from 3 weeks to 19.5 months, with an average of 8.5 months, and a median of 1.5 months. Four of the patients had lesions due to breast cancer and the fifth was due to endometrial cancer. The lesion sites included four of the breast or chest wall and one of the abdomen. The types of dressings previously used by the patients included Flagyl ointment and ETE dressing, Flamazine cream and dry gauze, Mesalt dressing,
Jelonet and dry gauze, wet saline gauze, Polysporin ointment and dry gauze, an unknown antibiotic ointment and dry gauze, and plain dry gauze.

One of the five participants had a lesion which had healed one month prior to being given the questionnaire. This participant had considerable experience with dressings since the wound had been present for a long time. Because she could easily recall important characteristics of the dressings she had used, she was not omitted from the sample.

Results of the Testing. Most of the questions were easily understood and only a few suggestions were made. Those patients using tape to hold the dressing in place needed to be reminded that the questions were related only to the dressing. At times, one of the participants wanted to respond to the frequency of the problem: for example, "Do you experience pain from the dressing while it is on?" Given the two extremes as "a great deal" and "not at all," she wanted to answer "sometimes." However, her final decision was to place a mark which reflected the average occurrence.

In 27 of 28 items, 3 or more of the participants found the subject of the questions important to them. The subject of the question was important to all 5 participants in 21 of 28 questions; to 4 of the 5 participants in 6 of 28 questions; and to 2 of the 5 participants in 1 of 28 questions. Overall, they found the questionnaire easy to fill out once they understood the process. The examples given in the letter of introduction proved to be useful for explaining the scale.
Development of the Pilot Questionnaire. The following revisions were made after reviewing the responses to the Preliminary Questionnaire:

From: Is there discomfort during the dressing change?  
To: Do you experience discomfort when the dressing is removed?

From: Do you experience pain when the dressing is changed?  
To: Do you experience pain when the dressing is removed?

From: Does the dressing stick to the wound?  
To: Does the dressing stick to the wound when it is being removed?

From: Is dressing fibre left in the wound when dressing is removed?  
To: Are there dressing fibres left in the wound when the dressing is removed?

From: Does the dressing rub roughly against the wound?  
To: Does the dressing rub roughly against the wound while it is on?

From: Can you use the dressing without tape or other devices which hold the dressing in place?  
To: Can you use the dressing WITHOUT tape, netting or other devices which hold the dressing in place?

Delete:
Does the dressing cause the wound to enlarge?  
Does the dressing cause a "gummy" feeling?  
Does the dressing cause itchiness to the skin surrounding the wound?

Given the above revisions and question deletions, the questionnaire was revised to include 25 questions. The general format was the same as the Preliminary Questionnaire. This then became the Pilot Questionnaire (Appendix E).

Reliability Testing

The Pilot Questionnaire was tested using the test/re-test method. The questionnaire was administered to four patients;
and re-administered one week later to three of the four patients. One patient was not feeling well enough to complete the second part of the testing.

**Characteristics of the Sample.** The three patients included two females and one male. Their ages ranged from 50 to 57 years, with an average of 53 years, and a median of 53 years. The length of time that they had their lesions ranged from 4 to 11.5 months, with an average of 6.8 months, and a median of 5 months. Two lesions were a result of breast cancer and one was a result of a neck cancer. The three lesion sites included the chest wall, the neck, and the arm. The types of dressings used included wet saline, Mesalt, Telfa, Flamazine cream and dry gauze, and plain dry gauze. One patient who participated was not using a dressing at the time of the testing as she was undergoing radiation treatment. When completing both questionnaires, she therefore referred to the dressing she had recently been using.

**Results of the Testing.** During the one week period, the lesions of each of the three patients remained stable. The patients continued to use the same dressing, or in the instance of one patient, continued to refer to the same dressing while completing both questionnaires.

The average difference between the first and second test for the 25 questions have been depicted in the form of a histogram (Figure 1). The marks made by the patients on the 10 cm VAS were measured to the nearest tenth of a centimeter. The second test result was subtracted from the first test
Figure 1. Histogram depicting the average differences between the 1st and 2nd test for the 25 questions on the Pilot Questionnaire.
result for each patient. The differences obtained for the three patients were then averaged for each question. The average differences for each question ranged from a negative 2.0 cm to a positive 2.5 cm. There were one to six questions for each 0.5 cm difference. A greater number of questions tended to be rated more positively on the first test than on the second.

Using the Pearson correlation coefficient, the correlation of results between the first and second administration of the Pilot Questionnaire was calculated to be quite strong at .75. Using the split-half method for testing internal consistency, the two subsets were analyzed. The first group revealed a correlation of .63, and the second group revealed a correlation of .75.

Regarding the questions' importance, some patients thought one of the questions was important one week and not the other. This occurred with one patient for the question "Does the dressing cause the wound to bleed when it is removed?" This also occurred in two questions with another patient for the questions "Do you experience pain from the dressing while it is on?" and "Does the dressing adapt to the shape of the wound?" One patient did not find the question "Does the dressing cause a stinging sensation?" important either time. The same patient did not find the question "Does the dressing cause a 'strange' odor?" important either time, and another patient found this question important one time and not important the other time.
In the situation where the patient had the same response each time, it may be interpreted that his opinion is strong enough to be maintained over a one week period. Where patients were not consistent in their opinion, it may be interpreted that their opinions were weaker because they were unable to carry them over a one week period. Overall, 19 of 25 questions were thought by all three patients to be important both times. Each patient changed his/her mind about the importance of one question - all of the questions being different. One patient felt two questions were not important to him and maintained this opinion over the one week period.

The Patient Satisfaction Questionnaire. The Patient Satisfaction Questionnaire was the final result of the previous steps of developing the content and testing the reliability. After considering the responses of the patients, it was determined that the comment about the question "Do you experience pain from the dressing while it is on?" was a valid remark. It was often difficult for the patient to determine if it was the dressing or the wound which was causing the pain. Also, since there were questions which related to the dressing causing a "stinging" or "burning" sensation, the topic was indirectly covered in the questionnaire. Therefore, this question was deleted while the remaining 24 questions remained unchanged, forming the Patient Satisfaction Questionnaire.
Discussion of the Findings

During the development of the Patient Satisfaction Questionnaire, many characteristics were identified as being important when evaluating satisfaction with a dressing. Many individuals repeated these characteristics. Their importance was reinforced during the testing for content validity and reliability. For some characteristics, patients found it difficult to decide if the undesirable characteristic was being caused by the dressing or the wound itself. For this reason, some questions were deleted.

Most patients were not familiar with the VAS as a response scale. Some patients had difficulty with it at first and required some explanation. This difficulty had also been experienced by others when using the VAS (Gift, 1989; Stewart, 1977). After completing a few questions, patients found the VAS easier to use. However, a few patients indicated that they preferred to have boxes to check instead of a line to mark. A study comparing Likert and visual analogue scales also found that the Likert scale was easier for the patients to understand, making it easier to administer (Guyatt, Townsend, Berman, & Keller, 1987). The introductory letter was useful in that it helped patients understand the questionnaire's purpose and gave them an example of using the VAS. Pre-questionnaire teaching, although time consuming, was useful in a previous study (Guyatt et al.), and the detailed instructions in an example form was previously recognized as being effective (Lorig, 1984). For this thesis, instructions
were placed at the top of each page of the questionnaire. It was felt that due to the difficulty patients had in completing the VAS, either pre-questionnaire teaching or an explanatory letter with an example was needed, additional to the brief instructions at the top of each page.

Two difficulties in responding to the questions occurred. The first one was with regard to those questions which patients wanted to answer with "sometimes." In those cases they needed encouragement to fill it in as "an average." The second difficulty was with questions where the person had not experienced the sensation asked about. Patients in this situation wanted to respond "no," an option not available using the VAS. Therefore, they responded close to the "not at all" anchor word, but rarely at the very end of the line.

The reliability testing using the test/re-test method revealed results which have limited interpretation since only three patients were involved. The average differences for the questions were depicted with a histogram and showed that patients tended to respond more positively on the first test than on the second. The Pearson correlation coefficient results showed a fairly strong correlation of .75 between the first and the second test. The testing for homogeneity of questions also suggested that the questionnaire had fairly good internal consistency. Overall, the patients liked the questionnaire's format and found the questions to be both understandable and important.
Study Findings

The results of the hypothesis testing are described in this section. Fourteen patients were involved in the study. The characteristics of the sample, the results of the Overall Evaluation Scale (Appendix H), and the Preference Scale (Appendix I) are presented and discussed. Because some of the patients discontinued the study earlier than planned, much of the data was statistically analysed in three subgroups. The findings of the analysis are discussed and general comments about the study are made.

Characteristics of the Sample

Of the 14 patients who participated in the study, 13 were female and 1 was male. Their ages ranged from 45 to 85 years, with an average of 65.6 years, and a median of 67 years. The length of time they had their lesions ranged from 3 to 33.5 months, with an average of 11.6 months, and a median of 10.25 months. The lesion resulted from breast cancer in 11 patients, the neck in 2 patients, and the ovary in 1 patient. The lesions involved the breast or chest wall in 10 instances, the neck in 2 instances, the groin in 1 instance, and the scalp in the remaining instance. Of the 14 patients accrued to the study, 7 patients were equally randomized into each dressing arm.

All patients were living in the Greater Vancouver Lower Mainland, and were living at home at the start of the study. During the study, two of the patients were admitted to the
hospital due to disease complications, unrelated to their wounds.

Many types of dressings were being used prior to entry into the study. They included Sofratulle and dry gauze, Flamazine and dry gauze, continuous wet saline dressings, Vaseline ointment and dry gauze, an unknown antibiotic ointment and dry gauze, Cicatrin powder & Telfa, Hygeol (sodium hypochlorite) solution and gauze, ETE dressing, Jelonet & dry gauze, and plain dry gauze. With the exception of Jelonet used by three patients, all other dressings were used by each of the remaining patients. One patient was using Kleenex to absorb the drainage, while another was using diapers. No patient had previously used Mesalt dressings and only one of the patients had used continuous wet saline dressings.

Of the solutions used to cleanse the wounds, six used normal saline solution, five used water, and one used Hygeol. Two patients did not cleanse their wounds. Seven of the patients had scant or a small amount of bleeding prior to entering the study, and two others had bleeding which required control through the occasional use of Gelfoam. Eight patients experienced some degree of odor, and four were taking Flagyl pills for odor control, prior to entry into the study. Six patients had no odor.

Seven patients were receiving medical treatment at the start of the study. Six were on hormones and one was undergoing chemotherapy. None of the treatments were
affecting the condition of the lesion. One patient did not enter the study until the clinical infection of her wound was resolved.

Study Completeness

Not all of the patients completed the entire study. Therefore, both the Overall Evaluation Scale and the Preference Scale have been statistically analyzed by groupings of 6, 8, and 10 patients, depending on the extent of study completion.

The first analysis included the six patients who completed both arms of the study; these patients are identified as subgroup A. The second analysis added two patients: one patient who completed two weeks of each study arm, and one patient who completed four weeks of one study arm and two weeks of the other; these patients are identified as subgroup B. The third analysis added two more patients to those already analyzed. These patients completed four weeks of one arm and one week of the second arm; these patients are identified as subgroup C.

Four of the original fourteen patients were omitted from the analysis. Two discontinued the first arm within one week or less and did not wish to change to the second arm. The third patient discontinued the first arm within one week and was on the second arm for only one week. The fourth patient completed the first arm, but due to the disease progression did not switch to the second arm. For the patients included
in the analysis, the randomization to the first dressing is indicated in Table 1.

Table 1

**Patient Randomization to First Dressing**

<table>
<thead>
<tr>
<th>Subgroups of Patients</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s First Dressing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesalt dressings</td>
<td>4</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Continuous wet saline dressings</td>
<td>2</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**Overall Evaluation Scale**

The first hypothesis tested was that Mesalt dressings would receive a more positive rating than continuous wet saline dressings with respect to patient satisfaction with dressing performance. This hypothesis was tested by asking the five questions in the Overall Evaluation Scale (Appendix H) and analyzing the results using the Wilcoxon signed-rank test (Neave & Worthington, 1988).

The first question asked was "How is the application of the dressing?" From subgroup A, five responses were analyzed. With n = 5, T = 2 and T critical = 0, the null hypothesis was supported and no difference between dressings was found. From subgroup B, six responses were analyzed. With n = 6, T = 2 and T critical = 2, the null hypothesis was rejected and there was support for Mesalt dressings having a more positive rating.
using a one-tailed test and an $\alpha = .05$. From subgroup C, eight responses were analyzed. With $n = 8$, $T = 3$ and $T_{critical} = 5$, the null hypothesis was rejected and there was strong support for Mesalt dressings having a more positive rating using a one-tailed test and an $\alpha = .05$.

The second question asked was "How is the removal of the dressing?" From subgroup A, four responses were obtained which were inadequate for analysis. From subgroup B, five responses were analyzed. With $n = 5$, $T = 10.5$ and $T_{critical} = 0$, the null hypothesis was supported and no difference between dressings was found. From subgroup C, eight responses were analyzed. With $n = 8$, $T = 10.5$ and $T_{critical} = 3$, the null hypothesis was supported and no difference between dressings was found.

The third question asked was "How much discomfort do you experience when the dressing is removed?" From subgroup A, four responses were obtained which were inadequate for analysis. From subgroup B, six responses were analyzed. With $n = 6$, $T = 13$ and $T_{critical} = 2$, the null hypothesis was supported and no difference between dressings was found. From subgroup C, eight responses were analyzed. With $n = 8$, $T = 17$ and $T_{critical} = 5$, the null hypothesis was supported and no difference between dressings was found.

The fourth question asked was "How comfortable is the dressing between dressing changes?" From subgroup A, five responses were analyzed. With $n = 5$, $T = 1$ and $T_{critical} = 0$, the null hypothesis was supported and no difference between
dressings was found. From subgroup B, seven responses were analyzed. With \( n = 7 \), \( T = 6 \) and \( T \text{ critical} = 3 \), the null hypothesis was supported and no difference between dressings was found. From subgroup C, eight responses were analyzed. With \( n = 8 \), \( T = 6 \) and \( T \text{ critical} = 5 \), the null hypothesis was supported and no difference between dressings was found. Despite the absence of significant results the ratings were almost more positive with the Mesalt dressings.

The fifth question asked was "How effective is the dressing in controlling odor?" Only three responses were obtained for both subgroups A and B, and provided inadequate numbers for analysis. From subgroup C, five responses were analyzed. With \( n = 5 \), \( T = 0 \) and \( T \text{ critical} = 0 \), the null hypothesis was rejected and there was support for Mesalt dressings having a more positive rating using a one-tailed test and an \( \alpha = .05 \).

Comments about the Analysis. In some cases, patients involved with the study were unable to complete the entire Overall Evaluation Scale. In two cases, the patients were hospitalized. As they were not involved in doing their dressing changes, they did not complete the questions relating to ease of application and ease of removal. In one case, the patient became terminally ill. Although she was able to respond verbally, she was unable to complete the questionnaire using the VAS. The analysis of the already small numbers of responses was also affected by the deletion of one difference in each of questions, two, three, four and five, as the
Because some patients experienced no odor during the entire study, they did not respond to the question about odor. The analysis of this question included two patients who had used Mesalt dressings for a period of only one week but noticed a difference in control of odor. One patient was unable to complete the question about odor as she was unable to smell. Both the Home Care Nurse and the investigator noted that there did not seem to be any difference between the two dressings for this patient.

The patients were randomized equally into subgroups B and C. Subgroup A was unbalanced since four were first randomized to the Mesalt dressings and the other two to the continuous wet saline dressings. Due to the already low numbers of responses of the group subgroup A, only questions one and four were affected; and in both instances the analysis showed no difference between the dressings.

Comments about the Overall Evaluation Scale. The patient sometimes found it difficult to understand the procedure for using the VAS. Explanations were made and an example was given. The investigator was in attendance during the completion of all evaluation scales. It was difficult for patients to mark the VAS with an "X." The instructions were therefore modified from "...put a X on the line..." to "...put a / on the line..."

In one instance, the investigator was not sure that the response given truly reflected the patient’s feelings. For
example, one patient indicated that she had quite a lot of discomfort when answering the question about discomfort during dressing removal. As this conflicted with the observations made by the investigator, the patient was questioned further. The patient clarified that her response reflected her discomfort with all dressing changes and not particularly about the removal. She maintained that her response was appropriate even when it was emphasized that the question related to the dressing "removal." After using the other dressing for four weeks, she indicated that the discomfort during the dressing removal was not too bad. In comparing the Mesalt dressings to the continuous wet saline dressings, she felt that both dressings were about the same with regard to discomfort during dressing removal. When this response was deleted from the analysis, the results for that question remained unchanged.

Discussion of Findings. Except for the uncertainty of one patient's response, each of the other patients' responses were generally expected. There is agreement between what the investigator observed during the study and the findings of the analysis. The finding that Mesalt dressings are easy to apply is supported by previous research (Gallant & Sibbald, 1986; Gross & Gerner, 1982, 1985; Jagelman & Spence, 1986; Ruth, 1979). The results indicating greater odor control with Mesalt dressings substantiate the earlier finding by Spencer (1988). Little difference was noted between the two dressings with regard to ease of dressing removal and
discomfort during the dressing change. Some patients felt that the continuous wet saline dressings were quite uncomfortable to wear, and further research may reveal more significant findings regarding discomfort of these dressings between dressing changes.

Of interest is the comparison of questions asked on the Overall Evaluation Scale and those identified for the Patient Satisfaction Questionnaire. The five questions from the Overall Evaluation Scale are similar to five of the questions patients identified for the Patient Satisfaction Questionnaire. Although the Patient Satisfaction Questionnaire includes many other questions, the five questions are recognized as being pertinent for evaluating patient satisfaction.

The evaluation of the second dressing was made without referring to the responses given for the first dressing. Some investigators recommend that the previous results should be shown to the patient, while others do not (Gift, 1989). It is difficult to know whether or not this would have had any effect in this study. However, the one instance regarding discomfort during the dressing change would probably not have occurred if this method was in place. Another approach would be to have the patients rate both dressings at the same time.

In summary, the Mesalt dressings were found to be significantly easier to apply and significantly more effective in controlling odor compared with continuous wet saline dressings. There appeared to be no significant
difference between the two dressings with regard to ease of removal and discomfort during and between dressing changes. The characteristics evaluated in the study were recognized as important to measure when evaluating patient satisfaction in the care of ulcerating metastatic skin lesions.

Preference Scale

The second hypothesis tested was that "Mesalt dressings would be preferred by patients to continuous wet saline dressings." This hypothesis was tested by use of the Preference Scale. Patients were asked to choose a preference between the "first dressing," the "second dressing," or alternatively, "no preference." The results were analyzed using the sign test (Neave & Worthington, 1988).

All patients responded to this question, two doing so verbally. The frequency distribution of preferences are divided into the three subgroups in Table 2.

Table 2
Frequency Distribution of Patient Preferences

<table>
<thead>
<tr>
<th>Patient Preferences</th>
<th>Subgroups of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td>Mesalt dressings</td>
<td>5</td>
</tr>
<tr>
<td>Continuous wet saline dressings</td>
<td>-</td>
</tr>
<tr>
<td>No preference</td>
<td>1</td>
</tr>
</tbody>
</table>
Of subgroup A, five preferred Mesalt dressings and one had no preference. With \( n = 5 \), \( S = 0 \) and \( S \text{ critical} = 0 \); the null hypothesis was rejected, and there was support for the conclusion that Mesalt dressings were preferred to continuous wet saline dressings using a one-tailed test and an \( \alpha = .05 \).

Of subgroup B, six preferred Mesalt dressings and two had no preference. With \( n = 6 \), \( S = 0 \) and \( S \text{ critical} = 0 \), the null hypothesis was rejected, and there was support for the conclusion that Mesalt dressings were preferred to continuous wet saline dressings using a one-tailed test, with an \( \alpha = .05 \).

Of subgroup C, seven preferred Mesalt dressings, two had no preference and one preferred continuous wet saline dressings. With \( n = 8 \), \( S = 1 \) and \( S \text{ critical} = 1 \), the null hypothesis was rejected, and there was support for the conclusion that Mesalt dressings were preferred to continuous wet saline dressings using a one-tailed test with an \( \alpha = .05 \).

**Comments about the Analysis.** The randomization to the first dressing was equal for subgroups B and C, and was unbalanced in favor of the Mesalt dressings for the subgroup A. It was difficult to determine if the randomization of the group of six affected the results obtained. However, the preference for Mesalt dressings in subgroup A appears consistent with the analysis of the other two groups.

**Revisions to the Preference Scale.** The Preference
Scale was revised using a VAS in an attempt to measure how strong the preference was, since there was no method for the patient to indicate the magnitude of their response (Appendix K). The anchor words were chosen with input from a number of non-health care workers. However, after the revision was made, only two patients were involved in completing the question. Therefore, there was an inadequate number of responses for analysis.

Analysis of the Open-Ended Question. The open-ended question asked "Why?" with regard to the patient's preference, if a preference was indicated. During the study the question was modified to "If you did have a preference (indicated above), why did you prefer the dressing?" This modification occurred at the same time the VAS was added to determine preference strength. The modification did not seem to have any affect on the type of responses received. Attempting to analyze the results using a theme approach was difficult. No one common theme appeared due to the small number of patients involved. Therefore, each response was considered individually.

The response received to the open-ended question helped to clarify the patient's choice and sometimes added information that was not evaluated on the Overall Evaluation Scale. In the group of 6, the responses from the 5 patients preferring Mesalt dressings included the comments that the dressings were easier to apply and manage, and that the fluid did not drain through so quickly. In one case the drainage
was less, the wound was cleaner, and the dressing was perceived to be very effective because it decreased the moisture in the wound. One patient preferred Mesalt dressings because they were quicker to apply, the process was not as messy, and there was minimal odor. This patient did not like the continuous wet saline dressings because they always felt wet and caused irritation at times. There was no comment from the patient who did not have a preference.

Of the additional 2 patients in the group of 8, the individual with no preference had no comment. The response from the patient who preferred Mesalt dressings indicated that the Mesalt dressing caused less scab formation on the ulcer and caused it to be drier.

Of the final 3 patients in the group of 10, one patient had no preference and no comment. The patient who preferred the continuous wet saline dressings did so because she found the Mesalt dressing "very distressing for my particular case." The patient who preferred the Mesalt dressings found that after a couple of days, the dressing was quite comfortable and the odor was greatly decreased. In addition, the dressings seemed to "dry the wound quite a bit."

Comments about the Preference Scale. Patients seemed to have no difficulty completing the question about preference. The addition of the VAS to determine strength of preference required additional explanation with an example, in order to be easily completed.

Discussion of Findings. The analysis revealed that
there were statistically significant results which support Mesalt dressings being preferred to continuous wet saline dressings. The preferences given were supported by the patients’ comments during the study. Where the two patients did not have a preference, the responses were unexpected. During the study, both of these patients made more favorable comments about the Mesalt dressings. One patient had been admitted to the hospital concurrent to entering the Mesalt dressing arm of the study. As a result, she was not involved in changing her own dressings. It is difficult to know what her response would have been if she had been changing her own dressings. The second patient found Mesalt dressings decreased the odor quite a bit. She found that the continuous wet saline dressings were uncomfortable between dressing changes and that they caused a great deal of sloughing of dead tissue, resulting in increased odor. Thus, she had to spend much more time cleaning the wound. However, by the end of four weeks, she felt that the cleanliness of the wound was an important characteristic and that the continuous wet saline dressings had caused her to clean more. Unfortunately, the vigorousness of this cleaning caused increased bleeding. Because the patient did not view this as a problem, in her overall evaluation of the dressings she did not prefer one dressing over the other.

The open-ended questions revealed more specific information regarding the rationale for preferring the dressing. Some of the comments were not reflected in the
Overall Evaluation Scale. This indicated that the patient's satisfaction with dressings was not totally evaluated using only the questions in the Overall Evaluation Scale. Of interest, most of the responses to the open-ended question were included in the Patient Satisfaction Questionnaire.

In summary, the results obtained showed a significant preference for the Mesalt dressings when compared with the continuous wet saline dressings, even with the small sample evaluated. Answers to the open-ended questions added more specific information about patients' reasons for preferring the dressings.

General Comments about the Study

Comments About the Study Design. The cross-over design was an appropriate method for comparing the two dressings. For those patients who used each dressing for four weeks, no carry-over or residual effects were apparent when the dressings were evaluated. The possibility of carry-over effects was minimized by the randomization to the first dressing. In general, the wounds remained stable throughout the study, a desirable situation for using the cross-over design (Beck, 1989; Pocock, 1983).

The concern about patients dropping out of the cross-over design (Beck, 1989) was a realistic problem in this study because many patients were unable to fully complete both study arms. The patients who discontinued the study after being on the second dressing for only one week found the one week
period adequate enough to evaluate all of the variables. The patient who used both dressings for two weeks also felt that he did not need to use the dressings for four weeks in order to evaluate them. The difficulty arose in the decision of time needed for adjustment to the dressings. Some patients were able to fully adjust to the dressings quickly, while others took more time. The length of time that a dressing should be used for this type of study depends on the variables being evaluated. The ease of application and removal of the dressing seemed to require less time to determine than did the control of odor and the comfort between dressings. Some patients noticed a great difference within a few days of using the dressing. In some cases the difference was so intolerable that they discontinued the use of the dressing or discontinued participation in the study itself.

Another problem was with the four-week time period for each study arm. It was a long period of time for some patients to remember what the dressings were like for the purposes of comparison. The difficulty in remembering has also been recognized in a previous study (Carlsson, 1983). However, the preferences indicated by the patients were generally supported by their comments during the study.

Comments About the Patients. Most of the patients were able to tolerate the study. Clinically, there were minimal changes in the patients' lesions. None of the patients developed a clinical infection while on the study. Many patients had a scant or small amount of bleeding prior to
the study, and this did not change greatly. A slight increase in bleeding was noted in some situations using the Mesalt dressings, but this also occurred with the continuous wet saline dressings. Despite the moistness of the dressings, in some cases the Mesalt dressings and continuous wet saline dressings stuck to the wound slightly. Why this occurred is not well understood.

A number of Home Care Nurses at the start of the study identified stinging from the Mesalt dressing as a concern. Out of the 13 patients on the study who used Mesalt dressings, 10 did not experience any stinging. Three did experience some stinging, and in one of these cases the stinging diminished within two weeks. One patient did not use the Mesalt dressing as she did not switch to the Mesalt dressing treatment arm.

Of interest, the drainage decreased in only three cases while using the Mesalt dressings. In one case the Mesalt dressings somewhat increased the drainage. In five cases the Mesalt dressings caused the wound to dry out or shrink. All of the patients felt that this was beneficial. In one case the wound completely dried and did not require dressing changes for five months. However, in most cases the drainage remained unchanged for the entire study period.

Most of the patients on medical treatment at the start of the study were on the treatment for the study duration. One patient started chemotherapy during the study. None of the treatments appeared to have affected the condition of the lesions.
For the patients who fully completed both arms of the study no difficulty occurred in tolerating the wound care protocol. In one case, however, the patient was asked to remain on one dressing for five weeks instead of four. This occurred after the physician received the swab result for culture and sensitivity, and ordered oral antibiotics for the patient. The patient had forgotten that she was not to take any medications that might interfere with odor, and the physician had forgotten that the patient was on the study. In this situation, the patient neither had a clinical infection nor noticed any change in the odor. This increased length of time on the study did not appear to affect any of the patient’s responses about satisfaction or preference.

The reasons for discontinuing the study early varied for each patient. One patient discontinued the continuous wet saline dressings early as the physician was planning to do some wound debridement. The patient felt he had used the dressing long enough to assess it and wanted to try the Mesalt dressings. He discontinued these after two weeks when the wound was debrided. One patient discontinued the Mesalt dressings early because the wound dried up. Another patient who found Mesalt dressings "too irritating" to continue with had great difficulty describing the exact feeling. In contrast, one other patient who used continuous wet saline dressings found them too uncomfortable to continue.

The four patients excluded from the analysis discontinued the study for various reasons. For one patient, several
factors contributed to the withdrawal: a gravely deteriorated condition; the Home Care Nurses’ inability to increase their visits for the continuous wet saline dressing arm of the study; and the Home Care Nurses’ reluctance to involve the family with complicated dressing changes. Two other patients discontinued the study after using only one of the dressings for one week or less. One patient experienced stinging with the Mesalt dressing; and the other patient, finding the continuous wet saline dressings uncomfortable, did not wish to have them changed more than once per day. The fourth patient tried both dressings but was more comfortable with a dressing she had used previously.

Another difficulty encountered in the study was with regard to maintaining protocol compliance. This occurred with those patients who were admitted to hospital. Considerable effort was needed to ensure that the protocol was followed. The staff in both hospitals involved, however, were very supportive. It was also difficult to maintain protocol compliance with patients who were completely dependent on Home Nursing care for their dressing changes. The dressing changes depended more on the availability of the Home Care Nurse rather than the patient’s need to have it changed. This was a major concern with the continuous wet saline dressings as they required dressing changes on a regular basis to maintain moistness and prevent sticking to the wound.
Patients' Comments and Post-Study Consultation

In general the patients had positive feelings about being involved in the study. They appreciated receiving feedback about how they were caring for their wounds and welcomed the weekly visits. One patient nevertheless became discouraged when he found a dressing he liked while on the study which was difficult to afford after the study was completed. All patients were offered two boxes (50 gauze) of the Mesalt dressings at the end of the study.

Consultation about the care of the lesion was offered after the study was completed. This involved discussing cleansing the lesion, controlling and preventing bleeding, preventing and managing clinical infection, controlling and preventing odor and containing drainage. Various dressing options were discussed, as were factors such as cost, places to obtain the dressings, and comments received previously from patients regarding comfort of dressings. Patients were also strongly encouraged to become involved with the local Home Nursing care program to monitor their own care of the lesion. One patient found the study visits so helpful that she wanted them to continue after the study was completed. She did not, however, wish to be involved in the Home Nursing care program. Those patients who appreciated the study visits the most were those quite able to do their own dressings and who did not wish to be involved with Home Nursing care. Those patients who were not receiving Home Nursing care had previously encountered many difficulties. These difficulties included
deciding on dressings and knowing where to purchase them. Furthermore, these patients did not find that their physician provided the information and reassurance that they required.

**Summary**

The results of both the development of the Patient Satisfaction Questionnaire, and the evaluation of patient satisfaction with Mesalt dressings compared with continuous wet saline dressings, have been presented and discussed. Patients with ulcerating metastatic skin lesions liked the questionnaire's format and found the questions to be both understandable and important. Though the Patient Satisfaction Questionnaire solicited input from patients in its development, it has had limited testing for validity and reliability.

In the study, however, Mesalt dressings received significantly more positive ratings in a group of 10 patients when compared with continuous wet saline dressings with regard to ease of application and odor control. The questions used to evaluate patient satisfaction in the study were considered appropriate since they were similar to those identified for the Patient Satisfaction Questionnaire. Notably, patients with ulcerating metastatic skin lesions significantly preferred Mesalt dressings to continuous wet saline dressings.
CHAPTER 5
Conclusion and Recommendations

Introduction

The limited knowledge related to the care of ulcerating metastatic skin lesions is addressed in this thesis. A Patient Satisfaction Questionnaire was developed, with patient input, to evaluate dressings used in the care of these lesions. Also, an evaluation of patient satisfaction with dressing performance comparing Mesalt dressings with continuous wet saline dressings in the same types of lesions was completed. Major conclusions, implications for nursing and recommendations for further study are presented in this chapter.

Major Conclusions Derived from the Results

Tool development involved considerable input from patients with ulcerating metastatic skin lesions. Many patients, having used dressings for long periods, had numerous ideas about what should be asked to evaluate patient satisfaction with dressings used in the care of their lesions. The questionnaire incorporated their ideas into a form which many patients felt was understandable and important. Though some testing for validity and reliability was done, it was limited.

The study evaluated patient satisfaction with Mesalt dressings as compared with continuous wet saline dressings in
the care of ulcerating metastatic skin lesions. The study had a limited accrual of 14 patients. Because not all the patients completed the study, the results were analyzed by groupings of 6, 8, and 10 patients, depending on the extent of study completion. The results of study were statistically analyzed with an $p = .05$.

The major conclusions were:

1. In the group of 10 patients, Mesalt dressings received a more significantly positive rating than continuous wet saline dressings with respect to ease of application and odor control.

2. In the smaller group of eight patients, Mesalt dressings received a more positive rating for ease of application.

3. No significant differences were found between Mesalt dressings and continuous wet saline dressings with respect to ease of removal and discomfort during and between dressing changes. Although not significantly positive, the ratings were high in favor of Mesalt dressings with regard to comfort between dressing changes.

4. A significant overall preference for Mesalt dressings was identified in comparison with continuous wet saline dressings throughout the analyses.

**Implications for Nursing**

The information obtained regarding patient satisfaction can be used in various ways. The Patient Satisfaction Questionnaire is the first known questionnaire which attempts
to evaluate dressings used in caring for ulcerating metastatic skin lesions, and in particular, incorporates the evaluation of patient satisfaction from the patient's perspective. Directly asking patients what was important to evaluate proved an effective approach, rather than limiting the patients' input to the evaluation of pre-determined criteria. The tool is now available for further research in the care of ulcerating metastatic skin lesions. The method used for developing this tool may outline an initial process for developing a tool to evaluate dressings used in the care of non-malignant wounds. Nurses can use the characteristics identified in the questionnaire as topics for discussion to help patients choose dressings. The questionnaire may further help nurses identify those characteristics which patients feel should be included in new dressing products.

This was the first known study to formally evaluate dressings used in the care of ulcerating metastatic skin lesions. The evaluation of Mesalt dressings and continuous wet saline dressings has provided both patients and health care professionals with useful information about patient satisfaction with dressings. Continuous wet saline dressings are commonly used and their performance was rated satisfactory in many cases. The use of Mesalt dressings in ulcerating metastatic skin lesions was a new application of a frequently used type of dressing. The Mesalt dressing appears to be a positive choice where ease of application and control of odor are important. Application ease may be particularly important
if the patient is having difficulty changing his/her own dressings. Odor control may be an added important reason for choosing Mesalt dressings, since odor can become extremely offensive and only a few options for its management are available. Mesalt dressings were also found to dry out or shrink some wounds, something which may be important if the patient is more comfortable with a drier wound. In one case where the Mesalt dressings dried the wound completely, the patient did not require dressing changes for some time.

What was not addressed during the study was the higher cost of Mesalt dressings, a factor which may deter some patients from using them. Overall, because the Mesalt dressings were significantly preferred to continuous wet saline dressings, they are a reasonable option to consider when choosing dressings for the care of ulcerating metastatic skin lesions.

Finally, the patients often commented that many health care professionals, mostly physicians and nurses, had little knowledge or experience in managing their lesions. Although many patients who independently cared for their lesions did not want to be involved in the Home Nursing care program, they felt they would appreciate regularly consulting a nurse who has specialized knowledge of the care required for their type of lesion. These patients often did not have regular follow-up with any health care professional; nor did they have much knowledge about the dressings available to them, the cost of the dressings and places to purchase them. Many recommended dressings are quite expensive and no insurance
plan covers the costs. Patients are often frustrated by this as the less costly dressings they must use, are not necessarily the most appropriate ones. It is therefore recommended that a nurse who has a specialized knowledge of the care of ulcerating metastatic skin lesions be available to consult with patients and to follow-up on the care of their lesions. In addition, financial assistance should be available to these patients in order that they be able to obtain the most appropriate dressing for the care of their lesions.

**Recommendations for Further Study**

Recommendations include further testing of the Patient Satisfaction Questionnaire developed for this thesis. It would also be of interest to have patients rank the importance of each of the questions.

The evaluation of Mesalt dressings and continuous wet saline dressings in the care of ulcerating metastatic skin lesions has greatly increased the available knowledge about patient satisfaction with the dressings. Further evaluation of all dressings available to patients needs to be completed. A systematic approach to evaluation is crucial since there are only a few patients with ulcerating metastatic skin lesions, and since most health care professionals have limited experience managing the care of the lesions. It is recommended that the evaluation of the dressings continue, coordinated by a limited group of nurses, in order to provide
consistency. An individual evaluation of a dressing patients' used may provide helpful information. However, a more structured comparison of two dressings would offer more information and a more systematic evaluation of the dressings. Given the remarks from the patients, a two-week trial seems to be an adequate length of time to adjust to the dressing and evaluate it. However, when specifically comparing effectiveness on control of odor, the time limit may need to be extended.

The study participants often emphasized the importance of using a dressing that did not stick when removed. Also evident was that some dressings stuck to one patient's wound but did not to those of others. This phenomenon did not seem simply to reflect the amount of drainage nor the consistency of the drainage. Further research therefore is needed in this area.

**Summary**

The Patient Satisfaction Questionnaire was developed as a tool to evaluate dressings used in caring for ulcerating metastatic skin lesions, and is now available for further testing. Because research related to the care of ulcerating metastatic skin lesions is limited, this study has evaluated two dressings: Mesalt dressings and continuous wet saline dressings. Mesalt dressings scored a more positive rating for ease of application and odor control in a group of 10 patients. Significant numbers of patients involved in the
study preferred Mesalt dressings over continuous wet saline dressings. This knowledge is useful when helping patients decide which dressings to use in the care of ulcerating metastatic skin lesions.
References


American Medical Association, Department of Drugs, Division of Drugs and Technology. (1986). Drug evaluations (6th ed.). Philadelphia: W.B. Saunders


APPENDIX A

Patient Satisfaction Questionnaire
Dear Participant,

Please find enclosed a Patient Satisfaction Questionnaire which evaluates dressings used in the care of cancerous wounds. Each question refers only to the dressing and does not include tape or other devices which hold the dressing in place.

When you answer the questions "Please place a mark through the line, between the two extremes to indicate the degree of your response." An example is given below:

Does the weather effect your mood?

A great deal __________________________/___________ Not at all

Thank you for your cooperation.
PATIENT SATISFACTION QUESTIONNAIRE

PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE:

ID#____

1. Is the dressing easy to apply?
   Not very easy ___________________________ Very easy

2. Is the dressing easy to remove?
   Not very easy ___________________________ Very easy

3. How long does it take to change your dressing?
   A long time ___________________________ Not very long

4. Do you experience discomfort when the dressing is removed?
   A great deal ___________________________ Not at all

5. Do you experience pain when the dressing is removed?
   A great deal ___________________________ Not at all

6. Does the dressing stick to the wound when it is being removed?
   A great deal ___________________________ Not at all

7. Does the dressing cause the wound to bleed when it is removed?
   A great deal ___________________________ Not at all

8. Are there dressing fibres left in the wound when the dressing is removed?
   Quite a few ___________________________ None at all
PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE:

9. Does the dressing cause the wound to dry up?
   A great deal ________________________________ Not at all

10. Does the dressing keep the wound clean?
    Not very well ________________________________ Very well

11. Is the dressing soft against your skin?
    Not very soft ________________________________ Very soft

12. Is the dressing comfortable while it is on?
    Not very comfortable __________________________ Very comfortable

13. Does the dressing cause a "stinging" sensation?
    A great deal ________________________________ Not at all

14. Does the dressing cause a "burning" sensation?
    A great deal ________________________________ Not at all

15. Does the dressing cause a "clammy" feeling?
    A great deal ________________________________ Not at all

16. Does the dressing rub roughly against the wound while it is on?
    A great deal ________________________________ Not at all
PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE:

17. Does the dressing decrease the odor (if there is any) from the wound?
   A great deal ........................................................... Not at all

18. Does the dressing cause a "Strange" odor?
   A great deal ........................................................... Not at all

19. Does the dressing absorb all of the drainage?
   Not very well .......................................................... Very well

20. Does the dressing prevent drainage from passing through to the outside of the dressing?
   Not very well .......................................................... Very well

21. Does the dressing adapt to the shape of the wound?
   Not very well .......................................................... Very well

22. Does the dressing have more bulk than is needed?
   A great deal ........................................................... Not at all

23. Can you use the dressing WITHOUT tape, netting or other devices which hold the dressing in place?
   Not very well .......................................................... Very well

24. Does the dressing cause irritation to the skin surrounding the wound?
   A great deal ........................................................... Not at all
APPENDIX B

Interview Guide
INTERVIEW GUIDE

1. What types of dressings have you used in the care of your open wound?

2. What did you like about each dressing?

3. What did you dislike about each dressing?

4. What do you want the dressing to do? or What characteristics of the dressing would you consider important in choosing a dressing?

5. What factors would influence your satisfaction with the dressing? or Can you describe the "perfect" dressing?
APPENDIX C

Preliminary Questionnaire
Is the dressing easy to apply?

Not very easy .................................................. Very easy

Is the subject of this question important to you?  Yes  No

Is the dressing easy to remove?

Not very easy .................................................. Very easy

Is the subject of this question important to you?  Yes  No

How long does it take to change your dressing?

A long time .................................................. Not very long

Is the subject of this question important to you?  Yes  No

Is there discomfort during the dressing change?

A great deal .................................................. Not at all

Is the subject of this question important to you?  Yes  No

Do you experience pain when the dressing is changed?

A great deal .................................................. Not at all

Is the subject of this question important to you?  Yes  No

Does the dressing stick to the wound?

A great deal .................................................. Not at all

Is the subject of this question important to you?  Yes  No
PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE?

ID#____

Does the dressing cause the wound to bleed when it is removed?
   A great deal _______________________________ Not at all

Is the subject of this question important to you?   Yes   No

Is dressing fibre left in the wound when the dressing is removed?
   A great deal _______________________________ Not at all

Is the subject of this question important to you?   Yes   No

Does the dressing cause the wound to enlarge?
   A great deal _______________________________ Not at all

Is the subject of this question important to you?   Yes   No

Does the dressing cause the wound to dry up?
   A great deal _______________________________ Not at all

Is the subject of this question important to you?   Yes   No

Does the dressing keep the wound clean?
   Not very well _______________________________ Very well

Is the subject of this question important to you?   Yes   No

Is the dressing soft against your skin?
   Not very soft _______________________________ Very soft

Is the subject of this question important to you?   Yes   No
PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE: 

Is the dressing comfortable while it is on? 

Not very comfortable ___________________________ Very comfortable ___________________________

Is the subject of this question important to you?  Yes  No

Do you experience pain from the dressing while it is on?  

A great deal ___________________________ Not at all ___________________________

Is the subject of this question important to you?  Yes  No

Does the dressing cause a "stinging" sensation?  

A great deal ___________________________ Not at all ___________________________

Is the subject of this question important to you?  Yes  No

Does the dressing cause a "burning" sensation?  

A great deal ___________________________ Not at all ___________________________

Is the subject of this question important to you?  Yes  No

Does the dressing cause a "gummy" feeling?  

A great deal ___________________________ Not at all ___________________________

Is the subject of this question important to you?  Yes  No

Does the dressing cause a "clammy" feeling?  

A great deal ___________________________ Not at all ___________________________

Is the subject of this question important to you?  Yes  No
PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE:

Does the dressing rub roughly against the wound?

A great deal _______________________________ Not at all

Is the subject of this question important to you? Yes No

Does the dressing decrease the odor (if there is any) from the wound?

A great deal _______________________________ Not at all

Is the subject of this question important to you? Yes No

Does the dressing cause a "strange" odor?

A great deal _______________________________ Not at all

Is the subject of this question important to you? Yes No

Does the dressing absorb all of the drainage?

Not very well ______________________________ Very well

Is the subject of this question important to you? Yes No

Does the dressing prevent drainage from passing through to the outside of the dressing?

Not very well ______________________________ Very well

Is the subject of this question important to you? Yes No

Does the dressing adapt to the shape of the wound?

Not very well ______________________________ Very well

Is the subject of this question important to you? Yes No

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PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE?  

ID#____

Does the dressing have more bulk than is needed?

A great deal ________________________________ Not at all

Is the subject of this question important to you?  Yes  No

Can you use the dressing without tape or other devices which hold the dressing in place?

Not very well ________________________________ Very well

Is the subject of this question important to you?  Yes  No

Does the dressing cause irritation to the skin surrounding the wound?

A great deal ________________________________ Not at all

Is the subject of this question important to you?  Yes  No

Does the dressing cause itchiness to the skin surrounding the wound?

A great deal ________________________________ Not at all

Is the subject of this question important to you?  Yes  No
APPENDIX D

Letter of Introduction
APPENDIX E

Pilot Questionnaire
PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE:

Is the dressing easy to apply?
Not very easy ___________________________________________ Very easy
Is the subject of this question important to you? Yes No

Is the dressing easy to remove?
Not very easy ___________________________________________ Very easy
Is the subject of this question important to you? Yes No

How long does it take to change your dressing?
A long time ___________________________________________ Not very long
Is the subject of this question important to you? Yes No

Do you experience discomfort when the dressing is removed?
A great deal ___________________________________________ Not at all
Is the subject of this question important to you? Yes No

Do you experience pain when the dressing is removed?
A great deal ___________________________________________ Not at all
Is the subject of this question important to you? Yes No

Does the dressing stick to the wound when it is being removed?
A great deal ___________________________________________ Not at all
Is the subject of this question important to you? Yes No

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PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE?

Does the dressing cause the wound to bleed when it is removed?

A great deal _____________________________________ Not at all

Is the subject of this question important to you? Yes No

Are there dressing fibres left in the wound when the dressing is removed?

Quite a few _____________________________________ None at all

Is the subject of this question important to you? Yes No

Does the dressing cause the wound to dry up?

A great deal _____________________________________ Not at all

Is the subject of this question important to you? Yes No

Does the dressing keep the wound clean?

Not very well _____________________________________ Very well

Is the subject of this question important to you? Yes No

Is the dressing soft against your skin?

Not very soft _____________________________________ Very soft

Is the subject of this question important to you? Yes No

Is the dressing comfortable while it is on?

Not very comfortable _________________________________ Very comfortable

Is the subject of this question important to you? Yes No

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PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE:  

Do you experience pain from the dressing while it is on?  
A great deal _______________________________ Not at all

Is the subject of this question important to you? Yes No

Does the dressing cause a "stinging" sensation?  
A great deal _______________________________ Not at all

Is the subject of this question important to you? Yes No

Does the dressing cause a "burning" sensation?  
A great deal _______________________________ Not at all

Is the subject of this question important to you? Yes No

Does the dressing cause a "clammy" feeling?  
A great deal _______________________________ Not at all

Is the subject of this question important to you? Yes No

Does the dressing rub roughly against the wound while it is on?  
A great deal _______________________________ Not at all

Is the subject of this question important to you? Yes No

Does the dressing decrease the odor (if there is any) from the wound?  
A great deal _______________________________ Not at all

Is the subject of this question important to you? Yes No
PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE:  

ID#_____

Does the dressing cause a "strange" odor?

A great deal ________________________________ Not at all

Is the subject of this question important to you?  Yes  No

Does the dressing absorb all of the drainage?

Not very well ________________________________ Very well

Is the subject of this question important to you?  Yes  No

Does the dressing prevent drainage from passing through to the outside of the dressing?

Not very well ________________________________ Very well

Is the subject of this question important to you?  Yes  No

Does the dressing adapt to the shape of the wound?

Not very well ________________________________ Very well

Is the subject of this question important to you?  Yes  No

Does the dressing have more bulk than is needed?

A great deal ________________________________ Not at all

Is the subject of this question important to you?  Yes  No

Can you use the dressing WITHOUT tape, netting or other devices which hold the dressing in place?

Not very well ________________________________ Very well

Is the subject of this question important to you?  Yes  No
PLEASE PLACE A MARK THROUGH THE LINE, BETWEEN THE TWO EXTREMES TO INDICATE THE DEGREE OF YOUR RESPONSE?

Does the dressing cause irritation to the skin surrounding the wound?

A great deal ________________________________ Not at all

Is the subject of this question important to you?   Yes   No
APPENDIX F

Medical History
MEDICAL HISTORY

DATE:_________________________  ID#____________________
   Day/Month/Year

DIAGNOSIS:____________________  DATE OF DIAGNOSIS:________

History of the Lesion

   Date at Appearance: ____________________  Day/Month/Year

   Ulceration: □ No  □ Yes  Date: ____________________  Day/Month/Year
   □ Yes -> When started  ________  Type  __________
   □ No  Specify

   Bleeding: □ No  □ Yes  Date: ____________________  Day/Month/Year
   □ Yes -> ________  Gelfoam  □ Kalostat  □ Other  Specify
   □ No  Specify

   Infection: □ No  □ Yes  Date: ____________________  Day/Month/Year
   □ Yes -> ________  Flagyl  □ Other  Specify
   □ No  Specify

CURRENT TREATMENT

Hormonal therapy  □ Yes -> When started  ________  Type  __________
   □ No  Specify

CURRENT LESION CARE

A. When Started: ____________________  Month/Year

B. Dressings type: □ NS  □ Dakins  □ Dry  □ Adaptic  □ Other ______
   #dressings: ________  #dressing changes/24 hours: ________

C. Cleansing solution: □ Yes -> □ NS  □ H_{2}O_{2}  □ Other  Specify
   □ No  Specify

D. Bleeding Control: □ Yes -> □ Gelfoam  □ Kalostat  □ Other  Specify
   □ No  Specify

E. Odor Control: □ Yes -> □ Flagyl  □ Other  Specify
   □ No  Specify

F. Infection Control: □ Yes -> □ Antibiotic:  ________
   □ No  Specify
APPENDIX G

Protocol for Wound Care
1. **CLEANSING OF WOUND**

Solution: Cleanse wound with Normal Saline (N/S) solution 0.9%. Following consultation with the Research Nurse, may use 1/2 strength Hydrogen Peroxide and rinse with N/S if indicated by the presence of crusting or dead tissue.

Method: Cleanse wound using gauze soaked with solutions described above. May also use other methods if gauze is inappropriate eg. cotton-tipped swabs, spray bottle, soft shower, squeeze from sponge over wound etc. *Use a gentle rubbing action unless tissue is friable, then NO rubbing.

2. **FREQUENCY OF CLEANING/DRESSING CHANGES**

To be determined by the Research Nurse depending on amount of drainage. Drainage which extends beyond the outer dressing (dry gauze dressing) indicates need for increase in dressing changes. Wet normal saline dressings will be changed every 4 to 6 hours depending on the dryness of the dressing. Mesalt will be changed when the area over the wound is saturated with drainage.

3. **CONTROL OF BLEEDING**

Apply Gelfoam or Kalostat to source of bleeding as required.

4. **DRESSING APPLICATION**

**INNER DRESSINGS (1st layer - applied directly to wound)**
- Mesalt or N/S soaked gauze (depending on study randomization)
- Apply dressing by laying gauze over top of wound
- For N/S soaked gauze, soak gauze in N/S solution so it is moderately soaked.

**OUTER DRESSINGS**

2nd layer - Dry gauze over Mesalt or N/S soaked gauze
3rd layer - (optional) Abdominal padding

**SECUREMENT OF DRESSINGS**

Secure dressing with any of the following:
- tape - Mefix
- netting eg. fastonet
- clothing eg. tube tops, camisoles, etc.

For the purposes of the study, do not use:
- creams, ointments, solutions, dressing materials, other than those specified
- anything that effects bacterial growth or odor.
APPENDIX H

Overall Evaluation Scale
OVERALL EVALUATION SCALE (patient)

ID#______________

Please put an X on the line to indicate:

1. How is the application of the dressing?

Very Difficult_________________________________________ Very easy

to apply
to apply

2. How is the removal of the dressing?

Very difficult_________________________________________ Very easy

to remove
to remove

3. How much discomfort do you experience when the dressing is

removed?

A lot of discomfort____________________________________ No discomfort

4. How comfortable is the dressing between dressing changes?

Very uncomfortable____________________________________ Very comfortable

5. How effective is the dressing in controlling odor?

Not effective at all____________________________________ Very effective
PREFERENCE SCALE (patient)

ID#__________________________

Which dressing did you prefer?

☐ The first dressing
☐ The second dressing
☐ No preference

Why? __________________________________________________________

________________________________________________________________

________________________________________________________________

________________________________________________________________
APPENDIX J

Preference Scale (Revised)
PREFERENCE SCALE (patient)

Which dressing did you prefer?

☐ The first dressing
☐ The second dressing
☐ No preference

If you did have a preference (indicated above), how strong was your preference?

(Please place a mark through the line, between the two extremes to indicate the degree of your response)

________________________________________________________________________

Not very strong

________________________________________________________________________

Very strong

If you did have a preference (indicated above), why did you prefer the dressing?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
APPENDIX K

Patient Information and Consent Form
EVALUATION OF DRY VS WET NORMAL SALINE DRESSINGS IN WOUND CARE

PATIENT INFORMATION AND CONSENT FORM

The purpose of this study is to compare two types of dressings used in the care of open wounds related to cancer. The main focus of the study is to determine the convenience of both dressings. The study also examines the effects of the dressing on odor control and infection. Both types of dressings have been previously used in the care of open wounds and to date, there has been no evidence of side effects from either type of dressing.

At the beginning of the study, the Research Nurse (a Registered Nurse assigned to the study) will see you either at the Cancer Control Agency of British Columbia or in your home. She will ask you questions about your wound and how you presently care for it. She will then examine you for any signs of infection and use a cotton swab to take a specimen of the drainage from your wound.

To compare these dressings, you will be randomly assigned to use one of the dressings for the first four weeks. This means that you will have an equal chance of being assigned to use either of the two dressings. Then for the last four weeks you will use the other dressing. The study will therefore involve a total of eight weeks.

The Research Nurse will instruct you about how to use each of these dressings. While you are on the study, the Research Nurse will visit you once a week in your home to collect information about your wound and how you are managing with the dressings. During the time you are on the study, you will be asked not to use any ointments or solutions upon the wound other than those specified by the Research Nurse. Specimens of the drainage from your wound, using a cotton swab will be taken before switching to the second dressing, and again at the end of the study. If you are involved in changing the dressing you will be asked to record the number of dressing changes required per day and the time it takes you to do the dressing.

The study will require about 15 minutes per week of your time for the Research Nurse’s visit and 5-10 minutes for recording information about the dressing changes. Although there may be no direct benefit to you by participating in this study, the knowledge
APPENDIX L

Content Identification Summary
CONTENT IDENTIFICATION SUMMARY

Characteristics of ideal dressings from interviews:
- not uncomfortable
- no strange odor
- not sticking to wound
- doesn’t cause bleeding
- absorbent
- drainage doesn’t pass through
- soft
- easy to use/apply
- contours to wound; doesn’t slip – adaptable
- appropriate size, not bulky
- not gummy/sticky
- not abrasive
- no lint
- dries up wound
- doesn’t cause wound to break down
- can use without tape
- easy to remove
- heals wound
- not a bother
- doesn’t sting

Additional characteristics from literature:
- control of odor
- controls drainage
- controls bleeding
- prevents infection
- cleans wound
- dries wound
- no pruritis of surrounding tissue
- no pain – wound
- no discomfort – wound
- comfortable
- decreases size of lesion (shrinks)

Additional characteristics from own experience:
- not irritating/stinging
  - wound
  - surrounding tissue
- easy to do dressing
- quick to change dressing
- keeps wound clean
- doesn’t promote infection
- comfort "during" dressing change
- not "clammy"
- decreases odor