A DESCRIPTIVE STUDY OF HEEL PRESSURE ULCERS:

A PILOT FEASIBILITY STUDY

By

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ABSTRACT

Using a descriptive research design, a pilot feasibility study was designed to assess the feasibility of conducting a study of the norms of healing of pressure ulcers that occur on the heels of older adults. Such a study was considered necessary because it was the perception of this writer that the number of cases of heel pressure ulcers among older adults in residential care had risen to unprecedented levels. However, there was little data to support this impression as the actual prevalence of heel pressure ulcers in British Columbia and the Lower Mainland had not been reported in the research literature. An apparent increase in the prevalence of pressure ulcers at the heel is a significant clinical problem because little is known about the norms of their healing. This is problematic because healing outcomes could be optimized if clinical decision-making could be based on knowledge of the norms of pressure ulcer healing. Since pressure ulcer research is expensive and the number of older adults with heel pressure ulcers was unknown, it was necessary to assess the costs of conducting such a study and the number subjects who could be identified. Also assessed was the utility of a novel Image Digitization Program “Mouseyes” in measuring pressure ulcer healing.

The study was conducted in the Simon Fraser Health Region between mid June and November 6 of 1998. A total of 23 subjects were identified and referred to the researcher. Fourteen were ineligible and a convenience sample of nine subjects were enrolled in the study. Two subjects were followed for a four month period in order that heel pressure ulcer healing could be described. Seven subjects were seen on a one time basis in order that the utility of the Mouseyes Program could be assessed. For all visits, the time required to assess pressure ulcer healing was described in order that estimates the personnel costs and logistics of conducting a larger study could be assessed.
Study results suggest that “Mouseyes” is an acceptable instrument for measuring healing in heel pressure ulcers and that a larger study of the norms of heel pressure ulcer healing is feasible if sufficient funds are available to support personnel costs. Analysis of logistical problems encountered during the study suggest that a larger study is feasible if two full time research facilitators can be hired to recruit subjects and conduct the wound healing assessments. To obtain a large enough sample, the study would need to run over a 12 to 18 month period.
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CHAPTER ONE:
INTRODUCTION

Background to the Problem

From the vantage point of a geriatric clinician, it was the perception of this writer that the number of cases of heel pressure ulcers among older adults in residential care had risen to unprecedented levels. Although the extent of the problem in Canada or in British Columbia’s Lower Mainland was unknown, data from three national surveys of pressure ulcer prevalence in the United States of America supported this impression. Meehan (1994) reports that among hospitalized patients, heel ulcers comprised 19% of all pressure ulcers in 1989, 26% in 1991 and 30% in 1993. This trend was troubling because heel pressure ulcers are problematic for the clients who experience them and the nurses who manage them. Much of the difficulty could be attributed to the fact that, in comparison to pressure ulcers at other sites, heel ulcers heal at a slower rate (Bates-Jensen, 1996) thereby increasing the risk of infection and amputation (Krasner, 1990). The already indolent nature of pressure ulcer healing is reflected in the definition of a pressure ulcer as “a disruption in the normal anatomic structure and function of the skin that results from an external force associated with a bony prominence and that does not heal in an orderly and timely fashion” (Margolis, 1995, p. 28-10).

According to wound care experts, the time required for pressure ulcer healing could be lessened (Lazarus et al., 1994) and the outcomes improved, if clinical management decisions were guided by knowledge of the norms of pressure ulcer healing (Tallon, 1995). This is because such knowledge as the average time required for granulation tissue to fill the wound bed, or for the wound to reduce in size by twenty-five or fifty percent provides a marker against which the success of treatment interventions can be measured (Bates-Jensen,
Although the apparent rise in the prevalence of heel pressure ulcers suggested an urgent need to study the norms of their healing, this research raised a number of concerns regarding feasibility. The concerns requiring immediate attention related to the availability of subjects and the cost of studying pressure ulcer healing. One approach to addressing these concerns was to conduct a pilot study assessing feasibility. The need for this type of research is evidenced in a discussion of both the factors that limit the number of potential subjects and the cost of measuring pressure ulcer healing.

Factors that Limit the Number of Subjects Eligible for a Study of Heel Pressure Ulcer Healing

Three factors limit the number of subjects eligible for inclusion in a study designed to describe the healing norms of heel pressure ulcers. The first relates to the fact that the wounds of interest in such a study are full rather than partial thickness ulcers. The second is that existing measures of pressure ulcer healing can be used in some, but not all, full thickness heel pressure ulcers. The third is that not all heel ulcers are pressure ulcers. Each of these points requires further discussion.

First, because they are the most severe and, take the longest time to heal, there is a pressing need for studies of the healing of full thickness heel pressure ulcers. This presents a challenge for attaining an adequate sample because various studies suggest that approximately 80% of all pressure ulcers are partial rather than full thickness ulcers (Bergstrom, Braden, Kemp, Champagne & Ruby, 1996; Harrison, Wells, Fisher & Prince, 1996; Meehan, 1994; Maklebust & Magnan, 1994; Meehan, 1994). The difference between full and partial thickness ulcers relates to the extent of tissue damage. Full thickness pressure ulcers are associated with an actual tissue loss such that the resulting defect is of a depth that extends through all of the dermal layers, and possibly, into the deeper tissues (Doughty,
These wounds heal through scar tissue formation, or connective tissue repair, a complex, multi-phase process that can take months to complete (Doughty, 1992). In contrast, partial thickness wounds are not characterized by a tissue defect and healing occurs through regeneration, a process that takes significantly less time to complete (Doughty, 1992).

Second, research based measures of pressure ulcer healing can only be applied to open wounds and not all full thickness heel pressure ulcers are managed in this manner. Although it is generally recommended that to prevent infection, necrotic tissue should be removed from most pressure ulcers, experts advise that eschar should not be removed from heel ulcers if the wound is stable, and does not appear infected (Bergstrom et al., 1994). While this advice is not based on controlled studies of heel pressure ulcer healing, experience has shown that the outcomes resulting from the creation of an open wound are poor (Sieggreen & Maklebust, 1997). At the present time, the prevalence of stable heel pressure ulcers and the frequency with which these ulcers become unstable, and in need of debridement, is unknown.

Third, not all heel ulcers are pressure ulcers (Margolis, 1995). In refining the definition of the term "pressure ulcer" to promote accuracy and consistency in research, Margolis (1995) advises that ulcers over the bony prominence of the heel can arise from such other causes as diabetic neuropathy or chronic venous hypertension. Margolis (1995) warns that failure to differentiate between pressure ulcers and other types of chronic wounds can lead to "substantial information bias" in wound healing studies (p. 28-9). This is because the predominant processes vary with each type of wound and, so also does the time it takes for healing to occur (Cooper, 1995). According to Margolis (1995), pressure ulcers can be differentiated from wounds of other etiologies on the basis of client characteristics and
mobility history. In clarifying this assertion, Margolis (1995) states that while diabetic ulcers are often referred to as “pressure ulcers”, they result from mobility and, in contrast, pressure ulcers result from immobility. On the basis of a synthesis of the epidemiological research, Margolis (1995) reports that typically, pressure ulcers only occur in persons with a range of functional disabilities. Margolis (1995) states that pressure ulcers occur in individuals who are “malnourished” or have a reduced ability to feed themselves, are “mostly bed-or chair bound, often incontinent” and experience an altered level of consciousness (p. 28-10).

Cost of Measuring Pressure Ulcer Healing

The slow rate of healing in heel pressure ulcers and the complexity of measuring this phenomenon makes studying them an expensive proposition. Much of this expense is related to equipment and personnel costs. Research findings related to the measurement of pressure ulcer healing suggest that assessments of healing must include an estimation of surface area from precise wound tracings (Rodeheaver & Stotts, 1995). For the degree of accuracy required in research, obtaining and analyzing this data necessitates appropriately trained personnel and specialized equipment. Since a study of the norms of pressure ulcer healing will require weekly assessments (Maklebust & Margolis, 1995) and experience suggests that heel pressure ulcers can take several months to heal, it is likely that personnel costs will be significant. Moreover, these costs will be increased because an additional measure, the Pressure Sore Status Tool, is required if the qualitative indicators of pressure ulcer healing are to be captured. Therefore, the time requirements for data collection needed to be estimated before cost projections and the feasibility of this research determined.

One possible solution to the expense of analyzing wound tracings was to use a novel computer program. A digitization program “Mouseyes” was designed to facilitate low cost, precision measurement of dermal wounds (Taylor, 1997). However, this program had not
been tested on pressure ulcers and a potential limitation of its use was that it had been found to have an error rate of plus or minus 10% when used to measure areas of less than one square centimetre (Taylor, 1997). Because the heel is a relatively small, well circumscribed area, the ulcers that result from pressure related injury are of a proportionate size. As a consequence, the surface area of some ulcers may be equivalent to two, three or four square centimetres and a tool that cannot accurately measure change at one centimetre may not be useful from a research perspective. It is possible that this limitation could be circumvented through the purchase of an ultra fine resolution vector graphics card (Taylor, 1997), but, this would increase equipment costs. Therefore, the extent to which Mouseyes was an appropriate tool for measuring healing in heel pressure ulcers needed to be determined.

**Research Problem**

There is a dearth of research based knowledge of the healing norms of heel pressure ulcers. This body of knowledge consists of one study in which data was elicited from the experiential knowledge of wound care experts. While it represents a starting point, this approach is limited because the most reliable means of generating knowledge of the norms of pressure ulcer healing is to observe and monitor the healing progression of actual pressure ulcers. Although subjects with heel ulcers have been included in wound healing studies, these efforts contribute little to the understanding of pressure ulcer healing because the samples were comprised of persons with wounds of disparate etiologies. Despite an apparent need to describe the healing norms of heel pressure ulcers, the lack of data to support the prevalence of the problem in British Columbia’s Lower Mainland necessitated an assessment of the feasibility of these efforts. Therefore, it was necessary to assess the frequency with which heel pressure ulcers occur in the population of functionally impaired persons identified by Margolis (1995). In addition, since the prevalence of pressure ulcers increases with
advancing age (Brandeis, Morris, Nash, Lewis & Lipsitz, 1990; Meehan, 1994), to begin to
describe the norms of healing and to provide guidance for the care of older adults, studies of
pressure ulcer healing in persons over the age of 65 years were required.

Research Purpose

The purpose of this pilot descriptive study was to assess the feasibility of conducting
a larger study designed to identify the norms of healing in adults aged 65 years and older
with heel pressure ulcers. The objectives of this study were to 1) identify the number of older
adults with full thickness heel pressure ulcers who were or who could potentially be eligible
for a study of pressure ulcer healing, and 2) to evaluate the extent to which the digitizing
program "Mouseyes" could be utilized as a measure of healing in heel pressure ulcers, 3) to
determine the average per visit cost of assessing pressure ulcer healing in order that the cost
of a larger study could be projected, and 4) to begin to describe the healing norms of heel
pressure ulcers in a convenience sample of older adults.

Research Questions

1. What number of adults aged 65 years and older with full thickness heel pressure
   ulcers can be recruited as subjects from the Simon Fraser Health Region during a four
   month period?

2. Of the adults aged 65 years and older with full thickness heel pressure ulcers, what
   number have stable ulcers and what number become unstable during the four month
   study?

3. What barriers are encountered in identifying and recruiting older adults with heel
   pressure ulcers?

4. What is the average time required per visit for data collection?
5. What is the average size of the identified heel pressure ulcers at the time of the initial assessment?

6. What is the average number of weeks from ulcer onset to reduction in wound size to one square centimetre?

7. What is the degree of correlation between estimates of surface area obtained through the use of "Mouseyes" and the scores that result from the Pressure Sore Status Tool?

8. What is the feasibility and usefulness of the image digitization program "Mouseyes" in measuring the surface area of heel pressure ulcers?

Through the process of answering the research questions, three results were expected: (1) the number of potential subjects would be described, (2) the utility of the computerized planimetry program ‘Mouseyes’ in measuring heel ulcers would be determined and, (3) personnel costs projected.

Framework

The theoretical framework for this study was based on the current understanding of pressure ulcer etiology and the nature and processes of pressure ulcer healing. This framework is comprised of three interrelated components. The first is the relationship between intrinsic physiological changes and the influence of the external forces of pressure, shear and friction in the etiology of pressure ulcers. The second component is the relationship between intrinsic factors and the nature of pressure ulcer healing. The third component relates the indicators of pressure ulcer healing to the processes of connective tissue repair. The framework is presented pictorially in Figure 1. The portion of the framework that describes the etiology of pressure ulcers is derived from a conceptual schema proposed by Braden & Bergstrom (1987).
Figure 1. Theoretical Framework Reflecting the Interrelationships between Intrinsic Physiological Factors, and the Influence of External Forces in Pressure Ulcer Etiology and Pressure Ulcer Healing

**Pressure Ulcer Etiology**

**Intrinsic Factors**
- Advanced age
- Malnutrition
- Disease Processes
- Level of mobility
- Altered Sensation/Perception Response
- Corticosteroid Medications

**External Forces**
- Pressure
- Shear
- Friction

**Tissue Tolerance**

**Pressure Ulcer Development**

**Continuum of Pressure Ulcer Healing**
- Progression
- Regression

Indicators of the processes:
- Deposition of Granulation Tissue
- Contraction
- Epithelialization

Relationship Between Intrinsic Characteristics and the Influence of the External Forces of Pressure, Shear and Friction in Pressure Ulcer Etiology

Although there are many gaps in the current understanding of pressure ulcer etiology (Bergstrom, 1992; Bridel, 1993), it is believed that intrinsic factors within the host alter the tolerance of tissues to the effects of such external forces as pressure, shear and friction (Braden, 1987; Bridel, 1993). The relationship between intrinsic characteristics and external forces is important because it explains why pressure ulcers occur in the population of persons who are malnourished, incontinent, bed or chair bound, and experience diminished levels of
consciousness. Since an understanding of the role of the external forces of pressure, shear and friction in pressure ulcer etiology is integral to appreciating why members of the specified population are more susceptible to pressure related injury, this content will be presented first. A brief discussion of the influences of intrinsic factors in pressure ulcer etiology follows.

**External Forces**

It is believed that pressure ulcers arise from the combined effects of pressure, shear, and possibly, friction (Bridel, 1993). Theoretically, the underlying mechanism through which pressure and shear exert their influence is tissue ischemia. Ischemia arises when pressure is applied with sufficient intensity that the arterioles, venules and capillaries of the microcirculation are occluded and blood flow is obstructed (Bridel, 1993). Ischemia also occurs when tissues “slide across surfaces” (Krasner, 1990, p. 75) angulating blood vessels (shearing) such that endothelial damage precipitates platelet aggregation and thrombotic occlusion of the microvasculature (Bridel, 1993). Although the role of friction in the etiology of pressure ulcers has not been definitively established (Bridel, 1993), it is theorized that friction alters tissue integrity by damaging the epidermis, thereby contributing to the effects of pressure and shearing (Bridel, 1993). Braden & Bergstrom (1987) and Bridel (1993) suggest that friction is promoted by moisture from various sources including urine and perspiration.

**Intrinsic Factors That Influence Tissue Tolerance to Pressure, Shear and Friction**

Intrinsic (within the host) factors affect the tolerance of skin and supporting structures to pressure and shear forces “by influencing the sensation/perception response mechanism and/or altering the structural constituents and perfusion of tissues” (Bridel, 1993,
The sensation/perception response and the role of intrinsic factors in altering the structural components of skin and tissue perfusion require more detailed discussion.

First, the sensation/perception response is a protective mechanism that normally stimulates a shift in position in response to the discomfort that arises from pressure or shear induced ischemia (Bridel, 1993). Any factor that interferes with the ability to perceive or respond to ischemic discomfort can and does lead to tissue anoxia, and consequently, cell death (Bridel, 1993). This can and does include any factor or disease process that affects mobility, peripheral sensation, or level of consciousness.

Second, it is thought that any factor that influences the quality and quantity of collagen, the major constituent of dermal tissue, reduces tissue tolerance to pressure and shear (Bridel, 1993). Currently, several factors are known to influence dermal collagen. The first is age greater than 60 years, the second is prolonged use of corticosteroid medications, the third is spinal cord injury and, although the link remains hypothetical, malnutrition (Bridel, 1993).

Third, in relation to tissue perfusion, it has been suggested that low systemic blood pressure, low haemoglobin and “pathologies which alter oxygen exchange/demand/supply” reduce tissue tolerance to pressure (Bridel, 1993, p. 237). Despite the seemingly logical conclusion that tissues that are already hypoxic would be more susceptible to pressure induced ischemia, these relationships “have not been adequately tested” and remain unproven (Bridel, 1993, p. 237).

**Relationship Between Intrinsic Physiological Factors and the Nature of Pressure Ulcer Healing**

The second component of the theoretical framework looks at healing time and the influences of intrinsic physiological factors on the healing process. According to Lazarus et
al (1994) and Alvarez, Rozint & Wiseman (1989), pressure ulcers are one type of chronic wound. These authors explain that advances in the past five to ten years in the understanding of the nature of chronic wounds and chronic wound healing have resulted in the knowledge that chronic wounds arise from pathological processes within the host, and that these same factors influence the time it takes for healing to occur (Alvarez, Rozint & Wiseman, 1989; Lazarus et al., 1994). They further assert that, in contrast to the prompt and predictable pattern of healing in traumatic or surgical wounds, chronic wounds do not “repair themselves” or cannot “be repaired in an orderly and timely process” (Lazarus et al., 1994, p. 490). The rate of healing in pressure ulcers, or the timeliness of tissue repair, is variable (Lazarus et al., 1994) and is influenced by a number of factors including the continued presence of the etiological factors (Cooper, 1995) and the severity of the wound (Lazarus et al, 1994). The lack of orderliness in the healing of chronic wounds, a characteristic that influences the time required for healing, is more fully explicated in the following section of this paper.

Relationship Between the Processes of Connective Tissue Repair and the Indicators of Pressure Ulcer Healing

In the third component of the framework, the relationship between the processes of connective tissue repair and the macroscopic indicators of pressure ulcer healing are described. Healing in full thickness pressure ulcers occurs via three processes of connective tissue repair: the deposition of extracellular matrix (granulation tissue), contraction and epithelialization (Cooper, 1995). Currently, pressure ulcer healing is assessed by observing changes in the nature of the wound and in the surface area of the wound. Although the following description of the indicators of healing suggests an orderly progression, the nature of chronic wound healing is best represented in terms of a continuum marked by episodes of
progression and regression (Bates-Jensen, 1997; Lazarus et al., 1994). This is related to the fact that as the etiological factors are ameliorated or recur, there can be a corresponding change in the direction of the healing process (Lazarus et al., 1994) and therefore, the severity of the wound (Bates-Jensen, 1997).

The indicators of pressure ulcer healing from the time of wounding through to the completion of the reparative process are described by Brown-Etris (1995). The first indicator of healing is the removal of necrotic eschar, which is accompanied by a reduction of inflammation in surrounding tissue and the beginning of granulation tissue ingrowth. With the removal of eschar and slough, exudate shifts from purulent to serosanguineous in nature, the size of the wound increases and undermining, if present, becomes evident. As the deposition of granulation tissue advances, wound depth and surface area reduce as contractile cells within granulation tissue exert their influence by beginning to approximate the wound margins. With the continued proliferation of granulation tissue, undermined areas fill, wound margin attachment begins, exudate diminishes and the size of the wound gradually reduces through continued contractile activity. When attachment of the wound margins is complete, epithelial tissue migrates over the granulating base, exudate ceases and the surface area of the wound reduces as healing progresses to closure through the processes of contraction and epithelialization.

**Operational Definition of Terms**

**Healing**

Healing was measured using the Pressure Sore Status Tool and Version 1.1 of the Mouseyes Image Digitization Program.
Full Thickness Pressure Ulcer

Full thickness ulcers were measured using the Pressure Sore Status Tool (Bates-Jensen, 1997) and the Pressure Ulcer Staging System developed by the National Pressure Ulcer Advisory Panel (NPUAP, 1989).

Stable Heel Pressure Ulcer

The stability of heel pressure ulcers was measured using the Pressure Sore Status Tool.

Unstable Heel Pressure Ulcer

The instability of heel pressure ulcers was measured using the Pressure Sore Status Tool.

Malnutrition

Malnutrition was measured using the nutrition subscale of the Braden Scale for Predicting Pressure Sore Risk. It was also indicated by a serum albumin level less than 3.5 mg/dL, or a total lymphocyte count of less than 1,800/mm$^3$ (Bergstrom et al., 1994). Where this biochemical data was not available, malnutrition was measured as a weight loss of 5% of total body weight in one month, or 10% in six months (Gilmore, Robinson, Posthauer & Raymond, 1995).

Level of Mobility

Level of mobility was measured using the mobility subscale of the Braden Scale for Predicting Pressure Sore Risk.

Continence Status

Continence status was measured using the Barthel Index.

Self Feeding Ability

Self feeding ability was defined using the Barthel Index.
Level of Consciousness

Level of consciousness was measured using the sensory perception subscale of the Braden Scale for Predicting Pressure Sore Risk.

Assumptions

The following assumptions underlie this research:

1. The natural history of healing in heel pressure ulcers needs to be established in order to begin to describe the norms of healing in these wounds.
2. The initiation of the process of describing heel pressure ulcer healing will allow for better management in future.

Scientific Significance

Currently, health care professionals are encouraged to utilize research based critical pathways in their practice. One of the most important functions of a critical pathway is to provide a means of quickly identifying clients who vary from the expected course and require additional evaluation (Tallon, 1995). In order to develop a pathway for the healing of heel pressure ulcers, the norms and variances in the patterns of their healing must be ascertained (Bates-Jensen, 1996; Tallon, 1995). The research described in this paper represents a step toward that process.

Significance to Client Care and Society

As the population ages, pressure ulcers will become more prevalent (NPUAP, 1989) and the need for well constructed critical pathways that prescribe safe, efficacious and cost effective approaches to care will become more pressing (Tallon, 1995). A persistent lack of suitable frameworks and tools for managing heel pressure ulcers may mean that health care professionals will be ill prepared to deal with increasing numbers of clients with these complex wounds.
Significance to Nursing

Nursing assumes much of the responsibility for ongoing chronic wound care (Harding, 1993). Therefore, it is important that a body of knowledge relating to the norms of heel pressure ulcer healing be developed to provide sound direction for nursing practice.

Summary and Conclusion

Heel pressure ulcers are a costly and significant problem for the elderly persons who experience them and for the nurses who manage them. While there is a growing interest in studying pressure ulcer healing, the selected area of heel pressure ulcer healing remains relatively unexplored. By participating in the evolution of this body of knowledge through engaging in research activities, nurses can provide needed information related to the norms of pressure ulcer healing for all members of the health care team. The preliminary work described in this report has the potential to initiate a contribution to nursing practice by documenting the healing of heel pressure ulcers.

A review of the research literature is presented in Chapter 2 and the methodology, sampling criteria and procedures are covered in Chapter 3.
CHAPTER TWO:
REVIEW OF THE RESEARCH LITERATURE

The review of the research literature is presented in three major sections. In the first section, the boundaries of existing knowledge in relation to the prevalence of heel pressure ulcers is explored and a research based profile of the characteristics of persons who develop pressure ulcers is presented. In the second, to substantiate the need for studies of the healing of heel pressure ulcers, the current state of knowledge in relation to the healing of these wounds will be reviewed. In the third, the body of knowledge in relation to the measurement of pressure ulcer healing will be analyzed and support for the selected measures of pressure ulcer healing provided.

Review of the Research Literature Pertaining to Pressure Ulcer Epidemiology

An extensive survey of the research literature reveals that until the 1990’s, rigorous, well constructed studies of pressure ulcer epidemiology were lacking. Prior to this time, studies of pressure ulcer epidemiology were flawed by inconsistent and often erroneous definitions of key terms and an almost universal focus on single site studies (NPUAP, 1989). For these reasons, the comparability of research findings between studies was limited as was the generalizability of results (NPUAP, 1989). In recognition of these barriers, wound care experts in the United States of America (USA) convened the first of a series of technical development conferences in 1989 to define key terms and to standardize approaches to pressure ulcer research. Delegates at the conference recommended that to promote generalizability of findings and to reduce the potential for bias, studies designed to assess pressure ulcer epidemiology should be conducted in multi-centre studies, and preferably, at the national level (NPUAP, 1989). Several pressure ulcer prevalence studies by Meehan (1994) satisfy this criterion and, because they are relevant to the prevalence of heel pressure...
ulcers, the results of these studies are reviewed. This is followed by an analysis of the research that describes the characteristics of persons who develop pressure ulcers.

**Pressure Ulcer Prevalence**

Although the prevalence of pressure ulcers in British Columbia and the Lower Mainland is unknown, a rising trend in the prevalence of heel pressure ulcers is documented in the results of three national level surveys of pressure ulcer prevalence in community hospitals in the USA (Meehan, 1994). In a comparative analysis of the longitudinal data from all three studies, Meehan (1994) reports that heel ulcers comprised 19% of all pressure ulcers in 1989, 26% in 1991 and 30% in 1993. The overall pressure ulcer prevalence rate for 1993 was reported to be 11.1%, up from 9.8% in 1989. While Meehan’s (1994) findings could suggest that the number of heel pressure ulcers is sufficient to support a study of the healing norms of these wounds, the extent to which American data may be used as an estimate of pressure ulcer prevalence in Canada is unknown. For this reason, an assessment of the number of subjects with heel pressure ulcers that can be identified locally is required.

**Characteristics of Persons who Develop Pressure Ulcers**

It is reported by Margolis (1995) that pressure ulcers occur in persons who are bed or chair bound, incontinent, malnourished, unable to feed themselves and who experience an altered level of consciousness. This claim is based on the findings of several national level studies conducted in the USA. The results of these large scale studies will be presented and because malnutrition and level of consciousness have been associated with pressure ulceration with less certainty, these correlates will be discussed in more detail.

Two national level surveys correlated pressure ulcers with functional impairments and with disease processes that are associated with limitations in self-care abilities. In a secondary analysis of data from a national medical expenditure survey, Spector (1994)
reported the characteristics of 2,803 residents of 699 nursing homes who developed pressure ulcers during the course of their stay. It was reported that pressure ulcers occurred among persons with diagnoses of Parkinson’s Disease, diabetes or paraplegia and in persons who were underweight, unable to walk or self feed and who were incontinent. Spector (1994) further reported that the odds of developing a pressure ulcer increased by 80% in persons who were both cognitively impaired and unable to self feed. Spector’s findings are supported by those of Brandeis, Ooi, Hossain, Morris & Lipsitz (1994) who surveyed 4,232 residents of 78 nursing homes in a 21 month prospective study. These authors reported that difficulty with ambulation, deficits in self feeding ability, disorientation and a diagnosis of diabetes were correlated with pressure ulcer development.

Malnutrition

Currently, there is no “universally accepted definition of the malnourished state” (Pinchcofsky-Devin, 1997, p. 73) and for this reason, there is no conclusive measure of this condition. Although a malnourished state is strongly suggested in Spector’s (1994) finding that pressure ulcers occurred in underweight persons and, to some extent, by the finding that these wounds occur among persons with deficits in self feeding abilities (Brandeis et al, 1994; Spector, 1994), the lack of a decisive definition is problematic. For this reason, until valid and reliable measures of this state are established, the link between pressure ulcers and malnutrition cannot be established with certainty. However, it is significant that a number of pressure ulcer researchers have associated malnutrition with pressure ulcer formation. In these studies, malnutrition has been defined in terms of: lymphocyte counts below 1,800/mm² (Allman, Goode, Patrick, Burst & Bartolucci, 1995; Bergstrom et al., 1994), serum albumin levels below 3.5 mgm/dL (Bergstrom & Braden, 1992; Hanan & Scheele, 1991; Pinchcofsky-Devin & Kaminski, 1986), unintentional weight loss of 5% of total body
weight in one month or 10% in six months (Gilmore, Robinson, Posthauer, & Raymond, 1995) and a reduction in intake by 50% for three days or longer (Braden & Bergstrom, 1992; Gilmore, Robinson, Posthauer, & Raymond, 1995). Given the number of studies that associate malnutrition with pressure ulcers, it can be said that malnutrition is probably a factor in the etiology of pressure ulcers.

**Level of Consciousness**

Of the characteristics identified by Margolis (1995), level of consciousness has been the least well defined, the least studied and, therefore, the least well supported in the research literature. This is because a clear conceptual definition of this phenomenon as it relates to pressure ulcer research is lacking. As a consequence, pressure ulcer researchers have defined this construct somewhat vaguely in terms of mental status (Gosnell, 1989; Norton, 1989; Maklebust & Magnan, 1994), disorientation (Brandeis, Ooi, Hossain, Morris & Lipsitz, 1994) or dichotomously as impaired/unimpaired on the basis of clinical judgement (Allman, Goode, Patrick, Burst & Bartolucci, 1995). It is possible that, as suggested by Braden and Bergstrom (1989), the ability to respond meaningfully to pressure related discomfort represents the essence of the relationship between levels of consciousness and pressure ulcer risk. However, the extent to which this is a possibility requires further research. In the intervening time period, pressure ulcer researchers will have to deal with the lack of clarity in relation to this phenomenon.

In summary, the body of knowledge of pressure ulcer epidemiology is in a relatively early stage of development. Given the fact that the histopathology and, therefore the etiology of pressure ulcers is not well understood (Bergstrom, 1992), additional risk factors and correlates may be identified in future. It is also possible that the pressure ulcer correlates identified in current research may not stand the test of future study.
Research Pertaining to Heel Pressure Ulcers

To date, there is a dearth of research based knowledge of the healing norms of pressure ulcers in general and of heel pressure ulcers in particular. Following an extensive review of the relevant literature, only three studies were found that addressed heel ulcers (Badwey, Rice & Kerstein, 1988; Bates-Jensen, 1996; Pecoraro, Ahroni, Boyko, & Stensel, 1991) and of these, only one (Bates-Jensen, 1996), focused on identifying healing norms in pressure ulcers. Because norms of pressure ulcer healing are specifically addressed in the study by Bates-Jensen (1996), this will be discussed first. It will be followed by a brief analysis of the remaining two studies. Finally, an introduction to the Braden Scale for Predicting Pressure Sore Risk (Braden Scale) will be given and the purpose for its use in the study proposed in this paper will be outlined.

In an effort to begin the process of differentiating normal pressure ulcer healing from "problematic" healing, Bates-Jensen (1996) designed a study to elicit normative data for the healing of sacral, trochanteric and heel pressure ulcers from the experiential knowledge of expert enterostomal nurses. While this approach is useful in that it represents a starting point in determining the norms of pressure ulcer healing, it is limited for two important reasons. The first is that survey respondents were not given a clear definition of the population of interest. With regard to heel pressure ulcers, this is particularly troubling. Although one could assume that since the nurses surveyed were "experts" and should be able to differentiate between pressure ulcers and heel ulcers of other origins, this is not necessarily so. The possibility that the surveyed experts melded the healing norms of such disparate wounds as pressure, diabetic and arterial ulcers in their responses is suggested by the finding that, in contrast to the norms given for ulcers at other sites, those identified for heel ulcers were highly variable. However, this could also be indicative of the nature of heel pressure
ulcer healing. Second, while experiential knowledge can be a valuable source of data, given the complex, dynamic nature of pressure ulcer healing, this phenomenon is most reliably assessed in prospective studies designed to observe, measure and report the healing progression of actual pressure ulcers.

Although subjects with heel ulcers have been included in two studies designed to monitor the progression of wound healing, these efforts contribute little to the understanding of pressure ulcer healing because the heel ulcers may not have been due to pressure. In the first study by Badwey, Rice & Kerstein (1988), it is apparent from the description of the research sample, that the heel ulcers were more related to arterial insufficiency rather than to pressure related injury. A similar problem is noted in a study by Pecoraro, Ahroni, Boyko and Stensel (1991), who studied the healing of diabetics with a variety of chronic, lower extremity wounds. This study is troublesome for two reasons. The first is that the sample is not well defined and, from the description of the subject characteristics, a higher level of mobility than one would expect of persons with pressure ulcers is suggested. Second, the authors failed to differentially describe healing by ulcer type or location. This is significant because, as Cooper (1995) explains, although all full thickness wounds heal through connective tissue repair, the predominant healing processes and therefore, the norms of healing, vary according to wound type and ulcer location.

As stated in the preceding analysis of existing studies of heel pressure ulcer healing, it is essential that pressure ulcer researchers accurately identify the population of interest. One measure that can assist researchers in identifying members of the population of persons with pressure ulcers is the Braden Scale for Predicting Pressure Sore Risk (Braden Scale). The Braden Scale was developed in the 1980's (Braden & Bergstrom, 1989) and was based on the understanding of pressure ulcer epidemiology of that time. It was derived from a
previously existing scale, the Gosniell Scale, which was revised to improve the clarity and precision of the operational definitions within each category of risk (Braden & Bergstrom, 1989). The risk factors that form the basis of the Braden Scale are consistent with the findings of the more recent national level surveys of pressure ulcer epidemiology that were discussed earlier in this Chapter. Because the Braden Scale reflects the current understanding of pressure ulcer epidemiology, its use can assist researchers in differentiating persons whose heel ulcers are pressure related from those that are most probably not.

Support for the use of the Braden Scale in identifying persons with heel pressure ulcers can be derived from the work of Tourtal et al (1997). To determine the best predictors of heel pressure ulcer development, these authors conducted two studies using a descriptive cohort design. In the first study, a number of variables that had been found in previous research to be associated with heel pressure ulcer development were tested in a sample of 221 subjects who were admitted to one of four acute care medical units. The variables that were found to be statistically significant predictors of heel pressure ulcers in the first study were tested in a second study comprised of 291 subjects from the same four units. The authors report that subjects who developed heel ulcers had lower Braden Scale scores and were more likely to experience incontinence than those who did not. They further report that two subscales of the Braden Scale were the best predictors of heel pressure ulcer development: the friction and shear scale and the moisture scale. The finding that moisture and specifically, incontinence, is predictive of heel pressure ulcer development is surprising. This is evident in the statement by Tourtal et al (1997) that “this parameter would be assumed to be predictive of sacral pressure ulcers where moisture has direct affect on the skin, not heel pressure ulcers where there is usually no direct affect on the skin” (p. 37). In attempting to explain this finding, Tourtal et al (1997) assert that “these findings may lead
one to assume it is the physical factors precipitating incontinence that also contribute to pressure ulcer risk. Therefore, these physical factors, not the moisture itself, may be predictors of heel pressure ulcers” (p. 37). The authors conclude that currently, the Braden Scale is the best predictor of heel pressure ulcer risk.

Review of Research on the Measurement of Pressure Ulcer Healing

Currently, pressure ulcer healing is measured through assessment of changes in surface area or volume (Gentzkow, 1995) and by observing qualitative changes in the wound bed that are indicative of the status of repair (Bates-Jensen, 1997). In the following two sections of this paper, the research based methods for quantitative and qualitative measurement are presented and discussed. The research findings in relation to the quantitative measurement of pressure ulcer healing will be presented first and this will be followed by an introduction to the qualitative measures.

Quantitative Measurement of Pressure Ulcer Healing

Many of the methods that have been proposed as quantitative measures of pressure ulcer healing fall under the “general categories of area and volume” (Gentzkow, 1995, p. 28-43). Methods for assessing area range from the most technically complex and potentially expensive measures as structured light and stereo-photogrammetry, to photography (using a 35 mm camera and specialized macro lens), to direct wound tracings with computerized analysis and, least complex of all, ruler based methods (Harding, 1995). Volumetric assessment options include the use of gel or alginate dental impression moulds (Gentzkow, 1995). Despite the recent interest in “high tech” methods, few techniques have been found to be more reliable or cost effective than acetate wound tracings and computerized imaging analysis (planimetry) (Rodeheaver & Stotts, 1995). Support for this method is evidenced in the results of four key studies.
First, in a study by Thomas and Wysocki (1990), the reliability and accuracy of three methods of measuring surface area in pressure ulcers and venous stasis ulcers were compared. In a total of 73 observations, each wound was assessed by: direct measurement using the Kundin wound measuring device (a hand held disposable ruler that measures length, width and volume), a photographic image taken with a 35 mm camera and a built in "reproduction ratio imprinting feature" (Thomas & Wysocki, 1990, p. 19), and finally, direct wound tracings. Estimates of surface area from the photographic images and wound tracings were obtained using computerized digital analysis. The authors report that the results for all three methods were correlated (r=0.93 or greater) suggesting that all methods provide a reliable index of healing (Thomas & Wysocki, 1990). However, the methods differed significantly in terms of estimated area. In contrast to the area estimates obtained from the photographic and wound tracing methods, it was reported that the Kundin device underestimated area in wounds that were irregular and not circular or elliptical in shape (Thomas & Wysocki, 1990). These findings can be explained by the fact that digital analysis of photographic images and wound tracings can accommodate irregularities in wound shape, but direct measures of length and width cannot (Harding, 1995). Since few wounds are perfectly symmetrical or uniformly circular or elliptical in shape (Taylor, 1997), this finding supports the use of digital analysis of photographs or wound tracings over direct measures using the Kundin device.

In a second study, similar conclusions in relation to the accuracy and comparability of photographs and wound tracings in measuring pressure ulcer healing were reached by Brown-Etris, Pribble, & LaBrecque (1994) after analysing 450 paired observations in 65 subjects. Photographs were taken with a 35 mm camera and a specialized macro lens. To promote accuracy in measurement, a linear measurement scale was placed adjacent to the
wound and photographs were taken with this device in the field of vision (Brown-Etris, Pribble & LaBrecque, 1994). Wound tracings were obtained using x-ray film and an ultra fine-tip, indelible ink marker, Sharpie brand. Estimates of surface area from the photographs and the wound tracings were ascertained by manually digitizing these images using an MS-Dos computer and a planar morphometry program. The authors report that the results from both methods were highly correlated (r=0.97) and the coefficient of variation was low (10 to 20%) suggesting that photography and wound tracings offer comparable results in terms of accuracy. However, these authors warn that if the photographer “does not possess the expertise, the equipment, and/or skill level required to take quality photographs utilizing a 35mm camera and a macro lens, outcome data may be unevaluable and disappointing at best” (Brown-Etris, Pribble & LaBrecque, 1994, p. 48).

In a third study, Cutler et al (1993) compared four methods of assessing wound size in 20 clients with pressure ulcers. The purpose of the study was to “examine the relationship between ulcer measurements, the amount and type of variability within each measurement, and the changes in ulcer size during the course of the study period” (Cutler et al., 1993, p. 25). Over a four week period, weekly estimates of wound size were made by: 1) directly measuring length, width and depth (depth was measured at the deepest point in the wound bed), 2) obtaining direct wound tracings using a plastic baggie placed over the wound, 3) photographing the wound and an adjacent calibration ruler with a 35 mm camera with a macro lens and, 4) assessing volume using alginate impression moulds. Except for the alginate mould, duplicate measures were obtained at each observation using all methods. Estimates of surface area obtained from the tracings and photographs were analysed planimetrically. Researchers reported equal magnitudes of variability within the three methods of measuring surface area suggesting that accuracy of measurement does not require
duplicate estimates of each measure at each observation (Cutler et al., 1993). With regard to between method variability for the area measures, the authors report that direct measurement overestimated wound area by an average of 1.5 square centimetres and that estimates calculated from photographs were more variable than those obtained from wound tracings. It is further reported that wound size estimates from direct wound measures, wound tracing measurement and photography were found to be more sensitive than the alginate mould in detecting early changes in wound size. No differences between the methods beyond the initial stages of healing are reported.

In the fourth study, conflicting findings from those of Cutler et al (1993) are reported by Schubert and Zander (1996) who studied four methods of measuring pressure ulcer size to determine the most valid measure of change over time. The methods included: 1) volumetric assessment using gel, 2) area and perimeter estimates obtained through the use of transparent film and either a digital planimeter or 3) digital measuring pen, and 4) depth measurement, using a millimetre probe. Eleven subjects with pressure ulcers were assessed once weekly for ten weeks using all four methods. Schubert and Zander (1996) found perimeter to be a less-reliable indicator of wound size than area and reported that the results of the two methods of area analysis (digital planimeter and pen) were comparable. The millimetre probe was found to be less reliable estimate of volume than gel. This was attributed to the fact that in general, wounds are not of a uniform depth making point volume assessment less accurate than what could be achieved using such measures of total volume as gels or moulds. In comparing wound size estimates obtained from volume and area measures, the authors report considerable variability between these methods and conclude that both area and volume measurements are necessary in studies of pressure ulcer healing.
The findings of Cutler et al (1993) that area measures are more sensitive than volume measures in detecting early changes in healing and Schubert and Zander's (1996) conclusion that both area and volume measures are necessary in wound healing studies requires some discussion. According to Gentzkow (1995), there are several technical problems known to influence the accuracy of volumetric measurement. The most important of these is that both gel and alginate impression moulds are subject to substantial measurement error because judgements must be made in relation to where the skin surface should be, a factor that influences the thickness of the applied medium (Gentzkow, 1995). Given this limitation and the fact that alginate moulds must be precisely measured, mixed and applied within the one minute period before drying occurs (Gentzkow, 1995), it is possible that these technical difficulties are responsible for the variations between area and volume estimates reported by Cutler et al (1993) and Schubert and Zander (1996).

For these reasons, and the fact that volume measures can actually disrupt the healing process (Gentzkow, 1995), healing is best assessed using estimates of area rather than volume. In addition, because wound tracings are comparable in accuracy to photography, and computerized digital analysis has been shown to be more accurate than ruler based methods, healing will be assessed using acetate tracings. Wound tracings will be analyzed using the Computerized Digital Planimetry Program, "Mouseyes".

Qualitative Measures Of Pressure Ulcer Healing

Currently two research based instruments have been designed to measure the qualitative indicators of pressure ulcer healing discussed in the previous Chapter. These are the Sessing Scale (Ferrell, Artinian & Sessing, 1995) and the Pressure Sore Status Tool (Bates-Jensen, 1992). The Pressure Sore Status Tool (PSST) has important advantages over the Sessing Scale. The first is that persons with heel pressure ulcers were included in the
testing of the PSST, but not in that done for the Sessing Scale. The second is that in contrast to the Sessing Scale, detailed accounts of the studies done to establish content validity and reliability of the PSST are available. The validity of the Pressure Sore Status Tool has been assessed in three separate studies as has its reliability. Further details of these studies can be found in Chapter 3.

Conclusion

The bodies of knowledge in relation to pressure ulcer epidemiology, the norms of pressure ulcer healing and the measurement of pressure ulcer healing are in an early stage of development. However, it is clear that to prevent perpetuating inaccuracies in studies of pressure ulcer healing, it is essential that the research sample be clearly defined. This chapter provides an epidemiological profile of the population of persons who develop pressure ulcers, and the limitations in this body of knowledge were discussed. Equally important is the gaining of knowledge of the norms of pressure ulcer healing. Current methods and tools used to assess healing were presented and analyzed. This analysis provides a framework for the decisions guiding this study as presented in Chapter 3.
CHAPTER THREE: METHODOLOGY

In this chapter, an outline is provided of the methods used to assess the feasibility of a study of the healing norms of heel pressure ulcers among a sample of persons aged 65 years and older. The research design, sampling strategy, data collection instruments and procedures are introduced, as are the data analysis plan, limitations of the study and, procedures for the protection of human subjects.

Research Design

A descriptive design was used in this study because it was the most appropriate design for use in answering the research questions. According to Diers (1979), descriptive level research is the most basic and is required in instances where the phenomenon of interest has not been studied. As established in Chapter Two of this document, relatively little was known of the healing norms of heel pressure ulcers or of their prevalence in Canadian settings. Also unknown was the usefulness of the Mouseyes Program in measuring healing in heel pressure ulcers. Finally and, very importantly, the cost of measuring pressure ulcer healing and the feasibility of conducting a larger study of the norms of heel pressure ulcer healing was also unknown. The fundamental nature of the information that was required to determine the feasibility of a larger study is evidenced in the research questions that guided the study design:

1. What number of adults aged 65 years and older with full thickness heel pressure ulcers can be recruited as subjects from the Simon Fraser Health Region during a four month period?

2. Of the adults aged 65 years and older with full thickness heel pressure ulcers, what number have stable ulcers and what number become unstable during the four month study?
3. What barriers are encountered in identifying and recruiting older adults with heel pressure ulcers?

4. What is the average time required per visit for data collection?

5. What is the average size of the identified heel pressure ulcers at the time of the initial assessment?

6. What is the average number of weeks from ulcer onset to reduction in wound size to one square centimetre?

7. What is the degree of correlation between estimates of surface area obtained through the use of “Mouseyes” and the scores that result from the Pressure Sore Status Tool?

8. What is the feasibility and usefulness of the image digitization program “Mouseyes” in measuring the surface area of heel pressure ulcers?

Through the process of answering the research questions, three results were expected: (1) the number of potential subjects would be described, (2) the utility of the computerized planimetry program ‘Mouseyes’ in measuring heel ulcers would be determined and, (3) personnel costs projected.

**Sampling Strategy**

A convenience sample of subjects with full thickness heel pressure ulcers who were receiving health care within the boundaries of the Simon Fraser Health Region were asked to participate in the study. Subjects were recruited by referrals from personnel on units known to be populated with persons at risk for pressure ulcers. This included such settings as acute medical units, discharge planning units, orthopaedic units and extended care units. Key informants were identified on each unit who acted as third party recruiters. The purpose and intent of the study was relayed to informants by letter (Appendix A) and through a personal visit or telephone call by the author. Contact with these persons was initiated prior to the
implementation date and was maintained regularly throughout the four month study period.

Subjects who were eligible for inclusion were those who:

1. were aged 65 years or older.
2. had a full thickness pressure ulcer on the non-weight bearing surface of the heel.
3. were able to give consent, or in the absence of this capacity, had a designated surrogate decision-maker capable of giving consent.
4. could safely turn to a position that permitted visualization of the wound(s).
5. had no history of sensitivity to Opsite (Smith & Nephew) and no impairment of the skin surrounding the wound were assessed as being a member of the population of persons who are malnourished (or experience difficulty with self feeding), often incontinent, bed or chair bound (Margolis, 1995) and, had a history of, or were experiencing impairments in their capacity to perceive or respond meaningfully to pressure related discomfort (Braden & Bergstrom, 1989).
   and/or
6. received a score on the Braden Scale for Predicting Pressure Sore Risk that fell within the parameter indicative of risk (18 in extended care level settings and 15 in acute care).

**Data Collection Instruments**

Six instruments were used in the generation of data. These included the Braden Scale for Predicting Pressure Sore Risk, the Barthel Index, the Pressure Sore Status Tool, the National Pressure Ulcer Advisory Panel (NPUAP) Pressure Ulcer Staging System, the Mouseyes Program and the data collection sheets that were designed for use in this study. Each instrument is described.
The Braden Scale for Predicting Pressure Sore Risk

The Braden Scale for Predicting Pressure Sore Risk is a research based screening instrument comprised of six subscales (see Appendix B). The subscales measure levels of mobility, activity, nutritional intake, sensory perception, the presence of moisture against the skin and the potential for friction and shearing. “All subscales are rated from 1 (least favourable) to 4 (most favourable), with the exception of the friction and shear subscale, which is rated from 1 to 3. Potential scores range from 6 to 23. Lower scores are indicative of higher risk” (Bergstrom, Braden, Kemp, Champagne & Ruby, 1996, p. 23). The Braden Scale was been selected in preference over other risk assessment scales because its reliability and validity has been assessed in more than one study.

Various authors report acceptable correlation coefficients for interrater reliability: .99 (Bergstrom, Braden, Laguzza & Holman, 1987), and .90 to .99 (Langemo et al., 1991). Bergstrom, Braden, Laguzza & Holman (1987) report that when used for research purposes, reliability ratings are highest when the assessment is completed in conjunction with a family member or the subject’s primary nurse.

In relation to validity, data is much more variable. Since the Braden scale is a screening tool, validity is measured in terms of specificity and sensitivity. Sensitivity is defined as “the extent to which a true characteristic is classified correctly” and specificity is the “the extent to which the absence of a characteristic is correctly classified” (Larson, 1986, p. 186). The sensitivity and specificity of the Braden Scale has been found to vary depending on the population being studied. Bergstrom, Braden, Laguzza and Holman (1987) report that the tool was found to be 100% sensitive and 64% specific when a score of 16 points or less was considered indicative of risk in patients on a medical-surgical unit. Langemo et al (1991) tested the validity of the Braden Scale and reported that cut scores of 15 yielded a sensitivity
rating of 55% and a specificity of 94% in an acute care setting. Bergstrom & Braden (1994) found that in an extended care setting, a score of 18 resulted in a sensitivity rating of 79% and a specificity rating of 74%. Additional data regarding sensitivity and specificity are reported by Tourtal et al. (1997) who tested the validity of the Braden Scale in predicting heel pressure ulcer risk. It is reported that “using a cut-off point of 12 on the Braden scale, sensitivity was 14 percent and specificity was 94 percent. Moving the cut-off point to 16, the sensitivity was 49 percent, but decreased the specificity to 76%” (p. 34).

While the ideal screening tool would be 100% sensitive, and 100% specific (Larson, 1986), the reported sensitivity and specificity ratings are acceptable. Moreover, it is unlikely that greater sensitivity or specificity will be possible until the etiology of pressure ulceration and the range of possible risk factors have been more completely explored (Bergstrom, 1992). Since the purpose of using this scale in the pilot study was to identify persons with heel ulcers that were most probably related to pressure, specificity was most important. Therefore, in the absence of data to suggest otherwise, a score of 16 in acute care patients and a score of 18 in an extended care setting was considered indicative that a subject with a heel ulcer was probably a member of the population of persons with pressure ulcers.

The Barthel Index

According to Novak, Johnson and Greenwood (1996), the Barthel Index is a measure of the extent to which the subject is dependent upon others in satisfying basic activities of daily living (ADL) needs. This instrument has been found to be a valid measure of ADL function in stroke patients (Granger, Dewis, Peters, Sherwood, & Barrett, 1979; Wylie, 1967), in persons with brain injuries with or without cognitive impairment (Novak, Johnson, & Greenwood (1996), and in persons with neuromuscular and musculoskeletal problems (McDowell & Newell, 1987). The Index is designed to be completed using medical records
data or direct observation (McDowell & Newell, 1987). Ten activities are assessed including: feeding, transferring, personal hygiene and grooming, getting on and off toilet, bathing self, walking, ascending and descending stairs, dressing, and controlling bowels and bladder. The overall scores range from 0 to 20, with 0 representing the greatest disability and 20 the greatest independence (Novak, Johnson, & Greenwood, 1996). Each category is variably weighted, with scores ranging from 0 to 2 points depending on the degree of complexity of the individual task (see Appendix C).

The Barthel Index was included in the pilot feasibility study for several reasons. The first was that, as discussed in Chapter 2, epidemiological research suggests that pressure ulcers occur among persons who are impaired in such basic functions as mobility, self feeding abilities and continence. The Barthel Index is a specific measure of these functions and, as such, it provides another measure to assist in judging the eligibility of study subjects. The second was that recent findings by Tourtal et al (1997) add weight to the importance of assessing functional status. In a study designed to identify predictors of heel pressure ulcer development among hospitalized persons, these authors report that ulcers occurred among those who experienced difficulties with continence and friction and shear. In explaining the unexpected finding that incontinence contributed to heel pressure ulcer development, the authors suggest that diminished physical function rather than the actual presence of moisture from incontinence is the underlying etiological factor. Although mobility and some dimensions of feeding and continence are measured in the nutrition and moisture subscales of the Braden Scale, the physical functions that are necessitated in the performance of self feeding and the maintenance of continence are not. Finally, in contrast to other ADL scales, reliability and validity data are available.
Inter-rater reliability for the Barthel Index was established in two studies. In the first, Colin, Wade, Davies and Horne (1988) designed a study to “investigate inter-observer reliability, the reliability of asking for information rather than testing and, the reliability of self-report” (p. 61). The authors found a “highly significant coefficient of concordance” between all rating methods (W=.93, p. <0.001). However, Colin, Wade, Davies and Horne (1988) warn that self-report is not reliable in the presence of cognitive impairment. This limitation was recognized by Novak, Johnson and Greenwood (1996) who clarified the use of the operational definitions of the Barthel Index for populations in which cognitive impairment is common. Since it was anticipated that many subjects in the pilot study would be cognitively impaired, the reliability of these definitions was important. Novak, Johnson and Greenwood (1996) report that inter-rater reliability was assessed using both the standard and the augmented definitions for two sets of assessments: one by a staff member and the other by an independent occupational therapist observer. The population of a 24 bed rehabilitation unit were tested daily by both observers for one week. The authors report greater inter-rater reliability with the augmented definitions (r=0.96) than with the standard definitions (r value not reported).

Evidence of the validity of the Barthel Index is provided by several groups of authors. Wylie assessed face and construct validity of the Barthel Index by comparing physician judgements of physical disability and the outcomes of care in 1,223 stroke patients who had been assessed using the Barthel Index. Wylie reports that Barthel Index scores were found to be consistent with clinical judgements of the degree of subject disability. It is further reported that the Barthel score on admission accurately predicted the success of rehabilitation outcomes, indicating that it is a valid measure of functional dependence. In a study designed to assess the outcomes of rehabilitation, Granger, Albrecht and Hamilton (1979), compared
the Barthel Index with another functional index, the Pulses Profile. The authors report that both the Barthel Index and the Pulses Profile appeared to measure the same construct, functional dependence. They note however, that the Barthel offers an advantage in that it is capable of measuring such discrete functions as mobility and feeding abilities. Granger, Albrecht and Hamilton (1979) report that scores obtained from the Barthel Index were predictive of rehabilitation outcomes, with a score of 40 (on a 0-100 point scale, or 8 on a 20 point scale) being indicative of significant dependence in ADL functions, and therefore, poor outcomes. Finally, Novak, Johnson and Greenwood (1996) report a strong correlation between Barthel Index Scores and the amount of caregiver time required, suggesting that this instrument is a valid measure of ADL dependence.

**The Pressure Sore Status Tool**

Qualitative assessment of pressure ulcer healing was accomplished through the use of the Pressure Sore Status Tool (PSST), a research based instrument designed to assess pressure ulcer severity (Bates-Jensen, 1997) (Appendix D). The PSST has incorporated the indicators of pressure ulcer healing into a “paper and pencil instrument comprised of 15 items: location, shape, size, depth, edges, undermining, necrotic tissue type, necrotic tissue amount, exudate type, exudate amount, surrounding skin colour, peripheral tissue edema, peripheral tissue induration, granulation tissue and epithelialization” (Bates-Jensen, 1997, p. 43).

Thirteen of the fifteen items are scored on a five point Likert Scale. Scoring is structured such that a score of one equals the least severity for that characteristic and five represents the greatest severity (Bates-Jensen, 1997). The scoring system permits tracking of improvement or deterioration in wound status (Bates-Jensen, 1997). All of the items are scored except two, location and size. The thirteen scored items are summed and the total
represents an overall wound status score ranging between thirteen and sixty-five (Bates-Jensen, 1997). A score of thirteen is indicative that the wound is fully repaired and a score of sixty-five represents the greatest possible ulcer severity on all thirteen items (Bates-Jensen, 1997).

Content and face validity of the PSST was established by a panel of nine nurses “known for their expertise in pressure sore identification, risk assessment and/or wound healing” (Bates-Jensen, 1992). This involved a two stage process. The first entailed three steps: “domain identification, item generation and instrument formation” (Bates-Jensen, 1992, p. 23). In the second, the expert panel was asked to rate the theoretical content, the operational definitions, the language level, and the degree to which each item supported the concept of pressure sore status (Bates-Jensen, 1992). The Content Validity Index (CVI) was used and, to be deemed valid, each item had to be rated “quite/very relevant” by seven of the nine members of the expert panel (Bates-Jensen, 1992). Initial testing at the .05 level of significance yielded an overall CVI of .78. The tool was revised and subsequently retested such that the “average CVI for the tool, across all five content validity questions and 15 pressure sore items was .91” (Bates-Jensen, 1992, p. 26).

Recent efforts by Bates-Jensen (1997) have provided an assessment of predictive validity. Bates-Jensen (1997) analyzed the results of 2,923 assessments of 718 pressure ulcers as a means of testing the Wound Intelligence System, the automated version of the PSST. Included in the data base were 527 assessments of 113 healed pressure ulcers. Several of PSST items were found to correlate with “time-to-healing” (Bates-Jensen, 1997, p. 67). These included “exudate type, exudate amount, undermining, epithelialization, and induration” (Bates-Jensen, 1997, p. 67). Three items were found to be highly correlated with healing and, according to Bates-Jensen (1997), were the best predictors of healing: size,
exudate type and amount (r values not reported). According to Bates-Jensen (1997), change in size, or in exudate (either an increase or decrease), at two and four weeks was predictive of healing. It is further reported that “any positive change in any three of the PSST items seemed to predict healing” (Bates-Jensen, 1997, p. 68). Further work in validating predictive ability is currently underway (Bates-Jensen, 1997).

Two studies of interrater reliability have been conducted. The first was conducted using two enterostomal therapists who assessed 20 pressure ulcers from a convenience sample of 10 patients. Each patient was assessed twice, once by each therapist “at two different times, 1½ hours apart” (Bates-Jensen, 1992, p. 26). “The interrater reliability of the total score was high for both rating occasions, .91 and .92 for Times 1 and 2, respectively (p. <.001)” (Bates-Jensen, 1992, p. 27). Intra-rater reliability yielded “moderate to excellent results” with kappa values of .67, and .40 for the first and second raters respectively. Subsequent reliability testing was conducted using “two physical therapists, seven licensed practical nurses, and six registered nurses” (Bates-Jensen & McNees, 1995). Participants were paired, and each pair assessed 16 wounds, twice each, two hours apart. “An expert ET (enterostomal) nurse also independently assessed the same wounds as the practitioner pairs” (Bates-Jensen, 1995, p. 81S). “Inter-rater reliability for the practitioners yielded a mean of 0.78. Reliability estimates for the practitioners versus the ET nurse yielded a mean of 0.82. Intra-rater reliability for the practitioners averaged 0.89” (Bates-Jensen & McNees, 1995, p. 81S).

The NPUAP Pressure Ulcer Staging System

The NPUAP Pressure Ulcer Staging System describes four stages of pressure related injury and associates degree of tissue breakdown with clinical presentation. The first two stages are descriptive of tissue damage in partial thickness ulcers and the latter two refer to
full thickness ulcers. This system is intended for use as a diagnostic tool in assessing the extent of tissue damage (Bates-Jensen, 1997) and, as such, it is used to assess pressure ulcers when they first appear, or if subsequent pressure related injury results in extension of the wound. The NPUAP Staging System can only be applied to ulcers that have been debrided of all necrotic eschar and slough (Bergstrom et al., 1994).

The stages and their clinical presentation are as follows:

“Stage I Non-blanchable erythema of intact skin; the heralding lesion of skin ulceration

Stage II Partial thickness skin loss involving epidermis and/or dermis. The ulcer is superficial and presents clinically as an abrasion, blister or shallow crater

Stage III Full thickness skin loss involving damage or necrosis of subcutaneous tissue which may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

Stage IV Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures” (NPUAP, 1989, p. 25).

No specific studies documenting reliability or validity of this system were found in the survey of literature. Despite the lack of formal reliability and validity testing of the NPUAP Pressure Ulcer Staging System, it has been adopted by a panel of experts as the staging system for use in pressure ulcer research, and does provide standardization (NPUAP, 1989).
Bates-Jensen (1997) reports concurrent reliability of ratings between the NPUAP Pressure Ulcer Staging System and the Pressure Sore Status Tool (PSST). In an analysis of 496 PSST scores completed by raters in 12 geographically distinct regions in the United States of America, Bates-Jensen (1997) reports that scores from the NPUAP Staging System and the PSST were found to correlate ($r=+0.55$). It is further reported that a score of 31 or greater on the PSST distinguishes partial from full thickness ulcers (Bates-Jensen, 1997). The finding that the PSST can differentiate partial from full thickness pressure ulcers is important from a research perspective because, in some instances, it can be difficult to differentiate a deep stage II ulcer from a stage III ulcer. However, in its current form, the PSST is not sensitive to differences between Stage I and II or Stage III and IV ulcers (Bates-Jensen, 1997).

The Mouseyes Program

Pressure ulcer healing was assessed quantitatively using Version 1.1 of the Mouseyes Image Digitization Program developed by Dr. R.J. Taylor (Taylor, 1997). The Mouseyes Program utilizes a standard IBM compatible personal computer, a ball tracking mouse and a vector graphics adaptor (VGA) screen. The system calculates area by using the interpixel resolution of the standard VGA graphics screen, “a pixel being smallest point that can be displayed on a vector graphics screen” (Taylor, 1997, p. 124). To calculate surface area, an acetate film containing an image to be digitized is attached to the monitor screen and the mouse is used to direct the computer cursor in tracing the wound outline. As the cursor moves from one pixel to the next, the “points described by the mouse are mapped onto the computer’s graphics screen coordinates” and a line appears on the screen (Taylor, 1997, p. 125). When a closed loop has been successfully digitized, area is calculated and expressed in terms of centimetres squared ($cm^2$) (Taylor, 1997).
The Mouseyes Program was tested using a sample of five volunteers who were asked to digitize twelve shapes a total of 3 times. The shapes included four circles, four rectangles and four irregular polygons, all of different dimensions. Data analysis revealed that "the accuracy of calculated areas was within an error of 1.3% or less. The coefficient of variation, with the exception of the 1 cm diameter circle, was typically less than 2%" (Taylor, 1997, p. 125). While this testing is not extensive, it is based on previous research designed to assess the accuracy of area estimates obtained through the use of a personal computer and digitizing tablet (Taylor, 1997). In this study, two digitizing tablets produced by different manufacturers were used to digitize images onto the vector graphics screen of a personal computer (Taylor, 1995). Dr. Taylor (1995) reported that "reproducibility of measurement, as defined by the coefficient of variation, was typically less than 2% (p. 25). Given the comparable findings between the two studies, Taylor (1997) suggests that Mouseyes offers a distinct advantage over digitizing tablets in that the latter requires specialist knowledge to accurately execute the measurement process.

A number of recommendations were suggested to reduce measurement error. Dr. Taylor recommended that when using Mouseyes, (1) digitization be carried out at a slow rate of speed, (2) each tracing be digitized several times and, (3) the average of these measures be taken as the best estimate of surface area. It was further advised that all measures be done using a computer screen with a resolution of no less than 640 by 480 pixels or .44 mm in both vertical and horizontal directions (standard VGA monitor). Although the monitor used in this study provided a resolution of .244 mm, Dr. Taylor (personal communication, September 4, 1997) explained that this will not influence the accuracy of results because, in the absence of a specialized graphics card, Mouseyes interprets all monitors as standard VGA resolution.
Op-Site Flexigrid (Smith & Nephew) a transparent film dressing was used as the medium for the tracing. There were two reasons for using this product. The first related to the fact that this is a sterile dressing and its use would in no way increase the risk of infection. The second was that Op-site Flexigrid is comprised of two attached, yet easily separable layers. The rationale for using this product was that it allows a wound tracing to be completed on the top layer, which could then be removed and retained as part of the research record.

Data Collection Sheet

Data was collected on two forms designed for the purposes of the study (Appendix E). On the data collection sheet for visit one, descriptive information relating to the subjects' age, gender, diagnoses, prescribed medications, date of ulcer onset, location and stage of the heel pressure ulcer and, the presence of pressure ulcers at other sites was documented. Scores from the Braden Scale and the Barthel Index were determined, recorded on a separate form and appended to the Data Collection Sheet. For each subject, the status of the ulcer was described and, in the case of ulcers covered with eschar, the stability was assessed and measures taken of eschar length and width. Scores obtained from the Pressure Sore Status Tool (PSST) were recorded on a copy of the instrument. Information relating to nutritional status, the method of managing pressure and the type of dressing utilized were recorded. Finally, the time required for assessment was noted as were events or circumstances that presented barriers in the identification and recruitment of potential subjects. For subjects who were deemed ineligible for the study, the reason for ineligibility recorded in the comments section of the data collection sheet or on the screening log. Logistical problems with the implementation of the study procedures were identified and described.
Data collected on subsequent visits included changes in the medication regimen, recent blood work relating to nutritional status, the methods utilized in managing pressure and, the type of dressing used for topical management. For both initial and subsequent visits, the acetate films used to obtain wound tracings were attached to the data collection sheet as were the detailed score sheets from the PSST. Logistical problems with the implementation of the study procedures were described.

**Data Collection Procedures**

The procedures used in recruitment of subjects and in the implementation of each of the research instruments are detailed as follows.

**Recruitment of Subjects**

The writer saw all subjects with heel ulcers who were willing to participate and were referred by key informants. The purpose and procedures of the study were fully explained and consent obtained. All subjects were assessed using the NPUAP Pressure Ulcer Staging System, the Pressure Sore Status Tool, the Braden Scale and the Barthel Index. If wounds were deemed to be Stage I or II, subjects were followed in the event that extension of the tissue damage occurred and they became eligible for inclusion in the study. Subjects with stable eschar were asked if they were willing to followed every three weeks throughout the four month study period in order that the stability of the eschar could be monitored.

Subjects with Stage III and IV (full thickness) heel pressure ulcers who were willing to be seen for five visits, were assessed once every three weeks for a fifteen week period. Subjects who were enrolled after the first full calendar month of the study received only one visit.
A screening log (Appendix F) was maintained for the purposes of recording data from subjects who were deemed ineligible or who indicated that they did not wish to be participate in the study.

**Data Collection**

**Braden Scale.**

1. An assessment was conducted at the initial visit and the results recorded on the Braden Scale form.
2. All assessments were conducted in conjunction with the subject’s primary nurse or regular registered nurse caregiver.
3. The means of pressure reduction were noted.
4. The source of moisture, if any, was noted.

**Barthel Index.**

An assessment of functional status was conducted at the initial visit and the results recorded on a copy of the instrument.

1. All assessments were conducted in conjunction with the subject’s primary nurse or regular registered nurse caregiver.

**Measurement of pressure ulcer stage**

For subjects with open wounds that were free from all necrotic tissue and slough, pressure ulcer stage was determined at the initial visit. For subjects with necrotic eschar covering the wound bed at the initial visit an assessment was completed using the Pressure Sore Status Tool. Staging was assessed when the wound bed was free from slough. Stable heel pressure ulcers covered with eschar were not staged.

1. Subjects whose wounds were healing were not staged. For these subjects, pressure ulcer healing was assessed using the Pressure Sore Status Tool.
Measurement of pressure ulcer healing.

Subjects willing to be followed for a fifteen week period were assessed once every three weeks for a possible total of five visits.

1. The average number of weeks from ulcer onset to the initial visit were determined from a survey of the clinical record.

2. At each visit, pressure ulcer healing was measured by obtaining a direct wound tracing and through the use of the Pressure Sore Status Tool.

3. To minimize the need for extra dressing changes, the researcher scheduled assessment visits to coincide with the subject’s regular dressing change. The dressing used in the management of the wound was noted.

**Pressure Sore Status Tool (PSST)**

1. Wounds were assessed using the PSST according to the instructions provided by the author, Dr. Bates-Jensen. Because this list is extensive and detailed, readers are referred to the document located in Appendix D of this chapter.

**Wound Tracings.**

Tracings were obtained using Op-Site Flexigrid and an ultra fine tip indelible marker, Sharpie brand.

1. For wounds that were debrided or were being debrided, a tracing was obtained unless the skin surround the ulcer was macerated, the surrounding skin was otherwise impaired, or the site was painful. For subjects willing to be followed for five visits, wound tracings were obtained every three weeks for a fifteen week period. To avoid disrupting the protective eschar covering stable ulcers, wound tracings were not obtained from these wounds.

2. Only one tracing was obtained at each visit.
3. To promote consistency of findings, subjects were placed in the same position for each wound tracing measurement.

4. Tracings were analyzed using the Mouseyes Program as soon as possible following the visit and the results recorded on the tracing. Each tracing was analyzed three times and the average of the three measures reported as the best estimate of surface area.

Measurement of stable heel pressure ulcers.

Stable ulcers were measured with a hand held ruler and estimates made of length and width of the eschar.

1. To promote consistency of findings, subjects were placed in the same position for each measurement.

Data Analysis Plan

According to Burns & Grove (1993), exploratory data analysis and descriptive statistics are appropriate for pilot and descriptive level research. Therefore, descriptive statistics and tables were used to describe the number of identified subjects, their ages, the total number of ulcers, their sizes, stages, and the distribution of ulcers over the medial, lateral and posterior surfaces of the heel. The means of pressure reduction were listed and categorized. Braden Scale scores, medical diagnoses and prescribed medications were described. Stable ulcers were described in terms of their average dimensions (length and width). The time required for completion of each wound healing assessment was summarized using descriptive statistics. Barriers to recruitment were listed and categorized.

Heel pressure ulcer healing was analyzed using exploratory and descriptive statistics. For subjects whose ulcers reduced in size to one square centimetre, the time in weeks from ulcer onset to reduction in size to one square centimetre and to closure was determined and
summarized. The products used in topical management and in reducing pressure at the heel were described. Heel pressure ulcer healing was described on the basis of percent change in surface area. For the two subjects who were followed for fifteen weeks, the approximate time to 25, 50, 75 and 100% reduction in surface area was estimated.

To assess the reliability of the Mouseyes Program as an index of healing, the average size of the ulcers at the initial and all subsequent assessments was assessed, as was the point at which ulcers diminished in size to one square centimetre. Problems experienced in obtaining tracings or in using the Mouseyes Program were detailed.

Finally, logistical problems encountered during the pilot study were detailed and analyzed.

**Limitations**

The pilot feasibility study has the following limitations:

1. It provided an estimate of the number of cases of heel pressure ulcers in only a selected geographical area in a four month period.

2. The Mouseyes program was previously untested in heel pressure ulcers.

3. The proposed study used a sample of convenience and, as a consequence, the results may be biased.

4. At this point in time, it is not possible to be absolutely certain that the heel ulcers identified as pressure ulcers are solely of pressure, shear and friction related origin.

5. Four months was not a long enough time to fully evaluate the natural course of healing for one of the subjects who was followed for this time period.

**Protection of Human Subjects**

Subjects rights to informed consent, privacy, confidentiality and freedom from harm were protected through the use of third party recruitment, the use of codes for subject
identification and study protocols for subject safety. Each of these provisions are detailed as follows.

Third party recruitment was utilized as described under Data Collection Procedures (p. 45). Referrals were received from key informants and from other parties only after a brief explanation of the intent of the study and a letter of introduction had been given to the subject (Appendix G) and/or substitute decision-maker (Appendix H) by the third party recruiter. Several of the subjects were cognitively impaired. For this reason, the substitute decision-maker was identified according to the policies of the agency in which the subject was residing or receiving treatment. Once the subject and/or substitute decision-maker expressed a willingness to participate, or to have their friend/family member participate, they were contacted by the researcher and further explanations given as appropriate. If the subject and/or the substitute decision-maker was willing to participate in the study, or to have their friend/family member participate, the consent form (Appendix I & J) was signed and witnessed. Three copies were made of the signed consent. One copy was given to the subject/substitute decision-maker, the other was provided to the agency to place on the subject’s clinical record. The original was retained by the researcher. Subjects and/or decision-makers were reminded of their right to withdraw consent at any time during the study.

Privacy/Confidentiality

To protect privacy and confidentiality, subjects were coded through the use of a number and surveys of the clinical record were restricted to documents relevant to the study. A coding sheet with the subject’s names and addresses was stored in a locked drawer in the author’s residence. For subjects who were seen more than once, a cross reference of subjects and coded data was maintained. The author’s copy of the signed consent form was stored in
the same location. Data Collection Sheets were stored separately. At the completion of the study and when all publications and presentations have been completed, all documents will be shredded. Documents in the clinical record that were surveyed included: medication profiles, notes pertaining to date of ulcer onset, health status at the time of and just prior to ulcer onset, lab data that describes nutritional status and records that describe and monitor wound status.

**Study Protocols**

To protect the right of subjects to freedom from harm, the study procedures were designed to safeguard the integrity of stable eschar, to avoid the introduction of potential pathogens into the wound and, to minimize the frequency of dressing changes. This was accomplished by avoiding the application of Op-Site to lesions covered with stable eschar and, by using a sterile product, Op-Site, to obtain wound tracings. In addition, wound measurements were timed to coincide with regular dressing changes. If evidence of maceration or other impairment of the surrounding skin was present, or if the site was painful, no tracing was obtained.

Prior to the initiation of the study, ethical review approval was sought and obtained from the ethics committees in the continuing care and acute care sectors of the Simon Fraser Health Region, and the Behavioural Research Ethics Board of the University of British Columbia.

**Conclusion**

An outline of the methods used to assess the feasibility of a study the healing norms of heel pressure ulcers over the age of 65 years has been provided. The research design, sampling strategy, data collection instruments, study limitations and procedures were identified as were the data analysis plan and procedures for the protection of human rights.
CHAPTER FOUR:
FINDINGS

As stated in Chapter One, the purpose of the study was to assess the feasibility of conducting a larger study designed to identify the norms of healing in adults aged 65 years and older with heel pressure ulcers. There were four objectives of the study. The first was to identify the number of older adults with full thickness heel pressure ulcers who were eligible and who could be recruited into the study. A second was to evaluate the extent to which the digitizing program “Mouseyes” could be utilized as a measure of healing in heel pressure ulcers. The third was to estimate the costs of a larger study and the fourth was to begin to describe the healing of heel pressure ulcers in a convenience sample of older adults. To facilitate reporting the study findings, the research questions are utilized as an organizing framework for the presentation of the findings. Through this process, a profile of subject characteristics is presented and the methods used in the implementation of the study are reviewed. This is followed by a summary of findings that describe the pressure reduction interventions used in managing subjects and a description of the pressure ulcer healing of study subjects. Study findings are discussed and interpreted in Chapter Five.

What Number of Adults Aged 65 Years and Older with Full Thickness Heel Pressure Ulcers can be Recruited as Subjects from the Simon Fraser Health Region During a Four Month Period?

A total of twenty-three subjects with heel ulcers were referred to the researcher between mid June and October 30 of 1998. All assessment visits occurred between June 23 and November 6, of 1998. A convenience sample of nine subjects were enrolled in the study. Fourteen subjects were ineligible. A profile of the characteristics of both the ineligible and
the enrolled subjects is presented in the sections of this chapter that follow. Subjects who refused consent, or who were deemed ineligible, are introduced first.

**Characteristics of Persons who Refused Consent or who did not Meet Eligibility Criteria**

Of the fourteen subjects who were referred to the researcher, but not enrolled in the study, six died before consent could be obtained and eight were ineligible. Of the subjects who were ineligible, one was younger than sixty-five years (21 years) and three had ulcers that fit the clinical picture of diabetic, mobility related ulcers. One subject had a methicillin resistant staphylococcus aureus infection and was excluded on that basis. Another was unable to turn or cooperate with study procedures. Two substitute decision-makers did not contact the researcher after being provided with an information letter. A third party recruiter reported that one substitute decision-maker refused consent because of a wish to not put their relative “through more”. Of the six subjects who died before consent could be obtained, three were referred from the extended care units on which they resided and three from various acute care units throughout the region.

**Enrolled Subjects: Profile of Characteristics**

The goal of the sampling plan was to obtain a sample of subjects whose ulcers were pressure ulcers rather than another type of chronic wound. Therefore, demographic data was collected to profile subjects as members of the population of persons at risk for pressure ulcers. As stated in Chapter One of this document, pressure ulcers typically occur in persons with a range of functional disabilities. According to Margolis (1995), pressure ulcers occur in individuals who are “malnourished” or have a reduced ability to feed themselves, are “mostly bed-or chair bound, often incontinent” and experience an altered level of consciousness (p. 28-10). To assess the extent to which subjects fit this profile, subjects were screened using the Braden Scale for Predicting Pressure Sore Risk (Braden Scale).
Functional status was measured using the Barthel Index. Also assessed was the subject’s age, gender, nutritional status and the number and type of medical diagnoses and prescribed medications. Data describing subject: age, gender, number and location of heel ulcers, Braden Scale scores, Barthel Index scores, nutritional status, number and type of medical diagnoses and prescribed medications is reported in the next several sections of this chapter. Through this process, it is demonstrated that each of the subjects fit the epidemiological profile described by Margolis (1995).

**Demographic data: age and gender.**

Subjects ranged in age from 70 to 90 years. The median age was 82 and the mean was 79.22 years. Five subjects were female, four were male (N=9). All were residents of the five extended care level facilities that are owned and operated by the Simon Fraser Health Region. Four subjects signed their own consent forms and, for five subjects, consent was obtained from their designated substitute decision-makers. One subject died within the first four weeks of enrollment in the study. Subject gender and the distribution of ages is displayed in Table One. Two of the nine subjects were assessed once every three weeks for a total of five visits. Seven subjects received only one assessment visit.

**Pressure ulcer stage, number and location of heel ulcers.**

Data describing the number of heel pressure ulcers, pressure ulcer location, age and gender of the enrolled subjects is displayed in Table 1. With the exception of one subject whose ulcer was located on the posterior aspect of the heel, all ulcers were located on either the medial or lateral surfaces. All ulcers were over the non-weight bearing surfaces of the heel, suggesting immobility related ulceration. Eight subjects had one ulcer each and one subject had two ulcers, one on each heel.
Table 1. Subject Age, Gender, Number and Location of Heel Pressure Ulcers.

<table>
<thead>
<tr>
<th>Subject Number and Age</th>
<th>Gender</th>
<th>Location</th>
<th>Number of Ulcers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 70</td>
<td>Female</td>
<td>left medial</td>
<td>1</td>
</tr>
<tr>
<td>2. 82</td>
<td>Male</td>
<td>right lateral</td>
<td>1</td>
</tr>
<tr>
<td>3. 86</td>
<td>Male</td>
<td>left medial</td>
<td>1</td>
</tr>
<tr>
<td>4. 82</td>
<td>Female</td>
<td>left posterior</td>
<td>1</td>
</tr>
<tr>
<td>5. 77</td>
<td>Male</td>
<td>Left: lateral</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Right: medial</td>
<td></td>
</tr>
<tr>
<td>6. 90</td>
<td>Female</td>
<td>right lateral</td>
<td>1</td>
</tr>
<tr>
<td>7. 70</td>
<td>Male</td>
<td>right lateral</td>
<td>1</td>
</tr>
<tr>
<td>8. 73</td>
<td>Female</td>
<td>left medial</td>
<td>1</td>
</tr>
<tr>
<td>9. 83</td>
<td>Female</td>
<td>left lateral</td>
<td>1</td>
</tr>
</tbody>
</table>

Ulcers were assessed to determine whether they were partial or full thickness wounds. Each ulcer was assessed using the Pressure Sore Status Tool (PSST) and, if the wounds were free from necrotic tissue, they were staged using the National Pressure Ulcer Advisory Panel Pressure Ulcer Staging System. Seven subjects had full thickness ulcers. Of this group of seven, six had eschar covering their ulcers and scores greater than 31 on the PSST, suggesting that the ulcers were full thickness wounds. The ulcer of one subject was free from necrotic tissue and was assessed as a Stage 3, or full thickness ulcer. Of the remaining two subjects, one had a partial thickness ulcer (Stage 2) and one had an almost completely healed ulcer. Of the six subjects with eschar covering their ulcers, two had stable ulcers and four had unstable ulcers. Stable ulcers are those that are covered with desiccated black eschar, but show no sign of erythema, drainage or pain. Unstable ulcers are those with desiccated or softening eschar and evidence of drainage, erythema and/or pain.
Scores on the Braden Scale for Predicting Pressure Sore Risk.

The Braden Scale for Predicting Pressure Sore Risk is a pressure ulcer screening instrument comprised of six subscales (see Appendix B). The subscales measure levels of mobility, activity, nutritional intake, sensory perception, the presence of moisture against the skin and the potential for friction and shearing. "All subscales are rated from 1 (least favourable) to 4 (most favourable), with the exception of the friction and shear subscale, which is rated from 1 to 3. Potential scores range from 6 to 23. Lower scores are indicative of higher risk" (Bergstrom, Braden, Kemp, Champagne & Ruby, 1996, p. 23). A summary of the distribution of Braden Scale scores is reported. To provide a more detailed profile of study subjects, this is followed by a summary of scores on each subscale of the Braden Scale and a review of subjects' pressure ulcer history and the presence of co-existing ulcers.

The distribution of Braden Scale scores ranged from 10 to 16. The median score was 14, and the mean was 13.56. Two subjects received a score of 10 points and one of 12 points. The remainder of the scores were distributed at two each for 14, 15 and 16 points (see Table 2). Therefore, all scores were below the operationally defined Braden Scale risk cut score of 18 for residents of extended care, indicating that all subjects were at risk for pressure ulcers.

A summary of scores for each subscale of the Braden Scale is useful in providing a more detailed account of the pressure ulcer risk profile of subjects and in characterizing them as members of the population of persons who develop pressure ulcers. In relation to the mobility subscale, all subjects were chair bound (score of 2). Moisture was a problem for all subjects. This is evidenced by the fact that six subjects were rated as occasionally moist (score of 3) and three as very moist (score of 2). On the remaining subscales of the Braden Scale, seven of the nine subjects were rated as slightly limited on the sensory perception subscale (score of 3) and two as very limited (score of 2). On the friction and shear subscale,
seven of the nine subjects were reported to have a potential problem (score of 2) and two were reported to have an actual problem (score of 1). On the nutritional intake subscale, three subjects received a score of very poor (score of 1), four were rated as probably adequate (score of 2) and two as excellent (score of 4).

Further evidence that subjects were members of the target population is that five subjects had a previous history of pressure ulcers and two had both a previous history of pressure related breakdown and co-existing ulcerations over boney prominences other than the heel. One subject had a co-existing pressure area over the ischium, the second had a sacral ulcer and the third had two additional pressure areas, one over the ankle and one over the sacrum (see Table 2). The Braden Scale scores for subjects with co-existing ulcers were 12, 14, and 15 points respectively.
Barthel Index Scores.

The Barthel Index is a measure of the extent to which a person is dependent upon others in satisfying needs related to basic activities of daily living (ADL) (Novak, Johnson, & Greenwood, 1996). The Index is designed to be completed using medical records data or direct observation (McDowell & Newell, 1987). Ten activities are assessed including: feeding, transfer abilities, personal hygiene and grooming, getting on and off toilet, bathing self, walking, ascending and descending stairs, dressing, and controlling bowels and bladder. The overall scores range from 0 to 20, with 0 representing the greatest disability and 20 the greatest independence (Novak, Johnson, & Greenwood, 1996). Using a similar process as for the Braden Scale, a review of the enrolled subjects’ total scores on the Barthel Index is reported. This is followed by a summary of the scores on each of the subscales of the Barthel Index.

Barthel Index scores for each of the subjects ranged from a total of 0 to 12 points, with a median of 3 and a mean score of 4.11. Scores for six subjects were indicative of severe functional deficits: four subjects scored zero, one scored 3 points and another, 4 points. Three subjects received comparatively higher scores of 8, 10, and 12 respectively, indicating more moderate levels of impairment.

Data describing the abilities of subjects on each of the Barthel Index subscales provides a more detailed picture of the impaired functional status of the group of study subjects. None of the subjects were able to manage stairs. All were dependent for bathing. None of the subjects were independent for dressing, although two could do about half unaided. Only one subject, subject eight, was independent for both grooming and transferring between bed and chair, the remainder were dependent for both functions. Three of the nine subjects (four, five and nine), were able to eat independently. Four subjects (four, five, seven
and eight) were continent of bowel and three of bladder (four, seven and eight), but only one, subject eight, was fully independent in toileting and another required assistance in completing this function.

**Nutritional status.**

Data describing nutritional status was collected because as reported in Chapter Two, researchers correlate impaired nutrition with reduced tissue tolerance to pressure related injury. Malnutrition was operationally defined in terms of serum albumin values, TLC values and weight loss. Serum albumin values were not available for any of the subjects, but data descriptive of at least one parameter, weight trend, or total lymphocyte counts (TLC) was available for eight of the nine subjects (see Table 3). Not unexpectedly, the clinical records for five subjects revealed evidence of significant weight loss meeting the definition for malnutrition (5% of body weight in one month, or 10% in six months). In contrast, the records for two subjects (five and seven) did not show a weight loss trend. Weight loss data was not available for two subjects (eight and nine). TLC data was available for four subjects (see Table 4). For only one subject did the TLC value fall below the equivalent of 1,800/mm³, a marker of malnutrition¹. Subject nine was reported to have a TLC count of 0.9 × 10⁹/L. Three subjects (subjects five, six and seven) had TLC values above 1.8 × 10⁹/L. One subject, subject six, had a value of 1.9 × 10⁹/L. While this latter value is above the established parameter for malnutrition, there was documented evidence of weight loss meeting the criteria for malnutrition. Subjects five and seven had TLC counts of 2.2 and 3.6 × 10⁹/L respectively. Of note is the fact that despite apparently adequate nutrition as indicated by a TLC value of 2.2 × 10⁹/L and the absence of a pattern of weight loss,

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¹Readers should note that a TLC of 1,800/mm³ is equivalent to 1.8 × 10⁹/L, the values used in Lower Mainland laboratories (Dr. Jacques Roy, personal communication, November 2, 1998).
Table 3. Parameters Descriptive of Nutritional Status Among Enrolled Subjects.

<table>
<thead>
<tr>
<th>Subject #</th>
<th>Total Lymphocyte Count</th>
<th>Evidence of Weight Loss (5% in one month, or 10% in six months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>not available</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>not available</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>not available</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>not available</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>2.2 X 10⁹/L</td>
<td>No</td>
</tr>
<tr>
<td>6</td>
<td>1.9 X 10⁹/L</td>
<td>Yes</td>
</tr>
<tr>
<td>7</td>
<td>3.6 X 10⁹/L</td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>not available</td>
<td>not available</td>
</tr>
<tr>
<td>9</td>
<td>0.9 X 10⁹/L *</td>
<td>not available</td>
</tr>
</tbody>
</table>

*values below 1.8 X 10⁹/L are indicative of malnutrition

subject five had co-existing pressure ulcers at multiple sites: both heels, the sacrum and the lateral malleolus. Similarly, the data for subject seven does not show a weight loss pattern consistent with malnutrition despite a recent history of pressure related breakdown.

**Number of medical diagnoses and prescribed medications.**

Subjects had between three and six medical diagnoses and were prescribed between three and nine types of medications. Unfortunately, this data is limited by the method used to categorize diagnoses and prescribed medications on the data collection form. In future studies, the actual medications and diagnoses should be recorded and if necessary, categorized during the reporting of the study findings. More detailed information relating to subjects diagnoses and prescribed medications can be found in the descriptions of pressure ulcer healing in the following section of this paper and on pages 73-80.
Of the Adults Aged 65 Years and Older with Full thickness Heel Pressure Ulcers, What Number have Stable Ulcers and What Number Become Unstable During the Four Month Study?

This question was asked because although experts advise that stable heel pressure ulcers need not be debrided, a research base documenting how long such ulcers remain stable and the outcomes of this approach is lacking. In addition, there was no evidence to suggest the extent to which clinicians had integrated this recommendation into practice. This lack of knowledge stimulated the author to try to generate data.

Of the enrolled subjects (N=9), two were identified as having, and one as having had, a stable heel pressure ulcer. Of the subjects with stable ulcers, all met the criteria for stability in that their ulcers were without inflammation of the surrounding tissue, pain or drainage. For one subject, subject one, the eschar covering what had apparently been a stable ulcer sloughed the week prior to the assessment visit and healing was almost complete. No subjects with stable ulcers were seen for more than one visit. This was because two subjects were enrolled after the end of the first full month of the study (the cut point for enrolling subjects to be followed for four months) and one died shortly following the first visit. Therefore, the question “What number of stable ulcers become unstable during the four month study” remains unanswered.

However, in the paragraphs that follow, some data relating to the clinical course of stable heel pressure ulcers is reported. While this data is limited, the healing course of subject one is noteworthy because almost complete healing had occurred by the time the eschar sloughed. For the remaining two subjects, the time frames through which the ulcers remained stable is clinically interesting because it provides some documentation of the length of time these relatively large ulcers remained stable. To provide a picture of the health and
functional status of each subject, such data as the Braden Scale score, Barthel Index, nutritional status, medical diagnoses and types of medications prescribed is provided.

According to health records, Subject One, a 70 year old female, was noted to have black eschar on the posterior medial aspect of the left heel, on April 22, 1998. Notes in the health record indicated that eschar sloughed on June 17, seven weeks following ulcer onset. When seen by the investigator June 23, almost nine weeks after ulcer onset (62 days), the score on the Pressure Sore Status Tool was 15 out of a possible total score of 65 points, indicating almost complete healing (a score of 13 is indicative of complete healing). The ulcer size had diminished to an estimated surface area of 0.2 cm$^2$. The wound was managed using a transparent film dressing. The subject’s Barthel Index score was zero and the score on the Braden Scale was twelve. Co-existing pressure ulceration was noted over the ischium. Medical diagnoses included cardiac and neurodegenerative processes, cerebrovascular accident and depression. Prescribed medications included the following agents: anti-Parkinson’s, antimicrobial, antidepressant and a variety of laxative agents. A weight loss pattern meeting the operational definition for malnutrition was noted. Given the subject’s malnourished status, the relatively short time frame for almost complete pressure ulcer healing could suggest that the wound was a borderline full thickness wound.

Subject Four, an 82 year old female diabetic, was noted on her health record to have a necrotic area over the left heel, posterior aspect on May 27, 1998. Medical diagnoses included: a cardiac history, diabetes, hypertension, sepsis and depression. Prescribed medications included the following agents: antidiabetic, antihypertensive, antimicrobial, cardiac, antipsychotic, laxatives, electrolyte replacement agents, nutritional supplements and an analgesic. The Barthel Index Score was 10 and the Braden Scale 14. The subject had both a previous history of pressure ulceration and had co-existing ulceration of the sacrum. At the
time of the investigator's assessment visit on July 25, eight weeks after onset (58 days), the eschar was intact and covered a surface area of 15 cm$^2$, a relatively large area. The wound was managed with Cicatrin powder and a dry gauze dressing. The PSST score was 35, suggesting a moderately severe wound. Although the subject consented to be followed for five visits to monitor stability of the eschar, further visits were not possible. The subject developed acute congestive heart failure, was too ill to be seen at the time of the second visit, and died shortly thereafter.

Subject Eight, a 73 year old female, developed necrotic tissue over the left heel, medial aspect, on August 27, 1998. When seen on November 6, 10.3 weeks later (72 days), the eschar was stable, although the edges were beginning to lift. The PSST score was 34 and the eschar covered a relatively large surface area of 15 cm$^2$. The ulcer was managed using a dry gauze dressing to protect the eschar. The subject's score on the Braden Scale was sixteen and the Barthel, twelve. There was no documented previous history of pressure ulceration and no evidence of pressure ulceration at any site other than the heel. Medical diagnoses included: cardiac and neurodegenerative processes, hypertension and depression. Prescribed medications included the following agents: antihypertensive, antidiabetic, anti-Parkinson's, antidepressant and laxatives.

*What Barriers are Encountered in Identifying and Recruiting Older Adults with Heel Pressure Ulcers?*

The barriers encountered in identifying and recruiting subjects are reported. On a more positive note, so also are the circumstances surrounding occasions when recruitment efforts were particularly successful.

Three main barriers were encountered in identifying and recruiting subjects. First, the primary barrier to recruitment was lack of access to subjects. The researcher was required to
contact the managers on each unit prior to approaching the clinical contact persons.

Although repeat telephone calls were made to several managers explaining the purpose of the study, some managers either did not follow through on a promise to return the call, or did not respond to calls placed to them. Second, some subjects were not identified soon enough after ulcer onset. This is illustrated by the fact that the time between ulcer onset, third party referral and the initial visit, ranged from 6 to 77 days (mean 40.4 days). This is a problem that must be addressed in future studies if pressure ulcer healing is to be described from the time of ulcer onset to the time of complete healing. One reason given for late referrals was workload. Two of the clinical resource staff who were used as contacts stated they had little time to assist with recruitment of subjects. Both indicated that identifying and contacting substitute decision-makers was too time consuming a task. A third barrier was posed by the fact that recruitment tended to be less successful when the researcher canvassed contacts over the telephone. This was a barrier because of the logistics of making frequent visits to all contact persons at all sites. Unfortunately, the time spent in terms of travel, telephone calls and canvassing of contact persons was not logged, and therefore, accurate data is not available. However, it is estimated that recruitment activities occupied between three to ten hours per week.

Recruitment tended to be more successful when the clinical contact persons expressed interest in the study. A number of potential subjects were identified by an enterostomal therapist in the region who did consultations in several sites. It was noted that managers were more receptive to the study when the researcher could assert that the subject had been identified by the enterostomal therapist. This facilitated access to a unit at a site where lack of access was a problem.
What is the Average Time Required per Visit for Data Collection?

Data describing the time required to complete the assessment visits was collected for the purposes of estimating the costs of a larger study. A total of 17 data collection visits were made. Nine were initial visits and eight were follow-up visits made to the two subjects who were followed for fifteen weeks. The data describing the time requirements for data collection, travel and mileage is provided in the paragraphs that follow. Also included is a summary of the factors that contributed to the variation in time requirements and a review of the difficulties encountered in the scheduling of visits.

Round trip travel time for all visits (initial and follow-up) ranged from a minimum of 23 to a maximum of 74 minutes. The mean travel time was 40.33 minutes. The round trip mileage ranged from 13 to 74 kilometres, the mean number of kilometres per trip was 36.11.

Data collection time varied according to visit type: initial or follow-up. The time required for the initial visit (including wound assessment and completion of Braden Scale and Barthel Index) ranged from 25 to 105 minutes. The mean was 58.11 minutes. The initial visit that required only 25 minutes was comparatively short because the subject was known to the researcher and data was readily accessible. If this one visit is considered an outlier and removed from the calculation of the mean, the average time required for the remaining eight initial assessment visits is 62 minutes. For follow-up visits, time requirements ranged from 35 to 80 minutes, with a mean of 47.50 minutes.

Several logistical factors contributed to the variability in data collection time. The main factor was the length of time required for staff to be ready to do the dressing in order that the wound assessment could be completed. Although arrangements were made prior to the visit, with the unpredictable nature of the work on nursing units, staff were often not ready at the designated time. Other factors that contributed to the variability included the
degree of difficulty experienced in positioning the subject, the number of ulcers, whether or not a tracing was obtained, the accessibility of information in the clinical record and the availability of staff to assist in completion of the Braden Scale and Barthel Index. An additional factor was the length of time it took to establish rapport with staff and subjects. Finally, another was the need of some subjects for information about the etiology of their ulcers and healing progress. One subject, subject five, required more time because of an expressed need to see evidence of healing in terms of a comparison of previous tracings and diminishing scores on the Pressure Sore Status Tool.

The scheduling of data collection visits to coincide with planned dressing changes represented a significant logistical problem. There were two reasons for scheduling visits in this manner. The first was the need to avoid unnecessary disruptions to the healing process. The second was that, for cost containment purposes, approval to conduct the study in two facilities was granted on the condition that extra dressing changes be avoided. As a consequence of these restrictions, scheduling of assessments was challenging and necessitated flexibility and perseverance because staff were not always able to accurately predict when a dressing change would occur. As a result, a number of assessments were done off hours and on weekends, a factor to consider when budgeting for staff costs.

*What is the Average Size of the Identified Heel Pressure Ulcers at the Time of the Initial Assessment?*

Data describing the average size of the heel pressure ulcers at the time of the initial visit was collected because a limitation of the Mouseyes Program is that it has a measurement error of plus or minus ten percent when used for images of one square centimetre or smaller. It was thought that this magnitude of error would render the Mouseyes Program not useful if most ulcers were small at the outset. Therefore, the researcher wished
to generate some data describing the average size of heel pressure ulcers. Because some measures of surface area were made on the basis of Mouseyes analysis and others were made using a ruler based estimate, data for the two types of measures is presented separately. Data for estimates of surface area taken from tracings is presented first and followed by that of ruler based data. Finally, the reasons for the high number of ruler based estimates are reported.

Wound tracings were taken at the initial visit for three subjects. All tracings were analyzed soon after they were obtained. Each tracing was digitized a total of three times and the average of all three measures is reported as the surface area. The recorded surface areas for the three subjects were: 2.71 cm$^2$, 4.35 cm$^2$ and 4.46 cm$^2$. The average area was 3.84 cm$^2$. The ulcer measuring 2.71 cm$^2$ was a partial thickness ulcer, the remainder were full thickness ulcers.

The full thickness ulcers of six subjects were measured using a ruler. Of these, the surface areas ranged from 0.2 cm$^2$ to 17.5 cm$^2$. The median was 9.0 cm$^2$ and the mean was 8.70 cm$^2$. The modal score (2) was 15 cm$^2$. Therefore, the data suggests that most heel pressure ulcers are larger than one square centimetre.

Ruler based measures were necessitated for several reasons. First, one subject was reluctant to have a tracing taken and when this hesitancy was not resolved through the researcher’s explanations, the right of the subject to decline the procedure was respected. Second, pain at the site or in the surrounding tissue precluded obtaining wound tracings for two subjects. Third, for one subject, a tracing was not obtained because the wound was small, and the edges indistinct. Fourth, for two subjects the eschar covering the ulcers was stable, and therefore, wound tracings were contraindicated.
What is the Average Number of Weeks from Ulcer Onset to Reduction in Wound Size to One Square Centimetre?

The purpose of collecting data to describe the average number of weeks from ulcer onset to reduction in size to one square centimetre was to assess the utility of the Mouseyes Image Digitization Program in measuring heel pressure ulcers. Since the rate of heel pressure ulcer healing was unknown, the primary intent in asking this question was to estimate the length of time Mouseyes could be used to measure heel pressure ulcers. As previously stated, the Mouseyes Program has an error rate of plus or minus ten percent when used to measure images of one square centimetre or smaller. For this reason, data descriptive of the number of weeks for ulcers to reduce in size to one square centimetre was collected.

However, the task of estimating the average number of weeks for reduction in wound size to one square centimetre was limited by two factors. The first is that only two subjects were followed for a fifteen week period and no conclusions can be drawn from this small a sample. The second is that these two subjects were seen once every three weeks. With such a long interval between visits, it is not possible to say precisely when wounds diminished in size to one square centimetre. Therefore, the estimate is a rough one. The time in weeks included: subject 2, eleven weeks (81 days), and subject five, fifteen weeks (108 days). In summary, the average time for the two subjects wounds to reduce in size to one square centimetre, was 13.7 weeks (94.5 days).

What is the Degree of Correlation Between Estimates of Surface Area Obtained Through the use of Mouseyes and the Scores that result from the Pressure Sore Status Tool (PSST)

The intent in collecting this data was to assess the construct validity of the PSST and the utility of the Mouseyes Program in measuring pressure ulcer healing. However, correlations between estimates of surface area and PSST scores have not been calculated because of the small sample size and the limited number of data points.
What is the Feasibility and Usefulness of the Image Digitization Program “Mouseyes” in Measuring the Surface Area of Heel Pressure Ulcers?

According to the originator of the Mouseyes Program, impending changes to the Mouseyes Program will increase the sensitivity of the program for measuring small images (Dr. Taylor, personal communication, January 4, 1999). Therefore, in view of the planned improvements to the program and the limited data collected during the pilot study, an assessment of the utility of the current version of Mouseyes is less relevant at this time. However, if Mouseyes is used in future studies, for reasons introduced below, it is important that it not be used in conjunction with Op-Site Flexigrid.

The task of obtaining and analyzing the tracings was complicated by the challenges experienced in managing the Opsite-Flexigrid. The nature of the difficulties with the Op-Site Flexigrid can be attributed to two factors. First, the margins of some wounds could not be visualized through the green tinge of the grid layer. The tint also made it difficult to visualize the Mouseyes cursor when digitizing the irregular margins of some wound tracings. This problem was overcome by maximizing the background lighting on the VGA monitor screen, but a more transparent material would translate to greater accuracy during image analysis. Second, the two layers of the Flexigrid dressing were difficult to separate after the dressing was removed from the wound. The adhesive of the wound contact layer stuck to the researchers gloves and to the top layer of the dressing. This made it difficult to maintain body substance precautions while separating the layers.

Pressure Reduction Interventions

In this section, a summary is presented of the strategies utilized in reducing pressure on the heel. Although this data is also included in descriptions of pressure ulcer healing detailed elsewhere in this chapter, it is summarized to provide the reader with an overview of the interventions used in reducing pressure to the heels of study subjects. The significance of
this data for future studies is discussed in Chapter Five. Data from subjects who were assessed once only is presented first and data from subjects who were assessed once every three weeks for fifteen weeks follows.

In terms of pressure reduction strategies, with the exception of subject eight who had no pressure reducing devices in use, some means of pressure reduction was evident for all subjects. Pressure reducing foam mattresses were evident on the beds of five subjects. For five subjects, local pressure reduction was provided by suspending the heels from a pillow. Other strategies included gel socks (1), and sheepskin (1) or quilted boots (1). For one subject, subject four, there was only one means of pressure reduction, heels suspended from a pillow. This was despite the fact that there was evidence of pressure not just at the heel, but also at the sacral site.

For subjects two and five who were followed for five visits for the purposes of describing pressure ulcer healing, there was variability in the strategies used for local pressure reduction. Foam pressure reducing mattresses were maintained for both subjects throughout the course of the study. For subject two, additional strategies included suspension of the heels from a pillow, or the use of a pillow and either a sheepskin or quilted boot. The use of sheepskin boots was noted for two of the five visits to subject 5.

**Pressure Ulcer Healing**

One purpose in conducting this pilot feasibility study was to begin to generate normative data. Although this objective cannot be satisfied because of the small sample size, the data describing pressure ulcer healing is important in that it represents a starting point in documenting objective observations of the healing of heel pressure ulcers. This data is presented in the next two sections of this chapter. Data for four subjects who were assessed on a one time basis is reported first. Although this data is limited, it contributes some
information relevant to the progress of these wounds through the markers of pressure ulcer healing. Following this, data describing the healing course of the two subjects who were followed for fifteen weeks is presented. Data for the three subjects with stable heel pressure ulcers was presented in an earlier section of this chapter. Pressure ulcer healing is described in terms of ulcer size (surface area) and Pressure Sore Status Tool (PSST) scores. To provide readers with a more comprehensive picture of each subject, the subject's age, gender, Braden Scale and Barthel Index scores, previous history of pressure ulcers, nutritional status, medical diagnoses, and prescribed medications are reported. Also included are the topical treatment and means of pressure reduction.

Pressure Ulcer Healing in Subjects Seen Once Only

Data for the four subjects who were assessed on a one time basis is reported. One subject was seen only once because the ulcer was a partial thickness ulcer and the wounds of interest in the study were full thickness ulcers. For the remaining three subjects, this was because recruitment did not occur until after the cut-off point for entering subjects to be followed for fifteen weeks had elapsed. Each subject is introduced and briefly described.

Subject Three, an 83 year old male, was seen July 9, eight days after ulcer onset on July 1. The wound size, as estimated from a tracing, was found to be 2.71 cm$^2$. The ulcer was assessed as Stage 2, a partial thickness ulcer. The PSST score was 20 out of a possible total of 65 points. The ulcer was free from necrotic tissue, drainage was non-existent and approximately 25% of the wound was covered with new epithelial tissue. The ulcer was managed with transparent film. Pressure reduction strategies included a high density foam mattress, suspension of the heels from pillows and the use of "gel socks". The score on the Braden Scale was fourteen out of a possible total of 23 and on the Barthel Index, zero out of a possible total of 20 points. There was evidence of weight loss meeting the operational
definition for malnutrition and a previous history of pressure ulcers. Medical diagnoses included a cardiac condition, hypertension and a cerebrovascular accident. Prescribed medication included cardiac, anticoagulant and analgesic agents.

Subject six, a 90 year old female, was assessed August 20, eighteen days after ulcer onset on August 2. The wound bed was obscured by soft black necrotic eschar. A tracing was not obtained because manipulation of the area appeared to cause discomfort. The wound measured 5 cm in length and 3 cm in width (surface area 15 cm²). The total score on the PSST was 43, a moderately severe wound. Drainage was purulent in nature, moderate in quantity. Treatment was directed at promoting autolysis using a hydrogel and a foam dressing. A high density foam mattress was in place on the bed and Spenco, or quilted boots, were applied to the feet. The Braden Scale score was ten and the Barthel Index score was zero. There was no previous history of pressure related breakdown. However, there was evidence of weight loss meeting the operational definition for malnutrition. Medical diagnoses included cardiac, metabolic and neurodegenerative processes. Prescribed medication agents included an anti-microbial, an antihypertensive, an anticoagulant and a nutritional supplement.

Subject seven, a 70 year old male, was seen August 29, approximately five days after ulcer onset on August 24. This ulcer may have existed for a longer time as the subject was reported to be resistant to staff inspecting or handling his foot on his hemiplegic side. The day the ulcer was first documented in the clinical records, staff reported having to remove maggots from the wound. A tracing was not obtained because the tissues on the subject's hemiplegic side were hypersensitive secondary to stroke induced neuropathy. The ulcer measured 1.5 cm in length, and 1.0 cm in width (surface area 1.5 cm²). It was assessed as a stage three ulcer, a full thickness wound. The PSST score was 33, also suggesting a full
thickness wound. Granulation tissue was evident in the wound bed and filled less than or equal to 25% of the wound bed. Induration around the wound was less than 2 cm but this assessment was difficult because of the hypersensitivity. Exudate was small in quantity and purulent in nature. The wound was managed using a hydrogel covered by telfa. The subject’s Barthel Index score was eight and the Braden Scale score was sixteen. There was no evidence of malnutrition as measured using the operational definitions. Pressure reduction strategies included a high density foam mattress and suspension of the heels from a pillow. Medical diagnoses included a cardiac history, diabetes, hypertension and a cerebrovascular accident. Prescribed medications included the following agents: antihypertensive, antidiabetic, and antimicrobial. There was a previous history of pressure ulcers.

Subject nine, an 83 year old female was seen November 6, 44 days or six weeks following ulcer onset on September 23. The wound surface area was estimated to be 3 cm$^2$ and could not be staged because the wound bed was obscured by loosely adherent yellow slough. The PSST score was 34 out of a possible total of 65 points. A tracing was not taken because the subject was hesitant to do so and the subject’s wishes were respected. The exudate was serous in nature, small in quantity. The surrounding skin was reddened, but there was minimal edema and induration around the wound. The wound was treated with an enzymatic debriding agent, collagenase, and a gauze dressing. The subject scored fifteen on the Braden Scale and a total of three on the Barthel Index. The subject’s TLC was reported to be 0.9 X 10$^9$ /L, meeting the operational definition for malnutrition. There were four medical diagnoses including diabetes, hypertension and depression. A repair of a hip fracture had been done within the previous two months. Prescribed medications included: bronchodilators, antihypertensives, antidiabetic, antiemetic, laxative, hypnotic, estrogen replacement and diuretic agents. A high density foam mattress was on the bed and heels
Pressure Ulcer Healing in Subjects Followed for Fifteen Weeks

Two subjects were followed for a fifteen week period. One subject had two ulcers (Subject Five), the other had one (Subject Two). Healing progress as measured by wound size, and Pressure Sore Status Tool (PSST) scores, is presented for each visit.

Subject Two

Subject Two, an 82 year old male, had a full thickness ulcer over the right heel. Medical diagnoses included: neurodegenerative processes, gastrointestinal stasis and depression. Prescribed medications included the following agents: antidepressant, gastrointestinal kinetic agents and analgesics. With the exception of the inclusion of an antimicrobial at the time of the second visit, no changes were made in the subject’s medication regimen throughout the course of the study. The Braden Scale score was 10 out of a possible total of 23 and the Barthel Index was 0 out of a possible total of 20 points. The Braden Scale and the Barthel Index assessments were not repeated at any of the follow-up visits for either of the two subjects. Weight loss meeting the operation definition for malnutrition was noted. There was a previous history of pressure related breakdown. Throughout the course of the study, pressure reduction interventions included a high density foam mattress, suspension of heels from a pillow and the use of Spenco, or quilted boots.

At the initial visit July 13, 12 days following ulcer onset on July 1, the wound was covered with firmly adherent, desiccated, black eschar. No tracing was taken. A transparent film dressing was in use to soften the eschar. Drainage was found to be purulent in nature and small in quantity. There was redness of the surrounding skin, non-pitting edema extending
less than 4 cm around the wound and induration less than 2 cm around the wound. The PSST score was 42 out of a possible total of 65 points.

The second visit occurred at five weeks, or 34 days following ulcer onset. The surface area, as measured from a tracing, was $4.35 \text{ cm}^2$. Greater than 50%, but less than 75% of the wound was covered with soft black eschar. Redness of the surrounding skin continued, the exudate remained purulent in nature and of the same quantity as the first visit. On the PSST, induration was less than 2 cm and there was minimal swelling around the wound. Granulation tissue was noted to fill less than or equal to 25% of the wound bed. The total score on the PSST was 37. Debridement continued using an enzymatic debriding agent (collagenase), with a cover dressing of telfa and gauze.

The third visit took place eight weeks, or 58 days after ulcer onset. Wound size had reduced to 2.56 cm², a reduction of 41% over the previous visit. Similarly, wound severity as measured by the PSST had declined to 28 from 37 at the previous visit. Less than 25% of the wound bed was covered by white/grey non-viable tissue, & or non-adherent yellow slough. Treatment had not changed from the previous visit. Exudate type remained purulent in nature and small in quantity. PSST scores for undermining, induration and edema, were minimal. Granulation tissue had increased in quantity to fill less than 75%, but greater than 25% of the wound bed. Epithelial tissue was evident and covered greater than 50% but less than 75% of the wound bed.

By the fourth visit, at 81 days, or eleven weeks after ulcer onset, wound size had diminished to less than one square centimetre (Mouseyes measure $0.861 \text{ cm}^2$, ruler measure one centimetre in diameter). This represented a change of 77% from the baseline surface area. All necrotic tissue was gone from the wound, the surrounding skin was normal in colour. Drainage was serosanguineous in nature, scant in amount. Undermining was less
than 2 centimetres, or minimal. Wound margins were attached with the wound base. The total PSST score had declined to 20. Treatment with collagenase continued with a cover dressing of Telfa. Granulation tissue had increased and was reported to fill between 75 to 100% of the wound bed. Epithelial tissue covered 75 but less than 100% of the wound and/or extended >0.5 cm into the wound.

At the fifth visit, 14 weeks, or 102 days after ulcer onset, the condition of the wound remained essentially unchanged since the previous visit. A ruler measure of the wound was 1.2 cm by 1 cm. The Mouseyes measure was .994 cm$^2$, or approximately, 1 cm$^2$. The PSST score had reduced one point to 19 from the previous score of 20. The difference from the previous measure related to the exudate type which had changed from serosanguineous to none or bloody. The treatment had changed to transparent film.

The healing of the heel ulcer of subject two is depicted graphically in Figure 2. Readers should note that the healing trajectory of both subjects appears linear.

Subject Five

Subject Five, a 77 year old male, was found to have two pressure ulcers, one on each heel. At the initial visit, the ulcer on the left heel was covered with necrosis. A healing ulcer with a score of 22 out of a possible total of 65 points on the PSST was noted on the right heel. Medical diagnoses included: cardiac pathologies, asthma and arthritis. Medication included the following agents: antimicrobial, cardiac, electrolyte replacement, nutritional supplement, antispasmodic and bronchodilator. There was both a previous history of pressure ulceration and co-existing pressure related ulceration on the right ankle and the sacrum. The Braden Scale score was 15 and the Barthel Index score was 4. The subject’s TLC value was well above the operational definition for malnutrition. Using the same process as for Subject
Two, pressure ulcer healing is described. The ulcer on the left heel is presented first, followed by that of the right heel.

**Left heel**

Subject Five was first seen 47 days (6.7 weeks) following ulcer onset. The size of the ulcer was 4.46 cm² and the PSST score was 42 out of a possible total of 65 points. The wound bed was obscured by loosely adherent yellow slough. The management of the wound was directed at autolytic debridement using a hydrophilic foam dressing and a hydrogel mixed with metronidazole, an antimicrobial agent. Undermining was less than 2 cm in any area. The nature of the drainage was foul purulent, moderate in quantity. The colour of the surrounding skin was white or grey pallor or hypopigmented (score of 3 on the surrounding skin subscale of the PSST). Scores for peripheral tissue edema and induration were minimal (score of 1 on each subscale of the PSST). No granulation tissue or epithelial tissue was
evident in the wound. A high density foam pressure reducing mattress was evident on the bed.

At the second visit, 67 days, or nine weeks after onset, the surface area had decreased to 3.2 cm$^2$, a reduction in surface area of 22% from the baseline measure. With the exception of wound size, all scores on the PSST were unchanged. The treatment also remained unchanged.

By the third visit, 87 days, or twelve weeks following ulcer onset, the surface area had reduced to 2.48 cm$^2$, a 44% reduction in surface area. The PSST score had reduced from 41 to 32 points. There was no necrotic tissue visible and pink or dusky red granulation tissue filled less than or equal to 25% of the wound bed. Less than 25% of the wound bed was covered with epithelial tissue. The wound margins were attached to the wound base and undermining was minimal (less than 2 cm in any area). Exudate continued to be purulent in nature, but the quantity had reduced from small to scant. Topical management was unchanged from the previous visit. In addition to the pressure reducing mattress, sheepskin boots were applied to both feet.

At the fourth visit, 108 days, or fifteen weeks after ulcer onset, the PSST score had reduced from 32 to 16 points (the score for a fully healed wound is 13 points). The wound appeared to be 100% covered with epithelial tissue. Therefore, no tracing was taken of the wound. A notation was made during this visit that the wound was difficult to classify on the PSST. The nature of this difficulty related to the continued presence of a small amount of slightly serosanguineous drainage, despite apparent closure of the wound. It is possible that some of this drainage may have come from the wound, or from an abrasion that was superficial in appearance and surrounding the wound. It is noteworthy that at this visit, the
subject had developed a new pressure ulcer over the sacrum. There was no evidence of the sheepskin boots utilized at the time of the previous assessment.

By the fifth visit, 136 days, or 19 weeks after ulcer onset, the PSST score was 13, indicating complete pressure ulcer healing. No tracing was taken at this visit. Readers are referred to Figure 2 in which the time to complete healing is presented graphically in Figure 1.

Right heel

When seen at the initial visit, 78 days or 11 weeks after onset, the score on the PSST was 22. A tracing was not taken because the edges were indistinct. The score on the PSST for size indicates a measurement of between 4 to 16 square centimetres. However, a more precise measure cannot be reported because the data was lost. The wound contained white/grey non-viable tissue &/or yellow non-adherent slough covering less than 25% of the wound. Drainage was serosanguineous in nature, scant in amount. The skin colour surrounding the wound was normal and peripheral tissue edema and induration were minimal. Granulation tissue was noted to fill 75 to 100% of the wound bed. The wound was epithelialized from 75 to less than 100 percent.

At the second visit, 98 days or 14 weeks following ulcer onset, the wound had deteriorated such that the PSST score had increased from 22 to 32 points. The wound edges had become distinct, the nature of the necrotic tissue had changed to loosely adherent yellow slough and covered 25 to 50% of the wound bed. Drainage was purulent in nature, scant in quantity. Less than 25% of the wound bed was covered with granulation tissue. Despite the fact that the wound had deteriorated as measured by the PSST, the wound size had diminished. The deterioration in the PSST score is accounted for by the change in the nature of the drainage, the percentage of the surface area covered by slough. A tracing was taken
and using Mouseyes, the surface area was estimated to be 0.860 cm$^2$. A ruler estimate of the length by width estimate of surface area was approximately 1.1 square centimetres. The treatment remained unchanged from the previous visit. Percent change in surface area has not been calculated because a precise measurement for the first visit is missing.

By the third visit, 118 days or 17 weeks after ulcer onset, the PSST score had reduced once again to a total of 22 points. No necrotic tissue was evident and the wound size had reduced to a ruler measure of 7mm by 7mm, or a surface area of 0.5 cm$^2$. The edges were distinct and the wound was 75 to less than 100% epithelialized. It was exuding a scant amount of serous drainage. The treatment remained unchanged from the first visit: hydrophilic foam and hydrogel with metronidazole.

At the fourth visit, 139 days or 20 weeks after ulcer onset, by a ruler measure, the wound had reduced in size to 0.3 cm in diameter. There was no drainage and the wound surface covered by epithelial tissue remained at 75 to less than 100 per cent. The treatment remained unchanged.

At the fifth and final visit, 24 weeks following ulcer onset, the PSST score was 14, one point off complete pressure ulcer healing. The wound appeared to be 100% covered with epithelial tissue, but a scant amount of drainage was apparent.

**Summary and Conclusion**

The research questions have been answered within the limits of the data. The study subjects have been characterized as members of the population of persons who develop pressure ulcers. Pressure ulcer healing has been described to the extent possible given the available data. The contrasts in the pattern of healing between subjects two and five are notable. The ulcer of subject two and the largest ulcer of subject five were of approximately the same size and degree of severity as measured by the PSST. However, the wound of
subject two was characterized by more rapid change initially, followed by a slowing of healing progress. For subject five, healing occurred at a slower rate at first, followed by a rapid reduction in size and closure of the wound. The contrasting patterns of the two apparently equivalent ulcers underscores the need for studies of the norms of pressure ulcer healing.

The fact that little data was gained in relation to the clinical course of stable heel pressure ulcers is disappointing. It is important that this need be addressed in future studies.
CHAPTER FIVE:
DISCUSSION

In this chapter, the findings of the pilot study are discussed. Included is an assessment of the feasibility of a larger study of the norms of pressure ulcer healing, an interpretation of the findings related to pressure ulcer healing and management and an evaluation of aspects of the study methodology. Finally, the implications of the pilot study for nursing practice, nursing education, nursing administration and health and social policy are identified.

Feasibility of a Larger Study of the Norms of Pressure Ulcer Healing

The assessment of the feasibility of a larger study of the norms of pressure ulcer healing was directed toward determining the number of subjects who could be recruited, the identification of barriers to recruitment and any logistical problems encountered in conducting the study. In addition, the utility of the Mouseyes Image Digitization Program was evaluated. A review of study data suggests that a large scale study of the norms of heel pressure ulcer healing is feasible if fiscal resources are adequate to hire staff to support recruitment efforts and to conduct the wound healing assessments. Because these costs will be significant, the justification and rationale for hiring personnel to facilitate these activities is discussed at some length. Finally, the utility of the Mouseyes Image Digitization Program is appraised.

Justification for Hiring Personnel to Assist with Recruitment Efforts

Identification and recruitment of subjects proved to be one of the greatest challenges experienced during the study. This is evidenced by the relatively small sample size. The nature of the challenges included a lack of access to potential subjects from some nursing units and an inability to identify subjects early enough in the healing process so that healing

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could be monitored and described over the course of the study. The following is a delineation and description of the implications of each barrier to future studies. Potential solutions that may be useful in resolving these barriers are proposed.

One solution to the problem of lack of access to potential subjects on some nursing units is to hire a research facilitator (s) who could work collaboratively with interested clinical nurse specialists, enterostomal therapists and other clinical resource staff. This would mean that future studies should only be implemented in agencies where an enterostomal therapist (ET) or a clinical nurse specialist (CNS) is willing to advocate on behalf of the study. Two groups of authors report success in using a facilitator role in conducting clinical research. Tranmer, Kisilevsky and Muir (1995) report that a research facilitator piqued staff interest and commitment to a research project in a neonatal intensive care setting. Miller, Johnson, Mackay and Budz (1998) report that, through fostering communication between researchers and staff, a research facilitator role was instrumental in generating support for their project amongst staff. This is notable because, as Miller et al report, the research project was conducted in a large tertiary care centre during a period marked by organizational restructuring, and therefore, a climate of change and uncertainty. In applying these successes to a study of pressure ulcer healing, the clinical nurse specialist or enterostomal therapist could be responsible for marketing the study with the managers and staff on the targeted units. With the unit gatekeepers on side, the facilitators could then work with staff and other clinical contact persons to identify subjects.

Second, it is possible that subjects could be recruited sooner in the healing process if research facilitators assumed responsibility for all recruitment activities including identification of subjects. As reported in Chapter Four, feedback from two clinical contact persons during the pilot study indicated that workload was a concern and, in particular, that
identifying substitute decision-makers of cognitively impaired subjects and distributing the
information letters was onerous. Miller et al (1998) reported that, in their experience, having
a research facilitator to coordinate recruitment activities was an effective strategy and was
one that was respectful of staff nurses workloads. These authors advise that when conducting
clinical research, it is important that the resources required to conduct a study be budgeted in
order that “nursing staff will not have to bear the burden of the study” (p. 215). It is unlikely
that an adequate sample can be attained in future studies if recruitment efforts fall to already
stressed staff nurses and clinical support personnel.

Justification for Hiring Staff to Conduct Wound Healing Assessments

A major logistical problem encountered during the pilot feasibility study relates to the
scheduling of wound healing assessment visits. This has important implications to the design
of future studies because, ideally, to capture the timing of such important markers of healing
as changes in the nature of exudate, or the beginning of wound margin attachment,
assessments should be done weekly. However, given the significant logistical problems that
were encountered in trying to complete wound healing assessments once every three weeks,
the nature of these challenges warrant some review. Two problems were encountered during
the pilot study in relation to scheduling of visits. Each are discussed in some detail.

First, the inability of staff to predict when dressing changes would occur posed a
logistical problem for scheduling of visits. Several factors can alter the timing of scheduled
dressing changes. One of the most obvious is that a dressing can fall off, be rubbed or pulled
off and require replacement in advance of the scheduled visit. Another is that wound
drainage may fluctuate, necessitating an extra change. Although it may be tempting to
request an extra dressing change to facilitate the scheduled research assessment visit, from an
ethical perspective, the researcher should do nothing to alter the healing of these
compromised subjects. Therefore, it is important that researchers have the time to devote to maintaining close contact with staff on the units so that opportunities are not missed. A research facilitator(s) hired on a full time basis should fulfill this need. The number of facilitators required is discussed in a later section of this chapter.

Second, during the pilot study, the researcher encountered delays when staff were not ready to do the dressing at the appointed time. This poses a challenge for scheduling of wound healing assessment visits because if one visit is delayed appreciably, it is probable that other visits scheduled for the same day will also be affected. While this may seem a problem that should be relatively easy to resolve, most subjects required two persons for positioning and with the narrow range of time available for staff to assist with this, it was not. For example, for staff nurses in continuing care settings, time for dressing changes is constrained by the demands of such operations as medication rounds and resident meals. A further limiting factor is the differing allocation of staff throughout the day; many facilities dedicate staffing to this function and thus, wound care only occurs between very circumscribed hours. Another is that assessments must be done when the subject is in bed in order that the wound may be adequately visualized. Hence scheduling is further restricted by the subject's social, therapeutic and recreational activities. It is possible that with a full time research facilitator, scheduling delays could be more readily accommodated. This would however, have implications for study costs.

Estimates of Costs: Implications for Personnel

During the planning phase of the pilot feasibility study, it was envisioned that an estimate of the time and travel requirements would provide the basis for projection of personnel costs. While this data provides some guidance for future studies, in view of the recruitment challenges and the logistical problems encountered with scheduling of visits, it is
the opinion of this author that it is not useful to base personnel projections on calculations of visit to visit costs. Instead, I believe this data is more valuable if it is applied to calculating the number of full time facilitators required.

Personnel costs will depend on several variables. These include the size of the sample and the number of sites that staff will need to travel between. In addition, according to a source in the Office for Nursing Research at the University of British Columbia School of Nursing, salary scales are dependent upon the source of funding (Janice Matawtia, personal communication, January 5, 1999). Therefore, it is difficult to give a precise estimate of the personnel costs at this time. However, some guidance for projecting personnel costs can be derived from data that describes the time that was required to complete the pilot study wound healing assessments. The average round trip travel time was 40.33 minutes, the average time for an initial visit was 58.11 minutes and for a follow-up visit, 47.50 minutes. Hence, on average for both types of visits, 40 minutes was required for travel and, for data collection, one additional hour. This means that unless several subjects could be seen at one site, a facilitator may need to devote almost two hours to complete one assessment. If the travel time could be reduced, significant cost savings could be realized. One way of reducing travel time is to cluster participating agencies into sectors based on geographic proximity. For example, if a future study is implemented cross regionally, aided by a part time facilitator on an as needed basis, one facilitator may be able to cover the Vancouver hospitals west of Fraser Street. Economies in travel time are important because wound healing assessments will need to be done by registered nurses, thereby necessitating a large budget for staff.

Although these figures are approximations, it is possible to make some preliminary projections of the overall cost of conducting a larger study. If independent research assistants are utilized for the study, allowing for a standard wage of eighteen dollars per hour
with an additional eighteen percent for benefits, the annual cost for one fulltime facilitator would be $41,970.24. Because it is likely that not all agencies will participate, it is possible that two facilitators hired on a full time basis over the course of one year to eighteen months could complete the study. The services of additional facilitators on an as needed basis may also be required depending on the number of interested agencies and the desired sample size. Therefore, if the study runs for eighteen months, this translates to an approximate cost of $125,900 for two full time personnel alone. The costs for part-time or casual personnel will need to be calculated once the number of participating agencies is known. A major advantage of having full time staff is that while it may not be logistically practical to do weekly assessments of wound healing for the entire sample, it may be possible for at least a subset.

Utility of the Mouseyes Image Digitization Program in Measuring Heel Pressure Ulcers

The primary purpose in evaluating the Mouseyes program for its utility in measuring heel pressure ulcers was because it was reported to have an error rate of plus or minus ten percent when used to measure images of one square centimetre or smaller. At the time the study proposal was conceived, the average size of heel pressure ulcers was unknown, as was the time required for ulcers to diminish in size to one square centimetre. Thus, the feasibility study was designed to include an assessment of the potential utility of the Mouseyes instrument. However, during a recent personal communication with Dr. Taylor (January 4, 1999), the originator of the Mouseyes Program, the author was advised that improvements to the graphics resolution capability of the program will occur sometime in 1999. It is expected that these changes will not only improve the accuracy of measurement for small images, but also the user friendliness of the calibration process and other operating procedures. With these changes, Mouseyes should be more than adequate for measuring the surface area of
heel pressure ulcers in future studies. However, the difficulties experienced in using Op-
Flexigrid require further comment.

If Mouseyes is used in future studies, it should not be used in conjunction with Op-
Site Flexigrid because the use of this product may have contributed to measurement error.
One reason for this was because the greenish tinge of the grid layer made it difficult to
visualize the irregular margins of some wounds when tracings were taken. A second is that
the green tinge made it difficult to distinguish the Mouseyes cursor when digitizing irregular
margins. In a study designed to evaluate wound measurement methods, Etris, Pribble and
LeBrecque (1994) reported that covering the wound with plastic topped with x-ray film was a
reliable method of obtaining a wound tracing. Therefore, it is the recommendation of this
researcher that a sterile transparent film dressing be used to cover the wound and that
tracings be obtained using precut pieces of clear overhead transparency film. This
modification will also result in improved infection control through eliminating the problem
of the two layers of the Op-Site Flexigrid sticking to each other on removal of the dressing.

Changes to Methodology for Future Studies: Points to Consider

Two additional methodological changes are recommended in the hope they will
provide guidance for future studies. First, experience gained in completing the pilot study
suggests that the target population of persons at risk could be more crisply defined by using
only the Braden Scale for Predicting Pressure Sore Risk (Braden Scale) when screening
potential subjects. Second, some difficulties were encountered in using and interpreting
qualitative data from the Pressure Sore Status Tool (PSST). The nature of the difficulties
with the PSST and the changes to subject screening procedures are described in the next two
sections of this chapter. Also included are recommendations for the design of future studies.
Through the process of introducing the recommended changes, implications for future research are identified.

**Defining the Target Population**

Overall, the characteristics of study subjects were consistent with Margolis' (1995) definition of the population of persons at risk for pressure ulcers. However, some contrasts are notable and these differences warrant comment because they provide the rationale for using only the Braden Scale to identify persons at risk for pressure ulcers. Also important is the fact that six potential subjects died before they could be enrolled and one died shortly following. Each of these concerns are reviewed in turn.

The primary purpose in using both the Barthel Index and the Braden Scale to screen potential subjects was to increase the certainty that the identified subjects did indeed have pressure ulcers rather than another type of chronic wound. While it is seemingly contradictory that two subjects with comparatively greater functional abilities and, therefore, higher Braden Scale scores also had pressure related breakdown, an explanation is offered from the findings of previous research. In a study designed to identify predictors of pressure ulcers in a group of 843 randomly selected subjects in tertiary care, veteran administration care centres and nursing homes, Bergstrom, Braden, Kemp, Champagne and Ruby (1996), identified the Braden Scale as the best predictor of pressure sore risk. The authors report that in the logistic regression model designed to identify predictors, activity and mobility were both strong predictors of pressure sore risk. Moreover, researchers warn that without prevention interventions, even subjects identified to be at lower risk on the Braden Scale have substantial rates of pressure related breakdown. Bergstrom and Braden (1992), define high risk on the Braden Scale as a score of 12 or below, moderate risk as between 13 and 15 and lower risk as 16 to 17. Braden (1998) warns that 50 to 60% of persons at low risk, 60 to
90% of persons at medium risk and 90 to 100% of persons at high risk will develop pressure ulcers. Since both the Braden Scale and the Barthel Index include mobility as a focus, it appears these instruments are measuring dimensions of the same phenomenon. Therefore, two measures are not required.

Further support for using only the Braden Scale to identify persons with heel pressure ulcers is drawn from research done by Tourtual et al (1997) who identified that two subscales of the Braden Scale were the best predictors of heel pressure ulcer risk. These were the moisture and friction and shear subscales. In the pilot feasibility study, seven of the nine subjects were reported to have a potential problem and two were reported to have an actual problem with friction and shear. Similarly, all subjects were identified as having a problem with moisture. Therefore, although conclusions are limited by the small sample size, it is the recommendation of this author that future studies utilize only the Braden Scale and clinical judgement in determining whether or not a heel ulcer is a pressure ulcer.

Finally, explanations for the deaths of six potential subjects and one enrolled subject can be drawn from work done by Kennedy (1989) and La Puma (1991). In analyzing the results of a five year retrospective study designed to identify the incidence of pressure ulcers in an intermediate care facility, Kennedy (1989) noted that “55.7% of the people who died with pressure ulcers did so within six weeks of the onset of their ulcer” (p. 45). La Puma (1991) attempts to explain this phenomenon by stating that “the skin is the largest organ of the body. If the heart, lungs, and kidneys are showing signs of failing, isn’t it logical that the skin would also show signs of failing?” (p. 43). It is noteworthy that of the subjects who were enrolled in the study, all were medically compromised as evidenced by the finding that subjects had multiple medical diagnoses with cardiac problems, hypertension, diabetes and neurodegenerative processes being the most frequent. Therefore, for future studies, it should
not be an unexpected finding that a proportion of the referred subjects will die either before or after enrollment. It is imperative that the sampling and data analysis plan be designed with this likelihood in mind. The use of the Kaplan-Meier time to partial healing and time to complete healing curves should satisfy this need (Polansky & van Rijswijk, 1994).

**Pressure Sore Status Tool (PSST): Implications for Future Studies**

Several difficulties were experienced in using the PSST. The first relates to the length of the tool and a second to interpreting the results of subscale scores during data analysis. Each are briefly discussed in turn and the implications for future studies identified.

First, although the scale provides an in-depth assessment of pressure sore status which should make it ideal for use in research, the length makes it less practical for use with a geriatric population. Most of the enrolled subjects could not maintain a position for a long enough time for the researcher to complete the detailed assessment and obtain a tracing. This necessitated multiple attempts at repositioning and many “quick” glances at the wound. As a consequence, the accuracy of some data may have been lessened. To compound the difficulty of this process, several subjects were cognitively impaired. As a consequence, they could not always comprehend the reasons why they were re-positioned and were, therefore, less able to comply with maintaining the desired posture. Although the PSST is a valid and reliable tool for describing the qualitative markers of pressure ulcer healing, it is long and further work is required to determine if some items could be deleted (Thomas, 1997). Unfortunately, while other pressure ulcer healing scales are under development, as Cuddigan (1997) asserts, none have been tested for both content and predictive validity. Moreover, none are short and easy to use (Cuddigan, 1997).

Second, one purpose in conducting the pilot study was to begin to describe pressure ulcer healing qualitatively in a small group of subjects. However, because of the wording of
some of the PSST subscales, some of the qualitative data is lacking in precision. An excerpt from the depth subscale of the PSST exemplifies this problem (see Appendix D). The third item in this subscale offers three choices in describing the appearance of a wound bed: "full-thickness skin loss involving damage or necrosis of subcutaneous tissue...&/or mixed partial & or full thickness &/or tissue layers obscured by granulation". By this description, the wound could have had a range of presentations on the day of the assessment. This difficulty is not limited to this subscale; similar difficulties are noted for a number of the subscales. One solution to this problem is to not only indicate the subscale score, but to underline or highlight the descriptors of the actual presentation of the wound.

For the above reasons, it is important that researchers be clear about the intent of future studies before using the PSST. If it is not economically feasible to do weekly wound assessments, then there may be little value in using a qualitative measure because many important markers of pressure ulcer healing will be missed. In the pilot study, it was hoped that such data as the number of weeks for debridement to be completed, or for exudate to change from purulent to serous could be reported. However, because the assessments were done once every three weeks, although some of this data was captured from visit to visit, it was not known if, for example, debridement was accomplished the first or second week after the previous visit, or just prior to the next. All there was to go on was that one visit the wound was covered with necrotic tissue and the next it was not. Therefore, many important changes were missed. If one goal of future research is to determine an estimate of wound severity as a function of a total score on the PSST, there may be merit in using this instrument.
Pressure Ulcer Healing

Because of the small sample size, no conclusions can be drawn from the descriptions of pressure ulcer healing detailed in Chapter Four. However, the number of strategies used in reducing pressure at the heel requires some comment. Also noteworthy is the fact that the methods used in topical management of pressure ulcers in the enrolled group were consistent with accepted practice. Finally, the implications for nursing practice that arise from the lack of sufficient data to begin to describe the norms of heel pressure ulcer healing are identified.

One possible explanation for the variability in the strategies utilized in reducing pressure at the heel is that a reliable means of doing so has not been identified. Therefore, there is little to guide practice. In attempting to synthesize the findings of research studies validating the efficacy of heel pressure reduction methods, Draper and Denis (1996) report that little direction can be derived from the findings of existing studies. This is because the instruments used to measure heel pressures vary across studies and, in the reports of some studies, data supporting the validity and reliability of these measures is either not provided or is questionable in nature (Draper & Denis, 1996). The lack of research based evidence of a reliable method of pressure reduction represents a significant gap because the heel is particularly susceptible to pressure because of the small surface area and the paucity of protective fat (Draper & Denis, 1996). Because there is little to guide nursing practitioners in the safety, use and selection of appropriate methods, there is an urgent need for rigorous research into this aspect of pressure ulcer care and prevention (Draper & Denis, 1996). However, given the array of products used for subjects in the pilot study, it is important that in future studies, a standardized method of reducing pressure at the heel be designated.

It is encouraging that the methods utilized in the topical management of subjects’ heel pressure ulcers were consistent with current standards of practice. It is apparent there is a
shift away from debriding all heel pressure ulcers. It is also evident that interventions for subjects with open wounds were consistent with the research based practice of utilizing products that promote moist wound healing. This may be an indication that the efforts of nurse educators have been successful in changing practice away from using dry gauze dressings.

However, it is significant that despite utilizing products that maintain a moist surface, debridement of the full thickness ulcers appeared to be a slow process. For only one subject, the ulcer bed was free from necrotic tissue relatively quickly post injury (five days). This may have been attributable to the action of the maggots, or the wound could have existed for a longer time than was reported. For the remaining subjects, there was relatively little progress after six weeks of therapy directed at promoting autolytic debridement. This is significant because the longer a wound remains covered with necrotic tissue, the greater the risk of infection. However, the most reliable and efficacious method of promoting autolysis and the variables that influence autolysis have not yet been identified. Therefore, research into these problems is required.

The fact that only two subjects were followed for the duration of the study is disappointing because there is little data to provide direction for nursing practice with respect to the norms of pressure ulcer healing. However, despite having wounds of apparently equivalent severity and size, the divergent healing courses of these subjects serves to underscore the importance of describing pressure ulcer healing in a larger sample. As stated in an earlier chapter, normative data is important in guiding clinical decision-making and in evaluating the efficacy of interventions (Tallon, 1995). Therefore, it is important that studies be designed and implemented in order that the norms of heel pressure healing can be identified. These efforts will however, require the support of nursing administrators, nurse educators and health and social policy.
Implications for Nursing Education, Administration and Health and Social Policy

The implications of the findings of the pilot feasibility study for nursing administration, nursing education and health and social policy are identified and briefly discussed.

The implementation of a large scale study of the norms of heel pressure ulcer healing will require the cooperation and support of all levels of nursing administration in creating and fostering a environment conducive to, and supportive of, pressure ulcer healing research. Ultimately, nurse administrators and clients themselves, will benefit from the reduced costs and shortened healing times that will follow from the enhanced clinical decision-making this information should engender.

Nurse educators need to play an important role in laying the groundwork for support for pressure ulcer healing studies among nursing staff and nurse administrators. Currently, most teaching in relation to pressure ulcer care focuses on the principles of wound management and little information describing the boundaries of the research based knowledge of pressure ulcer healing is disseminated. For this reason, few staff nurses and nurse administrators understand that rigorous studies of rudimentary aspects of pressure ulcer healing and pressure ulcer care have not been done. Therefore, they do not fully appreciate the urgent need for research into this problem and their role in facilitating this work. It may be that this knowledge deficit could account for the barriers to recruitment and the scheduling problems that were experienced during the pilot study. Therefore, it is important that nurse educators inform themselves and others of the limits of existing knowledge and the need to expand research based knowledge of pressure ulcer healing.

Finally, it is important that funding agencies give priority to pressure ulcer healing research. With the current demographic trend toward an aging society, pressure ulcers will
become an increasingly prevalent problem among older adults. If research attention is not
directed toward generating knowledge of the norms of pressure ulcer healing, it is likely that
in the next ten to twenty years, the costs of pressure ulcer care will represent a significant
social burden. Therefore, it is essential that funding agencies recognize the importance of this
research and provide the required funding.

**Summary and Conclusions**

The feasibility of undertaking a study of the healing norms of heel pressure ulcers
among older adults has been studied. The need for a pilot feasibility study was based on the
author’s clinical impression that the incidence and prevalence of heel pressure ulcers was
reaching unprecedented levels. This lead to such questions of feasibility as “are there enough
persons with heel pressure ulcers to warrant a study” and “what are the costs of conducting
such a study?”. Although an increased prevalence of heel pressure ulcers was suggested in
the results of several national level studies done in the United States of America, the
prevalence of heel pressure ulcers in British Columbia and the Lower Mainland was
unknown. Also unknown were the pitfalls of pressure ulcer research as they related to the
recruitment of subjects, the logistics of conducting such a study and the suitability of
conducting wound healing assessments using a novel Image Digitization Program,
Mouseyes.

A study designed to answer the questions of feasibility was implemented in the
Simon Fraser Health Region. Prior to its implementation, the study was submitted for ethical
review to the University of British Columbia and the Clinical Investigations Committee of
the Simon Fraser Health Region. The study design included efforts to determine that
subjects did indeed have pressure ulcers rather than another type of chronic wound. This
assessment was based on clinical judgement and results of scores on the Barthel Index and
the Braden Scale for Predicting Pressure Sore Risk. Nine subjects were enrolled in the study and their ulcers were assessed using the PSST and where appropriate, a tracing of the ulcer was taken using Op-Site Flexigrid. The tracings were subsequently analyzed using the Mouseyes Program.

Analysis of the study data resulted in a number of recommendations for future studies of the norms of heel pressure ulcer healing. First, it was demonstrated that a larger study is needed and it is feasible to do such a study if sufficient funding is provided. Second, to resolve the barriers encountered in the recruitment of subjects, it is suggested that planners utilize research facilitators if subsequent studies are contemplated. This should not only expedite recruitment, but should also overcome the factors that contributed to the logistical problems with the scheduling and completion of wound healing assessment visits. Third, subsequent studies should be conducted in sites across the Lower Mainland where interested clinical nurse specialists and/or enterostomal therapists can advocate on behalf of the study. Fourth, the screening of potential subjects should be done using clinical judgement and only the Braden Scale. Fifth, Mouseyes should be used for subsequent studies, but in combination with a sterile transparent dressing and a precut square of clear overhead acetate film. Sixth, researchers must carefully consider the goals of future studies and evaluate the use of the Pressure Sore Status Tool on that basis.
REFERENCE LIST


97


Thomas, D.R. (1997). Existing tools: Are the meeting the challenges of pressure ulcer healing? Advances in Wound Care, 10 (5), 86-89.


Appendix B

The Braden Scale for Predicting Pressure Sore Risk
Braden and Bergstrom (1988)

Date of Assessment: ____________________

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation, OR limited ability to feel pain over most of body surface</td>
<td>Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensor impairment which limits the ability to feel pain or discomfort over ½ of body</td>
<td>Responds to verbal commands, but cannot always communicate discomfort or need to be turned OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities</td>
<td>Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Moisture degree to which skin is exposed to moisture</th>
<th>1. Constantly moist</th>
<th>2. Very moist</th>
<th>3. Occasionally Moist</th>
<th>4. Rarely Moist</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned</td>
<td>Skin is often, but not always moist. Linen must be changed at least once a shift</td>
<td>Skin is occasionally moist, requiring an extra linen change approximately once a day</td>
<td>Skin is usually dry, linen only requires changing at routine intervals</td>
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<tbody>
<tr>
<td>Confined to bed</td>
<td>Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair</td>
<td>Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair</td>
<td>Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours</td>
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<tbody>
<tr>
<td>Does not make even slight changes in body or extremity position without assistance</td>
<td>Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently</td>
<td>Makes frequent though slight changes in body or extremity position independently</td>
<td>Makes major and frequent changes in position without assistance</td>
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</table>
Appendix B, continued

The Braden Scale for Predicting Pressure Sore Risk
Braden and Bergstrom (1988)

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<tbody>
<tr>
<td>Never eats a complete meal. Rarely eats more than 1/3 of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement. OR is NPO and/or maintained on clear liquids or IV's for more than five days.</td>
<td>Rarely eats a complete meal and generally eats only about 1/3 of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement. OR receives less than the optimum amount of liquid diet or tube feeding.</td>
<td>Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products) each day. Occasionally will refuse a meal, but will usually take a supplement if offered.</td>
<td>Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.</td>
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</tr>
</tbody>
</table>

| Friction and Shear | 1. Problem | 2. Potential Problem | 3. No Apparent Problem | |
|--------------------|-------------|----------------------|------------------------|
| Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent reposition with maximum assistance. Spasticity, contracture or agitation leads to almost constant friction. | Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restraints, or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down. | Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair at all times. | |

Total Score
Appendix C

The Barthel Index


Bowels
0 = incontinent
1 = occasional accident (once/week)
2 = continent

Bladder
0 = incontinent, or catheterized and unable to manage
1 = occasional accident (max once per 24 hours)
2 = continent (for over 7 days)

Grooming
0 = needs help with personal care
1 = independent face/hair/teeth/shaving (implements provided)

Toilet Use
0 = dependent
1 = needs some help, but can do something alone
2 = independent (on and off, dressing, wiping)

Feeding
0 = dependent
1 = needs help cutting, spreading butter etc.
2 = independent (food provided within reach)

Mobility
0 = immobile
1 = wheelchair independent including corners etc.
2 = walks with help of one person (verbal or physical)
3 = independent (but may use any aid, e.g. stick)

Transfer
0 = unable-no sitting balance
1 = major help (one or two people, physical), can sit
2 = minor help (verbal or physical)
3 = independent
Barthel Index
Page 2

Dressing
0=dependent
1=needs help, but can do about half unaided
2=independent (including buttons, zips, laces, etc)

Stairs
0=unable
1=needs help (verbal, physical, carrying aid)
2=independent up and down

Bathing
0=dependent
1=independent (or in shower).

Total= 0-20
Barthel ADL Index

Guidelines for Completion

A. The guidelines provided relate to general instructions provided by Collin, Wade, Davies and Horne (1988).

"The index should be used as a record of what a patient does, not as a record of what a patient could do.
The aim is to establish degree of independence from any help, physical or verbal, however minor and for whatever reason.
The need for supervision renders the patient not independent.
A patient's performance should be established using the best available evidence.
Asking the patient, friends/relatives and nurses will be the usual source, but direct observation and common sense are also important. However, direct testing is not needed.
Usually the performance over the preceding 24-48 hours is important, but occasionally longer periods will be relevant.
Unconscious patients should score 0 throughout, even if not yet incontinent
Middle categories imply that patient supplies over 50% of the effort.
Use of aids to be independent is allowed" (p. 63).

B. Specific instructions for use of each of the subscales are provided by Novak, Johnson and Greenwood (1996). Total scores of 8 or below are indicative of functional dependence.

1. Bowels
   2 = "Patient requires no staff supervision whatsoever to avoid accidents"
   1 = "Patient requires no staff supervision to avoid accidents"

2. Bladder
   2 = "Patient is able to control bladder day and night. Spinal cord injury patient (or others) who wear an external device (or catheter) must put them on independently, clean and empty leg-bag and stay dry day and night"

3. Grooming
   1 = "The patient must recognize the need to groom and be able to request toiletries as required. A patient who requires telling to wash/shave is dependent".

4. Toilet
   2 = "Patient must both recognize the need to use the toilet and be able to get there independently"
   1 = "Patient requires directing or moving to the toilet"

5. Feeding
   2 = "Food should not be pureed, soft or cut up, the patient should require no supervision and must be aware of the need to eat and appropriateness of time and place".
1 = “Some help is necessary (with cutting up food etc., as listed above) or encouragement to commence eating but the patient is then able to feed him/herself without further assistance or supervision”.

5. Mobility
3 = “She/he must be able to negotiate obstacles in home or ward environment”. Walking or wheelchair mobility must be purposeful.

6. Transfers
3 = “Patient must recognize the need to transfer and do so in appropriate circumstances without supervision”.

7. Dressing
2 = “Patient must recognize the need to dress and undress and do so at appropriate times”.
1 = “He/she requires to be instructed to dress or undress, or requires help with selecting clothes”.

8. Bathing
1 = “The patient recognizes that he/she needs a bath/shower”.

9. Stairs
2 = “Climbing of stairs must be purposeful, e.g. a person who needs to be told to go upstairs to bed/toilet etc. needs supervision”.
0 = “.because of cognitive impairment demands constant supervision”.
Appendix D

The Pressure Sore Status Tool
Instructions for Use
Developed by Bates Jensen (1990)

General Guidelines:
Fill out the attached rating sheet to assess a pressure sore’s status after reading the definitions and methods of assessment described below. Evaluate once a week and whenever a change occur in the wound. Rate according to each item by picking the response that best describes the wound and entering that score in the item score column for the appropriate date. When you have rated the pressure sore on all items, determine the total score by adding together the 13 item scores. The HIGHER the total score, the more severe the pressure sore status. Plot total score on the Pressure Sore Status continuum to determine progression of the wound.

Specific Instructions:
1. Size: Use ruler to measure the longest and widest aspect of the wound surface in centimetres; multiply length X width

2. Depth: Pick the depth, thickness, most appropriate to the wound using these additional descriptions:
   1=tissues damaged but no break in skin surface
   2=superficial, abrasion, blister or shallow crater. Even with, and/or elevated above skin surface (hyperplasia).
   3=deep crater with or without undermining of adjacent tissue
   4=visualization of tissue layers not possible due to necrosis
   5=supporting structures include tendon, joint capsule

3. Edges: Use this guide:
   Indistinct, diffuse = unable to clearly distinguish wound outline
   Attached = even or flush with wound base, no sides or walls present; flat
   Not attached = sides or walls are present; floor or base of wound is deeper than edge
   Rolled under, thickened = soft to firm and flexible to touch
   Hyperkeratosis = callous-like tissue formation around wound and at edges
   Fibrotic, scarred = hard, rigid to touch

4. Undermining: Assess by inserting a cotton tipped applicator under the wound edge; advance it as far as it will go without using undue force; raise the tip of the applicator so it may be seen or felt on the surface of the skin; mark the surface with a pen; measure the distance from the mark on the skin to the edge of the wound. Continue process around the wound. Then use a transparent metric measuring guide with concentric circles divided in 4 (25%) pie-shaped quadrants to help determine percent of wound involved.
5. Necrotic tissue type: Pick the type of necrotic tissue that is *predominant* in the wound according to colour, consistency and adherence using this guide:

- **White/gray non-viable tissue**: may appear prior to wound opening; skin surface is white or gray.
- **Nonadherent, yellow slough**: thin, mucinous substance; scattered throughout wound bed; easily separated from wound tissue.
- **Adherent, soft, black eschar**: soggy tissue; strongly attached to tissue in centre or base of wound.
- **Firmly adherent, hard/black eschar**: firm, crusty tissue; strongly attached to wound base and edges (like a hard scab).

6. Necrotic tissue amount: Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved.

7. Exudate Type: Some dressings interact with wound drainage to produce a gel or trap liquid. Before assessing exudate type, gently cleanse wound with normal saline or water. Pick the exudate type that is predominant in the wound according to colour and consistency, using this guide:

- **Bloody**: thin, bright red.
- **Serosanguinous**: thin, watery pale red to pink.
- **Serous**: thin, watery, clear.
- **Purulent**: thin or thick, opaque tan to yellow.
- **Foul Purulent**: thick, opaque yellow to green with offensive odour.

8. Exudate Amount: Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie shaped quadrants to determine percent of dressing involved with exudate. Use this guide:

- **None**: wound tissues dry.
- **Scant**: wound tissues moist; no measurable exudate.
- **Small**: wound tissues wet; moisture evenly distributed in wound; drainage involves <25% dressing.
- **Moderate**: wound tissues saturated; drainage may or may not be evenly distributed in wound; drainage involves >25% to <75% of dressing.
- **Large**: wound tissues bathed in fluid; drainage freely expressed; may or may not be evenly distributed in wound; drainage involves >75% of dressing.

9. Skin Color Surround Wound: Assess tissues within 4cm of wound edge. Dark skinned persons show the colors “bright red” and “dard red” as a deepening of normal ethnic skin colour or a purple hue. As healing occur in dark skinned persons, the new skin is pink and may never darken.
Pressure Sore Status Tool
Instructions for Use Continued

10. Peripheral Tissue Edema: Assess tissues within 4 cm of wound edge. Non-pitting edema appears as skin that is shiny and taut. Identify pitting edema by firmly pressing a finger down into the tissues and waiting for five seconds; on release of pressure, tissues fail to resume previous position and an indentation appears. Crepitus is accumulation of air or gas in tissues. Use a transparent metric measuring guide to determine how far edema extends beyond wound.

11. Peripheral Tissue Induration: Assess tissues within 4 cm of wound edge. Induration is abnormal firmness of tissues with margins. Assess by gently pinching the tissues. Induration results in an inability to pinch the tissues. Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to determine percent of wound and area involved.

12. Granulation Tissue: Granulation tissue is the growth of small blood vessels and connective tissue to fill in full-thickness wounds. Tissue is healthy when bright, beefy red, shiny and granular with a velvety appearance. Poor vascular supply appears as pink or red skin. In partial thickness wounds it can occur throughout the wound bed as well as from the wound edges. In full-thickness wounds it occurs from the edges only. Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved and to measure the distance the epithelial tissue extends into the wound.

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Note: This tool may be copied and used without specific permission of the author.
Complete the rating sheet to assess pressure sore status. Evaluate each item by picking the response that best describes the wound and entering the score in the item score column for the appropriate date.

**Location:** Anatomic site. Circle, identify right (R) or left (L) and use “X” to mark site on body diagrams:
- Sacrum or coccyx
- Ischial tuberosity
- Lateral ankle
- Heel
- Trochanter
- Medial ankle
- Bow/Boat
- Other Site

**Shape:** Overall wound pattern; assess by observing perimeter and depth. Circle and date appropriate description:
- Irregular
- Linear or elongated
- Oval
- Round/oval
- Square/rectangle
- Butterfly
- Other Site

**Date**

<table>
<thead>
<tr>
<th>Item Assessment</th>
<th>Date Score</th>
<th>Date Score</th>
<th>Date Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Size</td>
<td>1 = Length x width &lt; 4 sq cm</td>
<td>2 = Length x width 4-16 sq cm</td>
<td>3 = Length x width 16-36 sq cm</td>
</tr>
<tr>
<td>2. Depth</td>
<td>1 = Non-blanchable erythema on intact skin</td>
<td>2 = Partial thickness skin loss involving epidermis and/or dermis</td>
<td>3 = Full-thickness skin loss involving damage or necrosis of subcutaneous tissue; may extend down to but not through underlying fascia; and/or mixed partial &amp; full thickness &amp;/or tissue layers obscured by granulation tissue</td>
</tr>
<tr>
<td>3. Edges</td>
<td>1 = Indistinct, diffuse, none clearly visible</td>
<td>2 = Distinct, outline clearly visible, attached, even with wound base</td>
<td>3 = Well-defined, not attached to base</td>
</tr>
<tr>
<td>4. Undermining</td>
<td>1 = Undermining &lt; 2 cm in any area</td>
<td>2 = Undermining 2-4 cm involving &lt; 50% wound margins</td>
<td>3 = Undermining 2-4 cm involving &gt; 50% wound margins</td>
</tr>
<tr>
<td>5. Necrotic Tissue Type</td>
<td>1 = None visible</td>
<td>2 = White/grey non-viable tissue &amp;/or non-adherent yellow slough</td>
<td>3 = Loosely adherent yellow slough</td>
</tr>
<tr>
<td>6. Necrotic Tissue Amount</td>
<td>1 = None visible</td>
<td>2 = &lt;25% of wound bed covered</td>
<td>3 = 25% to 50% of wound covered</td>
</tr>
<tr>
<td>7. Exudate Type</td>
<td>1 = None or bloody</td>
<td>2 = Serosanguinous: thin, watery, pale red/pink</td>
<td>3 = Serous: thin, watery, clear</td>
</tr>
<tr>
<td>8. Exudate Amount</td>
<td>1 = None</td>
<td>2 = Scant</td>
<td>3 = Small</td>
</tr>
<tr>
<td>9. Skin Color Surrounding Wound</td>
<td>1 = Pink or normal for ethnic group</td>
<td>2 = Bright red and/or blanches to touch</td>
<td>3 = White or grey pallor or hypopigmented</td>
</tr>
<tr>
<td>10. Peripherial Tissue Edema</td>
<td>1 = Minimal swelling around wound</td>
<td>2 = Non-pitting edema extends &lt; 4 cm around wound</td>
<td>3 = Non-pitting edema extends &gt; 4 cm around wound</td>
</tr>
<tr>
<td>11. Peripherial Tissue Induration</td>
<td>1 = Minimal firmness around wound</td>
<td>2 = Induration &lt; 2 cm around wound</td>
<td>3 = Induration 2-4 cm extending &lt; 50% around wound</td>
</tr>
<tr>
<td>12. Granulation Tissue</td>
<td>1 = Skin intact or partial thickness wound</td>
<td>2 = Bright, beefy red; 75% to 100% of wound filled &amp;/or tissue overgrowth</td>
<td>3 = Bright, beefy red; &lt; 75% &amp; &gt; 25% of wound filled</td>
</tr>
<tr>
<td>13. Epithelialization</td>
<td>1 = 100% wound covered, surface intact</td>
<td>2 = 75% to &lt; 100% wound covered &amp;/or epithelial tissue extends &gt; 0.5 cm into wound bed</td>
<td>3 = 50% to &lt; 75% wound covered &amp;/or epithelial tissue extends to &lt; 0.5 cm into wound bed</td>
</tr>
</tbody>
</table>

**TOTAL SCORE**

| SIGNATURE |

**PRESSURE SORE STATUS CONTINUUM**

Plot the total score on the Pressure Sore Status continuum by putting an "X" on the line and the date beneath the line. Plot multiple scores with their dates to see-at-glance regeneration or degeneration of the wound. © 1990 Barbara Bates-Jensen

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Appendix E

Visit One Data Collection Sheet

Date: __________ Subject number: _____ Age: _____ Gender: 1. Male 2. Female

Place of assessment: 1. residential care 2. acute care

Number of beds on unit: ____________________

Medical diagnoses: 1. Cardiac 5. Cerebrovascular 9. GI

Prescribed medications:

6. Anti-Parkinson’s

Date(s) of ulcer(s) onset: __________________________________________

Preceding event(s): 1. Immobility related to trauma
                    2. Immobility related to surgery
                    3. Immobility related to acute illness
                    4. Immobility related to chronic disease process
Visit One Data Collection Sheet

Page 2

Previous history of pressure ulcers: 1. Yes 2. No

Evidence of pressure ulcer at other locations: 1. Yes 2. No

Site: 1. Sacral 2. Trochanteric 3. Ischial 4. Other:

Location of Heel Ulcer:
1. Left 3. posterior 4. medial 5. lateral
2. Right 3. posterior 4. medial 5. lateral


Method for Pressure Reduction:

Moisture Source: 1. Incontinence 2. Diaphoresis 3. Other
Visit One Data Collection Sheet

Page 3

Management Approach

Debridement

1. Enzymatic
2. Autolysis
3. Surgical
4. Not applicable

Dressing Utilized:
1. Foam
2. Non-foam absorbent
3. Gauze
4. Tulle
5. Telfa
6. Silicone mesh
7. Hydrogel
8. Hydrophilic fibre
9. Alginate
10. Transparent Film
11. Hydrocolloid

Nutritional Status

Serum albumin:
1. 3.5 mg/dL or <
2. 3.6 mg/dL or >
3. Not available

Total lymphocyte count:
1. 1,800/mm$^3$ or <
2. > 1,800/mm$^3$
3. Not available

Weight (include date of measure):

Evidence of weight loss of 5% of total body weight in one month or 10% in six months:

1. Yes
2. No
3. Data not available

Time requirements

1. For data collection (in minutes):
2. Travel time (min): Km

Comments: (note difficulties/barriers encountered)
Data Collection Sheet for Visits 2 to 5

Date: _______________  Subject number: ___________  Visit No: ___________

Place of assessment: 1. residential care  2. acute care (note # of beds on unit: ____)

Additions/Deletions to Prescribed Medications since last visit:
6. Anti-Parkinson’s

Nutritional Status (note changes or new blood work since last visit)

Serum albumin: 1. 3.5 mg/dL or <  2. 3.6 mg/dL or >  3. Not available
Total lymphocyte count: 1. 1,800/mm³ or <  2. > 1,800/mm³  3. Not available

Weight (include date of measure):

Evidence of weight loss of 5% of total body weight in one month or 10% in six months:
1. Yes  2. No  3. Data not available

Method for Pressure Reduction:

1. None  4. Sheepskin boots  7. Spenco or quilted boots
2. Heels suspended from pillow  5. Low air loss mattress  8. Air fluidized mattress
3. High density foam mattress  6. Gel socks
Data Collection Sheet for Visits 2 to 5

Page 2


Management Approach


Dressing Utilized: 1. Foam 6. Silicone mesh
4. Tulle 9. Alginate
5. Telfa 10. Transparent Film
11. Hydrocolloid

Time requirements

1. For data collection (in minutes):_______ 2. Travel time (min):_______Km

Comments: (note difficulties/barriers encountered)
Appendix F

Screening/Subject Refusal Log

<table>
<thead>
<tr>
<th>Screening #</th>
<th>Located on what type unit</th>
<th>Reason for Ineligibility/Refusal</th>
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